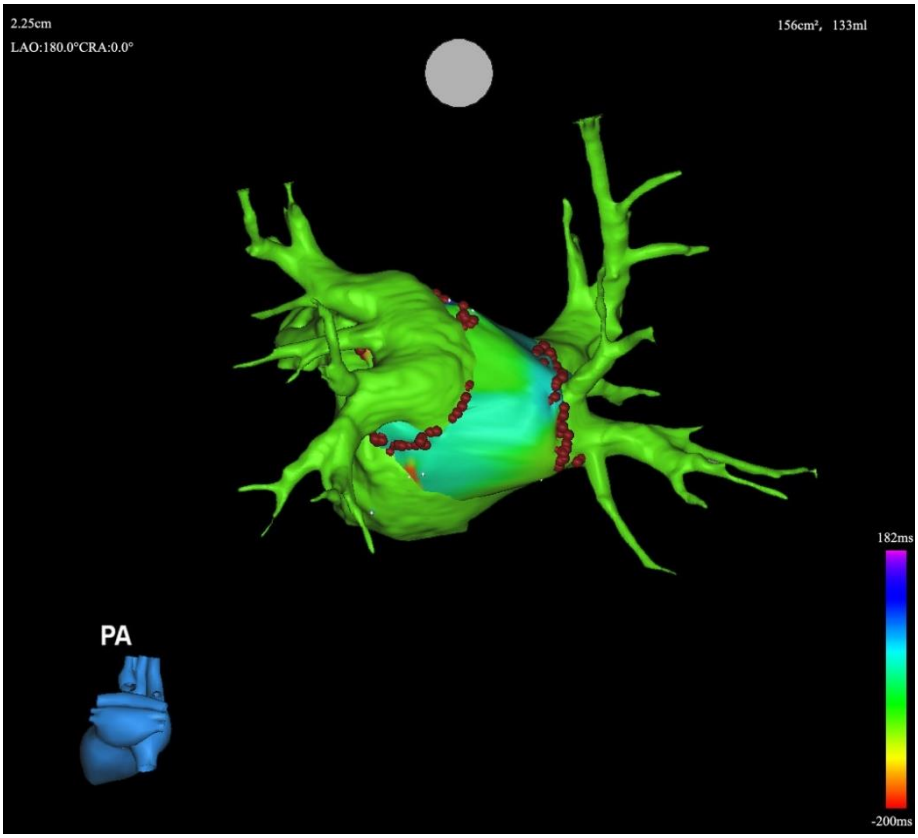
EverPace™

Type: EPE-SYS-1A

Columbus™

3D EP Navigation System

User Manual



Shanghai MicroPort EP MedTech Co., Ltd.

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Declaration

This manual is only used as an instruction for installation, operation, maintenance and maintenance of Columbus™ 3D EP Navigation System. All diagnostic conclusions are given by the physicians authorized to use the system based on their own medical expertise and are the responsibility of the physicians themselves. Shanghai MicroPort EP MedTech Co., Ltd. is not legally responsible for any diagnostic conclusions and corresponding treatment measures.

Follow the instructions in this manual, which contain important information.

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Contents

Chapter I Introduction

This chapter is a basic overview of the Columbus™ 3D EP Navigation System (hereinafter referred to as the Columbus™ system) and includes:

- Functional principle of Columbus™ system
- System performance and operation concept
- Introduction to System Installation

1.1 Technology of Columbus™ 3D EP Navigation System

The Columbus™ system includes the following technologies:

- **Accurate mapping: Integrate local ECG signals with local anatomical locations. Using this technology, the system can provide real-time 3D excitation map, voltage map and excitation conduction map.**
- **Real-time display: Accurately and real-time display of catheter position and movement status. A real-time, dynamic display of a simulated catheter icon that shows the precise position, orientation, bending, and motion changes of the catheter in the heart cavity, instructs the manipulation of the catheter, and serves as a helpful judgment in your procedure.**
- **Magnetic field positioning: By providing accurate real-time positioning, the time for X-ray fluoroscopy can be shortened, which can create a safer environment for both doctors and patients.**

1.2 Concept of operation

The Columbus™ system is designed to acquire, analyze, and display electroanatomical images of the human heart and to display catheter locations in real time on a constructed three-dimensional map.
The system consists of two parts: Console and instrument car.
The console mainly includes host workstation, display screen, printer and other equipment for clinical workers.
The instrument car includes the patient interface unit, interface unit power supply box, display screen, accessory cable and other medical electrical parts.
The console is connected with the instrument cart in a safe isolation mode conforming to GB1/IEC60601-1. The host workstation obtains the patient physiological signals and equipment positioning signals collected by the patient interface unit for observation by clinical staff.

1. 2. 1 3D Maps

The final map obtained by the system is obtained by integrating cardiac electrophysiological signals and their relative position information. The user can view the color 3D graphics representing the heart chamber in real time on the screen. The data viewed and analyzed included local activation time (LAT) and voltage information.

You can rotate and change the orientation of the map generated by the Columbus™ system to obtain a better view

of the cardiac anatomy, or you can examine some of the details on it. For example, you can view the ECG signal at a specific point on the activation map, edit it manually, and redraw the map. Figure 1-1 shows the full 3D reconstruction of the simulated chamber created using the Columbus™ system.

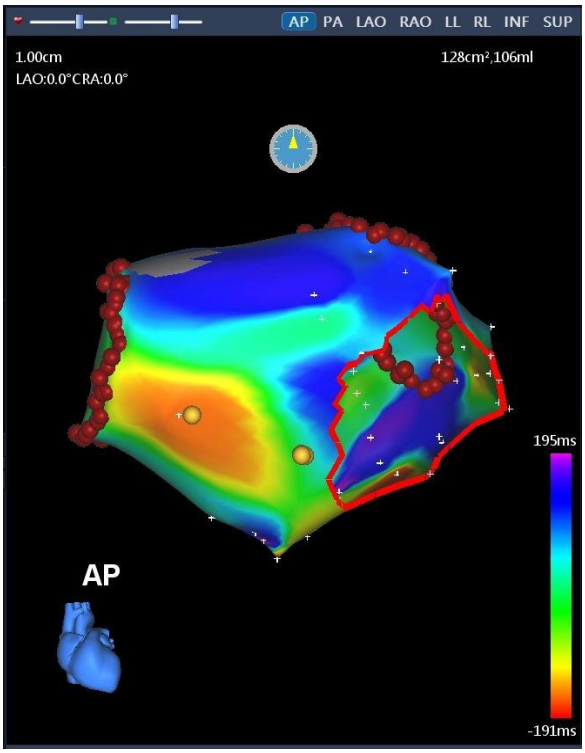


Figure 1-1. Chamber Map Collected By The Columbus™ System

1. 2. 2 RTM Diagram

RTM is able to quickly construct anatomical maps by processing large amounts of data rather than point-by-point mapping. Based on the characteristics of the Magnetic Positioning Sensor and Mapping Catheter, a geometrical model of the chamber is continuously constructed as the catheter moves within the chamber and the modeling resolution is adjusted with 5 steps.

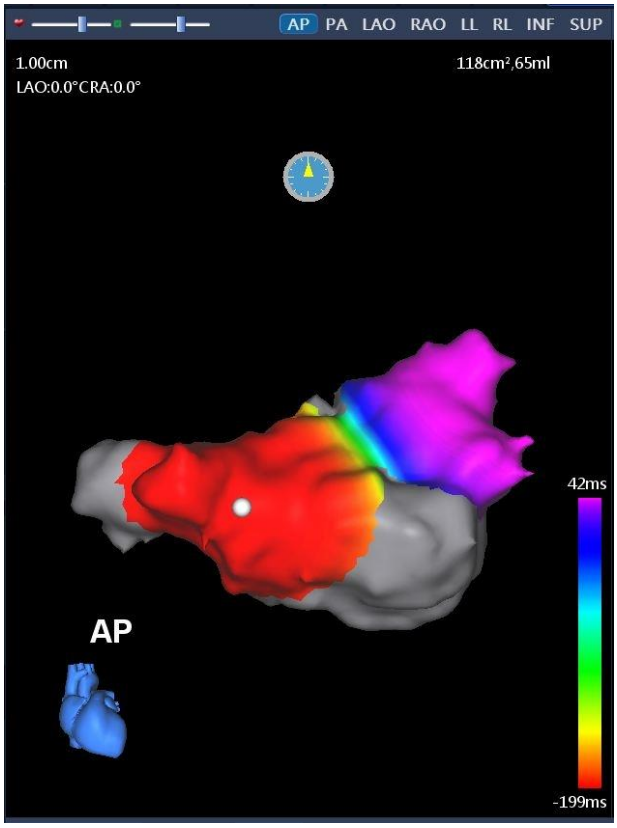


Figure 1-2 RTM

1. 2. 3 Multi-graph display

You can map and view different chambers and rhythms in the same procedure. Each graph can be assigned a unique name. To quickly and easily view all maps and related data, the system creates a patient-based tree directory that contains all of its procedures and maps during the procedure.

1. 2. 4 Importing, Editing, and Using CT/MRI Images

With the ability to import, segment, and edit MRI and CT image data, the Columbus™ system allows you to import and process pre-acquired CT/MRI study data into a 3D segmented surface image of the desired chamber or structure. During the procedure, you use segmented CT/MRI volume rendering to obtain surface images to guide and verify 3D mapping of anatomical structures in specific areas.

1.3 **Initial installation and uninstallation**

The Columbus™ system and its components should be installed by a qualified Shanghai MicroPort EP MedTech Co., Ltd. system deployment engineer. Packaging containing system components should be opened by Shanghai MicroPort EP MedTech Co., Ltd. personnel.

1. 3. 1 Software installation

Confirm the normal use of the computer system at the beginning of the installation, and then perform the following operations:

1）Double-click the installation file and click Next, as shown in the following figure:

Figure 1-3

2）Input Company Name and click Next, as shown in the following figure:

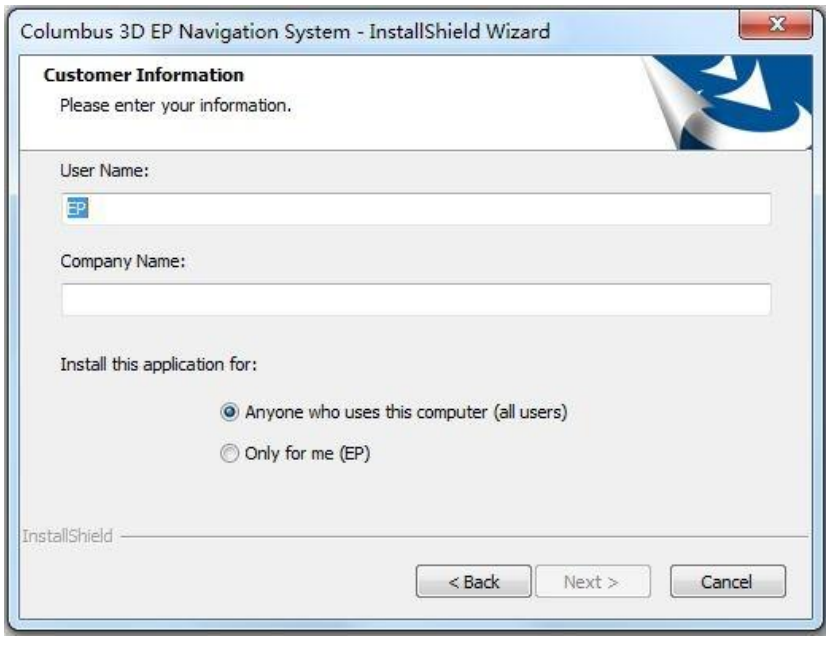


Figure 1-4

3）Click Next until the FG version is selected, select V1orV2 according to the FG used, and click Next, as shown in the following figure:

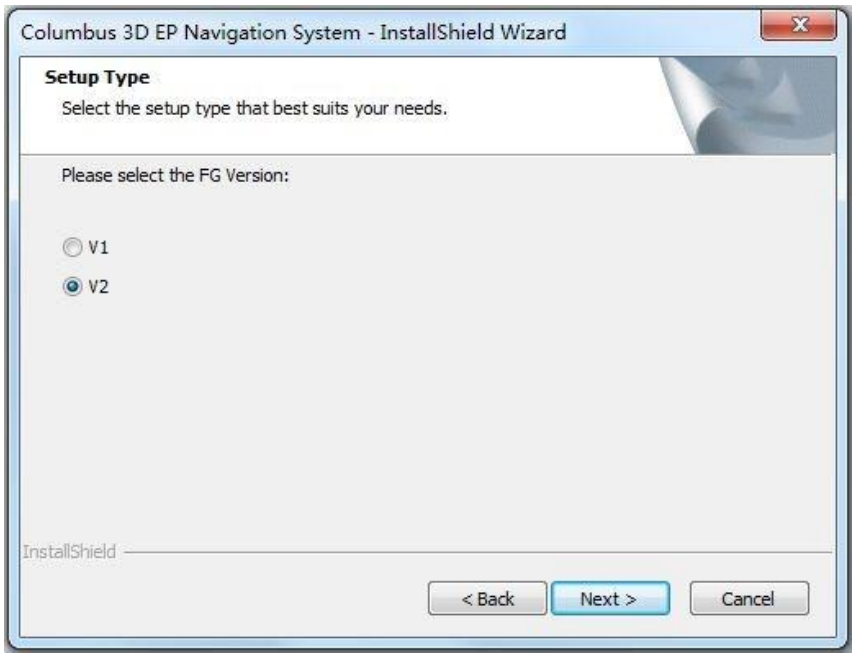


Figure 1-5

4）Select RS 422 or RS 232 according to the actual use and click Next, as shown in the following figure:

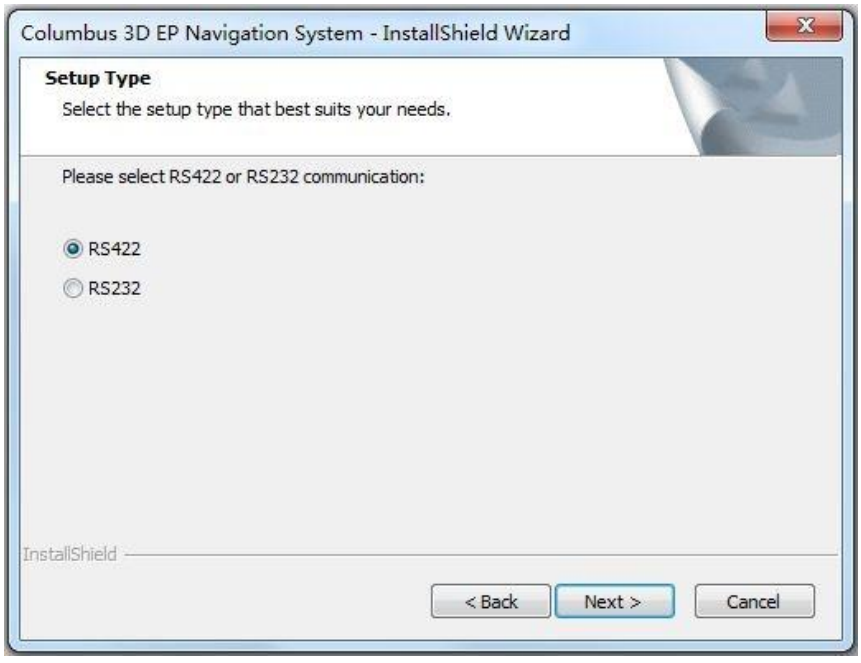


Figure 1-6

5）The Restart Database screen pops up. Click any key on the keyboard after the database is restarted successfully, as shown in the following figure:

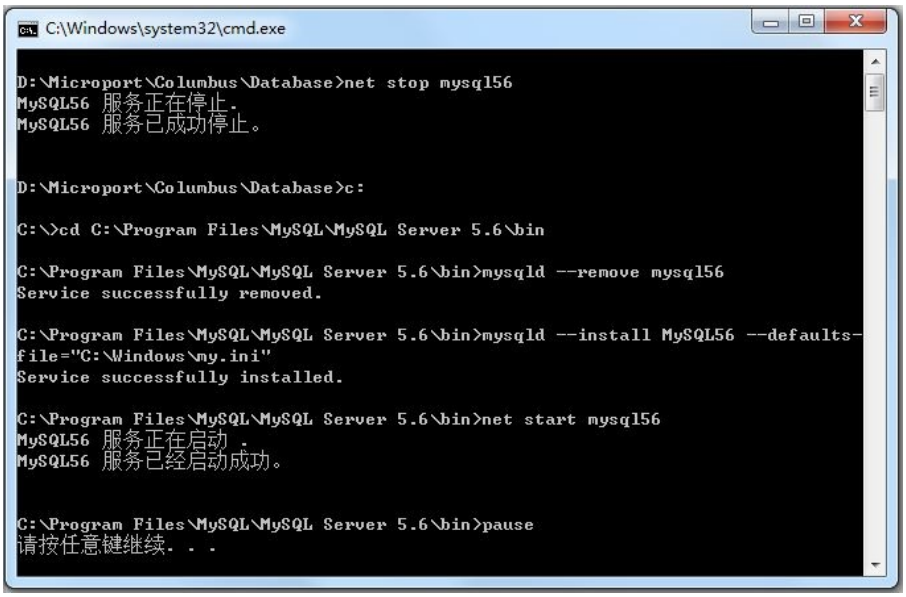


Figure 1-7

6）Update the encryption lock drive automatically. After the update is completed, click OK, as shown in the following figure:

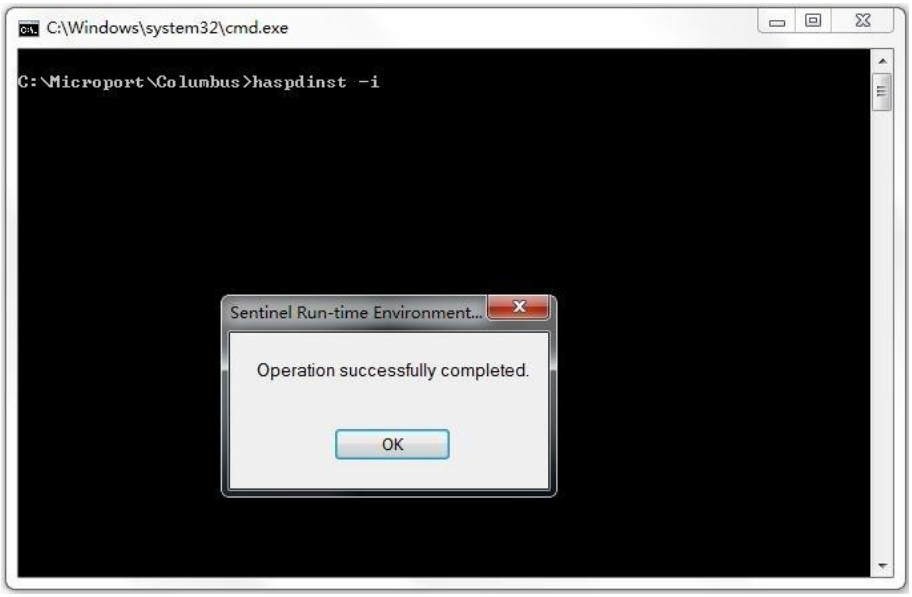


Figure 1-8

7) Enter the support library installation process, check the "I agree to license terms and conditions (A)" option, and click Install to enter the installation support library process. As shown in the following figure:

Figure 1-9

8) Click Finish to end the entire software installation process.

Figure 1-10

1. 3. 2 Software uninstallation

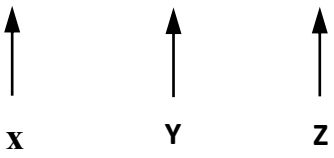
When the software needs to be uninstalled, select When the software needs to be uninstalled, select Start -> Control Panel -> Uninstall Program.
Load Columbus 3D EP Navigation System ."

1.4 **Software version information**

Software release version: V5
Software full version naming rules

The Columbus™ 3D EP Navigation System software is identified by a uniquely identifiable software version number. The definition of the complete software version number is divided into three items: X.Y.Z, all fields and their meanings are as follows:

Full Version Example: **V 5. 0. 001**



X is the release version: It indicates a major enhancement change, including a change in the overall software architecture, a change in the core algorithm, an increase in important functions required for clinical surgery, and an increase in modules with a safety level of B and above.

Y: Indicates minor enhancement changes, including optimization of use procedures, optimization of performance of existing functions, increase of minor functions not affecting clinical procedures, and increase of modules with safety class A.

Z: Indicates correction type change, including software bug correction, internal construction, etc.

Chapter II Safety Information

This chapter contains important information about the safety and performance of the Columbus™ system.

Warning: Failure to follow the development and instructions provided in this chapter may result in a malfunction of the Columbus™ system or create a safety risk.

2.1 Safety Classification and Standards

The Columbus™ system is classified as:

1） According to anti-shock type: Class I equipment.
2） According to the anti-shock degree: Type CF application part.
3） Defibrillation-proof function: Defibrillation-proof application part.
4） Protection classification of liquid inlet: IPX0, footswitch: IPX8.
5） Protection against combustible anesthetic gases: Equipment not classified as AP or APG.
6） By operation mode: Continuous operation.
7） Signal input/output part: There is signal input/output part.

2.2 System Setup Criteria

The Columbus™ system shall be installed in an electrophysiology operating room equipped with fluoroscopy equipment.

The Columbus™ system must be installed and configured by qualified Shanghai MicroPort EP MedTech Co., Ltd. technicians.

Before putting the Columbus™ system into clinical use, it must be thoroughly tested and verified by Shanghai MicroPort EP MedTech Co., Ltd.'s standard procedures that its performance and safety meet the requirements.

Workstations provided with the Columbus™ system are computers designed to work with the Columbus™ system. This workstation should not be used for other purposes, nor should unauthorized software be installed on it. Doing so may cause the Columbus™ system to work unsteadily.

In order to ensure the performance of the equipment, the power supply of each part of the system shall be turned on at least half an hour in advance before the formal start of the operation for preheating, so as to make each part of the system in good and stable working condition.

All modifications to the Columbus™ system setup must be approved by the prior authorization of the Shanghai MicroPort EP MedTech Co., Ltd. personnel.

2.3 **Scope of Application and Contraindications**

This product is a catheter-based system for electrophysiological mapping and positioning of the atrium and ventricle. In conjunction with the Magnetic Positioning Cardiac Mapping/Ablation Catheter and Columbus™ External Reference Patch, 3D graphics of the human heart are displayed in real time by acquisition and analysis of cardiac electrophysiological activity.

The Columbus™ system has no clear contraindications.
This product is suitable for adults(over 18 years old(including 18 years old)and under 75 years old)who are diagnosed with arrhythmia and need electrophysiological surgery according to doctors.

2.4 **Prevent fire, explosion and electric shock**

To continuously protect the equipment from the risk of fire, replace the old fuse with a new fuse of the same model and current rating as the original fuse of the system. The Columbus™ system uses 220 V/50 Hz AC power.

Please note that prior to replacement of the fuse, the consent of an authorized MicroPort EP person is required and any electrical connection to the supply network is completely disconnected prior to replacement;

In order to avoid the risk of electric shock, the equipment must only be connected to the power supply network with protective grounding, and the power cable with grounding provided by the equipment must be used.
In order to avoid the risk of electric shock, the accessory cables of the equipment must be used.

Before using the Columbus™ system, the grounding cable from the patient interface unit must be properly connected to the grounding terminal in the operating room.
Equipotential equalization columns are recommended to be connected with equipment used at the same time, such as generator and irrigation pump, to reduce potential difference.
Equipotential equalization column shall not be used as protective grounding;

Before each use of the equipment, the operator shall observe whether the equipment surface has serious damage, water inlet and other external structure abnormalities, and shall listen to whether the cooling fan of the equipment works normally.
The equipment shall be used at a distance of not less than 1 meter from the wall and shall not be placed in a position where it is difficult to disconnect the mains outlet.

It is not allowed to add other equipment on the console and the power row of the instrument car for power supply without the authorization of the authorized personnel of MicroPort EP; Random addition of equipment may result in a reduction in the safety level of the system.
It is not allowed to switch the network power frequency and voltage switch of the console and instrument car without authorization of MicroPort EP authorized personnel;

The equipment cannot be used in oxygen-enriched environment. If inflammable agents and other drugs are used during the operation, the clinical personnel shall ensure safety before operation;

2.5 **Warning**

The Columbus™ system must be operated in strict accordance with all instructions in this manual and in accordance with current medical practice.
The following warnings appear in a sequence independent of their importance.

General Warning

- Pacing catheters for life support cannot be connected via the Columbus™ system.
- Do not connect or disconnect the connecting cable during the startup of the Columbus™ system. Otherwise, the user may get an electric shock or the hardware may be damaged. Make sure that the cables and electrodes connected to the patient are not connected to any other conductive parts, including grounding.
- Do not use the Columbus™ system in the presence of combustible anesthetic mixtures or other combustible gases.
- Do not place liquid material close to the Columbus™ system as the system is not specifically designed to protect against spills.
- When the patient interface unit and power supply module of the Columbus™ 3D EP Navigation System are running, do not cover the vents of the main units, which may damage the equipment.
- During operation of the Columbus™ system, do not use a mobile phone in the operating room.
- Use only parts and accessories manufactured or recommended by Shanghai MicroPort EP MedTech Co., Ltd.. The components and accessories used must comply with the requirements of the GB1 Code and the system configuration must comply with the GB1 Medical Electrical Equipment Part 1: General Requirements for Safety. The use of accessory equipment that does not meet this standard will result in a reduction in the overall safety level of the system. Equipment that does not comply with the 9706.1 standard should be placed outside the patient environment. Contact Shanghai MicroPort EP MedTech Co., Ltd.'s technical support personnel before connecting any equipment not mentioned or indicated in this manual to the Columbus™ system.
- When other equipment outside the patient environment is used together with the equipment, the product must reach the same safety level as that required by other safety standards (national standards or IEC and ISO safety standards).
- The equipment shall not be connected to the network without the consent of MicroPort EP, and other equipment shall not be connected to the equipment in any way of network/data coupling.
- The input and output of all current signals shall only be connected to a defibrillation resistant connector on an approved medical device. The equipment shall be connected to a public protective earth in the room or to a separate device.
- The patient surface ECG cable provided by Shanghai MicroPort EP MedTech Co., Ltd. is non-defibrillation-proof and the defibrillation-proof device is located inside the patient interface unit. Use the surface ECG cable provided by Shanghai MicroPort EP MedTech Co., Ltd.. Failure to do so may damage the system hardware.
- If the patient surface ECG cable needs to be replaced, the connector specifications suitable for the Shanghai MicroPort EP MedTech Co., Ltd. must be ensured without affecting the interference immunity.
- Conductive parts and accessories of wires and electrodes shall be kept away from other conductive parts and ground at all times.
- During use, do not touch the patient and equipment at the same time, including but not limited to housing, cart, display screen and other devices.
- During defibrillation, the surface ECG cable and intracardiac catheter electrode should always be reliably connected to the patient.
- During defibrillation, do not touch the housing of the patient interface unit and the housing of the power module

and any interfaces on their surfaces.

- After defibrillation, the signal on this device may distort or disappear for up to 5s, after which time the signal will be displayed again.
- Although the environment of the system is expected to be used with the generator, it is necessary to note that the neutral electrode and tail line of the generator have a certain space distance from the accessory cable of the device, so as to avoid harm to the patient or operator caused by the generator as a high-frequency surgical device.
- Although the system is expected to be used in combination with the electrophysiological stimulator, the operator should pay attention to any abnormal cardiac conditions of the patient. It is recommended to confirm the stimulation voltage and current before using the electrophysiological stimulator to reduce the harm to the patient.
- If the system may interfere with a patient with a pacemaker, the protection of the patient should be considered prior to the procedure, referring to the pacemaker manufacturer's statement if necessary;
- Before turning on the power supply of each part of the system, please confirm that the corresponding value of the voltage change-over switch behind the power supply module is consistent with the local voltage value. If not, please contact the technical support personnel of Shanghai MicroPort EP MedTech Co., Ltd. immediately.
- Rotating the DSAs or adjusting the table position during the procedure affects the precise positioning of the Columbus™ system. DSA or table adjustment is prohibited during a continuous collection of data. If adjustments are required, you must abandon the previously collected data.
- When the Columbus™ system is used with other equipment, you must be careful not to exceed the safety standards.
- The multi-hole socket provided by the console of the Columbus™ system can only be used for power supply of the equipment composing the medical system. Access of any other equipment not composing the medical system to the multi-hole socket may cause the system not working properly.
- The multi-hole socket provided by the console of Columbus™ system can only be installed on the equipment. It is forbidden to disassemble the multi-hole socket and place it on the ground for use.
- A multi-outlet provided by the trolley of the Columbus™ system with a maximum allowable load of 1.2KVA.
- The display in the patient environment (instrument car) of the Columbus™ system must be powered by the multi-hole socket on the instrument car. It is forbidden to use other external network power supply. Otherwise, unexpected interference will occur, which will affect the normal operation of the system.
- The multi-hole socket provided by the instrument car of the Columbus™ system can only be used for power supply of the equipment composing the medical system. Access of any other equipment not composing the medical system to the multi-hole socket may cause the system not working properly. The magnetic field generator, patient interface unit and power supply module in the system are medical devices and can be used in the patient environment.
- The electrode used with the surface lead wire should be resistant to polarization voltage≥300 mV, otherwise the recovery time after bias potential defibrillation may be very long due to polarization.
- Do not connect the stimulator without stimulation.
- Do not place the foot switch where it is easy to step on it by mistake.
- When using the trolley for equipment use, pay attention to the locking wheels to prevent unexpected movement.
- When installing movable structural parts such as display bracket and display screen, please pay attention to fixing to prevent unexpected accidents.
- When using trolley for equipment, please pay attention to each floor and total maximum bearing weight of trolley to avoid accident.
- Although the trolley is equipped with a power interface with a non-detachable structure to prevent the cables from falling or being interchanged, please pay attention to the risk that the power cable of the trolley is dragged

and caused to fall and the risk that the cables are used excessively due to interchange.

- The trolley has a limited bearing weight, please note that the limit shall not be exceeded;
- When not in the operating room, the equipment shall be placed in the packing box and transported and moved in the manner of packing box.
- Portable and mobile RF communication equipment may affect the performance of the product. When using the Columbus™ system, care shall be taken to avoid strong electromagnetic interference, such as close to mobile phones and microwave ovens.
- It is prohibited to install software, update the system, and upgrade the system in the host workstation of the system without the authorization of MicroPort EP.
- Without the authorization of minimally invasive electrophysiology, it is forbidden to install external third-party devices such as wireless mouse and keyboard, Bluetooth receiver and transmitter, wireless network card and other devices on the host workstation of this system.
- It is forbidden to install external third-party devices such as wireless mouse and keyboard, Bluetooth receiving transmitter and wireless network card on the host workstation of the system without the authorization of MicroPort EP.

2.6 **Electromagnetic compatibility information and technical description**

Electromagnetic compatibility information and technical instructions require a special preventive measure for electromagnetic compatibility and must be installed and used in accordance with the EMC information provided in this user manual.

⚠Warning: In order to complete its intended function, it is necessary to cooperate with the radio frequency generator host to emit electromagnetic energy. Nearby electronic equipment may be affected. The user shall pay attention to the operation of other electronic equipment nearby. If abnormal operation is found, measures shall be taken immediately to remove the equipment or add shielding. Operation affected by portable and mobile RF communication equipment.

⚠Warning: Use of accessories, converters and cables other than those specified may result in increased radiation or reduced immunity to interference, except for converters and cables approved by the manufacturer as replacement parts for internal components.

⚠WARNING: IT SHOULD NOT BE USED CLOSE TO OR STACKED WITH OTHER EQUIPMENT. IF IT MUST BE USED CLOSE TO OR STACKED WITH OTHER EQUIPMENT, IT SHOULD BE OBSERVED AND VERIFIED THAT IT CAN OPERATE NORMALLY UNDER THE CONFIGURATION USED.

Guidelines and Manufacturer's Declaration - Electromagnetic Emission

The Columbus™ system is intended to be used in the electromagnetic environment specified below, and the purchaser and user shall ensure that it is used in such electromagnetic environment.

Emission test	Compliance	Electromagnetic Environment - Guide
Radio Frequency TransmitterGB 4824	Group 1	RF energy is used only for its internal function. Therefore, its RF emission is very low and there is little possibility of interference with accessory electronics *
RF emission GB4824	Class A	Suitable for use in non-domestic and all facilities not directly connected to the public low-voltage supply network of domestic dwellings
Harmonic emission GB17625.1	Not applicable	
Voltage fluctuation/flicker emission GB17625.2	Not applicable	

*** This product does not have the function of RF ablation energy emission and is only used as the RF transfer channel to transfer the energy of the RF ablation emission equipment to the RF ablation catheter.**

Guidelines and Manufacturer's Declaration - Electromagnetic Immunity			
The Columbus™ system is intended to be used in the electromagnetic environment specified below, and the purchaser and user shall ensure that it is used in such electromagnetic environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic Environment - Guidelines
Electrostatic discharge GB/T 17626.2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	The floor shall be wood, concrete or ceramic tiles and if covered with synthetic material the relative humidity shall be at least 30%
Electrical fast transient pulse train GB/T 17626.4	±2 kV pair power cord ±1 kV pairs of input/output lines	±2 kV pair power cord ±1 kV pairs of input/output lines	Mains power should be of typical commercial or hospital quality
Surge GB/T 17626.5	±1 kV wire-to-wire ±2 kV line to ground	±1 kV wire-to-wire ±2 kV line to ground	Mains power should be of typical commercial or hospital quality

Voltage dips, short interruptions and voltage changes on the power input line GB/T 17626.11	<5 %Ut for 0.5 cycle (On Ut, sagging of >95%) 40% U% for five cycles (On Ut, 60% dip) 70% U% for 25cycles (On Ut, 30% dip) <5% Ut for 5s (On Ut, sagging of >95%)	<5 %Ut for 0.5 cycle (On Ut, sagging of >95%) 40% U% for five cycles (On Ut, 60% dip) 70% U% for 25cycles (On Ut, 30% dip) <5% Ut for 5s (On Ut, sagging of >95%)	Mains power should be of typical commercial or hospital quality. If the user of the [prototype 007] needs to run continuously during power interruption, it is recommended that the [prototype 007] be powered by an uninterruptible power supply or battery.
Power frequency magnetic field(50 Hz/60 Hz) GB/T 17626.8	3A/m	3A/m	The power frequency magnetic field shall have the characteristics of power frequency magnetic field level in typical commercial or hospital environment
Note: Ut refers to the AC network voltage before the test voltage is applied.			

Guidelines and Manufacturer's Declaration - Electromagnetic Immunity			
The Columbus™ system is intended to be used in the electromagnetic environment specified below, and the purchaser or user shall guarantee its use in such electromagnetic environment			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic Environment - Guidelines
RF conduction GB/T 17626.6 Radio-frequency radiation GB/T 17626.3	3 V(Valid values) 150kHz～80 MHz 3 V/m 80MHz～2.5 GHz	3V(Valid values) 3 V/m	Portable or mobile RF communication equipment shall not be used in any part closer to the recommended isolation distance, including cables. This distance shall be calculated by the formula corresponding to the frequency of the transmitter. Recommended Isolation Distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80MHz～800MHz $d=2.3\sqrt{P}$ 800MHz～2.5GHz Where, P is the maximum rated output power of the transmitter provided by the transmitter manufacturer, in watts (W); D - recommended isolation distance in meters (m). The field strength of the fixed RF transmitter is determined by electromagnetic site survey a and shall be lower than the compliance level in each frequency range b. Interference may occur in the vicinity of equipment marked as conforming to the following.

Note1: At 80 MHz and 800 MHZ frequency points, use the formula of higher frequency band.

Note 2 These guidelines may not be appropriate for all situations where electromagnetic propagation is affected by absorption and reflection of buildings, objects and human bodies.

A fixed transmitters, such as base stations for wireless (cellular/cordless) telephones and terrestrial mobile radios, amateur radios, AM and FM radio broadcasts, and television broadcasts, are not theoretically accurate. In order to assess the electromagnetic environment of fixed RF transmitters, an electromagnetic site survey shall be considered. If the measured field strength of the site is higher than the applicable RF compliance level above, it shall be observed to verify proper operation. If abnormal performance is observed, supplemental measures may be necessary, such as reorienting or positioning.

B The field strength shall be less than 3 V/m over the entire frequency range of 150 kHz ~80 MHz.

Recommended separation distances between portable and mobile RF communication equipment and

Columbus™ system phase is used in electromagnetic environment with controlled radio frequency radiation disturbance. Depending on the maximum rated output power of the communication equipment, the purchaser or user can prevent electromagnetic interference by maintaining the portable and mobile radio frequency communication equipment (transmitter) and the minimum distance between them as recommended below

Maximum rated output power of transmitter W	Isolation distance/m corresponding to different frequencies of the transmitter		
	150kHz～80MHz $d=1.2\sqrt{P}$	80MHz～800MHz $d=1.2\sqrt{P}$	800MHz～2.5GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1. 2	1. 2	2. 3
10	3. 8	3. 8	7. 3
100	12	12	23

For the maximum rated output power of the transmitter not listed in the above table, the isolation distanced, in meters (m), can be determined by the formula in the corresponding transmitter frequency column, where P is the maximum rated output power of the transmitter, in watts (W), provided by the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz frequency points, the formula of higher frequency range is used.

Note 2 These guidelines may not be appropriate for all situations where electromagnetic propagation is affected by absorption and reflection of buildings, objects and human bodies.

2.7 **Interference with other equipment**

The low-intensity magnetic field generated by the magnetic field generator is necessary for the normal operation of the Columbus™ system and may interfere with the surrounding equipment, so you should pay special attention to:

- The Columbus™ system may interfere with programming of implantable cardiac stimulators, in vivo cardiac defibrillators, or other such devices while in operation. Do not use this system when communicating with any cardiac stimulator or defibrillator setup procedure. If you need to set a program or communicate with a

stimulator or defibrillator, temporarily turn off the magnetic field generator of the Columbus™ system. For details, see Chapter 5 of this manual.

- The normal use of the stimulator will not be affected by the Columbus™ system.
- The Columbus™ system interferes with fluoroscopy systems using magnetic field sensors.
- The Columbus™ system may interfere with the digital fluoroscopy system.
- ColumbusMAX system has adopted the design of anti-electrosurgical knife and met the relevant standards. However, in the course of use, it is inevitable that the equipment will be affected by factors such as the operator's use method and power. At this time, please read the precaution.

2.8 **Positioning interference**

The three-dimensional position data calculated by the Columbus™ system may deviate due to interference for a variety of reasons. The following points should be noted during your use to avoid adverse effects on the procedure.

- Ferromagnetic materials present in and around the working area of the magnetic field generator can interfere with the positioning accuracy of the Columbus™ system. Items similar in size to those commonly used in surgery, such as scissors, scalpels, metal terminals of surface electrode patches, etc., are generally not allowed to be located within 10 cm of the space between the catheter and the magnetic field generator and the catheter tip. For the generator of DSA in the operating room, the minimum allowable distance from the magnetic field generator is 20 cm; For the receiver of the DSA, it allows a minimum distance of 40 cm from the magnetic field generator.
- During map acquisition, rotate the DSA's handpiece. The DSA position and table position should be kept unchanged during a continuous data collection. If you need to adjust the position and angle, you must discard the current data and collect new maps again.
- The patient interface unit (PIU) and power supply module shall be at least 1 meter away from the magnetic field generator.
- The catheter handle should be located 20 cm from the magnetic field generator.
- The catheter should be within the measurable range.
- The catheter should not be subjected to improper handling or storage conditions, such as exposure to extreme temperatures or excessive mechanical pressure.
-

2.9 **DSA interference**

When the Columbus™ system works, its magnetic positioning function will be interfered by DSAs and their handpieces. When the DSA angle is changed or the table position is adjusted, the positioning data of the system for the magnetic positioning area will drift. Therefore, you must keep the DSA angle and the position of the operating table unchanged during a procedure.

If you need to adjust the DSA angle or table position, you must be aware that the surgical data collected previously will not match exactly the data collected later. In this case, you may need to abandon the surgical data collected previously.

2.10 User training

The Columbus™ system must be qualified as a practitioner and trained in the use of the Columbus™ system.

2.11 System maintenance

Warning: Users are prohibited to repair or modify the Columbus™ system by themselves or by a third party not approved by MicroPort EP.
No internal parts of the Columbus™ system, other than fuses, need to be serviced by the user. If the Columbus™ system is not operating properly or malfunctions, contact Shanghai MicroPort EP MedTech Co., Ltd. Customer Support.

2.12 Storage and Transportation Conditions

Storage and transportation temperature range of Columbus™ system is -40℃~+55℃, relative humidity is 10 %~80%, atmospheric pressure range is 500hPa~1060hPa, no corrosive gas, dry, cool, well ventilated and clean environment.
Heavy pressure, direct sunlight and rain and snow leaching shall be prevented when transporting the Columbus™ system.

2.13 Working conditions

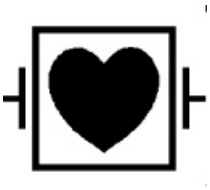
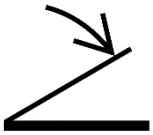
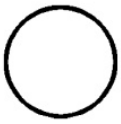
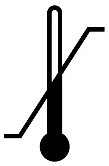
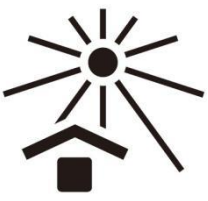
1) Ambient temperature: +5~+40℃.
2) Relative humidity: 10 %~80%.
3) Atmospheric pressure: 700hPa~1060hPa.
4) Altitude: ≤3000 m
5) Power supply: Voltage: AC 220 V, frequency: 50 Hz.
6) System power: 2000 VA.

2.14 Scrapping

At the end of the expected service life, the equipment and accessories of the system shall be handled with reference to the local laws and regulations, and discarding the equipment and accessories at will may cause harm to the environment and have potential laws and regulations risks.

2.15 Symbol Description

The Columbus™ system is shipped with the accompanying documents. Before starting to use the system, please read all the accompanying documents of the system carefully.

Warning		Defibrillation-proof CF application part	
Instructions must be read		Equipotential equalization	
Footswitch		Data connection	
Power OFF		Power ON	
European Standard Compliance		Manufacturer	
Electrostatic sensitive equipment		Not disposable	
Transport Humidity Limit		Transport Temperature Limit	
Atmospheric pressure limit		Afraid of rain	
Fragile articles Careful handling		Fear of sun	

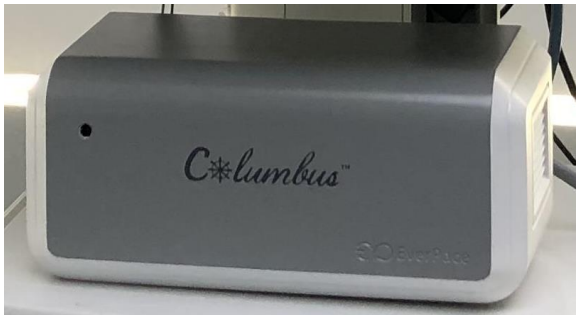
2.16 Explanation of Chinese and English Abbreviations

Chinese name	English abbreviation
Intracardiac ECG	IECG
Surface electrocardiogram	SECG
Patient Interface Unit	PIU
Magnetic field generator	FG
Communication interface	COM
Optical fiber interface	OPT
Oxygen saturation	SpO
Invasive pressure	IBP

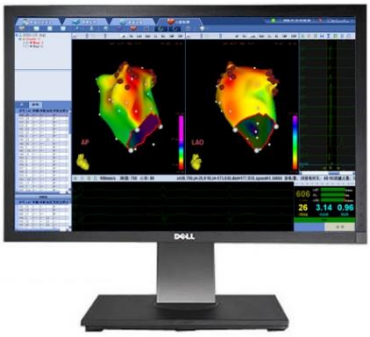
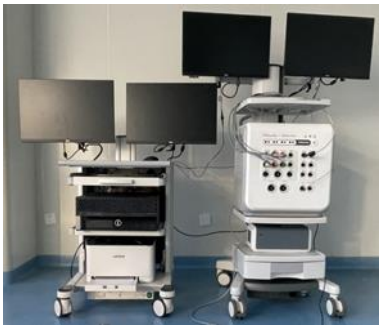
Chapter III Overview of Columbus™ System Equipment

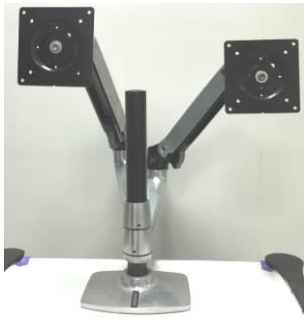
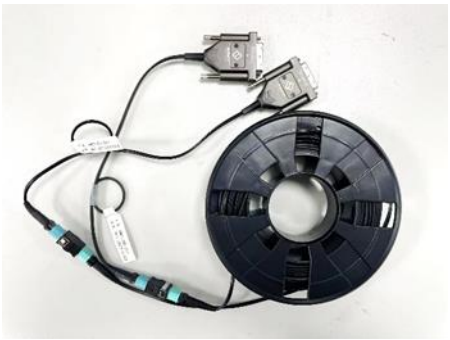
3.1. **Overview**

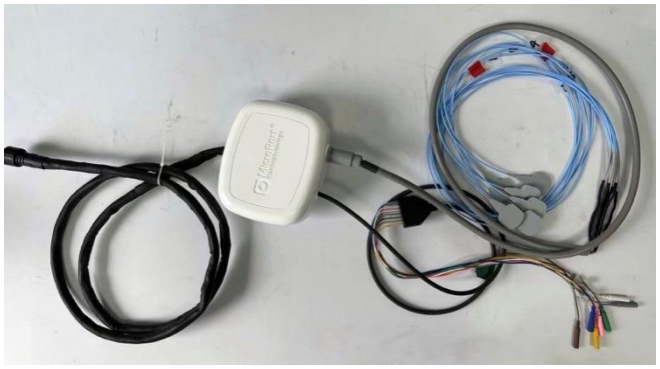
The Columbus™ system consists of the following components:

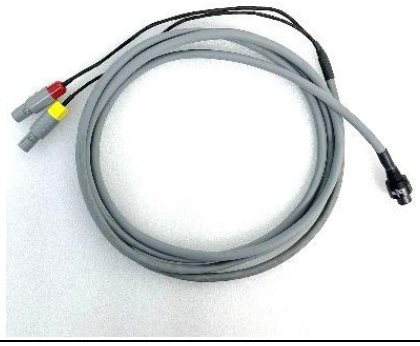
	Patient Interface Unit (PIU)	The unit includes a magnetic positioning operation function, an electrophysiological processor, and provides an interface for electrical connection between the patient and the EP system, RF generator, and stimulator. It provides 12-channel body surface ECG signal and multi-channel heart electrical signal detection function. It can receive the electrical signal data from the mapping catheter and the electrical signal at each excitation electrode on the human body and transmit it to the workstation.
	Power supply module	Used to power the patient interface unit

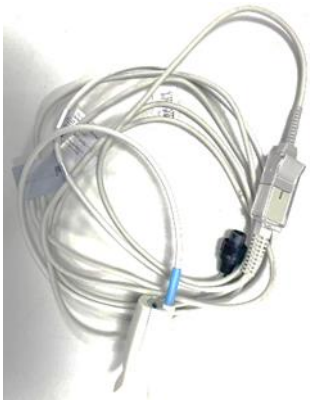
	BioLink intracardiac signal Adapter box	An additional 34-way internal electrical signal input can be provided to the patient interface unit.
	BioLink Standard SECG Adapter box	Twelve standard surface ECG signals can be output from the Columbus™ system.
 	Magnetic field generator(FG) Bracket type and window type	A device located below the operating table and capable of generating alternating electromagnetic fields for accurate position detection by a position sensor in the catheter.

	Workstation	The workstation of the Columbus™ system that executes the 3D mapping software of the Columbus™ system. Includes computer, keyboard and mouse. All patient data and images are stored on the computer hard disk. The computer is pre-installed with the operating system above Windows7.
	Display(24in, 1920* 1200 resolution)	Used to display the operator interface, patient data and images of 3D mapping software. The system can connect 4 monitors, two of which are used to display real-time operation information, and the other two can be used as review screen.
	Printer	Used to provide printing of records requiring paper review/preservation.
	Network switch	Used to receive and transmit data from computer workstations and patient interface units.
	Instrument car and console	The instrument car is used for the placement of patient application end parts; The console is used to place the parts at the operation end.

	Monitor stand	Used for display adjustment and fixed placement.
	Power cord and power extension cord	For product power connection.
	12-conductor surface ECG lead wire	Used for surface ECG signal lead.
	DVI Fiber Video Cable	For video signal output lead(Splitter to display)
	Splitter	It is used to copy the video signal output from the workstation.

	Video cable	Used to output video leads from the workstation to the splitter
	Optical fiber communication line	Used for signal transmission from the patient interface unit to the network switch.
	Magnetoelectric leads and Columbus™ External Reference Patch	It is used to transmit excitation signal and magnetic signal of acquisition patch position to computer workstation through serial port. Pasted on the back of the patient to provide positioning reference data for the Columbus™ system.
	Grounding cable	Used for operating room equipotential terminal connection.

	Stimulation input cable	Signal lead for cardiac stimulator and patient interface unit.
	Tail line of generator connection	Used for patient interface unit and RF signal lead of cardiac generator.
	Invasive blood pressure tail line	Used to connect the invasive blood pressure sensor and the invasive blood pressure extension line
	Invasive blood pressure extension line	Used for connecting the patient interface unit with the invasive blood pressure tail line.

	Blood oxygen cable	Used to connect blood oxygen sensor to PIU.
	Multi-lead output adapter cable A	Used to transfer intracardiac signals to multi-channel devices.
	Multi-lead output adapter cable B	Used to transfer intracardiac signals to multi-channel devices.
	Fast insertion tail line	Used in conjunction with the common conduits of ColumbusMAX mapping system, there are different types of tails according to different types of conduits.
	Serial communication line	Connect the PIU with the host workstation to transmit data.

	Foot switch	Carry out samping point mapping
	Patient interface unit power supply line	Connect the patient interface unit and the power box to supply power to the patient interface unit

The Columbus™ system can be ued with following combination device to achieve the intended use or function.

Combined device	Function
Ablation Catheter (2D/3D)	Apply the ablation energy to lesions for radiofrequency ablation procedure
Mapping Catheter (2D/3D)	Electrophysiological signals and electrode position information acquisition for ECG analysis and heart cavity modeling
Reference Patch	Connects the Back and Chest Patches to the PIU, and transfers location data from the patch sensors.
Cardiac Electrophysiology Stimulator	Device used for the generation of pacing signals and sequences.
Generator	Device used for generating radiofrequency energy for ablation
Cable for 3D Catheter Cable for Mapping Catheter	Data transmission

3.2. **Cable connection of the system**

Before starting the procedure with the Columbus™ system, check that all parts are connected as shown in Figure 3-7. Table 3-5 details the system connection diagrams and identifies the interfaces and connection points between the various components.

NO.	Name	Cable length（m）	Whether to shield or not	Remarks
1.	Pedal switch cable	2.5	Yes	/
2.	Communication optical fiber line	10	NO	Optical fibre
3.	Serial Line	10	Yes	PIU-workstation
4.	Magnetic generator cable	4.5	Yes	/
5.	Stimulation input patch cord	2.5	NO	PIU-stimulator
6.	PIU-RF instrument connection tail	2.5	Yes	PIU-cardiac radiofrequency instrument
7.	CS plotting tail line	2.5	Yes	PIU-catheter
8.	TF ablation tail line	2.5	Yes	PIU-catheter
9.	High density mapping tail line	2.5	Yes	PIU-catheter
10.	QUAD mapping tail line	2.5	Yes	PIU-catheter
11.	Non-mangnetic CS tailline	2.5	Yes	PIU-catheter
12.	Inner electric junction box cable	2.5	Yes	/
13.	Multi-conductor output patch cord a	2.5	Yes	/
14.	Multi-conductor output patch cord b	2.5	Yes	/
15.	Magnetoelectric lead box tail wire	1.5	Yes	
16.	Magnetoelectric conducting wire-1	2.3	Yes	/
17.	Magnetoelectric conducting wire-2	2.3	NO	/
18.	12 Conductor Centroid Conductor Connection connection	3.4	Yes	Patient cable2.1,Lead wire1.3
19.	12 -conductor ECG output box cable	2.2	Yes	/
20.	Invasive blood pressure rxtension line	2.5	Yes	/
21.	Invasive blood pressure	2.9	Yes	/
22.	Blood oxygen	2.4	Yes	/
23.	Video optical fiber line	10	NO	Optical fibre*2
24.	Instrument vehicle power cord	2.5	NO	Used for instrument
25.	Console power cord	2.5	NO	Used for console power
26.	Equipotential equalizing conductor of operation console	2.5	NO	Operations area
27.	Equipotential equalization conductor of instrument vehicle	2.5	NO	Instrument truck

Generally, the patient interface unit (PIU) is placed on the trolley, which can be moved in the operating room according to actual needs. The host workstation and its trolley can be located in the operating room or nearby control room; The magnetic field generator is fixed under the operating table; The accessory cables of the application part shall be placed on the operating table.

Note: When using the trolley to move in the operating room, please pay attention to fixing the monitor bracket, drawer and any other accessories that may move unexpectedly to avoid accidental injury to the operator and equipment.

When the trolley moves, all cables shall be disconnected without operation. In case of obstacles such as door sill, attention shall be paid to movement mode and pulling mode shall be adopted to avoid equipment damage caused by hard pushing.

Warning: Do not connect or disconnect any cables halfway through the Columbus™ system. This behavior may cause electric shock or damage to the equipment.

Warning: The system is not expected to communicate with non-MicroPort EP-approved devices, and the connection of the system to the IT- network containing other devices may result in previously unidentified risks to the devices, patients, operators, and third parties. The responsible party should identify, analyze, evaluate and control these risks; The responsible party shall make supplementary analysis on the possible introduction of new risks in the subsequent modification of IT- network; It network modification envelope, but not limited to configuration change, network update, upgrade, new equipment, etc.

⚠ Note:

Workstations and displays shall be at least 1.5 meters from the operating table.
The patient interface unit should be at least 1 meter from the magnetic field generator.
The catheter handle should be at least 20 cm from the magnetic field generator.
All grounding cables must share a common grounding terminal.
All cable connectors must be securely plugged in.
Cable lines shall be tied together using winding tubes or straps.
Cables shall be laid in such a way as to avoid being trampled or run over by hospital equipment.
Warning: If the user has more than one Columbus™ system, do not swap patient interface units or magnetic field generators. Doing so may prevent the system from working properly.

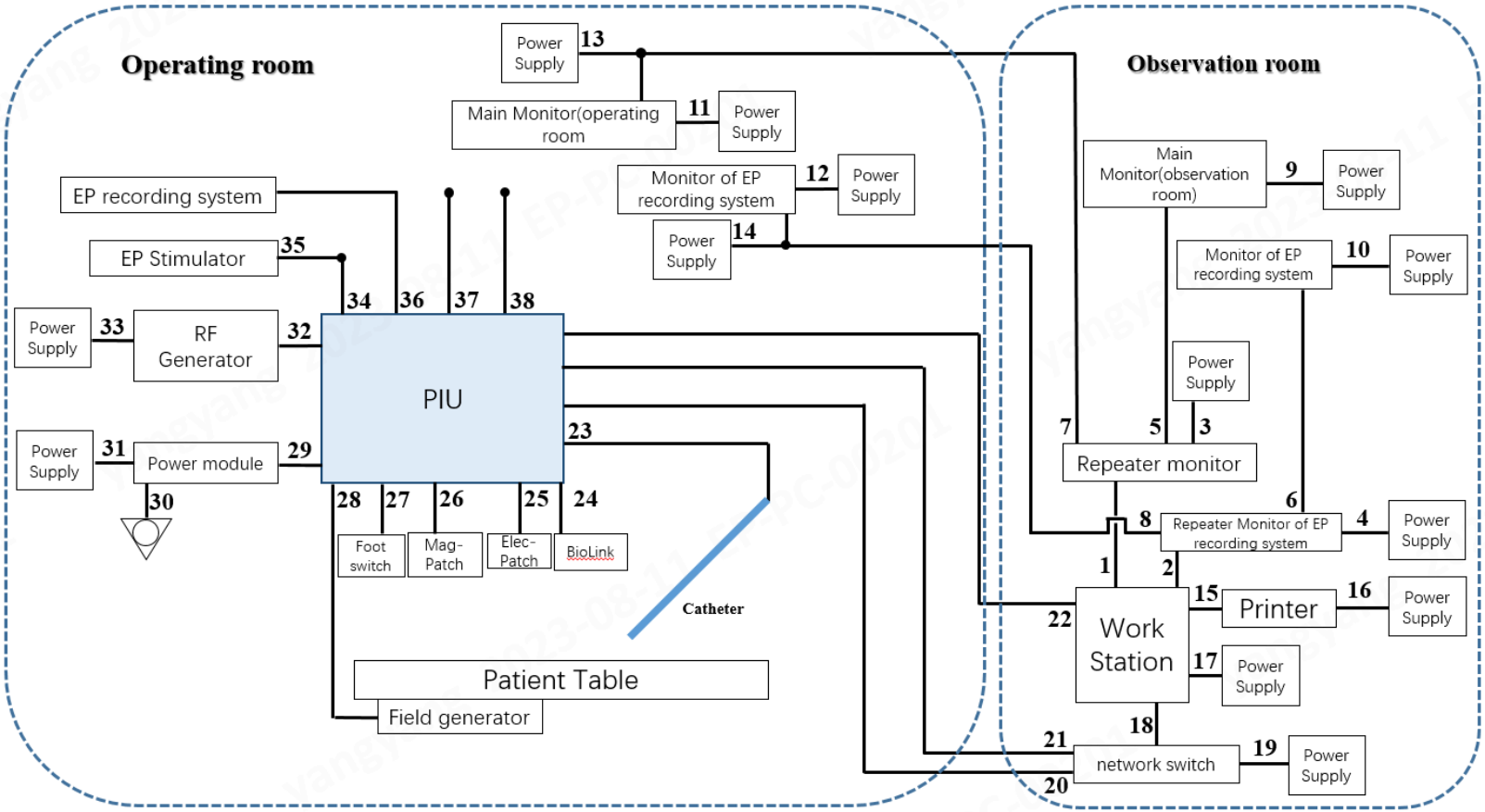


Figure 3-1 Columbus™ System Wiring Diagram

Table 3-1: Wiring Description Of Each Component Of The System

Wire number	Cable name	From	To
1	Video cable	Workstation video output	Main Splitter Video Input
2	Video cable	Workstation video output	Multi-channel splitter video input
3	Splitter adapter cable	Main Display Splitter	Power socket
4	Splitter adapter cable	Multichannel screen splitter	Power socket
5	Video cable	Main display splitter video output	Video input end of main display screen of console
6	Video cable	Video output of multi-channel display splitter	Console multi-channel display video input
7	Video cable(Optical fiber)	Main Splitter Video Output	Instrument owner display video input
8	Video cable(Optical fiber)	Multi-channel splitter video output	Multi-channel display video input terminal of instrument car
9	Power cord	Power socket of console main display screen	Power socket
10	Power cord	Console multi-channel display power socket	Power socket
11	Power cord	Instrument owner display power socket	Power socket
12	Power cord	Power socket for multi-channel display screen of instrument car	Power socket
13	DVI cable adapter cable	Instrument owner display screen DVI cable	Power socket
14	DVI cable adapter cable	DVI cable of multi-channel display screen of instrument car	Power socket
15	Print data line	Workstation	Printer
16	Power cord	Printer power socket	Power socket
17	Power cord	Workstation power socket	Power socket
18	Network communication line	Workstation	Network switch
19	Power cord	Network switch	Power socket
20	Optical fiber communication line	PIU back fiber interface	Network switch fiber interface
21	Optical fiber communication line	PIU back fiber interface	Network switch fiber interface
22	DB9 serial port communication line	Back DB9 serial port of PIU	DB9 serial port of the workstation
23	Catheter connection tail	PIU front socket	Catheter
24	BioLink module cable	PIU front "BOX socket	BioLink module
25	Magnetic lead wire	"PATCHES" socket for PIUs	Magnetic positioning electrode patch

Wire number	Cable name	From	To
26	Columbus™ External Reference Patch connection tail	"PATCHES" socket for PIUs	Columbus™ External Reference Patch
27	Foot switch cable	PIU Back "FS" Socket	Footswitch
28	FG control line	PIU Back "FG" Socket	Magnetic field generator
29	Power supply line of patient interface unit	Power output interface of power module	PIU back power input interface
30	Equipotential equalization cable	"" Grounding post of power module	Equipotential equalization column for other equipment
31	Power cord	Power input interface of power module	Power socket
32	Connection tail of PIU-generator	PIU front "RF GEN" socket	RF output socket of cardiac RF generator
33	Power cord	Cardiac radiofrequency generator	Power socket
34	Stimulator cable	Stimulation patch cord	Cardiac electrophysiological stimulator
35	Stimulation input cable	"Stimulator," "plus" and "minus" sockets of the patient interface unit	Red and black terminals of output line of stimulator
36	Connecting cable of multi-channel physiological recorder	"IC OUT" socket on front panel of PIU	Multi-channel physiological recorder
37	12-channel surface ECG output cable	"SECG OUT" socket for PIUs	Electrode conversion box for BioLink or other EPs system
38	12-conductor surface ECG lead wire	Patient Interface Unit Front "SECG IN" Socket	Patient's extremities and chest surface
* The following cables are not configured for the system, but need to be connected to the system PIU for supplementary instructions.			
38	Stimulator cable	Stimulation patch cord	Cardiac electrophysiological stimulator
39	Connecting cable of multi-channel physiological recorder	Multi-lead output adapter	Multi-channel physiological recorder

Note:

The module marked with a red dotted line in the part name in Figure 3-1 belongs to the auxiliary medical device provided by the Company or a third party during the radiofrequency ablation procedure with this 3D mapping system, and is not the own component of this 3D mapping system. They are the operating table, generator, stimulator and common mapping catheter, and other electrophysiological systems. These companion devices are listed here to better explain how the system works and uses. The front and rear panels of the patient interface unit and the corresponding cable connections are shown in Figure 3-2, Figure 3-3, Figure 3-5 and Table 3-

1.

The patient interface unit can turn on the power switch of the power module only after the test system is connected correctly.

Warning: Before starting the power module switch, check whether the voltage value corresponding to the power switch is adjusted to a value consistent with the local voltage, and check whether the correct fuse is installed in the fuse box of the power input port. (Corresponding installation T6.3AL250V fuse)

Caution: Do not cover or block the vents on the side of the patient interface unit for heat dissipation.

3.3. **Patient Interface Unit**

Figure 3-2 Front Of Patient Interface Unit

Table 3-2 Description Of The Front Wiring Of The Patient Interface Unit（D 版第 26 页 不同

Non-catheter interface		
Serial Number	Name	Connected to
1	4-pair stimulator interface	Stimulator
2	Power indicator	/
3	Generator interface	RF Generator
7	SECG input interface	Patient surface ECG cable
8	Standard SECG output	Standard ECG cables for BioLink surface ECG transfer boxes or other EPs
13	4 IBP interfaces	IBP detection module
14	Excitation output	Tail line of magnetic lead line and Columbus™ External Reference Patch
17	Multi-lead transfer interface	Used to transfer and input signals of other multi-lead devices
18	SpO2 interface	SpO2 detection module

19	Ultrasonic output port	(Reserved)
Catheter-type interface		
Serial Number	Name	Connected to
4	Ablation Catheter Interface(Magnetic positioning function)	Ablation Catheter
5	Mapping Catheter Interface(Magnetic positioning function)	Ten-pole mapping catheter
6	Quadrupole Mapping Catheter Interface A	Quadrupole Mapping Catheter
9	High Density Mapping Catheter Interface (Including magnetic positioning function)	High Density Mapping Catheter
10	Mapping Catheter Interface	Non-magnetic ten-pole mapping catheter
11	Quadrupole Mapping Catheter Interface B	Quadrupole Mapping Catheter
12	Quadrupole Mapping Catheter Interface C	Quadrupole Mapping Catheter
15	High Density Mapping Catheter Interface	High density mapping catheter supporting up to 62 electrodes
16	Input port of BioLink adapter box	BioLink adapter box, which can be connected to electrode 1-34

The interfaces in the front of the patient interface unit are all application parts.

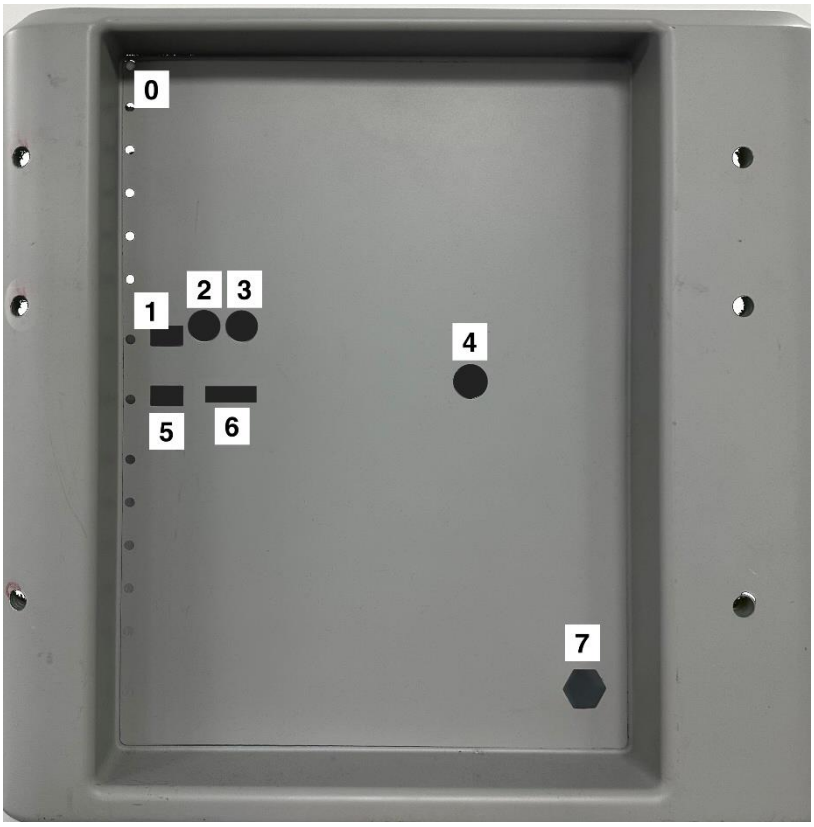


Figure 3-3 Back Of Patient Interface Unit

Table 3-3 Wiring Instructions On The Back Of The Patient Interface Unit

Serial Number	Name	Connected to
0	14 circuit board status indicators	/
1	Fiber output interface(OPT)	Network switch SC socket
2	Foot switch interface	Footswitch
3	Reserved interface	/
4	Control interface of magnetic field generator	Magnetic field generator
5	Fiber output interface(OPT)	Network switch SC socket
6	RS 422 Interface	Workstation
7	Power input interface	Power output interface of power module

3.4. **Power supply module**

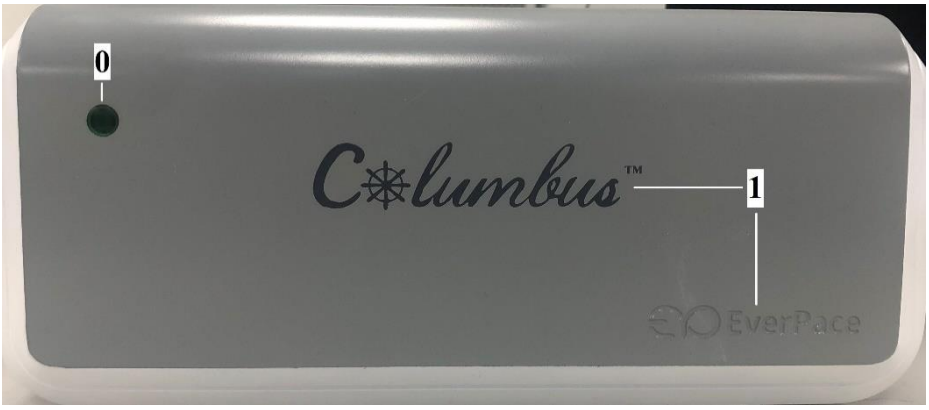


Figure Front Of 3-4 Power Module

Table 3-4 Description Of The Front Wiring Of The Patient Interface Unit

Serial Number	Name	Connected to
0	Status indicator	/
1	Product label	/

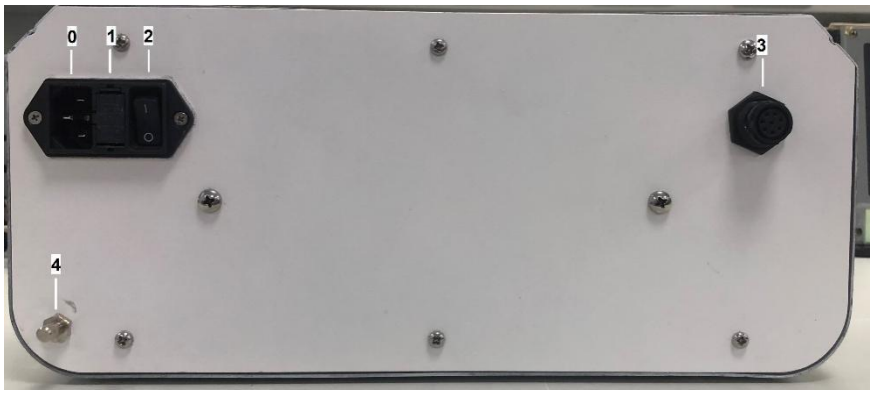


Figure Back Of 3-5 Power Module

Table 3-5 Wiring Instructions On The Back Of The Patient Interface Unit

Serial Number	Name	Connected to
0	Power input interface	Power socket
1	Fuse	/
2	Power switch	/
3	Power output interface	Power input interface of the patient interface unit
4	Equipotential equalization column	Equipotential equalization cable

Basic connection of electrophysiology surgery

Refer to Figure 3-1, Figure 3-2, Figure 3-3 and Figure 3-5 and connect the patient interface unit to

the corresponding device as follows:

1） One end of the power module is connected to the power connector of the patient interface unit (back 7) with a power cable, and the other end is connected to the power socket with a power cable.

2） One end of the serial port communication cable is connected to the RS6 serial port on the back of the patient interface unit, and the other end is connected to the RS6 serial port on the host.

3） One end of the two fibers is connected to the back fiber connector of the patient interface unit (back 1 and back 5), and the other end is connected to any SC fiber connector of the network switch.

4） Insert the field generator cable into the FG control interface of the patient interface unit (back 4).

5） Connect the magnetoelectric lead wire to the front excitation connector of the patient interface unit (front 14), connect the excitation patch at the other end, and stick it to the position of the patient's body surface as instructed.

6） Insert the FORLNK™ Cable for 3D Irrigated Ablation Catheter into the catheter connector (front catheter connector) corresponding to the front of the patient interface unit, and connect the magnetic positioning catheter to the other end of the tail line.

A typical connection diagram is shown in Figure 3-1.

Typically, the user may need to obtain the IECG via another additional general electrophysiological mapping catheter. In this case, the additional intracardiac catheter can be connected to the IECG input interface socket (front catheter-like interface).

Once the operator powers on the power module, the power indicator on the front of the patient interface unit lights up.

Note: The tail line connected to the positioning catheter socket must be sterile, but the device is not sterile.

3.5. **Connecting the generator**

The patient interface unit has RF ablation generator and cardiac programmed stimulator signal input interfaces. The generator is not part of this 3D device. See Figure 3-6.

Warning:
Unless specifically permitted in the stimulator manufacturer's instructions for use, simultaneous radiofrequency ablation procedures are prohibited when you choose to perform stimulation with the Magnetically Located Mapping/Radiofrequency Ablation Catheter Tip electrode (M1-M2). Failure to do so may result in an adverse event of ventricular fibrillation or microbubble formation. Microbubbles increase the risk of thrombosis.

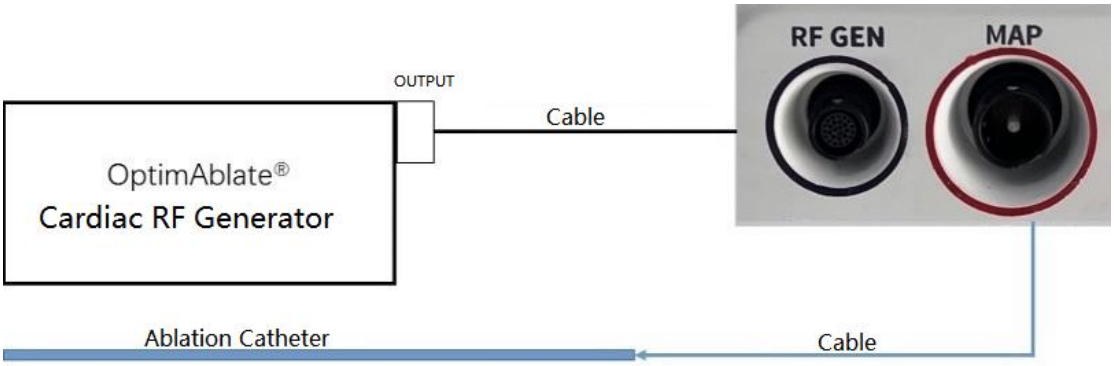


Figure 3-6 Connection Diagram Of Patient Interface Unit And Generator

When using a cardiac RF generator to connect an ablation catheter from another manufacturer, the signal collected by the ablation catheter can still be displayed by signal switching.

Columbus™ 3D EP Navigation System Refer to the following table for the recommended models of RF generator for this system. When using the radio frequency meter, please note to use the Electrical umbilical of the corresponding model manufactured by Shanghai MicroPort EP MedTech Co., Ltd. specified in the table:

RF Generator Model	RF generator manufacturer	Electrical umbilical	Cable interface
OptimAblate	Shanghai MicroPort EP Medical Technology Joint stock limited company	EPE-300A-2A	
Stockert EP shuttle	Us Johnson & Johnson	EPW ST	

Warning: If other models of RF generators are to be used, contact the Shanghai MicroPort EP MedTech Co., Ltd. technician prior to use to assess the compatibility of that model.

3.6. **Connect the stimulator**

The patient interface unit has a cardiac stimulator stimulation signal input interface. The stimulator is not part of this system. The stimulator can transmit the stimulation signal of the external stimulator to the four pairs of "+" and "-" stimulation input holes of the patient interface unit through the stimulation input cable. See Figure 3-7. The recommended cardiac stimulator models for this three-dimensional system are shown in the table below.

Cardiac Stimulator Model	Manufacturer of cardiac stimulator
DF-5A	Suzhou Dongfang Electronic Instrument Factory

Warning: If other cardiac stimulators are to be used, the compatibility of the cardiac stimulator model should be assessed by contacting the Shanghai MicroPort EP MedTech Co., Ltd. technician prior to use

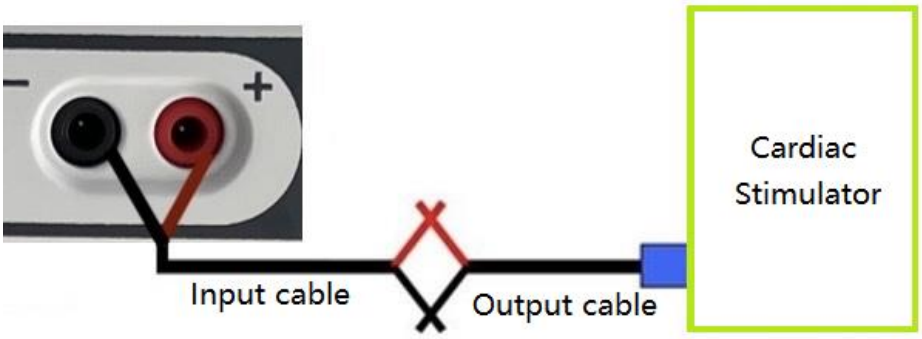


Figure 3-7 Connection Diagram Of Patient Interface Unit And Stimulator

3.7. **Output to other electrophysiological system**

The Patient Interface Unit allows the SECG to be output to other EP recording systems (see Figure 3-1).

To output the SECG signal to another EP recording system, you can insert one end of the BioLink module provided by the Shanghai MicroPort EP MedTech Co., Ltd. into the SECG OUT output interface on the front panel of the patient interface unit and connect the connector on the other end to another EP recording system.

Warning: ECG cables of other EP- recording systems connected to the standard SECG output terminal (metal surface electrode buckle) shall not be longer than 3m.

3.8. **Install and remove the magnetic field generator bracket**

The magnetic field generator of the Columbus™ system is fixed to the underside of the operating table by a magnetic field generator bracket or strap, and its center is located near the underside of the patient's heart to release a range of magnetic fields. The patient interface unit controls the operation of the magnetic field generator through the cable.
The bracket type magnetic field generator is fixed and installed in the bracket at the factory. The rack is specially designed to be installed under the operating table to ensure that the magnetic field generator is relatively fixed to the operating table during the whole operation, and can be removed from the operating table after the operation is completed for further storage.

Figure 3-8 Magnetic Field Generator

Note: Installation of the magnetic field generator under the operating table or removal of the magnetic field generator from the operating table should not be done by one person alone. The rack and the magnetic field generator may be damaged due to falling of the rack and the magnetic field generator by one person. When the window type magnetic field generator is installed, the magnetic field generator shall be fixed by one person and the strap shall be fixed to the operating table by the other person.
Before starting the electrophysiology procedure, adjust the fine adjustment knob on the side of the field generator rack so that the field generator is in the middle of the rack, and then install the field generator rack in the position below the patient's abdomen under the operating table. First pull the hanging arms on both sides of the magnetic field generator bracket outwards, and the distance between the hanging buckles is slightly larger than the width of the operating table. Then keep this width, lift the bracket under the operating table, slowly release the hanger arm to retract it inward until it is firmly hung under the operating table, and then tighten the 'lock pin' on the left rear side of the bracket to fix the bracket to prevent accidental falling.

Note: The factory setting of the hooks on both sides of the bracket type magnetic field generator corresponds to the operating table width of 460 mm; If the distance between the hooks on both sides is less than the width of the operating table, remove the locating pin on the back of the bracket, adjust the right hook to a proper position, install the locating pin, and then hang the bracket under the operating table.

Note: The magnetic field generator bracket can adjust 460 mm, 480 mm and 500 mm to correspond to different operating tables.

To remove the rack from the table, simply operate its installation steps in reverse order.
These personnel are to be installed by MicroPort EP approved personnel.

3.9. Recommended positioning catheters and Columbus™ External Reference Patch

For 3D mapping ablation procedures, this device can only be used with magnetic positioning mapping/ablation catheters and Columbus™ External Reference Patch manufactured by Shanghai MicroPort EP MedTech Co., Ltd..

At the end of the procedure, the MPM/Ablation Catheter and Columbus™ External Reference Patch should be removed and all used MPM/Ablation Catheters and Columbus™ External Reference Patch destroyed.

Note: When the Columbus™ External Reference Patch and positioning catheter are used for more than 24 h, the system reports an error and gives an error message.

Chapter IV Operation Basis

This chapter describes the basics of working with the Columbus™ system. Here we assume that you have the ability to use computers and are familiar with standard computer devices such as keyboards, mice, and displays.

Basic operations on the Columbus™ system include:

- Computer Foundation
- Working status
- User login
- Operation page

4. 1. Software Version

The system software version is V5.

4. 2. Computer Foundation

Before you start using the Columbus™ system, familiarize yourself with its workstations, especially its power buttons, DVDs, mice, and keyboards.

Using the mouse

The workstation is equipped with a three-button mouse. Depending on your needs, you will use the left, middle, and right mouse buttons.

- **Left key: Perform basic operations such as clicking buttons and selecting functions.**
- **Middle key: Operate the map for 3D rotation.**
- **Right-click to open the shortcut menu. The shortcut menu appears depending on the cursor position.**

Using Menu Options and Commands

There are three ways to use system functions and commands:

- **Shortcut menu: Right-click in a specific area of the screen to display shortcut menu options.**
- **Toolbar: Click the icon on the toolbar to use the corresponding function.**

- **Function key: The function key refers to the key assigned with common commands on the keyboard, usually F1-F12.**

Adjust window layout

The Columbus™ system's Cardiac Mapping page is divided into several sub-windows, some of which you can hide or adjust the relative size of each window.

1. Click the Show List button () in the toolbar to toggle between hiding or displaying the list of procedures and points on the left side of the screen.
2. Click the Show Adjustment Window button () in the toolbar to toggle between hiding or displaying the mark window to the right of the screen.
3. You can change the size allocation of multiple windows by clicking and dragging the boundaries between them. Click the drop-down arrow to the right of the Show Custom Layout button () to return to the system default initial window layout status or to set the current window layout as a custom widget in its drop-down menu. You can click the Show Custom Layout button at any time (except when the Playback dialog is open) to switch to the saved custom window layout.

Dialog box

When the dialog box appears in the Columbus™ system, the operator is required to make some form of input (such as input data, selection options).

Use Dialog:

1. Click OK to accept your changes and close the dialog box.
2. Click Apply to accept your changes, but do not close the dialog box.
3. Click Cancel to discard your changes and close the dialog box.
   Note:
   If you click Apply before clicking Cancel, the previous changes will not be canceled.
4. If no key appears, you can close the dialog box by clicking the icon  in the upper right corner.
5. Click and drag the top border of the dialog box to move it anywhere on the screen.

4. 3. Working status

The working status of the Columbus™ system is generally divided into two modes: Acquisition mode and playback mode.

Acquisition mode: Sometimes referred to as real-time mode. All functions related to the acquisition of map data are performed in this mode. This mode has four operating states:

a. **Ready state: In Ready state, the Acquisition button is available, and you can acquire data points to a 3D map.**
b. **Freezing status: When the Freeze button is clicked, the Columbus™ system will enter the freezing status immediately.**
   In the frozen state, you can carefully examine the point data to be collected to decide to accept or discard them. You can also edit the mark of the freezing point or use a label for that point.
c. **Edit Status: When you select a point in acquisition mode to browse or edit, the system enters edit status. The Acquisition button changes to the Continue button. The system does not collect new data before exiting the edit state.**
d. **Error status: If an error occurs and you are not allowed to continue, the system enters the error status and an error prompt button appears on the collection button.**
   The error prompt button acts as a toggle switch for displaying or hiding the system status panel containing all relevant error messages. Once the error is corrected, the system automatically returns to the state before the error. For details, see Processing Error Information.

Playback mode: The Columbus™ system will enter the playback mode if the Columbus™ system is opened by the operator and browses the existing medical record files on the hard disk or CD, or imports the CT/MRI study data from the CD for image processing and segmentation without the connection of the magnetic positioning mapping/RF ablation catheter. The Columbus™ system operates in playback mode, which is equivalent to the system operating when the magnetic positioning function is not enabled. In addition to creating a new map or acquiring real-time 3D data, you can perform other browsing and editing operations in playback mode. Therefore, when working in playback mode, all work is performed and saved on the workstation.

4. 4. User login

After starting the workstation of the Columbus™ system, the Columbus™ 3D EP Navigation System software (hereinafter referred to as the Columbus™ system software) will start automatically and enter the user login interface (Figure 4-2).

The Columbus™ system provides two types of users with access to the system software: Doctor and administrator. The latter is designed for use by Shanghai MicroPort EP MedTech Co., Ltd. technical support personnel. The user can choose to log in as a doctor and change the login password.

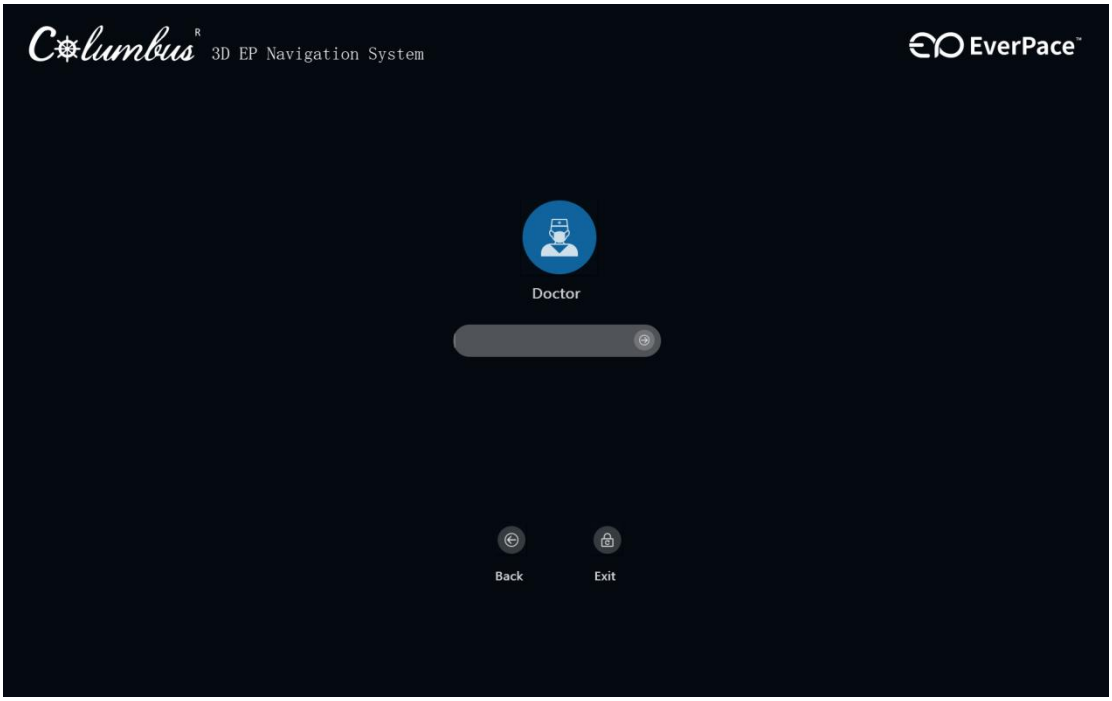


Figure 4-1 Doctor Login Interface

Figure 4-1 Password Modification Dialog Box

Note: Consult Shanghai MicroPort EP MedTech Co., Ltd. technical support regarding the initial password configured by the system software for the user. The external interface of the host shall not be connected to other storage media without permission.

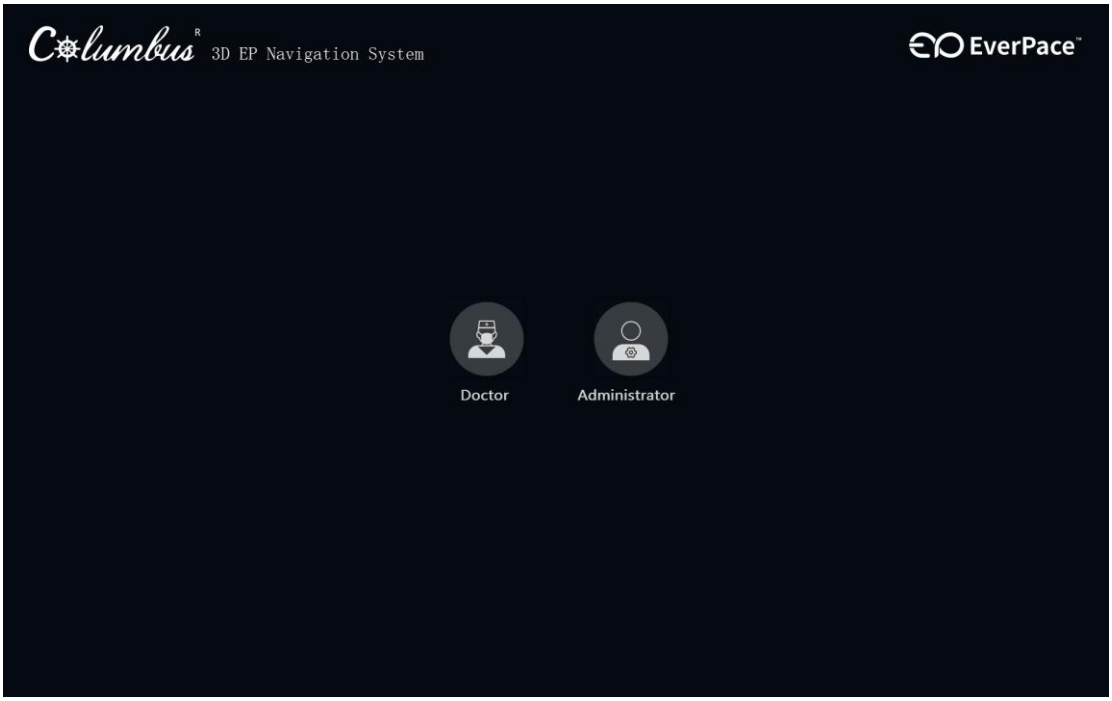


Figure Login Interface Of 4-2 Columbus™ System Software

4. 5. Operation page

The main operation interface of the Columbus™ system software includes the following four pages:

- Patient information login page
- Image Processing Page
- Channel Setup Page
- Cardiac Mapping Page

Figure 4-3 Columbus™ Operation Page Of System Software

Patient information login page

The patient information page is the default page after the Columbus™ system software is started. Before starting a new procedure, the operator needs to complete the patient and procedure information on this page. You will not be able to start a new procedure until you have completed the required items.

Patient Information:
Patient information includes basic patient information and contact details, including: Last name, first name, patient ID, gender, date of birth, and age. The last name, first name, patient ID, and date of birth are mandatory items.

Procedure Information:
Surgical information includes information about the procedure, including: Preoperative diagnosis,

surgeon, date of procedure, and comments.

You can switch to the Patient Information page to view patient information at any time while the procedure is in progress. If you need to create a new procedure during the procedure, or open the patient's medical record for browsing, you must end the current procedure first.

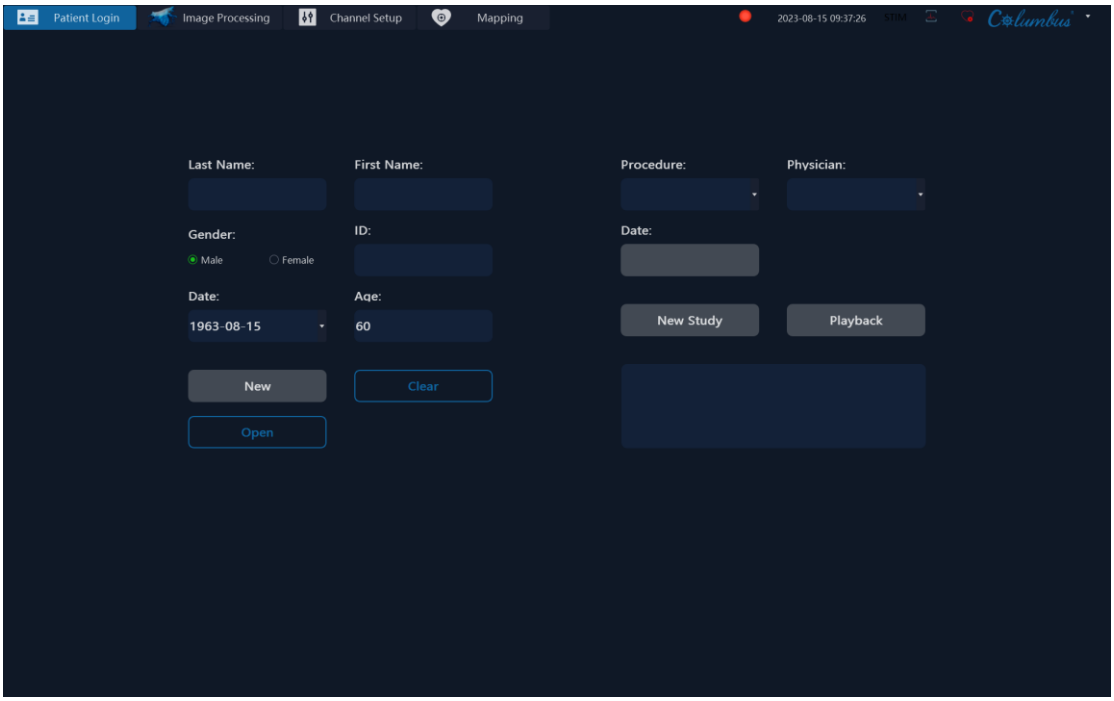


Figure 4-4 Patient Information Login Page

Image Processing Page

The Image Processing page is the page for the Columbus™ system to import and edit image data from CTs or MRIs. You can import study data from CTs or MRIs into the Columbus™ system via CDs and segment and edit them to generate surface images of the desired chambers.

"Scan DICOM"
The largest part of the image processing page is the segmentation window. The user can browse the 2D original DICOM image, 3D volume image or the segmented 3D surface image, or segment and edit the volume image.

"Patient database"
Import a set of raw sequences or image data and all 2D slices will be redrawn as 3D volume images. Segmentation is the division of a 3D volume image into structures of interest, usually the atria or ventricles mapped in real time.

Image Segmentation column
The Image Segmentation column contains the function keys for segmenting 3D volume images and a list of surface images that display the segmentation results. The operator can use these

function keys to place seeds and segment the volume images in the segmentation window, and directly edit the name and color of the volume images through the volume image list below them, or directly delete undesirable segmentation results.

For the operation method of importing CT/MRI images and segmenting volume images, please refer to Chapter 9 Segmentation and Registration.

Channel Setup Page

On the Channel Setup page, you can set the filter parameters and other options for the surface and intracardiac channels. You can change the parameters of the collected channel by clicking the channel setting page at any time during the procedure. It is recommended that you redo the channel setup each time you start a new procedure. If a new procedure is started, the default settings are automatically applied.

The channel settings of the Columbus™ system include: Body surface, intracardiac, interest window parameters, and stimulation channel settings. By creating and saving a template, you can save a custom channel setup protocol as a template, which can be invoked at any time in future operations.

For details on channel setup, see Chapter 6, Surgical Setup.

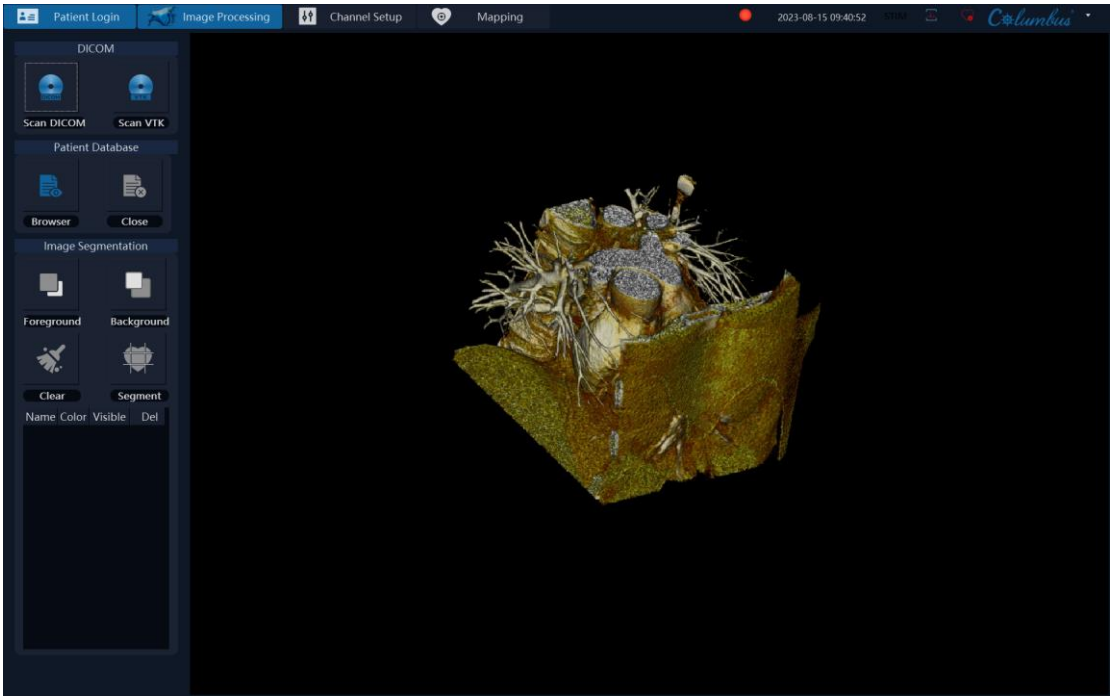


Figure 4-5 Image Processing Page

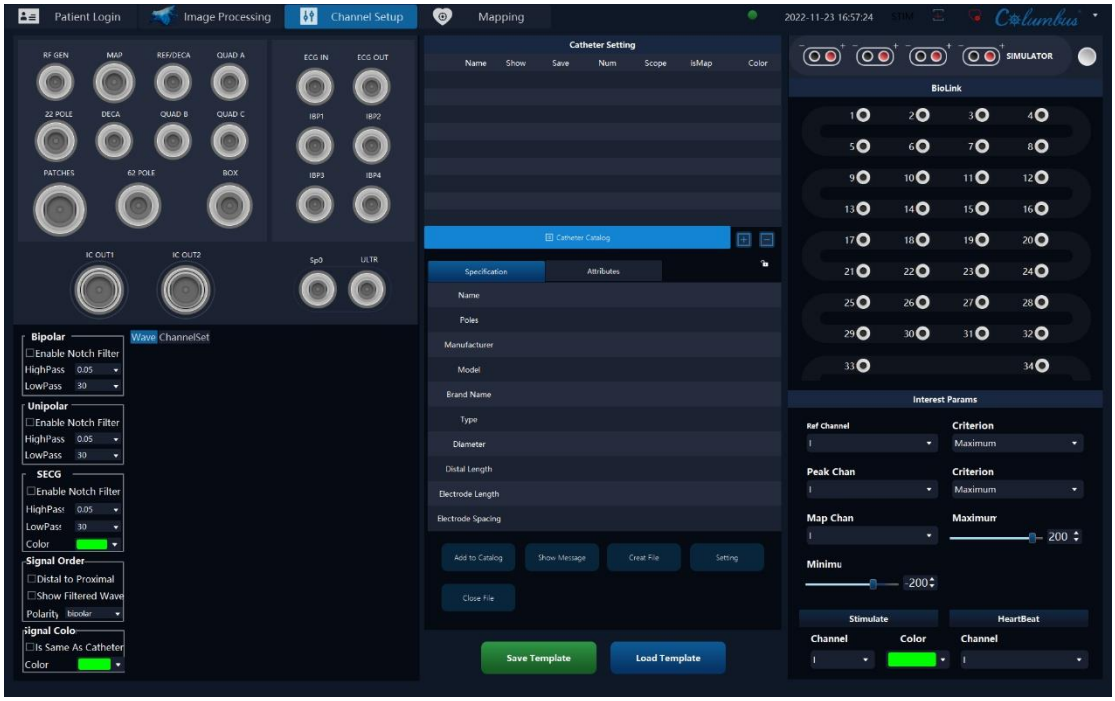


Figure 4-6 Channel Setup Page

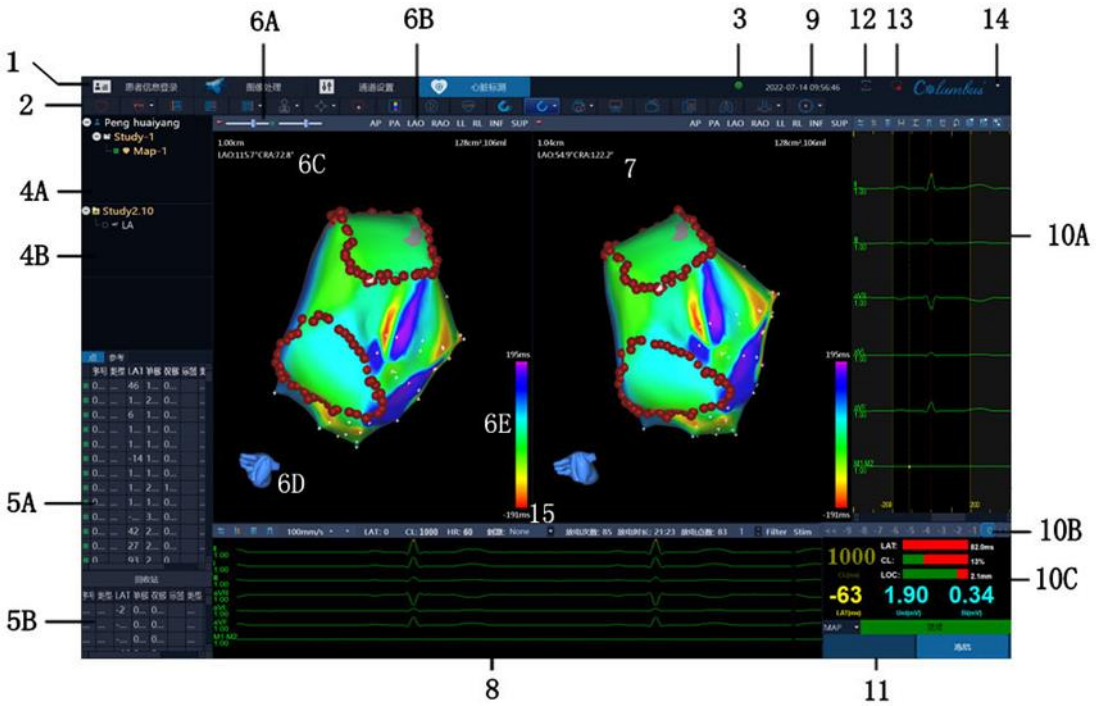
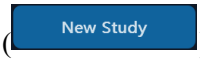
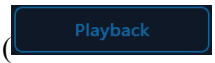


Figure 4-7 Cardiac Mapping Page

Cardiac Mapping Page

When you complete the system setup and need to start a new procedure, you need to switch to the Cardiac Mapping page by clicking the New Procedure button (

). In the initial state, the contents are not displayed in the map window. In Playback mode, you can enter the Cardiac Mapping page directly by clicking the Playback button (

).

The Cardiac Mapping page is the main working interface for the operator to perform three-dimensional cardiac electrophysiological mapping procedures, including the following different sub-windows:

Parts	Function
(1) Operation page	Switch the tabs of different operation interfaces.
(2) Toolbar	Icon button for quick access to common functions, including new map, page layout, etc.
(3) System Status Bar	Display the system hardware working status; Save the medical record quickly and exit the system.
(4) Procedure List	Browse and access the procedures and maps belonging to the current patient through the tree directory. (4a): 3D Mapping Procedure List: All procedures and maps of the current patient can be accessed. (4b): Image Study List: All surface images of the current patient can be accessed for registration with a 3D map.
(5) Point list	Data about points in the map can be accessed. (5a): List of mapping points. Includes point tab and reference tab. (5b): Recycle bin, where the content is the deleted point of the current map.
(6) Map Window	Display map and related information. (6a): Fill in the threshold column to adjust the integrity of the map display. (6B): The projection angle button can directly switch the view in the mapping window to the corresponding projection direction. (6C): Map information, including the scale of the current view, the surface area and volume of the map. (6D): Projection icon, displaying the current viewing direction. You can select different projection angles from the icon's right-click menu. (6E): Color scale to display the color change and upper and lower limits in the current mapping window.
(7) Map Window	In the second map window, all functions are identical to those in the first map window.
(8) Monitoring window	Displays only in acquisition mode, providing a continuous display of ECGs during the procedure. The toolbar of the monitor window only

	provides access to commands that are present in the monitor window.
(9) Date/Time	Displays the current date and time.
(10) Mark Window	Displays references, maps, and other selected channels. The toolbar above the markup window only provides access to commands found in the markup window. (10a): Channel panel, displaying all selected channels. (10b): Heartbeat cache. The sampling time can be selected from the last 10 heartbeats in frozen state. (10 C): Value of the stability column and point, showing the catheter tip position, heartbeat cycle and stability, and LAT and single and bipolar peak-to-peak voltage values. The value in this column is the value of the current point in the map window.
(11) Collect button	Acquisition, acceptance and abandonment of points can be achieved.
(12) Multichannel instrument window button	Open and close the multichannel analyzer window
(13) Complete Surgery button	Complete the current operation and return to the patient information login screen.
(14) Pull-down menu button	Display Case Management, Help, About, Exit
(15) Stimulation channel button	Choice of stimulation channels

For detailed functions and usage of each window in the cardiac mapping page, refer to Chapter 7: Mapping Page.

Chapter V Mapping Principles

This chapter deals with the working principle of the Columbus™ system and describes some operation steps related to the principle. A full understanding of these principles will help you understand how to use the entire system. This chapter will cover the following points:

- Understand point data, including various types of points, and how to collect points.
- Mapping and positioning.
- Magnetic field interference.
- Recognize the catheter icon.
- Processing error information.

5. 1. Mapping and positioning

When using the Columbus™ system, close attention must be paid to the location of the Columbus™ External Reference Patch and Magnetically Located Mapping/RFA Catheter. They must be located inside the precise positioning area to ensure accurate detection of the catheter's position during surgery.

Note:

- Catheters used with the Columbus™ system are disposable supplies and can only be used with disposable. A magnetic positioning mapping/radiofrequency ablation catheter and Columbus™ External Reference Patch are required for mapping.
- If the system is connected to a previously used Magnetically Positioned Mapping/RFA Catheter or Columbus™ External Reference Patch, an error message appears and you are advised to replace the catheter. The Columbus™ system does not allow you to use a previously used catheter for a new procedure.

5. 2. Positioning area

The software allows you to view the working area of the Columbus™ system with accurate positioning capability and the current relative position relationship between the A Columbus™ External Reference Patch and the magnetic field generator. The system ensures reliable positional accuracy and stability of the measured positional data only when the magnetic mapping/radiofrequency ablation catheter is located on top of the precise positioning area of the Columbus™ system. In general, the size of the precisely positioned area of the Columbus™ system is sufficient to contain the adult heart. Before starting the procedure, the magnetic field generator bracket needs to be adjusted so that the patient's heart chamber is in the precise positioning area.

5. 2. 1. Magnetic Mapping/Radiofrequency Ablation Catheter Localization Area

For magnetic mapping/radiofrequency ablation catheters, although three-dimensional position data can still be collected outside the precise positioning area of the Columbus™ system, the operator must always be aware that the error in the data collected may be large or the stability of the data may be reduced. If not necessary, the Columbus™ system does not recommend that the operator collect data outside the precise positioning area of the system. Therefore, the Columbus™ system can display the position of the magnetically positioned mapping/ablation catheter in the magnetic field at any time during the procedure.
During the procedure, the accuracy of the positioning is ensured only when the tip of the magnetic mapping/radiofrequency ablation catheter and the point of acquisition are inside the sphere.

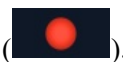
5. 2. 2. Placement of Columbus™ External Reference Patch

The Columbus™ External Reference Patch patch must be attached to the patient's back before starting the procedure. The correct location of Columbus™ External Reference Patch for use with the Columbus™ system is the upper midline between the left subscapular corner line of the patient's back and the ridge process, and the 9th to 10th intercostal position of the back.

To ensure accurate and effective positioning of the Columbus™ External Reference Patch, the Columbus™ External Reference Patch patch must be firmly attached to the skin on the back of the patient and adhered to the same location until the end of the procedure. Do not attach Columbus™ External Reference Patch to the patient's clothing or moving limbs.

In order to ensure that the patient's heart chamber and Columbus™ External Reference Patch are within the optimal measurement range of the system, you will also need to position the patient in the appropriate position before starting the procedure through the positioning setup function. For details, refer to the "Positioning Setup" section of "Chapter 6: Surgical Setup."

5. 2. 3. Movement of Columbus™ External Reference Patch

You receive an error message from the system if there is a large offset in the position of the Columbus™ External Reference Patch during the procedure (position offset greater than 5 mm or angle offset greater than 5°). The acquisition button changes to the system status icon at the top right of the screen and changes to the red icon (). You first need to determine whether this

occurred because the Columbus™ External Reference Patch moved with the patient or fell off the patient.

Handling Columbus™ External Reference Patch movement:

1） The Columbus™ External Reference Patch moves with the patient.
Clicking on the System Status icon at the top of the screen will open the System Status window and you will see the actual location of the current Columbus™ External Reference Patch (Figure 5-1). The gray circle represents the position of the time Columbus™ External Reference Patch of the last map point. You can see how Columbus™ External Reference Patch has offset by referring to the information in this diagram. At this point, if conditions permit, you can attempt to move the Columbus™ External Reference Patch back to its original position by adjusting the relative position of the field generator bracket and the patient.
The Columbus™ system compensates for position data collected at the catheter tip based on the movement of the Columbus™ External Reference Patch. Therefore, if you find that the Columbus™ External Reference Patch is always firmly affixed to the back of the patient and is within the recommended working range of the system, you can click the OK button to ignore this error prompt and proceed with the procedure. However, if the patient's body posture is rotated, the view displayed in the mapping window at this time will not correctly reflect the correct angle of the catheter and chamber with respect to the table, but will not affect the accuracy of positioning and mapping. You may need to set up manually to display the contents of the map window correctly.

2） Recalibrate the reference pole direction.
If the patient rotates an angle and the system compensates for its movement, you see that the map view does not rotate in the map window and you can continue to collect map points in the existing map. At this point, however, you need to be aware that because the patient's current posture does not coincide with the beginning of the procedure, the viewing angle displayed in the mapping window is different from the patient's actual posture, which may cause the mapping and catheter orientation in the mapping window to differ from the image angle and orientation you see in the X-ray image.
If you need to correct the angle display inconsistency, you should create a new map and click the "Re-calibrate Reference Pole Orientation" button in the toolbar (), and a dialog box will pop up, prompting you to confirm the operation. After a recalibration of the reference direction, the original angle compensation for the catheter fails and is reset according to the current position of the Columbus™ External Reference Patch. This action only works with data collected after this action, so it is recommended that you discard maps that were collected before the action was performed.

3） Columbus™ External Reference Patch was removed from the patient.
When you find that Columbus™ External Reference Patch is detached from the patient, you need to paste the Columbus™ External Reference Patch patch onto the patient's surface again. The Columbus™ system cannot correctly calculate and compensate the Columbus™ External Reference Patch movement caused by falling off, so you need to stop collecting new points in the current map and rebuild a new map.

Figure 5-1 Columbus™ External Reference Patch Location information.

Note:
If the detached Columbus™ External Reference Patch does not stick firmly to the patient's surface again, you will need to re-stick the surface electrodes with other fixation methods (such as tape) or replace with a new Columbus™ External Reference Patch.

5. 3. Principles and Procedures for Using Magnetically Located Mapping/RFA Catheters

The Magnetic Mapping/RFA Catheter is used for 3D mapping procedures with the Columbus™ system. Data from the catheter tip is frozen as the catheter moves within the cardiac cavity. This set of data is called "point data." After checking the data, you can decide whether to accept or discard it.

5. 3. 1. Understanding Point Parameters

The point parameters include electrophysiological information and location information. Each point has its own location in space; Electrophysiological data are displayed in the LAT, unipolar, and bipolar columns of the point list. If you apply a label to a point, you can select how the point's data works for this 3D map by changing the Point Type.

The value of the point is displayed in a marked window with a stability bar. In acquisition mode, these values are constantly refreshed with reference marks. If the system enters the frozen state, the value of the frozen point is displayed.

The local activation time (LAT) value is the time difference between the map marker and the reference marker. In the calculation, the reference mark is set to time 0.

The heartbeat cycle (CL) value is the time interval between two consecutive reference marks in the reference channel of the acquisition point.

Unipolar and bipolar voltage values are measured directly from the mapping catheter electrode and updated with each acquisition point. The displayed values are peak-to-peak measurements in the window of interest.

5. 3. 2. Collection Point

After freezing a point using the Columbus™ Magnetic Location Mapping System, the Acquisition button allows you to decide to accept or discard the point. Before accepting a point, you can look up the point data for the last 10 beats through the heartbeat cache and choose to accept the beats that you think have the best mark.

5. 3. 3. Using the Collection Button

The collection button (Figure 5-2) is used to freeze the point data so that it can be checked more carefully before acceptance. You can then use these buttons to accept or discard this point.

Note: If the acquisition point is frozen in the real-time display mode of the catheter image in the mapping window, to ensure the accuracy of the acquisition point, make sure that the tip of the catheter is stable at the desired acquisition point for 3 seconds.

Use the Acquisition button:

1） In the Ready state (Figure 5-2 A), click Freeze to enter the frozen state and review or edit the point data. When the system enters the freeze state (Figure 5-2B), the Freeze button changes to the Reject and Accept buttons respectively.
2） Click Accept to accept a point (Figure 5-2B).
3） Click Reject to discard a point (Figure 5-2B).
4） If you access the list of points or other valid commands in the Ready or Frozen state, the system automatically enters the Edit state and the Frozen button changes to the Continue button. Click Continue to return to Ready or Frozen (Figure 5-1C).

A

B

C

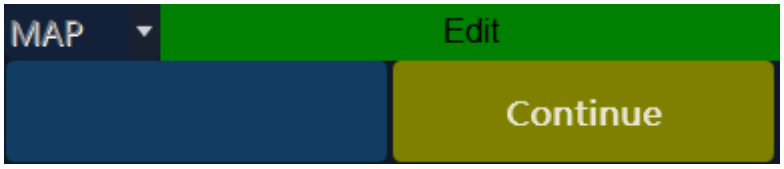


Figure 5-2 Acquisition Button

A) Ready status. B) Frozen status. C) Edit Status

5. 3. 4. Heartbeat cache

The heartbeat cache is located at the bottom of the marker window. Whenever a point is frozen, its contents are updated.

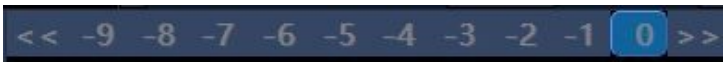


Figure 5-3. Heartbeat cache.

When a point is frozen, the system stores the last 10 heartbeats before freezing in the heartbeat cache. You can view point data for all 10 beats and accept one beat with the best marker.

Use heartbeat cache:

1） Use the Collection button to freeze a point.

2） Click the left arrow or right arrow of the heartbeat buffer to display the next or previous heartbeat.

- The point data of the selected heartbeat is displayed.
- You can also click any number in the heartbeat buffer bar to go directly to any single heartbeat.

Note:

The values and stability columns of the points also change to display new data for the selected heartbeat. In addition, to reflect this change, the plot is updated if the points are accepted.

3） Use the scroll bar to view data before or after marking. Edit markers and references as needed, or view data for another heartbeat.

4） When you click Accept, the selected heartbeat and its corresponding position are saved to the map.

5. 3. 5. Select Point

To view or edit data for a point, you must first select the point. You can select one or more points to delete, move, copy, and mark them.

Select a point in the point list or graph:

- Click a row in the list of points, or a point in the map.

The point is conspicuously marked in the point list and presents a cross in the graph that represents the selected point.

Regardless of the selection, a cross is displayed in the map to indicate the selected point.

5. 3. 6. Edit Map Marker and Reference Marker

Sometimes you may need to edit the map marker or reference marker, and the resulting changes only affect the selected points.

When editing a map or reference mark, the window of interest is moved according to the position of the new reference mark and the map mark is recalculated accordingly. These changes only affect the points that have been edited.

Note: When you edit a reference mark, you may need to add a description to the comment bar of the point list.

Edit the map marker after accepting a point:

1） Select the point in the map window or in the list of points.
If the system is in acquisition mode, it will enter editing status.
2） Drag the map marker point to the marker you think is correct.
3） If you are editing in acquisition mode, click Continue to return to the Ready state.
The acquisition button appears again.

Edit the reference mark after accepting a point:

1） Select the point in the map window or in the list of points.
If the system is in acquisition mode, it will enter editing status.
2） Click the Adjust Guides button () in the markup window toolbar. You can adjust the reference mark only if the function is enabled.
3） Drag the reference mark point to the mark you think is correct.
4） If you are editing in acquisition mode, click Continue to return to the Ready state.
The acquisition button appears again.

Restore the label to its original value:

- Select a point in the map window or in the list of points and click the "Retreat" icon in the markup window toolbar ( )

  The map marker and reference marker are restored to their original auto-detection position.

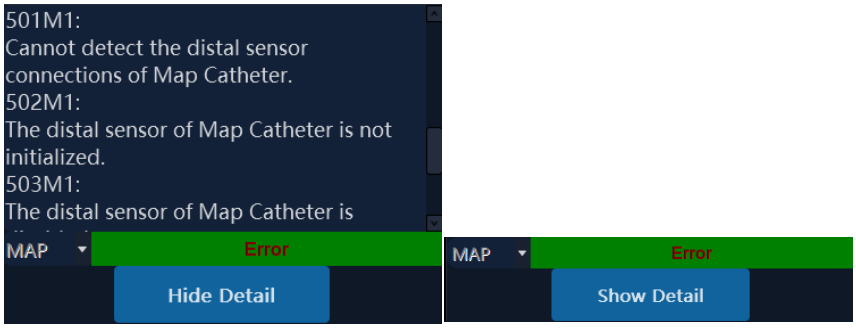
5. 4. Error message

During the procedure, you may encounter an error message. The following is a list of the information typically encountered and the possible causes of these problems.

A. Hardware/Communication
B. Catheter/positioning reference patch function
C. Catheter/positioning patch out of measurement range
D. Other error information

Processing error information:

The error message appears above the acquisition button, covering the original acquisition button, and the specific error message is displayed in the original stability bar. You can view more detailed information about the error by clicking the Show Error Details button (Figure 5-4). Click the Hide Error Details button to hide the error details and continue viewing point data information. Once the problem is resolved, the error message automatically closes. You can view and edit maps and related data until the problem is resolved, although you cannot proceed with the procedure.



A B

Figure 5-4 Error Message

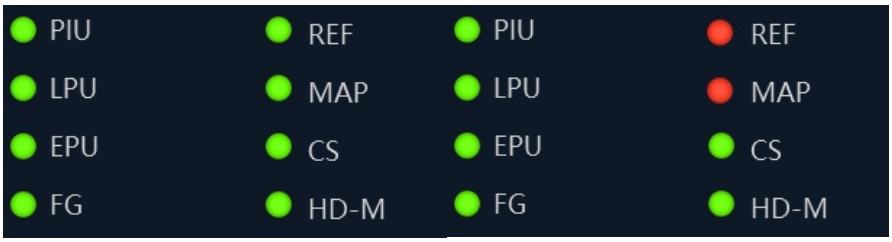
A) Typical error message when magnetic mapping/ablation catheters are disturbed. B) Error details are hidden.

Note: If you choose to hide the error details when correcting the error, the error details will be hidden the next time an error is detected. To view error details, simply click the Show Error Details button.

You can also view the hardware status and corresponding error information of the device and catheter at any time by clicking the system status icon at the top right of the screen. If multiple error messages occur at the same time, it may be that the hardware parts of the system are faulty or the data communication is abnormal. The system status icon at the top right of the screen changes to a red icon (). Click the icon, and the system will prompt you which parts are faulty through the hardware working status indication bar in the pop-up window to guide you to check and troubleshoot possible connection faults on site.

The hardware working status indicator (Fig. 5-5) indicates the working status of the patient interface unit (PIU), positioning processing unit (LPU module), magnetic field generator, magnetic positioning mapping/radiofrequency ablation catheter (positioning catheter) and Columbus™ External Reference Patch (reference electrode). The green color indicates that the corresponding component is working normally (Fig. 5-5A). The red color indicates that the system detects the abnormal status on the hardware (Fig. 5-5B). It can be that the related component is faulty or disconnected.

With system status indication and detailed error information, you can initially find out where the abnormal status occurs. For example, in Figure 5-5B, the system indicates that both the Magnetic Location Mapping/RFA Catheter and the Columbus™ External Reference Patch are malfunctioning, but the Patient Interface Unit is working properly, so it may be preliminarily judged that the Magnetic Location Mapping/RFA Catheter and the Columbus™ External Reference Patch are not connected, or their tail lines, or both are malfunctioning.



A B

Figure 5-5 Hardware Working Status Indicator

A) All hardware and catheters are properly connected.

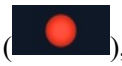
B) Typical Tips when Magnetic Mapping/RFA Catheter and Columbus™ External Reference Patch are not connected.

For a detailed list of common error information, see Appendix 1: Error Information.

Field Generator On and Off

The magnetic field generator is on by default.

1. To turn off the magnetic field generator, first click the system status icon () on the top right of the screen to pop up the system status indication bar, and then click the magnetic field generator

switch button  to turn off the magnetic field generator. At this time, the system status icon is displayed in red (), the magnetic field generator switch button icon is displayed in red,  and the status bar on the left displays "302 F magnetic field generator is turned off." (Figure 5-6).

2. To start the magnetic field generator, also open the system status bar as described above and click the button  to start the magnetic field generator. At this time, the system status icon is displayed in green (), and the magnetic field generator switch button icon is displayed in green  .

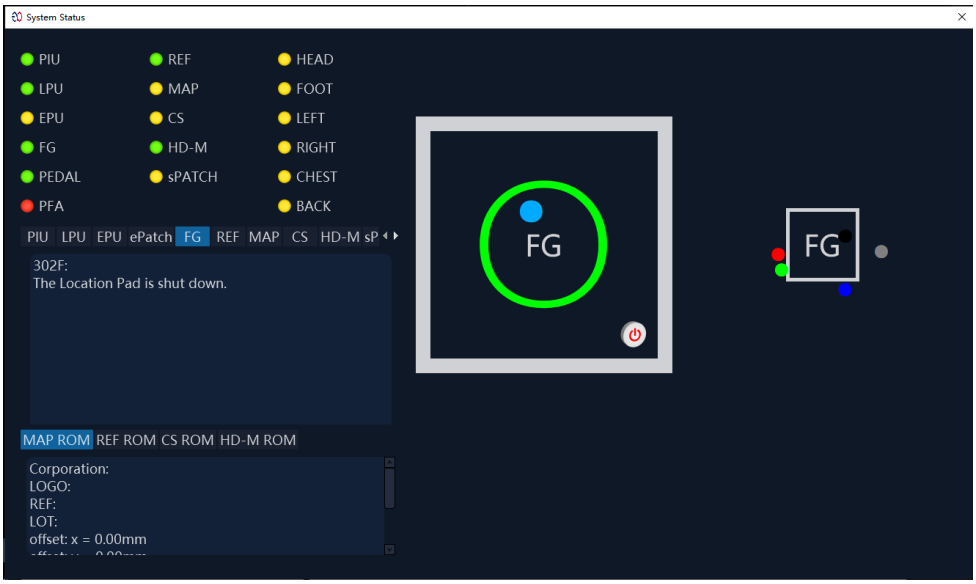


Figure 5-6. Field Generator Off Status

Chapter 6 Surgical Setup

A series of surgical settings is required before you start a new procedure each time. This chapter covers the Setup Wizard and all its options, including:

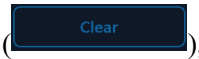
- Patient Information Login
- Loading and saving surgical templates
- Channel Setup and Flag Setup

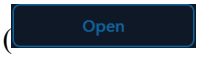
6. 1 Patient Information Login

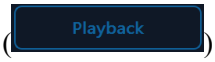
The patient information page is the default page after the Columbus™ system software is started. Before starting a new procedure, the operator needs to complete the patient and procedure information on this page. You will not be able to start a new procedure until you have completed the required items.

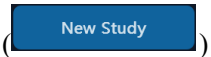
Patient Information:

Patient information includes the patient's basic information and contact information, including: Last name, first name, ID, gender, date of birth, and age. The last name, first name and ID are mandatory items.
The function button for loading patients is located below the patient information bar. Once the necessary items in the patient information have been completed, the New Case button (

) becomes available. Click New Patient Record to create a new patient record based on the above patient information. If the information is entered incorrectly, you can click the Refill button (

), and the system will clear all the filled information in the patient information field.
If you know that the patient already exists with the system, you can access the Patient Information Management window through the Browse Medical Records button (

). Open an existing patient from the local disk. On the left-hand side of the Patient Information Management window is a patient list showing the historical medical record data saved in the workstation hard disk. You can find and open the existing patient files according to the system default time. You can click the "Playback" button (

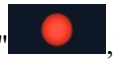
) to switch to the Cardiac Mapping page for review and browsing. Or add a new procedure to the record.
When you create or open a patient record, you simply enter the patient information and the New Procedure button (

) becomes available. Click the New Procedure button to add a

new procedure to the patient's medical record.

Procedure Information:
Surgical information includes information about the procedure, including: Preoperative diagnosis, surgeon, date of procedure, and comments. Items other than past medical history are selected through the drop-down menu.
You can switch to the Patient Information Landing page while performing the procedure and while playing back historical medical records. You can view and modify information about the current procedure at any time in the procedure information field on this page.

6. 2Check system status

The working status of the Columbus™ system is represented by the icon on the upper right of the main interface of the 3D mapping software. When all hardware connections are correct and the status is normal, "  " is displayed. When a part of hardware is disconnected or fails, the icon will be changed to "  ," and the user can know whether the Columbus™ system is working properly at any time through the system status icon.

Click the system status icon to display the system working status dialog box, which displays the hardware parts of the Columbus™ system, the patch position of the Columbus™ External Reference Patch, and the working status of the connected catheter. In case of hardware failure or disconnection, the user can use the message prompt message in the window to preliminarily identify the problem.

Note: In the error state, some error information will also be displayed in the error information bar of the cardiac mapping page.

3D Signal Status:

The icons in the three-dimensional signal status bar represent the working status of each component of the Columbus™ system. When the system is connected and working normally, all hardware and catheters of the system are displayed in green, and the relevant hardware information of the connected catheters will be displayed in the Columbus™ External Reference Patch and positioning catheter information bar below.
If a hardware part of the system or a catheter is disconnected from the system or a fault occurs, the corresponding item in the system status bar changes to red, and an error dialog box pops up to interrupt the user's data collection until the fault is removed. When an error occurs, the system status page displays the corresponding error prompt information, error code and suggestions for troubleshooting. For details, see Chapter 5: Error Reporting Information of Mapping Principles.

6. 3Positioning Settings

The positioning setting ensures that the Columbus™ External Reference Patch is in the correct position, thus ensuring that the patient's heart chamber is in the optimal positioning area. Before starting the acquisition of a map point, you must adjust the Columbus™ External Reference Patch to the correct position by adjusting the patient's body position and posture on the table according to the prompts in the System Status window.

Note: Refer to the section "Placement of Columbus™ External Reference Patch" in Chapter 5 for the location of Columbus™ External Reference Patch on the back of the patient.

You can click the system status icon () on the top right of the main screen of the 3D mapping software to open the system status window. Figure 6-1 shows the display in the System Status window when the Columbus™ External Reference Patch is in a different position. The different figures in the illustration represent the following:

- Blue dots: Indicates the current position of the Columbus™ External Reference Patch.
- Gray box: Indicates the position of the magnetic field generator.
- Green: The outer circle represents the normal operating range of the Columbus™ External Reference Patch.
- Red: The Columbus™ External Reference Patch position is outside the system acceptable range and the green range is displayed in red.

When you move the Columbus™ External Reference Patch, the blue ball moves on the screen. The best working position of the Columbus™ External Reference Patch is the center of the green ball circle. You need to adjust the relative position relationship between the patient and the magnetic field generator according to the prompt information in the system status window so that the Columbus™ External Reference Patch is in the center of the best possible working range.

(A) (B)

Figure 6-1 Positioning Settings

These two diagrams show the display in the System Status window when the Columbus™ External Reference Patch is in a different position.

(A) : The Columbus™ External Reference Patch is in the best position recommended by the system.
(B) : The Columbus™ External Reference Patch position is outside the acceptable range of the system.

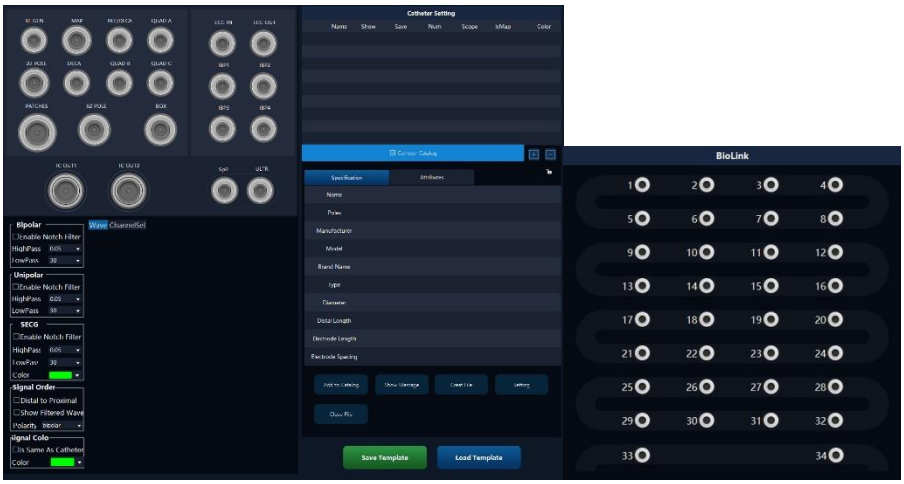
6. 4Channel and mark settings

On the Channel Setup page, you can set the filter parameters and other options for the surface and intracardiac channels. You can change the parameters of the collected channel by clicking the channel setting page at any time during the procedure.

Set the surface ECG channel:
The operator can set the ECG signal channel parameters through the channel setup bar. The Columbus™ system provides standard 12- channel surface ECG signals and multi-channel heart electrical signals by default. The system automatically collects 12-channel body surface signals by default.

1） Find the "SECG" column on the lower left of the channel setting interface, and in the color column, select the color to be applied to all body surface channels. The default color is green.
2） Set different options in the "Qualcomm" column. High-pass filters eliminate signals with a frequency less than or equal to the set value. Very slow signals can be weakened by high-pass filters.
3） Set different options in the Low Pass column. Low-pass filters eliminate signals with a frequency greater than or equal to the set value. A very rapid signal (pulse) can be weakened by a low-pass filter.
4） Check the Power Frequency Filter box to use a notch filter for any channel. Its default setting is on. A notch filter can be used to remove noise at the 50 Hz grid frequency from the specified signal.

Select Catheter and Template Setup:



1） Click in the upper left area to select the connected catheter.

Note: For high density catheters, right-click to select the appropriate catheter type. For the catheter connected through the BioLink, manually click the corresponding electrode and set the catheter information on the Catheter Setup screen.

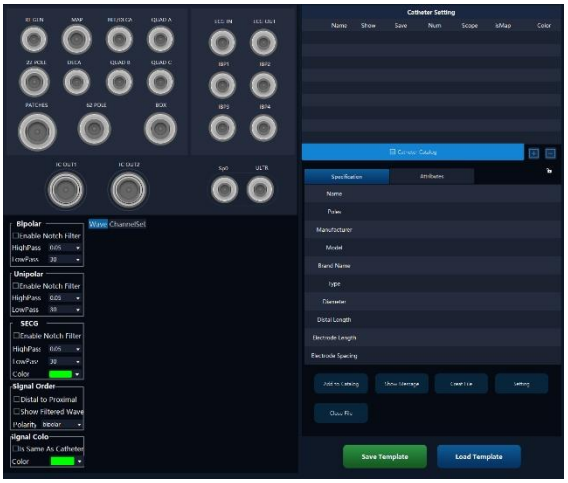
2） Catheter information can be set in the "Catheter Setup" column in the middle area, including product name, number of electrodes and spacing.

（ 

）The Catheter Catalog column can read stored catheter types. For catheters that do not store information, you can also enter relevant information on the Catheter Setup screen and enter it into the system for subsequent use.

3） You will need to apply a template for this procedure each time you create a new procedure. You can quickly call up the commonly used surgical configuration and channel setup scheme through "Template Save" and "Read Template" under the middle area. For details on setting up templates, see the section "Using Channel Templates" in this chapter.

To set the intracardiac ECG channel:



1） Select the catheter to be set on the Catheter Setup screen.

2） Select the channel to acquire ECG signals by clicking the Channel Setup option. In the Polarity menu in the Signal Sequence column at the bottom left, click Select to set the single bipolar

channel.

3） Select the appropriate reference. The intracardiac reference of the Columbus™ system provides options such as GND, WCT (Wilson Central Terminal), Mapping Catheter Electrodes, etc. When you combine an intracardiac channel with WCT, such as M1-WCT, the signal is defined as a single-pole signal.

Note: The channel settings contain a set of M1-M2 bipolar channels that cannot be changed as the default mapping signal for the catheter tip. M3-M4 A combination of fixed settings for the system, you cannot combine M3s and M4s with other channels.

4） Set the high-low-pass filter parameters of each channel and the on and off of the power frequency filter in the "High-pass" and "Low-pass" columns respectively.

5） Set different options in the "Qualcomm" column. High-pass filters eliminate signals with a frequency less than or equal to the set value. Very slow signals can be weakened by high-pass filters.

6） Set different options in the Low Pass column. Low-pass filters eliminate signals with a frequency greater than or equal to the set value. A very rapid signal (pulse) can be weakened by a low-pass filter.

7） Check the Power Frequency Filter box to use a notch filter for all channels. Its default setting is off. The notch filter can effectively reduce the interference of 50 Hz signal in the specified channel signal.

6. 5Setting parameters of the window of interest

You can define the reference and mapping channels and their detection modes by setting the parameters of the window of interest. The system selects the corresponding channel as the reference channel and mapping channel in the mapping process based on the data you enter here, and which detection algorithm should be used to calculate the mark position.

1） Reference Channel: A reference channel is a surface ECG channel or intracardiac channel from a non-magnetically localized mapping/radiofrequency ablation catheter. The default reference channel of the system is II.

2） You can adjust the detection sensitivity to reduce missed or erroneous detection.

3） When the intracardiac channel is selected as the reference channel, the chamber wave can also

be filtered by setting the ventricular gating to improve the detection accuracy.

4） Mapping Channels: Mapping channels are typically intracardiac channels from magnetically positioned mapping/radiofrequency ablation catheters. The default mapping channel for the system is M1-M2, which corresponds to the large tip and Ring electrode at the distal end of the Magnetically Located Mapping/RFA Catheter.

5） Detection: Set the detection mode of reference mark and map mark, including "maximum value," "minimum value," "rising edge" and "falling edge."

6） Minimum value of the window of interest and maximum value of the window of interest: Enter a negative integer and a positive integer respectively, which is a time period related to the reference mark. The system automatically selects the best marker position in the window of interest according to the mapping marker and its detection method. The minimum and maximum values of the window of interest range from -1999 ms to 490 ms, and the difference between the maximum and minimum values is greater than 20 ms. The default minimum value of the interested window is -200 ms, and the minimum value of the interested window is 200 ms.

The reference mark defines a straight line with time equal to 0. All settings less than 0 are on the left side of the reference mark and all settings greater than 0 are on the right side.

- The earliest time (in milliseconds) is entered in the Minimum Value field of the window of interest. This determines the earliest time allowed to label the intracardiac channel. Mapping markers will not be performed before this time.
- Enter the latest time (in milliseconds) in the Maximum Value of the Window of Interest field. This determines the latest time allowed to label the intracardiac channel. Mapping markers will not be performed after this time.

6. 6Set stimulation channel

When stimulating with the Columbus™ system, you must select an intracardiac electrode. During stimulation, limit the output current to no more than 20 mA and voltage to no more than 10 V. Higher currents or voltages may result in reduced intracardiac signal quality.

Set the stimulation channel:

1） Click the stimulation channel on the upper right of the channel setup page.

Or click the "Stimulation" drop-down menu in the tool bar above the real-time window under the map page.

Or in the multi-channel recording window, click the Stimulation drop-down menu in the toolbar above the real-time signal window.

2） Select M1-M2 to stimulate via M1-M2, or R1-R2 to stimulate via R1-R2.

- The default setting is None.
- All enabled intracardiac channel combinations are optional.
- The stimulation channel can be highlighted.

Warning:
Unless specifically permitted in the stimulator manufacturer's instructions for use, simultaneous radiofrequency ablation procedures are prohibited when you choose to perform stimulation with the Magnetically Located Mapping/Radiofrequency Ablation Catheter Tip electrode (M1-M2). Failure to do so may result in an adverse event of ventricular fibrillation or microbubble formation. Microbubbles increase the risk of thrombosis.

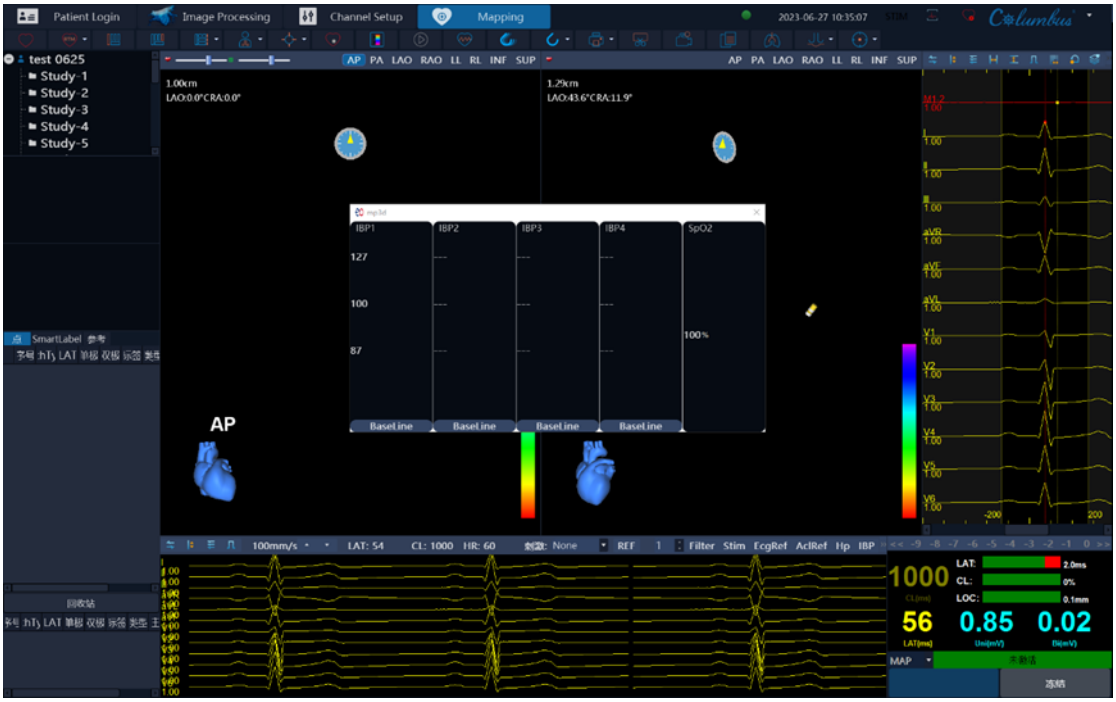
6. 7Oxygen saturation channel

SpO2 plethysmography parameters measure arterial oxygen saturation, that is, the percentage of total oxygenated hemoglobin. For example, in red blood cells of arterial blood, hemoglobin molecules accounting for the total ninety-seven percent combine with oxygen, then this blood has ninety-seven percent SpO2 oxygen saturation, and the SpO2 reading on the equipment should be ninety-seven percent. SpO2 value shows the percentage of oxygen-carrying hemoglobin molecules that form oxygenated hemoglobin. The single measurement period is about 10 seconds.

During SpO2 measurement, please ensure that the patient touches the following parts:
1. Blood flow pulsation is normal and circulation perfusion is good.
2. The thickness of blood vessels is uniform, and there is no big difference, and the sensor can be attached to the wearing part normall

SpO2 measurement steps:
1. Insert the tail wire of SpO2 module into the SpO2 socket hole of the patient interface unit.
2. Clip the SpO2 finger in the proper position of the patient's finger.
3. Click the "IBP" button to open the SpO2 monitoring function of ColumbusMAX system and observe the parameters.

Warning: **Check the wearing area every 2 to 3 hours to ensure good skin texture and correct light alignment. If the skin texture changes, please move the sensor to another part. Change the wearing area at least every 4 hour.**



Note:

1. If the SpO2 sensor is not working properly, reconnect the sensor or replace it with a new one.
2. If the sensor package or sensor shows signs of damage, please do not use this SpO2 sensor.
3. Continuous and prolonged monitoring may increase the risk of undesirable changes in skin characteristics, such as abnormal sensitivity, redness, blistering or compressive necrosis, especially in patients with perfusion disorders and changed or immature skin morphology. Special attention should be paid to the correct optical path alignment and attachment method to check the sensor placement position according to the skin quality change. It is necessary to periodically check that attachment position of the sensor and change the attachment position when the skin quality decrease. Due to the different status of individual patients, more frequent examinations may be required.
4. Incorrect measurement site or prolonged measurement time (more than 4 hours) may cause skin damage. Please test the sensor regularly according to the requirements of the instruction manual.
5. Only minimally invasive electrophysiological sensors and extension cables can be used. Other sensors or extension cables may affect the performance of the equipment or bring harm to patients.
6. Make sure your nails block the light. The probe wire should be placed on the back of the hand. When measuring, hands should not be too cold, and nails should not be painted with nail polish, so as not to affect the accuracy of data.
7. Don't put sensors on limbs with arterial intubation or intravenous infusion tube or inflated blood pressure cuff.
8. The function tester can not be used to evaluate the accuracy of blood oxygen, but the function of the pulse oximeter sensor can still be verified and monitored by the functional SpO2 tester.
9. The pulse oxygen saturation of this device has been calibrated to display the functional oxygen saturation.
10. The materials contacted by patients or other personnel meet the ISO 10993 standard.
11. Misapplication caused by wrong sensor type may lead to inaccurate reading or no reading.
12. This equipment will not give an alarm to the monitoring of physiological parameters including SpO2, etc., because the operator is at the patient's side in real time when this equipment is used, so

it can pay attention to the physiological changes of the patient in real time.
13. As a reusable sensor, SpO2 sensor should be cleaned regularly.
14. SpO2 sensor and extension cable are designed to be used together with ColumbusMAX system. Do not connect to other devices, otherwise it may lead to performance degradation and/or patient injury.
15. When the power supply of the equipment is interrupted, the data before the power failure will be saved in the case, and the data can be reviewed after being powered on again.
16. When the system detects that the oxygen saturation may be incorrect, it will display a "?"on the interface. The operator should pay attention to the accuracy of oxygen saturation at this time.

This information is very useful for clinicians who perform phototherapy:
The pulse oxygen saturation sensor contains LED, which can emit red light with a wavelength of about 660nm and infrared light with a wavelength of about 905nm. The maximum optical output power of LED is 2 mW.

The following factors will cause measurement interference:
1. Injection dyes such as methylene blue or hemoglobin with dysfunction in blood vessels (such as ferrohemoglobin and carbohemoglobin) will lead to inaccurate measurement results.
2. The surrounding light is too strong (hint: cover the wearing part with opaque material);
3. Electromagnetic interference;
4. Patients exercise too much and the range is too large.

Prompt information of oxygen saturation:
This system detects the failure of the monitoring part of oxygen saturation, which will be indicated in the interface. The common failures are as follows:
1. The blood oxygen probe is disconnected (please check whether the blood oxygen probe is poorly connected, and plug or replace the blood oxygen probe again);
2. The search time is too long (please check whether the blood oxygen probe and finger are attached well, and clip the blood oxygen probe again);
3. No finger was found (put the finger into the blood oxygen probe);
4. The blood oxygen signal is weak (please check the clamping position of the blood oxygen probe and clip it again; Or check whether the patient's fingers have sufficient blood flow);

6.8 Invasive blood pressure channel

Before setting up the channel, you need to insert the IBP catheter into the blood vessel in the appropriate part of the patient through puncture. Please inject normal saline into the IBP catheter to ensure that the external port of the IBP catheter is directly connected with the pressure sensor. Through the pressure transmission between liquids, the intravascular pressure signal will be transmitted to the external pressure sensor through the liquid in the IBP catheter, thus helping ColumbusMAX system to obtain the dynamic waveform of intravascular pressure change in real time. At present, the patient interface unit can provide three-channel IBP measurement results and display the pressure (systolic pressure, mean pressure and diastolic pressure) of each channel.
Note: the IBP of this system has no adjustable filter and mode.

Specific steps for measuring IBP:
1. Insert the IBP tail into the corresponding socket on the front panel of the patient interface unit, and check that the power supply of the patient interface unit is connected.
2. Fill the IBP module with physiological saline solution to ensure that there are no bubbles in the IBP catheter.
3. Connect the IBP catheter to the pressure pipe to ensure that there is no air in the catheter and pressure pipe or sensor.
4. Place the sensor at the same level as the heart, approximately at the axillary midline.
Save channel setup template:

5. Click the "IBP" 

button to open the IBP monitoring function of ColumbusMAX system.

6. Click the "Reset" 

button to reset the pressure sensor.

7. Observe IBP parameters.
8. If bubbles appear in the sensor or pressure pipe, flush the channel with normal saline until there are no bubbles, otherwise the blood pressure monitoring is inaccurate;

The specific steps of the zero correction operation:
To obtain accurate pressure readings, the radiofrequency ablation device requires an effective zero point. Zero the sensor as required by hospital or local laws and regulations. Zero correction must be performed in the following situations:
1. Use a new sensor or connection tube.
2. Reconnect the sensor cable to the PIU each time.
3. If you suspect that the PIU pressure reading is incorrect.

The pressure measurement is zeroed as follows:
1. Close the valve leading to the patient.
2. Open the sensor to atmospheric pressure to compensate for the static pressure and atmospheric pressure applied to the sensor.
3. In the pressure setting menu, select IBP pressure Zero.
4. When you see the message that IBP pressure zero is complete, close the valve leading to atmospheric pressure and open the valve leading to the patient.

Note:
CF type blood pressure sensor must be used in this device, and the safe use time of the sensor should be checked on the outer package of the sensor.
For more detailed blood pressure sensor operating procedures, refer to the invasive blood pressure sensor manual.
If a third-party ME device or system is also connected, the device or system should meet IEC60601-2-34/9706.234 and other standards.
Warning:
Disposable invasive blood pressure sensors shall not be reused, and disposable invasive blood pressure sensors shall be disposed of in accordance with the laws and regulations of the local regulatory authorities after use;

6.9 Setting a Heartbeat Channel

Separate the heartbeat channel from the reference channel and add a separate setting. The heartbeat channel is used for heartbeat detection and compensation. The optional range is the same as that of the reference channel.

Note: Since the Cl of the multi-channel window is the heartbeat interval of the heartbeat channel, and the Cl below the window of interest is the heartbeat interval of the reference channel, they may be different.

6.10 Using channel templates

The Columbus™MAX™ system offers two different template management options: the channel setup template and the System template, which are used to manage the channel setup and other custom Settings of the system, respectively, for direct invocation the next time the same type of surgery is performed. The channel Settings template only provides the ability to save and call the channel Settings mode, while the system template covers most of the parameter Settings in the Columbus™MAX™ system, including the channel Settings. You can use and manage these two different templates in your surgery according to your actual needs. For details on using system templates, see Chapter 10: Using System Templates.

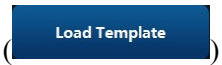
Save the channel Settings template:

Click the "Save Template" button (

) to pop up the "Template Setting" dialog box (Figure 6-1).

1） Enter a custom template name and click Save. Or click the existing channel setting template in the selected list and save it again to overwrite the original template.

Load channel setup template:

1） Click the "Load Template" button (

) to pop up the "Template Setting" dialog box (Figure 6-1).

2） Click the channel setting template to be loaded in the selected list, or enter the name of the existing template. Click Load to apply the channel setting of the template to the current operation.

3） Select the template in the list, and click Delete Selection to delete the specified channel setting template.

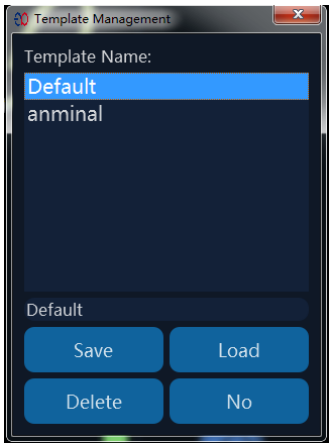


Figure 6-2 Channel Template Setting Dialog Box

Chapter VII Mapping Page

This chapter describes how to use the different child windows in the Cardiac Mapping page, including the following:

- Mapping Window
- Procedure List
- Point list
- Monitoring window
- Marking window

7.1 Mapping Window

The following is displayed in the map window:

- Acquired 3D map. By default, the center of view in the window is the common center of gravity position of all maps displayed therein.
- The patient icon represents the position and orientation of the head and face of the patient and displays the current working status of the system (Figure 7-1).
- Position the catheter icon. Open the "Display Catheter" option in the right-click menu of the map window, select a map point to display the shape of the catheter at the time of historical acquisition of the map point, drag the time axis of the review screen, and review the history catheter to play back the shape of the corresponding history catheter over time. The ECG signals at all times during the procedure and the corresponding catheter position can be reviewed.

- Catheter projection. Open the Show Catheter Projection option in the right-click menu of the map window, display the projection of the catheter tip at the nearest point on the surface of the map in a gray circle on the map, and move the catheter gray circle as the catheter moves. The linear distance from the catheter to the projection (white number) is displayed near the gray circle.
- Label projection. Open the Show Label Projection option in the right-click menu of the map window to display the projection of label points on the model in a circular shape with the same color as the label points.
- Point projection. Open the Show Point Projection option in the right-click menu of the map window to display the projection of the map point on the model as a small white point.
  Note: This function is only set in the left map window and the setting is valid for both map windows.
- Auto earliest activation map. Open the "Auto earliest activation map" option in the right-click menu of the map window. The white stereo arrow will appear on the earliest activation point. When any operation causes the earliest point to change (sampling point, deleting point, setting

type, etc.), the prompt will be updated in real time.

Note: This prompt is only displayed when the map is an LAT map. It is not displayed in the anatomy, unipolar and bipolar maps. This function can only be set in the left map window and is valid for both map windows.

- Coordinate background grid. It can be canceled, but the scale value is always displayed.
- Respiratory compensation. Please refer to Chapter X
- Projection icon.
- Color scale bar.
- The volume of the map.

You can select whether to display the above items through the right-click menu in the map window.

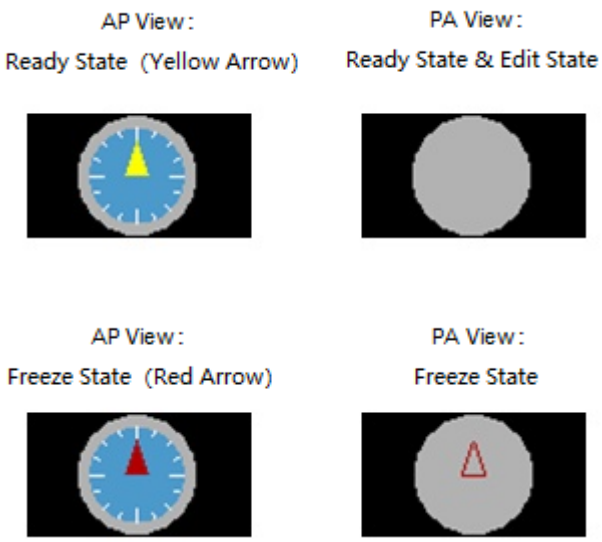


Figure 7-1 Patient Icon

Coordinates and scales of the map view

The origin of the coordinate system is located in the center of the screen and consists of three orthogonal lines. The positive half-axis of the X-axis points to the left of the patient, the Y-axis is perpendicular to the table surface downward, and the positive half-axis of the Z-axis points to the head of the patient.

By default, the center of gravity of the map is centered in the map window so that the map is centered in the map window. The white ball in the figure represents the mapping point, and the white cross represents the currently selected mapping point. When the point is frozen, the center of gravity of the image is calculated and aligned to the center of the map window.

Note:
The cross mark representing the current point changes color depending on the displayed background color (for example, if a white background is selected, the original white mark changes to black).

The top left corner of the map window displays the length of the grid's current scale, which helps you estimate the size and distance of some anatomical locations in the map. The intervals of the scales are fixed, but the length they represent varies depending on the scale. The upper part of the map window also displays the angle information of the current angle of view. The three edges of the grid are displayed in three different colors, red, green, and blue, which will also help you visualize the current viewing angle and orientation within the map window.

Map Window Shortcut Menu

In the Map Browser, you can access different shortcut menus by clicking on different sections:

- Right-click the map to open the Map Options shortcut menu.
- Right-click the background to open the Background Options shortcut menu.
- Right-click the projection icon to open the Toggle View shortcut menu.
- Right-click the color bar to open the color bar options shortcut menu.

Change the orientation and projection direction of the map

There are several ways to change the orientation and viewing angle of a map. The following is a detailed description:

Rotate the map using the mouse:

- Middle-click the map and drag it to rotate it to the desired direction.
  The map rotates as the mouse moves.

Select Select Standard Viewpoint from the Tools button:

- Click the standard projection icon (AP, PA, LAO, RAO, LL, RL, INF, SUP) above the map window.
  The map switches to the selected viewing angle.

Select the standard projection via the projection icon:

- Right-click the projection icon (Figure 7-2) and select the desired viewing angle.

Custom viewpoints (up to two defined):

1） Rotate the map to the desired viewing angle.
2） Right-click the projection icon (Figure 7-2) and select Define.
3） Click View 1 or View 2 to save the custom view.
4） Continue with the map.
5） Right-click the projection icon and select ViewPoint 1 or ViewPoint 2 to return to the custom viewpoint. The map is displayed in a custom view.

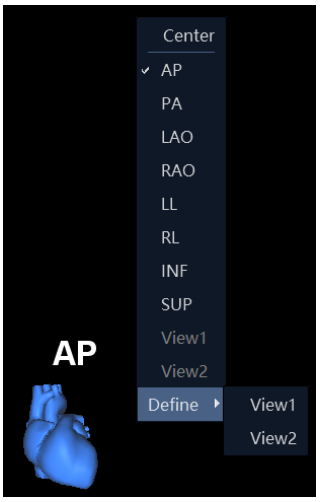


Figure 7-2 Use the projection icon.
Left) The position of the icon represents the selected viewing angle with a text description. Right) Projection icon shortcut menu.

Zoom in/out map

The display size of the map can be adjusted by the middle mouse button wheel. The upper left corner of the map window displays a value with a length that represents the actual length represented by the unit grid.

Zoom in or zoom out the map:

1） Scroll up the mouse wheel to zoom out.

2） Scroll down the mouse wheel to enlarge the view.

Display and operate multiple maps

The Columbus™ system can display multiple different maps in a procedure at the same time. When you operate on multiple maps, you can quickly switch between them.

View and operate multiple maps:

1） Only maps under the currently active procedure can be displayed in the map window. Double-click the map or procedure you want to view in the procedure list, or select the Activate item in the shortcut menu by right-clicking it.

If you activate a map, the procedure it belongs to will also be activated.

A. The data in the point list is updated to the data of the current active graph.

B. All newly collected points will be collected to the activity map.

2） All maps in the currently active procedure can be displayed in the map window. There is a checkbox to display maps before all map names, and only selected maps are displayed in the map window.

Center display map

The map displayed in the map window is displayed in the middle of the window by default, and the center button in the upper left corner of the map window is displayed as (). If you need to pan the map, you can hold down the <Alt> key while clicking and dragging the map with the left mouse button to move it to the desired position.

When the map is moved, the map window is not centered, and the center button in the upper left corner of the map window is displayed as (). You can reset the map window to centered display by clicking the Center button. 

Note: When you add or remove a map from the map window, the map window does not automatically revert to centered display. In the synchronous state, the centering state of the two mapping windows remains the same. Any centering related operations on the current map window will be performed in both map windows, including icon display and map display.

Second Mapping Window

The Cardiac Mapping page of the Columbus™ system has two mapping windows. The two mapping windows are functionally identical. For comparison, you can view different information of the same image through two separate windows.

The available options for the map window apply to both windows, but both can have separate color rulers and fill thresholds.

Correlation of two mapping windows:
Right-click in the background of any map window to select the following window association options in the shortcut menu:

1） Asynchronous. All settings for the two mapping windows will be independent of each other.
2） Synchronization. Enables the map in another map window to rotate and scale synchronously with the map in that map window.
3） Complementary. Switch the projection azimuth of one mapping window, and the other mapping window will be displayed in 90°. For example, if AP projection is displayed in one map window, RL projection is displayed in the other map window(See Table 7-1 for details)

Table 7-1 Complementary perspectives that can be displayed in the mapping window.

Current Map Window	Another mapping window
AP	RL
PA	LL
SUP	AP
INF	AP
LAO	RAO

RAO	LAO
LL	PA
RL	AP

Additional View Window

For comparison, you can view any map of the same patient through an additional view window (Figure 7-3).

Open the Additional View window:

- In the list of mapping procedures, right-click the map to be viewed through the Additional View window and select the Additional View option from the shortcut menu.

Additional view windows are view-only, and you can open up to 3 additional view windows at the same time to view different maps, but you cannot edit them. Any allowed actions in the additional view window will not affect the content in the map window.

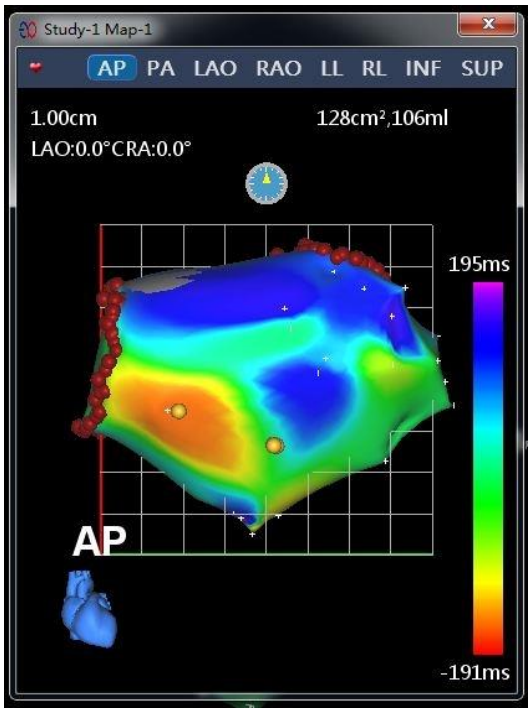


Figure 7-3 Additional View Window

7.2 Procedure List

The procedure list (Figure 7-4) is divided into two parts: A three-dimensional mapping procedure list and a body image study list, which shows all procedures, maps, and body images included in the patient's medical record.

In the 3D mapping procedure list, represents the current patient; Represents a procedure; Represents a map; Represents a remap; An icon with a cross, for example, represents

the latest medical record added within the last 24 hours; A gray icon  indicates that the chemistry is not currently active. In the list of image studies,  represents an image study and  represents a surface image.

The name of the currently active map is displayed in red characters. Each map and volume image corresponds to a check box in the procedure list. If this box is checked, when the procedure or study to which the map and volume image belong is activated, they will be displayed in the view of the mapping window. Open the right-click menu of the mapping window with the option "preoperative image." The two mapping windows can display or hide the surface image separately.

Right-click an item in the procedure list to access the procedure list shortcut menu.

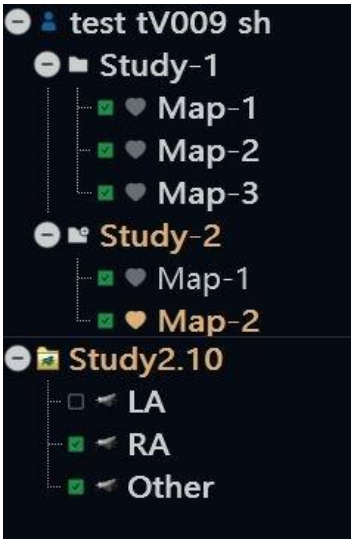


Figure 7-4 List Of Procedures

7.3 **Point list**

The Columbus™ system map was generated from map point data that was collected (in frozen state) through the catheter tip in contact with tissue. After you freeze a point, it appears in the list of points (Figure 7-5). Point lists allow you to access point data for the activity map. You can:

- Page the list and view the values for all map points.
- Set labels and annotations against points.
- Hide points or show points.
- Delete points or undelete.
- View the positioning reference information of each point.
- Copy and paste points.

List of Points Used

1） Click any point in the point list. The point is highlighted in the list and marked with a cross on the map.

To select multiple points, press the <Ctrl> key and click the desired point continuously.

2） Page up and down in the points list to browse the data of each point:

- Serial Number: Displays the serial number assigned to each point.
- Lat: Displays the local activation time (Local Activation Time) of the point.
- Unipolar: Displays the unipolar voltage at the point.
- Bipolar: Displays the bipolar voltage of the point.
- Label: Displays the label abbreviation for this point.
- Type: Displays the type of the point.
- Note: Displays the note for this point. If you need to add your own comments, double-click the column to open the comments dialog box for input editing.
- Time: Displays the time the point was collected.

3） Click any text label in the point list (for example, LAT), and the point list will sort all points by the data of this group. By default, it is sorted by point sequence number.

4） Right-click the point you want to operate, and a shortcut menu appears. Select the desired option.

- Hide: Hide selected points. Hidden map points have no effect on color interpolation.
- Show: Show hidden points.
- Delete: Deletes the selected point. The deleted map points are saved in the recycle bin.
- Edit Label: Opens the Point Label and Type dialog box to apply labels or change the type of point. See "Application Point Label" for details.
- Edit Comment: Opens the comment dialog for this point, where you can add a comment.

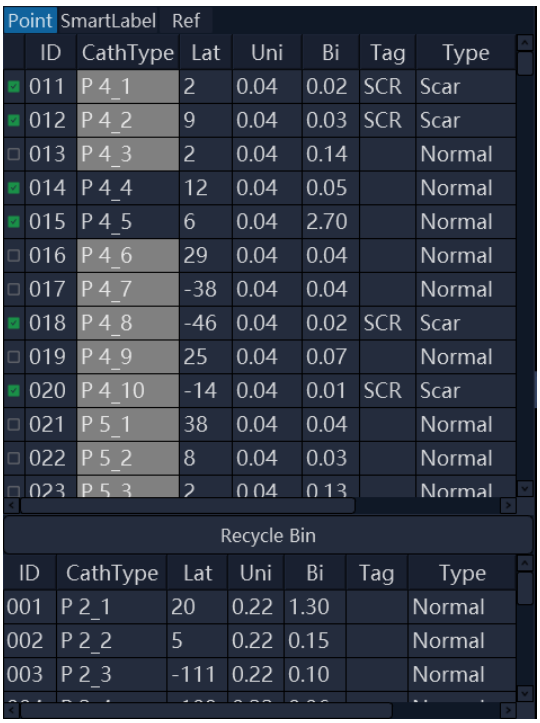


Figure 7-5 List Of Points

5） When the mouse focus is in the point list, the point can be switched by the up and down arrow

keys.

Hidden points

You can hide a point by listing it or selecting a point on the map.

In addition, the checkboxes in front of the points list provide shortcuts to hidden points. Uncheck this point to hide, if you select multiple map points and use the right-click menu in the point list to disposable hide multiple map points.

Hide points by point list or map:

1） Select the point to hide (on the point list or map).

2） Right-click and select Hide.
The point disappears from the map.

Display point

You can show hidden points through a list of points.

In addition, the checkbox in front of the point list provides a shortcut for displaying points. Select this point in the checkbox. If multiple mapping points are selected and displayed through the right-click menu in the point list, disposable displays the hidden multiple mapping points.

Show hidden points through the list of points:

1） Select the points to display (in the Points list).

2） Right-click and select Show.
This point is displayed on the map.

Delete Point

You can delete a point from the point list or by selecting a point on the map.

In addition, function key <F7> provides a shortcut for deleting points. If no point is selected, <F7> deletes the last collected point. If a point on the point list or graph is selected, <F7> deletes all selected points.

Delete points by point list or map:

1） Select the point to delete (on the point list or map).

2） Right-click and select Delete.
The point is moved to the Recycle Bin.

Delete points via the <F7> function key:

1） If no point is selected, pressing the <F7> key deletes the last collected point.

2） Press <F7> to delete all selected points.

Copy Paste Point

You can copy points from one map to another map under the same procedure from a list of points.

Copy and paste map points:

1） Select one or more map points of the current map in the point list, right-click to open the point list shortcut menu, and select the "Copy" option. The selected points can now be copied to other maps.

2） Right-click the target map belonging to the same procedure in the mapping procedure list and select the Paste option from the shortcut menu. The copied points are added to the map.

Note: To copy a map point, make sure that the map marks and reference marks of the two maps are the same. If the point to be copied does not match the map mark or reference mark setting of the target map, you are prompted that the point cannot be copied.

Create/Edit Comment

You can add or edit comments for all points in the points list.

Add or edit comments:

1） Double-click the comment bar of the selected point in the point list, and a text entry dialog box appears.

2） Enter comments and click OK. This comment will be added to the corresponding column of the points list.

Show/Hide Comments

You can select any map point in the point list to show/hide map point annotations.

Show or hide comments:

1) Double-click the comment column of the selected point in the point list to enter the comment and click "OK," and the comment is added to the corresponding column of the point list;

2) Select this point to open the right-click menu and select "Show Comment," and the map point annotation is displayed next to the corresponding map point in the map window (Figure 7-6);

3) Select this point again to open the right-click menu and select "Hide Annotation," and the annotation of this mapping point will not be displayed next to the corresponding mapping point in the mapping window.

Note:

- The point list and map map can edit the annotation of the points, and display/hide the annotation of the points.
- The left and right maps can edit the annotation of the map points, and display/hide the annotation of the map points. However, the left and right map windows cannot edit the annotation of the same map point.
- The Point List allows you to select multiple points to display map point annotations at the same

time.

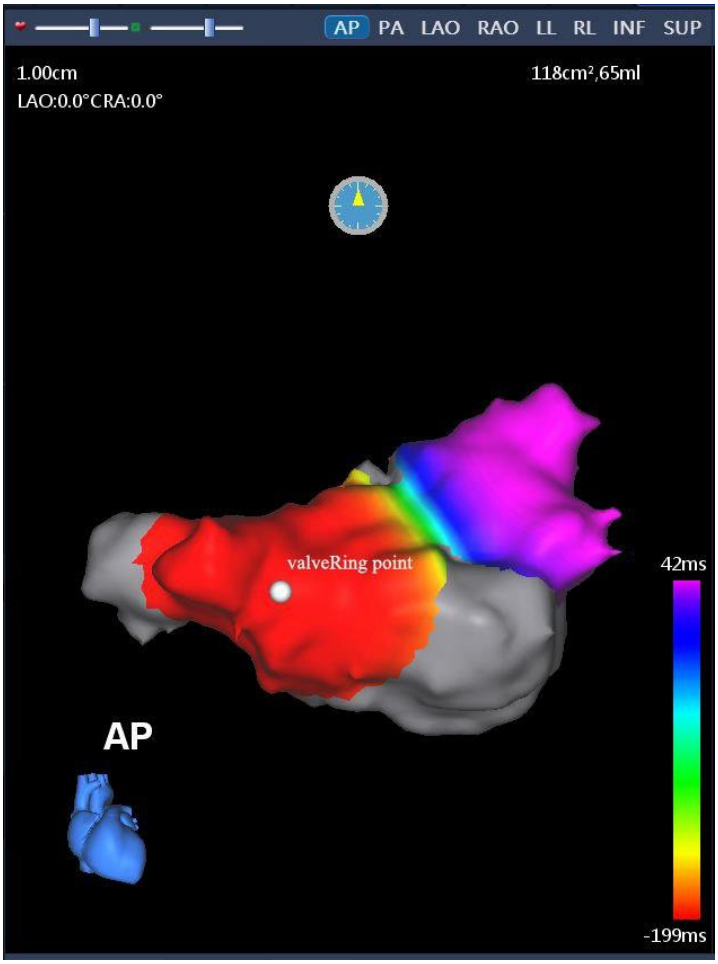


Figure 7-6 Show Map Point Annotations

Use Recycle Bin

Used map points deleted from the map are permanently stored in the recycle bin (below the list of points).

Restore deleted points to the map:

1） Select the point you want to restore and right-click to display a shortcut menu.
Multiple points can be selected at one time by pressing the <Ctrl> or <Shift> key and selecting the desired point.

2） Click Restore or press the <F9> key on the keyboard and the point is restored to the map.

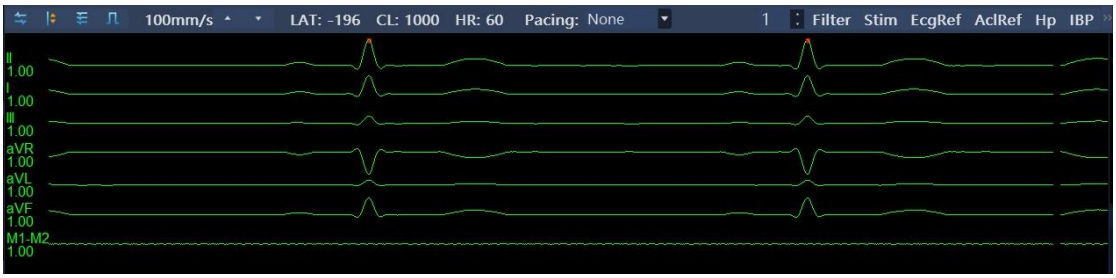
Use Reference Tab

The reference tab gives the three position coordinate information X-, Y-, Z- and three angle coordinate information RX (alpha angle), RY (beta angle), RZ- (gamma angle) recorded by the Columbus™ External Reference Patch at the time of acquisition of each mapping point.

7.4 Monitoring window

When starting a new Columbus™ mapping procedure, the monitoring window is located below the mapping window (Figure 7-6). Throughout the procedure, the monitoring window continuously displays the ECG channels. By default, only the reference and map channels are displayed in the Monitoring window. However, you can show or hide any acquired channel in this window. You can also change the time scale of the signal, or the gain of a particular channel.

Warning: The Columbus™ system is not designed to be used as a patient monitor. For monitoring purposes, a dedicated patient monitor should always be used with the Columbus™ system.



7-6 Monitoring window

Monitoring window options

The Monitoring Window toolbar provides the following options:

Setup ( ): Opens the Show/Hide Channels dialog box to add or remove channels in the Monitoring window.

Even score ( ): Without changing the scale of each display channel, the monitoring window displays all channels uniformly.

Gain ( ): When enabled, the channels used in the monitoring window are set to the same gain as the last channel displayed in the window.

Calibration ( ): Enable/disable the display of the voltage scale icon.

Increase channel screen speed ( ): Increase the screen speed of all displayed channels.

Decrease channel screen speed ( ): Decrease the screen speed of all displayed channels.

Add or delete channels within the monitoring window:

1） Click the Setup ( ) button and the Show Channels setup dialog box appears (Figure 7-8).

2） Select the channel to display in the Display check box. Changes will take effect immediately.

You can select multiple channels as needed. Click the display bar at the top of the list, and all channels can be set to "Display" or "Hide."

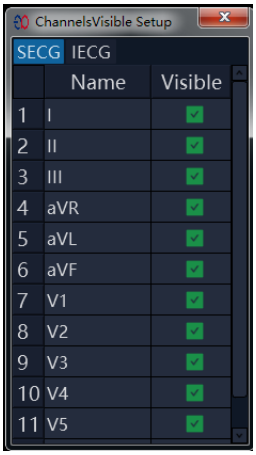


Figure 7-7 Display Channel Setting Dialog Box

Note: Channels that are set to not be acquired in the Channel Setup page will not appear in the Show/Hide Channels dialog box.

Adjust the channel display:
In some cases, after adding/hiding some channels to the monitoring window (or marking window), the content of the window may appear congested. Click the "Even Score" ( ) button on the toolbar of the monitor to evenly distribute the display of each channel.

Change the screen speed of all displayed channels in the monitoring window (or marking window):

- In the toolbar of the monitoring window or marking window, click the up and down arrows to increase or decrease the channel screen speed accordingly.
- You can choose 12.5, 25,50, 100, 200, or 400 mm/sec.
- The selected screen speed is applied to all displayed channels.

Change the signal gain in the monitoring window (or mark window):

1） Click a signal. When the signal channel is selected, the color is displayed in white.
The icon appears:. 1.0
2） Click the up and down arrows to increase or decrease the scale accordingly.
When the cursor leaves the signal, the icon disappears automatically.

Caution:
When the Columbus™ system distorts the signal due to polarization voltage, a warning sign "ECG Distortion" appears above the monitoring window. You should check to confirm and rule out the abnormality at this time. You can close the prompt by clicking the icon to proceed with the procedure.

7.5 **Marking window**

All ECG channels selected in the Channel Setup tab and set to Display are displayed in the Marker window (Figure 7-8). In the initial state, the displayed content is centered on the Window of Interest (WOI), and you can view the content on either side of the window of interest by using the horizontal scroll bar.

In the Ready state, the displayed content is an ECG that is constantly refreshed and centered on the window of interest. When the system enters the freezing state, editing state or playback mode, the channel waveform recorded at the freezing time of the selected point is displayed. In these cases, the display changes depending on the selected point. (In playback mode), no channels are displayed until you select a point.

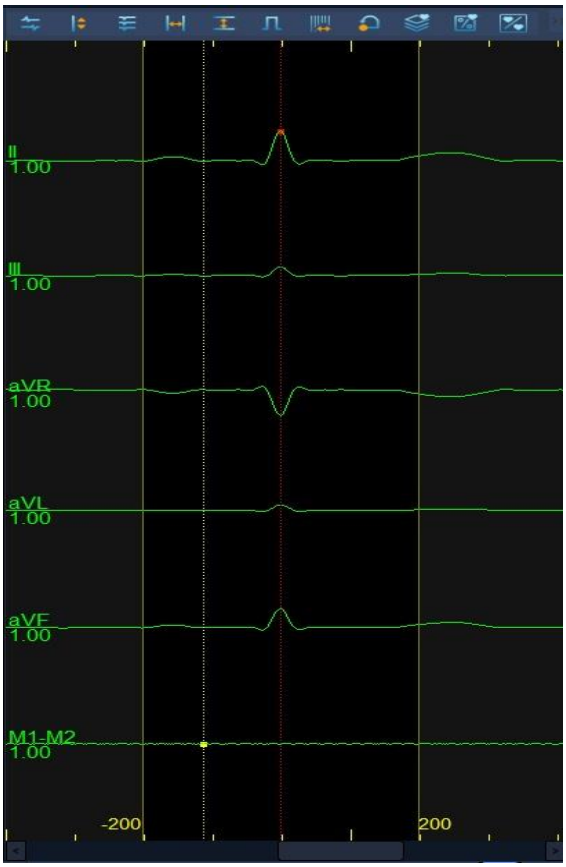


Figure 7-8 Marking Window

Mark Window Toolbar

The Markup Window toolbar provides the following options:

Settings ( ): Opens the Show/Hide Channels dialog box to show or hide the selected channels.

Average score ( ): Display channels uniformly in the marking window.

Gain ( ): Displays all signals at the same gain. When this function is activated, all signals are adjusted to the same gain. Thereafter, changing the gain of any one signal will affect all displayed

signals.

Time measurement ( ): On/off time measurement caliper.

Voltage measurement ( ): Turn the voltage measurement caliper on/off.

Calibration ( ): Show/hide the voltage scale icon.

Adjust Reference Line ( ): Turn on this function to adjust the reference mark position of the current point.

Retreat ( ): Restores the edited map marker or reference marker to its original position (valid only for the selected point).

Select template ( ): Select template, turn on/off template selection.

Display template ( ): Show template, show/hide template.

Toggle display of surface/intracardiac channel contrast ( ): SECG/IECG, toggle display of surface/intracardiac channel contrast.

Measurement:

1） Click the Time ( ) or Amplitude ( ) icon on the markup window toolbar.

2） In the mark window, click the left mouse button and two lines appear.
Displays the distance between both sides of the caliper:
A． Time measurement is in ms.
B． The voltage is measured in mV.

3） Click and drag any caliper line to adjust the size of the range to be measured.

4） Click and drag the caliper centerline to move the caliper as a whole.

5） Right-click the placed caliper to turn off the caliper display.

6） Clicking the measurement icon again will clear all calipers in the mark window.

Template comparison

1） Freeze a point.

2） Click the Select Template ( ) icon on the Markup Window toolbar.

3） In the mark window, click the left mouse button and two blue lines appear.
Select the desired template range.

4） Click "Select Template" on the toolbar of the mark window again, and the blue line disappears.

5） Click the Display Template ( ) icon on the Markup Window toolbar (Figure 7-10).
Dark gray template shadow display, using blue lines to display the selected template range.
The upper right corner of the template displays the average contrast of the listed surface

channels.

The contrast is displayed to the right of each body surface channel template.

6） Click the Toggle Display Surface/Intracardiac Channel Contrast icon ( ) on the Marker Window toolbar (Figure 7-11).

The intracardiac template shadow is displayed, while the skin channel template shadow remains.

The upper right corner of the template shows the mean contrast of the listed intracardiac channels (except for the three intracardiac channels M1-M2, M3-M4, M1).

The three intracardiac channels M1-M2, M3-M4 and M1do not participate in the comparison.

When this icon is pressed, the intracardiac channel contrast is selected and the contrast is displayed to the right of each intracardiac channel template.

When this icon is raised, select Body Channel Comparison and the contrast is displayed to the right of each Body Channel Template.

7） Select Accept or Reject, the mark window is refreshed in real time, and template comparison can be performed in real time. The mean body surface/intracardiac similarity and body surface/intracardiac similarity were updated in real time.

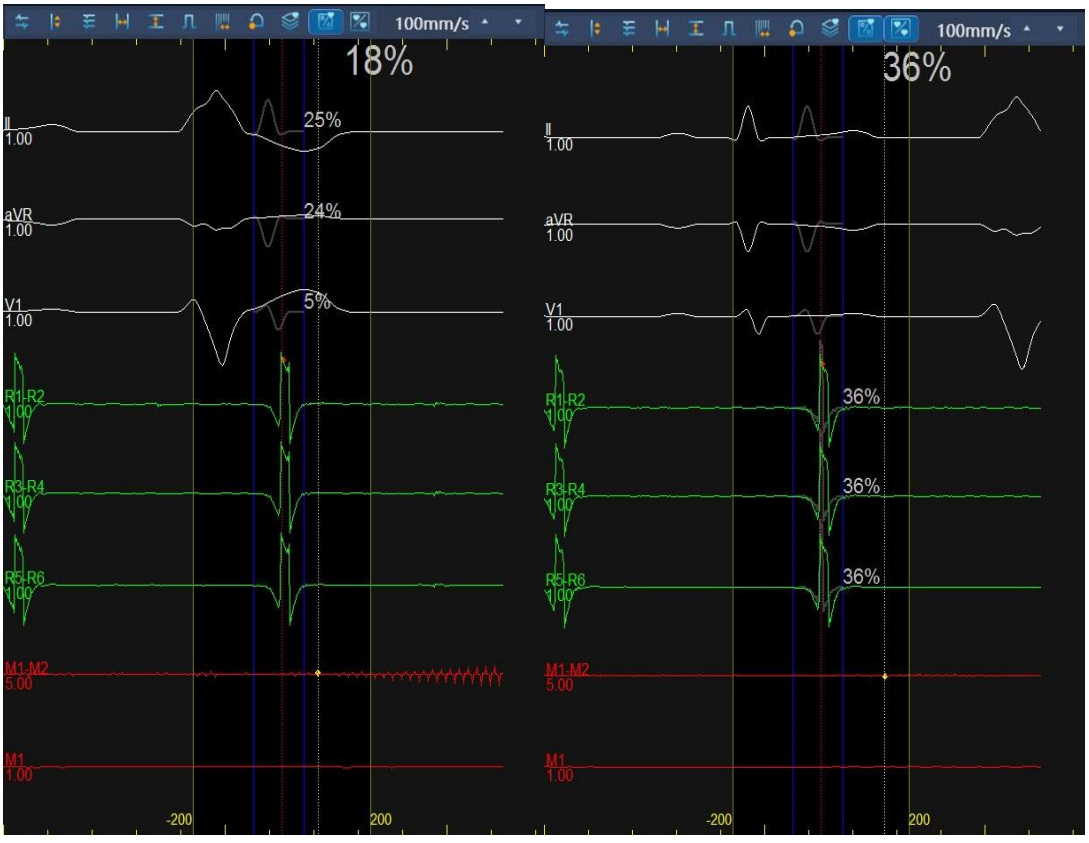


Figure 7-10 Display Template Figure 7-11 Intracardiac Channel Comparison

Stability Bar

The stability in the stability column represents the stability of the catheter and channel sampling data. When the red part of the stability bar is more than the green part, it indicates that the stability is poor and still in a barely acceptable range. The stability of a point is only a reference for measuring

the quality of the sampled data at that point, and it is entirely up to you to accept the point.

The Columbus™ system defines three levels of stability for 3D mapping data:

1） **LAT (local activation time): The LAT stability column shows the stability of the local activation time between beats. Red indicates the deviation of LATs between consecutive heartbeats in ms. The entire column represents 10 ms.**

2） **CL (heartbeat cycle length): CL stability shows the deviation between the current heartbeat cycle length and the heartbeat cycle length of the first mapping point in the current map. The entire column represents a deviation of 20%.**

3） **LOC (Position): The LOC Stability column shows the stability of the current heartbeat versus the previous heartbeat and the stability of the catheter tip position. Red indicates the position deviation measured at different heartbeats. The entire column represents a deviation of 12 mm.**

Figure 7-12 Stability Bar

7.6 **Toolbar**

The Columbus™ system has a variety of surgical tools to study maps and data. With these tools, you can easily view information and data of interest.

Including;

- How to use mapping tools, including point labels and multiple display functions
- View scar area
- Playback
- View the morning and evening connection area
- Display Catheter
- Print out map and related data
- Create video recordings and screenshots
- Use System Template
- Respiratory compensation
- Pressure Catheter Display
- Mapping Catheter and High Density Catheter Display

Refer to Chapter 10: Mapping and Surgical Instruments for details on mapping and data.

Figure 7-13 Cardiac Mapping Page Toolbar

Chapter VIII Map

The map created by the Columbus™ system is displayed as a color 3D reconstruction. As acquired points are continuously added to the map, their values affect the map in different ways, depending on the type of map displayed.

This chapter shows you how to use a map and the information it contains.

This chapter includes:

- Figure Appearance and color.
- Color scale and fill threshold.
- The type of map and the data it represents.

8.1 Figure Shape

The 3D map created by the Columbus™ system is obtained by 3D reconstruction based on the position information obtained from the actual sampling of the magnetic mapping/radiofrequency ablation catheter tip, and each collected point shall represent the anatomically real position of the heart chamber or vessel wall. Where no points are collected, the 3D reconstruction is calculated by interpolation from other known points.

Color of figure

The color of the map usually changes from red to purple at different locations. Red represents the minimum value, purple represents the maximum value, and other colors transitioned between them are assigned linearly by the system.

The color scale is located in the lower right corner of the map window. In the default state, the color scale represents the activation time. Depending on the type of map displayed, the meaning of its representation and its units change.

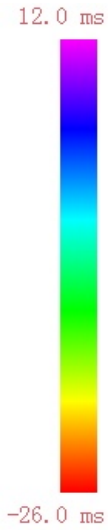


Figure 8-1 Color Scale

Hide/Show Color Ruler:
Right-click the background section of the map window and select Color Ruler to hide or display the color ruler.

Color interpolation

Color interpolation is the coloring of areas between points on a map. Color interpolation between two points is linear; Therefore, the greater the density of acquisition points in a region, the more accurate the result of color interpolation.

Each time a point is accepted, deleted, or edited, the shading of the map is re-calculated.

Change the color scale

Each point has map data. The color of the area between points reflects the interpolation results from the values of adjacent points.

Right-click the color scale bar to set the lower and upper limits of the values displayed in the figure. You can choose to set the color scale bar manually, automatically, or according to a preset default value.

Manual and automatic color scales

When you select Auto Color Scale, the system takes the maximum and minimum values of the corresponding types and data (e.g. mV, ms) of all maps in the map window as the maximum and minimum values of the shading.

You can also define the upper and lower limits of the color scale by manually setting the color scale. Therefore, when the manual color scale is selected, all points below the lower limit are colored red, and all points above the upper limit are colored purple. The manual color scale settings are saved

with the procedure. Double-click the color ruler bar to switch between automatic and manual color rulers.

Use Auto Color Scale:

- Right-click the color scale bar and select Auto Color Scale.
  Changes made to this setting are immediately applied to all maps in the map window.

Use manual color scale:

1） Right-click the color scale bar and select "Manual color scale" in the shortcut menu (Figure 8-2A).

2） Identification lines appear at the top and bottom of the color scale bar and display values next to them. Drag the logo line to the desired value (Figure 8-2B).

- The point whose value is lower than the lower limit will be colored red; Points with values above the upper limit are colored purple.
- This manual color scale is saved in the current procedure depending on the type of value.

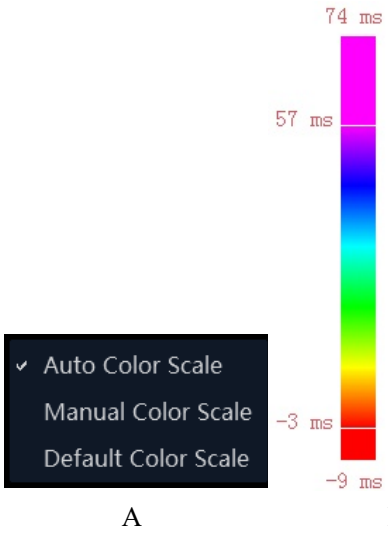


Figure 8-2 Setting the color scale.
A) Change the color scale bar through the right-click shortcut menu. B) Drag the upper and lower color limits of the scale bar to the desired specified position.

Use default color scale

You can use predefined color rulers for LAT, unipolar, and bipolar maps. Values can be saved with the procedure or into a template.

Set and use the default color scale:

1） Click the Color Bar Settings button () in the toolbar to display the Default Color Range dialog box (Figure 8-3).

2） Enter the upper and lower limits for LAT, unipolar, and bipolar plots.
All areas below the lower limit are colored red and all areas above the upper limit are colored

purple.

3） Close the Default Color Range dialog box. Your changes will be saved with the procedure.

4） Right-click the color scale bar and select Default Color Scale.

Changes made to this setting are immediately applied to all maps in the current map window.

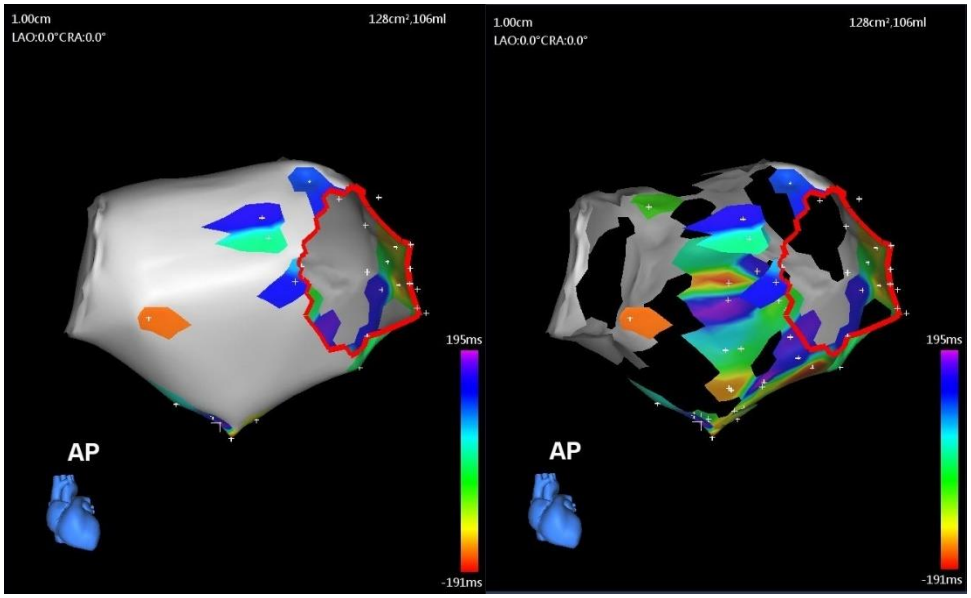
Figure 8-3 Default Color Range Dialog Box

8.2 **Fill Threshold**

The fill threshold reflects the extent of the 3D surface reconstructed at each mapping point. By increasing the fill threshold, the display area of the 3D surface around the mapping point can be enlarged to make the entire 3D reconstruction surface appear more complete.

The two Fill Threshold scroll bars are located on the upper left of the map window (Figure 8-4 A) and control the Geometry Fill Threshold and Color Fill Threshold for the corresponding window, respectively. The fill threshold of the map in this window can be changed by clicking the mouse and dragging the rails. The far left represents a fill threshold of 0, that is, only the map points are displayed and the reconstructed 3D surface is not displayed. By default, the geometric fill threshold and the color fill threshold are correlated, i.e., the values are equal. You can cancel the correlation by clicking the check box between the two scroll bars to adjust the fill threshold of the color electrophysiology information for 3D reconstruction.

A



B

C

Figure 8-4 Change the fill threshold.

A) The Fill Threshold scroll bar in the upper left corner of the map window.

B) Larger geometric fill threshold and smaller color fill threshold. C) Smaller geometric fill threshold.

In general, the greater the density of points collected in an area, the more accurate the 3D reconstruction and coloring will be. Therefore, setting the appropriate fill threshold can help you easily find out if there is a sparse area where data is collected evenly across the chamber.

8.3 **Type of Graph**

There are many different types of maps in the Columbus™ system, and you can switch between the required map types in the map window for browsing. You can also display different types of maps in the left and right map windows for comparative observation.

LAT Diagram

Lat (Local Activation Time) map is the default display type of the map window, and the color of the map is obtained by interpolation according to the activation time of each point.

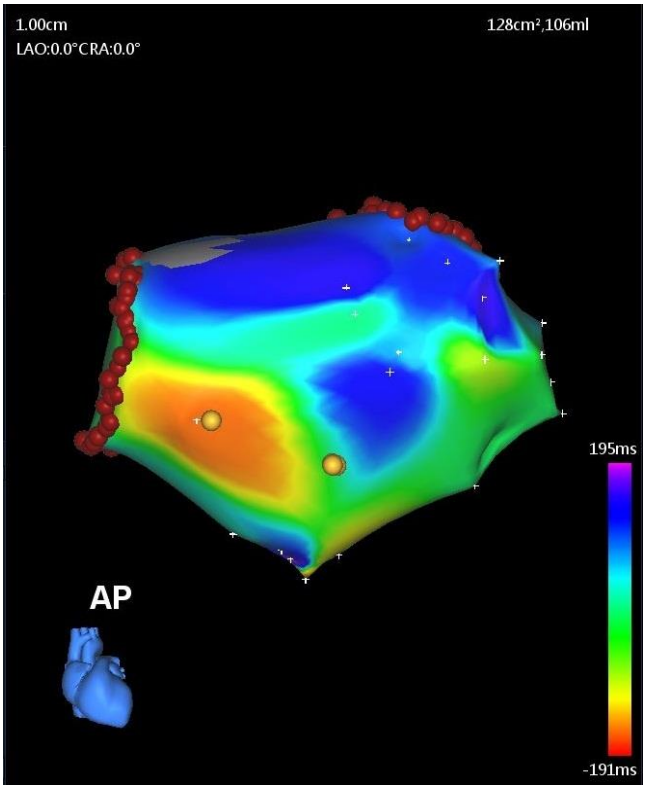


Figure 8-5 Map of a standard Columbus™ system. The color on the 3D anatomical reconstruction represents its electrical information; The earliest excitement was in red and the latest in purple.

Voltage diagram

The voltage diagram is divided into unipolar voltage diagram and bipolar voltage diagram. The value of the voltage map at each mapping point represents the peak-to-peak value of the unipolar or bipolar voltage of the mapping channel in the window of interest of each point. The unipolar and bipolar voltage values for each point are displayed below the stability bar. Changing the position of the window of interest will reset the voltage value at that point and affect the displayed results of the map.

To view a unipolar or bipolar voltage plot:
Right-click the map and a shortcut menu appears. Select Unipolar or Bipolar depending on the type of map you want to display.

Change the window of interest:

1） Displays a unipolar or bipolar voltage plot.
2） Freeze or select a point.
3） Drag the left and right interest windows to the range to be measured. Changing the window of interest interval affects the voltage measurement at the current point, and may also change the activation time at that point.
The new voltage value of the current point is immediately updated in the map and point list.

Excitation conduction diagram

With an excitation conduction map based on LAT data, you can observe that electrical signals

propagate in a curve within the heart, forming a continuous loop. The propagation map consists of red and blue parts. Red represents the currently activated tissue and blue represents the unactivated tissue. When the propagation chart is displayed, the color scale changes to blue with a red cross-band. The red band moves synchronously with the agitation flow along the color bar.

View the excitation conduction map:

1） Click the Activation Conduction icon ( ) on the toolbar in the Cardiac Mapping page. At this time, the map is converted into an activation conduction map, and the color scale bar is changed to blue with a red transverse band. The movement of the red band along the color bar is synchronized with the activation band and represents the period of activation represented by the activation band.

2） In this case, an activation conduction dialog box pops up, and the function button can be used to play and control the propagation of the conduction band.

: Go to the beginning of the activation conduction cycle.

: Play the activation conduction cycle automatically.

: Freeze the activation conduction map at any time. You can use this function when you want to carefully examine certain parts of the conduction cycle, or when you want to pause or print the graph.

: Go to the end of the excitation conduction cycle.

Close: Close the Activation Conduction dialog box and return to the map displayed earlier.
Window width: Adjust the width of the conduction band in milliseconds.
Step length: Adjust the activation time spanned by each transmission step of the conduction band, in milliseconds.

Note: The Activation Conduction Map function applies only to the currently active map.

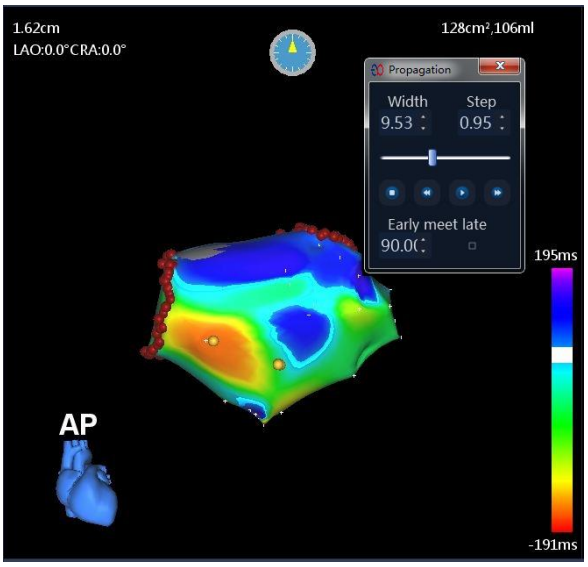


Figure 8-6. Activation conduction diagram.

Isochronal diagram

The agitation isochronogram is a ribbon showing the agitation time, with a total of 8 color distributions.

Right-click the map and a shortcut menu appears. Select Isograph depending on the type of map you want to display.

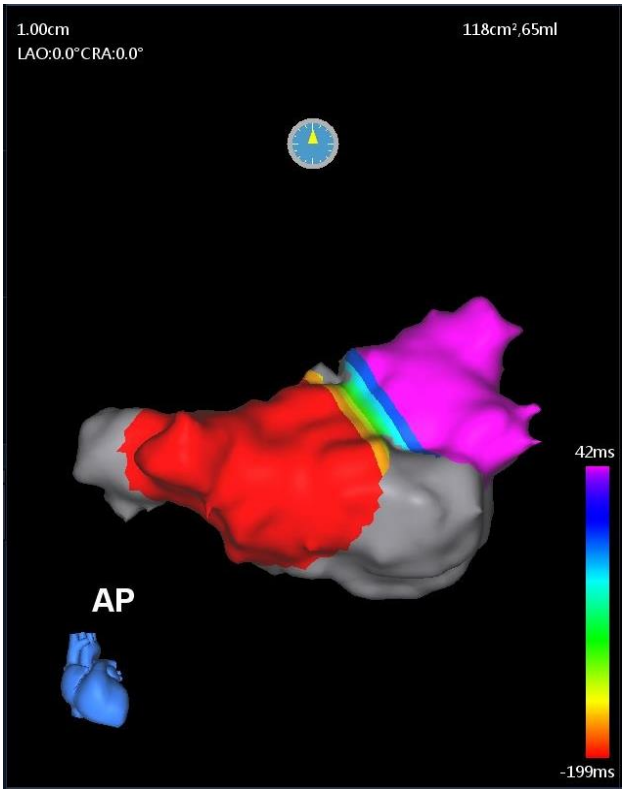


Figure 8-7 Isochronous Diagram

Impedance plot

The impedance map records the impedance values of the collected map points and is used to reveal the impedance distribution of the entire map.

Right-click the map and a shortcut menu appears. Select Impedance Graph depending on the type of map to display.

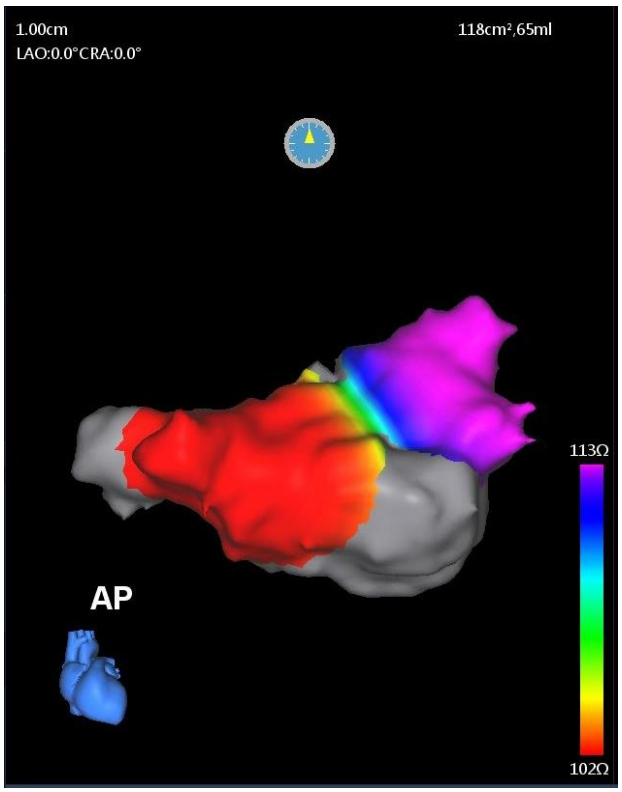


Figure 8-8 Impedance Diagram

Grid diagram

The grid map gives the mesh frame and grid points representing the map, while showing the basic shape and color interpolation. Therefore, setting the color range and fill threshold will also affect the display of the grid map.

View the grid diagram:
Right-click the map and select Grid, and the map in the map window will become a grid map.

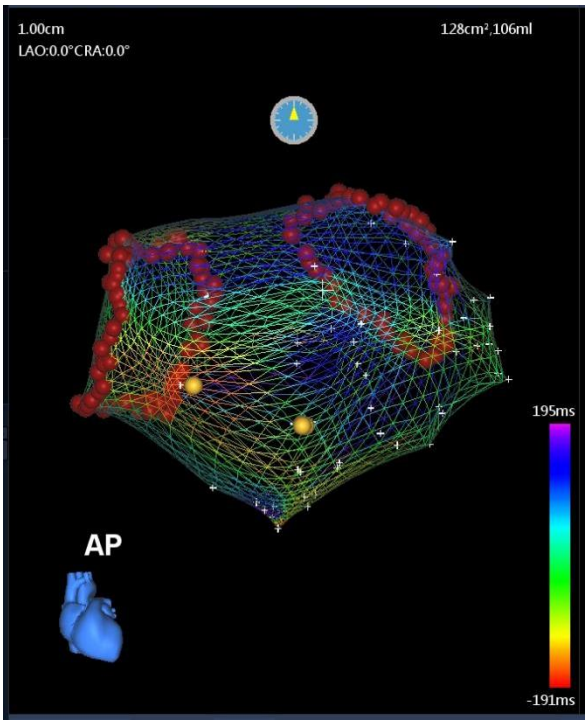


Figure 8-9 Grid diagram.

Anatomy

Anatomy is only a form reconstruction and does not display electrophysiological information. If multiple maps are displayed in the map window, they can be displayed simultaneously in the form of anatomical reconstruction.

View anatomy:

- Right-click the map, select Anatomy, and the map is converted to an anatomy.

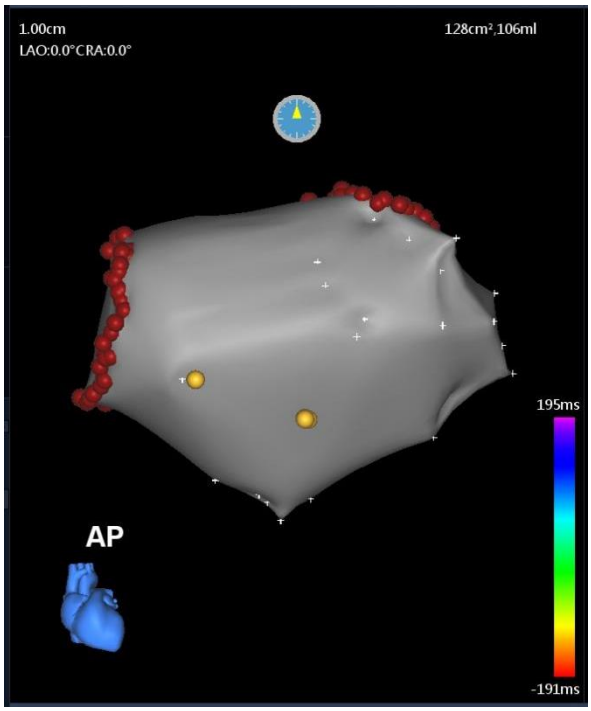


Figure 8-10 Anatomy

Transparent

Make the map transparent, you can see the structure and relationship of the heart cavity more clearly;

1） Open the map right-click menu and select Transparent.

2） Press and hold the model with the left mouse button while pressing "plus" or "minus" in the keypad to adjust the transparency of the model (Figure 8-11).

"+" makes the model brighter (i.e. less transparent).

"-" makes the model darker (i.e. more transparent).

At most, it can be adjusted to be completely transparent (that is, the model is not visible and only the mapping points are visible). Even if the model is completely transparent, the points inside the model cannot be selected. Points inside the model are still selected by point projection or point list.

Note:

- The label projection will change with the change of transparency, but the point projection will not, even if it is completely transparent, still show clearly.
- If Transparency is selected for both mapping windows, the transparency of both mapping windows is fully synchronized, and the transparency of either one is adjusted and the transparency of the other one is changed.
- Adjusting transparency requires holding the model with the left mouse button, not adjusting transparency if pressed on a map point or point projection, and opening the annulus centered on the point if it is an annulus point or contains an LO label.

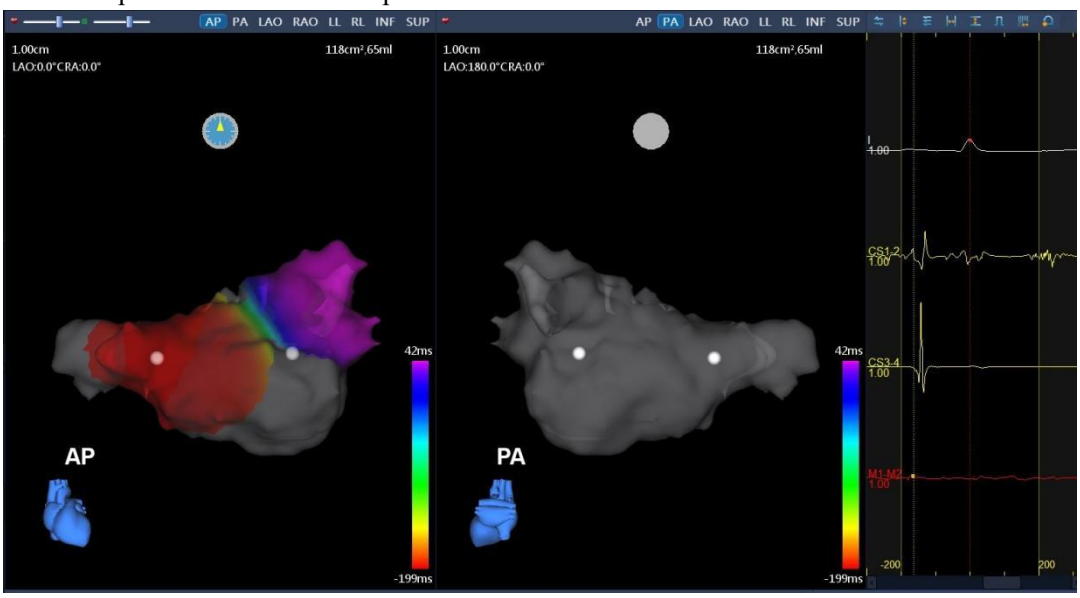


Figure 8-11 RTM Transparent Display

Glassy

Make the map glass display, can more clearly see the structure of the heart cavity and the relationship between before and after;

3） Open the map right-click menu and select Glass.

4） Press and hold the model with the left mouse button while pressing "plus" or "minus" in the keypad to adjust the model glass transparency (Figure 8-12).
"+" makes the model brighter (i.e. less glassy).
The "-" makes the model darker (i.e. greater glassy transparency).
At most, it can be adjusted to be completely glassy transparent (that is, the model is not visible and only the mapping points are visible). Even if the model is completely glassy transparent, the points inside the model cannot be selected. Points inside the model are still selected by point projection or point list.

Note:

- The label projection will change with the change of transparency, but the point projection will not, even if it is completely transparent, still show clearly.
- If Transparency is selected for both mapping windows, the transparency of both mapping windows is fully synchronized, and the transparency of either one is adjusted and the transparency of the other one is changed.
- Adjusting transparency requires holding the model with the left mouse button, not adjusting transparency if pressed on a map point or point projection, and opening the annulus centered on the point if it is an annulus point or contains an LO label.

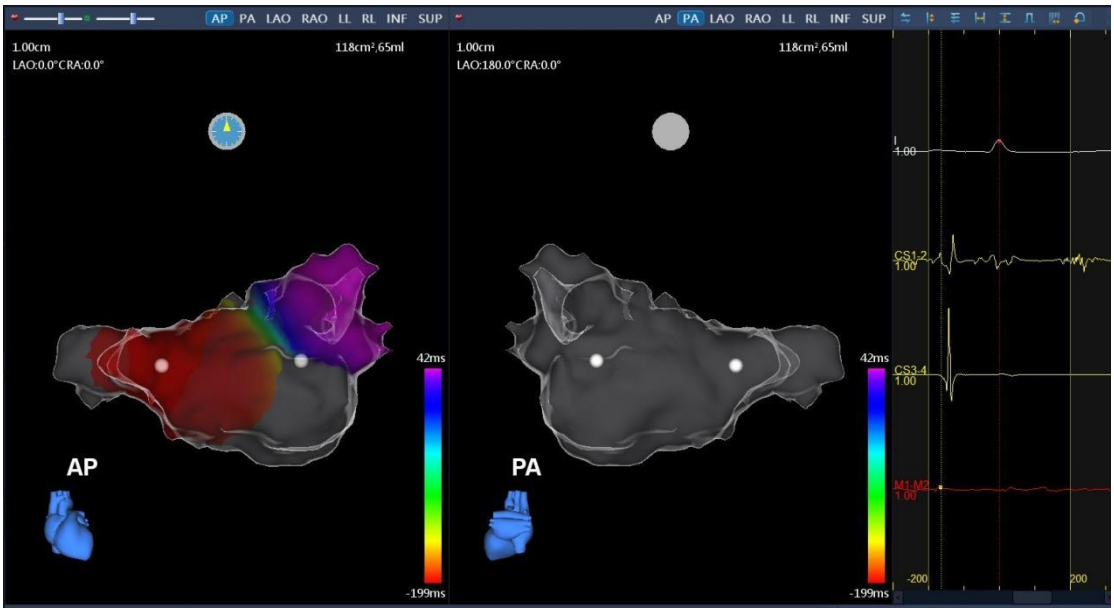


Figure 8-12 RTM Glass Display

RTM Diagram

View the RTM chart:

- RTM is another way to build a chamber model. Right-click Study, select "New RTM Graph," and click "on" to move the catheter through the heart cavity to create an RTM Graph.
- Quick volume: Shows the trace of the catheter during the construction of the RTM map, in gray.
- When "anatomy" is selected, the RTM map does not show the color gradient of superimposed electrophysiological signal, but is fixed gray; If Grid Map is also selected, the RTM map is also displayed as a grid.
- Mapping points can be collected during the process of building a cardiac chamber model using

RTM. Mapping points do not participate in the construction of RTM maps, nor do they construct separate electroanatomical maps. However, the ECG information of mapping points is projected onto the RTM maps.

Different types of catheters construct a geometric model of the heart cavity:

1） Right-click Study and select New RTM Graph.

2） Select the catheter type in the stabilization window (Figure 8-13).

3） The CS/HD-M catheter was selected to build a geometric model (Figure 8-14).

Note:

When the CS/HD-M catheter was selected to build a geometric model, the CS/HD-M catheter was not available and the ablation catheter was available.

Figure 8-13 Selection Of Different Catheter Types

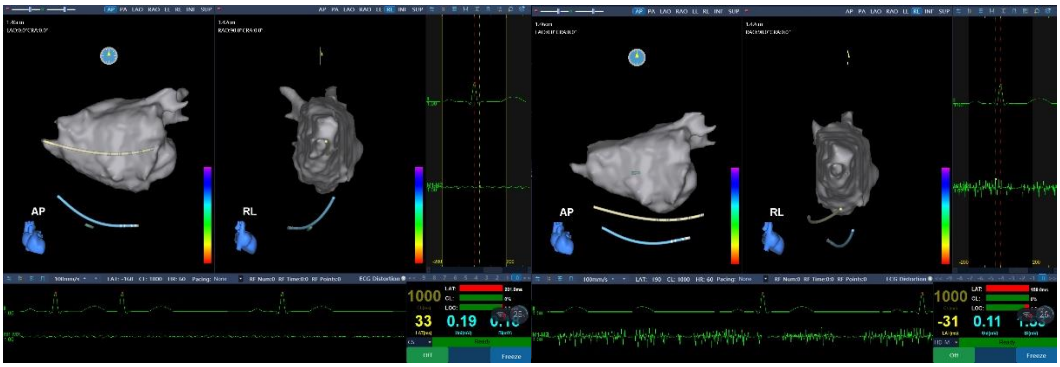


Figure 8-14 CS. LS Catheter Construction Geometry Model

RTM Resolution Settings:

Different resolutions can be used for modeling.

Click the "New RTM" drop-down box and select the appropriate resolution for modeling. The default resolution is four levels (Figure 8-15).

Note: The resolution level is divided into 5 levels, the resolution level 0 is the highest, and the resolution level 4 is the lowest.

Figure 8-15 Modeling Resolution

Model erase mode:

1） Grid erase

- Long press "Shift" + long press the left mouse button, the grid diagram and red circles appear.
- Drag the mouse to erase the interpolated grid.

2） Catheter Trace Erase

- Long press "Ctrl+Shift" and long press the left mouse button, the grid map and green circles appear, and all traces of the catheter are displayed in gray in the mapping window.
- Drag the mouse to erase the catheter trace.

3） Catheter Trace Erase(Layer by layer wipe)

- Long press "Shift" + long press the middle mouse button, the grid map and pink circles appear, and all traces of the catheter are displayed in gray in the mapping window.
- Drag the mouse to erase the catheter trace.

To undo a wipe:

The last wipe can be revoked.

1） Edit the model (any mode);

2） Select the map in the left map window, open the right-click menu and click "Undo Model" or press the "Ctrl+Z" shortcut key to undo the previous rub and restore the previous rub status.

Note:

- Only the right-click menu of the left map can be opened.
- This function is disabled when the model is not edited.
- Only the previous wipe operation can be canceled;
- Quick key for canceling die wiping: "Ctrl+Z";
- After editing the RTM map, activate other MAPs and reactivate the RTM map. This function is disabled.
- Point-by-point diagram This function is disabled.

Eraser size adjustment:

Used to modify the wipe radius.

1) Select the map in the left map window, open the right-click menu, and click Set Eraser to pop

up the Set Eraser dialog box.

2) Adjust the required eraser size and click OK.

Note: Only the left map right-click menu opens the function.

Chapter IX Segmentation and Registration

9.1 General Concept

Data collected during standard cardiac electrophysiology 3D mapping procedures include electrophysiology and anatomy data for accurate 3D reconstruction of the heart (mapping).
Important anatomical information about the heart can also be obtained through CT and MRI studies; The Columbus™ system allows the user to import and view existing CT and MRI images and register to a real-time acquisition of cardiac 3D maps during surgery.

Existing CT and MRI studies can be imported into the Columbus™ system via CD/DVD and saved on the hard disk. You can import the original sequence of CT and MRI studies and use it to create a single 3D volume rendering image.

When the volume image is successfully imported, you can adjust various display parameters for optimal viewing. The Columbus™ system has advanced segmentation algorithms to help you accurately and quickly segment the desired anatomy. These segmentation results are called surface images, and you can view the segmented surface images in the 3D map window and register either surface image with the currently active 3D map. After registration, the additional anatomical information provided by the surface image provides an additional reference for data collection and surgery.

9.2 Image Processing Page

The Image Processing page is the interface for the Columbus™ system to import and segment CTs and MRIs.

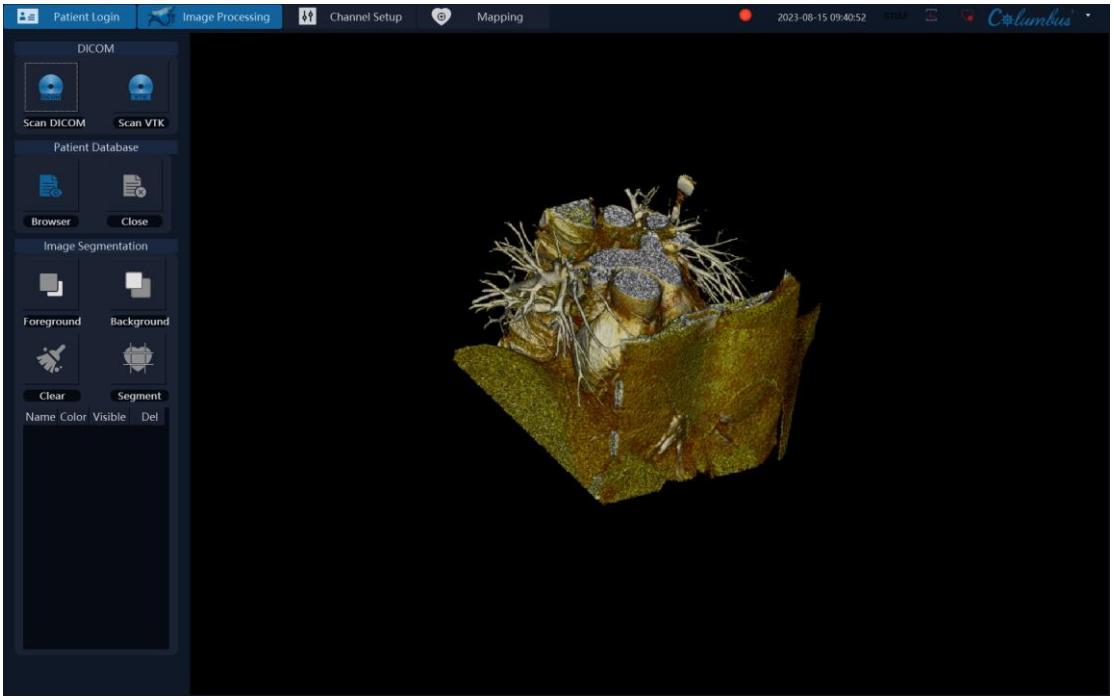


Figure 9-1 Image processing page.

The left side of the image processing page is the function panel, which includes a series of buttons to operate and segment image data. The lower left is the surface image list, displaying the three-dimensional surface images of each chamber obtained after the volume image is segmented.
The right side of the image processing page is the segmentation window, which is mainly used to display the 3D volume rendering generated after the DICOM image data is imported to the Columbus™ system. The user views the volume drawing in this window and performs further segmentation operations.

9.3 **Importing CT and MRI Images**

The raw data for CTs and MRIs are usually stored in the CD/DVD as a complete study. You can import CT or MRI studies into the Columbus™ system via CD/DVD. By default, you must create a new or open a patient before importing the original DICOM image study from the CTs to the Columbus™ system.

To import CT or MRI image studies into the Columbus™ system:

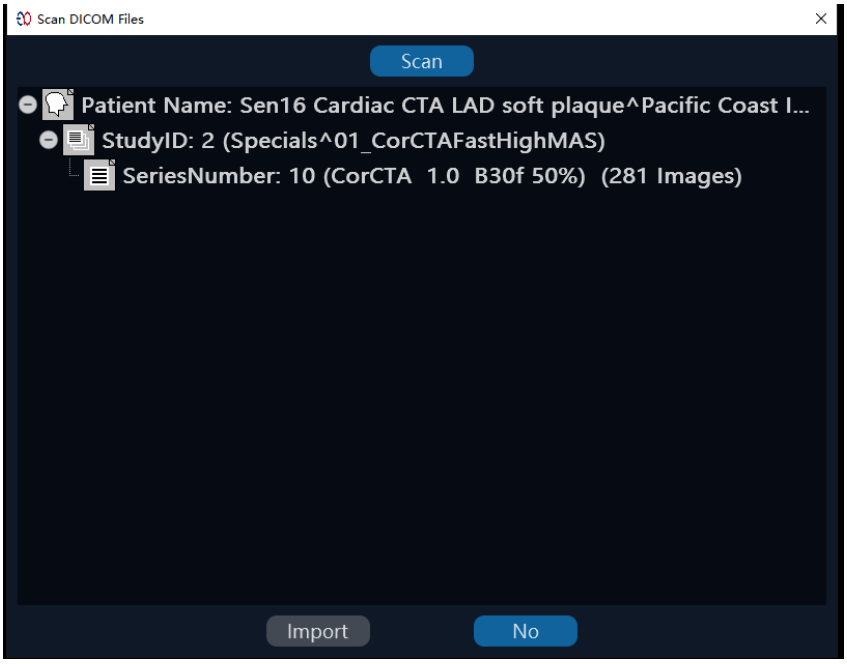
1） Create a new patient record in the patient information login page, or open an existing patient record.
Note: You can only operate on the Image Processing page if a patient record has been pre-created or opened. Before importing a DICOM image study, verify that the correct patient record has been created or opened, otherwise the image study will be incorrectly created in the incorrect patient record.
2） Place the CD/DVD with CT or MRI data in the optical disk drive of the Columbus™ system

workstation.

3） Click the Image Processing page icon (

) to enter the image processing page.

4） Click the Scan DICOM button () and the Scan DICOM Files dialog box appears. Clicking Scan will automatically scan the CT/MRI image study data on the CD/DVD. This process may last for several minutes, depending on the amount of data stored on the CD/DVD. Once the scan is complete, a directory of image studies and their underlying DICOMs appears in the Scan DICOMs File dialog box (Figure 9-2).



5） Select the series to be imported and click Import. The selected CT or MRI study series will be automatically imported into the patient record. This process may last for several minutes, depending on the amount of data stored on the CD/DVD. Once the import is complete, a prompt dialog box appears (Figure 9-3). DICOM data in image research is automatically converted to 3D volume rendering (volume image).

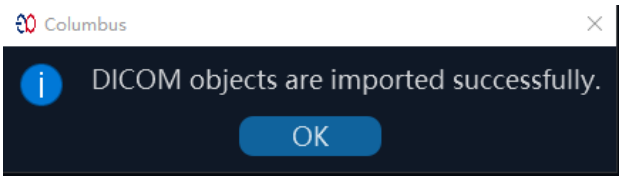


Figure 9-3 Prompt For Successful Import Of DICOMs

Note:

1) If the patient information of the DICOM data you use is not consistent with the patient information of the 3D mapping procedure you are currently operating on, you will be prompted before you import the DICOM data, and you will be asked to confirm whether to continue the operation of importing the data. The system supports importing up to 3 DICOM sequences from the same patient.

2) If part of the DICOM data you use is missing or the slice intervals are not consistent, a prompt appears and the DICOM data cannot be imported into the system (Figure 9-4).

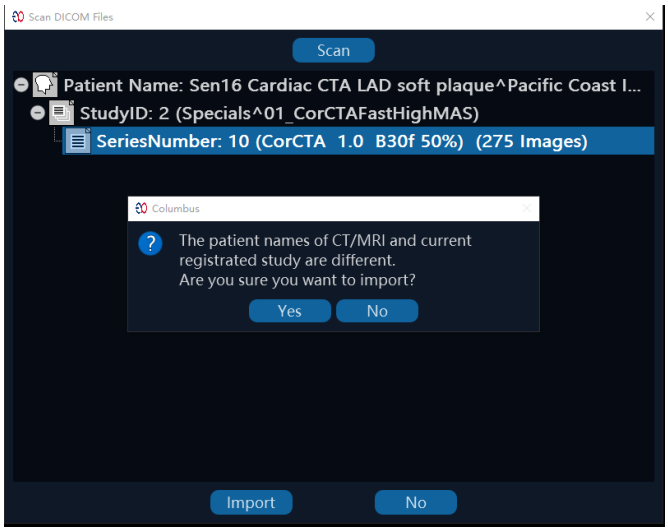


Figure 9-4 DICOM Prompt Information For Missing Data Parts Or Inconsistent Slice Intervals

9.4 **View Volume Drawing**

Volume rendering, which is created by importing patient records via DICOM data, is the basis for segmentation operations. The Columbus™ system contains a variety of common features that allow you to browse volume rendering in a similar way as in a general imaging workstation.

Click the "Browse" icon on the left panel of the image processing page to view all 3D volume plots included in the current patient record. Select the desired volume drawing and click the Accept button, or double-click the volume drawing directly to load the volume drawing in the main split window (Figure 9-4).

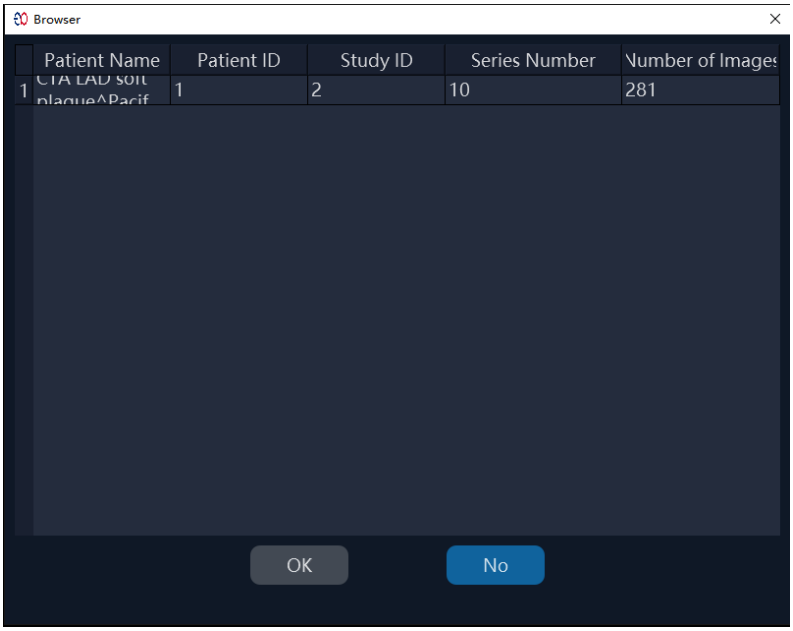


Figure 9-4 Patient Browse Dialog Box

Figure 9-1 shows the volume rendering images that have been imported in the Image Browse window. You can make a series of adjustments to the display of volume rendering as needed:

Rotate: Click the middle mouse button and drag the volume image to rotate the viewing angle.
Zoom: Adjust the middle mouse wheel up and down to zoom in and out of the drawing view.
Projection azimuth: The projection azimuth button above the window is used to quickly switch to the standard projection position.
Tangent plane: Click the right mouse button in the window and select "tangent plane" in the shortcut menu to open the tangent plane function. The mouse changes to an icon with small scissors. Press the <Shift> key in the keyboard and hold the left mouse button in the window. Drag the mouse up and down to translate the position of the tangent plane in volume drawing, so as to observe the content of the tangent plane with different depths in volume drawing.
Window level/window width (Window/Level): Press the <Alt> key on the keyboard and hold the middle mouse button in the window. Drag the mouse upward to increase the window width of volume drawing. Drag the mouse downward to reduce the window width of volume drawing. Drag the mouse to the left to reduce the window level of volume drawing. Drag the mouse to the right to increase the window level of volume drawing.
Reset: Select the "Reset" option in the right-click menu to restore the volume drawing form to the default state.
Close Volume Drawing: Click the "Close Information" icon in the left panel to close the current image study.

9.5 **Segmented surface image**

The Columbus™ system has advanced segmentation algorithms that allow you to quickly segment the 3D surface image of the target chamber through extremely simplified operations. To segment a target chamber, you must first see the chamber with the aid of a tangent plane and place a segment marker (foreground marker) at a location inside it, usually in the appropriate center, from which the Columbus™ system can automatically obtain a three-dimensional surface image of the desired anatomy.

To segment the desired surface image from 3D volume rendering:

1） Right-click in the segmentation window, open the tangent plane, and adjust its position in volume drawing until you can clearly observe the anatomy of the desired segmentation in the tangent plane (Figure 9-6A).

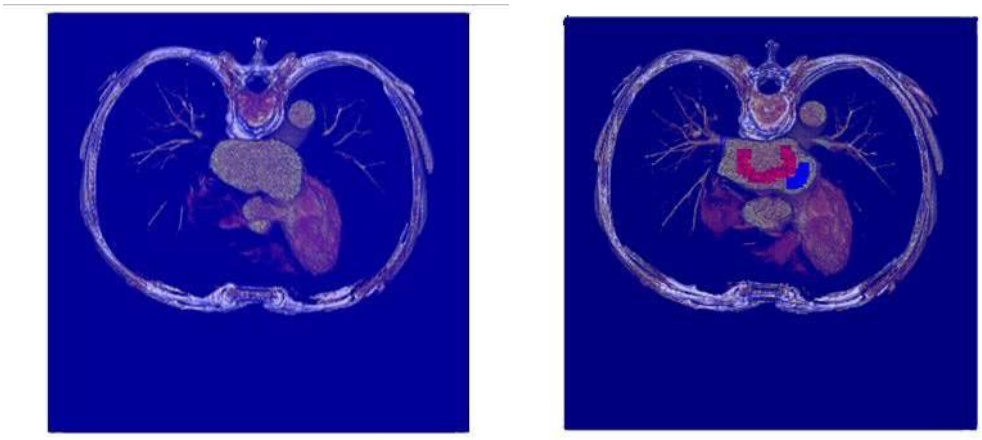
2） Click the Select Foreground icon () in the left function panel and the mouse changes to the icon for the combination of a red brush and small scissors (). The mouse now has a pen-like function in the split window. You can tick the red foreground mark inside the desired

segmented target structure by clicking and dragging the left mouse button (Figure 9-6B).

3） If you do not need some anatomy connected to the target chamber (such as the left atrial appendage), you can use the Select Background icon () to change the mouse to the icon for the combination of a blue brush and a small scissor (), delineating the blue background marker in these anatomy to indicate that the structure should not appear in the segmented structure (Figure 9-6B).

4） To clear the previously set segmentation mark, click the Clear icon () and all foreground and background marks in the precursor plot will be cleared. 

Note: In order to achieve better segmentation results, you may need to adjust the segmentation markers repeatedly to pinpoint the segmentation area.



A B

Figure 9-6 Setting The Division Mark

A) Adjust the tangent plane to the proper position. B) Sketch foreground and background markers in volume rendering.

5） After setting the foreground mark and background mark, click the "Split" icon  () in the left function panel, and the system will automatically split the target chamber according to the mark you set and generate the corresponding surface image.

6） After the segmentation operation is completed, the obtained surface image is automatically saved to the corresponding image study of the current patient, and the contents of the image study list in the cardiac mapping page are updated immediately.

7） Each time a new surface image is segmented, the system will automatically enter the state of editing the surface image. At this time, all marks will be cleared automatically, and the system will turn off the display function of volume drawing and tangent plane. “The Select Foreground icon is automatically activated for you to further edit the segmentation results.

8） To continue segmenting the next surface image, unactivate the Select Foreground or Select

Background function, right-click inside the segmenting window, and reopen the volume drawing and tangent plane in the shortcut menu.

9） Repeat the above steps to continuously segment multiple surface images. Figure 9-7 shows the Columbus™ system continuously segmenting surface images of multiple different chambers and tissue structures on the same volume rendering.

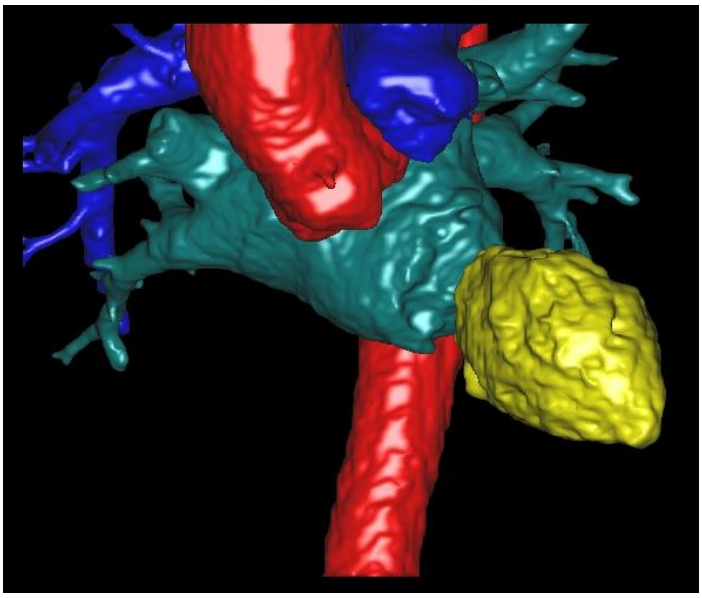


FIG. 9-7 draws a plurality of surface images continuously segmented from the same volume. The figure shows the left atrium, left ventricle, aorta, and pulmonary artery.

Note: For the same volume rendering, the system supports the generation of up to 5 surface images.

9.6 **Edit Surface Image**

Each time a new surface image is segmented, a new segmentation result is added to the surface image list below the function panel (Figure 9-8). You can rename and modify the color, or delete the incorrect segmentation result. At this time, the system will automatically enter the state of editing the surface image, and the volume drawing and tangent plane will be hidden. You can edit and edit the surface image in the image segmentation window.

Figure 9-8 List Of Segmentation Results

Clip Surface Image:

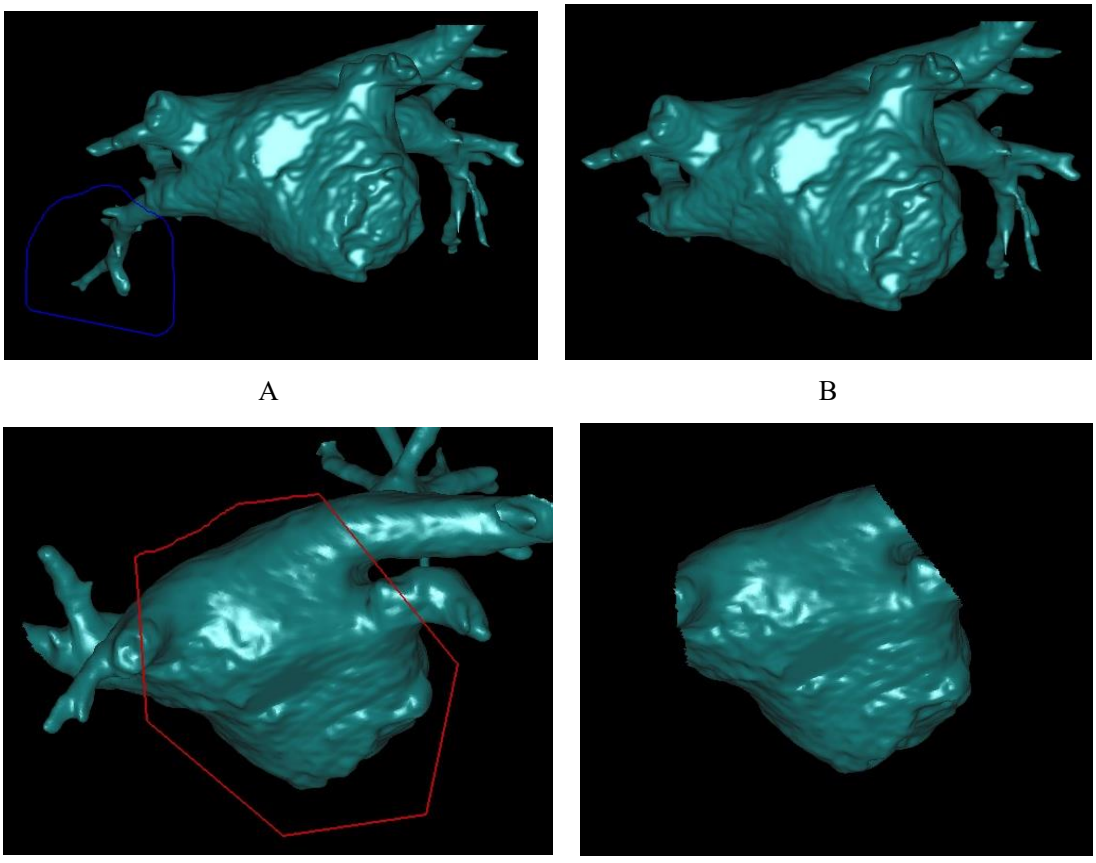
1） After a new surface image is segmented each time, the system will automatically enter the state

of editing the surface image. At this time, volume rendering will be automatically hidden, and the functions of "Select foreground" and "Select background" buttons will become the operation of clipping and editing the surface image.

2） Click on the "Select Background" icon ( ), the mouse has a brush function in the split window. You can draw a continuous curve or line segment around the detail of the surface image to be deleted by clicking the left mouse button, and double-click the mouse to form a closed contour (Figure 9-9 A). Click the Split icon ( ) to cut the delineated part from the surface image (Figure 9-9 B).

3） Click the "Select Foreground" icon ( ), the mouse has a brush function in the split window. You can draw a continuous curve or line segment around the detail of the surface image to be deleted by clicking the left mouse button, and double-click the mouse to form a closed contour (Figure 9-9 C). Click the Split icon ( ) to cut the portion outside of the delineated range from the surface image (Figure 9-9 D).

4） Click the Clear icon ( ) to delete the already set clip line.



A B C D

Figure 9-9 Clipping The Surface Image

A) Select the section to be cropped. B) The left atrial surface image of the right inferior pulmonary

vein was removed. C) Select the part to be retained. D) Left atrial surface images of all pulmonary veins and atrial appendages were removed.

9.7 Registering a Surface Image to a 3D Map

When a patient's medical record contains an image study with a surface image segmentation result, you can view the surface image in the patient's medical record at any time and register it with the map through the image study list during the operation that performs the three-dimensional mapping. The Columbus™ system provides the ability to fuse and register surface images with maps in 3D mapping procedures. The 3D surface image obtained from CT or MRI image research segmentation is superimposed with the 3D map of Columbus™ system in the same view, which provides more intuitive and accurate surgical guidance for cardiac electrophysiology 3D mapping surgery.

Note: To perform the registration operation, you must first activate a 3D map in the Cardiac Map page.

1） Double-click the image study in the image study list, or right-click the image study in the image study list, and select "Activate" in the right-click shortcut menu to activate the corresponding surface image in the study.
2） The activated surface image is displayed in the map window along with the map. Click the checkbox for the surface image in the Image Study list to hide or display each surface image separately.
3） Manually align the surface image with the target map. Press the <Ctrl> and <Alt> keys at the same time, and then click and translate the position of the surface image relative to the map with the left mouse button. If you middle-click and drag the mouse at this point, the surface image is rotated. You can move the surface image to approximately the same position and orientation as the map by repeatedly performing translation and rotation operations.
4） The Columbus™ system registers the surface image with the currently active map. Right-click the surface image to be registered and select Register from the shortcut menu. The system automatically registers and fuses the surface image with the specified 3D map.
5） Once registration is complete, the error of the current registration result is displayed in the map window, including the mean, minimum, and maximum deviation between the map point and the surface image (Figure 9-10). Registration errors may serve as a reference for you to assess the quality of the registration results.

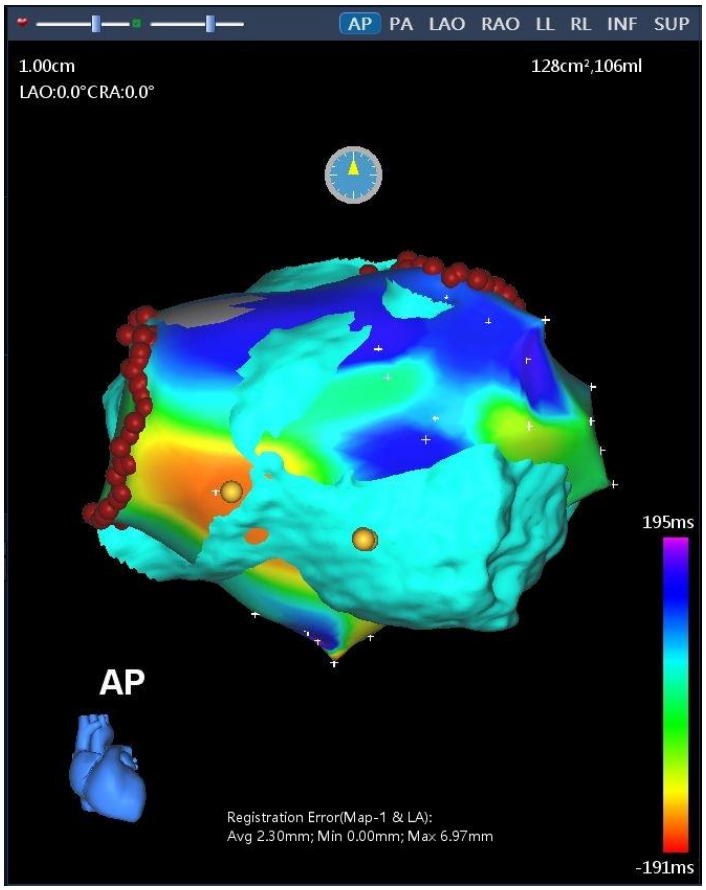


Figure 9-10 Registration Error Display

6） Opens the map right-click menu with the option "Registration View." When this option is selected, the error range of each point will be represented in different colors on the map, covered on the map point in the form of dots, and the registration error value of each point will be displayed next to each map point, and displayed below the map:
Registration accuracy: Green dot: 0-4.9 mm Yellow dot: 5.0-9.9 mm Red dot: >10.0 mm.
This value range is not adjustable and is fixed. See Figure 9-11 below.

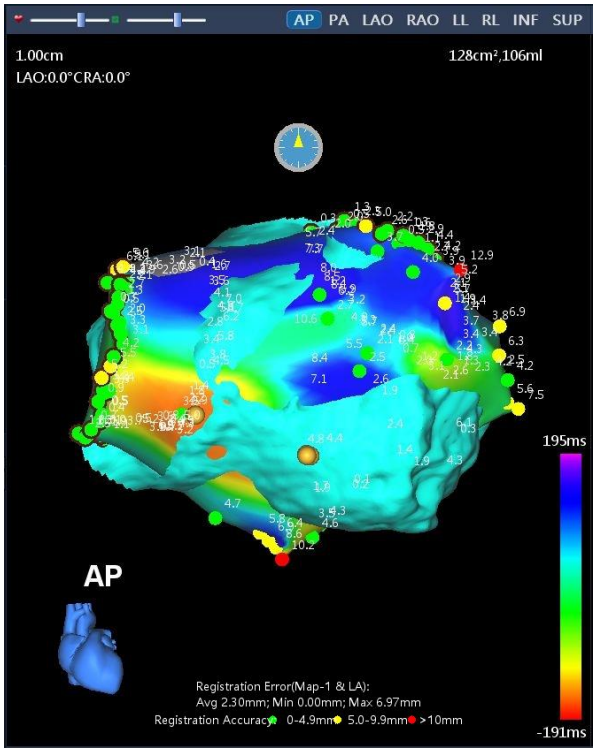


Figure 9-11 Registration View

When there are multiple surface images in the active image study, you can select to show or hide each surface image by ticking in the checkbox in the list.

Warning: Do not use the surface image used for registration as a guide to ablation in areas with significant registration errors.

9.8 **Scan VTK**

The VTK raw data are usually stored in the CD/DVD as a complete study. You can import VTK studies into the Columbus™ system via CD/DVD. By default, you must create a new or open a patient before importing the original VTK image study to the Columbus™ system.

Import VTK Image Study to Columbus™ System:

1） Create a new patient record in the patient information login page, or open an existing patient record.
Note: You can only operate on the Image Processing page if a patient record has been pre-created or opened. Before importing a VTK image study, verify that the correct patient record has been created or opened, otherwise the image study will be incorrectly created in the incorrect patient record.

2） Place the CD/DVD with the VTK data in the optical disk drive of the Columbus™ system workstation.

3） Click the Image Processing page icon (

) to enter the image processing page.

4） Click the Scan VTK button (

) and the Scan VTK File dialog box appears (9-12). Select the VTK file and click Import. This process may last for several minutes, depending on the amount of data stored on the CD/DVD. Once the import is complete, the VTK Model Import Successful dialog box pops up (Figure 9-13).

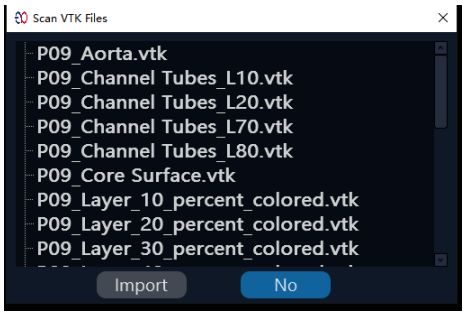


Figure 9-12 Scan VTK File Dialog Box

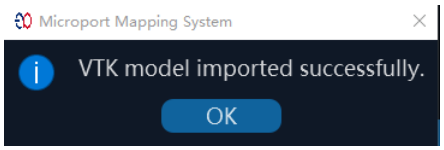


Figure 9-13 VTK Model Import Success Dialog Box

9.9 **Register VTK Images to 3D Map**

When a patient's medical record contains a VTK image, you can view the VTK image in the medical record and register it with the map through the VTK image study list during the procedure where the 3D map is performed. The Columbus™ system provides the ability to fuse and register VTK images with maps in 3D mapping procedures. Superimposed display of VTK images and Columbus™ system 3D maps in the same view provides more intuitive and accurate surgical guidance for cardiac electrophysiology 3D mapping procedures.

Note: To perform the registration operation, you must first activate a 3D map in the Cardiac Map page. Exit Surgery This VTK image is not saved.

1） Double-click the VTK image study to activate the corresponding VTK image in the list.
2） The activated VTK image is displayed in the map window along with the map. Click the check box of the VTK image in the image study list to hide or display each VTK image separately.
3） Manually align the VTK image with the target map. Press the <Ctrl>, <Alt> and <Shift> keys at the same time, and then click and move the position of the VTK image relative to the map with the left mouse button. If you middle-click and drag the mouse at this point, the VTK image is rotated. You can move the VTK image to approximately the same position and orientation

as the map by repeatedly performing translation and rotation operations.

4） The Columbus™ system registers the VTK image with the currently active map. Right-click the VTK image to be registered and select Register VTK from the shortcut menu. The system automatically registers and fuses the VTK image with the specified 3D map.

5） Once registration is complete, the error of the current registration result is displayed in the map window, including the mean, minimum, and maximum deviation between the map point and the VTK image (Figure 9-14). Registration errors may serve as a reference for you to assess the quality of the registration results.

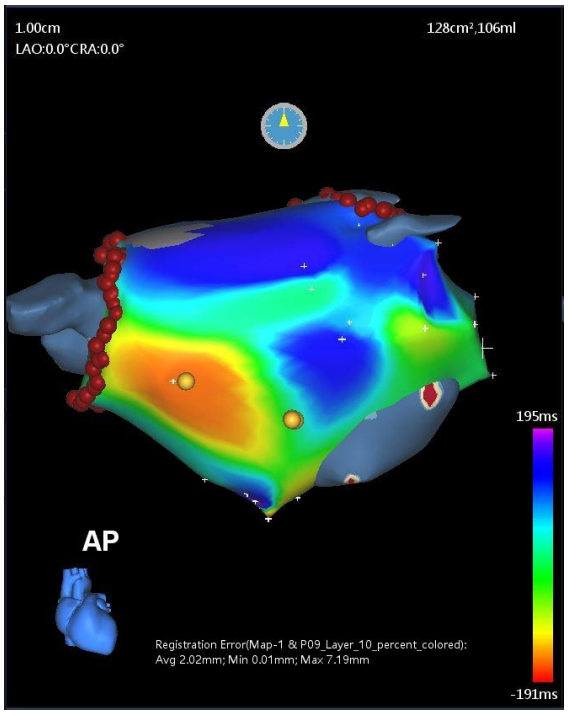


Figure 9-14 VTK Registration Error Display

6） Opens the map right-click menu with the option "Registration View." When this option is selected, the error range of each point will be represented in different colors on the map, covered on the map point in the form of dots, and the registration error value of each point will be displayed next to each map point, and displayed below the map:
Registration accuracy: Green dot: 0-4.9 mm Yellow dot: 5.0-9.9 mm Red dot: >10.0 mm.
This value range is not adjustable and is fixed. See Figure 9-15 below.

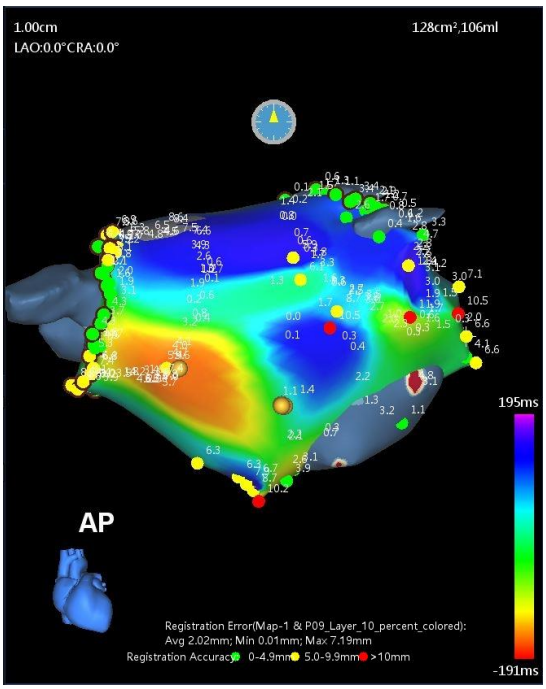


Figure 9-15 Registration View

When there are multiple VTK images in the active VTK image study, you can select to show or hide each VTK image by ticking in the checkbox in the list.

Warning: Do not use the surface image used for registration as a guide to ablation in areas with significant registration errors.

Chapter X Mapping and Surgical Instruments

The Columbus™ system has a variety of surgical tools to study maps and data. With these tools, you can easily view information and data of interest. In addition, you can print the map on paper or output it as an image file format.

This chapter covers;

- How to use mapping tools, including point labels and multiple display functions
- Map Point Color Fill Threshold
- Map Point to Model Distance Threshold
- View scar area
- View the morning and evening connection area
- Playback
- Display Catheter
- Tip of catheter sheath
- Catheter bending direction prompt
- Print out map and related data
- Create video recordings and screenshots
- Use System Template
- Respiratory compensation
- Pressure Catheter Display
- Mapping Catheter Display
- Mapping Catheter Review Display
- Mapping Catheter Electrode Highlight
- High Density Catheter Display
- Multi-electrode simultaneous mapping
- RF parameter display
- Multi-channel temperature display
- Pointwise ring opening
- RTM Annulus Opening
- Line drawing
- III Reference
- Tangent plane
- Distance measurement
- Edit patient and surgical data
- Rename Surgery and Map
- Dominant frequency analysis

The Columbus™ system has a number of different software functions for manipulating data and viewing maps. These tools are detailed below.

10.1 Point label

Point labels are used to mark certain special points in the map. The Columbus™ system provides several preset point labels, and you can also create custom point labels. After you place a label on a point, you can change how the point works for the entire 3D reconstruction by changing the "type" of the label.

Type of Point

The type of label determines how the data for this labeled point will work for the entire reconstruction:

- Normal: The position information and electrophysiological data of the normal point will participate in the reconstruction of the 3D map. General map points without point labels are normal points.
- Solitary Point (Floating): After the solitary point is collected, the relevant data does not participate in the reconstruction or color interpolation of the map shape. Therefore, the isolated point is displayed as free.
- Position Point (Location Only): The position point only participates in the 3D reconstruction of the map, and its electrophysiological data has no effect on the color interpolation of the map.
- Scar spot (Scar): The area around the scar spot is marked as a scar area.

Viewing labels and types of points

If multiple point labels are set for a point, the text content of the label displayed in the point list is displayed according to the priority of the label, and the label name with the highest priority is displayed at the front of the column. The label displayed by default in the map window is the label type with the highest priority.

Example: Priority of Label Type

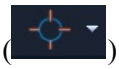
The His tag has the highest priority if two tags are set for one point (one is the His tag for the normal point and the other is the Location Only tag for the position point).

Setpoint Label

You can place a point label by selecting a point from the point list or directly from the map.

Placement Point Label:

1） Perform one of the following steps to open the Point Label and Type dialog box (Figure 10-1):

a. Click the "Display Point Edit Dialog Box" icon () in the toolbar (there is "Size Setting" option in the drop-down box of the icon, and the "Map Point Size Setting" dialog box will pop up after selection, as shown in Figure 10-1 right).
b. Right-click a point in the point list and select Edit Label from the shortcut menu.
c. Right-click a point in the map window and select Label from the shortcut menu.

2） Click to select the desired label.

- Click OK to close the dialog box and place a colored label on the selected point in the map.
- If it is frozen at this time, please note:
  - Clicking Apply will accept the labeled point while keeping the Point Label and Type dialog open.
    The next time you freeze, the content in the Point Label and Type dialog boxes is cleared, and the content corresponding to the newly acquired point is generated when you freeze.
  - Clicking OK will accept the labeled point and close the Point Label and Type dialog boxes.

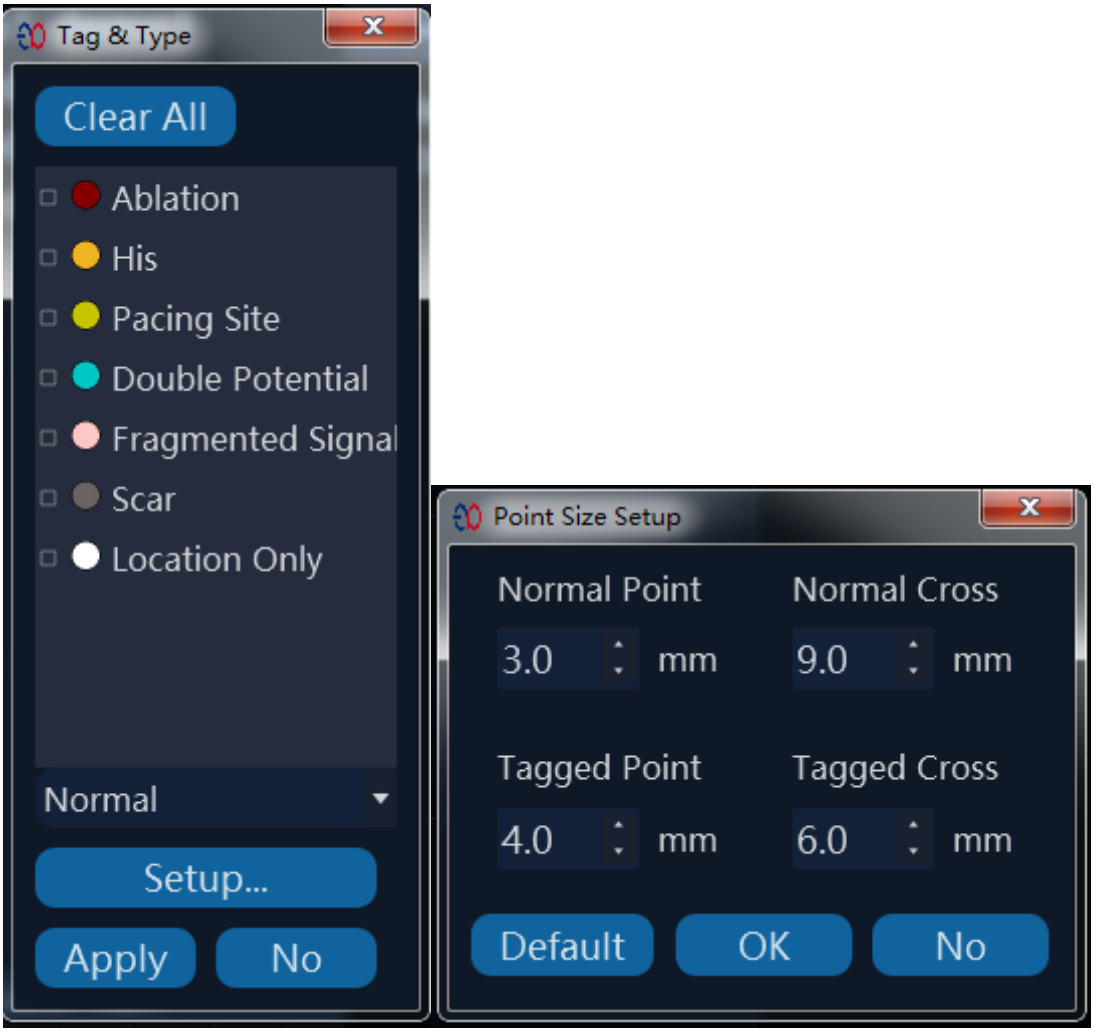


Figure 10-1 Point Label And Type Dialog Box

Left) Point Label and Type Dialog Box Right) Map Point Size Setup Dialog Box

3） Special: If a map point is acquired during ablation, it is automatically marked as an ablation point (Ablation);

Change Label Type

You can change the type of a point label directly in the Point Label and Type dialog box, or make

global changes through the Point Label Setup dialog box.

Change the label type of a point:

1） Select one or more points to open the Point Label and Type dialog box.

2） Select the type you want to set in the drop-down menu.

3） Click Apply or OK to save the settings.

Custom Point Label

You can use several system preset labels from the beginning. Although you cannot change their names, you can change their types, or you can create new point labels from the Point Label Settings dialog box and give them custom properties such as color, type, and label characters.

Change the preset point label type:

Click the Settings button in the Point Label and Type dialog box, or click the Type Edit option in the drop-down menu next to the Show Point Edit dialog icon in the toolbar to open the Point Label Setup dialog box (Figure 10-2).

1） Select the label to edit.

2） In the Type column, select the type to apply to the label. The changes you make here will be applied to all subsequent labels.

3） If you want to change the type of a previously placed label, select the point and make the change through the Point Label and Type dialog box.

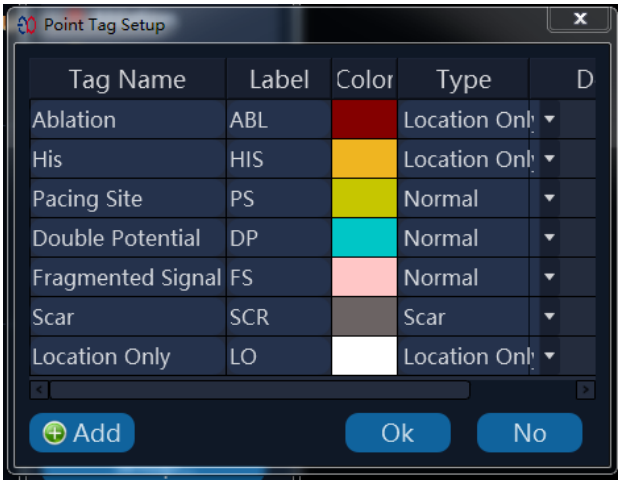


Figure 10-2 Point Label Setting Dialog Box

Create custom point labels:

1） Opens the Point Label Setup dialog box.

2） To define a new point label, click Add.

A blank column appears in the Point Label Setup dialog box.

3） Enter the name of the label in the Label Name field.

4） Enter the characters that uniquely identify the label in the Label field. These characters appear in the label bar of the point list.

5） In the Color bar, select the color in which the label appears in the figure.
6） Select the type you want to apply in the Type column.

10.2 Map Point Color Fill Threshold

Fill the model color with the set threshold.
1） Click the drop-down menu of the Display Point Edit dialog box;
2） Select the color fill range of the map point, and a slider bar for setting the color fill range of the map point is displayed.
3） Drag the slider to set the appropriate threshold (Figure 10-3).

Note:
- Different MAP thresholds can be set.
- The slider position is movable (mouse selected title, mouse moved).

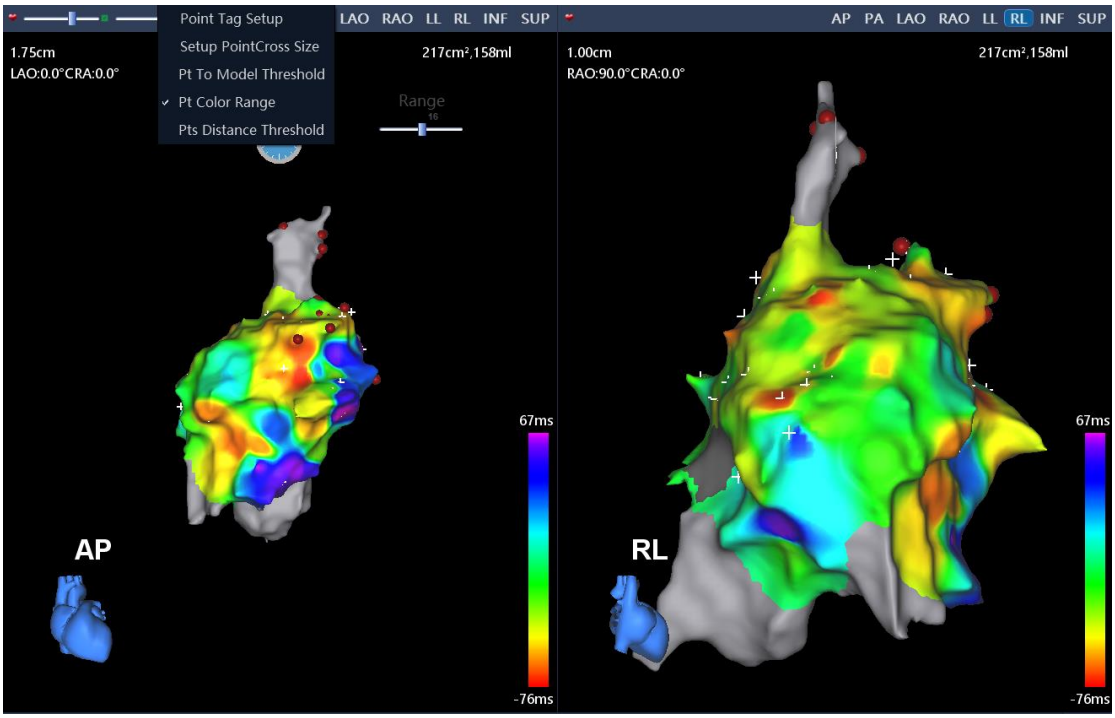


Figure 10-3 Color Fill Of Mapping Points

10.3 Map Point to Model Distance Threshold

When the distance between the mapping point and the model meets (less than or equal to) the threshold condition, the mapping point participates in the model color interpolation calculation. When the distance between the mapping point and the model does not meet (greater than) the threshold condition, the mapping point does not participate in the model color interpolation

calculation. The map points that do not meet the threshold conditions are hidden by default. The catheter type column of the point list becomes gray, indicating that the map point does not participate in the model color interpolation calculation.

1） Click the drop-down menu of the Display Point Edit dialog box;
2） Select Maps to Model Distance Threshold, and the Maps to Model Distance Threshold Slider is displayed.
3） Drag the slider to set the appropriate threshold (Figure 10-4).

Note:
When two or more mapping points project to the same position of the model, only the mapping points close to the model are displayed, and other mapping points are hidden.
Manually hidden mapping points still participate in the model color interpolation calculation, and the sampling catheter type column in the point list remains the same.
Different MAP thresholds can be set.
This function is only applicable to RTM diagram, and is disabled for point-by-point diagram;
The slider position is movable (mouse selected title, mouse moved).

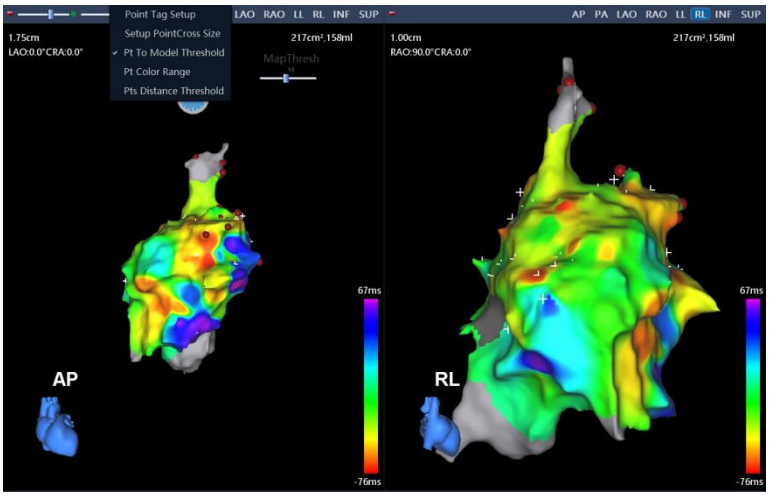


Figure 10-4 Mapping Point To Model Distance Threshold

10.4 View scar area

You can choose to mark scar points either automatically or manually, with dark gray areas on the map representing low-voltage scar areas.

Note:
- Scar setting is only valid for activity maps. This allows you to make different scar settings for each image.
- Click OK to apply the scar threshold to the activity map. If you accidentally open the scarring settings dialog box, click Close to return to the map without using the scarring threshold.

How to display scar areas during surgery:

1） Click the Scar Setup icon () on the toolbar.
The Scar Setup dialog box appears (Figure 10-5).

2） Enter a value in the monopolar scar threshold (mV) or bipolar scar threshold (mV) column. Each click of the arrow increases or decreases the 0.01 mV.
If you change the scar threshold for the activity map, all scar labels are deleted and recalculated and then applied to the map according to the new settings.

3） To place scar labels automatically, enable Auto Mark on Collection.
When this option is selected, all accepted points that fall below the unipolar or bipolar scar threshold are automatically assigned a scar label.

Note:
If you manually place a scar label that does not meet the criteria specified by the scar threshold, the scar label is removed from that point.

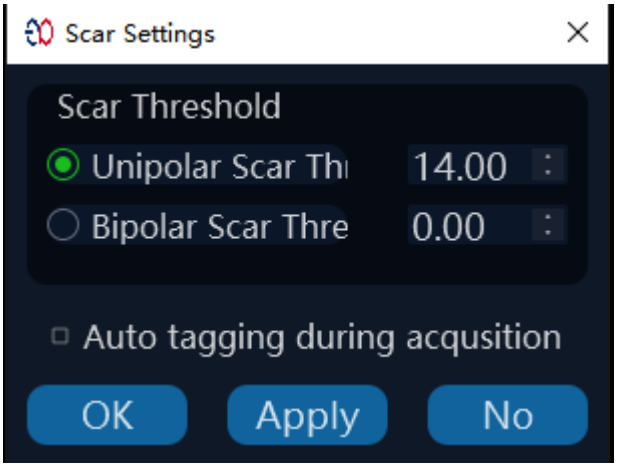


Figure 10-5 Scar Setup Dialog Box

10.5 View the early reception area

The Early Late (Early Meets Late) option can be used to find areas with reentrant loops or conduction blocks. These areas are often referred to as "morning and evening" or "end to end" areas.

To detect these areas, the system checks the difference in LAT between two adjacent points based on the range defined by the automatic color range. If the difference is greater than or equal to the criterion, a piece of the oldest and the last end-to-end area is displayed on the map and displayed in dark red (covering the normal interpolation color) (Figure 10-6 right).

By default, the Early Night option is not enabled and its threshold is 90%.

Define the early/late area in the map:

1） Click the Activation Conduction icon () on the toolbar to open the Activation Conduction Setup dialog box (Figure 10-6, left).

2） Enter any value between 70and 100 in the "Early to Night" (Threshold) field and click in the box to enable the function.

- The default setting is 90% of the color range.
- If the value is set to 100, the Early/Late area is not displayed.

10.6 Playback

The view in the map window displays the map points in which the map is displayed. Sometimes, however, you may want to review previously acquired mapping data. The Playback tool allows you to play back the creation of an activity map in its acquisition point order.

View playback function:

Click the Playback icon in the toolbar (). The Playback dialog box pops up (

). Click the desired control to review the map:

 Restart: Play the map from the point of the first acquisition.

 Backward: Play backward one point at a time.

 Play: Plays the reconstruction process of the entire map.

 Stop: Stop playing.

 Forward: Forward fast forward one point at a time.

 End: Go to the point of the last acquisition and display the entire map.

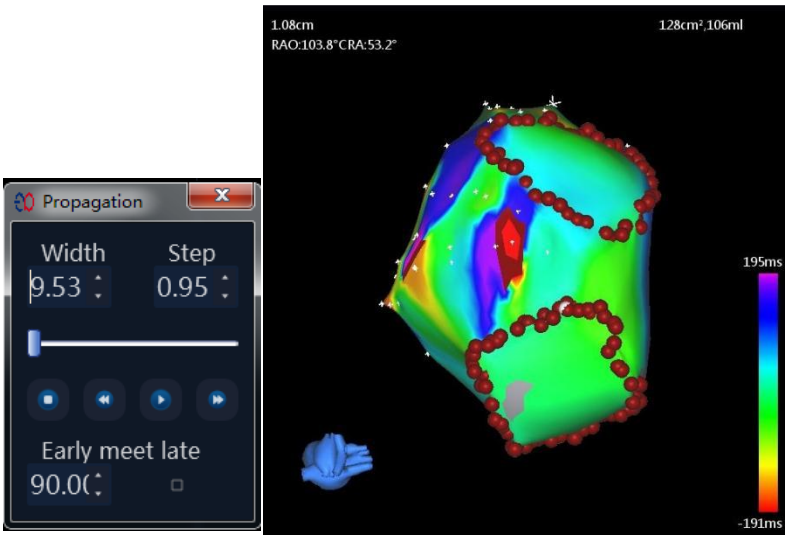


Figure 10-6 Early Reception Area
Left) Activation Conduction Setup dialog box. Right).

10.7 **Display Catheter**

Show catheter bend:

With the aid of multiple position sensors in the Magnetic Location Mapping/RFA Catheter, the Columbus™ system is able to emulate the magnetic location mapping/RFA Catheter bend in real time at the map window height. The ability to display a simulated catheter bend allows the operator to visualize the orientation and posture of the catheter within the heart chamber, significantly reducing the time to perform fluoroscopy during surgery.
The Columbus™ system always displays simulated catheter bends under default settings. You can also switch the display of the catheter bend to show only a small segment of the catheter tip by clicking Catheter Bend ( ) in the toolbar. Click Catheter Curved again ( ).

Note:
The Columbus™ system can detect whether the two position sensors (sensor) of the mapping catheter are out of the valid measurement range of the magnetic field generator (FG). Once the sensor is out of the range, the system will provide an error prompt immediately. The user can click the "Catheter Curved" function button on the "Mapping Page" to cancel the prompt and alarm information of the second position sensor, and the system status will change to "Yellow." The user cancels the prompt and alarm of the second sensor. Even if the second sensor is abnormal or out of the measurement range, the system will not give an alarm and the operation can be continued.

Warning:
If the patient moves during the procedure, but the operator fails to reset the orientation of the Columbus™ External Reference Patch, the catheter orientation displayed in the mapping window may not match the actual orientation. In this case, the operator is required to reset the orientation of

the Columbus™ External Reference Patch so that the catheter bend correctly simulates the actual magnetic mapping/ablation catheter. Therefore, the simulated catheter bend type cannot replace the doctor's personal judgment as the diagnostic basis in the actual operation.

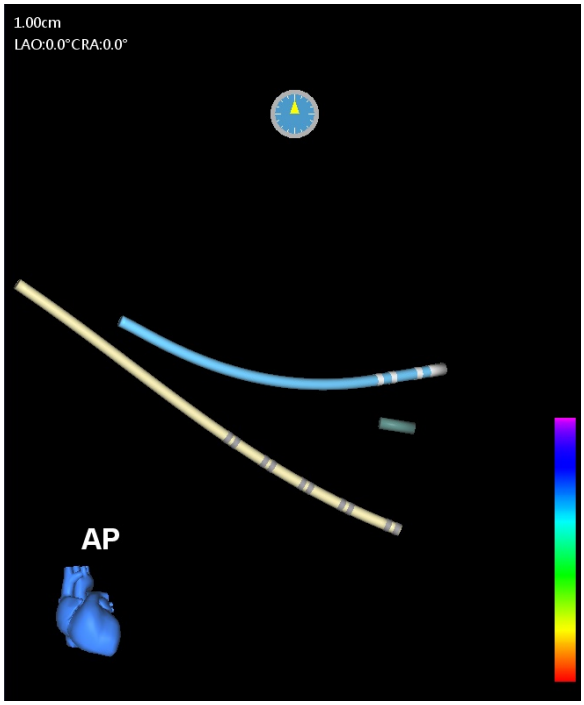


Figure 10-7 Multiple Catheter Display

The Columbus™ system can display multiple catheters simultaneously, up to three magnetic positioning catheters of different sizes.

Trigger/continuous display mode

In the default state, the Columbus™ system does not continuously display the real-time position of the catheter, but updates the position of the catheter when ECG signals that meet the detection conditions are detected, that is, updates the display catheter by triggering the marker criteria of the reference channel. You can also choose to display the catheter's real-time motion status continuously at all times.

Switch the catheter trigger display mode:

When the display mode is triggered, click the Display Mode button () in the toolbar to change the display mode of the catheter to the continuous display mode.

In continuous display mode, click the Display Mode button () in the toolbar to change the display mode of the catheter to the Trigger display mode.

Note:

If, when you select Trigger Mode, the catheter big tip does not detect an ECG signal that meets the detection criteria and the Columbus™ system continues to fail to detect a valid ECG waveform, the contents of the marker window and the catheter graphics in the map window will not be updated. In

this case, if you need to observe the real-time position of the catheter, turn off the display of the trigger mode of the catheter and turn on the continuous display mode.

Caution:
In continuous display mode, if you are moving the catheter, the current position of the catheter displayed on the screen may not match the position recorded in the system based on the heartbeat trigger. Therefore, when continuously displaying the status of the catheter, you need to freeze the node 1~2 seconds after the catheter stabilizes.

10.8 Catheter Curved Length Adjustment:

The length of the bend display can be easily set based on the original catheter full bend display function.

1） Click the "Tube bend" pull-down box and select "Adjust tube length";

2） The Catheter Length Adjustment window appears, enter the appropriate length, and click OK.

Note: This setting does not automatically recover after shutdown until it is set again.

10.9 Tip of catheter sheath

When used with a multi-channel impedance generator and connected to the OptimAblate™ generator using a communication cable, a corresponding prompt can be made on the catheter when the catheter enters and exits the sheath, and the electrode will turn black when any electrode enters the sheath (Figure 10-8).

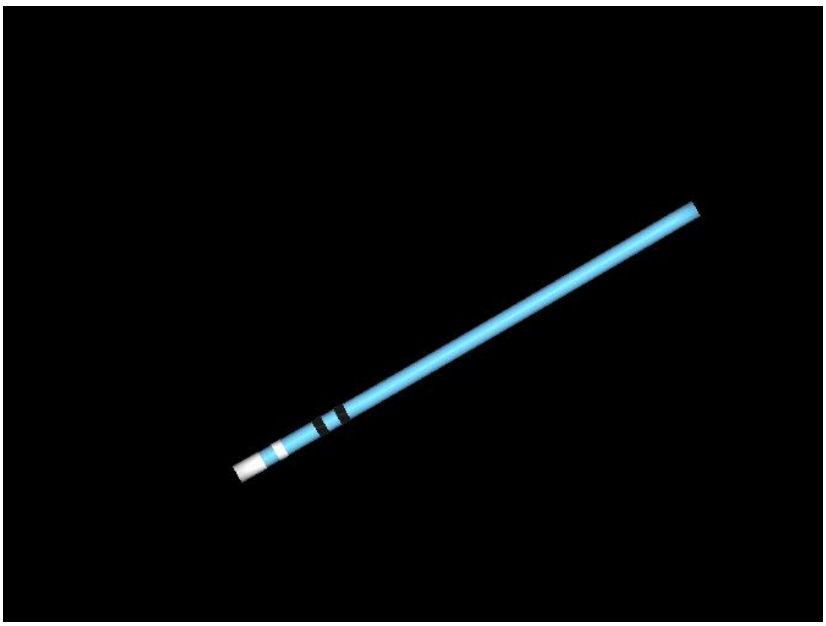


Figure 10-8 Prompt Of Catheter Sheath

10.10 Catheter bending direction prompt

When using the 6D Ablation Catheter, right-click the left mapping window to pop up a right-click menu. In the right-click menu, there is the "Display Curve Control Direction" option, which can be used to display/close the control direction respectively. Select "Display Curve Control Direction." The Catheter Tip electrode displays a prompt indicating the control direction. The red color block indicates the control direction of the catheter (Figure 10-9).

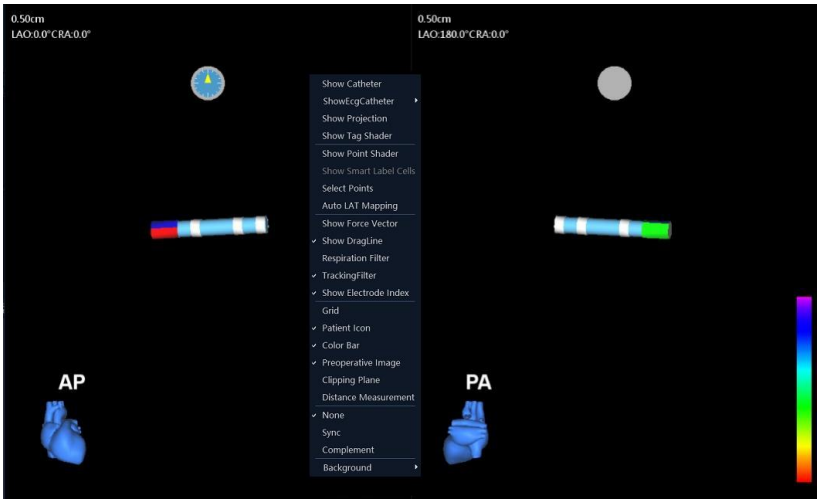


Figure 10-9 Catheter Bending Direction Prompt

10.11 Print out map and related data

You can print all the data in the map, ECG, or point list, or you can output the interested content in PNG format.

To print a map, ECG, or point list:

1） Turn on the printer.

2） Click the drop-down menu arrow next to the Print icon in the toolbar and select Print Setup from the Print menu.

3） Select the item to print in the Print Setup dialog box (Figure 10-10):

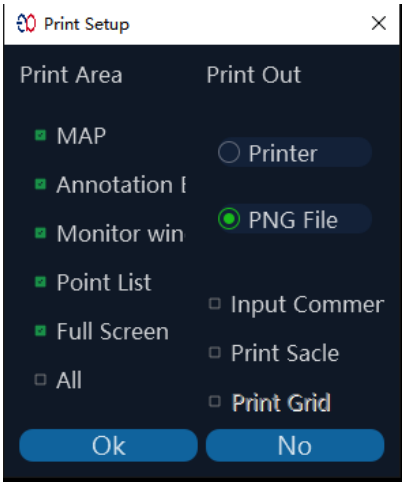


Figure 10-10 Print Setup Dialog Box

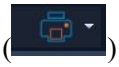
Print area:

- Map: Print the contents displayed in the map window.
- Mark window ECG: Print the selected ECG channel according to the setting of the mark window.
- Monitor window ECG: Print the selected ECG channel according to your settings on the monitor window.
- Point list: Print all data in the point list.
- Full screen: Print thumbnails of the main screen.
- All the above: Print or output all the above items.

Output to:

- Printer: Sets the output mode to print out from the printer.
- PNG file: Save the output contents in the PNG image format in the patient's database. The saved picture can be saved to the CD through data backup.

Click OK to save the print settings.

4） Click the "Print" icon () in the toolbar to output the corresponding data directly.

5） Select the "Fill in printing notes" option in the printing setting dialog box, and then a dialog box will pop up when you start "printing."

6） Select the "Print Large Grid" option in the Print Setup dialog box to print the large grid when printing ECG. The grid is not printed by default.

7） Select the "Print Small Grid" option in the print setup dialog box to print small grid when printing ECG. This option can be operated only when the "Print Large Grid" option is selected.

8） You can also select "Print Preview" in the print menu to enter the print preview window. You can view the content and form of the data to be output directly in the Print Preview window. In this case, you can also directly access the shortcut icon above the print preview window to print or output directly.

10.12 Create video recordings and screenshots

You can create a screenshot of all or part of the content displayed on the 3D map page as a video clip (AVI format) or PNG format when needed. You can create a screenshot or video at any time by clicking the screenshot or video icon on the toolbar. After you have created the required screenshots or recordings, you can copy them to a CD.

Create a screenshot:

1. Click the screenshot () icon in the 3D map page toolbar.
2. Follow the prompts to select the area to be screened:

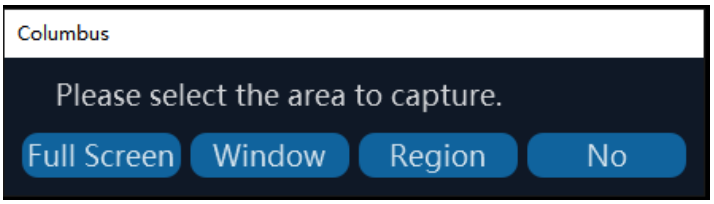


Figure 10-11 Select Screenshot Area

   a. Select Full Screen to automatically capture the full image of the current screen.
   b. By selecting Window, you can select any window in the 3D map page for screenshot. Depending on the point of your mouse operation, the perimeter of the target window is highlighted with a highlighted border. Click the left mouse button again to save the screenshot in the window.
   c. By selecting Area, you can use the left-click and drag mouse button to select any custom rectangular area range in the screen and save the screenshot (Figure 10-12).

Note: Prompt for file name before saving screenshot file.

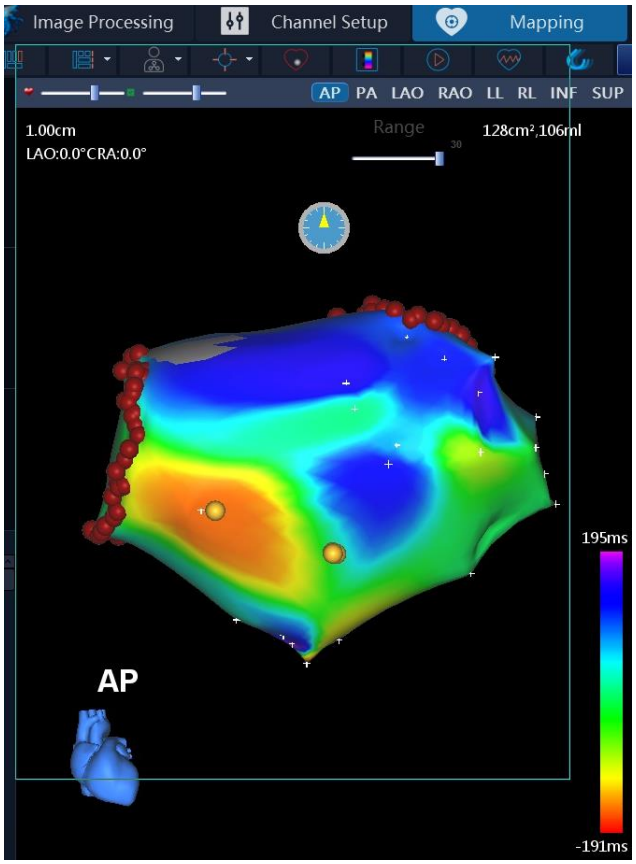


Figure 10-12 Select Custom Screen Capture Area

Create a video recording:

1. Click the Video ( ) icon in the 3D Mapping page toolbar. The system records the whole 3D mapping page in full screen by default.
2. The status of the recording icon changes ( ), indicating that the system is recording. Click the icon again to end the screen recording and restore the recording icon to the default state ( ).

Note: The video file needs to be named and saved. Whether to continue will be prompted for 30 minutes. If so, the new file will be created and saved.

Copy the screenshot and video to a CD:

You can find the saved screenshots and videos in the medical record management window. All multimedia files are stored in the corresponding patient record files. You can back up the required screenshots and videos to a CD via the CD Backup feature. Please refer to Chapter 12: Medical Record Management.

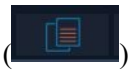
10.13 Use System Template

You can save many system settings in a custom template. Creating your own template makes it easy

to perform procedures with the same markings and channel settings, and you can save your personal preference for the layout displayed on the screen in the template.

Create a custom template:

1） A series of settings for a particular type of study, including various parameter settings for the channel, display layout, and custom options and function settings.

2） Click the Template Management () button in the toolbar of the 3D map page to display the System Template Management dialog box (Figure 10-13).

3） Enter the name of the template in the Template Name field and click the Save button.
If you click an existing template, the changes are saved and the template is overwritten.

4） The template is saved and appears in the list of loadable templates every time a new operation is created.

Note:
You cannot modify the default template or create a new template named Default.

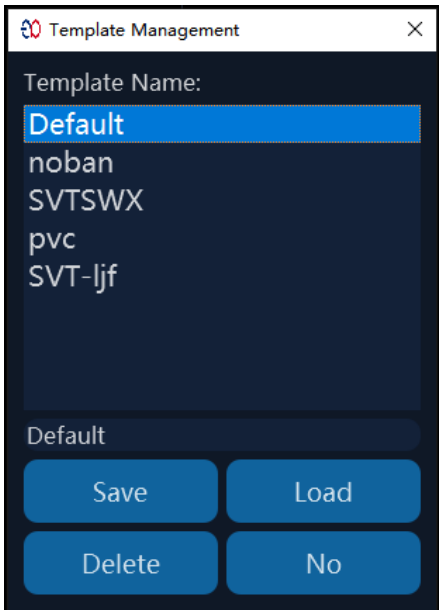


Figure 10-13 System Template Management Dialog Box

10.14 Respiratory compensation

When the catheter displays motion with a significant respiratory rate during the procedure, you can choose to turn on respiratory compensation.

Open Respiration Compensation Method:

1） Open the right-click menu of the map window and select Respiration Compensation.

2） Click the Show Respiration Curve () function button to open the Respiration Curve window (Figure 10-14).

- Upper left corner: Display the position of the respiratory detection channel and detection electrode. The default respiratory detection channel is LS (LS, Chest, Back and CS can be selected for the respiratory detection channel).
- Upper right corner: It is prompted whether to reset the threshold.
- Middle position: Displays the respiration curve.
- Right: End-phase threshold adjustment slider, used to adjust the end-phase threshold

Note: This function can only be set in the left map window.

Figure 10-14 Respiration Curve

Switch the respiratory detection channel:

1） Click the border of the dialog box to select the Respiration Curve dialog box;

2） Click the "B" button on the keyboard to switch the respiratory detection channel, and switch the respiratory detection channel to Chest.

3） Click the "B" button on the keyboard again, and switch the respiratory detection channel to Back.

4） Click the "B" button on the keyboard again, and switch the respiration detection channel to CS.

Note:

- Switch the respiratory detection channels to LS, Ches, Back, and CS in sequence, which can be cycled.
- The shortcut B does not take effect when the mouse is clicked on a position outside the border of the Respiration Curve dialog box.

End phase modeling:

1） Open the right-click menu in the left map window and select Resp Compensation.

2） Open the right-click menu again in the left map window and select Resp Gating.

Note: The catheter can be modeled only when it is in the end phase of respiration, and no model is created at other times.

10.15 Pressure Catheter Display

The Columbus™ 3D EP Navigation System is compatible with ablation catheters with pressure sensors, and can display pressure values, pressure curves, and force vectors in real time on the interface.

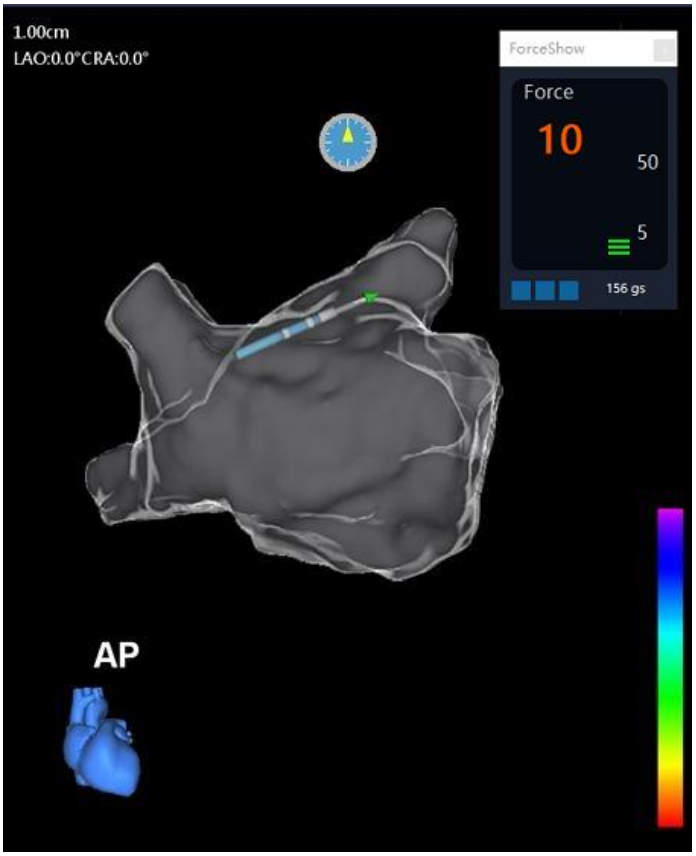


Figure 10-15 Pressure Ablation Catheter And Force Vector Display

Click the button  on the toolbar of the mapping page to pop up the pressure value display window (as shown in Figure 10-16). Click the pull-down arrow next to the button to pop up the pull-down menu as shown in Figure 10-17, including five options: Display pressure curve, display RF parameters, display multi-channel temperature, display pressure statistics value and display multi-channel temperature statistics. Select "Display Pressure Curve" to pop up the pressure curve dialog box as shown in Figure 10-18. The window displays the change curve of pressure value in real time; Select Show RF Parameters to open the RF Parameters dialog box. Select "Display multi-channel temperature" to pop up the multi-channel temperature parameter dialog box; Select "Display Pressure Statistical Value" to pop up the statistics result of pressure data in the whole operation process, as shown in Figure 10-19, including the ratio of average FTI value, average force value and 5-40 g force value; Select Show Multiplex Temperature Statistics Five Options to pop up the statistical results of the multiplex temperature data throughout the procedure as shown in Figure 10-20.

Figure 10-16 Pressure Value Display Window

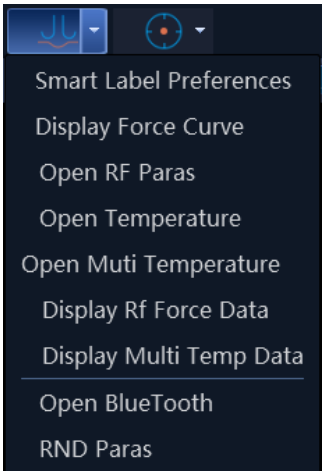


Figure 10-17 Pressure Button Pull-Down Menu

Figure 10-18 Pressure Curve Display

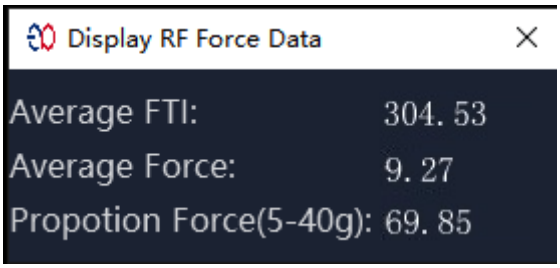
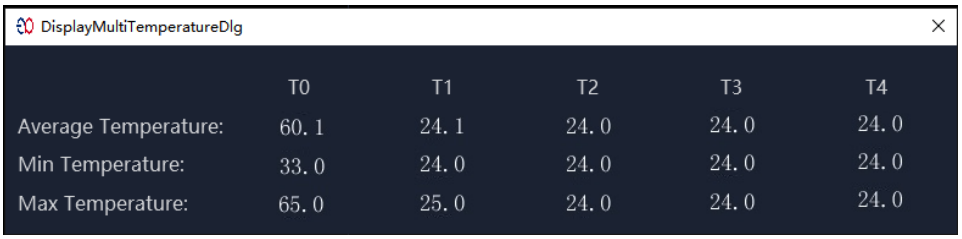


Figure 10-19 Pressure Data Statistics



	T0	T1	T2	T3	T4
Average Temperature:	60. 1	24. 1	24. 0	24. 0	24. 0
Min Temperature:	33. 0	24. 0	24. 0	24. 0	24. 0
Max Temperature:	65. 0	25. 0	24. 0	24. 0	24. 0

Figure 10-20 Multichannel Temperature Data Statistics

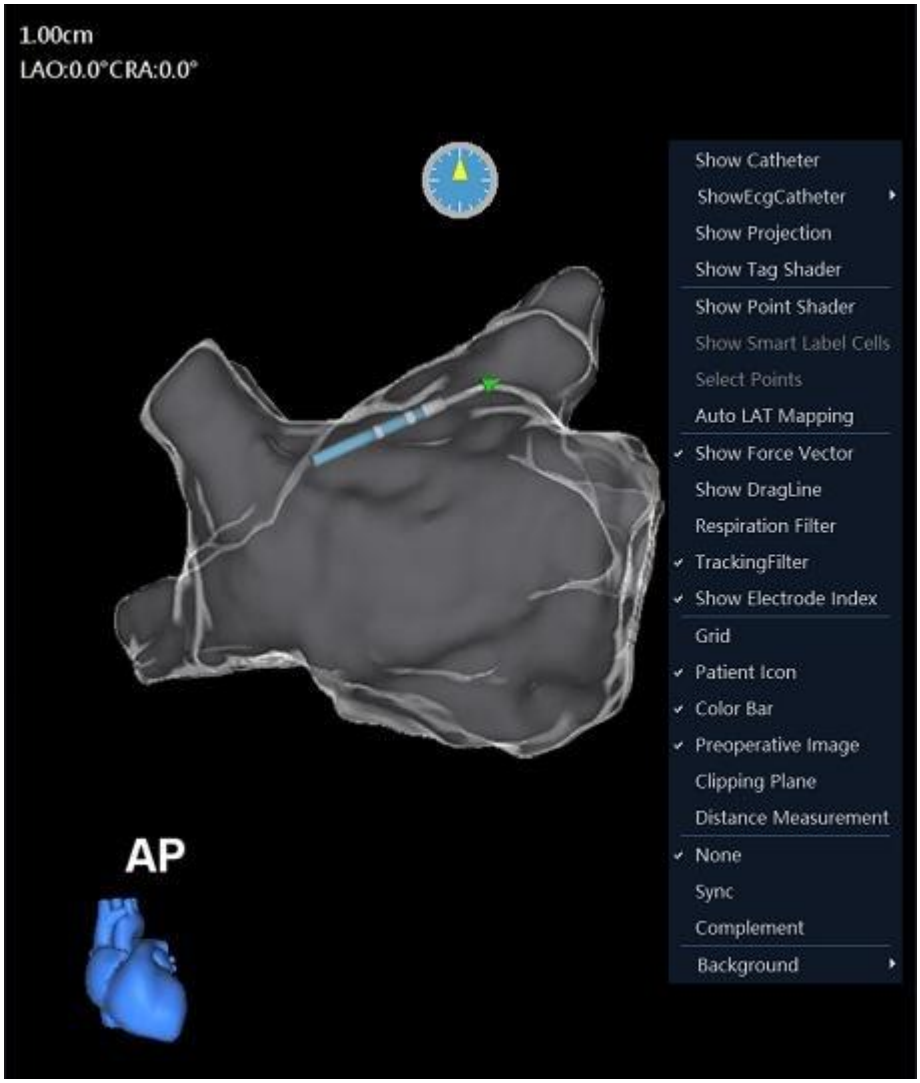


Figure 10-21 Mapping Window Right-Click Menu

Right-click the left map window to pop up a right-click menu. There is a "Show Force Vector" option in the right-click menu, which can be used to display/close force vectors respectively (Figure 10-21).

There are buttons below the Pressure Curve Display dialog box, including Zero and Set. Click the "Clear" button to clear the current data and start data collection again; Click Setup to open the Pressure Parameter Setup dialog box, where you can set pressure-related parameters, including maximum and minimum pressure thresholds, elastomer temperature source, integration time, display interval, and other reset conditions. Figure 10-22 shows the Pressure Parameter Setup dialog box.

Figure 10-22 Pressure Parameter Setting

10.16 Mapping Catheter Display

When the magnetic field generator, LPU, and PIU are connected normally and can work, the tail line of each catheter electrode on the connection EPU and PIU, and the network switch communication is normal, the Columbus™ 3D EP Navigation System can display the head end of the loop lung mapping catheter, the curved shape of the deflectable ten-pole mapping catheter and the high-density mapping catheter in real time.

Connect the magnetic positioning loop lung mapping catheter to the LS jack on the PIU side panel, and then click the button  on the toolbar of the mapping page. When the button is

displayed as  , it indicates that the electrical positioning function is enabled. If the button is clicked again, the electrical positioning function is disabled.

When the electrical positioning function is turned on, the mapping window displays the entire loop lung mapping catheter normally, and the corresponding electrode number is displayed next to each electrode.

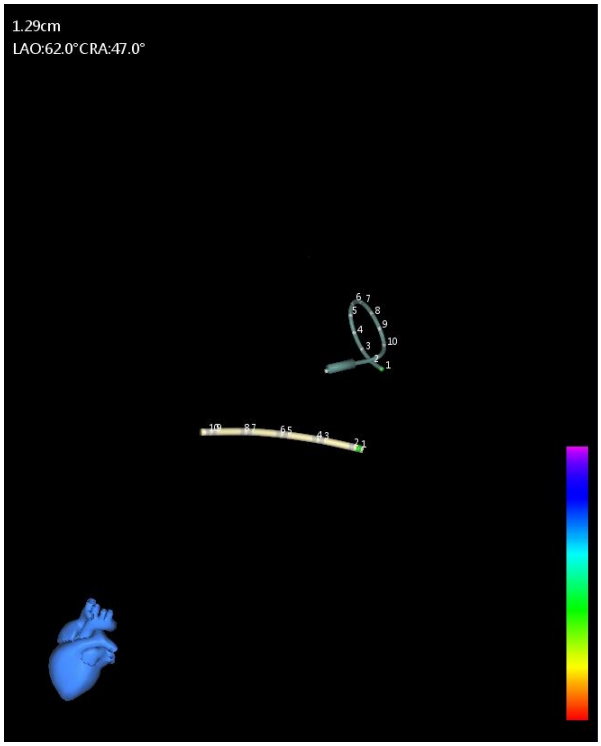


Figure 10-23 Mapping Window Shows Magnetically Located Ring Lung Mapping Catheters And Ten Pole Mapping Catheters

10.17 **Mapping Catheter Review Display**

The shadow of the catheter can be associated with intracardiac signals to review the entire procedure.

Open the right-click menu of the map window to select the reviewed catheters respectively (Figure 10-24).

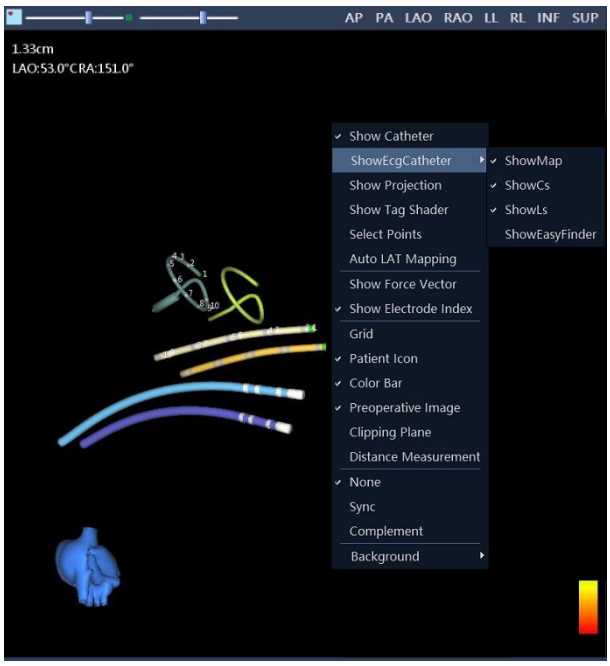


Figure 10-24 Catheter Review Display

10.18 **Mapping Catheter Electrode Highlight**

Click any channel signal in the real-time signal window/mark window/multichannel window (select L4-5 channel in the figure), and the corresponding electrode is displayed in red (Figure 10-25).

Note:
The 10-pole channel must be R1-R2, R3-R4, R5-R6, R7-R8, R9-R10 (five channels in total);
The circulatory channels must be R17-R18, R18-R19, R19-R20……R25-R26 (nine in total).

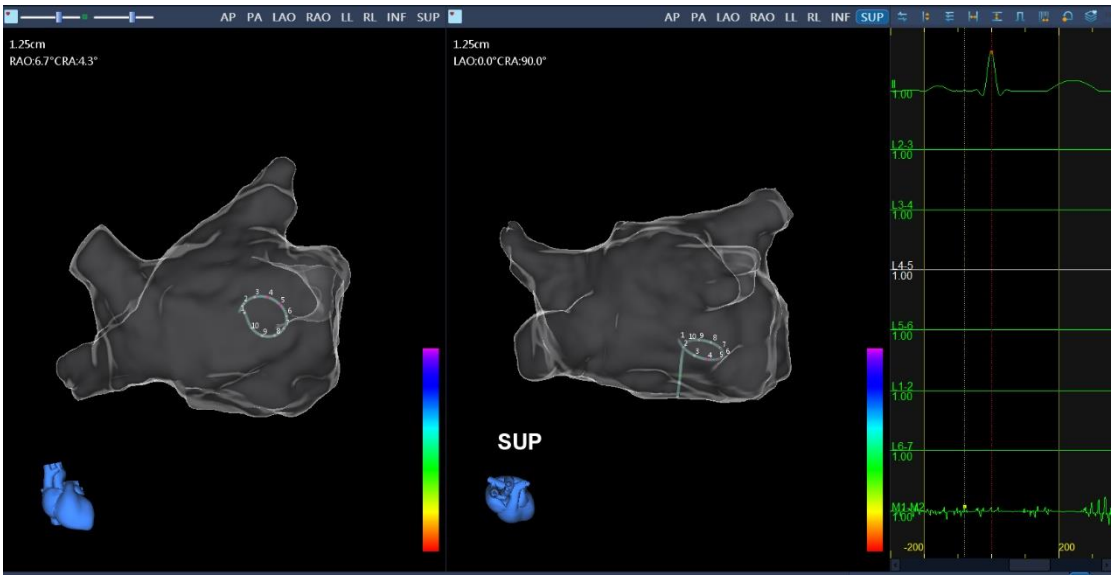


Figure 10-25 Mapping Catheter Electrode Highlight

10.19 High Density Mapping Catheter Display

Connect the high-density mapping catheter to the LS jack on the PIU side panel to ensure that the first Sensor information is normal, and then click the Electric Positioning On button  to change it to  . The high-density mapping catheter can be displayed normally in the mapping window, and the corresponding number of each electrode is displayed near each electrode (Figure 10-26).

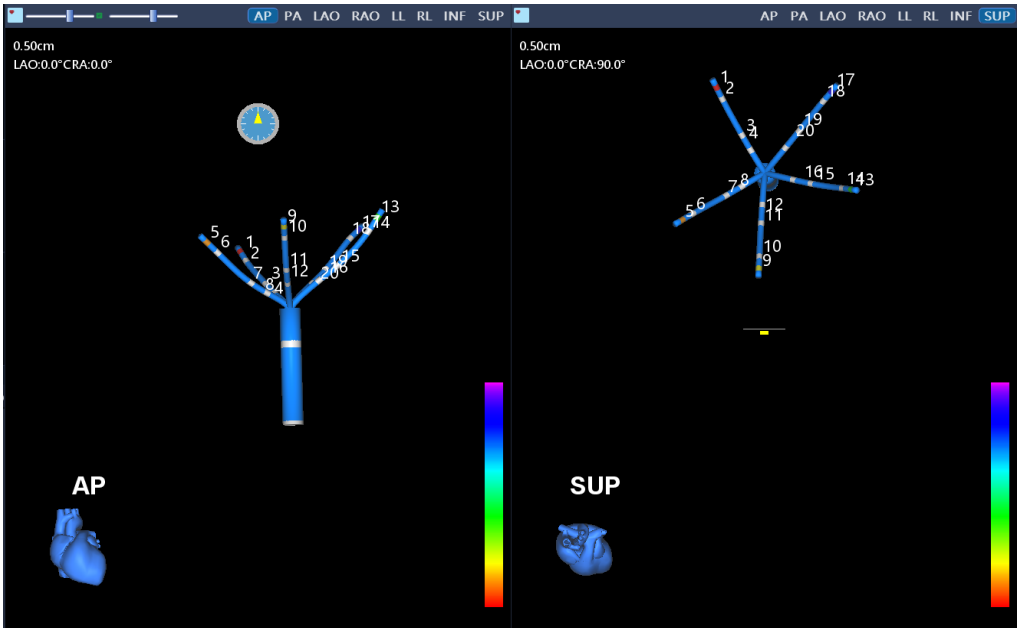


Figure 10-26 Mapping Window Showing High Density Mapping Catheters

Note:

- When HD-M is selected in the Stability Status column, a three-dimensional cardiac chamber model can be constructed in real time using a loop lung mapping catheter or a high density mapping catheter (Figure 10-27, Figure 10-28).

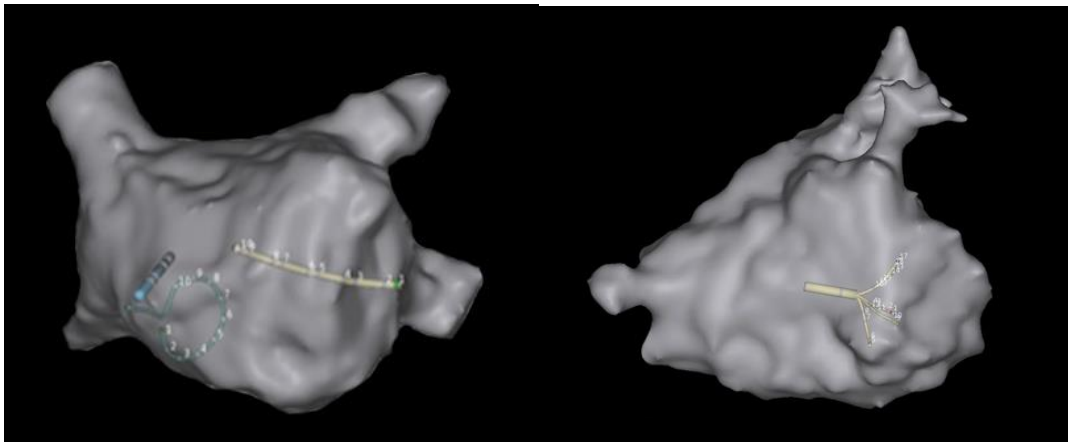


Figure 10-27 Circular Lung Mapping Catheter Modeling Figure 10-28 Density Mapping Catheter Modeling

10.20 **Multi-electrode simultaneous mapping**

Simultaneous mapping of multiple electrodes of the Cyclic Lung/High Density Mapping Catheter.

1） Set the signal channel:
Set the corresponding signal channel according to the mapping catheter to be used.

2） Select Display Cyclic Lung/High Density Mapping Catheter, enable electrical positioning, and display the Cyclic Lung/High Density Mapping Catheter.

3） Press the F11 key
If the ablation catheter is selected, 1 Normal point is collected;
If the loop lung mapping catheter is selected, 9 Normal points are collected.
If a high density mapping catheter was selected, ten normal points were collected (Figure 10-29).

Note:

1） Enter Point
If the ablation catheter is selected, one LocationOnly point is collected;
If the loop lung mapping catheter is selected, 9 Normal points are collected.
If a high-density mapping catheter is selected, collect 10 Normal points;

2） The F11 acquisition map point mode can be rejected, and the Enter key acquisition map point mode can only be accepted.

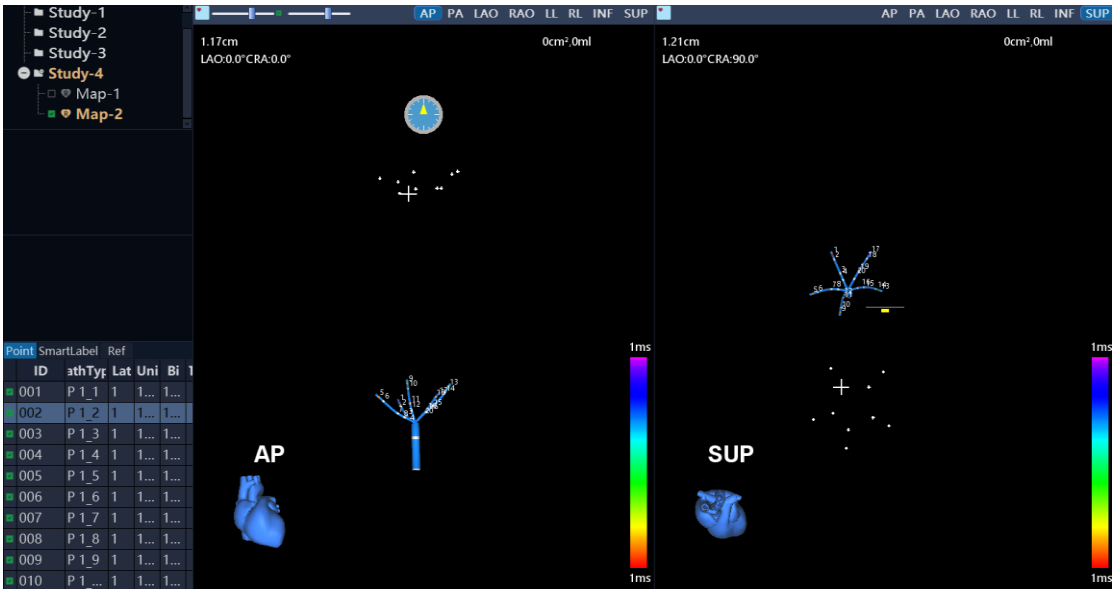


Figure 10-29 High-Density Mapping

10.21 RF parameter display

When the communication cable is connected to the OptimAblate™ generator, you can manually open the RF parameter box to display the RF parameters. If the window is not open, it will automatically pop up when the ablation is initiated (Figure 10-30).

Note: If the communication cable is not connected to the OptimAblate™ generator, the RF parameter box will not pop up automatically when the ablation is started. No data update even when manually opened.

Figure 10-30 RF Parameter Window

10.22 Multi-channel temperature display

When used with a multi-channel temperature generator, you can manually open the multi-channel temperature parameter box to display the multi-channel temperature parameters after connecting to the OptimAblate™ generator using a communication cable (Figure 10-31).

Note:
When discharge is not started, the multi-channel temperature is displayed in white. When the

discharge is started, the maximum value in the multi-channel temperature is displayed in bold green when it does not exceed 55 ° C, and in bold red when it exceeds 55 ° C.

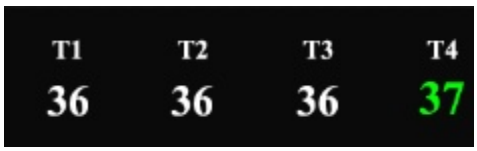


Figure 10-31 Multi-Channel Temperature Parameter Window

10.23 **Pointwise ring opening**

Setting the anatomical label helps to mark the valve, vascular anatomical annulus (Figure 10-32).

1） Press the <Ctrl> key while selecting three mapping points on the map that can include the annulus area to be set. At this point, the map point used to define the annulus opening appears blue.

2） Once 3 map points are assigned to define the annulus opening, the system automatically generates the annulus opening on the map.

3） Right-click the annulus opening and a shortcut menu appears. You can choose to change the color of the annulus opening, or remove unwanted annulus openings.

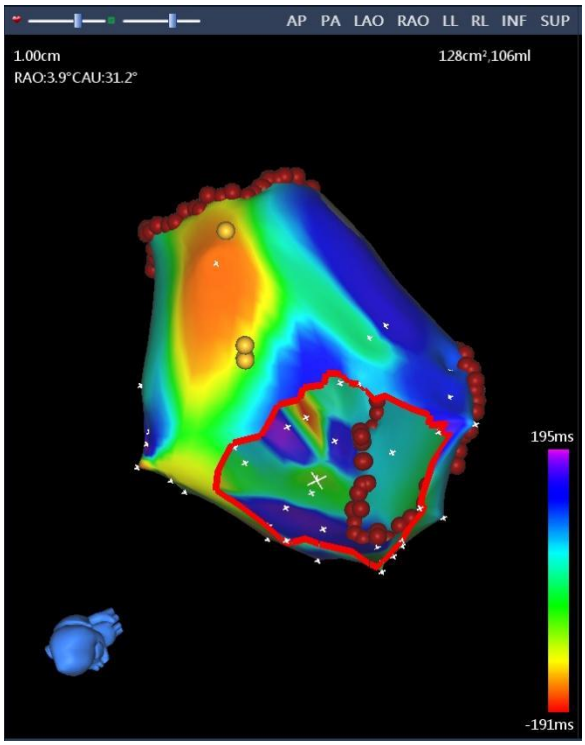


Figure 10-32 Annulus Opening

10.24 **RTM Annulus Opening**

RTM Annulus Opening Method 1:

1） Initial state: Build the model.

2） Hold down the Ctrl key while using the mouse to click the position on the model where you want to open the annulus. The clicked position will generate an annulus point with the label LO and type Floating.

3） Press and hold the point with the left mouse button and adjust the annulus size through the "plus" and "minus" on the keypad (Figure 10-33).

"+" means to increase the annular radius, but the radius has a maximum value and cannot be increased infinitely.

"-" to reduce annulus radius, minimum not to show annulus.

The annulus is created by a transparent sphere with this point as the center.

Note:

- The generated annulus point is the same as the normal sampling point principle, so it must be in the sampling point state. When it is in the editing state (i.e. the yellow "Continue" button in the lower right corner), the annulus point cannot be generated.
- Annulus points cannot be generated in a transparent, grid state, but the generated annulus points can adjust the annulus.
- Deleting the annulus point will also delete the annulus, and restoring the annulus point from the recycle bin will also restore the annulus; However, hiding the annulus point has no effect on the annulus.
- This annulus generation mode is not disabled in the point-by-point diagram, but it is not recommended to use it. If the display is abnormal due to a small probability, the point-by-point diagram still recommends opening the annulus according to the original method. If it does need to be used, delete the point when it is found that the display is abnormal.
- The annulus point can be saved, but the opened annulus cannot be saved. After exiting the operation and re-entering, all annuli need to be re-adjusted with +/-. There was no effect of switching Map with the procedure.
- Opening the annulus does not guarantee that the point seen from the annulus can be selected, and whether you want to select the point inside the model depends on the point projection or on the point list.
- Opening the annulus makes the label projection within the annulus invisible, but does not affect the display of the point projection.
- Do not generate the annulus point again in the opened annulus or in the tangential plane, it is possible to generate the wrong annulus point (generate to the opposite of the model, overlap with the annulus point of the annulus, etc.).
- +/- can be used to adjust the annulus at any time (normal, transparent, grid, tangent plane, historical surgery, etc.), regardless of whether a new annulus point can be generated.
- All points labeled as LOs, or points with multiple labels containing LOs, can be annulus-opened as annulus points, regardless of their normal, Floating, Location Only, Scar; At this time, the projection of the point on the model is the center of the annulus. Holding the point projection of this point with the left key is also effective when adjusting the annulus with this point.

Note: The LAT value of the annulus point generated in this way has no meaning. It is forbidden to

set the point type to Normal.

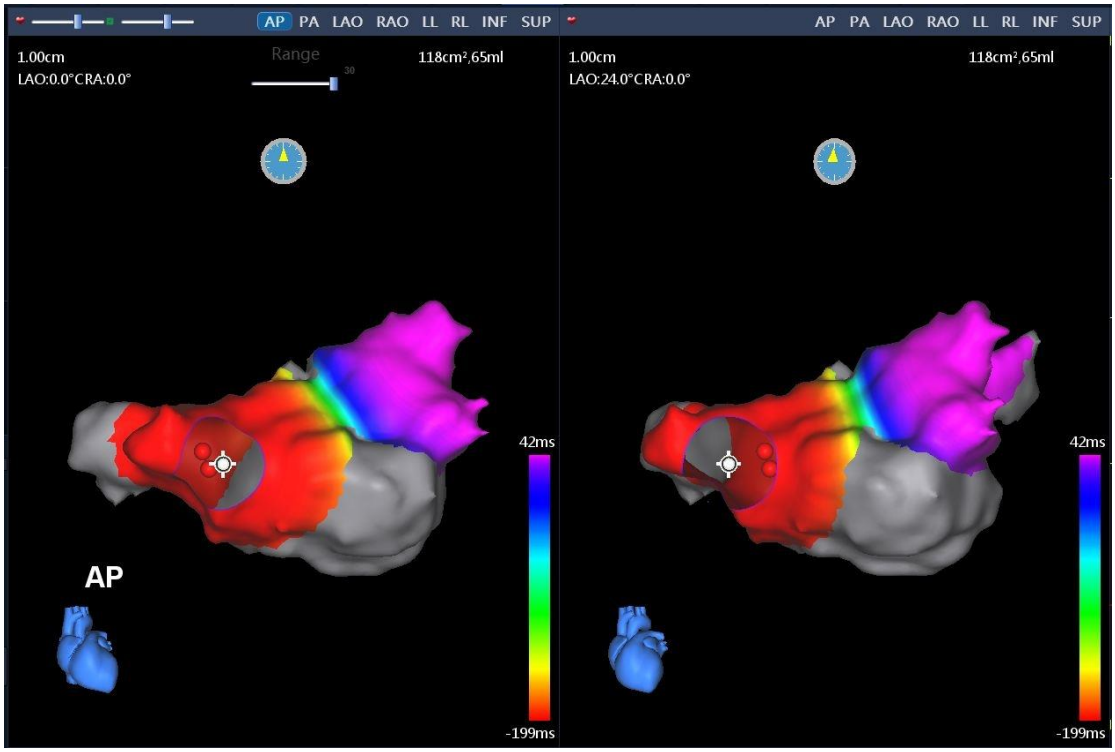


Figure 10-33 RTM. Annular Opening

RTM Annulus Opening Method II:

Create multiple anchor mode open annulus.

1） Initial state: Build the model;
2） Select the map in the left map window, open the right-click menu, and click Open Annulus to display the Setup Annulus dialog box.
3） Press Ctrl and the left mouse button at the same time, and collect 3-8 anchor points on the model to form an annular surface.
4） Click Apply to determine the number of anchor points. Click OK to open the annulus. (If annular adjustment is not necessary, click "OK" directly to open the annulus, and the shape of the annulus cannot be adjusted directly after opening the annulus) (Figure 10-34).
5） Select the anchor point to open the right-click menu, and select Delete to delete the annulus.

Note:

- Only the right-click menu of the left map can be opened.
- 3-8 anchor points must be created to open the annulus;
- A maximum of 8 anchor points can be created in one annulus.
- Up to 8 annulus can be created in one MAP;
- Open the setup annulus window shortcut key: "Ctrl+A";
- The shape of the annulus cannot be adjusted directly after the annulus has been opened. The annulus shape can be adjusted only after the annulus surface is displayed.

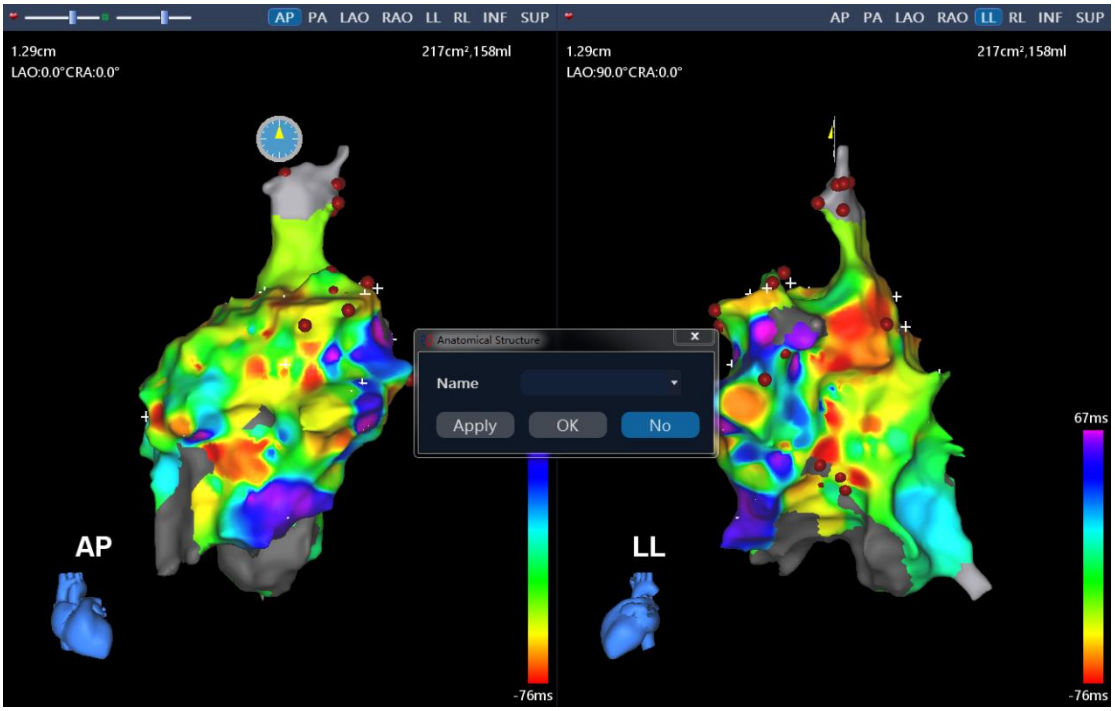


Figure 10-34 RTM. Annular Opening

10.25 **Line drawing**

Used to draw arbitrary lines on the model surface as markers, ablation path planning, etc.

Line drawing method:

1） Select the map in the left map window, open the right-click menu, and select "line drawing." The mouse changes to a cross cursor.

2） Hold down the left mouse button and move the mouse. The default color of the line is white and the default width is 3.

3） Select a line and click the right mouse button to pop up a right-click menu, where you can edit the color, width or delete the line (Figure 10-35).

Note:

- Only the right-click menu of the left map can be opened.
- Lines can only be drawn on the left map and displayed on the left and right maps.
- Lines can only be edited on the left map.
- When the end of the line is less than 5 mm, a closed loop is automatically formed.
- When the start end of the second line and the end end of the first line are less than 5 mm, a line is automatically synthesized and broken;
- When multiple maps are displayed at the same time, only the lines on the active map are displayed.

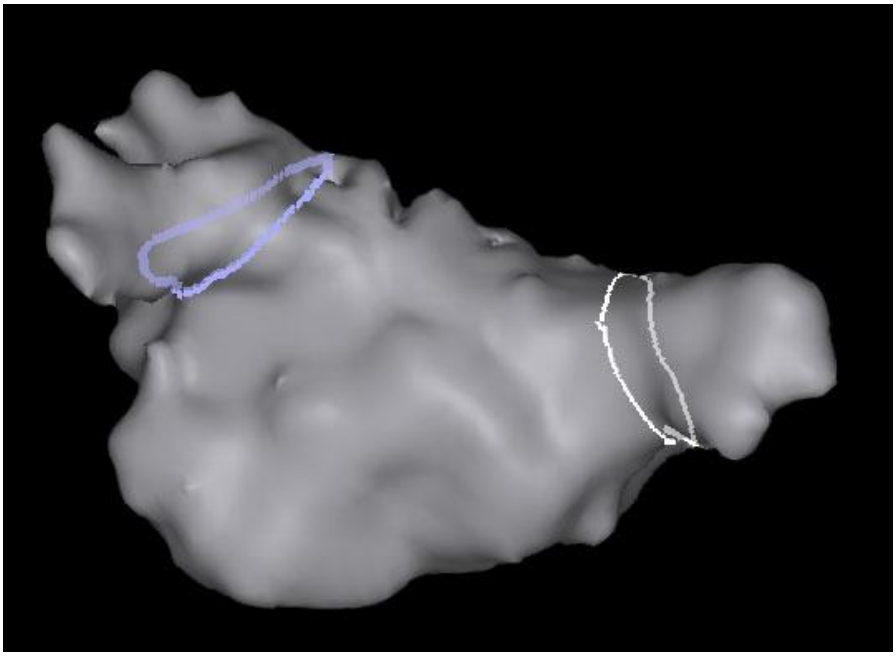


Figure 10-35 Line Drawing

10.26 III Reference

The magnetic positioning reference electrode is changed from single reference mode to three reference mode, which improves the stability of the positioning reference point and realizes more stable catheter navigation.

Three-reference combination mode

Click the "Recalibrate Reference Pole Orientation" drop-down menu and select three reference combination modes. There are four three reference combination modes for selection (Figure 10-36):

- PIU mode: The method of connecting the reference electrodes with the side holes of the PIU. Three reference electrodes are required.
- EPU mode: Use the two positioning magnetic poles (green and blue) of the EPU and the reference electrode.
- One-to-two mode (CS): Use a two-to-two tail line to connect to the CS hole on the side of the PIU and connect 2 positioning magnetic poles. The 2 positioning magnetic poles and the reference electrode are used as the combination reference.
- One-to-two mode (LS): Use one-to-two tail line to connect to the LS hole on the side of PIU and connect 2 positioning magnetic poles, 2 positioning magnetic poles and reference electrode as combined reference.

Note:

After setting the reference mode, you must click the Recalibrate Reference Pole Orientation  button. Reference shifts and re-modeling also require clicking. The system will automatically recalibrate when you create a new Study.

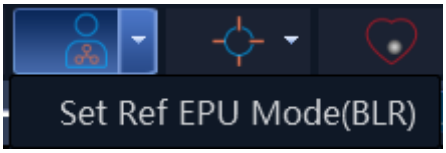


Figure 10-36 Three Reference Combinations

Three-reference display

When three reference combinations are selected, all three references are displayed in the Reference Status bar (Figure 10-37).

Figure 10-37 Third Reference Display

III Reference alarm prompt

Error prompt when reference is lost/shifted.

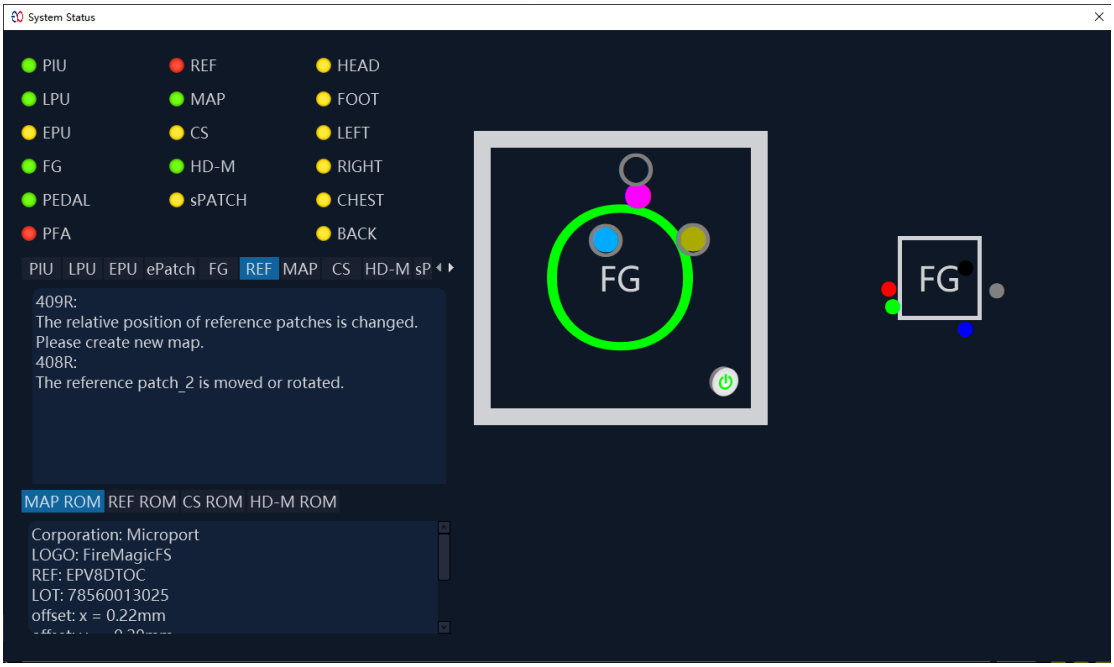


Figure 10-38 Reference Alarm Prompt III

10.27 **Tangent plane**

To view clear images inside the map, you can turn on the tangent plane function of the Columbus™ system. By default, the tangent plane is parallel to the view of the map window and shows the portion of the map on the side of the tangent plane.

Open or close the tangent plane:
Right-click on the background of the mapping window, select Tangent Plane from the shortcut menu, and the mouse changes to an icon with small scissors ( ).

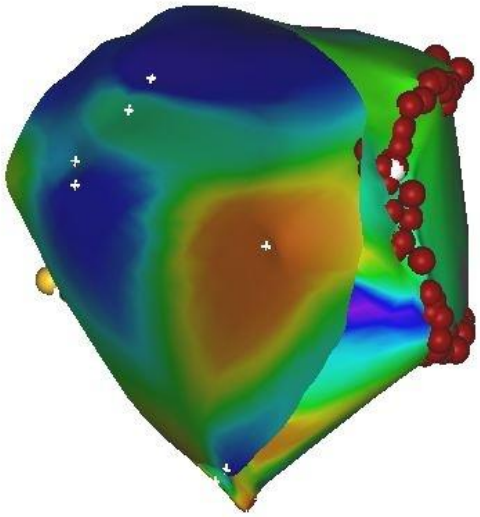
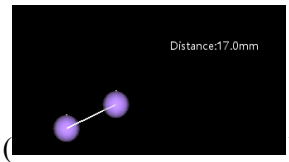


FIG. 10-39 Tangential Plane

10.28 Distance measurement

You can perform distance measurements on a Cardiac Map (or CT Segmented Image) to obtain the distance between any two points on the Cardiac Map (or CT Segmented Image).

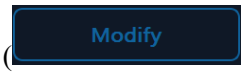
Turn distance measurement on or off:
Right-click the background of the mapping window, select the "Distance Measurement" option in the shortcut menu, the mouse changes to ( ), click any point on the mapping map (or segmented image) to draw a purple ball, click another point to draw a purple ball, draw a white line between two purple balls, and display the distance measurement result (

) (unit: mm). Right-click the mouse and select the distance measurement option again to exit the function. The mouse changes to the arrow.

Note: The distance measurement function is disabled when the map is a grid map or the registration view is displayed after registration. When distance measurement is selected, the tangent plane is disabled. Distance measurement is disabled when the tangent plane is selected.

10.29 Edit patient and surgical data

Edit Patient Data:

1） You can switch to the Patient Information Login page and click the "Modify Patient Record" (

) button to display the Patient Information Modify dialog box (Figure 10-40).

2） Enter what you want to change in the Last Name, First Name, Patient ID, Date of Birth fields, then click Modify to save the changes and close the dialog box.

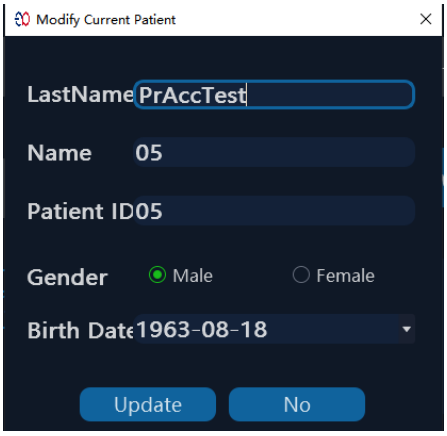


Figure 10-40 Modify Patient Information Dialog Box

Edit Surgical Information:
You can switch to the Patient Information landing page where you can view and modify information about the current procedure at any time while the procedure is in progress and while the historical medical history is being played back.

10.30 Rename Surgery and Map

From the shortcut menu of the procedure list, you can rename the procedure and map:

1） In the 3D mapping procedure list, select and right-click the map or procedure to be renamed, and the rename appears.

2） Click "Rename" in the shortcut menu, and the selected item name will change to the input state requiring renaming.

3） Enter the new name, confirm and save.

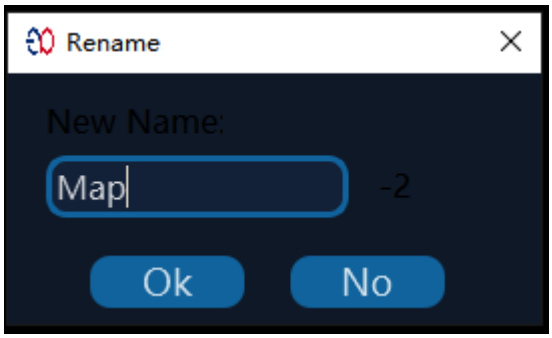


Figure 10-41 Rename Dialog Box

10.31 Dominant frequency analysis

Click the pull-down arrow () on the right of the Columbus™ system icon in the upper right corner of the screen, and select "Primary Frequency Analysis" in the pull-down menu

to enter the primary frequency analysis window (Figure 10-42).

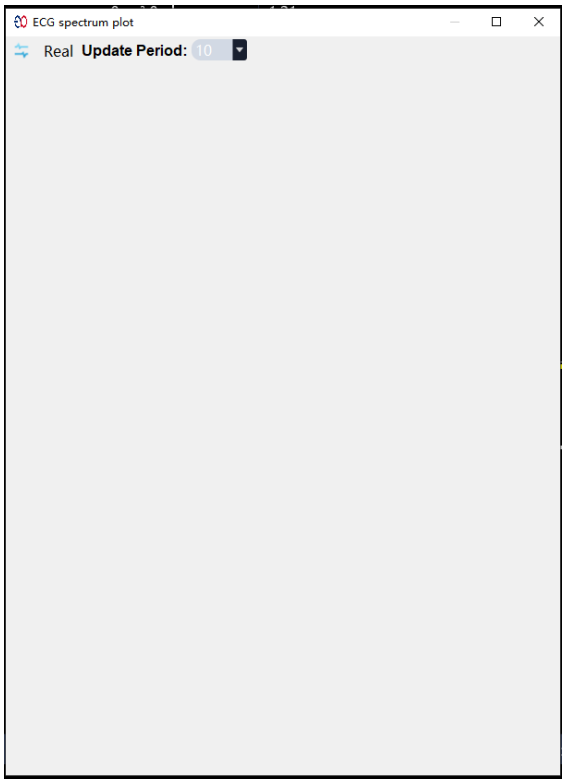


Figure 10-42 Primary Frequency Analysis Window

The main frequency analysis window toolbar provides the following options (Figure 10-43):

Setup ( ): Opens the Show/Hide Channels dialog box to add or remove channels within the Primary Frequency Analysis window.

Real-time: Display the dominant frequency analysis in real time.

Update Interval: The interval displayed for updating the dominant frequency analysis. The default is 10 s.

10-43 Main frequency analysis window toolbar

Add or delete channels in the frequency analysis window:

1） Click the Setup ( ) button and the Show Channels setup dialog box appears.

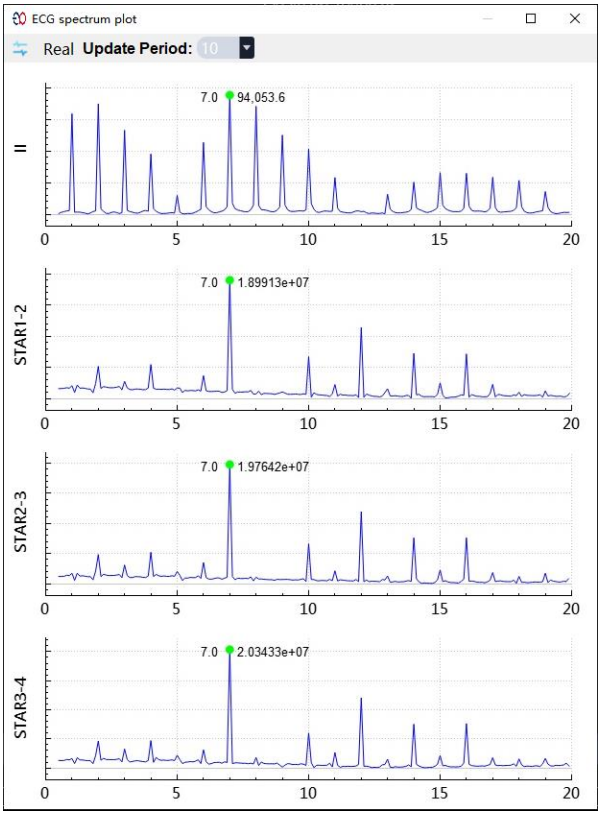
2） Select the channel to display in the Display check box. Changes will take effect immediately.

Real-time display of dominant frequency analysis:

1）Select the channel to be displayed in the Display Channel setting dialog box.

2）Click the Update Interval drop-down box to change the update interval. The default is 10 s.

3) Click Real Time to display the dominant frequency analysis in real time (Figure 10-44).



10-44 Dominant frequency analysis

10.32 **Help**

You can set and activate the default printer and display by clicking on the drop-down arrow () to the right of the Columbus™ system icon in the upper right corner of the screen to select Help.

10.33 **About**

Select About to display software version and copyright information by clicking the drop-down arrow () to the right of the Columbus™ system icon in the upper right corner of the screen.

Chapter 11 Multi-channel Recording Window

The Columbus system can connect up to four displays to display multiple recording windows. This window allows you to view all ECG information from this procedure. The multi-channel recording function can be used separately from the magnetic positioning system to display ECG signals collected by any electrophysiological catheter.

12.1 Viewing Multichannel Record Data

If your Columbus system is equipped with four displays, the multichannel recording window will automatically appear in that display. You can view the waveform data of all ECG channels at any time in this procedure by adjusting the slider at the bottom of the window.

If your system is not equipped with this display, you can open a floating multi-channel recording window by clicking the () icon in the upper right corner of the 3D mapping page. You can adjust the size of the floating window or close it at any time.

Note: The data in the multi-channel record window is saved with the surgical medical record. You can back up the .ecg files under media study from the Medical Records Management page.

12.2 Multiple Record Window Options

By default, the multi-channel recording window is divided into the left and right columns. The left half is a real-time window that displays real-time ECG signals. The right half is a frozen window that displays frozen ECG signals. In the frozen window, the ECG data of historical surgery can be reviewed (Figure 11-1).

Figure 11-1 Multi-Channel Recording Window

The Multitrack Live Window toolbar provides the following options (Figure 11-2):

Setup ( ): Opens the Show/Hide Channels dialog box, enabling you to add or delete channels in the Multichannel Recording Real-Time window.

Average score ( ): Without changing the scale of each display channel, the multi-channel recording real-time window displays all channels uniformly.

Gain ( ): When enabled, the channels used in the multi-channel recording real-time window are set to the same gain as the last channel displayed in the window.

Calibration ( ): Enable/disable the display of the voltage scale icon.

Time measurement ( ): When this option is enabled, the waveform time length in the multi-channel recording window can be measured (when freezing is clicked, this function is available).

Voltage measurement ( ): When enabled, the waveform voltage amplitude in the multi-channel recording window can be measured (click Freeze, this function is available).

Print ( ): Click this icon to directly output and print the data in the multi-channel recording window (click Freeze, this function is available).

Print to picture ( ): Click this icon to directly print the data in the multi-channel recording real-time window to the picture (click Freeze, this function is available).

Freeze: Freezes the multi-channel recording real-time window ECG signals.

Body surface: Display the whole body surface quickly, press the whole body surface setting, and lift to restore the original setting.
Hide: Hides the frozen window.
Stimulation: Refer to Chapter 6, Stimulation Channel Setup

Note:

- The function of time measurement, voltage measurement, printing and printing to picture can be used only after freezing is clicked.
- Since the display is 24 inches, a page of A4 printing paper cannot contain the entire screen. Therefore, it is recommended that frozen windows should not be set too large when printing to prevent waveform from being visible on A4 paper.

Figure 11-2 Toolbar Of Multi-Channel Recording Real-Time Window

Add or delete channels within the Multichannel Real-Time window:

1） Click the Setup () button and the Show Channels setup dialog box appears.

2） Select the channel to display in the Display check box. Changes will take effect immediately.

You can select multiple channels as needed. Click the display bar at the top of the list, and all channels can be set to "Display" or "Hide."

The Multichannel Record Freeze Window toolbar provides the following options (Figure 11-3):

Setup (): Opens the Show/Hide Channels dialog box, enabling you to add or delete channels in the Multichannel Record Freeze window.

Even score (): Without changing the scale of each display channel, the multi-channel record freezing window displays all channels uniformly.

Gain (): When enabled, the channels used in the multi-channel record freezing window are set to the same gain as the last channel displayed in the window.

Calibration (): Enable/disable the display of the voltage scale icon.

Time measurement (): When enabled, the time length of the waveform in the freeze window can be measured.

Voltage measurement (): When enabled, the waveform voltage amplitude in the multi-channel recording freeze window can be measured.

Print (): Click this icon to directly output and print the data in the frozen window of multiple

records.

Print to picture (): Click the icon to print the data in the real-time window of multiple records directly to the picture.

Synchronization: Click this function to synchronize the channel setting information in the real-time window to the freezing window (synchronization information includes: Full-surface or intracardiac switching, channel position, display, gain and name).

Select template (): Select template, turn on/off template selection.

Auto compare (): Auto comparison. After the template is selected, it is used to determine whether to automatically compare the ECG template of the multi-channel window.

Display template (): Show template, show/hide template.

Toggle display of surface/intracardiac channel contrast (): SECG/IECG, toggle display of surface/intracardiac channel contrast.

Compare with the previous heartbeat (): Display the template and compare with the previous heartbeat.

Backward one heart beat comparison (): Display the template and compare the backward one heart beat.

Body surface: Display the whole body surface quickly, press the whole body surface setting, and lift to restore the original setting.

StiTring: Click this function, and the trigger line is automatically aligned with the last waveform of the stimulation wave.

Manual events: Add manual events.

Hide: Hide the multi-channel event recording window.

Note:

- After clicking the display template, the function of forward heartbeat comparison and backward heartbeat comparison can be used.
- Since the display is 24 inches, a page of A4 printing paper cannot contain the entire screen. Therefore, it is recommended that frozen windows should not be set too large when printing to prevent waveform from being visible on A4 paper.

Figure 11-3 Multi-Channel Record Freezing Window Toolbar

Add or delete channels within the Multichannel Record Freeze window:

1） Click the Setup () button and the Show Channels setup dialog box appears.

2） Select the channel to display in the Display check box. Changes will take effect immediately.

You can select multiple channels as needed. Click the display bar at the top of the list, and all channels can be set to "Display" or "Hide."

Template comparison (Figure 11-4):

1） Click the Select Template () icon on the Freeze Window toolbar.

2） In the freeze window, click the left mouse button and two blue lines appear.
Select the desired template range.

3） Click Select Template () on the Freeze Window toolbar again and the blue line disappears.

4） Click the Display Template () icon on the Freeze Window toolbar.

Dark gray template shadow display, using blue lines to display the selected template range.
The upper right corner of the template displays the average contrast of the listed surface channels.
The contrast is displayed to the right of each body surface channel template.

5） Click the Auto Compare () icon on the Freeze Window toolbar.

Auto comparison of ECG templates in frozen window
The body surface similarity and mean body surface similarity are displayed in real time.

6） Click the Toggle Display Surface/Intracardiac Channel Contrast () icon on the Freeze Window toolbar.

The intracardiac template shadow is displayed, while the skin channel template shadow remains.
The upper right corner of the template shows the mean contrast of the listed intracardiac channels (except for the three intracardiac channels M1-M2, M3-M4, M1).
The three intracardiac channels M1-M2, M3-M4 and M1do not participate in the comparison.
When this icon is pressed, the intracardiac channel contrast is selected and the contrast is displayed to the right of each intracardiac channel template.
When this icon is raised, select Body Channel Comparison and the contrast is displayed to the right of each Body Channel Template.

Note: After clicking the display template, the function of forward heartbeat comparison and backward heartbeat comparison can be used.

Figure 11-4 Template Comparison

12.3 Multichannel performance

External characteristics of the body surface:

Lead: Standard 12-lead I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, and V6

Lead wires: 10 LA, RA, LL, RL, V1, V2, V3, V4, V5, V6

Internal characteristics of the body surface:

Defibrillation protection voltage: 5000 V; DC polarization voltage: ±300 mV, sensitivity change ±5%

Frequency response: When the gain is 10 mm/mV, it shall be consistent with the requirements specified in the following table.

In addition, the equipment shall respond to the following pulse signals:

- A 0.3 mV·s (3 mV continuous 100 ms) pulse input signal shall not produce a greater than 0.1 mV offset outside the pulse region.
- The slope of the response of a 0.3 mV·s (3 mV continuous 100 ms) pulse input signal after the end of the pulse shall not exceed 0.30 mV/s.

Frequency response

Method	Rated input amplitude	Input frequency and waveform	Relative output response
A	1. 0	0.67 Hz~40 Hz, sine wave	±10 %a)
B	0.5	40 Hz~100 Hz, sine wave	+10%, -30%%)
	0.25	100 Hz~150 Hz, sine wave	+10%, -30%%)

C	0.5	150 Hz~500 Hz, sine wave	+10%, -100 %a)
D	1. 5	□1 Hz, 20 ms, triangular wave	+ 0%, -10%%)
a) Output relative to 10 Hz b) Output relative to 200 ms			

Dynamic input range: 10 mV Calibration voltage and its accuracy: 1 mV, ±5%
Common-mode rejection ratio: >60 dB; System noise: 15μVp-v≤
Nonlinear error: ±10%; Baseline drift: 1 mm≤
Temperature drift: Within 5℃－40℃, the baseline drift is not greater than 0.5 mm/℃.

Intracardiac and external characteristics:

Lead: 16- lead R1-R2, R3-R4, R5-R6……R27-R28, M1-M2, M3-M4

Intracardiac characteristics:

Defibrillation protection voltage: 5000 V; DC polarization voltage: ±300 mV, sensitivity change ±5%

Frequency response: When the gain is 10 mm/mV, it shall be consistent with the requirements specified in the following table.

Method	Rated input amplitude	Input frequency and waveform	Relative output response
A	1. 0	0.67 Hz~450 Hz, sine wave	±10%, -30%
B	0.5	450 Hz~1200 Hz, sine wave	±10%, -100%
Relative 40 Hz output			

Dynamic input range: 10 mV Calibration voltage and its accuracy: 1 mV, ±5%
Common-mode rejection ratio: >90dB; System noise: 30μVp-v≤
Nonlinear error: ±10%; Baseline drift: 1 mm≤
Temperature drift: Within 5℃－40℃, the baseline drift is not greater than 0.5 mm/℃.

12.4 Multi-channel recording window event function

The multi-channel recording window can automatically record events, including manual events, ablation events, stimulation events, bradycardia events, tachycardia events, printing events, and freezing events.
Event Settings:

Figure 11-5 Event Settings Dialog Box

1） Click the "Setup" button to pop up the "Event Setup" dialog box (Figure 11-5).

2） Check the Event to be logged option.

3） Record events of event type can be set, and click "Default" button to restore to the default setting.

The default events are Manual Event, Stimulation Event, Print Event and Freeze Event.

4） Click the Filter drop-down menu to select the type of event to be recorded (Figure 11-6).

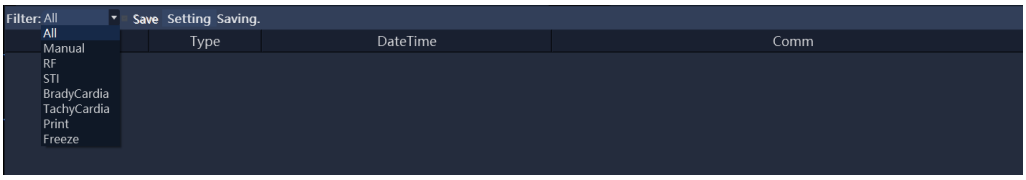


Figure 11-6 "Filter" Settings

The event comment information is displayed and printed (Figure 11-7):

1） Double-click Event Remarks to open the Remark Entry window and enter the Remarks.

2） Click OK and the event comment information has been updated.

3） Click this event again, and the note information is updated and displayed after the event name on the review screen.

4） Click Print or Print to Picture to print the comments.

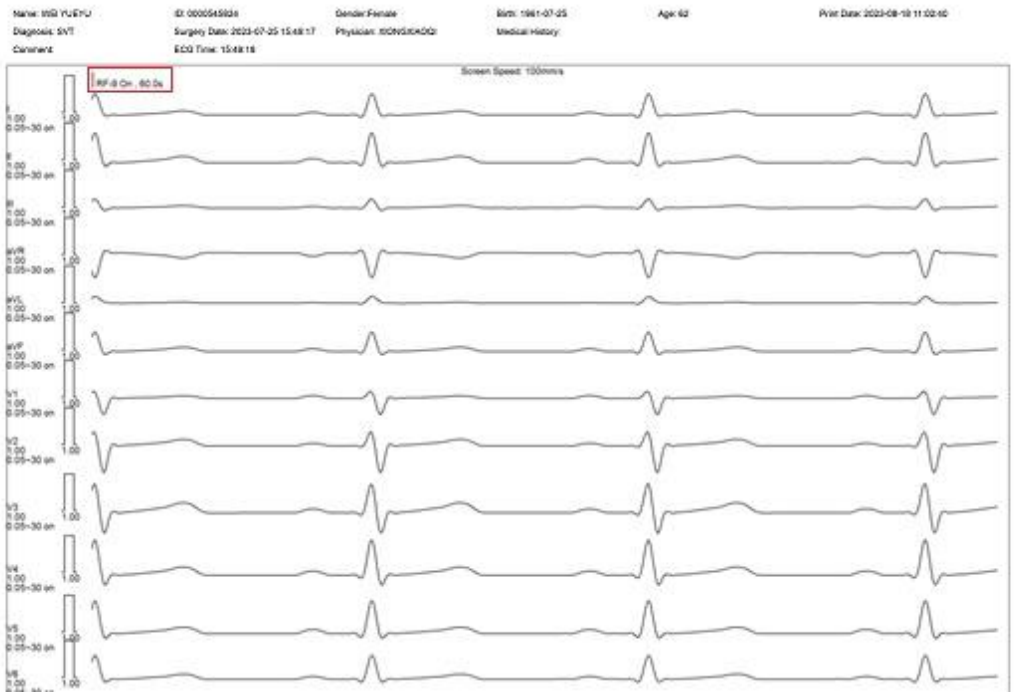


Figure 11-7 Event Remarks Print And Output

Event Delete:

1） Select the event to delete.

2） Right-click and select Delete (Figure 11-8).

3） The event will be moved to the Recycle Bin.

Note: Event information is permanently stored in the Recycle Bin.

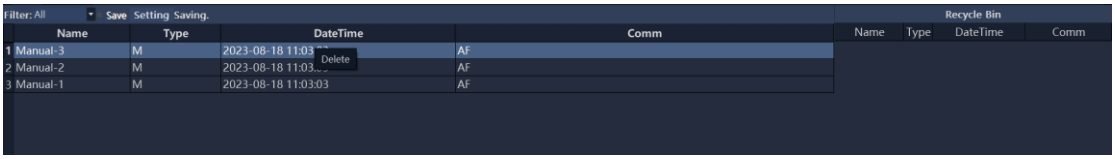


Figure 11-8 Event Deletion

Event recovery:

1） Select the event you want to recover and right-click to display a shortcut menu (Figure 11-9).

2） Click Restore to restore the event to the event list.

Figure 11-9 Event Recovery

Chapter XII Case Management

All patient cases, maps, and screenshot files are initially stored on the system hard disk of the workstation computer. Be sure to back up your files regularly. You can manage existing data files by opening the Case Management window.

This chapter details the contents and functions of case management, including:

- Back up the patient case to CD.
- Recover the patient case from the CD.
- Delete data from the system hard disk.

12.1 When data needs to be backed up

When your computer's hard disk capacity is close to full, you will not be able to create a new patient case file or procedure. Therefore, you need to back up them, and we recommend that you back up all new patient files after each procedure or every day after work. We recommend that you choose to back up the patient case data after completing a new procedure.

If you choose not to back up patient case data at the end of a procedure, make sure that you can back up and delete all the data on the hard disk on a regular basis.

Note:
Make a text label of the CD so that you can quickly find and view the patient's information.

Caution:
You should always have two copies of the patient data. Be sure to back up the patient data to a DVD before deleting it, because the data saved on the hard disk cannot be restored once it is deleted.

12.2 Media for Backup and Recovery

The Columbus™ system uses DVD±R discs to back up data. If needed, you can easily restore data stored in DVDs to a Columbus™ system-appropriate hard disk.

Note:
Once you back up the data to a disc, you cannot edit or delete the data on the disc.

12.3 Accessing Case Management Functions

You can enter the Case Management window (Figure 12-1) by clicking the drop-down arrow to the

right of the Columbus™ icon in the upper right corner of the screen () each time you start the Columbus™ system or return to the patient landing page after completing a procedure.

If you need to be in acquisition mode or playback mode, you must first exit the current procedure. If you attempt to open the Case Management window during a procedure, you are prompted to exit the current procedure and then automatically enter the Case Management screen.

12.4 Backup data to DVD:

When backing up patient data, note that the maximum available data space for a single DVD is 4.3 GB.

Backup data to DVD:

1. Place an empty DVD±R in the optical disk drive.
2. Opens the Case Management window.
   - See Figure 11-2. All case files stored on the workstation hard disk are displayed in the patient list in the leftmost local hard disk directory.
   - The default backup media is DVD, and the default backup path is the optical disk drive of the workstation.
3. Browse to the patient case, procedure, or map to be backed up to the CD in the local hard disk directory on the left side of the case management window.
   Note:
   When a map is selected, its preview is displayed immediately.
   a. Select the file to be backed up and right-click and select Backup in the right-click menu to add the file to the backup queue.
   b. From the Backup Queue list, select the file you want to cancel the backup and click Remove. Depending on the data selected in the backup list, the size of the data to be burned and its percentage of all free space on the disc is displayed below it. You cannot back up patient data that exceeds the maximum capacity of the disc itself in a single disc.
4. After adding the complete sequence, click Burn to begin writing data to the disc.
   - The progress bar visually displays the progress status of the burn.
   - If no blank disc is inserted into the drive, a message box will pop up prompting you to insert a blank disc first.
5. When the data is successfully backed up to the CD, the system will automatically eject the CD drive.

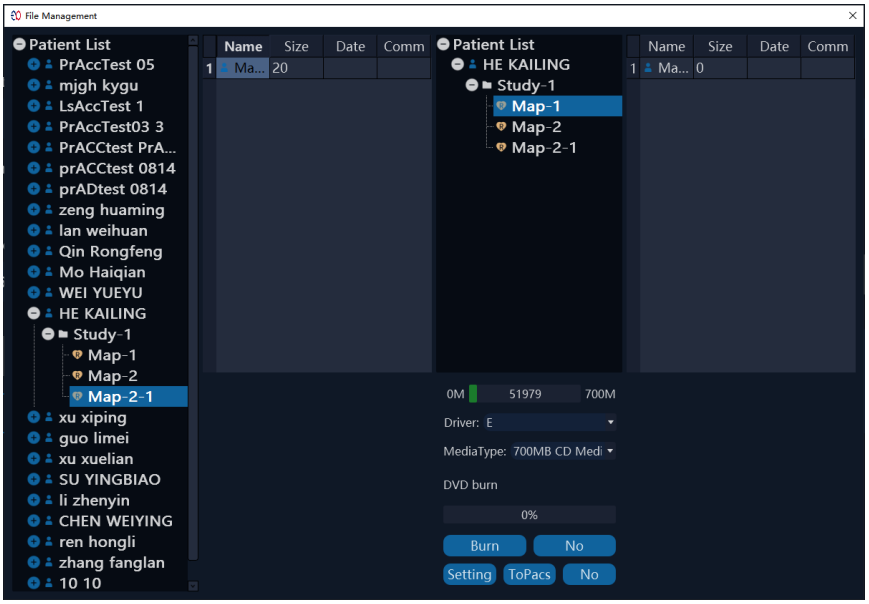


Figure 12-1 Case Management Window.

12.5 Restore data file to hard disk

The Import Data function is used to restore (or copy) patient files that have been backed up on the CD to the system hard disk.

Restore data from CD:

1. Place the DVD with the backup data in the optical disk drive.
2. Open the case management window, as shown in Figure 12-1. All patient files stored on the CD are displayed in the CD directory list on the right.
3. Browse to the patient case, study, or map to restore (copy) to the system hard disk. Select the file to be imported, right-click, and select "Restore" in the right-click menu. The patient file is imported into the local hard disk and the contents of the local hard disk directory on the left are automatically updated accordingly.

12.6 Delete Patient Data

You will need to periodically delete existing patient case files to ensure that the system has sufficient storage space for new procedures. Before deleting data, make sure that the existing data has been backed up, and you will not be able to recover the deleted data if the patient case, procedure, or map is not backed up to CD.

Delete Patient Case:

1. Open the case management window, as shown in Figure 12-1. All case files stored on the workstation hard disk are displayed in the patient list in the leftmost local hard disk directory.

2. Browse to the patient case, study, or map to delete. Select the file to be deleted, right-click, and select Delete from the right-click menu.

Chapter 13 General Operation Process

This chapter describes how to use the Columbus™ system in a manner similar to normal operation, and details the steps of a typical Columbus™ system procedure.

This chapter is based on the premise that you have completed the Shanghai MicroPort EP MedTech Co., Ltd. Columbus™ system training course and are a qualified doctor.

Before starting the procedure, make sure that all system components are connected and the system is turned on. See Chapter 3: Equipment Overview.

Procedure Overview

A typical mapping procedure using the Columbus™ system can be performed in nine steps:

1） Surgical Setup.
2） Create RTM map (optional).
3） Collection points.
4） Edit the mark of the point (optional).
5） Registration with the surface image (optional).
6） Create a new map.
7） Save and close the procedure.
8） Continue with another procedure (optional).
9） Playback mode (optional).
10) Exit the system.

This chapter details the basic content of point acquisition to the map in a three-dimensional cardiac electrophysiological mapping procedure. However, you may need to acquire several maps during a complete three-dimensional cardiac electrophysiological mapping procedure. For details on other special functions used during mapping, see Chapter 5: Mapping Principles and Procedures, and Chapter 10: Mapping and Surgical Tools.

In acquisition mode, the system automatically detects hardware problems (e.g., loss of connection to the catheter, communication problems). If such an error is detected, you will receive warning advice or error messages immediately, along with brief instructions on how to proceed.

Step 1: Surgical Setup

After you enter the main interface of the Columbus™ system, you will see multiple surgical setup

modules. This section describes how to perform the surgical setup following the recommended steps. Of course, you can also complete the various settings in free order. See Chapter 6: Surgical Setup for details on how to perform surgical setup.

Procedure Setup Steps:

1） Complete the patient and surgical setup by performing one of the following steps:
   a. Fill in the necessary patient information in the patient login page and click "New Patient Record" to create a new patient record file. Make sure you have entered data in all required fields. When a new patient is created, the New Procedure button becomes available.
   b. Click Browse Medical Records, select and open an existing patient file in the patient list. You can continue with the latest historical surgery within the last 24 hours, or click "New Surgery" to start a new surgery. The system supports a maximum of 5 procedures.

2） Select a system template in the displayed Load Template dialog box. The template contains some user-defined settings and pre-set parameters. You can use the default template predefined by the system, or you can create your own template and apply it to a new procedure.

3） Paste the Columbus™ External Reference Patch on the back of the patient (refer to "Chapter 5: Mapping Principle" for details). Click the system status icon, and check whether the Columbus™ External Reference Patch position is correct according to the positioning reference position prompt in the window. If the display is incorrect, move the field generator to the correct position by moving the field generator bracket back and forth on the operating table or adjusting the fine adjustment knob on the right side of the field generator bracket to move the field generator left and right.

4） Click the Channel Setup page to access the channel setup options. Perform one of the following steps to complete channel setup:
   a. All surface ECG channels can be parameterized in the Body Surface column.
   b. In the "Intracardiac" column, you can select and combine the intracardiac ECG channels to be collected, and set the parameters for all intracardiac ECG channels.
   c. In the "Window of Interest Parameters" column, you can set the reference and mapping channels, the detection method of markers, and the size of the window of interest.
   d. In the Stimulation Channel Setup column, you can set the stimulation channel.
      Note:
      - When you enter the Channel Setup page again, you will see the last channel setup you used.
      - You can view and modify the channel settings during the procedure by clicking the Channel Settings page.
      - You can use different channel settings for different maps in one procedure.

Step 2: Create RTM Diagram(Optional)

Multiple maps may be required during the procedure, including general maps and RTM maps. The initially constructed RTM map is displayed in green. With the acquisition of mapping points, the RTM map superimposes electrophysiological information.

To create an RTM map:

1) Click the "New RTM Map" button on the toolbar () to create a new one. RTM map and activated under the current procedure.

2) Reference and map channels can be modified on the Channel Setup page.

A new RTM map is created and other maps are hidden in the map window. You can click the checkbox in front of the map in the procedure list to display it in the map window.

3） Click the "on" button to start creating the RTM map. The RTM map was constructed continuously as the mapping catheter moved within the cardiac cavity.

4） Click the "off" button to stop the construction of the RTM map.

5） Right-click the RTM map and select Transparent. The RTM map can be displayed transparently.

6） The constructed RTM map can be edited. Press "ctrl+ left mouse button," the grid diagram and red circle appear, which can be used to erase the interpolated grid; Press "shift+ctrl+ left mouse button," the grid map and green circles appear, and all traces of the catheter are displayed in gray in the mapping window, which can be erased by the green circles.

Step 3: Collect Mapping Points Using a Magnetically Positioned Mapping/RFA Catheter

After all surgical settings have been completed correctly,

Once you have identified the catheter tip position through fluoroscopy, you can start the acquisition point.

The collection points are divided into 4 steps. These procedures must be performed with the cooperation of the surgeon performing the surgical procedure and the person working at the workstation. The doctor only needs to communicate the operation he wants to perform to the operator of the workstation, and the operator of the workstation will perform the corresponding operation through the mouse.

After each point is collected, the following data are saved:

- ECG at all acquisition points, ranging from 2 seconds before marking to 0.5 seconds after marking.
- Heartbeat cycle, unipolar voltage, bipolar voltage, and LAT (local activation time) values.
- Position and angle information for Magnetic Mapping/RFA Catheter Big Tip, Bend, and Columbus™ External Reference Patch.

Continue to collect points until you are satisfied with the detail quality of the map.

Note:

If different settings are applied during the acquisition of a map (for example, you change the detection settings for a reference or map marker in the middle of the map), the last applied settings

are saved with the map.
You need to place the catheter as close to the inner wall of the chamber as possible and collect mapping points on the inner wall of the chamber.

Maps collected from Magnetically Located Mapping/RFA Catheters are based on data collected from catheter heads. The data is collected by a separate big tip as you move the catheter along the inner wall of the chamber. If you are unsatisfied with the quality of the map displayed in the Map Browser, you can edit the points one by one immediately.

Points are collected into a standard Columbus™ system map;

1） Move the catheter to the position where mapping is required in the cardiac cavity. Dragging the catheter tip along the intracardiac surface is usually the simplest way to acquire a point.
   - Points can be collected in any order.
   - If stimulation is performed through the Patient Interface Unit, set the stimulation channel through the channel setup page or the upper part of the monitoring window on the mapping page.

2） Click the Freeze Collection button to freeze the display.
   - The system enters a frozen state, which allows you to view the point's data more easily in the markup window. The map is temporarily updated to see how the map will change if you accept this newly acquired point. The system will continue to display the catheter motion status. Its position is continuously updated in real time, while other displays remain frozen.
   - A text prompt "Freeze" appears on the Collection button.

3） Check the quality of the point by viewing the information displayed in the mark window and in the stability bar. The options displayed here help you determine whether the quality of the point meets the criteria that can be collected. Please note:
   - Map in Marker Window: You can view the current ECG for the point for up to 2.5 seconds.
   - Heartbeat cache: You can view the data for the last 10 heartbeats at the point and accept the best heartbeat for the parameter. See "Using the heartbeat cache" for details.
   - Stability column: The stability column represents the stability or mass of the catheter tip in contact with the heart interior. Green stands for good stability; Red indicates poor stability. See "Stability column" for details.

4） Accept or abandon the point.
   To accept the point, click the Accept button again. This point is added to the diagram and the system returns to the Ready state. You can continue to collect more points.
   To discard the point, click the Reject button. The point is not added to the graph and the system returns to the Ready state.

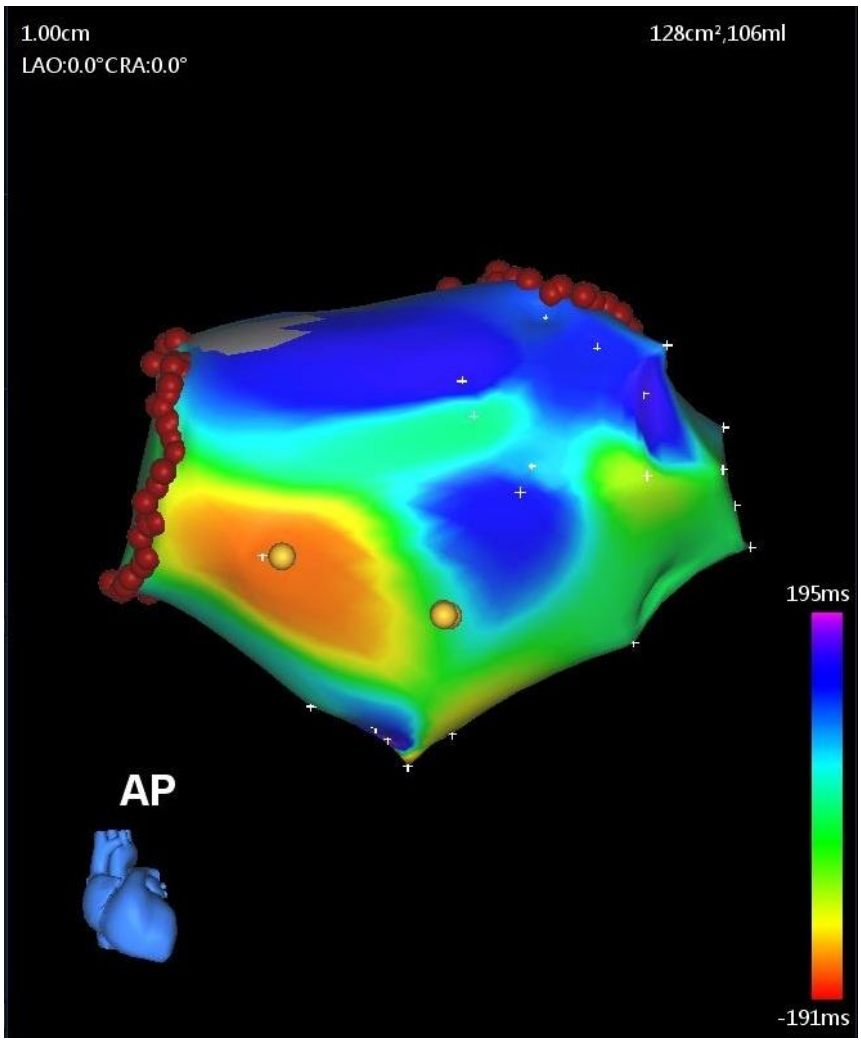


Figure 13-1 Map Of A Standard Columbus™ System

The color on the 3D anatomical reconstruction represents its electrical information; The earliest excitement was in red and the latest in purple.

Note 1:
The map given by the Columbus™ system is a simulated three-dimensional reconstruction based on data from acquisition points. Areas without collection points may not be accurately expressed. In order for the map to truly reflect the anatomy of the chamber, you need to collect as many points as possible evenly across the chamber.
Note 2:
The Columbus™ system provides footswitch acquisition position points, and the same effect can be achieved with the Enter key.

Step 4: Edit the mark of the point(Optional)

You can edit the map markers in any phase of the acquisition or in the marker window in playback

mode.

Edit Map Marker:

1） Click a point on the map or in the point list. The points in the points list are highlighted, and the large crosshairs are identified in the view of the map window.
   If the system is in the Ready state, it enters the Edit state. You will notice the following:
   - The collect button is changed to edit status.
   - The content displayed in the mark window is the ECG channel data of the selected point at the acquisition time.
2） Move the map marker line as described earlier.
3） If the system is in the edit state, click Continue to return to the Ready state. The Acquisition button appears.

Edit Reference Mark:

1） Click a point on the map or in the point list.
2） Click the Adjust Guides icon () on the Markup Window toolbar. When the Adjust Reference Line function is enabled, you will be able to move the reference mark line.
3） If the system is in the edit state, click Continue to return to the Ready state. The Acquisition button appears.

Restore the marker to its original value:

1） Click on the graph or point list to specify a point.
   The channel data of the selected point is displayed in the mark window.
2） Click the Retreat icon () in the Markup Window toolbar.
   The tag is restored to its original set value.
   If you have edited a map marker or reference marker for that point, they are restored to their original collected values.
   Note:
   When you change the window of interest, the flags are recalculated based on the new settings.

Step 5: Register with Surface Image(Optional)

If registration of a 3D map with a 3D surface image from CT or MRI image data is required during a 3D cardiac electrophysiology mapping procedure, the patient's CT or MRI data is imported into the workstation of the Columbus™ system and segmented. During the procedure, the operator can directly open the segmented surface image for registration. Refer to Chapter 9: Segmentation and Registration for details on how to import and segment CT or MRI study data.

To register a 3D map with a surface image:

1） Activate the image study to be opened and the surface image under it in the image study list.
2） The activated surface image is displayed in the map window along with the map. Click the

checkbox for the surface image in the Image Study list to hide or display each surface image separately.

3） Manually align the surface image with the target map. Press the <Ctrl> and <Alt> keys at the same time, and then click and translate the position of the surface image relative to the map with the left mouse button. If you hit the key and drag the mouse, the surface image is rotated. You can move the surface image to approximately the same position and orientation as the map by repeatedly performing translation and rotation operations.

4） Activate the map to be registered and the Columbus™ system registers the surface image with the map you specify.

5） Right-click the surface image to be registered and select Register from the shortcut menu. The system automatically registers and fuses the surface image with the specified 3D map.

Note: If there are multiple maps in the mapping procedure, the system default registration target is the current active map in the mapping procedure. If you delete a map designated as the registration target, you may need to activate another map before the next registration.

For details on the import, segmentation, and registration of CT/MRI images, see Chapter 9: Segmentation and Registration.

Step 6: Create a new map and remap

In one procedure, you may need to acquire multiple maps and remaps, and the system supports a maximum of 10 maps. The remap function creates a new map based on the original 3D map anatomy. This feature can be very helpful for quick mapping of areas where excitation conduction changes.

The remap uses the same anatomy as the original map to record the activation sequence of the new acquisition points. The shape of the original map area is colored gray. Color interpolation on the remap will only be applied to newly acquired points. Normal map points on the reference image are automatically set to Location Only in the remap. Also in the list of points, these points also get a comment for the "Base Point."

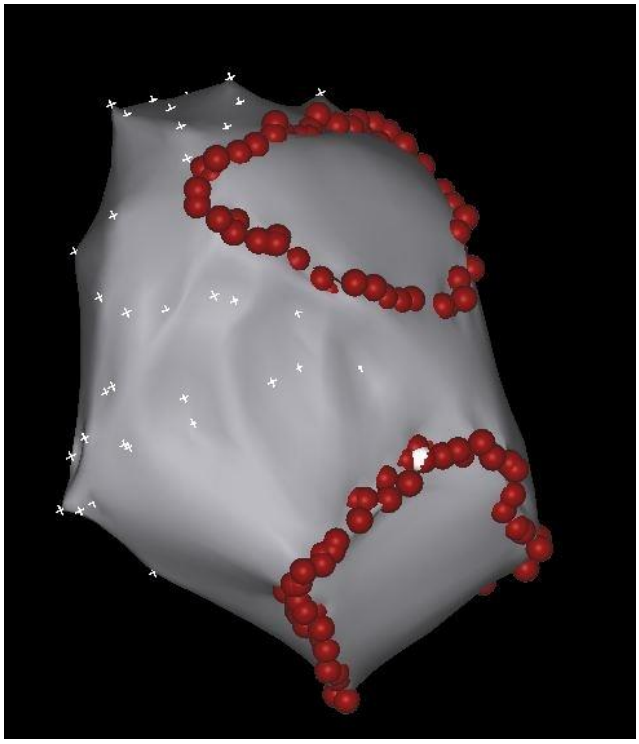


Figure 13-2 Simulated Remap

The original reconstruction is displayed in gray. Only points newly added to the remap are color interpolated.

Create a new map:

1） Clicking the New Map icon ( ) on the toolbar will create and activate a new map in the current procedure.

2） You may need to make the necessary changes to the reference and map channels in the Channel Setup page.
When you create a new map, other maps under the same procedure are hidden in the map window. Click the check box before the name of each map in the operation window to select to display multiple specified maps in the map window.

3） Return to step 3 to start the acquisition point.

Create a remap:

1） Right-click a map in the 3D map operation list, and select "Remap" in the shortcut menu. The system will create a new map of the map in the current operation ( ).

2） You may need to make the necessary changes to the reference and map channels in the Channel Setup page.
When a new remap is created, other maps under the same procedure are cleared in the map window. Click the check box before the name of each map in the operation window to select to display only a specified map in the map window.

3） Return to step 3 to start the acquisition point.

Example: Naming Rules for Remap
If the map you first collected is named Map – 1, it appears as Map - 1 in the list of mapping procedures. If you created a remap, it appears as Map - 1 - 1 in the list of mapping procedures.

You can activate other existing maps at any time during the operation: Browse the map list in the current operation in the map surgery window, double-click the map to be activated, or right-click and select "Activate" in the shortcut menu.

Step 7: Close the procedure

Once you have completed the procedure, you will need to end the operation on the current patient record and the system will automatically save all patient data.

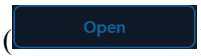
Closure:
After you complete a procedure, click the End Procedure button in the upper right corner of the screen ()  . After you select the appropriate operation, the system will automatically exit to the patient information login page of the Columbus™ system.

If necessary, you can reopen the procedure within 24 hours without creating a new procedure to acquire more points (continue the procedure), or edit the acquired map in playback mode.

Step 8: Continue Surgery(Optional)

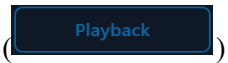
After saving the procedure, you can continue with the data collection procedure by opening the last procedure performed within the previous 24 hours, if necessary.

To continue a procedure:

1） Click the "Browse medical record" button (

) in the patient information login page, select the patient to be operated, and click the "Start" button to enter the acquisition mode.
2） Activate the map in the Map Surgery window by double-clicking on the left key or right-clicking on the shortcut menu.
At this point, the map you selected becomes the currently active map, and you can collect new data into the map.

Step 9: Playback mode(Optional)

Playback mode enables you to view and edit all the data in the patient record file of the existing Columbus™ system. After opening a patient record, click the Playback button (

) to enter the Playback mode immediately.

All changes made to the procedure will be saved. When a point on the map or in the point list is selected, you can view the following data:

- The data of the selected point is displayed in the mark window.
- Displays the stability when the point is accepted in the Stability bar.
- The ECG waveforms of the heartbeat cycle, local activation time, voltage value, map, reference channel, and each point are also displayed.
- Displays the time the point was acquired in the point list.

To open the procedure in playback mode:

1） Click "Open Patient Record" in the patient information login page to enter the Open Patient Record dialog box.

2） Select a patient in the patient list and click OK to open the patient's medical record file.

3） Click the "Playback" button, the system will switch to the cardiac mapping page, enter the playback mode, and activate the procedure in the mapping procedure list.
All maps of the activated procedure are automatically displayed in the map window.

4） If you want to view another image in the procedure at the same time, select the check box before the map name in the procedure window. If you want to view another image in another procedure, you should activate that procedure before the map belonging to that procedure is displayed.

Step 10: Exit the Columbus™ system

If you need to end the work of the day and close the whole system, click the drop-down arrow (

) on the right of the Columbus™ icon in the upper right corner of the screen, and select "Exit" in the drop-down menu. The system will exit to the user login interface. Click "Exit," and the Columbus™ system will automatically exit to the initial user login page.

Chapter 14 Maintenance and Support

This chapter describes the basic contents of system maintenance.

14.1 Replacement Parts

The Columbus™ system itself does not require user maintenance, and the fuse is the only part that can be replaced by the user.
The fuse in the Columbus™ system is located in the power supply module. The fuse specification on the power supply module is T4AL250V.
The fuse specification at the rear of the Columbus™ system instrument car is T6.3AH250V. The fuse specification of the console is T8AH250V. Only qualified technicians or hospital personnel are allowed to change the fuse.

Warning:
The connection to the system power supply must be cut off before replacing the fuse.

Replace the fuse of the power module of the Columbus™ system:
1） Disconnect the patient interface unit from the power supply module.
2） Disconnect the power supply module from the main power supply.
3） Using a screwdriver, gently press the fuse box (above the switch) aside and lever it out of the slot.
4） Remove the fuse to be replaced from the fuse box. Replace the blown fuse with a new fuse of the same model and current rating as described on the rear side of the patient interface unit.
5） Replace the fuse box.

Replace the fuses of the instrument cart/console of the Columbus™ system:
1） Disconnect the power connection of the power wiring block on the instrument cart/console.
2） Pry open the fuse socket with a slotted screwdriver (Figure 14-1 A).
3） Remove the old safety tube (Figure 14-1 B). Replace the blown fuse with a new fuse of the same model and current rating.
4） Replace the fuse holder.

A B

Figure 14-1 Replace the fuse of the instrument cart/console.

Note:
If the fuse is still blown more than once, contact your Shanghai MicroPort EP MedTech Co., Ltd. technician.

14.2 Cleaning

You need to clean the patient interface unit, power supply module, and enclosure of the workstation regularly. The components of the system do not require sterilization or disinfection.

1) Take care to avoid extremely high or low temperatures and humidity, and the equipment is not waterproof.
2) Protect equipment from spills or other debris. Do not eat or smoke near the device during surgery or maintenance.
3) Wipe the instrument housing, front panel, and power cord with a neutral cleaner and damp cloth.
4) Do not sterilize the instrument in the system with steam or high temperature. Do not soak in any disinfectant or liquid. Do not allow liquid to enter any conductive connections or inside the equipment.
5) You can use a soft cloth dipped in a conventional medical equipment cleaner, such as isopropyl alcohol, mild cleaning soap.
6) Do not spray or pour any cleaning agent into the equipment, and do not use acetone solution.
7) When cleaning the foot pedal, wipe the surface of the foot switch and connecting wire with cleaning agent and wet cloth. No liquid shall enter.
8) Be careful not to wet the electronic connection of the connector. Do not use corrosive cleaning agents.
9) Do not sterilize the footswitch.
10) The foot switch can be sterilized by dipping a soft cloth in the alcohol solution commonly used in hospitals.
11) If fluid enters by accident, make sure the fluid is fully volatilized before switching on the power again.

The cables in contact with the patient need to be cleaned, and the accessory cables are non-disposable medical device accessories. After use, it is recommended to clean and wipe the surface of connection tail line with the disinfection technical specification specified by the Ministry of Health.

Note:
Do not immerse the cable in liquid.
Do not reuse the catheter tail more than 10 times. More than 10 uses will impair the normal function

of the tail line. Company will not be responsible for direct or secondary adverse consequences due to repeated use of the tail line beyond a limited number of times.
It is recommended that the ECG cable should not be used more than 100 times, or the signal quality may be reduced.
Warning:
Always disconnect the components from the power supply before cleaning.

14.3 When the system is idle

After exiting the Columbus™ system, it is recommended that you turn off the workstation and power module switches and turn off the main power to the system after the cooling fan has stopped completely.

14.4 Recommended service life of equipment

The recommended service life of the product in normal use under the specified service environment is 10 years.

14.5 Equipment maintenance

The equipment itself does not require user maintenance, but MicroPort EP will still have qualified after-sales engineers to carry out regular maintenance activities to ensure that the equipment can operate efficiently and safely.

Note: Equipment should not be maintained or serviced during surgery or when connected to a patient.

Basic Safety:

Maintenance time	Maintenance Operations
Once a year	Inspect the housing for cracks or other damage. Inspect all wires and cables for wear or other damage. Check all plugs, cables and connectors for bent pins or pins. Verify that all wires and connectors are secure. Check the foot rest for proper operation. Check the protective grounding: The resistance between the protective grounding connector of the power plug and the available conductive parts of the protective grounding shall not be greater than 0.2Ω; Note: The annual maintenance of the equipment shall only be carried out by qualified technicians approved by the Company.

The replaced devices, including but not limited to power cables, circuit boards, accessory cables,

etc., shall use the qualified devices provided by MicroPort EP, and the equipment can be put into use only after the corresponding test verification is completed.

Equipment performance:
The basic performance of the system will be periodically tested by authorized personnel according to the table below, and the test method and acceptance results will be carried out in accordance with the technical requirements of the system (or equivalent test method). When the requirements are met, the equipment can continue to be used.

Maintenance time	Maintenance Operations
Once a year	1. Defibrillation protection; 2. Electrosurgical interference; 3. Accuracy of invasive blood pressure; 4. Accuracy of SpO2; 5. Signal incomplete indication of SpO2 6. Abnormal operation indication of SpO2 7. Effect of filter on electrocardiogram; 8. Electrostatic discharge; 9. Electrical fast pulse group; 10. Conducted harassment;

In items 1, 2, 8, 9, and 10 of the table, authorized technicians can check whether the shell is intact, whether the connector or connector pin is intact, whether the ground impedance is not greater than 0.2Ω, and whether the protective measures of the accessory cables are intact.

Chapter 15 Technical Parameters

15.1 Performance Index

Number of ECG leads on the surface: 12
Number of intracardiac ECG channels: ≥136
Stimulation input channel: 4 channels

The system error and frequency response of the surface ECGs are tested according to A, B, C, and D of 5.2.7.2 in YY 1139-2013.
Surface ECG ESU protection:
Cutting mode: 300 W
Condensation mode: 100 W
Recovery time: ≤10 S
The time deviation between channels is not more than 100us.

Invasive blood pressure measurement range: -50~+300mmHg Resolution: 1mmHg.
Accuracy of invasive blood pressure: reading 4% or 4 mmhg (whichever is greater)
Sensitivity of blood pressure sensor: 5μV/V/mmHg.
Frequency response of invasive blood pressure: DC~10Hz
Volume displacement of pressure transmission diaphragm: 4.5*10-4 in3/100 mmHg.

Pulse oxygen saturation measurement range: 0~100%
Pulse oxygen saturation measurement accuracy: 70%-100%, 4%; Below 70%, no definition;
Pulse oxygen saturation display resolution: 1%
Data update cycle: 1S
Wavelength:
Red light: 660±3nm
Infrared light: 905±5nm

Recovery time of defibrillation: 5s

Communication interface: Optical fiber, serial port
Supply voltage: 220 V~
Power frequency: 50 Hz
Power consumption (console and instrument car): 2000 VA
Console fuse: T8AH 250 V
Fuse of instrument car: T6.3AH 250 V
Power box fuse: T4AH 250 V
Dimensions (PIUs): 500 mm* 480 mm* 300 mm
Weight (PIU): ≤30Kg

15.2 Basic performance characteristics

Columbus™ 3D EP Navigation System can work safely and normally. The basic performance related to equipment safety complies with the standards of GB- 9706.1 and YY- 9706.102, which include the normal operation of the following functions:
1. Defibrillation protection;
2. Electrosurgical interference;
3. Accuracy of invasive blood pressure;
4. accuracy of spo 2;
5. Signal Incompleteness Indication of SpO2
6. Abnormal operation instruction of SpO2
7. The influence of filter on ECG;
8. Electrostatic discharge;
9. Electric fast pulse group;
10. Conducting harassment;

See Chapter 14.5 for details about the necessary periodic testing of basic performance, including measures, methods and recommended frequency.

Note: The display is not part of the Essential Performance. The monitor only provides information and is not used for treatment. The displayed content is temporarily unclear or the characters that should not be displayed (e.g. due to interference) do not affect the safety of the procedure. Permanent loss of display capability can lead to surgical termination, but does not pose an unacceptable risk to the patient.

Appendix I

Processing error information

Most error messages begin with a number followed by a letter code, for example:

301M

Shanghai MicroPort EP MedTech Co., Ltd.'s services and support departments use codes to identify the exact type of error. The letter code indicates the nature of the error as follows:

- P: Patient interface unit(PIU module)
- R: Columbus™ External Reference Patch or its connection
- M1: Magnetic Mapping/RFA Catheter First Sensor or its connection
- M2: Magnetic Mapping/RFA Catheter Second Sensor or its connection

The PIU contains the LPU, the positioning processing unit.

When you contact Shanghai MicroPort EP MedTech Co., Ltd.'s technical support to report a device failure, you will be asked to provide an error code (including letters) and what happens when the problem occurs for Shanghai MicroPort EP MedTech Co., Ltd.'s technicians to analyze the cause of the problem.

Common error information is as follows:

Schedule 1 Common Error Information.

Error code	Error Message	Problem/Countermeasure
101P	Patient interface unit initialization failed.	The connection of the patient interface unit is abnormal. Check whether the optical fiber communication cable connecting the computer and the patient interface unit is properly connected.
102P	Communication between patient interface unit and workstation failed.	The connection between the computer and the patient interface unit is abnormal. Check whether the optical fiber communication cable connecting the computer and the patient interface unit is properly connected.
202L	Communication timeout between LPU and workstation	The connection between the computer and the positioning processing unit is abnormal. Check whether the DB9 serial cable connecting the computer and the patient interface unit is properly connected and whether the magnetic field generator is correctly connected to the patient interface unit.
203L	LPU initialization failed	The positioning processing unit is connected abnormally. Check whether the DB9 serial cable connecting the computer and the patient interface unit is connected normally.
301F	Magnetic field generator cable pulled out	The connection of the magnetic field generator is abnormal. Check whether the FG connection cable is properly connected to the patient interface unit.
302F	Field generator off	The magnetic field generator is turned off. Check that the field generator switch button in the system status bar is turned off.
401R	Reference electrode pulled out	Unable to detect Columbus™ External Reference Patch. Check whether the Columbus™ External Reference Patch is connected to the tail line or whether the tail line is connected to the patient interface unit.
402R	Reference electrode not initialized	Columbus™ External Reference Patch does not work properly. Please check whether the Columbus™ External Reference Patch is connected to the patient interface unit; If the Columbus™ External Reference Patch is connected correctly, try replacing the catheter pigtail and Columbus™ External Reference Patch in turn to troubleshoot and replace the faulty part.

403R	Reference electrode port disabled	Columbus™ External Reference Patch does not work properly. Please check please check that the Columbus™ External Reference Patch is connected to the Patient Interface Unit.
404R	Reference electrode out of range	The Columbus™ External Reference Patch is outside the working area of the magnetic field generator. You need to adjust the position of the magnetic field generator relative to the patient or reposition the Columbus™ External Reference Patch to bring the Columbus™ External Reference Patch into the operating range of the system.
405R	Reference electrode not allowed	Columbus™ External Reference Patch does not work properly. Please check please check that the Columbus™ External Reference Patch is connected to the Patient Interface Unit.
406R	Reference electrode data loss	The magnetic positioning function of the system does not work properly. It may be because the magnetic field generator or Columbus™ External Reference Patch is strongly disturbed by the magnetic field. Try adjusting strong interference sources such as DSA handpieces.
407R	Reference electrode out of accuracy range	The Columbus™ External Reference Patch is outside the working area of the magnetic field generator. You need to adjust the position of the magnetic field generator relative to the patient or reposition the Columbus™ External Reference Patch to bring the Columbus™ External Reference Patch into the operating range of the system.
408R	Reference electrode movement or rotation	Columbus™ External Reference Patch Movement or rotation. Check whether the reference electrode on the back of the patient falls off.
501M1	Positioning catheter first sensor removed	The positioning sensor at the distal end of the magnetic mapping/radiofrequency ablation catheter is not working properly. Check that the positioning catheter port of the Patient Interface Unit is properly connected to the Magnetic Positioning Mapping/RFA Catheter.
501M2	Positioning catheter second sensor removed	The magnetic mapping/radiofrequency ablation catheter proximal positioning sensor is not working properly. Check that the positioning catheter port of the Patient Interface Unit is properly connected to the Magnetic Positioning Mapping/RFA Catheter.
502M1	The first sensor of the positioning catheter is not initialized	The positioning sensor at the distal end of the magnetic mapping/radiofrequency ablation catheter is not working properly. Check whether the positioning catheter port of the patient interface unit is correctly connected to the magnetic positioning mapping/RF ablation catheter; If the catheter is connected, attempt to replace the tail line of the catheter and the catheter in turn to troubleshoot and replace the faulty part.
502M2	The second sensor of the	The magnetic mapping/radiofrequency ablation catheter proximal positioning sensor is not working properly. Check whether the

	positioning catheter is not initialized	positioning catheter port of the patient interface unit is correctly connected to the magnetic positioning mapping/RF ablation catheter; If a Magnetically Located Mapping/RFA Catheter is connected, attempt to replace the catheter tail and then the catheter, troubleshoot and replace the faulty part.
Error code	Error Message	Problem/Countermeasure
503M1	The first sensor port of the positioning catheter is disabled	The positioning sensor at the distal end of the magnetic mapping/radiofrequency ablation catheter is not working properly. Check that the positioning catheter port of the Patient Interface Unit is properly connected to the Magnetic Positioning Mapping/RFA Catheter.
503M2	The second sensor port of the positioning catheter is disabled	The magnetic mapping/radiofrequency ablation catheter proximal positioning sensor is not working properly. Check that the positioning catheter port of the Patient Interface Unit is properly connected to the Magnetic Positioning Mapping/RFA Catheter.
504M1	The first sensor of the positioning catheter is out of magnetic field range	The distal end of the Magnetically Located Mapping/RFA Catheter extends beyond the working area of the magnetic field generator. If the MAGNETIC POSITIONING MAPPER/RFA CATHETER is located in the heart cavity of the patient, you need to adjust the relative position of the magnetic field generator to the patient so that the MAGNETIC POSITIONING MAPPER/RFA CATHETER re-enters the operating range of the system.
504M2	The second sensor of the positioning catheter is out of magnetic field range	The proximal end of the Magnetically Located Mapping/RFA Catheter is beyond the working area of the magnetic field generator. If the MAGNETIC POSITIONING MAPPER/RFA CATHETER is located in the heart cavity of the patient, you need to adjust the relative position of the magnetic field generator to the patient so that the MAGNETIC POSITIONING MAPPER/RFA CATHETER re-enters the operating range of the system.
505M1	The first sensor of the positioning catheter is not allowed	The positioning sensor at the distal end of the magnetic mapping/radiofrequency ablation catheter is not working properly. Check that the positioning catheter port of the Patient Interface Unit is properly connected to the Magnetic Positioning Mapping/RFA Catheter.
505M2	The second sensor of the positioning catheter is not allowed	The magnetic mapping/radiofrequency ablation catheter proximal positioning sensor is not working properly. Check that the positioning catheter port of the Patient Interface Unit is properly connected to the Magnetic Positioning Mapping/RFA Catheter.
506M1	Missing first sensor data for positioning catheter	The magnetic positioning function of the system does not work properly. This may be due to strong magnetic field interference from the magnetic field generator or Magnetic Mapping/RFA Catheter, or excessive motion of the Magnetic Mapping/RFA Catheter. Try

		adjusting strong sources of interference such as the DSA head, or avoid magnetic localization mapping/ablation catheters to collect data in areas with large heartbeats, such as the annulus.
506M2	Missing second sensor data for positioning catheter	The magnetic positioning function of the system does not work properly. This may be due to strong magnetic field interference from the magnetic field generator or Magnetic Mapping/RFA Catheter, or excessive motion of the Magnetic Mapping/RFA Catheter. Try adjusting strong sources of interference such as the DSA head, or avoid magnetic localization mapping/ablation catheters to collect data in areas with large heartbeats, such as the annulus.
600Ref	Reference electrode expired	The reference electrode has been used for more than 24 hours and fails. Replace the reference electrode with a new one, or contact technical support.
600Map	Mapping catheter expired	The mapping catheter has been in use for more than 24 hours and has failed. Replace the mapping catheter with a new one, or contact technical support.
ECG Distortion	Skin lead off indication	This indication appears when the surface lead is off or when the polarization voltage is too high. Check the connection status of the lead wire or the status of the electrode pads on the patient.

Note:
A fault in one situation may cause multiple error messages to appear. Handle the fault problem in sequence according to the error messages.

Appendix II

Troubleshooting

If you encounter difficulties with your Columbus™ system, you can solve them in many different ways, depending on the situation.

- You can use the error message on the main screen to find out the cause of the error. These messages relate to the following:
  - Communication between workstation (computer) and communication unit,
  - Connection of catheter/reference pole, and
  - Location of catheter/reference pole.
- Follow the steps recommended in this chapter to help you identify the exact cause of the problem.

Shanghai MicroPort EP MedTech Co., Ltd. Customer Support will provide you with help information that is not covered in this chapter and you can contact them by phone.

Quick Troubleshooting

The following is a list of the most common problems encountered by a typical Columbus™ system user. Other sections of this chapter discuss issues that require further resolution.

1） Problems with workstations (e.g., power failure, poor operation).
   - Refer to the documentation provided with the workstation.
   - If you are unable to identify the cause of the problem, contact MicroPort's technical support personnel.

2） Issues with LCD displays (e.g. no images, power indicator flashing).
   - Refer to the documentation provided with the LCD.
   - If you are unable to identify the cause of the problem, contact MicroPort's technical support personnel.

3） The message "Location Processing Unit Communication Abnormal" appears after a new procedure is created.
   - Check whether the fiber-optic communication cable between the patient interface unit and the network switch is connected or damaged.
   - Check whether the network cable between the network switch and the workstation is connected or damaged.
   - Check that the magnetic field generator is properly connected to the patient interface unit.

4） An error message is received indicating that the Columbus™ External Reference Patch or

Magnetic Mapping/RFA Catheter (or both) is out of range.

- The Magnetic Mapping/RFA Catheter or Columbus™ External Reference Patch is located outside of the positioning area. You need to readjust the relative position between the magnetic field generator and the patient.
- Magnetic Mapping/RFA Catheter not connected to tail line.
- Check that the magnetic field generator is installed in the correct position.

5） An error message is received indicating that the positioning data of the positioning catheter is missing.

- Check that the field generator is installed correctly.
- Check for strong ferromagnetic interference with the Magnetic Field Generator or Magnetically Located Mapping/RFA Catheter. Try adjusting the DSA and table position.
- Check that the Magnetic Mapping/RFA Catheter is in a strenuous position. Try moving the Magnetic Mapping/RFA Catheter to a more stable area.

6） No errors are displayed in the system state, but no heart signal appears in the map or reference channel.

- FORLNK™ Cable for 3D Irrigated Ablation Catheter failed or disconnected. Check the tail line and replace if necessary.
- If you are unable to identify the cause of the problem, contact MicroPort's technical support personnel.

7） Noise and distorted signals are present in the monitoring window.

- The patient's surface ECG lead connector is loose.
- Surface electrodes on right leg loose.
- Check the connection of the Magnetically Located Mapping/RFA Catheter and FORLNK™ Cable for 3D Irrigated Ablation Catheter.

8） The catheter icon moves in the opposite direction as expected.

- The installation direction of the magnetic field generator is wrong. Follow the instructions in the manual to reinstall the magnetic field generator. You will need to abandon the previously collected data.

9） When printing a map, the content of the printout is incorrect (for example, another patient's map).

- The printer was offline, so the print job queue has the last print. Once the previous task has been completed, the current map is printed.
- If you are unable to identify the cause of the problem, contact MicroPort's technical support personnel.

Appendix III

Shortcut Key List

Collection position point	**Enter key**
Freezing/Receiving Mapping Points	**F11**
Reject Mapping Point	**F12**
Delete Point	F7
Recovery Point	F9
Open/Close Point Label Dialog Box	F8
Toggle Transparent/Non-Transparent	F5
Reduce the point-by-point filling threshold	F3
Increase the dot-by-dot filling threshold	F4
Switch different perspectives, such as AP, PA, etc.	F6
Small amplitude rotation map(3 °steps)	Up/down/left/right arrow
Pointwise ring opening	Ctrl+ select three points in turn
RTM generates annulus point	Ctrl+ left mouse button
RTM Regulating Annulus	Left mouse button hold annular point + keypad(+/-)
Transparency adjustment	Left mouse button hold map + keypad(+/-)
Erase grid of RTM map	Shift+ left mouse button
Erase the QuickVolume and grid of the RTM map	Ctrl+Shift+ left mouse button
Rotary map	Middle mouse button
Pan map	Alt+ left mouse button
Freeze multi-channel screen + generate freeze event	Space bar
Record multiple manual events	**F1**
The ECG playback screen is updated to the start position.	Home button
ECG playback screen updated to the latest	End button
Turn the ECG playback screen forward	PageUp button/up arrow
Turn back the ECG playback screen	PageDown button/down arrow
Browse the ECG playback screen forward	Left arrow

Backward browsing of ECG playback screen	Right arrow
Switch the breath detection channel	Click to select the Breathing window, then press B
Recalculate respiratory detection threshold	F10