	BioCONTROL MEDICAL BCM LTD	INSTRUCTIONS FOR USE	
	Doc No. RU-53-001	REV. H	
SUBJECT: UNIFIED PHYSICIAN PROGRAMMER			Page 1 of 40

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A	ARI KEREN-YAAR	06/08/2006	---	First Issue
B	ARI KEREN-YAAR	31/10/2006	---	Editorial Changes
C	ARI KEREN-YAAR	11/12/2006	---	Addition of buttons; add applicable icons and authorized representative
D	YITZHAK SINAI	01/02/2007	136	Update of device and software to 7.14
E	LEVY ITSIK	15/03/2007	---	Changes According TO ITL Remarks.
F	ROMANO AVINOAM	05/05/2008	153	Update to software 1.0.105
G	LEVY ITSIK	15/08/2008	KEMA 2103063	Adding battery lifetime contour; list of abbreviations; clarification of terms and warnings
H	RIGLER DAVID	28/12/2008	KEMA 2103063- 17.9.08	Addition of follow-up requirements; RF and FCC symbols and text Addition of ICD compliance; updating to software 1.0.14; updating troubleshooting and EMC requirements.

cardiofit™

Neurostimulator For Heart Failure Therapy

UNIFIED PHYSICIAN PROGRAMMER MODEL 5300

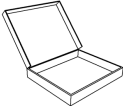


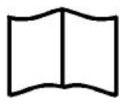






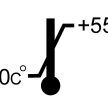
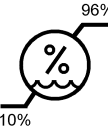

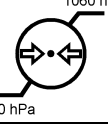



INSTRUCTIONS FOR USE (IFU) & TD


Caution: Limited by Federal Law to Investigational Use

CE 0344 (2008)

BIO
CONTROL
MEDICAL

Explanation of symbols on package labeling

Symbol	Explanation	Symbol	Explanation
	Contents		Warning: Patient Might Be Compromised
SN	Serial Number		Caution: possible damage to device
	Product Literature		Note: Important Information
	Consult Instructions For Use		Do Not Use If Package Damaged
	Type B Applied Part		Manufacturer
CE	European Approval Mark		Date Of Manufacturing
	On		Storage Temperature Range
○	OFF		Storage & Transport Relative Humidity Range
	Stepping Prohibited		Storage & Transport Atmospheric Pressure Range
	Sitting Prohibited	EC REP	Authorized Representative In The European Community
	Do Not Dispose Of. Contact BCM For Recycling.		Complies with FCC part 15

	Contains RF transmitters		
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List of Abbreviations

Abbreviation	Explanation
BCM	BioControl Medical
CIS	CardioFit™ Implanted Stimulator
CRT-D	Cardiac Resynchronization Therapy - Implantable Cardioverter - Defibrillators
CSL	CardioFit™ Stimulation Lead
ECM	Electromagnetic protection mode
HR / BPM	Heart Rate / Beats Per Minute
ICD	Implantable Cardioverter-Defibrillators, Single, or Dual chamber
IHRR	Instantaneous heart rate reduction
ISE	Intracardiac Sensing Lead
NYHA	New York Heart Association
PPB	Pulse Per Beat – The number of pulses provided by the stimulator per heartbeat
PRI	Pulse Repetition Interval – The distance between pulses when PPT > 1
QTP	Quasitrapezoidal Pulse – Shape of the default pulse
TD	Technical Dossier
UniPP	Unified Physician Programmer
VF	Ventricular Fibrillation
VT	Ventricular Tachycardia

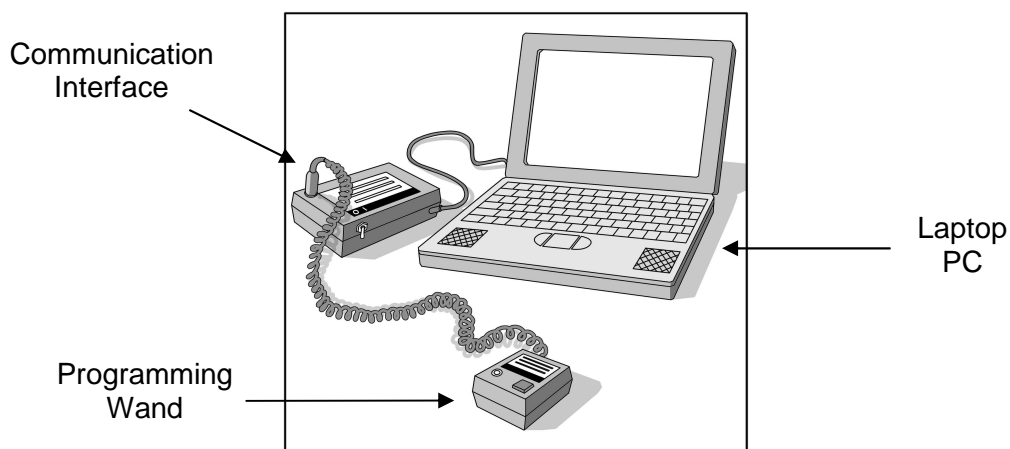
1. DESCRIPTION

Introduction

The model 5300 Unified Physician Programmer (UniPP) is used to interrogate and program the BioControl model 5000 CardioFit™ neurostimulator (the stimulator). The UniPP can retrieve data and set programmable parameters of the CardioFit™ stimulator via wireless communication. Programming is done using the CardioFit™ Physician Programmer software installed on a PC compatible laptop, a communication interface and a programming wand. The wand is the only part of the Programmer that contacts the patient.

The Physician Programmer software uses the communication interface and the programming wand to convert digital output from the Laptop PC to wireless signal format that is required for communication with the stimulator (**Figure 1**).

Figure 1 – Model 5300 Physician Programmer



Specifications and user information regarding the wireless technology

The CardioFit system uses a short-range (3-6 cm) inductive coupling communication scheme in frequency of 27kHz. The system is ready to communicate when green light is blinking in 1-2Hz on the programming wand. See warnings and precautions that should be exercised when using the system under Sections 3 and 4 below.

Contents of package

The model 5300 Physician Programmer package contains:

- a. One Laptop PC installed with BioControl CardioFit™ Unified Physician Programmer software version 2.0.x;
- b. One Communication Interface and Programming Wand (Model 4320);
- c. Medical grade power supply Model 4300/MPU100-106;
- d. Instructions For Use;

2. INTENDED USE / INDICATION

The model 5300 Physician Programmer is intended for use only with CardioFit™ systems, and is subjected to the same indications for use.

In the US: BioControl's CardioFit is an investigational device under IDE. It is intended for the treatment of Heart Failure patients who are in NYHA class II – IV. It is indicated for patients who have failed to achieve symptomatic improvement through standard evidence based management. See Investigational Plan for inclusion and exclusion criteria.

In Europe: BioControl's CardioFit is intended for the treatment of Heart Failure patients who are in NYHA class II-III. It is indicated for patients who have failed to achieve symptomatic improvement through standard evidence based management.

3. PRECAUTIONS

- Do not immerse any part of the Physician Programmer in liquid.
- Laptop PC should be used outside the patient environment (i.e. not closer than 1.5 m to patient).
- Operator should not touch Laptop PC and patient simultaneously.
- Do not connect the programming wand to external equipment while the battery compartment of the interface is open.
- The use of non-BioControl components with BioControl components may result in patient injury, loss of stimulation or components damage.
- Avoid using the Physician Programmer and the BioControl stimulator near sensitive electronic equipment. The low-level wireless signals transmitted by the two devices may interfere with the electronic equipment.
- Compatibility with other (non-BioControl) implanted devices should be verified prior to implantation (see section 7)
- This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.
- This equipment generates; uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.
- Modifications not expressly approved by the manufacturer could void the user authority to operate the equipment under FCC Rules.
- A distance of at least 15cm between the equipment and all persons should be maintained during the operation of the equipment.

4. WARNINGS



US users:

Please refer to the study protocol for a complete list of eligibility criteria.

- No modification of this equipment is allowed.
- Do not connect any equipment to Laptop except dedicated Communication interface and medical grade power supply Model 4300/MPU100-106.
- To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.
- Pediatric use – safety and effectiveness of Physician Programmer for pediatric use, has not been established.
- When using the programming wand in a sterile field, place it into a sterile sleeve. The wand is not sterile and cannot be sterilized.
- Wireless signals from the Physician Programmer may interfere with the performance of other devices.
- Portable and mobile RF communications equipment can affect the CardioFit
- Keep your cellular phone at least 6 inches (15 cm) away from the device. The cellular phone is a source of EMI and could affect device's operation.
- Using the programming wand over a metallic field may decrease its operating range.



CAUTION:

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference; and
(2) This device must accept any interference received, including interference that may cause undesired operation.***



FCC WARNINGS:

Modifications not expressly approved by the manufacturer could void the user authority to operate the equipment under FCC Rules received, including interference that may cause undesired operation.

5. SETTING UP THE SYSTEM

5.1 Charging the Physician Programmer

1. Charge laptop battery prior to use and make sure it is fully charged.
2. Install a 9-volt battery (use only alkaline 9V battery) in the communication interface.

5.2 Getting started

1. Connect the programming wand plug to the communication interface and then, connect the interface to the parallel port of the PC.
2. Turn "ON" the PC and the communication interface.

- Run the Physician Programmer program (from the desktop or the program menu. Do not advance beyond the first, “Welcome”, screen, which shows the ‘interrogate’ button.

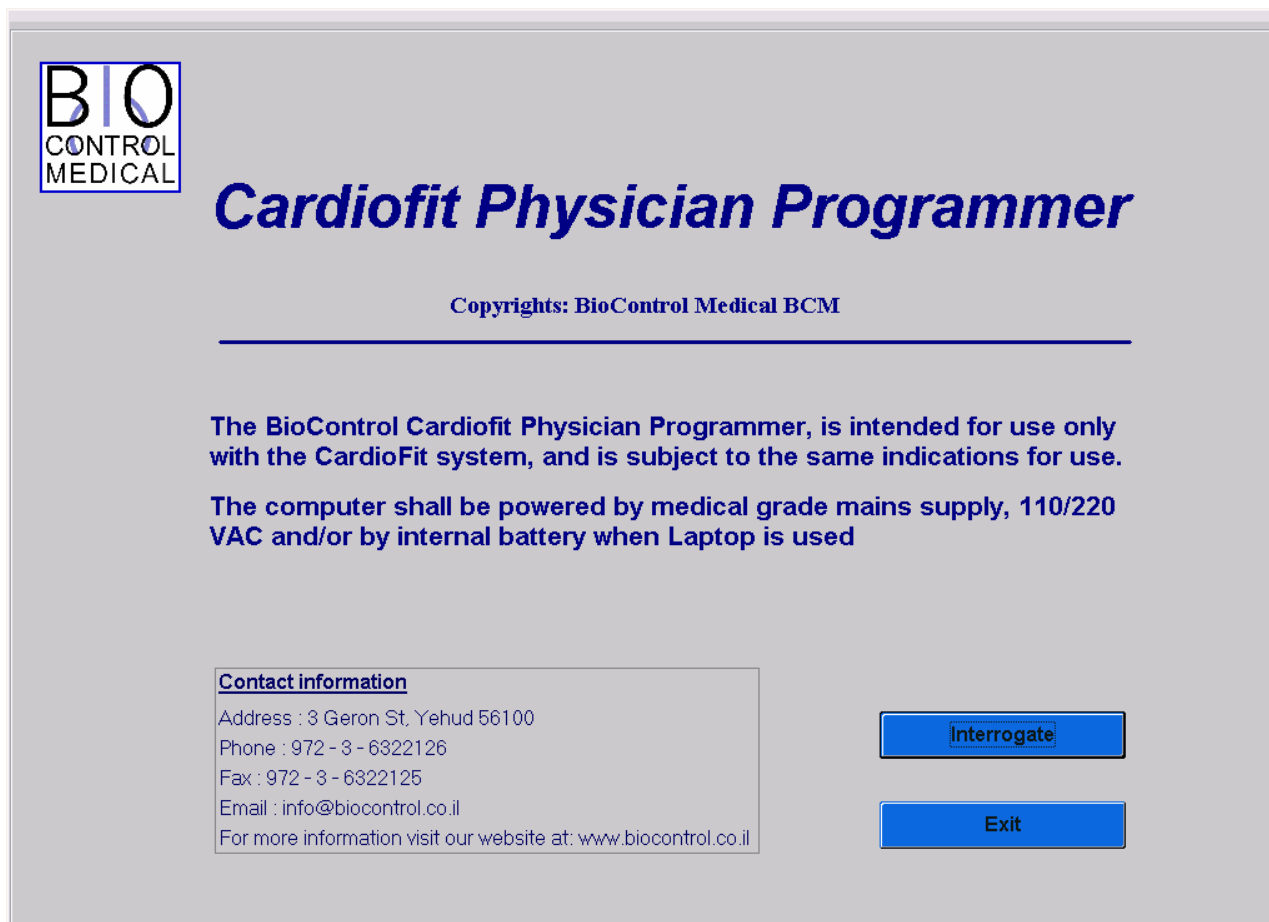


Figure 2: Welcome Screen

- Position the programming wand directly above the stimulator’s area.



WARNING:

Avoid direct contact with patient skin – place above thin clothing or use a thin wrapper around the wand to reduce the risk of skin irritation and/or cross contamination between patients

A green light blinks, usually at a constant frequency of 1 or 2 Hz (every 1 or 2 seconds respectively), depending on whether the device is active or sleep mode. Such blinking verifies proper communication and readiness for receiving and transmitting signals.



NOTE:

If communication difficulties are experienced, reposition the programming wand at different angles relative to the stimulator.

5.3 General System Interface Description

Select the “INTERROGATE” (F1) button. This initial interrogation sets up the Physician Programmer screen with the panes and programmable buttons relevant to the version of the device interrogated.

The Programmer interface consists of 4 tabs, which can be freely navigated by pressing on the tab name on the left.

General tab: Shows general device settings and allows recording of patient and system information

Statistics tab: Shows device heart rate statistics and allows for statistics counter reset

Settings tab: Main tab used for programming device stimulation parameters.

Technician tab: Shows device technical parameters

5.3.1 The "General" Tab

BIO CONTROL MEDICAL

Patient information

Name	XXXXXXXX
Date of birth	12/Feb/99
Date of implantation	11/Mar/97

Device information

Serial	2883
Firmware version	15
Hardware version	8
Mechanics version	200

Lead information

Serial	1234567890
Model	abcdefghijkl
Size	1234567

Sensing lead information

Serial	abcdefghijkl
Model	332211

Notes

1234567890abcdefghijklmnpqrst
uvwxyz12345678901234567890

Battery status

Battery: 100% (N/A V)

The battery will last: 324 additional months

Clear advisory notes

Interrogate [F1] Send [F3] Print report Exit

Figure 3: The General tab following device Interrogation

The general tab is divided into 3 panes:

The left pane includes patient and system information:

- Patient Information
 - **Patient name** – An editable text view. Up to 14 characters
 - **Patient date of birth** – An editable date field – double click to change date
 - **Date of implantation** – An editable date field – double click to change date
- CIS information (automatically recognized by the device)
 - **Serial number** - Displays the device's serial number
 - **Firmware version** - Device's software version
 - **Hardware version** - Device's hardware version
 - **Mechanics version** - Device's mechanical version
- Lead information
 - **Lead serial** - An editable text view up to 32 characters
 - **Lead model** - An editable text view up to 32 characters
 - **Lead size** - An editable text view up to 32 characters
- Sensing lead information
 - **Serial** - An editable text view up to 32 characters
 - **Model** - An editable text view up to 32 characters
- Notes
 - An editable text view which can be used at the physician's discretion

The right pane includes:

- An overview of current device settings including Active, On time, Off time, On cycles, Off cycles, Duty cycle, PPB, Current
- Battery status and estimated running time.

For a detailed description of these parameters, please see section 5.3.3, The Settings tab

• Advisory Notes

Advisory notes will appear in case the device has experienced one of the following conditions:

- Battery voltage is too low
- Indication of insufficient discharge of stimulation electrode was given
- Indication from runaway protection mechanism was given
- CardioFit performed reset
- Bad memory shadow indication was given
- Magnet was applied to disable stimulation

Actions that should be taken following each advisory note are described in section 9

Pressing the “Clear Advisory Notes” button will clear advisory notes

The bottom pane includes 4 buttons:

Interrogate [F1]

Device Interrogation provides current device settings.

Interrogation checks the parameters of the device and presenting the current values of all programmable buttons. The interrogate function does not change parameters stored in the stimulator

Send [F3]

In order to communicate updates of programmable buttons press this button. It will also perform interrogation and update output parameters such as counters.

Print Report

Generates a hardcopy report with device parameters.

Create an image file (*.JPG) in which major counters values and the latest display graph are presented. The image file will be created on a connected external removable drive (disk-on-key).

After pressing the ‘print report’ a separate window will appear. The image file will be placed in a subdirectory “NNNN” in the external removable disk where “NNNN” is the device serial number.

File name: “Report__NNNN_YYYY-MM-DD_hh-mm-ss.jpg”	
NNNN	is the device serial number.
YYYY-MM-DD	is the creation date, in year/month/day format.
hh-mm-ss	is the creation time, in 24h format.

Example:

a report was printed on 18 May 2010 at 1:53 pm for device 2812, where the external disk drive letter is E: The report will be in file:

E:\2812\Report_2812_2010-05-18_13-53-00.jpg

Exit

Exits the Physician Programmer and returns to Windows

These 4 buttons also appear in *setting* tab and have similar functions

5.3.2 The "Statistic" tab; Therapy evaluation.

The UniPP calculates and analyses the stimulation parameter setting effect on patient heart, thus enabling evaluation of optimal therapy setting. Measures are presented numerically and graphically.

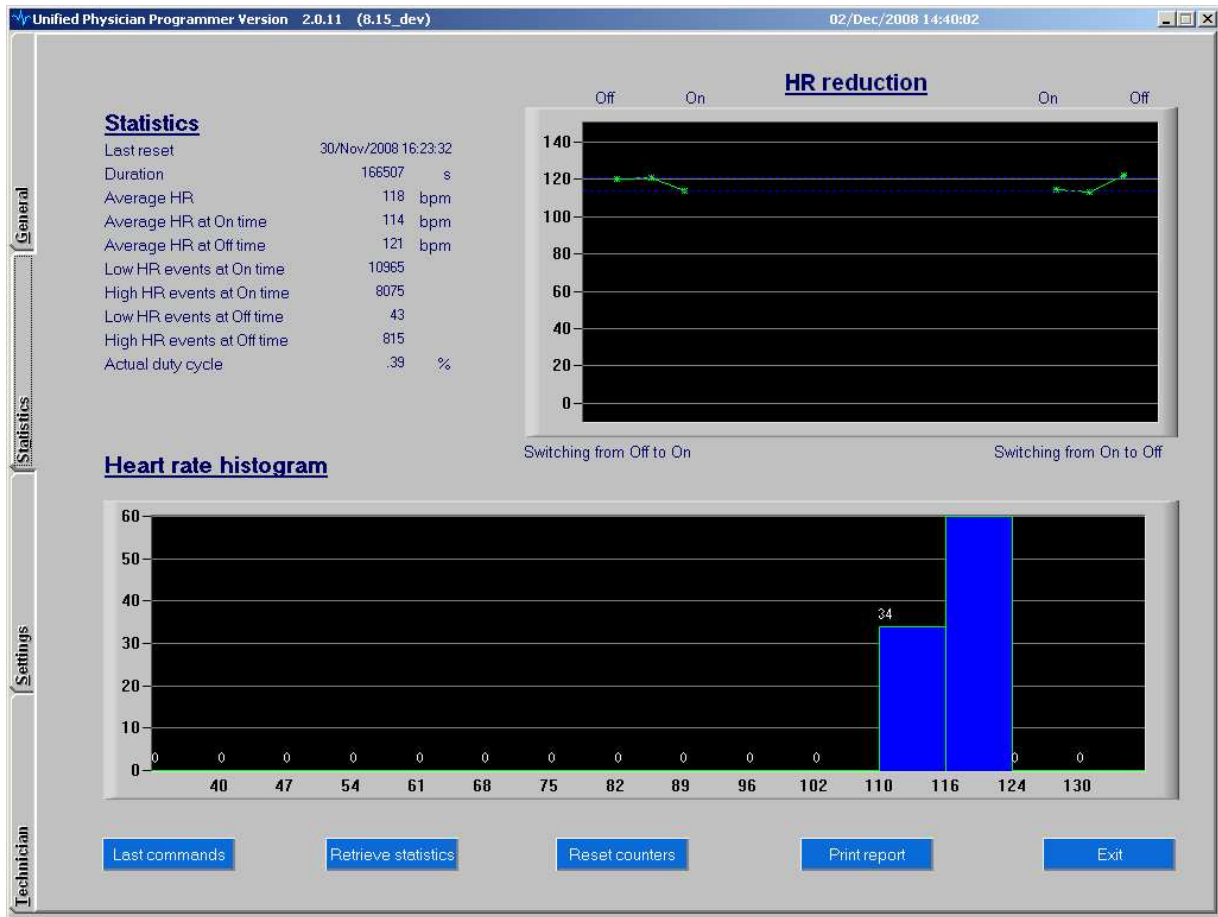


Figure 4: The Statistic tab

The Statistic tab is divided into 3 panes:

The left **Statistics** pane includes the HR numerical information:

- **Last reset** – Date and time of the last statistical information reset
- **Duration** – Time period of which the statistic is calculated and presented
- **Average HR** – the average HR detected (R waves) and calculated by the device
- **Average HR at On time** - the average HR detected (R waves) and calculated by the device during stimulation
- **Average HR at Off time** - the average HR detected (R waves) and calculated by the device while stimulations are not given
- **Low HR events at On time** - A counter registering how many detection events (R waves) are occurring at a rate below that defined as **Low HR Threshold**. Therefore, this counter actually registers bradycardia occurring while device is giving stimulations
- **High HR events at On time** - A counter registering how many detection events (R waves) are occurring at a rate above that defined as **High HR Threshold**. Therefore, this counter registers tachycardia occurring while device is in giving stimulations

- **Low HR events at Off time** - A counter registering how many detection events (R waves) are occurring at a rate below that defined as **Low HR Threshold**. This counter registers bradycardia occurring while device does not stimulate
- **High HR events at Off time** - A counter registering how many detection events (R waves) are occurring at a rate above that defined as **High HR Threshold**. Thus, this counter registers tachycardia occurring while device does not stimulate
- **Actual Duty cycle** – The ratio (in percentage) between the period while stimulation was ON and the period while stimulation was OFF

The right **HR Reduction** pane includes graphical presentation of the average heart rate reduction for the time duration indicated in the left pane.

HR reduction graph

The graph provides visual evaluation of the effect of stimulation on the heart rate.

The three left points are the HR for the 2 last beats before switching from off to on and the HR for the first beat after switching from off to on respectively. The three right points are the HR for the 2 last beats before switching from on to off and the HR for the first beat after switching from on to off respectively. The heart rates shown are averaged over all on/off cycles that occurred since the last reset.

Two blue thresholds line are indicated as well demonstrating the average HR at On time and average HR at Off time

The bottom **Heart rate histogram** pane includes graphical presentation of the heart rate histogram for the time duration indicated in the left pane and the functional button.

Heart Rate Histogram

This is a bar graph presenting the distribution of the patient HR during the evaluated period.

Last commands

Pressing this button will results with opening a new window, which present most of the CardioFit parameters, new line will be opened each time the operator has changed a parameter,

“Last command” will present all the commands given by the operator from the 1st interrogation at a specific session.

Retrieve statistic

Present the statistic parameters including update of the HR reduction figure as well as the HR histogram,

Updating is from the last “retrieve statistics” or from the last “reset counters” commands.

Reset counters

Resetting the CardioFit statistic counters.

Low/High HR during On/Off time counters will not be reset by this function.



NOTE:

Pressing “Reset counters” button will not update the screen with reseted counters; for the updated numbers please use the “retrieve statistic”.

5.3.3 The "Setting" Tab

This screen allows the operator to control the stimulation therapy delivered by the device to the patient. Adjustment of HR detection and vagal nerve stimulation therapy programming and changes are performed through the Setting tab.

On the top pane, a switch screen of IEGM and HR streaming is appeared. Clicking the relevant tab on the top of the screen makes the switch between the screens. Description of buttons and panes below the switch screen is found under the HR screen.

IEGM screen

The CardioFit detects right ventricle signal in order to synchronize stimulation with the cardiac cycle. The max detection sensitivity = 2mVolt.



Figure 5: The IEGM Setting tab

Update IEGM (F9)

Button is located at the right pane of the setting screen

Pressing the button will update the three windows that compose the IEGM screen. Each window represents one second.

Please note: the three windows are not consecutive in time.

Zooming in/out

Buttons are located at the left side of the IEGM screen as + and –.

Pressing the + results in IEGM magnifying, each press will provide higher magnification, allow better view of the IEGM and ease threshold setting.

Pressing the – button will decrease the IEGM magnification.

Stimulation annotation line

Appears as a white line below the IEGM and the threshold graph,

When stimulation is being delivered tall bar will be presented, when stimulation is being inhibited a short bar will be presented, in addition, a letter representing the inhibition cause will appear below the bar as follow:

Inhibition letter legends:

O – Off time, Off cycle

M – Magnet has been applied.

F – Fault (lead status out of range, low battery, bad shadow, device reset)

R – Runaway protection has been activated.

D – Discharge, in case the electrode has not been sufficiently discharged.

H – High HR, short RR.

L – Low HR, Low daily Avg. HR

IEGM max measured amplitude

Below each IEGM window screen, the “Peak” value of the R wave is presented.

Detection Threshold

The threshold for detection appears on the grid of the display as a bright purple line that can be set higher or lower by left clicking and dragging or by entering the numeric value. The relative scale for displaying voltage amplitude of the acquired signal appears in mVolts.

An optimal threshold setting should be at the one-third upper scale of the R wave.

If the “visible” box is not checked, the threshold will not be shown.

Invert signal

Marking the check box will invert the heart signal; use this button when the negative projection of the signal is much greater then the positive.

HR screen

The HR screen presents the heart rate in bpm during the last 128 RR intervals with marks for stimulations. The figure enables on-line evaluation of the heart rate response to stimulation.



Figure 6: The HR Setting tab

View HR storage [F8]

Button is located at the right pane of the setting screen

Pressing this button will display a graph of heart rate of the last 128 RR intervals. Every such heartbeat is marked by a green dot on the graph. Stimulated R waves will be marked in bigger dots.

Zooming in/out

Marking the desired area in the graph to be zoom-in while left click in the “mouse” will provide focused area of interest. Repeat the procedure for higher magnification if required.

Right click will reset the axis scale.

The bottom pane of the “setting” tab includes stimulation parameters setting:

Stimulation Settings:

Active

Box can be made blank to put device into 'non active' mode; not sensing or counting and not stimulating - or it can be checked to activate the device.

Delay from R

Determines the time between the R wave detection and the first stimulation pulse in mSec. The range is 8 ~ 1000 msec in 7-8msec steps. The default value is 70msec.

Current

Sets the amplitude of the current provided by the stimulation lead in milliamps (mA). Value can only be chosen from a table appearing when button is left-clicked, as a safety measure. Current should not be increased by more than 0.2mA at one time. The default value is 0mA, max value is 6mA.

PPB

Pulse **P**er **B**eat will set a constant number of pulses per single heartbeat. Max PPB value is 3 in regular use and 8 in implantations (only appear in the CardioFit-X version).

PRI

Pulse **R**epetition **I**nterval. Sets the interval between pulses constituting a single stimulation event. Default value is 55 msec.

Blanking

Determines the duration of blanking period following stimulation. The purpose of blanking during which there is no detection, is to prevent T wave detection, as well as to prevent the stimulation itself from causing misdetection. Range: 8 ~ 1000 msec in 7-8msec steps. It appears in the IEGM as uncolored line area. The default value is 102msec.

Max detectable heart rate

The number appearing is the maximum regular beats, or more precisely - Intracardiac signals, per minute that may be detected. This value is the product of several variables, including: PRI, PPB, blanking and Delay from R. The 'Max detectable HR' field became red if the programmed 'High HR Threshold' is greater than 90% of the max detection rate.



WARNING:

In case the High HR Threshold is higher than the Max detectable HR, the device may not be able to prevent stimulation when it is resulted from detection of noisy signal

Stimulation Limits:

High HR Threshold

The heart rate above which no stimulation is provided no matter what the mode, the cycle or stimulation parameters are. The default value is 150 BPM.

Low HR Threshold

The heart rate below which no stimulation is provided no matter what the mode, the cycle or stimulation parameters are. The default value is 56 BPM.

Daily Average RR

This feature cancels the stimulation Cycle mode. It automatically use the calculated last 24 hours average heart rate by the device and enable stimulation only when the measured heart rate is higher than the average value. The value is updated automatically every 24 hours.

In the first time used, the value should be set manually.

When the default 'Off' value is presented the stimulation limitation ignores this feature.

Intermittent Mode Settings:

Treatment mode

The CardioFit™ stimulation logic consists of four combined time intervals, the On/Off Time and the On/Off Cycles.

CardioFit administers stimulation in an intermittent, periodic manner. The period is determined by the "**on time**" and "**off time**" programmable parameters.

A "stimulation cycle" is the time period consisting of a single "off" period followed by a single "on" period.

The "**On cycle**" and "**Off cycles**" programmable parameters give further control of the intermittent administration of stimulation by allowing a long period in which no stimulation is administered. CardioFit will administer "On cycle" normal stimulation cycles, to be followed by a period of "Off cycles" stimulation cycles in which no stimulations will be administered.

For example: See Figure 7, where the following parameters are programmed:

on time=4 sec, off time=1 sec, on cycle=2, off cycle=3.

Based on these parameters, the stimulation cycle=off time + on time = 5 sec. Therefore, 10 seconds (2 cycles) of intermittent stimulation are followed by 15 seconds of no stimulations, etc.

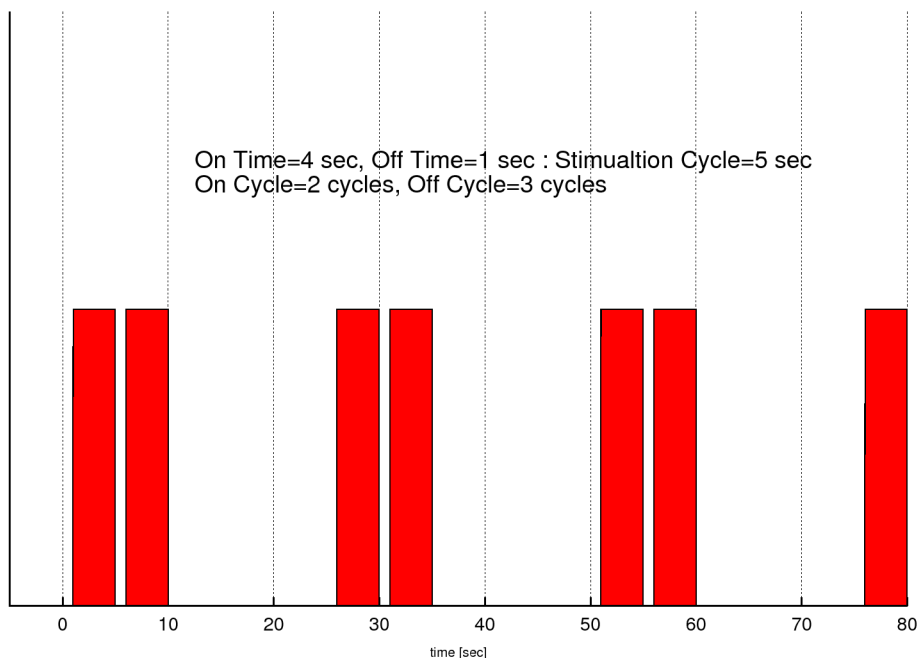


Figure 7: On/Off time and On/Off Cycle operation parameters.

Duty Cycle

The duty cycle indicator calculates and present the actual activation time according to the last programmed settings. The indicator becomes red if the calculated value exceeds 30%

$$DutyCycle = \frac{OnTime \cdot OnCycle}{(OnTime + OffTime) \cdot (OnCycle + OffCycle)}$$



NOTE:

Values for the treatment mode parameters can only be chosen from a table appearing when button is left-clicked, as a safety measure

Lead Status

Calculates the CSL lead impedance and provide an indication status: Short, OK, High or Unknown



WARNING:

Lead status 'Short' or 'High' may indicate on lead break or damaged insulation and need to be reported immediately to BioControl representative

The result will be displayed in the dialog box and on the Lead status button and will be written in the log files as a comment.

To perform the test press the 'lead status', the test take a minute and is part of a routine On Time cycle, a progress bar indicate on the test status.

In order to perform the test, four conditions must be fulfilled. The conditions are:

On time ≥ 1
On cycle ≥ 1
Active On
R wave detection



NOTE:

If one of the conditions is not fulfilled the results of the lead status test will be "Lead Status: unknown"

Battery Status

Battery capacity indicator is shown as a blue strip containing a measure percentage of full capacity, **Battery Voltage** is provided in Volt units in parenthesis.

Battery expected remaining time is expressed in months.

If less than 3 months remain for battery operation (assuming no change in setting) a message will appear in the gray space below "Please schedule battery replacement".



NOTE:

If less than 3 months remain for battery operation (assuming no change in setting) a message will appear in the gray space below "Please schedule battery replacement".

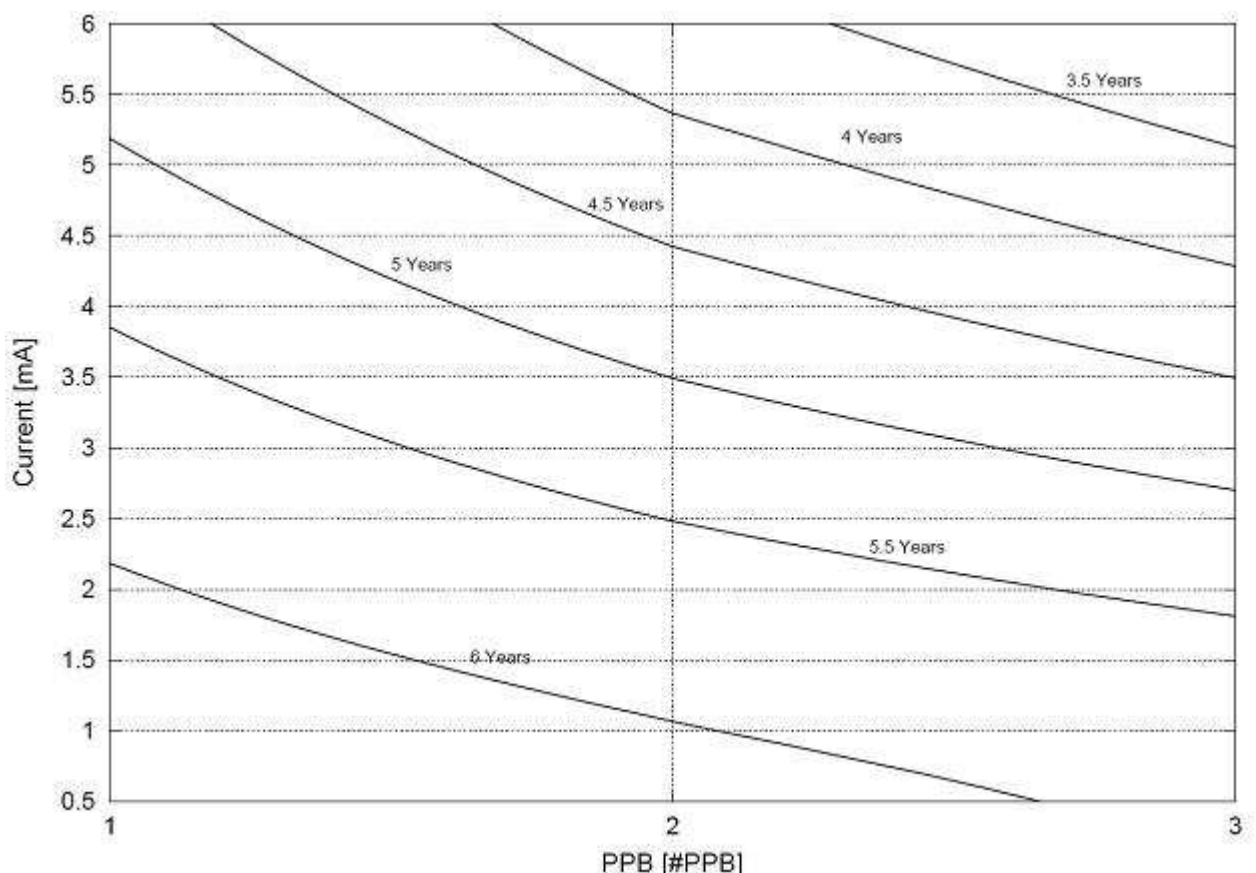


Figure 8: Predicted device life time as function of current and PPT

The nominal predicted lifetime of the CardioFit™ Implantable Stimulator battery in the maximal therapeutic setting is 5.0 years and the minimum is 3.5 years.

Under the following conditions:

Stimulation electrode Impedance: 1740Ω; Capacity: 4.7μF

Stimulation current: 5mA, 3 pulses per trigger,

Average HR: 100bpm, Stimulation duty cycle: 25%.

Print Report

See section 5.3.1

Add Remarks

Adds a line in the log file, on which user remarks may be written. Remarks could be chosen from a dropdown list or added as a free text.

Exit

Exits the Physician Programmer and returns to Windows.



NOTE:

When a button is pressed or a new parameter is typed a light blue box will appear around it, until the button “Send” [F3] has been pressed. It is possible to program several parameters together and then press the “Send” button.

Range and default of programmed parameters list:

Parameter	Range	Default
On Time [sec]	0...(1)...10...(5)...255	0
Off Time [sec]	0...(1)...10...(5)...255	0
PPB	1, 2, 3	1
Current [mA]	0...(0.1)...6	0
PRI [mSec]	16, 55, 148, 250, 350	55
On Cycles	0...(1)...127	1
Off Cycles	0...(1)...127	0
Low Stimulation Limit [BPM]	30...(4)...320	56
High Stimulation Limit [BPM]	Off, 30...(4)...320	150
Daily Average HR	Off, 30.1 - 7680	Off
Blanking [mSec]	8...(8)...1000	102
Delay from R wave	0...(8)...1000mSec	70
Detection Threshold (mV)	1.88 to 39.69	39.69
Detection Thresholds sensitivity (mV)	≥2	39.69

6 THERAPY SETTING AND OPTIMIZATION PROGRAM



WARNING:

The Physician Programmer should be used only by authorized and trained personal



NOTE:

Make sure the programming wand is correctly positioned over the stimulator, and a green blinking light appears. Hold the programming wand in place until the transmitted parameters had been programmed.



NOTE:

After each time a button is pressed or a parameter is typed the “send” button on the screen should be pressed, or alternatively press the keyboard “F3” button.

6.1 General

This section provides guidance and recommendation regarding use of the CardioFit Unified Physician Programmer (UniPP) for device activation and parameter setting optimization in patients implanted with the CardioFit™ System during the adjustment period that all implanted subjects undergo in order to provide them with optimal CardioFit therapy. This period is defined as "optimization period". The optimization period starts at weeks 3-4 post operation (depending on patient recovery from system implantation and wound healing), and lasts around 4 weeks. In order to optimally set the therapy, approximately 6 setting sessions are required during that period depends on patient adjustment and tolerability to the stimulation.

6.2 Therapy Optimization Goal

The goal of the optimization is to adjust the stimulation parameters to the patient specific physiological characteristics in order to achieve the optimal CardioFit therapy settings.

Optimal setting criteria are:

- Statistically significant Instantaneous Heart Rate Reduction ("iHRR") in an interval ≥ 24 -hour
- Minimal discomfort to the patient

6.3 Communication rules with the patient

- Prior to each session consult with the patient's physician regarding his or her condition. Physical examination is required prior to each optimization session.
- Ask the patient for his/her condition - presence of adverse events or unusual feelings since last visit and during the visit.
- It is recommended to use standard stimulation sensation scale to standardize patient comfort with the programmed therapy setting level.

6.4 Visit Activities Flow

- Physical examination should be performed prior to parameter change.
- Review the last patient clinical outcome
 - Stimulation discomfort characteristic - Interview patient for his response to therapy and general clinical feeling. Ask patient to determine the stimulation discomfort level since last visit, if any, using the stimulation sensation pain scale
 - Adverse events
 - Electrocardiogram from most updated 12-lead ECG/Holter. Identify any new significant abnormalities (Heart rate, conduction, arrhythmias, etc.)
- Interrogate the device and review the information appeared in the "General" tab of the UniPP. Identify any parameter settings discrepancy or system malfunctions.

- Switch to the "Statistic" tab and press the "retrieve statistic" button. Review the last interval heart rate outcome.
- Set therapy parameters
- After the last parameter setting change, follow the patient for any discomfort for at least 30 minutes before release.

6.5 **Parameter setting process**

- Use the "Setting" tab in the UniPP for setting parameters
- Verify that "active" button is marked
- HR wave detection:
Press the IEGM tab to view IEGM and then press the "Update IEGM" [F9]. Verify correct signal threshold for detection.
Detection thresholds should be set to the 2/3 amplitude of R wave. Minimum sensitivity is 2 mV.
- At the first activation of the device set the parameters as indicated in following table.

Parameter	Value
On Time [sec]	10
Off Time [sec]	15
PPB	1
Current [mA]	0.1
PRI [mSec]	250
On Cycles	30
Off Cycles	20
Low Stimulation Limit [BPM]	56
High Stimulation Limit [BPM]	130
Daily Average HR	Off
Blanking [mSec]	70
Delay from R wave	250

- Increase current in steps of 0.2 mA and press "Send [F3]" button. Allow patient to adjust the change for 5 minutes.
- When the patient detects stimulation, ask him/her to determine the stimulation sensation level. If the sensation is intolerable, wait for at least 15 minutes before proceeding. In case that sensation level does not decrease, reduce current in 0.1 mA steps until comfortable sensation of stimulation is achieved. Set the final parameters for the optimization session accordingly.
- Continue with the same procedure at each optimization session up to 5.5 mA and continuously evaluate the effect of the stimulation setting on iHRR.

6.6 **Instantaneous HRR evaluation and PPB/ON time change**

iHRR can be observed at the "Statistic" tab: HR statistic, HR reduction figure and HR distribution histogram for the last interval and in the "Setting" tab: HR figure

- ON Time setting change;

- Review the HR reduction figure appears in the "Statistic" tab after pressing the "Retrieve" button at the beginning of each session.
- Increase ON time, if the HR value at the last measuring point of the Stimulation ON time is lower or equal to the HR value of the previous measuring point and the average HR.
- Decrease ON time, if the HR value at the last measuring point of the Stimulation ON time is higher than the HR value of the previous measuring point and the average HR.
- Please note that whenever the On time is modified, the Off time should be modified accordingly in order to keep the overall Duty Cycle constant.
- PPB setting change;
When statistically significant iHRR in an interval ≥ 24 -hours is observed switch setting to 2 PPB.
 - The change may require eventually reduction of 0.5mA in pulse current
 - Re-evaluate the iHRR in the following visit. In case the measured iHRR value decreased following the change, revert to the last setting with the 1 PPB.
- It is mandatory to print report at the beginning and completion of visit, all reports should be reviewed and signed by the patient physician.



NOTE:

Press the EXIT key after parameter setting is completed

7. INTERACTIONS WITH IMPLANTABLE CARDIOVERTER DEFIBRILLATORS

This section provides the procedure to be followed when programming CardioFit in a patient with an implanted pacemaker and/or implanted Cardioverter defibrillator. Following this procedure shall minimize the risk of interaction between the two implanted devices and will allow safe delivery of therapy from both of them.

Programming device parameters

Use the following guidelines to set pacing/sensing parameters in the devices. These guidelines minimize the possibility of CardioFit and the other device sensing each other's stimulations as cardiac events.

- Avoid using atrial sensing if possible
- Set the CardioFit sensing threshold to be between 50% and 70% of the R-wave amplitude
- Set the other device's sensitivity to the most un-sensitive setting possible as recommended by the manufacturer of that device.
- Note that it is possible and common for a device (e.g. a CRT/D) to be both anti-bradycardia and anti-tachycardia. In this case guidelines for both types of modes should be followed
- For several parameters below, conversion from beats per minute (bpm) to milliseconds (ms) is required. Use the following formula:

$$Ms = 1000 * 60 / \text{bpm}$$

$$\text{Bpm} = 1000 * 60 / \text{ms}$$

- The stimulation duration is the time from detection to the end of the last pulse. The duration is calculated as:

$$\text{Delay From R} + (\text{PPB}-1) * \text{PRI} + \text{PPB}$$

Example 1:

Delay From R = 50 ms

PPB = 2

PRI = 50 ms

Stimulation duration = $50 + (2-1) * 50 + 2 = 102$ ms

Example 2:

Delay From R = 50 ms

PPB = 1

PRI = 50 ms (in this case PRI is irrelevant to the calculation since PPB=1)

Stimulation duration = $50 + (1-1) * 50 + 1 = 51$ ms

- When the other device is using atrial sensing (not recommended)
 - The other device's and CardioFit's parameters shall be set to values such that the other device's parameter governing the atrial refractory period after ventricular pacing/sensing (e.g. Post-Ventricular Atrial Blanking) is greater than the CardioFit stimulation duration.

Example:

CardioFit stimulation duration = 150 ms

Other device's PVARP should be set to be greater than 150 ms.

- The other device's and CardioFit's parameters shall be set to values such that the other device's parameter governing the maximal delay from sensed atrial event to paced ventricular event (e.g. Sensed AV interval) is smaller than the CardioFit delay from R.

Example:

Other device's Sensed AV interval = 150 ms.

CardioFit delay from R should be set larger than 150 ms.

- When the other device is using ventricular sensing
 - The other device's and CardioFit's parameters shall be set to values such that the other device's parameter governing the ventricular refractory period after ventricular pacing/sensing is greater than the CardioFit stimulation duration.

Example:

Other device's ventricular refractory period = 130 ms.

CardioFit stimulation duration should be set to smaller than 130 ms.

- When the other device is an anti-bradycardia device:
 - CardioFit Low HR threshold shall be set to be above the other device's basic pacing rate



CAUTION:

In case that CardioFit low HR threshold is set below the other device's basic pacing rate, the CardioFit will stimulate on paced beats. The physician should take this into account when programming CardioFit stimulation parameters, or should consider abolition of CardioFit implantation

- When the other device is using bi-ventricular pacing
 - The other device's and CardioFit's parameters shall be set to values in which the other device's V-V delay is smaller than the CardioFit maximal detectable heart rate

Example:

Other device's V-V delay = 50 ms.

50 ms = 1200 bpm.

CardioFit Maximal detectable heart rate should be smaller than 1200 bpm.

- When the other device is an anti-tachycardia device
 - The other device's and CardioFit's parameters shall be set to values in which the CardioFit Maximum detectable HR is about 10% above the other device's VT zone (to ensure correct CardioFit tracking of the VT)

Example:

Other device's VT zone = 180 bpm.

CardioFit High Maximum detectable HR threshold should be above 200 bpm.

- The other device's and CardioFit's parameters shall be set to values in which the CardioFit High HR threshold is about 10% below the other device's VT zone (to ensure no CardioFit stimulation during VT therapy).

Example:

Other device's VT zone = 180 bpm.

CardioFit High HR threshold should be below 160 bpm.

- The other device's and CardioFit's parameters shall be set to values in which the CardioFit High HR threshold is about 10% below the other device's anti-tachycardia pacing interval (to ensure no CardioFit stimulation during ATP therapy).

Example:

Other device's anti-tachycardia pacing interval= 200 ms.

200 ms = 300 bpm

CardioFit High HR threshold should be below 270 bpm.

Patient follow-up

During patient follow-up special attention should be taken to ensure that the above guidelines are still in effect.

Also, any irregular events should be scrutinized to ensure that they did not occur due to device-device interactions. Such events may include:

- Defibrillation shocks.
- Pacemaker detection problems (double-counting).
- CardioFit detection problems.



NOTE:

Please note that the term 'ICD' refers to: Single chamber Implantable Cardioverter-Defibrillators, Dual chamber Implantable Cardioverter-Defibrillators and Cardiac Resynchronization Therapy- Implantable Cardioverter-Defibrillators (CRT-D)



NOTE:

Both devices, ICD and the CardioFit cannot be interrogated simultaneously



WARNING:

It is advised to ensure proper sensing by the CardioFit of intrinsic and paced beats

8 MAINTENANCE, HANDLING, AND STORAGE

8.1 Maintenance

Except for periodical battery replacement of the communication interface and PC battery charging, the Physician Programmer does not require maintenance:

- Use only alkaline 9V battery.
- Remove the 9-volt battery from the communication interface device if the Physician Programmer will not be used for an extended period.
- Replace the 9-volt battery only after the communication interface has been disconnected from all external equipment.
- Do not sterilize the programming wand.
- Return the Physician Programmer to BioControl if repair or replacement is required.
- If required, the Physician Programmer components can be cleaned with a moistened cloth.

8.2 Handling

- Never immerse the programming wand in liquid.

- Never connect the communication interface to external equipment while the battery compartment is open.

8.3 Storage

- Do not store the Physician Programmer where it might be exposed to water or other liquids. Moisture can damage its functionality!
- Store the Physician Programmer between 0°C and 45°C. Temperature outside this range can damage the Physician Programmer.
- Relative Humidity (RH): Between 10% and 95% RH.
- Atmospheric Pressure: Between –400m and 3000m (700-1060 hPa).
- Store the Physician Programmer in a secure place.

9. TROUBLESHOOTING

The following table presents possible errors and suggested solutions:

Error	Feature	Suggestion
Communication error	Green light not blinking	<ol style="list-style-type: none"> 1. Reposition wand. 2. Ask patient to change his/her position. 3. Check physician programmer operation on a neutral CardioFit™-X device. 4. Check/change the 9-volt battery of the communication interface device. 5. Verify that the Physician Programmer components (i.e. PC; communication interface; and programming wand) are properly connected. 6. Change the programming wand and the communication interface. 7. In case green light is, still, not blinking contact BioControl Medical (BCM).
	Green light blinking in a high frequency	<ol style="list-style-type: none"> 1. Check if the CardioFit programming wand is located in the proximity of another programming wand (ICD, CRT). 2. Try to isolate the CardioFit programming wand from others electrical devices 3. Contact BioControl Medical (BCM).
Physician Programmer not responding or a persistent malfunction not related to communication.		<ol style="list-style-type: none"> 1. Close the Physician Programmer program and restart the program. 2. If the problem is not resolved, restart the laptop. 3. Contact BioControl Medical (BCM).



CAUTION:

In case of unsuccessful Turn-off of the neurostimulator while using the Physician Programmer, use safety magnet to turn the neurostimulator OFF. Please contact BioControl Medical personnel, immediately.

The following table presents possible error messages:

Message	Description	Action
"A different CardioFit was interrogated, do you wish to proceed?"	After interrogation, the serial number of the device is different from the last SN.	Press YES in case the new device (patient) interrogation was scheduled or press NO and interrogate again the right device in the case of a mistake.
"Communication battery voltage too low!"	Whenever the battery voltage is too low.	Turn on the communication interface or replace the battery, use 9v alkaline battery only.
"There is no communication"	Indicates a communication error.	See the table above.
"There is no Communication interface connected to this computer, or CP93.Vxd file is not found in the current folder."	When a communication box is missing, or faulty parallel connection between the interface box and the PC.	Connect the communication interface to the programmer.
"Unfamiliar device or old device version or communication error"	Unexpected model or version was read, may indicate an old device version.	Re-interrogates the device, if the message still appears contact BioControl Medical.
"Unable to write to a log file"	In case of an error in writing to a log file.	Make sure all log files are closed.
"Unable to read from the log file"	A problem in reading the log file.	Make sure all log files are closed.
"Disk on key is not connected, operation canceled! "	Disk on key should be connected in order to perform this action.	Connect a Disk-On-Key to the programmer.
"The operation cannot be performed when device is not active"	The desired action requires an active CardioFit.	Appears when updating IEGM or HR while the device is set to "active off", set the device to "Active on".
"Please schedule device replacement"	When CardioFit longevity is less than 3 months.	Schedule device replacement.

10. PRODUCT INFORMATION AND SUPPORT

For technical support for the CardioFit™ system Physician Programmer or any of its accessories, please contact BioControl:

BioControl Medical (B.C.M) Ltd.
3 Geron St.
Yehud, 56100
ISRAEL
TEL: + 972-3-6322126
FAX: +972-3-6322125
Email: info@biocontrol.co.il

11. DISCLAIMER OF WARRANTY


Although the Physician Programmer hereafter referred to as “Product” has been carefully designed, manufactured and tested prior to use, the Product may fail to perform its intended function satisfactorily for a variety of reasons. Warnings contained in the Product labeling provide more detailed information and are considered an integral part of this disclaimer. BioControl, therefore, disclaims all warranties, both expressed and implied, with respect to the Product. BioControl shall not be liable for any incidental or consequential damages caused by any use, defect or failure of the Product, whether the claim is based on warranty, contract, tort or otherwise.

The exclusions and limitations set out above are not intended to, and should not be construed so as to, contravene mandatory provisions of applicable law. If any part or term of this disclaimer of warranty is held by any court of competent jurisdiction to be illegal, unenforceable or in conflict with applicable law, the validity of the remaining portion of the disclaimer of warranty shall not be affected and all rights and obligations shall be construed and enforced as if this disclaimer of warranty did not contain the particular part or term held to be invalid.

APPENDIX A. Electromagnetic environment – guidance IEC 60601-1-2

Guidance and manufacturer's declaration – electromagnetic emissions		
The Physician Programmer model 5300 & CardioFit-X Ver 8.15 are intended for use in the electromagnetic environment specified below. The customer or the user of the Physician Programmer model 5300 & CardioFit-X ver 8.15 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 2	The Physician Programmer model 5300 & CardioFit-X ver 8.15 must emit electromagnetic energy in order to perform their intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The Physician Programmer model 5300 & CardioFit-X ver 8.15 are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. ⁹
Harmonic emissions IEC 61000-3-2	Class D	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Physician Programmer model 5300 & CardioFit-X Ver 8.15 are intended for use in the electromagnetic environment specified below. The customer or the user of the Physician Programmer model 5300 & CardioFit-X Ver 8.15 should assure that it is used in such an environment.			
Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
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 floors 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 input/output lines	±2 kV for power supply lines ±1 kV for input/output 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 the Physician Programmer model 5300 & CardioFit-X Ver 8.15 requires continued operation during power mains interruptions, it is recommended that the Physician Programmer model 5300 & CardioFit-X Ver 8.15 be powered from an uninterruptible power supply or a battery
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Physician Programmer model 5300 & CardioFit-X Ver 8.15 are intended for use in the electromagnetic environment specified below. The customer or the user of the Physician Programmer model 5300 & CardioFit-X Ver 8.15 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 V 3 V/m	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Physician Programmer model 5300 & CardioFit-X Ver 8.15, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> <p>$d = 1.2 \sqrt{P}$</p> <p>$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2,5 GHz</p> <p>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).</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> <p>^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 the Physician Programmer model 5300 & CardioFit-X Ver 8.15 are used exceeds the applicable RF compliance level above, the Physician Programmer model 5300 & CardioFit-X Ver 8.15 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Physician Programmer model 5300 & CardioFit-X Ver 8.15</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.</p>			

Recommended separation distances between portable and mobile RF communications equipment and the Physician Programmer model 5300 & CardioFit-X Ver 8.15

The Physician Programmer model 5300 & CardioFit-X Ver 8.15 are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Physician Programmer model 5300 & CardioFit-X Ver 8.15 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Physician Programmer model 5300 & CardioFit-X Ver 8.15 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 $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3 \sqrt{P}$
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	7.2
100	12	12	23

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 applies.

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



cardiofit™

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The system and its use for treatment of cardiological pathologies is protected under one or more of United States patents nos. 6,600,954, 6,684,105, and 7,346,398, as well as corresponding international patents. Other patents are pending.

IN THE US -

CAUTION - Investigational Device.

Limited By Federal Law To Investigational Use.

Hereby, BioControl Medical BCM Ltd., declares that CardioFit™ Neurostimulator is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC

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