

Operator's Manual

Heart Failure PARTNER™

Model 2936

**Heart Failure Diagnostic
Retrieval System**

GUIDANT

The following symbol is a trademark of Guidant Corporation:



Interrogation symbol

Table of Contents (English)

Product Description 3

Intended Use 4

Contraindications 4

Warnings and Precautions 4

Federal Communications Commission (FCC) 5

Package Contents 5

Contacting Guidant 5

Inspection and Setup 6

How to Interrogate an Implanted Heart Failure Device 6

How to Print Reports 8

Qualified Printers 10

How to Delete Diagnostic Records 10

HF PARTNER Device Functions 11

Language selection 11

Speaker control 12

Voice Messages	12
Reminder Label	15
How to Care for the HF PARTNER Device	16
Cleaning	17
Operating Temperatures	17
Battery Replacement	17
Pairing the HF PARTNER Device with a Compatible Printer	19
Troubleshooting	20
Specifications	23
Explanation of Product Markings	24
Package Content Symbols	25

Product Description

The Heart Failure (HF) PARTNER™ system consists of a Model 2936 HF PARTNER device, a printer adapter, and a printer. The HF PARTNER device is a handheld, battery-powered product used to communicate with an implanted device. It provides easy access to patient and device diagnostic data by interrogating the patient's implanted heart failure device and sending the data to a printer through the printer adapter.

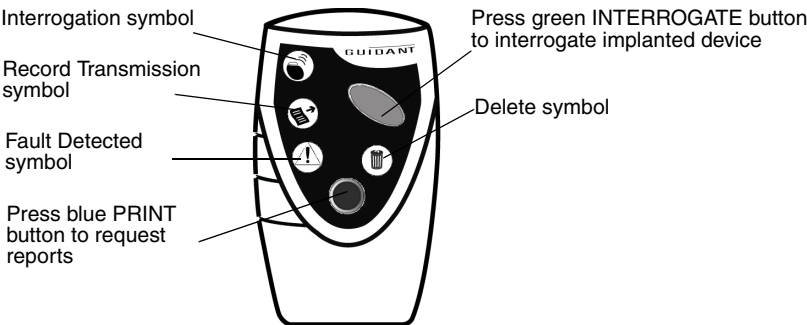


Figure 1. Model 2936 HF PARTNER device with lighted symbols and buttons shown.

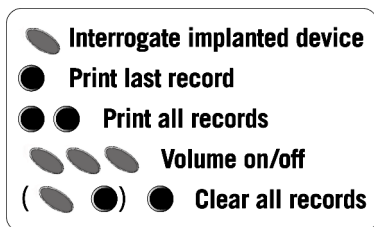


Figure 2. Reminder instructions on back of the HF PARTNER device.

Intended Use

The HF PARTNER device is intended for use in a clinical setting. Physicians and clinicians can use the HF PARTNER device to collect device and patient diagnostic data from an implanted heart failure device and send the data to a paired printer only. The HF PARTNER device has no programming abilities, or ability to provide therapy of any kind.

The HF PARTNER device can be used with any compatible Guidant cardiac resynchronization therapy (CRT) device except CONTAK CD. To verify compatibility, please call Guidant Technical Services. See “Contacting Guidant” on page 5.

Contraindications

There are no contraindications for the HF PARTNER device.

Warnings and Precautions

- Use of the HF PARTNER device is for medical professionals only and should be used within a clinical setting.
- Only a clinician/medical professional can make diagnostic or interpretive decisions regarding the health of a patient based on the data presented or acquired by the HF PARTNER device.

- Only Guidant-recommended accessories, such as the Bluetooth enabled printer and Bluetooth accessory should be used with the HF PARTNER device.
- The HF PARTNER device is not intended to sound any physiological alarms.

Federal Communications Commission (FCC)

This device complies with Title 47, 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 of the device.

CAUTION: Changes or modifications not expressly approved by Guidant could void the user's authority to operate the equipment.

Package Contents

The following items are included in the HF PARTNER device package:

- Model 2936 HF PARTNER device with batteries installed
- Operator's manual
- Warranty
- Blank notebook
- IFU poster
- Guidant brand label
- Declaration letter

Contacting Guidant

Use the following methods to contact Guidant Technical Services:


- US 1.800.CARDIAC (1.800.227.3422)
- European +32 2 416 93 57 or eurtechservice@guidant.com

Inspection and Setup

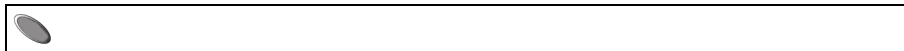
Inspect the HF PARTNER device, printer and printer adapter package contents for any signs of damage or defects. If any defect or damage is visible, contact your Guidant sales representative or call Guidant Technical Services. See “Contacting Guidant” on page 5.

The following steps explain how to setup your HF PARTNER system:



1. Connect the USB cable to the printer adapter and the USB port on the printer.
2. Attach the printer adapter power cord to the printer adapter and plug the printer adapter power cord into a standard wall outlet.
3. Attach the printer power cord to the printer power input and plug the other end of the power cord into a standard wall outlet.
4. Press the printer ON button.


Press the green INTERROGATE button  to ensure that the HF PARTNER device is operational; the symbols on the front will light up and a voice message will be heard.

How to Interrogate an Implanted Heart Failure Device



Use the following steps to interrogate an implanted heart failure device using the HF PARTNER device:

1. Press the green INTERROGATE button . The “Interrogation requested” voice message will be heard, followed by “Locate implanted device”.
2. Move the HF PARTNER device over the patient’s implanted device (Figure 3). The visual indicators on the front of the HF PARTNER device will light in consecutive sequence until the communication with the implanted device is established. During interrogation, the Interrogation light  will blink while data is transmitting. At the end of a successful interrogation, the HF PARTNER device

will emit the “Interrogation complete” message. The Interrogation light  will stay on for five seconds after successful interrogation.

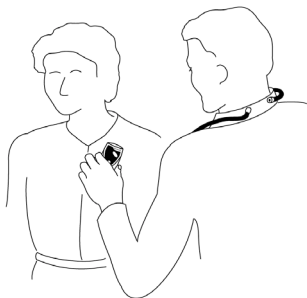



Figure 3. Hold the HF PARTNER device over the patient’s implanted device, with buttons and lights toward you.

NOTES:



- *You have about 10 seconds from the time you press a button until you locate the implanted device. If the HF PARTNER device is unable to locate the device, the voice command “Locate implanted device” will be repeated. Position the top half of the HF PARTNER device over the implanted device and move the HF PARTNER device slowly. If the interrogation is unsuccessful, hold the HF PARTNER device over the patient’s implanted devices with the button and lights AWAY from you.*
- *If the interrogation was unsuccessful, the HF PARTNER device will notify you by communicating “Interrogation unsuccessful, please interrogate again”. Repeat the interrogation process until you receive the “Interrogation complete” message.*
- *If you hear the “Locate implanted device” message (NOT followed by the “Interrogation unsuccessful, please interrogate again” message), you have requested the interrogation of an incompatible device. Ensure that you have a compatible Guidant device.*
- *If communication is lost during interrogation, the visual indicators on the front of the HF PARTNER device will light in consecutive sequence. Reposition the*

HF PARTNER device over the patient's implanted device to resume communication.

- If the implanted device exhibited a lead or heart failure device fault, including when the implanted device's battery is due for replacement, the fault detected light  will stay on for five seconds after completion of the interrogation. Contact the physician who follows this patient's implanted device.





How to Print Reports

Diagnostic Report

-  Last record requested
-  All records requested

The HF PARTNER device prints a Diagnostic report that provides patient diagnostic data collected by the device. You may choose to print the last record or all records in the device memory.

Use the following steps to print desired reports:

1. Place the HF PARTNER device near the printer adapter and press the appropriate button sequence (Figure 4). To print the last record, press the blue PRINT button  once. To print all records press the blue PRINT button  twice. All lights will flash sequentially while the HF PARTNER device is looking for a printer.
2. When a printer is located, you will hear the "Connecting" message. The record transmission light  will blink while data is transmitting. Continue to keep the HF PARTNER device near the printer adapter. Upon successful data transfer you will hear the "Records transmitted" message and the report will print.
3. After printing is complete, the record transmission light  will stay on for five seconds.

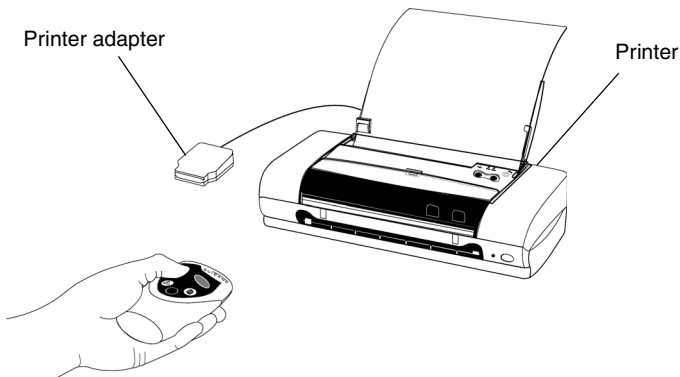


Figure 4. Hold the HF PARTNER device near the printer adapter.

The Diagnostic report will include the following information:

- Patient Data
- Events Summary
- Counters and Histograms
- Atrial Arrhythmia Counters
- Battery Status
- Device Settings
- Trends (includes Activity Log, Heart Rate [HR] trends, Heart Rate Variability [HRV], Autonomic Balance Monitor [ABM], and Standard Deviation of Averaged Normal R to R intervals [SDANN])


If four or more events have occurred since the last device physician follow-up with a programmer, a list of up to 50 of these events will appear at the end of the report.

This report will also document whether a problem with the implanted device system has been detected. The following messages may be seen on the report:

- Implanted device fault
- Lead fault
- Battery fault

If you see any of these messages, contact the physician who follows this patient's implanted device.

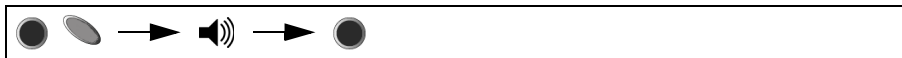
NOTES:

- *The availability of each report feature is dependent upon the device interrogated. Refer to the heart failure device's system guide for information about available features or call Guidant Technical Services. See "Contacting Guidant" on page 5.*
- *If the HF PARTNER device is unable to interpret the information from the implanted device, the record will show ????. Interrogate the implanted device using a Guidant programmer to receive more information. See "Contacting Guidant" on page 5.*
- *The HF PARTNER device can store up to 10 records. When the HF PARTNER device memory is full, the oldest record will be deleted to allow the newest record to be stored. The delete light  will stay on for three seconds.*






Qualified Printers

The HF PARTNER system will be provided with a tested and qualified printer. To verify compatibility of other printers, please call Guidant Technical Services. See "Contacting Guidant" on page 5.

How to Delete Diagnostic Records



Use the following steps to delete all of the diagnostic records stored in the HF PARTNER device's memory:

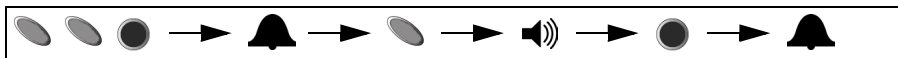
1. Press the blue PRINT button  and the green INTERROGATE button  within three seconds. You will hear the “Confirm request to clear all records” message. The “Delete” light  will flash.
2. Press the blue PRINT button  within 10 seconds of the voice message to confirm that you want to delete the records. Otherwise, the HF PARTNER device will time-out and no records will be deleted. The “Delete” light  will stay on for five seconds to indicate the records have been deleted.

NOTE: When 10 records are stored in the HF PARTNER device, the device will automatically delete the oldest record.





HF PARTNER Device Functions

NOTE: When using the HF PARTNER device, the button sequences for all commands must be pressed within three seconds.

Language selection




The HF PARTNER device allows a choice of English, French, German, Italian, Portuguese and Spanish languages for the voice messages and printed reports. English is the default language. Follow the steps below to select the desired language:

1. Press the green INTERROGATE button  twice and the blue PRINT button  once within three seconds. This will put the HF PARTNER device into Configuration Mode. You will hear a tone from the HF PARTNER device.
2. Press the green INTERROGATE button  once to access the Language List. The HF PARTNER device will verbally cycle through the list of available languages.
3. Press the blue PRINT button  when the desired language is identified. You will hear a tone from the HF PARTNER device indicating the selected language has been implemented.

Subsequent communication will remain in that language until it is changed by accessing the Configuration Mode. All diagnostic reports will print in the selected language.

Speaker control



The speaker of your HF PARTNER device can be turned On or Off by pressing the green INTERROGATE button  three times within a three second period of time. When the speaker is turned Off, the “Speaker Off” message will be heard. A tone will be heard when the speaker is turned back On.

Voice Messages

Table 1 lists the voice messages that you may hear and the associated action. The Speaker Control must be On to hear these messages. The voice message is shown in bold text.

Table 1. Voice Messages



Interrogation Requested
Action: You pressed the green INTERROGATE button  .
Interrogation completed
Action: The interrogation has been successfully completed.
Locate Implanted Device (followed by the message interrogation unsuccessful, please interrogate again)
Action: You pressed the green INTERROGATE button  . You should move the HF PARTNER device over the patient's implanted device to initiate communication between the HF PARTNER device and heart failure device.
Locate implanted device (NOT followed by the message interrogation unsuccessful, please interrogate again)
Action: You requested the interrogation of an unsupported heart failure device.

Table 1. Voice Messages (Continued)

Interrogation unsuccessful, please interrogate again Action: The diagnostic interrogation request was unsuccessful. Interrogate the device again.
Connecting Action: You requested that a diagnostic report be sent to the enabled printer and pointed the HF PARTNER device toward the printer adapter. Connection with the printer adapter can take up to 30 seconds. This message is repeated up to two times while attempting to connect with the printer system.
Last record requested Action: You requested to print the most recent record using the "Last record requested" command. Place the HF PARTNER device near the printer adapter to print the record.
All records requested Action: You requested to print all saved records by using the "Print all records" command. Place the HF PARTNER device near the printer adapter to print all of the saved records.
Records transmitted Action: You requested to print one or more records, which were successfully transmitted to the printer.
Records not transmitted Action: The requested print command was not completed successfully. Repeat the command to print the desired record.
No record to transmit Action: You requested to print a record, but no records are stored in the HF PARTNER device's memory.

Table 1. Voice Messages (Continued)






Confirm request to clear all records Action: You pressed the blue PRINT button  and green INTERROGATE button  ; the HF PARTNER device will ask you to confirm that you want to delete all records. Press the blue PRINT button  within 10 seconds of this voice message to confirm that you want to delete all records.
Battery Low Action: You should replace the HF PARTNER device batteries. This voice message will be heard with the speaker control turned On or Off.
Speaker Off Action: You turned the speaker Off.
PARTNER Fault Detected Action: The HF PARTNER device failed a self-test due to a reason other than depleted batteries. A system status report can be printed from a qualified printer. You should call Guidant Technical Services to report the problem. See “Contacting Guidant” on page 5.
Language list Action: You pressed the green INTERROGATE button  once while the HF PARTNER device was in Configuration Mode. This accessed the list of available languages. Now you can select your preferred language by pressing the blue PRINT button  . See “Language selection” on page 11.
Printer paper error Action: The printer is out of paper or there is a paper jam. If it is out of paper, reload paper. If the paper is jammed, clear the paper path of any obstruction.
Printer toner error Action: The printer is out of toner; replace the toner cartridge. This message will also be heard when the wrong toner cartridge has been inserted.































Table 1. Voice Messages (Continued)

Printer status error

Action: There are several errors that may cause this message: the printer top may be open, the printer carriage may be jammed, or the printer may be busy.

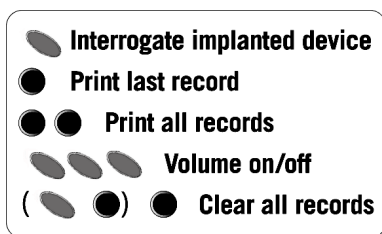
Table 2 provides a summary of HF PARTNER device commands and their associated button sequences.

Table 2. HF PARTNER Device Commands

Interrogate Implanted Device 
Print Last record 
Print All records  
Print Status Report page   
Volume On/Off   
Clear All records   →  → 
Language selection    →  →  →  →  → 
Printer Pairing    →  →  →  →  → 

Reminder Label

Before you hold the HF PARTNER device over your patient's implanted device, you can use the label on the back of the HF PARTNER device to remind you which buttons to push (Figure 5). Read the instructions in this book for full details.



One button means to push the button just once and wait for the requested information.

Multiple buttons means to push the buttons in the sequence shown and wait for requested information.

The buttons in the parenthesis () means to press those buttons first.

Figure 5. Reminder label on the back of the HF PARTNER device.

How to Care for the HF PARTNER Device

The HF PARTNER device is designed to be handled on a daily basis. However, the following precautions should be taken to avoid damaging or breaking the unit.

CAUTIONS:

- Do not drop or mishandle the unit in a manner that would cause damage.
- Avoid getting liquid on the unit other than cleaning it with a moistened cloth.
- Do not submerge the unit in liquid.
- Do not use abrasive cloth or solvents to clean the unit.
- Do not open the unit except to change the battery.

NOTE: *In case of accidental submergence in liquid, remove the batteries, dry the HF PARTNER device with a soft cloth, then allow air to circulate around it for a minimum of 24 hours. For example, place it in front of a fan. Then install new batteries. If the HF PARTNER device does not function properly, call Guidant Technical Services. See “Contacting Guidant” on page 5.*

Cleaning

When necessary, clean the HF PARTNER device with a soft cloth moistened in water or mild detergent. Do not allow moisture to accumulate on or around the labels, speaker holes, or the case seam.



Operating Temperatures

The HF PARTNER device will operate with best results at temperatures between 10° C and 50° C (50° F and 122° F). Keep the HF PARTNER device within this range of temperatures if possible. Allow it to warm up if it has been in colder conditions. Avoid leaving it in direct sunlight or in unventilated enclosed spaces.

Battery Replacement

The HF PARTNER device is shipped with the required two 3.0 volt CR2 batteries installed.

Replace the batteries when:

- You receive a Battery Low audible message.
- The symbols don't light up when you press the green INTERROGATE button  or blue PRINT button .

CAUTIONS:

- When the unit is open while changing the battery, do not attempt to disassemble any other part. The unit may not function properly.
 - Do not remove the batteries within 5 minutes of performing an operation. Failure to adhere to this recommendation could place the HF PARTNER device in an unusable state.
1. Flip up the quarter turn fastener ring.
 2. Turn the fastener one quarter turn counter-clockwise.

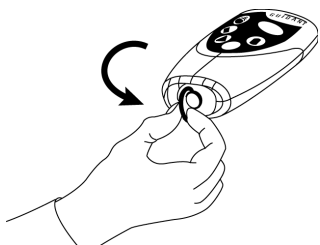


Figure 6. Turning the fastener.

3. Slide the rubber case bottom off.

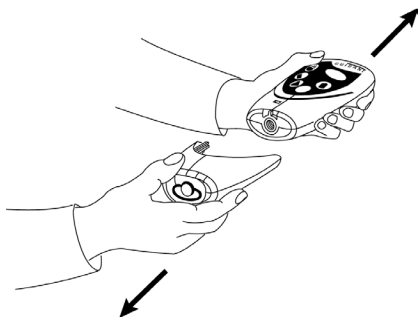


Figure 7. Removing the bottom case.

4. Remove the batteries from the HF PARTNER device.

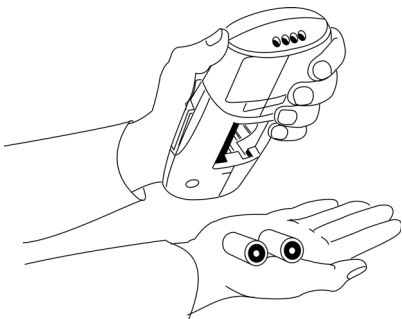

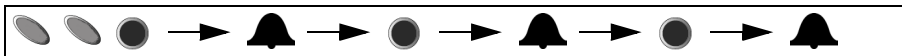




Figure 8. Removing the batteries from the HF PARTNER device.




5. Insert the new batteries.
6. Replace the rubber case bottom on the HF PARTNER device.
7. Properly dispose of the old batteries.
8. Press the green INTERROGATE button  to ensure that the HF PARTNER device is functioning properly.

Pairing the HF PARTNER Device with a Compatible Printer



A printer must be paired to the HF PARTNER device to transmit a diagnostic report securely. Reports can only be printed to a paired printer. The HF PARTNER system is paired before it is shipped; however, follow these steps to set up the printer should you get a new system component:

1. Go into the configuration mode by pressing the green INTERROGATE button  twice and the blue PRINT button  once within three seconds.

2. Wait for the configuration mode tone to sound, then press the blue PRINT button .
3. When a printer has been located, a double tone will be heard and a system status page will be printed.
4. Press the blue PRINT button  within 60 seconds of the double tone to confirm.
5. The double tone will then be heard again.
6. If the double tone is heard but the status page is not being printed, or is being printed from the wrong printer, press the green INTERROGATE button  to start the pairing process again.
7. If the double tone is heard but the user does not press any button within 60 seconds, the pairing will fail.
8. If pairing failed for any reason, a low-pitched double tone will be heard.

NOTE: Before beginning the pairing process, verify the printer power is On and there are no printer errors (e.g., paper jams, no paper, etc.).

Troubleshooting

Problem	Possible Solution
Symbols do not light up.	Change the batteries.
Voice messages sound crackly.	Change the batteries.
Symbols flash randomly when a button is pressed.	Change the batteries.
New batteries have been inserted, but button presses do not turn the HF PARTNER device On.	Check if the batteries are inserted properly (see “Battery Replacement” on page 17). If it still doesn’t turn On, call Guidant Technical Services. See “Contacting Guidant” on page 5.
HF PARTNER device buttons were pressed but no function was performed	The HF PARTNER device may be completing the previous function. Wait three seconds and press the desired command sequence again.

Problem	Possible Solution
You replaced the batteries but still received the “Battery low” message.	If you just printed diagnostic reports, let the HF PARTNER system recharge for 30 to 60 minutes. If you still hear this message after letting the batteries recharge, call Guidant Technical Services. See “Contacting Guidant” on page 5.
The HF PARTNER device cannot communicate with an implanted device.	<ul style="list-style-type: none"> • Move the HF PARTNER device around gently until communication is made with the implanted device (see Figure 3 on page 7), or try repositioning the HF PARTNER device (such as turning it over). • Verify the implanted device is a compatible Guidant device.
Voice messages cannot be heard.	Turn the speaker On using the steps on page 12.
Voice messages are no longer in the language of your choice.	The selected language may have been changed. Reset the HF PARTNER device to the language of your choice. See “Language selection” on page 11.
The report won’t print	<ul style="list-style-type: none"> • Change the distance between the HF PARTNER device and printer. Optimal performance is 3-15 feet. • Check that the printer adapter is turned On (look for flashing lights when the transmission occurs). • Check the printer for warning lights. • Pair with printer again.
System status report will not print properly during printer pairing	If a new printer is being used, the printing of the test page may interfere with the pairing. Clear the printer and start the pairing process again.

Problem	Possible Solution
The printed reports appear incomplete (only black lines or only colored areas printed)	Check the printer cartridges and replace if empty.
The printed reports appear faded	Replace the printer's toner cartridges.
The printer won't turn On	Check the power cord and make sure it is plugged in to a standard wall outlet and securely attached to the printer.
The printer adapter won't turn On	Check the power cord and make sure it is plugged in to a standard wall outlet and securely attached to the printer adapter.
Can't pair the HF PARTNER device with printer	Change the distance between the HF PARTNER device and printer. Optimal performance is 3-15 feet. Verify the printer has no errors.
Printer error message while pairing; printer did not have error and was not paired to	A printer in the area was found with an error. Repeat the pairing process again to search for the printer you would like to use.

Specifications

Plastic Box Dimensions (inches): 6.75 x 2 x 6.63

Device Dimensions (inches): 4.7 x 2.8 x 1.1

Power Source: Two 3.0 volt CR2 batteries

Battery Longevity: Approximately 80 uses (one use includes one interrogation and one printed report)

Operating Temperature: 10° C to 50° C (50° F to 122° F)

Storage Temperature: -20° C to 55° C (-4° F to 131° F)

Relative Humidity: Up to 85%, noncondensing

Mode of Operation: Capable of continuous use per UL 60601-1:2003 Medical Electrical Equipment, Part 1: General Requirements for Safety




Classification with Respect to Electric Shock: Internally powered

Protection from Electric Shock (IEC 601-1:2002): Type BF





Protection Against Ingress of Liquids: Ordinary equipment

Safety and EMC Compatibility Standards: IEC 68 Magnetic Materials, IEC 60601-1-2:2001/EN60601-1-2:2001 Medical Electrical Equipment covering safety and EMC, EN 300-330-2 V1.1.1 Radio Equipment and systems, EN 300-328 V1.4.1 Data Transmission Equipment in 2.4 GHz ISM band and EN 301-489-01 V1.3.1 Electromagnetic compatibility and Radio matters

Explanation of Product Markings

	Refer to the Instructions For Use
SN	Serial Number
CE 0086 ⓘ	Conformity with the applicable EU Directives; AIMD 90/385/EEC, RTTE Dir 99/5/EC, and EMC Directive 89/335/EEC, with involvement of Notified Body No. 0086.
	(Medical Electrical Equipment) WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 60601-1/CAN/CSA C22.2 NO. 601.1 9P96 Conformity with applicable portions of UL60601-1:2002 and UL 94
	Non-ionizing electromagnetic radiation (UL 60601-1:2002)
	Type BF Equipment
	DANGEROUS VOLTAGE
	Conformity with the applicable portions of Directive 2002/96/EC.
FCC #/ Canadian	FCC ID: ESCCRM293604 IC: 4794A-CRM29364
Bluetooth Qualification Body (BQB)	Bluetooth Qualification Certificate Contains radio module FCC ID: POOWML-C09XX

Package Content Symbols

	Package contents
	HF PARTNER device with batteries installed
	Refer to the Instructions For Use
	Radio and Telecommunications Terminal Equipment (RTTE). Indicates that device does not operate in a harmonized bandwidth.

Guidant Corporation

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