EverPace™

Columbus™

Cardiac Electrophysiology Stimulator

User Manual

Shanghai MicroPort EP MedTech Co., Ltd.

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CE 0123

Statement

This user manual is only used as instructions for installation, operation, maintenance and repair of Columbus™stimualtor. All diagnosis conclusions should be drawn by the doctor using this stimulator according to his own medical expertise and all the liabilities arising thereof shall be borne by the doctor himself. Shanghai MicroPort EP Medtech Co., Ltd. shall bear no liability for any of such diagnosis conclusions or any corresponding medical measure.

Please strictly observe the instructions given in this manual which introduces some important information.

The content contained in this manual may be altered without prior notice.

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Table of Contents

Read carefully these instructions before use.

1. Overview

DF-5A cardiac electrophysiology stimulator is a new high-tech product with high-precision integrated technology and medical technology. It was designed meticulously by combining clinical practice of many years and absorbing the constructive suggestions from experts in terms of cardiac electrophysiology. This instrument has the following features: multiple functions, stable performance, easy access, safe and reliable, compact and smart design.
DF-5A cardiac electrophysiology stimulator adopts advanced microcomputer technology and is specific for cardiac electrophysiologic examination. Its service life is 5 years.
The stimulator is an important way for cardiac electrophysiologic examination. It's used to impose one or several electric pulse stimulus in certain moment of cardiac cycle, observe the cardiac feedback to the stimulus, learn the cardiac electrophysiologic features, clarify the mechanism of arrhythmia so as to guide clinical diagnosis and treatment.
Mode of stimulus pulse is divided into basic stimulus (non-programmable) and premature beat stimulus (programmable).

2. Application

Columbus™ Cardiac Electrophysiology Stimulator is used to impose one or several electric pulse stimulus in certain moment of cardiac cycle, observe the cardiac feedback to the stimulus, learn the cardiac electrophysiologic features, clarify the mechanism of arrhythmia so as to guide clinical diagnosis and treatment for the tachyarrhythmia.

3. Safety Information

3.1 Contraindications and indications:

Contraindications: Severe cardiac insufficiency, acute myocardial infarction, unstable angina pectoris, syndrome of long Q-T, ventricular tachycardia or Adams-Stokes. For stenocardia, deterioration of cardiac function and malignant arrhythmia may be caused during the process of pace-making and little clinical significance, the examination should be abandoned.

Indication: Columbus™ Stimulator is used to impose one or several electric pulse stimulus in certain moment of cardiac cycle, observe the cardiac feedback to the stimulus, learn the cardiac electrophysiologic features, clarify the mechanism of arrhythmia so as to guide clinical diagnosis and treatment for the tachyarrhythmia.

3.2 Warnings

① Columbus™ Cardiac Electrophysiology Stimulator can only be used with the Columbus™ 3D EP Navigation System. In case of being used with other system, Columbus™ Cardiac Electrophysiology Stimulator may work abnormally or cause improper Stimulus output.

② Medical personnel of the hospital should monitor the battery level to avoid no enough electricity to complete

the stimulus

③ Columbus™ Cardiac Electrophysiology Stimulator should be placed away from or stacked with other devices when used. If it's really required to be used as this, remember to check if Columbus™ Cardiac Electrophysiology Stimulator operates normally under such situation.

④ Intentional misuse of Columbus™ Cardiac Electrophysiology Stimulator may cause serious injury to the operator and patient.

3.3 Cautions

① Before the operation, check the performance of the instrument, make sure the electricity quantity is sufficient and be familiar with the operation process.
② The operator should read the application sheet carefully and ask for any unclear points so as to know well the status of the patient.
③ Make sure whether the patient has any contraindication.
④ Explain the necessity and safety of the check to the patient and his/her relatives to eliminate their worries.
⑤ Stop to use the drug which may effect the examination results for at least 45h. The drugs are mainly for anti-arrhythmia that will effect the cardiac electrophysiological properties.
⑥ Abrosia is not necessary if the examination is 2h after the patient having meal.
⑦ Equip electrocardiogram, electrocardiogram with oscilloscope or polygraph electrocardiogram recorder. Keep the equipment functions well and prepare enough electrocardiograph paper.
⑧ R wave signal input wire, pulse output wire and connection wire that are not damaged and function well.
⑨ Prepare iodine tincture, ethyl alcohol, adhesive plaster, gauze, etc.
⑩ To prevent accident, prepare defibrillator, oxygen, instrument for venous transfusion, rescue drugs and anti-arrhythmia drug.
⑪ It needs 1 doctor and 1 technician (nurse) to operate the instrument; one controls the stimulator and the other record electrocardiogram.
⑫ It's prohibited to use cellphone when the instrument is in operation.
⑬ Operation in close proximityto a shortwave or microwave therapy me equipment may produce instability in the stimulator output.
⑭ Advice that a patient with an implanted electronic device (for example a cardiac pacemaker) should not be subjected to stimulation unless specialist medical opinion has first been obtained.
⑮ To prevent explosion hazard, never use the Cardiac electrophysiology stimulator in environments with flammable anesthetic.
⑯ To prevent electric shock and fire hazard, keep Cardiac electrophysiology stimulator from excessive wet.
⑰ The equipment has been tested to be in accordance with restricted conditions for medical device specified in IEC 60601-1-2, which conditions are designed to provide reasonable protection against harmful interference during installation of general medical devices.

A:High-energy RF interference (RFI) and electromagnetic radiation (EMR) from outside may lead to false alarm or malfunction of electrical unit like Cardiac electrophysiology stimulator. What's more, such electrical units as Cardiac electrophysiology stimulator may also cause ECG monitoring system which is not under optimal condition to generate false signals. Although the Cardiac electrophysiology stimulator described in this manual is designed with capability to prevent such interference, safe running inspection should be conducted on it before it's used with RF electric surgical device, electromagnetic navigation system and ECG monitoring system on patient. In case of any disturbance, please reconfirm position of Cardiac electrophysiology stimulator.

B:Failing to install and use it may cause harmful interference over other devices near it. The pump has been tested to meet restricted conditions of medical device, but we cannot promise certain installation won't produce any disturbance. In case harmful interference really occurs to other devices (to determine by turning on and off the

pump system), user can eliminate it in one or more ways listed below:
Change direction or position of the receiving device.
Expand distance between devices.
Connect the pump system to socket in other circuits, which is different from that used by other devices.
Consult manufacturer for help.

⑱ The Cardiac electrophysiology stimulator does not contain any parts with user-performed maintenance.

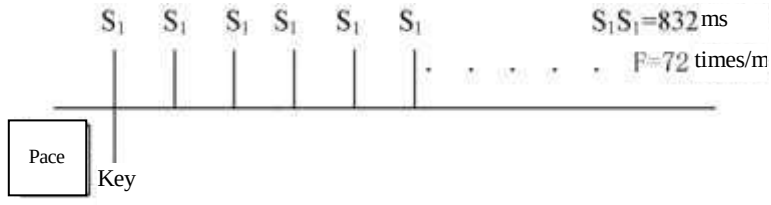
⑲ The Cardiac electrophysiology stimulator should be calibrated by manufacturer; any setting modification may lead to abnormal running of the equipment and shall void warranty.

4. Function

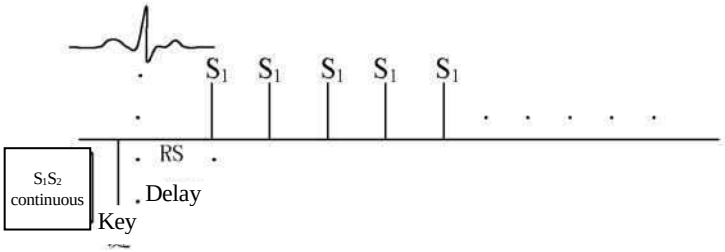
There are two types of stimulating pulse of DF-5A cardiac electrophysiology stimulator: basic stimulus and premature beat stimulus.

4.1 Basic stimulus

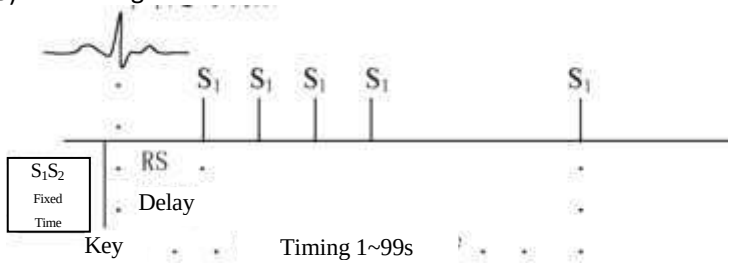
(1) pacing stimulus



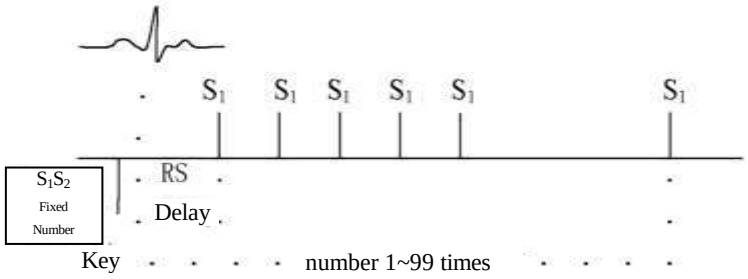
(2) S_1S_1 continuous stimulus



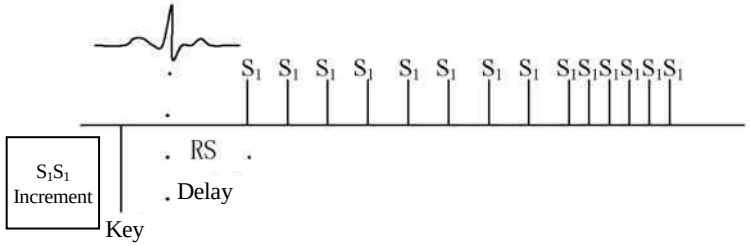
(3) S_1S_1 timing stimulus



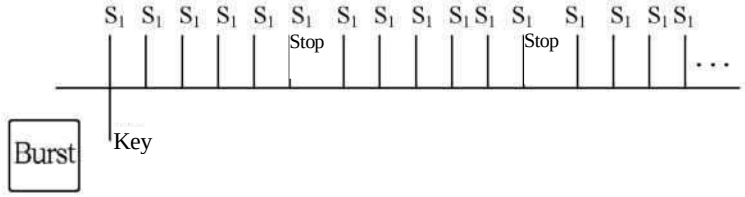
(4) S_1S_1 numbering stimulus



(5) S_1S_1 stimulus increasing/decreasing

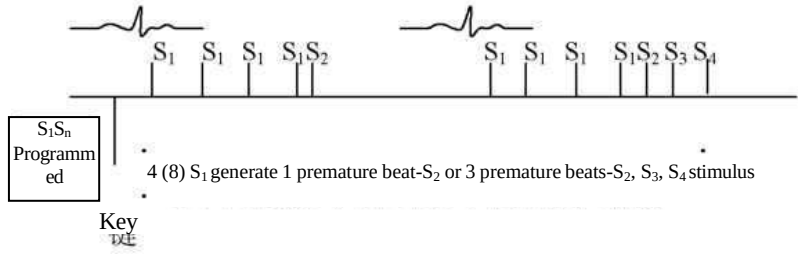


(6) Quick stop stimulus

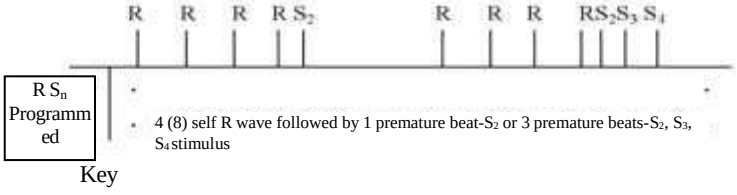


4.2 Premature beat stimulus

(1) S_1 Synchronous programmable premature beat stimulus, short for $S_1S_2(S_3)(S_4)$ stimulus



(2) R-wave synchronous programmable premature beat stimulus, short for $RS_2(S_3)(S_3)$ stimulus



5. Technical Index

5.1 Safety Classification

① Product type: DF-5A
② Protection against electric shock: internally powered equipment.
③ Applied Parts type : Type CF Applied Parts and Defibrillation-proof Applied Parts
④ Protection against harmful ingress of water or particulate matter: it is non-protective equipment.
⑤ Protection against flammable anesthetic gas: it does not belong to category AP or APG equipment.
⑥ Mode of operation: Short-time continuous operation.
⑦ According to its signal input/output component: No signal input/output component.
⑧ In accordance with requirement in standard IEC 60601-1 Chapter 8, the corresponding classification as below:

- Overvoltage category II
- Rated operating altitude 2000m
- Comparative tracking index (CTI) IIIb
- Pollution degree II

5.2 Generation of stimulus pulse

The output of stimulus pulse is triggered by R wave, i. e. By pressing the generation key, the stimulus pulse is generated after sensing 1 R wave and delaying 1 RS_1 interval. The value of RS_1 is automatically calculated by the heart rhythm of the patient sensed by the instrument. So the delayed generating stimulus is positioned by R wave and will not fall on the refractory period and the vulnerable period so as to generate effective and safe stimulus. But the S_1S_1 stimulus pulse can be released randomly (there's no mode of R wave sensing).

5.3 The setting range of each coupling interval and frequency

5.3.1 S_1S_1 coupling interval 60~1999 ms initial value 832 ms
S_1S_1 stimulus frequency 30~1000 times/min. initial value 72times/min.
5.3.2 S_1S_2, S_2S_3, S_3S_4 coupling interval 60~999 ms
initial value 500ms

5.4 Setting range of S_1S_1 timing stimulus

1~99 s initial value 30 s

5.5 Setting range of S_1S_1 numbering stimulus

1~99 initial value 8

5.6 Number of premature beat stimulus

Optional S_2, S_3, S_4; it can scan automatically for the last premature beat stimulus and the previous coupling interval.

5.7 Scanning step length

Positive scanning: +5, +10 initial value 0
Negative scanning: -5, -10

5.8 Programmable premature beat stimulus ratio selecting

The setting of intracardiac 8:1, 4:1 is selected by “output selection” switch.

5.9 Output range

Intracardiac stimulating voltage 0~8V continuously adjustable
（load impedence is 500±10%）

5.10 Output pulse width
Intracardiac stimulating pulse width 1ms factory set, unadjustable.

5.11.10 R wave heart rate sensitivity
body surface ≥1mv

5.12 Power supply
1 set of rechargeable polymer lithium battery (2000mAh), power supply 7.4V. The battery must be charged continuously for 5~6 hours.

⚠ **Excessive charging may cause the battery leakage or reduce battery life, please according to 12"The Use of Charger and Battery"**

5.13 Charger
Input AC voltage 100-240V, 50/60HZ
Output DC voltage DC9V, 1.1A

⚠ **Please use the charger provided by the original manufacturer to charge, use other charger to charge may damage the battery.**

5.14 Power consumption
Max. current 200mA, Min. current 85mA.

5.15 Operation duration
10 hours of continuous use after the battery was charged sufficiency.

5.16 Operation environment
Good ventilation, no corrosive gas, no high voltage interference, ambient temperature 0℃~35℃, relative humidity below 80%, barometric pressure 900hPa~1060hPa.

5.17Storage and transportation conditions

1） Temperature: -40℃- +50℃

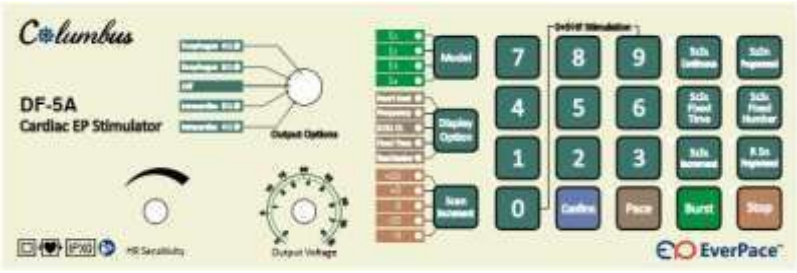
2） Relative humidity: ≤80%, non-condensation

3） Atmospheric pressure: 500hPa - 1060hPa

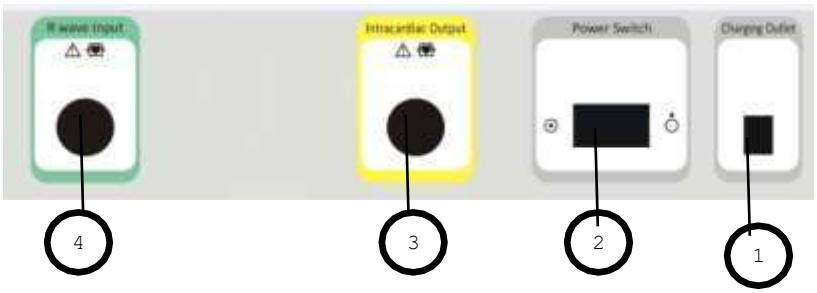
5.18 Dimension
320mm × 190mm × 80mm

5.19 Weight
1.5Kg (exclude package)

6. Front View of the Instrument



7. Rear View of the Instrument



8. Accessory

9. Functions of the Instrument and Instruction of Key Panel

9.1 Description of functions key

①Battery charging socket
The plug of the charger which outputs VDC is inserted into the socket to charge the battery; it should be charged continuously for 5~6 hours.

②Power switch
Press “On” to switch on; press “Off” to cut off the power.

③ R wave input socket(Applied part)
Insert the plug of R wave input-wire (green) into R wave input socket; connect one clamp of the wire onto the right upper extremity of the patient, and the other onto the left lower extremity.

⚠ **Avoid making those clamps falling down the ground to cause danger**

④ Pulse output socket(Applied part)
Use the output switch on the key panel to choose intracardiac (yellow) (max. 8V) output.

⚠ (**Avoid making those clamps falling down the ground to cause danger**

⑤Heat rate-sensing knob
Turn the knob anticlockwise to lower sensitivity. Turn the knob clockwise to increase sensitivity till the instrument can stably sense the R wave signal.

6 Output level knob
The inner circle with green figure 0~8V presents the output voltage of intracardiac stimulus;
7 Output selection switch
Intracardiac: used for intracardiac stimulus (8:1, 4:1 optional)
Off: turn off the output circuit, no output.
8 Display window
Display: R-R self heart rate, S_1S_1 stimulus frequency, the coupling interval of S_1S_1
9 Display window
Display: S_1S_2 or the coupling interval of RS_2 premature beat stimulus
10 Display window
Display: S_2S_3 the coupling interval of the second premature beat stimulus
11 Display window
Display: S_3S_4 the coupling interval of the third premature beat stimulus
12 Display window
Display: S_1S_1 the time and quantity of basic stimulus
13 Unit indicator
Indicate the unit of the parameter in the display window including indicator of times/min., ms, s, number.
14 Power display
Display current power quantity and charging indication
15 Sensing lamp
Flash once when it senses R wave signal, and the instrument makes a short beep sound.
16 stimulus lamp
Flash once when it senses a stimulus pulse and the instrument makes a short beep sound.
17 Charger
Insert two pieces of sheet metal of the charger into the AC power socket of 100-240V, 50/60HZ; insert the DC output plug into the charging socket of the instrument.
18 Intracardiac output cable (yellow)
19 R wave input cable
One end of it is connected to the instrument; the red clamp of the other end is connected to the right upper extremity and the black clamp is connected to the left lower extremity.

9.2 Instruction of functions of key panel

9.2.1 (Display Option) key
Select parameters showed on the display window
9.2.1.1 "Heart beat"
Display selection key, when the lamp for heart rate lights, the display window indicates self R-R heart rate (in case of sensing R wave); if it does not sense the R wave, the display window will show figures randomly.
9.2.1.2 "Frequency"
Display selection key, when the lamp for frequency lights, the display window indicates S_1S_1 stimulus frequency, initial value 72times/min.
9.2.1.3 "S_1S_1 CL"
Display selection key, when the lamp for interval lights, the display window indicates the interval of S_1S_1 basic stimulus, initial value 832 ms.
9.2.1.4 "Fixed Number"
Display selection key, when the lamp for stimulus number lights, the display window indicates the number of S_1S_1 stimulus, initial value 8.

9.2.1.5 “Fixed Time”

Display selection key, when the lamp for stimulus time lights, the display window indicates the time of S_1S_1 stimulus, initial value 30 s.

9.2.2 (Mode) key

9.2.2.1“S_1”

In Stimulus mode, when S_1 lights, the display window only indicates the frequency and interval of S_1S_1; the instrument only generate S_1S_1 basic stimulus. The way of S_1S_1 stimulus includes: S_1S_1 continuous, S_1S_1 increasing/decreasing, S_1S_1 timing, S_1S_1 number.

9.2.2.2 “S_2”

In Stimulus mode, when S_2 lights, it generates 1 premature beat stimulus; display window indicates the coulping interval of S_1S_2, initial value 500 ms.

9.2.2.3 “S_3”

In Stimulus mode, when S_3 lights, it generates 2 premature beat stimuluses; S_2S_3 display window indicates S_2S_3 coupling interval, initial value 500 ms.

9.2.2.4 “S_4”

In Stimulus mode, when S_4 lights, it generates 3 premature beat stimuluses; S_3S_4 display window indicates S_3S_4 coupling interval, initial value 500 ms.

9.2.3 (Scan Increment) key

10.2.3.1 “-10”

The lamps lights when select "-10" by scanning step length key, negative scanning is S_1S_2, RS_2, S_2S_3, S_3S_4, S_3S_4 decreases 10 ms.

9.2.3.2 “-5”

The lamps lights when select "-5" by scanning step length key, negative scanning is S_1S_2, RS_2, S_2S_3, S_3S_4, S_3S_4 decreases 5 ms.

9.2.3.3 “0”

The lamps lights when select "0" by scanning step length key, in state of initialization, neither negative scanning nor positive scanning.

9.2.3.4 “+5”

The lamps lights when select "+5" by scanning step length key, positive scanning is S_1S_2 RS_2, S_2S_3, S_3S_4 increases 5 ms.

9.2.3.5 “+10”

The lamps lights when select "+10" by scanning step length key, positive scanning is S_1S_2, RS_2, S_2S_3, S_3S_4 increases 10 ms.

9.2.4 (S_1S_1 Continuous) key

Before operation, set (Display Option) key to make “Frequency” lights. Set the stimulus frequency of S_1S_1 by number key “0~9”, press (Confirm) key, then press (S_1S_2 Continuous) key to generate continuous stimulus pulse. Press (Stop) key to stop.

9.2.5 (S_1S_1 Fixed Time) key

Before operation, set (Display Option) key to make “Frequency” lights. Set the stimulus frequency of S_1S_1 by number key “0~9”, press (Confirm) key, then set (Display Option) key to make “timing” lights. After setting the stimulus time of S_1S_1 by number key “0~9”, press (S_1S_1 Fixed Time) key to generate stimulus pulse. When the timing is finished, the stimulus will stop automatically.

9.2.6 (S_1S_1 Fixed Number) key

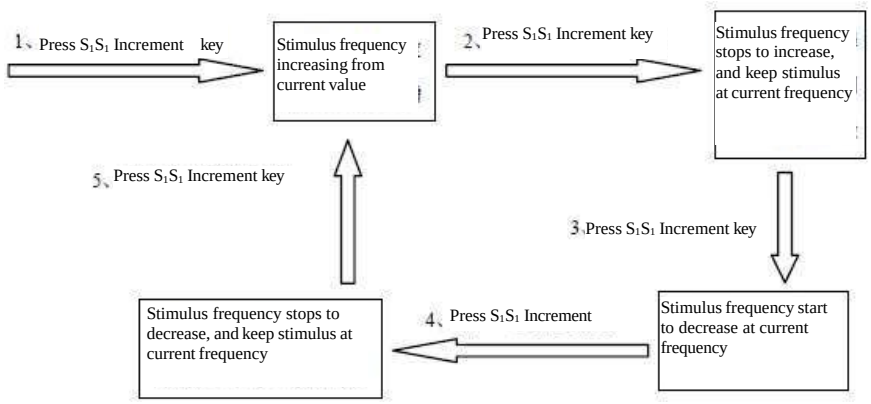
Before operation, set (Display Option) key to make “Frequency” lights. Set the stimulus frequency of S_1S_1 by number key “0~9”, press (Confirm) key, then set (Display Option) key to make “ stimulus number” lights. After setting the stimulus number of S_1S_1 by number key “0~9”, press (S_1S_1 Fixed Number) key to generate stimulus pulse. The instrument, in state of count-down, generates stimulus, when the numbering is finished, the stimulus will stop automatically.

9.2.7 (S_1S_1 Increment) key

Before operation, set (Display Option) key to make "Frequency" lights. Set the stimulus frequency of S_1S_1 by number key "0~9", press (Confirm) key, then press (S_1S_1 Increment) key to generate stimulus pulse, and the frequency will be increased to generate stimulus.
Description as follows:

When press S_1S_1 stimulus increasing/decreasing key for the first time, the instrument will activate S_1S_1 frequency increasing (If "0+9"combination key is not set before generating increasing stimulus, when the frequency is over 256 times/min., the instrument will stop stimulus automatically, This is due to its function of high frequency output limitation. If it needs to be over 256 times/min., use "0+9"combination key, see 10.2.13.2).
When press S_1S_1 stimulus increasing/decreasing key for the second time, stimulus frequency will stop to increase, and keep the stimulus at current frequency.
When press S_1S_1 stimulus increasing/decreasing key for the third time, stimulus frequency will decrease the stimulus from current frequency.
When press S_1S_1 stimulus increasing/decreasing key for the fourth time, stimulus frequency will stop to decrease, and keep the stimulus at current frequency.
When press S_1S_1 stimulus increasing/decreasing key for the fifth time, stimulus frequency will increase again. The above functions form a cycle. Press stop key to stop stimulus.

The operation process indicated as below:



9.2.8 (Pace) key
In any status, press this key, the instrument will generate a pace-making frequency of 72times/min. without any other setting.
9.2.9 (Burst) key
In any status, press this key, the instrument will quickly generate 6 tachycardia-terminating frequencies. The termination frequency of intracardiac is 180 times/min., 200times/min., 230times/min cycling.
9.2.10 (Confirm) key
Every time set a new value, it must press OK key after the setting, and otherwise the set value is invalid.
9.2.11 (S_1S_n Programmed) key
S_1S_n stimulus is a programming premature beat stimulus; the coupling interval of S_2 is matched up S_1. First set the interval of S_1S_1, then that of S_1S_2 or S_2S_3, S_3S_4. Select to increase or decrease the scanning step length, and the ration is 8: 1, 4:1. It means after 8 or 4 S_1 basic stimulus, generate one more premature beat stimulus S_2, or 2 (3) premature beat stimulus S_3 (S_4).

9.2.12 (RS_n Programmed) key
RS_n stimulus is a programming premature beat stimulus; the coupling interval of S_2 is matched up self R wave. Set RS_2 or S_2S_3 (S_3S_4) coupling interval, select scanning mode of positive or negative, ratio 8:1. This function can only be used

in case that R wave sensing is stable; every 8 self R wave followed by 1 or 2 premature beat stimulus.

9.2.13 "0+9" combination key

This key is for high frequency output limitation.

9.2.13.1 Function of high frequency output limitation

The instrument owns function of high frequency output limitation. When S_1S_1 stimulus frequency is over 256times/min., it will stop stimulating automatically.

If the stimulus frequency needs to be over 256times/min., it necessary to use the combination key before or in process of stimulating. Set as follows: Press and hold "0", then press "9" till hear a long beep to make stimulus frequency over 256 times/min., When this function is canceled in the following stimulus, the frequency is still limited to 256times/min.

10. Basic operation procedure:

The operation of atrial pacing in DF-5A cardiac electrical stimulation instrument.

10.1 scanning routine ECG

Patients with atrial pacing were examined by routine ECG examination.

10.2 intubation

The patient supine position, catheter head has good disinfection slightly bend a radian. With gauze to hold the catheter, through the puncture needle insertion. Insert action should be gentle, try to reduce the stimulation. Slowly down, such as the case of resistance can not be forced too much, should be returned a little, a little turn catheter, and then sent forward.

10.3 location

The optimal location of the atrium is determined by locating the electrode catheter. P wave shape is usually recorded in the lead, to determine the location, choose P wave positive and negative two-way or upright, and the most high amplitude of the location of the best pacing point. Electrode catheter is located in the ideal position, the patient's position should be as little as possible, so as to avoid electrode dislocation.

10.4 connection

10.4.1 chest lead electrode is placed in the V1 position according to the common electrocardiogram method.

10.4.2 connected to stimulate the pulse output line, will stimulate the pulse output line into the pulse output socket, in which the black clip close to the end electrode, the red clip connected to the distal electrode (P wave positive and negative values).

10.4.3 connect heart rate sensing input line. One end of the heart rate sensing input wire is inserted into the instrument's heart electrical signal input socket, the other end of the Black clamp is connected with the patient's left lower limb lead electrode, and the red clip is connected with the electrocardiogram electrode of the right upper limb. If the connected according to the above method, in case of a few patient limb lead low voltage, of low R wave perception of poor or do not perceive, the red clip from the right upper limb change precordial electrode connected, placed in V2.

10.5 boot

Before switching on the power switch, the output selector should be placed in the "8: 1 or 4: 1", "the output amplitude (V)" is placed in the "0" position. At this time, the boot status indicator". The numerical display and the unit indicator light show that the instrument is in normal condition.

10.6 tone heart rate sensing

Adjusted heart rate sensing sensitivity. The stimulus pulse of the instrument adopts the R wave trigger mode, that is, according to the release key, to perceive a R wave, in the delay of a RS1 interval, and then send out the stimulus pulse. The delay value of RS1 is calculated by the instrument based on the perception of the patient's own heart rate. R wave positioning of the stimulus, will not fall on the refractory period or the duration of the duration of the period, in order to ensure the effectiveness and safety of the stimulus. So it is very important to adjust the perceptual sensitivity.
The specific method is: the perception sensitivity knob along slowly rotating clockwise, transferred to the perception to the R wave can hear instrument issued a "beep... Du..." The sound of the buzzer, the display of the window of the perception of light synchronous flashing lights. In order to ensure that the instrument can stably all sense R wave, the sensitivity should be slightly higher. The sensitivity of the adjustment must be suitable for. Sensitivity is too high to perceive other interfering signals. Low sensitivity is not fully aware of the R wave.

10.7 measurement threshold

To measure the pacemaker threshold, the pacemaker threshold is the minimum pacemaker voltage that can lead to the activation of the heart. In different parts of the heart to stimulate, the required stimulation voltage is different, the voltage of the heart chamber stimulation of 0 ~ 8V adjustable,
The pacing threshold was measured by continuous pacing. Set at frequencies higher than its heart rate 20 times per minute about pacing, pacing pulse width of 10 ms (instrument has been set esophageal block pulse width is 10 ms). After the start of S1S1 stimulation, the output amplitude knob is adjusted by the low to the high slow output voltage range. To observe the effect of pacing on the ECG and the ECG, and determine the pacing threshold. All cardiac pacing is in after each stimulus pulse has a corresponding to the QRS wave, in the actual operation, in order to ensure the stimulation can all atrial pacing, pulse voltage amplitude should be higher than the pacing threshold 2 ~ 5V.

10.8 record ECG

Atrial pacing can choose different ways to record ECG, single channel ECG machine, choose I and II lead or lead V1, its advantages: I lead recorded baseline is relatively stable, small pulse potential, small P wave voltage; lead II log P wave visible, but the pulse potentials, sometimes P wave pulses mask; V1 log P wave was clear, but baseline stability is relatively poor. The best choice for 12 lead ECG synchronous record or selecting I, V1, AVF and intracardiac lead, contribute to the initial location of the reentrant pathway analysis and accessory pathway.
It is best to use a single lead ECG recording with ECG, in order to operate the continuous monitoring of ECG, according to the need to record ecg.

10.9 check

According to the patient's medical history, according to the examination of the purpose of a variety of modes of electrical stimulation, after all, press the "stop" button, cut off the power switch, dial out the electrode catheter.

11. Operation for Generating Stimulus Pulse

11.1 S_1S_1 continuous stimulus

11.1.1 The instrument is in sate of stop.
11.1.2 Select intracardiac stimulus by "Output Option" switch.
11.1.3 (Mode) key in position S_1.
11.1.4 (Display selection) key in position frequency.
11.1.5 Set stimulus frequency (0~20times/min. higher than self heart rate) by number key "0~9", then press "Confirm".
11.1.6 Press (S_1S_1 Continuous) key to generate S_1S_1 continuous stimulus pulse.
11.1.7 Press (Stop) key to stop.

11.2 "S_1S_1"timing stimulus.

11..2.1 The instrument is in state of stop.
11.2.2 Select intracardiac by "Output Option" switch.
11.2.3 (Mode) key in position S_1.
11.2.4 (Display Option) key in position frequency.
11.2.5 Set stimulus frequency by number key "0~9" then press "Confirm".
11.2.6 (Display Option) in timing position.
11.2.7 After setting the timing by number key "0~9", press "Confirm" (initial value 30 s.)
11.2.8 Press (S_1S_1 Fixed Time) key to generate S_1S_1 countdown stimulus; when stimulus time ≤10 s., the tune of the beep sound of stimulus pulse will change to remind the operator to record electrocardiogram; stimulus generating will stop automatically when the countdown is finished.

11.3 "S_1S_1"numbering stimulus

11.3.1 The instrument is in state of stop
11.3.2 Select intracardiac stimulus by "Output Option" switch.
11.3.3 (Mode) key in position S_1.
11.3.4 (Display Option) key in position frequency.
11.3.5 Set stimulus frequency by number key "0~9" then press "Confirm".
11.3.6 Display the selection in numbering position.
11.3.7 After setting the number of stimulus by number key "0~9", press "Confirm" (initial value 8)
11.3.8 Press (S_1S_1 Fixed Number) key to generate S_1S_1 countdown stimulus; stimulus generating will stop automatically when the countdown is finished.

11.4 "S_1S_1" increasing/decreasing stimulus

11.4.1 The instrument is in state of stop.
11.4.2 Select intracardiac stimulus by "Output Option" switch.
11.4.3 (Mode) key in position S_1.
11.4.4 (Display Option) key in position frequency.
11.4.5 Set stimulus frequency by number key "0~9" then press "Confirm".
11.4.6 Press (S_1S_1 Increment) key to generate S_1S_1 stimulus frequency and increase stimulus of each frequency on base of setting.
11.4.7 When reach to the required stimulus frequency, if keep the stimulus frequency not to increase, press (S_1S_1 Increment) key once again.
11.4.8 If the stimulus needs over 256times/min., use combination key "0+9".
11.4.9 Press (Stop) key to stop, refer to 10.2.7.

11.5 "S_1S_2"or"$S_1S_2S_3$"($S_1S_2S_3S_4$) programming premature beat stimulus

11.5.1 The instrument is in state of stop.

11.5.2 Select intracardiac stimulus by "Output Option" switch.
11.5.3 (Mode) key in position S_1.
11.5.4 (Display Option) key could be in position both of frequency and interval.
11.5.5 Setting of S_1S_1 stimulus frequency or S_1S_1 stimulus interval are both OK. For setting of S_1S_1 stimulus frequency, it needs to be higher self heart rate; for setting of S_1S_1 stimulus interval, it needs to be smaller than self R-R interval. Press "Confirm" after finishing the setting.
11.5.6 Stimulus mode key is set in S_2.
11.5.7 Set coupling S_1S_2 interval, S_1S_2 interval smaller than S_1S_1 interval, then press "Confirm".
11.5.8 Select positive scanning (+) or negative scanning (-) by scanning step length key.
11.5.9 Stimulus ratio are 8:1 and 4:1, i.e. 8 (4) of S_1 followed by 1 added premature beat S_2, It is switched by "Output Option".
11.5.10 Press (S_1Sn Programmed) key to generate S_1S_2 programming premature beat stimulus, stop for 5 seconds then automatically generate stimulus pulse. If it induces tachycardia, after pressing (Stop) key, then press Burskey to generate quick stimulus frequency to stop tachycardia.
11.5.11 If 2 premature beats need to be added, i.e. S_2S_3 stimulus, set (Mode) key in S_3 on base of S_1S_2 premature beat stimulus; set S_2S_3 interval; the interval of S_2S_3 should be smaller than that of S_1S_2, then press (Confirm) key. Select scanning: positive or negative, when the key for generating is also for pressing (S_1Sn programmed) , the coupling interval of S_2S_3 is changing whereas the coupling interval of S_1S_2 is fixed. It stops for 5 s. before next stimulus till complete the required examination.
11.5.12 If 3 premature beats need to be added, operate as above.

11.6 "RS_2"or"RS_2S_3" ($S_1S_2S_3S_4$) programming premature beat stimulus

11.6.1 The instrument is in state of stop.
11.6.2 Select intracardiac stimulus by "Output Option" switch.
11.6.3 (Mode) key in position S_2.
11.6.4 Set the coupling interval of RS_2, The interval of RS_2 should be smaller than R-R interval, then press "Confirm" key.
11.6.5 Scanning step length selects positive (+) or negative (-) scanning.
11.6.6 Select ration 8:1, i. e. 8 cardiac cycles followed by 1 premature beat stimulus S_2; if select ration 4:1, i. e. 4 cardiac cycles followed by 1 premature beat stimulus S_2.
11.6.7 Press (S_1Sn Programmed) key, the instrument is to generate stimulus, i. e. 8 (4) cardiac cycles followed by 1 added premature beat stimulus S_2; the coupling interval increases or decreases gradually till complete the required examination.
If it induces tachycardia, press (Stop) key, then press Burs **key to stop.**
11.6.8 If 2 or 3 premature beat stimulus need to be added, i.e. RS_2S_3 (S_4), its parameter setting is the same as that of $S_1S_2S_3$.

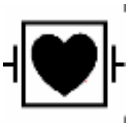
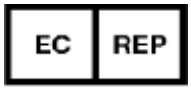
12. The Use of Charger and Battery

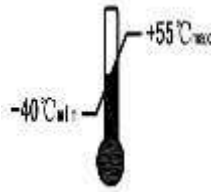
Turn on the power switch of the instrument, if the light column displayed in the "power display" is less than 2 squares, it will not light, which indicates that the battery voltage is not sufficient and charging is needed. During the charging, the instrument is turned off; connect the plug of the charger to AC 100V-240V,50/60HZ network power supply; the DC output plug of the charger is connected with the socket for charging of the instrument; during the charging, the "power quantity display" window flashes, which indicates that it is in process of charging; when the power is full, the window stops to flash and lights; the charging usually takes 4~5 hours. When the charger is charging for the internal battery of the instrument, the instrument will cut off internal power supply to guarantee power safety.

If the instrument is not in use for a long time, it should charge once a month to increase service life. It is polymer lithium battery with battery capacity of 2.0Ah .

⚠ **Instrument should not be put in place where it is difficult to operate the device.**

13. Figures Description

Refer to instruction manual		The Stimulator should be accompanied with corresponding documents when it leaves the factory. Before starting to use the system, please thoroughly refer to instructions for use.
Defibrillation-proof Type CF Applied Part		The equipment is mark of defibrillation-prevention of CF type
Authorized representative		The identification is “Authorized representative in EU market”
Manufacturer		Representing the identification of Stimulator manufacturer
Caution		Please read the specification before using the Stimulator
Upward		Correct placement direction of packing case during transportation
Fragile		The goods are fragile, and please handle with care during transportation

Keep dry		Please keep dry during transportation
No heavy load		To prohibit the placing of heavy objects on a surface.
Temperature Limitation		The temperature during transportation shall be kept in between -40℃ and 55℃.
Humidity Limitation		The humidity during transportation shall be kept in between 10% and 90%.
Separate collection of electronic and electrical equipment		The equipment and accessories shall abide by requirements of separate collection of electronic and electrical equipment at end of life;
Serial number		Product ID

14. Packing, Transportation, Storage, Maintenance ， Waste disposal

Packing
The stimulator is wrapped by neutral plastic bag and put into aluminum case. There should be compliance certificate, packing list, warranty card, charger, accessory and instruction manual.

Storage and transportation
Pull out the AC plug before long-time storage of the stimulator. Store and transporting the stimulator in environment recommended in section **5.17 "Storage and transportation conditions"**.

Maintenance
If the instrument is in the warranty period, manufacturer is responsible for maintenance. In case of out of warranty period, please contact with the manufacturer. The electrical diagram and elements list is not included in the instruction manual.

The stimulator should be operated in ambient room in environment recommended in section **5.16 "Operation environment"**, good ventilation, no corrosion gas. The operation duration is 5 hours.

Keep the surface of the instrument clean; wipe its surface use lint-free flannel/mat dipped in 75% ethyl alcohol after each use and put into the aluminum case. Otherwise it may result bad effect.

Clean its input/output wire use lint-free flannel/mat dipped in 75% ethyl alcohol after each use; do not leave them about to avoid damage.

Waste disposal

Electronic wastes not disposed properly may lead to environmental and health risks. Please abide by local laws and regulations concerning e-waste disposition. In order for appropriate disposition, you may send the discarded Stimulator to local agent for disposition. When lower power is displayed for Stimulator and can not be resolved by charging, contact the manufacturer for replacement under guidance of professionals or by after-sales personnel.

15. After-sale Service

Note:

To ensure safety performance of the product, repair and safety inspection can only be performed by the manufacturer, the engineer or service centre approved by the manufacturer. According to IEC / EN 60601 – 1 and its sub-standard as well as IEC /EN 62353, at least one safety check is required every year after repair.

the user is not allowed to dismount and maintain other parts of Columbus™stimualtor. Maintenance or modification of any stimualtor and accessories must be performed by manufacturer or the service engineer and service center approved by manufacturer.

MANUFACTURER will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair.

15.1 Warranty period
Free warranty period for DF-5A cardiac electrophysiology stimulator is 12 months from the date of purchasing (subject to the purchase invoice) on condition that the user observing the application rules

15.2. Warranty method

In case that the DF-5A cardiac electrophysiology stimulator is in fault within the warranty period (except the man-made damage, such as falling down, misuse), the factory will provide maintenance for free.
In case that the DF-5A cardiac electrophysiology stimulator is in fault within the warranty period, without the agreement from the manufacturer, the disassemble or fix by user are not warranted; for any discrepancy or altering to the instrument serial number or warranty card No., the instrument is not warranted.
In case that the DF-5A cardiac electrophysiology stimulator is in fault out of the warranty period, the user can mail the instrument back to manufacturer together with warranty card. The fees generated from test and maintenance is on actual base.

15.3.Safety inspection

Self-test of is required before every use, and maintenance is not allowed during the stimulator application (connected to patient). Specific inspection items are as below:

- All the knobs are not released, adjustment of the knob can modify values on the screen properly.
- All the keyboard button without exception， adjustment of the button can modify values on the screen properly.
- There's no damage or loosening of the socket.
- There's no damage of the power cable.
- Electricity to keep the full grid state

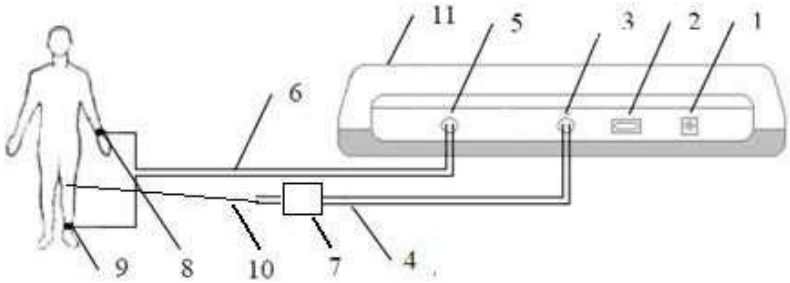
Perform the above and following verifications once a year:

- The equipment is transported with complete label and legible text.
- Pulse output width， range.

If necessary, sign a service contact; please contact the customer support.

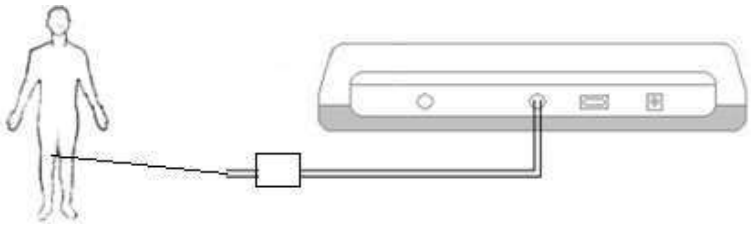
Appendix I: connection diagram

a) R wave sensing mode:



1. Charging socket 2. Power switch 3. Intracardiac output socket
4. Stimulus lead wire 5. Sensing input socket 6. Sensing lead wire
7. EP Recording System 8. L (left hand) lead (green) 9. F (left foot) lead (yellow) 10. Catheter 11. DF-5A stimulator

b) Random generating mode (no R wave sensing mode)



Appendix II：EMC Information

The data in the following table shows that the stimulator conforms to requirements in IEC60601-1-2:2007;

Guidance and manufacturer's declaration – electromagnetic emissions- for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration – electromagnetic emission		
DF-5A/Cardiac EP stimulator is intended for use in the electromagnetic environment specified below. The customer of the user of DF-5A/Cardiac EP stimulator should assure that it is used in such and environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	DF-5A/Cardiac EP stimulator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	DF-5A/Cardiac EP stimulator is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacture's declaration – electromagnetic immunity –
for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
DF-5A/Cardiac EP stimulator is intended for use in the electromagnetic environment specified below. The customer or the user of DF-5A/Cardiac EP stimulator should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for signal lines	±2 kV for power supply lines ±1 kV for signal lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of DF-5A/Cardiac EP stimulator requires continued operation during power mains dip & interruptions, it is recommended that DF-5A/Cardiac EP stimulator be powered from an uninterruptible power supply or a battery.

Power frequency (50/60Hz) magnetic field IEC61000-4-8	3A/m	3A/m	Power frequency magnetic fields Should be at levels characteristic of a typical location in a typical
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity –
for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity			
DF-5A/Cardiac EP stimulator is intended for use in the electromagnetic environment specified below. The customer or the user of DF-5A/Cardiac EP stimulator should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the DF-5A/Cardiac EP stimulator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz *d* Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which DF-5A/Cardiac EP stimulatoris used exceeds the applicable RF compliance level above, DF-5A/Cardiac EP stimulator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the DF-5A/Cardiac EP stimulator.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the DF-5A/Cardiac EP stimulator

DF-5A/Cardiac EP stimulator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.

The customer or the user of DF-5A/Cardiac EP stimulator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and DF-5A/Cardiac EP stimulator as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range

Appendix III：Common failures and troubleshooting

Failure phenomena	Cause of failure	Trouble shooting
R wave perception	Nearby there is a source of interference	Remove interference source or change site
	Lead electrode contact	Re clean the skin
	line fault	Replacement of lead wire
R wave sensing wave	Respiratory disturbance	Make the patient as calm as possible
	Electrode or lead wire shaking	Re placement of electrodes and lead wires
High threshold voltage	Electrode oxidation	Cleaning polishing electrode or replacement catheter
Stimulus no output	Stimulus lead wire break Stimulus circuit fault	Contact manufacturer for replacement Contact factory maintenance