MODIFICATION INSTRUCTION NO.:		**MODIFICATION DATE: 10/03/10**	
MODIFICATION DESCRIPTION:	Update to PP software and application instructions per ECO 172 and CardioFit 8.17 changes		

ISSUED BY	**TITLE**	**DATE**	**SIGNATURE**
DUDU RIGLER	DIRECTOR OF CLINICAL AFFAIRS	10/03/10	

APPROVAL LIST			
NAME	**TITLE**	**DATE**	**SIGNATURE**
TSACHI CZACZKES	DIRECTOR OF ENGINEERING		
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VERSION	**NAME**	**DATE**	**ECO NO:**	**MODIFICATION DESCRIPTION**
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	DUDU RIGLER	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.
I	DUDU RIGLER	24/03/09	167	Layout Review; Editorial Changes; Type BF applied part.

J	DUDU RIGLER	4/06/09	151 (additional items not identified before) + 165	Update 8.16 version and software 2.0.31: (1) impedance measurement details (DI#002 in 5.3.3); (2) indication on inhibition due to magnet application (DI#004 in 5.3.1) (3) estimation on HRR during on time (DI#005, USRM#11 in 5.3.2) (4) histogram of pt. HR (DI#006 in 5.3.2, 5.3.3, 6.6) (5) Explanation on low and high HR thresholds (DI#007/008 in 5.3.3) (6) Clarification of parameter setting in the existence of CRM implantable devices (in 7) (7) Remove US IDE indications and labeling (in 2) (8) Interrogation includes the last measured RR interval (DI#165/009 in 5.3.1, 5.3.2) (9) Update GUI according to usability report (USRM#1/#4)
K	DUDU RIGLER	10/03/10	172	Layout Review; Editorial Changes; Update 8.176 version and software 2.0.33: (1) Use of USB programming Wand (2) Communication indicators, USRM#38 (3) Inserting the printer in the system content (4) Training indication per USRM#2 (5) Update GUI screens (6) Impedance rage and accuracy (7) Reduce PPB setting for use without CRMs. (8) Update battery longevity information following 3-years of shelf life (9) Change to FCC class A (10) Update troubleshooting

cardiofit™

Neurostimulator For Heart Failure Therapy

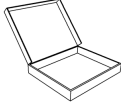# PHYSICIAN PROGRAMMER MODEL 5300

INSTRUCTIONS FOR USE (IFU)
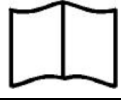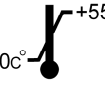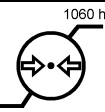
$C \in$ **0344**

!USA

CAUTION – Investigational Device. Limited By Federal Law To Investigational Use

B|O
CONTROL
MEDICAL

Explanation of symbols in 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 BF Applied Part		Manufacturer
	European Approval Mark		Date Of Manufacturing
	On	+55c° / -10c°	Storage Temperature Range
	OFF	96% / 10%	Storage & Transport Relative Humidity Range
	Stepping Prohibited	1060 hPa / 700 hPa	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		

CONTENTS:

List of Abbreviations

Abbreviation	Explanation
BCM	BioControl Medical
CIS	CardioFit™ Implanted Stimulator
CRT-D	Cardiac Resynchronization Therapy - Implantable Cardioverter - Defibrillators
CSL	CardioFit™ Stimulation Lead
EMI	Electromagnetic interference
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
RF	Radio Frequency
TD	Technical Dossier
PP	Physician Programmer
VF	Ventricular Fibrillation
VT	Ventricular Tachycardia

1.   DESCRIPTION

Introduction
The model 5300 Physician Programmer (PP) is used to interrogate and program the BioControl model 5000 CardioFit™ neurostimulator (the stimulator). The UniPP can retrieve data from and set programmable parameters in the CardioFit™ stimulator via wireless communication. Programming is done using the CardioFit™ Physician Programmer software installed on a PC compatible laptop and a programming Wand.

The Physician Programmer uses the programming Wand to transmit a wireless signal in a format that is required for communication with the stimulator (**Figure 1**). During communication, the Wand is placed over the skin next to the stimulator position.

Figure 1 – Model 5300 Physician Programmer

Specifications and user information regarding the wireless technology
The CardioFit system uses a short-range (up to 5 cm) inductive coupling communication scheme in frequency of 27 kHz. The system is ready to communicate when the green light is blinking 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 consists of:

a. One Laptop PC installed Model 5310 with BioControl CardioFit™ Unified Physician Programmer software version 2.0;
b. One Programming Wand (Model 5320);
c. One Portable Printer - Model 5330;
d. 1 X Product Literatures

2.   INTENDED USE / INDICATION

The model 5300 Physician Programmer is intended for use only with CardioFit™ system, and is subjected to the same indications for use. In Europe, please refer to RU-05-001. When using the device under clinical investigation, please refer to the study protocol.

3.   ⚠W PRECAUTIONS

- Do not immerse any part of the Physician Programmer in liquid.
- Physician Programmer (excluding Wand) should be at a distance of at least 1.5 meters from the patient during operation.
- Operator should not touch the PP and patient simultaneously.
- The use of non-BioControl components with BioControl components (other than supplied and/or approved by BioControl) may result in patient injury, loss of stimulation or components damage.
- Avoid using the PP 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 A 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.

4.   WARNINGS

- Physician, or other qualified healthcare provider should be trained in using the programmer. Training programs are available from the manufacturer.
- No modification of this equipment is allowed.
- Do not connect any equipment to Laptop except dedicated Programming Wand, and formatted USB Memory Stick.
- 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 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 cellular phones at least 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 might decrease its operating range.

C   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.

W   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

⚠ WARNING:

Programming the CardioFit stimulator should be done only in controlled environments, such an operating room or a clinic

5.1   Charging the Physician Programmer
1. Charge the PP prior to use and make sure it is fully charged.

5.2   Getting started
1. Verify that the Wand is connected to the programming Wand USB port of the PP.
2. Turn "ON" the PP. The CardioFit Physician Programmer "*Welcome*" screen will be automatically uploaded.
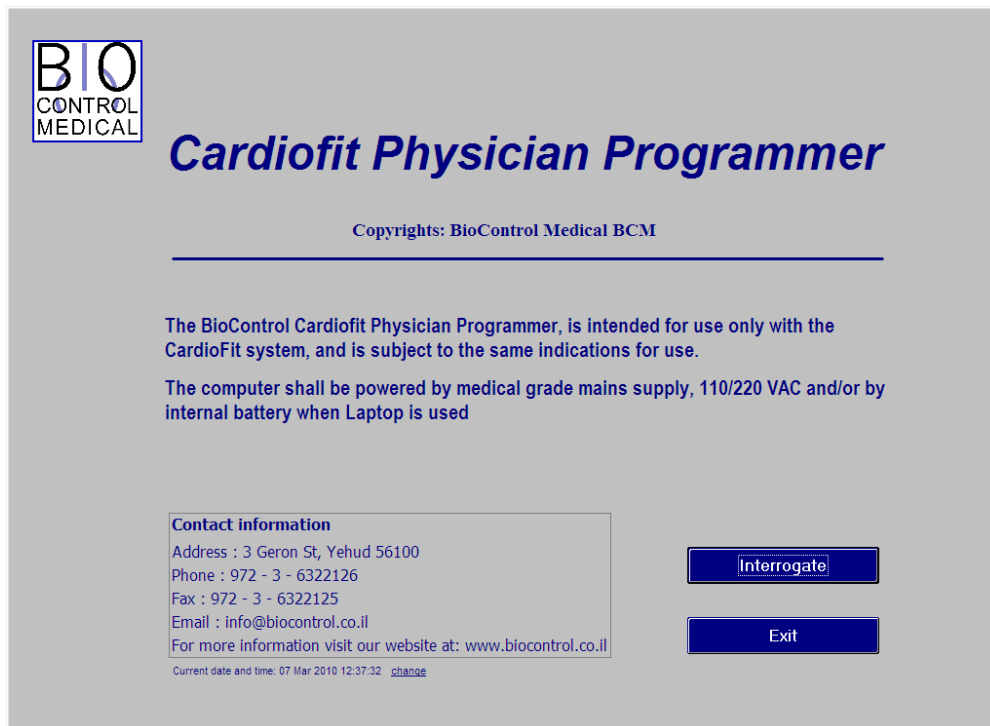
Figure 2: Welcome Screen

The green led (ready) of the Wand will light, indicating proper initialization of the system.

3. Position the programming Wand over the patient's clothes, directly over the implantable stimulator's location.

⚠ **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

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The blue led (communication) of the wand should blink at a constant frequency of 0.5 Hz (every 2 seconds). Such blinking shows proper communication and readiness for receiving and transmitting signals.

4. Check the UniPP clock. In case of incorrect time, click "CHANGE" button and adjust the time using the keyboard.

5.3 General System Interface Description

Select the "INTERROGATE" (F1) button on the "*Welcome*" screen. 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

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
    - **Date of implantation** – An editable date field

- CardioFit Implantable Stimulator (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 number** - 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 number -* 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 Activity status: 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 CIS 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
    - High/low impedance indication was given
    .
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 presents the current values of all programmable buttons and includes last measured RR interval. The interrogate function does not change parameters stored in the stimulator

Send [F3]
Press this button in order to communicate and apply the parameter setting changes. It will also perform interrogation and update output parameters such as counters.

Print Report

This button generates a hardcopy report with device parameters.
After pressing the 'PRINT REPORT' button, the image file will be ready for printing.
Single click on the Power button will turn on the printer. Double clicks will turn it off.
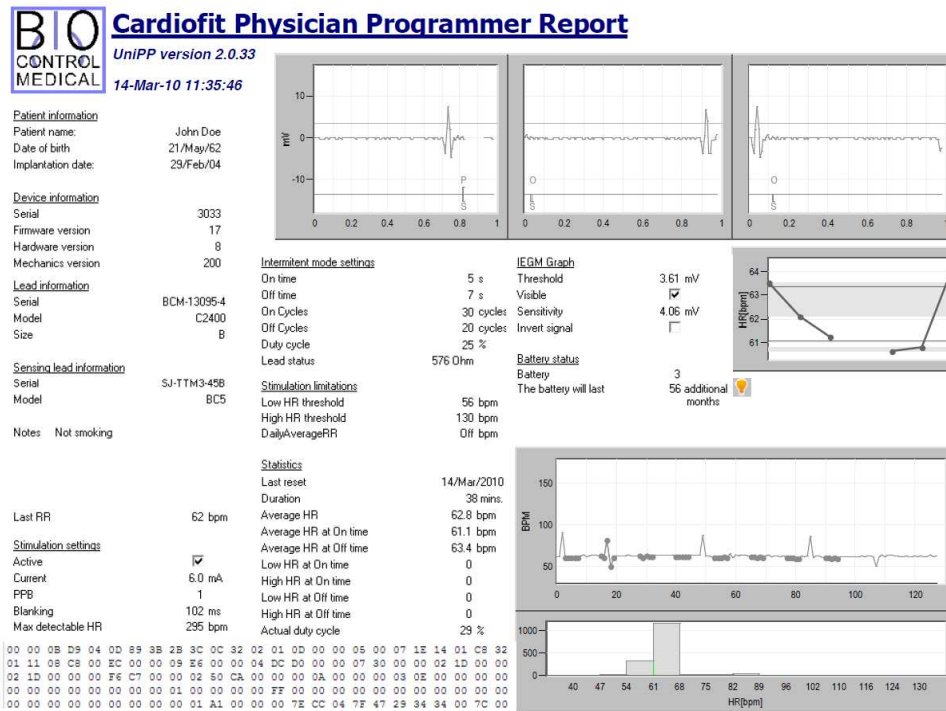
Figure 4: A Sample Print Report

Exit

Exits the Physician Programmer.

⚠ **NOTE:**

Before exiting the PP and ending the visit with the patient, it is recommended to save the device logs onto a USB memory stick for further off- line analysis of the therapy when it is required. Plug the memory stick to the USB port and press Ctrl+Alt+L button on the UniPP Keyboard

⚠ **WARNING:**

Format the USB memory stick prior to use with the Physician Programmer

These 4 buttons (Interrogate [F1], Send [F3], Print Report, and Exit) appear also in the *setting* tab and have similar functions.

5.3.2 The "Statistic" tab; Therapy evaluation.

The UniPP calculates and analyses the effect of the stimulation parameters on the patient's heart, thus enabling evaluation of optimal therapy setting. Measures are presented numerically and graphically. Statistics are accumulated by the CIS. The statistics can be reset manually.

The "Statistic" tab information is typically used at the beginning of the patient visit, in order to estimate the effect of the last prescribed therapy.
At the end of the visit, the "Statistic" tab should be revisited in order to reset the data and enable estimation of therapy effect at the next visit.
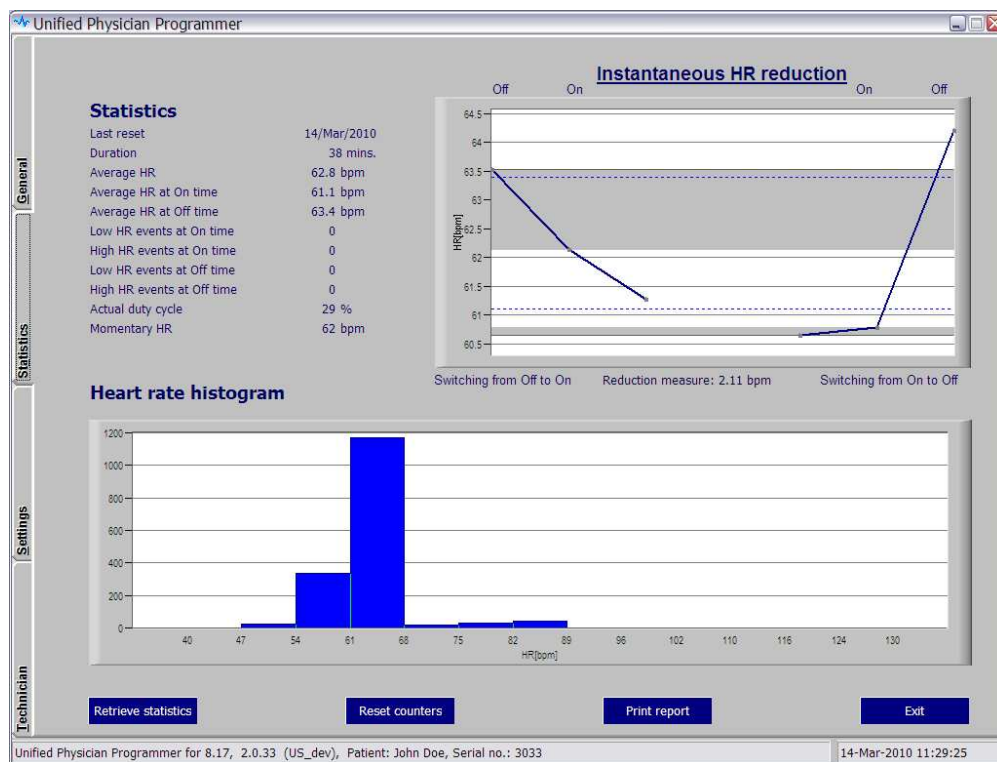
Figure 5: The Statistic tab

The Statistics tab is divided into 3 panes:

The left **Statistics** pane includes the Heart Rate (HR) numerical information:
- *Last reset* – Date of the last statistical information reset
- *Duration* – Time period over which the statistics are calculated and presented
- *Average HR* – The average HR of all heart beats detected by the device
- *Average HR at On time* - The average HR of the heart beats detected within the pre-specified HR detection thresholds (low and high HR) and calculated by the device while stimulation was delivered

- *Average HR at Off time* - The average HR of the heart beats detected within the pre-specified detection limits (low and high HRs) and calculated by the device while <u>stimulation was not given</u>
- *Low HR events at On time* - A counter registering how many detection events (R waves) occurred at a rate below that defined as *Low HR Threshold*.
- *High HR events at On time* - A counter registering how many detection events (R waves) occurred at a rate above that defined as *High HR Threshold*.
- *Low HR events at Off time* - A counter registering how many detection events (R waves) occurred at a rate below that defined as *Low HR Threshold*.
- *High HR events at Off time* - A counter registering how many detection events (R waves) occurred at a rate above that defined as *High HR Threshold*.
- *Actual Duty cycle* – The ratio (in percentage) between the period at which stimulation was administrated and the period at which stimulation was not administrated.
- *Momentary HR* – The value of the last RR interval measured by the device in bpm

The right **HR Reduction** pane includes graphical presentation of the average instantaneous heart rate reduction (iHRR) for the time duration indicated in the left pane.
The graph provides visual evaluation of the effect of stimulation on the heart rate. The three left points are the average HR for the last 2 beats before the stimulation is switched from off to on and the average HR for the first beat after switching from off to on respectively. The three right points are the average HR for the 2 last beats before the stimulation is switched from on to off and the average 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.
The iHRR value is presented below the figure. It is calculated from the mean value of the first two points (off stimulation) minus the mean of the following two points (on stimulation).
Two blue dashed lines are drawn at the values of the average HR at On time and average HR at Off time.

  Zooming in/out
  Marking the desired area in the graph to be zoomed-in while left clicking the "mouse" will provide focused area of interest. Repeat the procedure for higher magnification if required.
  Right click will reset the axis scale.

⚠ **NOTE:**

The iHRR figure statistic is reliable only if the interval duration (since last reset counters) is greater than 24 hours

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

Retrieve statistics
Updates the statistics parameters including update of the HR reduction figure as well as the HR histogram,

Click the 'PRINT REPORT' button after pressing the 'RETRIEVE STATISTICS' button for patient history records. This report documents the therapy performance since last visit (since last reset counters activation).

Reset counters
Resetting the CardioFit statistics counters. After pressing the button, a message box appears and indicates successful reset action.

Click the 'PRINT REPORT' button after pressing the 'RESET COUNTERS' button for patient history records. This report documents the end of visit therapy parameter setting.

⚠ **NOTE:**

Pressing "Reset counters" button will not update the screen with reset counters; for the updated numbers please use "retrieve statistics".

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 Vagus nerve stimulation therapy programming and changes are performed through the Setting tab.

The top pane contains a switch screen of IEGM and HR streaming. Clicking the relevant tab on the top of the screen switches 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 = 2mV.

Figure 6: The IEGM Setting tab

Update IEGM (F9)
The 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 continuous in time.

Zooming in/out

The zoom control buttons are located at the left side of the IEGM screen marked by **+** and **–**.

Pressing the **+** results in IEGM magnifying, each pressing 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 black line below the IEGM and the threshold graph,

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

Inhibition letter legends: (also available when pressing the "?" button)

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

I – Impedance not measured

P – Pulse

S - Sense

IEGM max measured amplitude

Below each IEGM window screen, the "Peak" R wave value is presented.

Detection Threshold

The threshold for R wave detection appears on the grid of the display as a bright purple/magenta line that can be set higher or lower by left clicking and dragging or by entering the numeric value.

An optimal threshold setting should be at two-thirds of the R wave peak.

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

The "Sensitivity" indicator shows the guaranteed sensitivity at the chosen detection threshold

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.
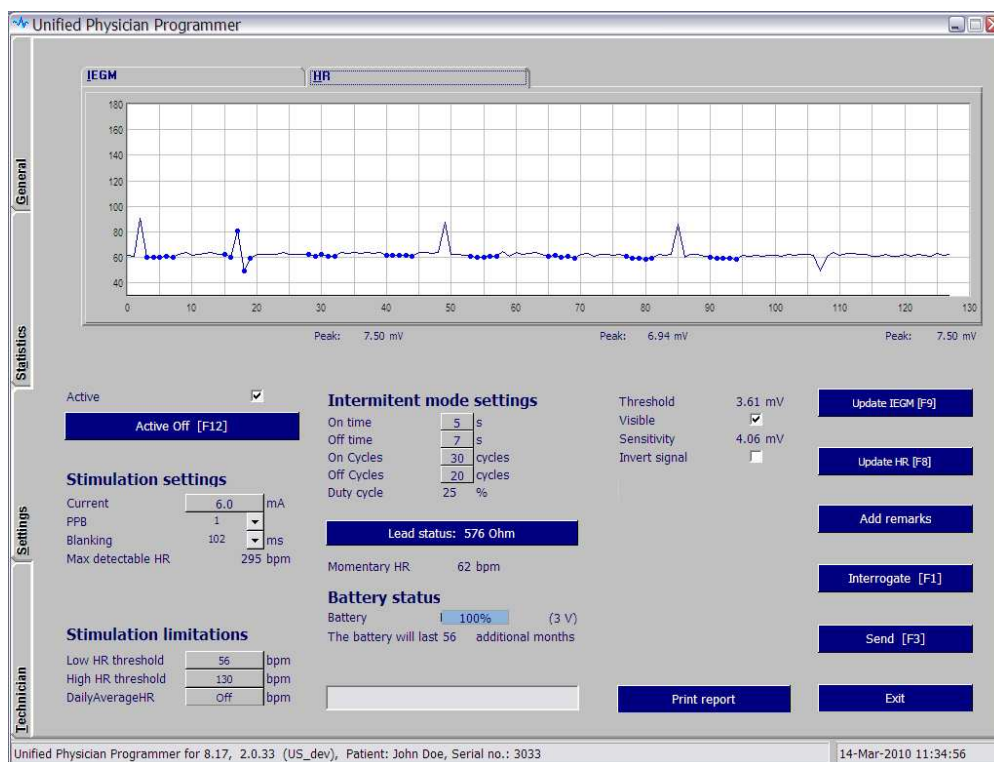
Figure 7: The HR Setting tab

Update HR [F8]
This 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 larger dots.

Zooming in/out
Marking the desired area in the graph to be zoomed-in while left clicking 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 settings:

Stimulation Settings:

Active
Check box may be un-checked in order to inactivate the device. In the 'non active'
mode the CIS is not sensing or counting and not stimulating. When the box is
checked the CIS is activated.

Current
Sets the amplitude of the current provided by the stimulation lead in milliamps (mA). Value can only be selected 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
Pulses **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).

The following table specifies stimulation interval duration from at each specified PPB

PPB	actual PPB	Delay From R [ms]	Pulse Repetition Interval [ms]
1	1	94	8
2	2	8	86
3	3	8	39

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 ms in 7-8ms steps. It appears in the IEGM as uncolored line area.
The default value is 102ms.

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: PPB, and blanking. The 'Max detectable HR' field becomes red if the programmed 'High HR Threshold' is greater than 90% of the max detection rate.

⚠ **WARNING:**

If 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, cycle or stimulation parameters are. Stimulations are inhibited when 3 out of 4 of the last RR intervals are shorter than this value. The default value is 130 BPM.

Low HR Threshold
The heart rate below which no stimulation is provided no matter what the mode, cycle or stimulation parameters are. Stimulations are inhibited when 3 out of 4 of the last RR intervals are longer than this value. 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.
At 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 algorithm 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 8, 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.
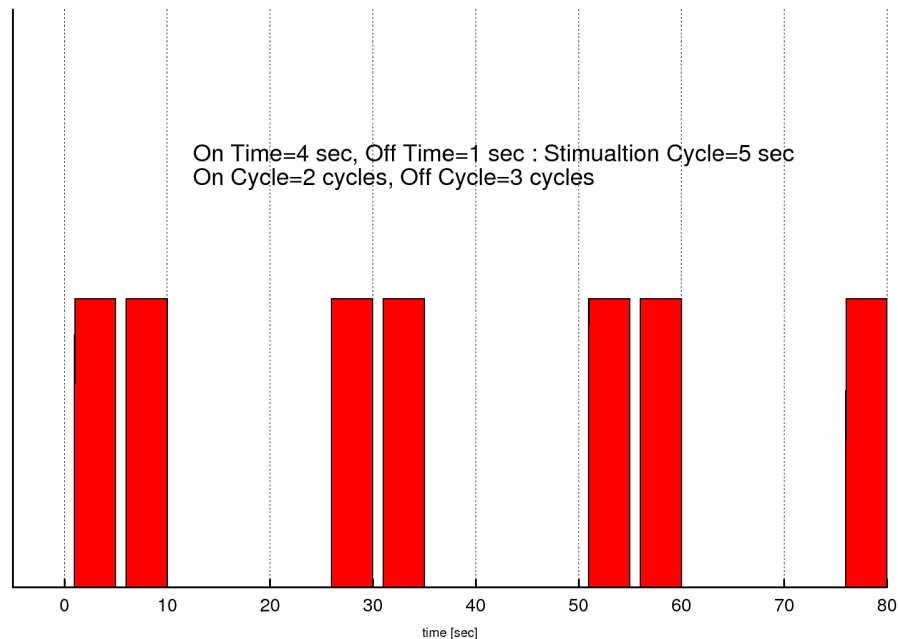
Figure 8: On/Off time and On/Off Cycle operation parameters.

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%. The duty cycle should not exceed 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 in 20% accuracy. Working range is 300 – 2500 Ω, 4 – 10µF.

⚠ **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 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 Programmer will issue a warning: "Impedance measurement was not performed. Verify that stimulation is not inhibited". The lead status shown will be from the last successful test. Stimulation will not be delivered if the lead status results is not "OK"

Battery Status

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

⚠ **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 device replacement".
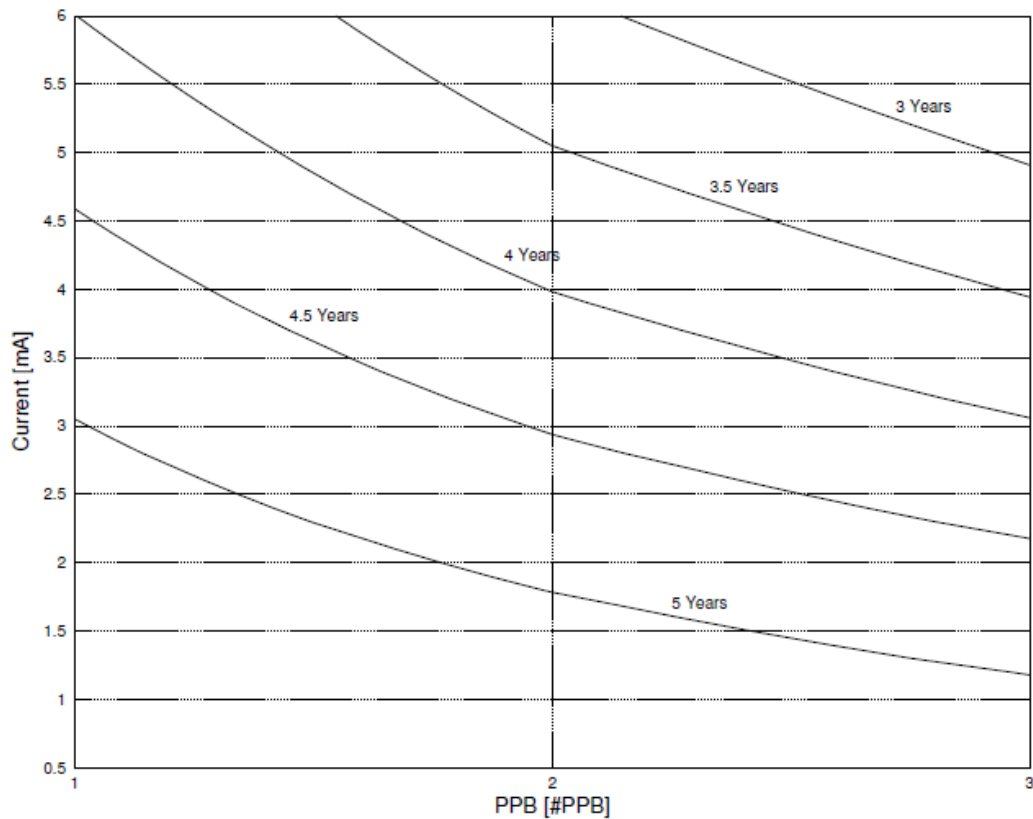
Figure 9: Predicted device life time as function of current and PPT

The nominal predicted lifetime of the CardioFit™ Implantable Stimulator battery in the maximal therapeutic setting is 4.5 years and the minimum is 3.0 years.
The nominal predicted lifetime is calculated under the following conditions:
Stimulation electrode Impedance: 1740Ω; Capacitance: 4.7µF
Stimulation current: 5mA, 3 pulses per beat,
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.

Emergency button [F12]
This button function is to switch the device to an active off mode without the need of pressing the "send" button, use this button when there is need to terminate the device function immediately.

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 one after the other and then press the "Send' button.

Range and default of programmed parameters list:

Parameter	Range	Default
On Time [s]	0…(1)…10…(5)…255	0
Off Time [s]	0…(1)…10…(5)…255	0
PPB	1, 2, 3	1
Current [mA]	0…(0.1)…6	0
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	0ff
Blanking [ms]	8…(8)…1000	102
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 light+ blue blinking light appears. Hold the programming wand in place until the transmitted parameters had been programmed.

Unified Physicain Programmer	IFU

> ⚠ **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 operative (depending on patient recovery from system implantation and wound healing), and lasts around 4 to 6 weeks. In order to optimally set the therapy, approximately 6 to 8 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 synchronized vagus nerve stimulation (with the depolarization rate of the ventricles), CardioFit therapy settings. Optimal setting criteria are:

- Instantaneous Heart Rate Reduction ("iHRR") greater than 0.5 bpm in an interval ≥ 24-hour; and
- 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 should be noted.
- 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

o 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 and compare it with the previous results.
- 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 than 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 [s]	10
Off Time [s]	15
PPB	1
Current [mA]	0.1
On Cycles	30
Off Cycles	20
Low Stimulation Limit [BPM]	56
High Stimulation Limit [BPM]	130
Daily Average HR	Off
Blanking [ms]	70

- 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 "Statistics" tab: HR statistics, HR reduction figure and HR distribution histogram for the last interval and in the "Setting" tab: HR figure.

- ON Time settings change:
  - o Review the HR reduction figure appears in the "Statistic" tab after pressing the "Retrieve" button at the beginning of each session.
  - o 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.
  - o 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.
  - o Please note that whenever On time is modified, the Off time should be modified accordingly in order to keep the overall Duty Cycle constant.
- PPB setting change;
  When significant iHRR in an interval ≥ 24-hours is observed switch setting to 2 PPB.
  - o The change may require reduction of 0.5mA in pulse current
  - o 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 CARDIAC IMPLANTABLE DEVICES

7.1   *Implanting CardioFit with another cardiac implanted device in the same patient*

This section provides the procedure that is to be followed when implanting CardioFit in a patient with an implanted cardiac device (e.g. pacemaker, bi-ventricular pacemaker and/or defibrillator) under the approved use of the CardioFit within the specific geography. 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.

> ⚠ **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)

Before implantation:
- Before implanting one or both of the devices, ensure that both devices can communicate with their respective programmers:
  - Place both devices at the same distance at which they will be implanted in the patient:
    - Do not remove the devices out of their sterile packages
    - If one of the devices is already implanted, place the other device (still inside the sterile package) on the patient on the area where it is to be implanted
    - Initiate communication with both devices and ensure communication is error free
    - If one device's programming wand interferes with the other devices programming wand, repeat the test with only one programming wand in the device area – both devices should be able to communicate with their programmer while the other programmer is not near
- If both devices can communicate proceed with implantation

7.2   *Programming device parameters*
After both devices are implanted, 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.

Note: It is possible and common for a device to be both anti-bradycardia and anti-tachycardia (e.g. a CRT/D). 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 needed. Use the following formula:

$$ms = 1000*60/bpm$$
$$bpm = 1000*60/ms$$

- Never use uni-polar sensing in a device implanted with CardioFit
- Set the CardioFit sensing threshold to be at least 50% of the R-wave amplitude
- Ensure that the other device has a refractory period of at least 135 ms following a sensed ventricular event
  - The 135 ms minimal refractory period should be set in all leads used for sensing by the other device. For devices that sense both in the atrium and ventricle, both the atrial refractory period after ventricular sensing (e.g. Post-Ventricular Atrial Blanking) and the ventricular refractory period after ventricular sensing should be greater than 135 ms

- If 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

  - Other device is using bi-ventricular pacing
    - The other device's and CardioFit's parameters shall be set to values such that 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
      130 ms = 1200 bpm
      CardioFit Maximal detectable heart rate should be smaller than 1200 bpm
- If the other device is an anti-tachycardia device
  - The other device's and CardioFit's parameters shall be set to values such that the CardioFit High HR threshold is well below the other device's VT zone
    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 such that the CardioFit High HR threshold is well below the other device's anti-tachycardia pacing interval

Example:
Other device's anti-tachycardia pacing interval= 200 ms
200 ms = 300 bpm
CardioFit High HR threshold should be below 280 bpm

7.3   Patient follow-up

During patient follow-up special attention should be paid 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
- Communication problems

It is recommended that any record of the IEGM from such an event be inspected to ensure that no device-device interaction had occurred.

⚠️ **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   MAINTANANCE, HANDLING, AND STORAGE

8.1   Maintenance

Except for PP battery charging and cleaning of the Programming Wand the Physician Programmer does not require maintenance:

- Do not sterilize the programming wand, use only disinfecting pre-moistened cloth and wipe the Wand surface.
- Return the UniPP to BioControl if repair or replacement is required.
- If required, the Physician Programmer components can be cleaned with a moistened cloth.

⚠️ **NOTE:**

For additional PC laptop and printer operation and maintenance instructions please refer to the vendors manuals included in this package

8.2   Handling

- Never immerse the programming wand in liquid.
- Place thermal A4 paper in printer

.

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 0ºC and 45ºC. 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	Blue light not blinking	Check the green light – if the green light is off take the following actions: 1. Start the Physician programmer. 2. Verify that the Physician Programmer and programming wand are properly connected. 3. disconnect the programmer from mains If the green light is on take the following actions: 1. Reposition wand 2. Ask patient to change his/her position. 3. Check physician programmer operation on a neutral CardioFit™-X device. 4. Change the programming wand. 5. change location together with the patient 6. In case the problem did not resolved contact BioControl Medical (BCM) Ltd.
	Blue light blinking in high frequency	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) Ltd.
Physician Programmer not responding or a persistent malfunction not related to communication.		1. Restart the program. 2. If the problem is not resolved, restart the system. 3. Contact BioControl Medical (BCM) Ltd.

⚠ C   **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.
"There is no communication"	Indicates a communication error.	See the table above.
"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 massage 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
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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 8.17 are intended for use in the electromagnetic environment specified below. The customer or the user of the Physician Programmer model 5300 & CardioFit-X ver 8.17 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 8.17 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 8.17 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 8.17 are intended for use in the electromagnetic environment specified below. The customer or the user of the Physician Programmer model 5300 & CardioFit-X Ver 8.17 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 8.17 requires continued operation during power mains interruptions, it is recommended that the Physician Programmer model 5300 & CardioFit-X Ver 8.17 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 8.17 are intended for use in the electromagnetic environment specified below. The customer or the user of the Physician Programmer model 5300 & CardioFit-X Ver 8.17 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	Portable and mobile RF communications equipment should be used no closer to any part of the Physician Programmer model 5300 & CardioFit-X Ver 8.17, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2,5 GHz 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 meters (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 the Physician Programmer model 5300 & CardioFit-X Ver 8.17 are used exceeds the applicable RF compliance level above, the Physician Programmer model 5300 & CardioFit-X Ver 8.17 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 8.17 [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the Physician Programmer model 5300 & CardioFit-X Ver 8.17			
The Physician Programmer model 5300 & CardioFit-X Ver 8.17 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 8.17can 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 8.17 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 meters (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.			

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CE 0344

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, 7561922, 7627384, 7634317 and 7,346,398, as well as corresponding international patents. Other patents are pending.

!USA   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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Year of
authorization:
2008