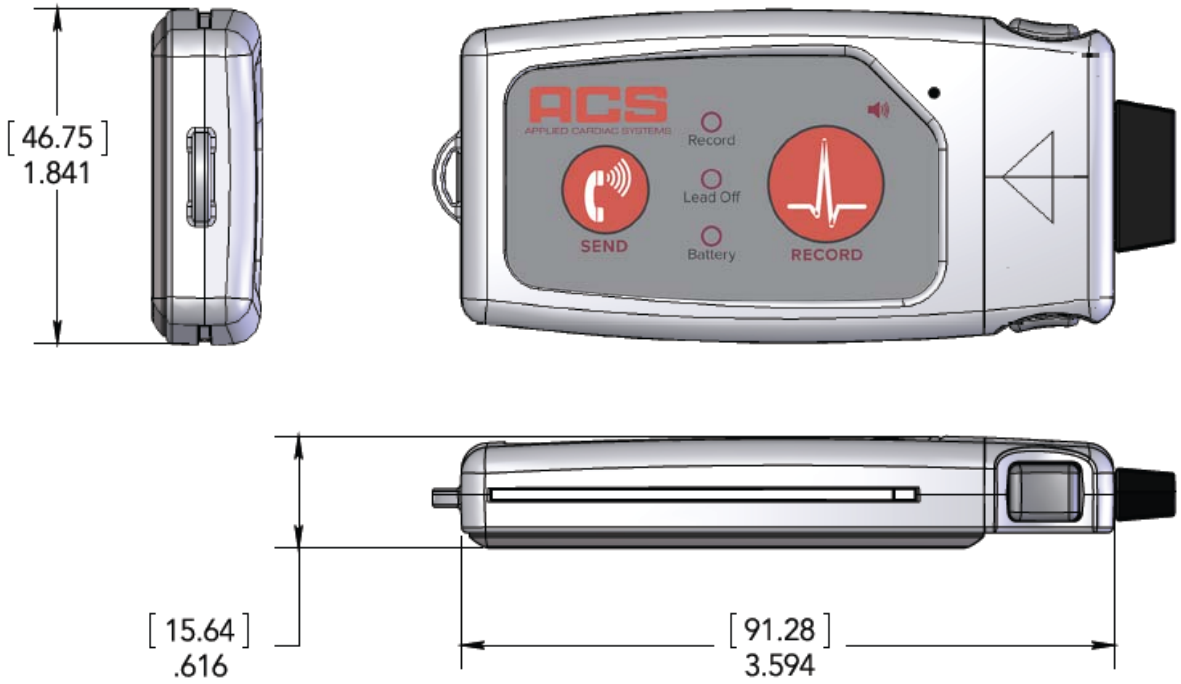
Holter Performer PLUS

USER MANUAL



Caution: **FEDERAL LAW RESTRICTS THIS DEVICE FOR SALE TO OR ON THE ORDER OF A PHYSICIAN.**

Carefully read all instructions prior to use. Observe all warnings and precautions noted in these directions. Failure to do so may result in patient complications.

Distributed By:

Applied Cardiac Systems, Inc., 22912 El Pacifico Drive, Laguna Hills, CA. 92653

Manufactured By:

IntriCon Datrix, 340 State Pl., Escondido, CA. 92029

Table of Contents

Notices

Conventions Used in this Manual

 **WARNING** Warning statements describe conditions or actions that can result in personal injury or loss of life.

 **CAUTION** Caution statements describe conditions or actions that can result in damage to the equipment or loss of data.

NOTE: Notes contain additional information on usage.

Manufacturer's Responsibility

IntriCon Datrix (manufacturer) and Applied Cardiac Systems, Inc. (distributor) are responsible for effects on safety and performance only if; the recording device is used as presented in this manual.

The warranty is only valid if you use manufacturer approved replacement parts and accessories.

User Responsibility

The user of this product is responsible for ensuring the implementation of a satisfactory maintenance schedule. Failure to do so may cause undue failure and possible health hazards.

Equipment Identification

The recording device is identified by a serial number printed on the back of the device. Take care not to deface these numbers.

Copyright and Trademark Notices

Other Important Information

IntriCon Datrix (manufacturer) and Applied Cardiac Systems (distributor) reserves the right to change or amend this manual at anytime without notice.

Applied Cardiac Systems, as a distributor, makes no warranty of any kind with regard to this material, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose. ACS shall not be liable for errors or omissions that may appear in this document. ACS makes no commitment to update or to keep current the information contained in this document.

Before using the Holter Performer PLUS Holter/Event recorder read this manual in its entirety and become thoroughly familiar with the contents.

User Safety Information

Intended Use

The Holter Performer PLUS recorder is a small, portable, digital Holter/Event recorder intended for use by medical professionals to acquire ECG data from a single patient in a clinical, point of care or outpatient setting.

Explanation of Symbols


READ MANUAL FIRST


KEEP AWAY FROM MOISTURE


TYPE BF DEVICE


DC CURRENT


NON-IONIZING RADIATION


ELECTRONIC EQUIPMENT
DISPOSE OF PROPERLY


MANUFACTURE YEAR


MANUFACTURER

CE MARK

Prescription Device Only

IP54 RESISTANT TO WATER AND DUST INGRESS
(when patient cable is attached)

Warnings

1. This device captures data reflecting a patient's physiological condition, that when reviewed by a trained medical professional, can be useful in determining a diagnosis. However, the data should not be used as sole means for determining a patient's diagnosis.

2. Use of accessories other than those recommended by IntriCon Datrix (manufacturer) and Applied Cardiac Systems (distributor) may compromise product performance.

3. To maintain designed operator and patient safety, any peripheral equipment and accessories that can come in direct patient contact must be in compliance with IEC 60601-1.

4. Hardware is designed to meet or exceed IEC 60601-1-2; however some environmental electrical interference may cause an artifact in the ECG. The quality of ECG signals may be adversely affected by electromagnetic interference from environmental sources resulting in non-physiological waveforms with the potential for misinterpretation.

5. This device is not intended for use during an MRI.

6. Before performing defibrillation or applying any high frequency surgical equipment to a patient, remove Holter Performer PLUS leads and electrodes from the chest area. Cable leads or electrodes trapped under defibrillator pads or paddles during defibrillation or electrodes in contact with high frequency electrosurgical equipment can cause patient burns.

7. Once one or more Holter Performer PLUS patient leads are connected to a patient, do not allow patient leads to meet with any grounded or live parts. Contact could cause unacceptable levels of electrical current to flow to the patient.

8. The equipment is not intended for infants weighing less than 10 kgs. (22 pounds).

9. Keep device and all accessories away from children as small parts may pose choking hazard.

Cautions

1. Although the plastic enclosure is designed for a clinical environment and can resist moisture, neither the device nor patient cables should be subjected to autoclaving or steam cleaning.
2. Recommended cleaning procedure is to wipe the exterior surfaces with a cloth dampened with warm water and mild detergent solution and then dry with a clean soft cloth.
3. No serviceable parts are inside. The case cannot be opened without destroying it.
4. Do not pull or stretch patient cables, as this could result in mechanical and/or electrical failures. Store patient cables after use by forming them into a loose loop.
5. Align patient cable connector key and Holter Performer PLUS key before plugging in patient cable. Forcing misaligned connectors can damage connector pins.
6. Avoid shock or sudden impact.

Notes:

1. Excessive patient movement could interfere with the operation of the device.
2. Proper patient preparation is important to successful application of ECG electrodes and operation of the device.
3. Changes or modifications not expressly approved by IntriCon Datrix (manufacturer) or Applied Cardiac Systems (distributor) for compliance could void the users authority to operate the equipment
4. 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. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the wireless transmission off and on, the user is encouraged to consult Applied Cardiac Systems.
5. Manually recorded Events can be transmitted using TTM via land line phone.
   Automatic Events (Auto Trigger) can only be downloaded via the Smart Dock.

Section 1: Introduction

This manual is written for clinical professionals. It is assumed that the reader and/or the assisting medical professional has a working knowledge of medical terminology and procedures as required for monitoring cardiac patients.

Purpose of the User Manual

The User Manual describes how to safely operate the Holter Performer PLUS Holter/Event recorder, Smart Dock and optional accessories. Topics covered are:

- Preparing the device for use
- Understanding and using the Keypad
- Acquiring and storing ECG data
- Transmitting stored ECG data
- Maintenance

System Description

The HPP Holter/Event system consists of the HPP recorder, Patient Cable, Smart Dock, optional Bluetooth Low Energy (BLE) dongle and optional tablet-based viewing application.

The HPP Holter/Event recorder is a portable, battery-operated ambulatory ECG recorder used by trained technicians to collect ECG data from patients in a clinical, point-of-care or an outpatient setting. The device can be configured to operate in the Holter or the Event modes.

In **Holter** mode, the HPP recorder stores up to 7 days of ECG data. Data can then be downloaded using the Smart Dock.

In **Event** mode, the HPP recorder stores ECG Event data which can later be accessed through the Smart Dock interface or by transmitting the data over a land line telephone via TTM. The data can then be reviewed by a physician or other qualified professionals.

NOTE: Manually recorded Events can be transmitted using TTM via a land line phone or downloaded via the Smart Dock when returned to physician's office. Automatic Events (Auto Trigger) can only be downloaded via the Smart Dock.

The Smart Dock has four primary functions:

1) Charging the HPP's (internal) battery
2) Establishing a connection to the recorder to select recording parameters
3) Quickly transferring ECG data from recorder to PC application
4) Updating recorder firmware.

The HPP recorder has a Bluetooth Low Energy (BLE) transmitter embedded in the device. Live ECG data can be transmitted to a PC equipped with an approved USB BLE dongle, or the optional mobile iOS application for iPad or iPhone, to verify proper patient hook-up and lead placement. A USB BLE adapter is not needed for tablet or phone based applications.

HPP Monitor & Accessories Listing

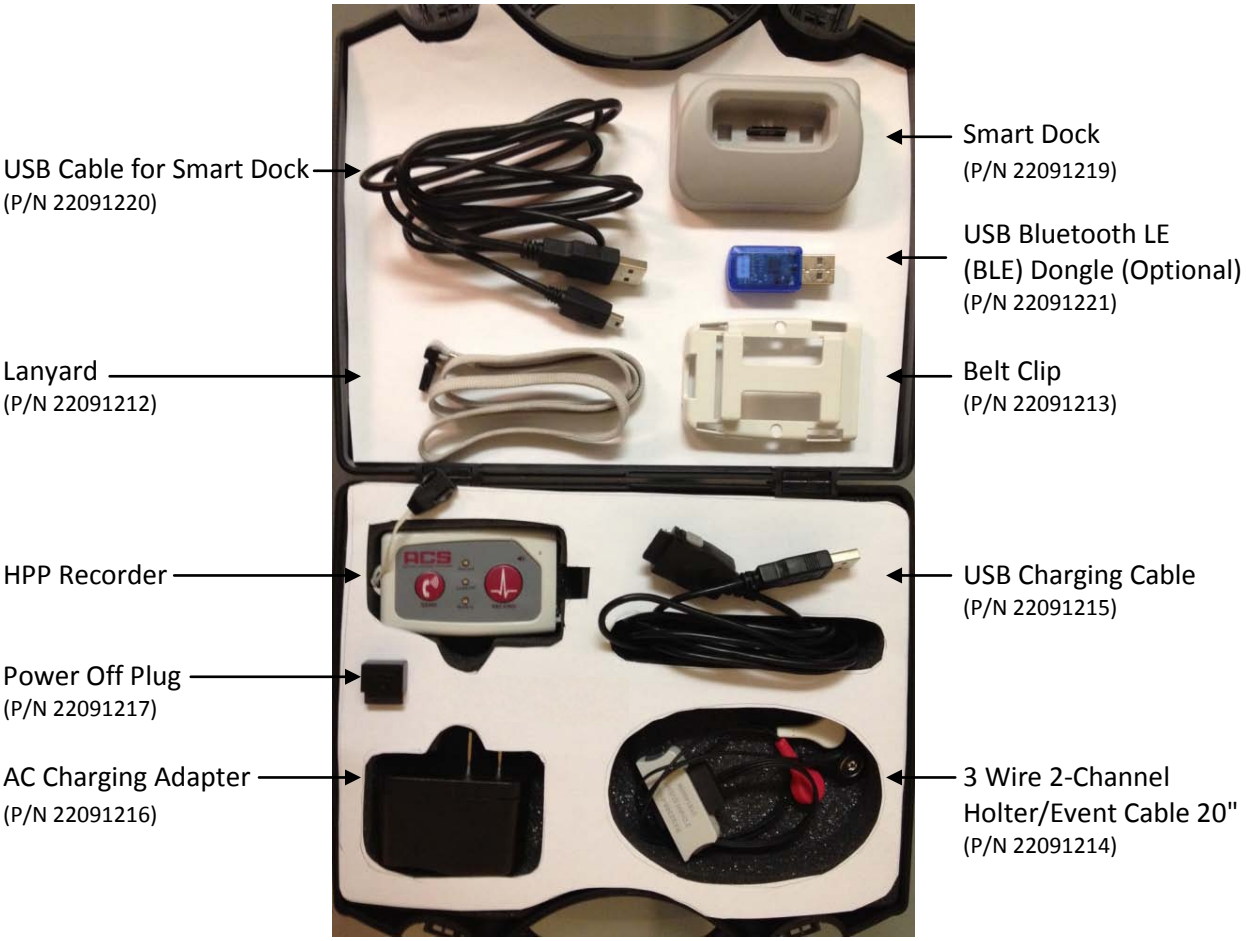


Figure 1-1: Holter Performer PLUS Monitor and Accessories

NOTE: All accessories should be kept away from children.

Section 2: Getting Started

Batteries

The HPP uses an internal lithium polymer battery that is not accessible in the field. The battery is designed to last for the life of the product.

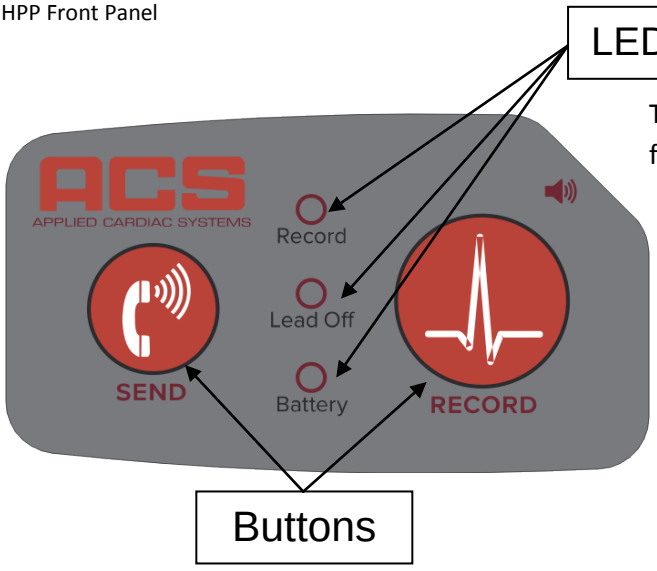
Caution:	**CONTAINS A LITHIUM RECHARGEABLE BATTERY. BATTERY USED IN THIS DEVICE MAY PRESENT A FIRE OR CHEMICAL BURN HAZARD IF MISTREATED. DO NOT DISASSEMBLE, HEAT ABOVE 100°C (212° F) OR INCINERATE.**

Caution:	**DISPOSE OF DEVICE IN ACCORDANCE WITH ALL APPLICABLE LOCAL REGULATIONS. KEEP AWAY FROM CHILDREN.**

NOTE: Always make sure the recorded ECG data is downloaded before storage or insertion of the Power Off Plug.

NOTE: Always use the supplied Power Off Plug (P/N 22091217) if the recorder will be stored for more than a couple of days. Insertion of the Power Off Plug will erase any data and configuration on the HPP.

HPP Front Panel



The HPP front panel contains two buttons and five LED lights (Light Emitting Diodes):

- RECORD Button
- SEND Button (Event mode only)
- Record LED - Green or Red
- Lead-off LED - Red
- Battery LED - Green or Red

Figure 2-1: Front Panel of Holter Performer PLUS

Section 3: Initial Device Setup

Charging

The HPP recorder may only be charged with equipment supplied or approved by IntriCon Datrix (manufacturer) and Applied Cardiac Systems (distributor). Either the Smart Dock or the USB Charging Cable may be used to charge the recorder. The charging devices can be connected to either a PC's USB port or a USB wall adapter to provide power for charging. A dedicated USB wall adapter (P/N 22091216) will charge the device faster than a PC's USB connection. The LEDs on the HPP recorder will inform the user of the state of the charge of the battery, as described below:

Condition	**Battery LED**	**Meaning**
Recorder on Dock / Charge Cable	Flashing Green	Charging
Recorder on Dock / Charge Cable	Solid Green	Battery is fully charged
Recorder on Dock / Charge Cable	Flashing Red	Charging fault
Recorder attached to patient cable	Flashing Green	Normal Operation
Recorder attached to patient cable	Flashing Red	Battery Voltage is LOW

Table 3-1: Battery LED Indicator

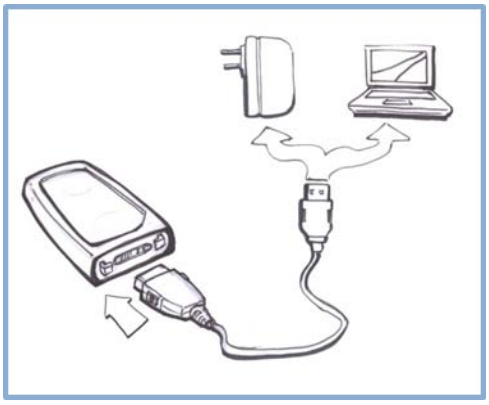


Figure 3-1. Charging with USB Cable

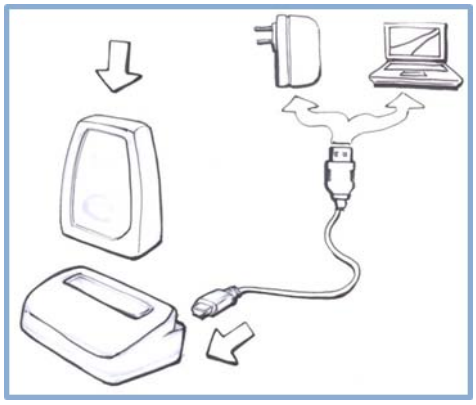


Figure 3-2. Charging with Smart Dock

NOTE: Preferred method of charging is using the AC Charging Adapter and the USB Charging Cable.

Establishing Connection to Recorder

Connection to the HPP recorder can be made directly using the USB Smart Dock attached to a PC with the Holter Reporter™ software. An iPad or iPhone can also be used with the optional iOS app.

The Smart Dock is connected to a PC with a mini-USB to USB cable. The mini-USB end plugs into the Smart Dock and the standard USB end plugs into the PC.

Connection to HPP Using Smart Dock using the Software

Select option in the Holter Reporter™ or Setup software to setup the Holter Performer PLUS. This will open a pop-up screen to connect to the HPP device and allow configuration. Placing the HPP recorder into the Smart Dock will automatically establish a connection between the PC and the recorder.

Figure 3-3. Holter Reporter™ Entry Menu

When successfully connected, the pop-up window will display one of the two messages below:

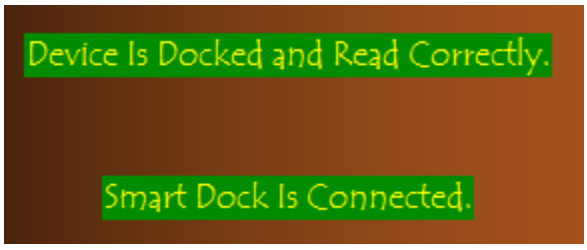


Figure 3-4. Holter Reporter™ HPP device status

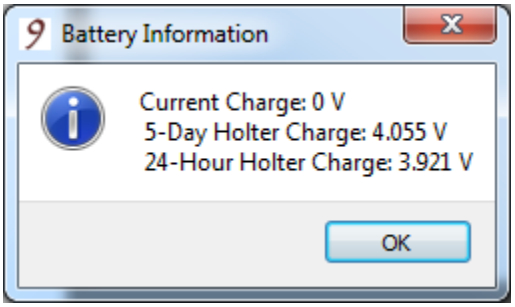


Figure 3-5. Setup HPP device status

Connection to HPP Wirelessly

The recorder's internal BLE transceiver is on for one hour after removal of power off plug or attachment of cable. Wireless connections can only be made during this one hour window. Connecting any HPP cable, patient leads or charging cable, on a paired device will cause a disconnection. The device will need to be paired again if a wireless connection is desired.

Note: Placing an HPP recorder in a Smart Dock will disconnect any wirelessly connected devices.

Connecting to HPP Using (Optional) iOS App

Insure the recorder is charged and not connected to a Smart Dock. Launch the Holter Performer iOS APP. Select the "Pair/Connect" button. A box with the available devices will pop-up. Select serial number of the device you wish to connect to. Once connected, a message box will confirm the connection and display the connected device's serial number.

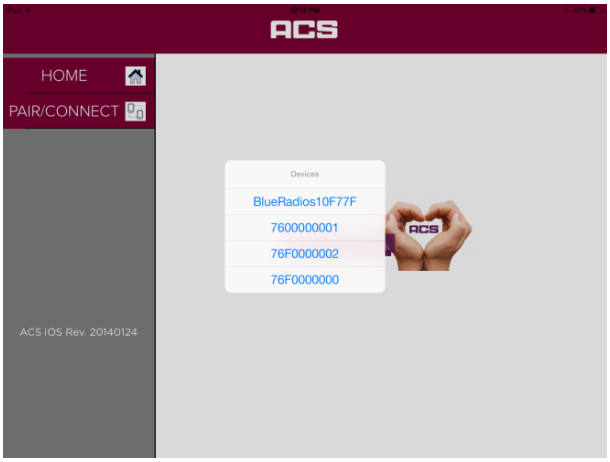


Figure 3-6. iOS APP Available Devices

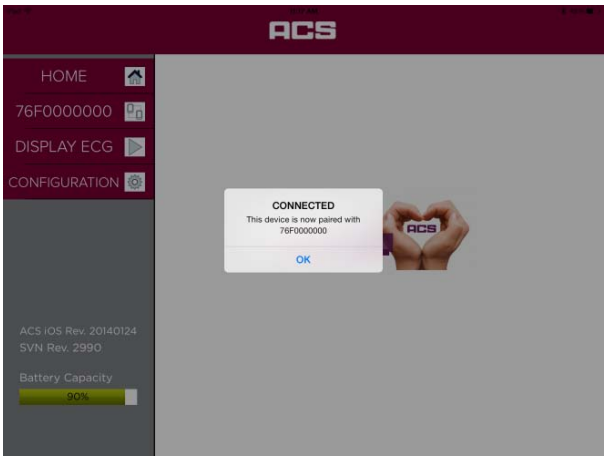


Figure 3-7. iOS APP Device Connection Status

Setting Device Parameters

Once connected, the HPP can be easily configured with different operational parameters. The device stores configuration parameters in internal memory.

The HPP Device serial number is set by the manufacturer; it is readable but not modifiable by the cardiac technician. A technician can read and modify several parameters before connecting the device to the patient. Device parameters can be configured using the Smart Dock and Holter Reporter™ software or done wirelessly with the iOS App.

Configuration

Configuring the HPP Using the (optional) iOS App:

After pairing via BLE (wirelessly), select "**Configuration"** to enter the Configuration Menu. The Patient ID should be set first. When you select the Patient ID field, it will bring up a keyboard enabling the technician to input the Patient's ID. To modify other settings, select the field and then select a choice from the pop-up window. After the patient ID and settings are finalized, select "**Write to Device"** to store the configuration on the device.

NOTE: Configuration settings cannot be written to device if ECG data still stored in memory. ECG data will need to be downloaded via the Smart Dock and erased from device before continuing.

Configuring the HPP Using the Smart Dock

The Holter Performer PLUS (HPP) can be configured to operate as either a Holter or an Event monitor. For each type of operation, using the setup software screen, the monitor can be further configured to function as desired, depending on your preference or needs.

Holter Mode Default Settings/Configuration

In Holter mode, for instance, you may choose settings such as the:

- Recording duration (24-168 hours)
- Recording Start Timeout (0-300 minutes)
- Live ECG Transmission Timeout (0-600 seconds)
- Event Pre-Trigger (30-45 seconds)
- Event Post-Trigger (30-90 seconds)

After configuration is complete, select "Write to Device" to save settings.

NOTE: For a more complete list/explanation of the settings, refer to **Appendix A** of this manual.

NOTE: Configuration settings cannot be written to device if ECG data still stored in memory. ECG data will need to be downloaded via the Smart Dock and erased from device before continuing.

Event Mode Default Settings/Configuration

In Event mode, for instance, you may choose settings such as the:

- Live ECG Transmission Timeout (0-600 seconds)
- Event Pre-Trigger (30-45 seconds)
- Event Post-Trigger (30-90 seconds)
- TTM Timeout (0-100 minutes)
- TTM Speed (1x or 3x)
- TTM Audible Alert (on/off)
- Event Count Alert Threshold (Default is 5)
- Event Auto-Trigger (on/off)
- Detect Tachycardia (on/off)
- Tachycardia Threshold (120-200 BPM)
- Detect Bradycardia (on/off)
- Bradycardia Threshold (20-70 BPM)
- Detect Pause (on/off)
- Pause Threshold (1000-5000 milli-seconds)

After configuration is complete, select "Write to Device" to save settings.

NOTE: For a more complete list/explanation of the settings, refer to **Appendix A** of this manual.

NOTE: Configuration settings cannot be written to device if ECG data still stored in memory. ECG data will need to be downloaded via the Smart Dock and erased from device before continuing.

Section 4: Patient Connection

Patient Preparation and Hook-Up

1. Wipe each electrode site with an alcohol prep pad. Be sure to clean the entire electrode area, including where the adhesive area will stick. Dry site thoroughly with gauze pad.
2. Shave appropriate electrode sites (see diagram below).
3. Pull the skin taut with thumb and index finger. Scruff the surface skin layer at the center of each electrode site with the abrasive pad supplied in the ACS Hook-Up kit. Apply three or four downward "scruffs" with moderate pressure. This should produce a slight redness on the skin.
4. Check the patient cable for damage or wear, replace if necessary. Snap the lead wires onto the electrodes before applying to the patient
5. Individually peel electrodes (lead wires attached) from the electrode strip. Follow the color codes in the diagram below and apply the electrodes to the prepared sites. Center the electrode gel cup over the site. Firmly press the outer ring of the adhesive area onto the patient. Do not press directly on the snap as this may cause the conductive gel to disperse.

Warning: CONDUCTIVE PARTS OF ELECTRODES AND ASSOCIATED CONNECTORS SHOULD NOT CONTACT OTHER CONDUCTIVE PARTS.

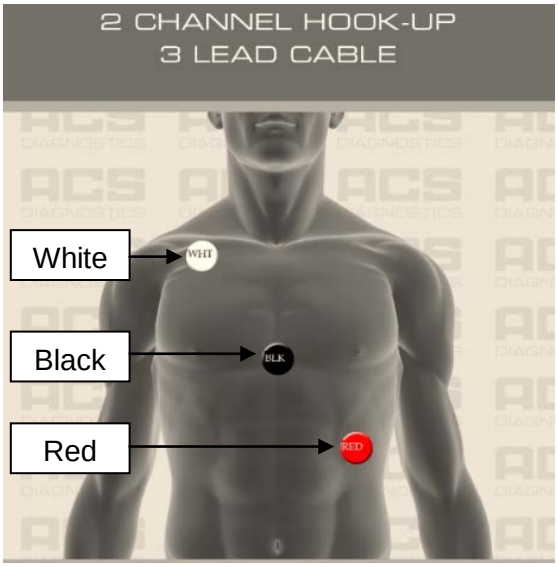


Figure 4-1. 2 Channel Hook-up w/3 Lead Cable

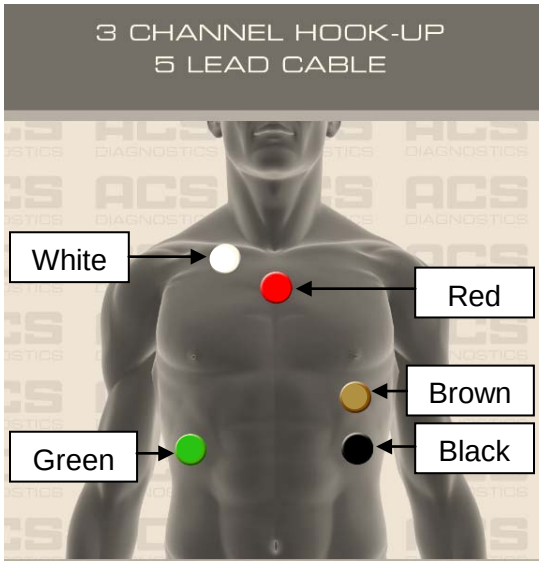


Figure 4-2. 3 Channel Hook-up w/5 Lead Cable

Warning: ECG REPORTS MUST BE REVIEWED BY MEDICAL PROFESSIONALS WITH FINAL INTERPRETATION BY PRESCRIBING PHYSICIAN.

Section 5: Starting ECG Study

Attaching Recorder to Patient Cable

The Patient cable is inserted into the connector on the side of the HPP recorder. The cable is both marked and keyed for proper alignment. When properly aligned, the embossed triangle on the cable will be on top pointing to the “Record" button. Press the two side buttons on the cable connector while firmly joining the cable to the recorder. Do not force a cable into position. Use only cable part numbers listed below.

3 Wire, 2 Channel Lead Set
(Holter and Event)
20” Lead set (P/N 22091214)
39" Lead Set (P/N 22091222)

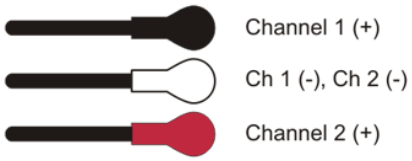


Figure 5-1. 3 Wire, 2 Channel Lead Set

5 Wire, 3 Channel Lead Set
(Holter only)
20” Lead set (P/N 22091223)
39" Lead Set (P/N 22091224)

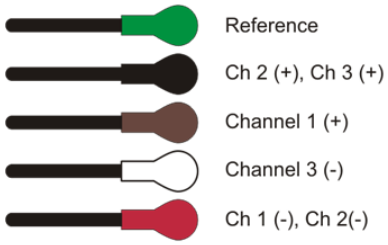


Figure 5-2. 5 Wire, 3 Channel Lead Set

Upon the connection of a cable, the recorder performs a system check and briefly flashes each LED. It will then sound two or three tones. The number of tones corresponds to the number of channels the cable is designed for. Repeat the process if not successful the first time.

NOTE: If the recorder was previously paired using the optional wireless connection, it will need to be paired again each time a cable is attached.

Lead Off Warning

The HPP will check for a lead-off condition the first 2 minutes after the cable is connected. The recorder will beep and the lead off indicator will flash red if any of the leads are not connected to a patient. Check all leads for proper connection before proceeding. Once properly connected, or 2 minutes has elapsed, the lead-off warning will stop.

Holter Mode

The Record LED will flash green once per second and the HPP will beep every 10 seconds until the Holter study is started. The study is started by pressing the Record button for 3 seconds. If the Record button has not been pressed, the HPP will automatically start the study after 30 minutes, or whatever configuration was set. During the course of the study the Record LED will flash green once every 10 seconds. The Battery LED will also flash green every 10 seconds until the battery gets low. Once the battery gets low, the Battery LED will flash red.

Event Mode

When in Event Mode the recorder will start immediately upon connecting the cable. There is no need to press the Record button for 3 seconds as with Holter mode. During the course of the study the Record LED will flash green once every 10 seconds. The Battery LED will also flash green every 10 seconds until the battery gets low. Once the battery gets low the Battery LED will flash red.

NOTE: In Event mode only, the HPP monitor will display a solid GREEN light on the “Record" LED as a way to alert the patient to contact the physician's office or the lab, as prescribed. If the patient does not contact the physician's office or the lab to transmit events via TTM, the recorded events must be downloaded via the Smart Dock when returned to the physician's office or lab.

NOTE: TTM requires a land line telephone. Cellular phones and Voice Over Internet Protocol (VOIP) phones are unreliable for ECG data that is being transmitted and not recommended.

Optional - Verifying ECG Signal

The ECG application (on mobile device or PC equipped with **optional** USB BLE adaptor) can be used to verify a proper ECG hook up. To view live ECG, first pair the device (as described in "Establishing Connection to Recorder" section of this manual), select **Display ECG** and select the **Live ECG** button. If properly connected, live ECG will scroll across the screen. This is a valuable tool to verify proper lead placement and hook up quality.

Instructions for Patient

Before the patient leaves the office, instruct the patient about:

a) Proper use of the HPP Recorder

b) Support contact information

c) Transmitting ECG data by TTM via land line (Event mode, Manually recorded events only)

d) LED message indicators

RECORD Button

The Record button is used to record an “event” in Event mode and to mark an event time in Holter mode. Pressing the Record button will store event ECG data to internal memory. In Holter mode the event time, when used in conjunction with a patient diary, provides a physician with the ability to correlate patient symptoms with the ECG data.

NOTE: In Event mode only, the HPP monitor will display a solid GREEN light on the “Record" LED as a way to alert the patient to contact the physician's office or the lab. If the patient does not contact the physician's office or the lab to transmit stored data, the recorded events must be downloaded via the Smart Dock when returned to the physician's office or lab, as prescribed.

SEND Button

The Send button is only active in Event mode. It is used to transmit event ECG over a land line based telephone. The recorder will sound an audible alert (if the audible alert is enabled) when the number of events stored is equal to or greater than the number previously set in the event threshold option. The patient must contact the lab using a traditional land line.

NOTE: TTM requires a land line telephone. Cellular phones and Voice Over Internet Protocol (VOIP) phones are unreliable for ECG data that is being transmitted and not recommended.

NOTE: Manually recorded Events should be transmitted using TTM via a land line phone as instructed. Events can also be downloaded via the Smart Dock when returned to physician's office or lab. Automatic Events (Auto Trigger) can only be downloaded via the Smart Dock when returned to the physician's office or lab.

After the lab technician answers, the patient will be instructed to hold the HPP speaker up to the phone’s mouthpiece and then press and hold the Send button for 2 seconds. This will transmit the stored events to the lab via Trans-Telephonic Monitoring (TTM). The unit should be held up to the phone until the sound stops. When the sound stops, the patient should get back on the phone to talk to the technician. The technician will then inform the patient of a successful transmission or instruct the patient to repeat the process in the case of an incomplete transmission.

Holter Performer PLUS Patient Interface Light Signals

There are several messages that could appear to alert you that action may be required, or simply to alert you that an error has occurred. These messages include:

LED	MESSAGE	ACTION
Battery LED flashes green once every 10 seconds	Device is functioning normally	None
Battery LED flashes red every 2 seconds	Low Battery	Charge the HPP by attaching it to the Charging cable and plugging it into an outlet
Lead-off LED flashes red every 2 seconds	Indicated lead disconnected or poor patient connection	Check leads for proper connection
Lead-off LED solid red	Cable recently disconnected	LED will turn off in 2 minutes if cable left detached
Record LED lights up green for 5 seconds	Record button has been pressed	None
Record LED solid green	Event data stored in recorder	Contact ACSD Lab for download of Events
Record LED flashes red continuously	Recording error	Perform device reset. If condition persists contact ACS Technical Support

Table 5-1: User Interface LED Indicator

Section 6: Device Maintenance

Inspection and Cleaning

Routine inspection will help maintain the safety and performance of your HPP Holter/Event recorder and Smart Dock. Before operating the device perform a visual inspection to identify any damage or excessive wear.

The outside surfaces can be cleaned with a cloth dampened with a mild soap and water solution.

Do not dispose of the unit in trash. Dispose of as the Waste Electrical and Electronic Equipment (WEEE) regulations for your area require.

Caution: DO NOT IMMERSE THE DEVICE IN LIQUID!

Caution: DO NOT AUTOCLAVE, USE ULTRASONIC CLEANERS OR USE ALCOHOL TO CLEAN THE PATIENT CABLE.

Caution: DO NOT USE ANY HARSH CHEMICALS SUCH AS ACETONE, AMMONIA OR IODINE TO CLEAN THE HOLTER PERFORMER PLUS.

Testing

The HPP executes a self-diagnostic check at these three times:

1. At power-up (Removal of Power Off Plug)
2. At the insertion of any cable
3. Upon removing the HPP recorder from the Smart Dock

Any errors in the unit's subsystems will be reported with an appropriate error message. If error messages persist (see Table 5-1), contact Applied Cardiac Systems service department. There are no user serviceable parts in the HPP. The unit must be returned to Applied Cardiac Systems for service.

The HPP recorder may also be tested by attaching the patient leads to a commercially available ECG simulator and verifying each lead has amplitude and morphology as described in the simulator's manual. Excessive artifact usually indicates the patient cable needs replacing. Use only replacement cables purchased from Applied Cardiac Systems, (800) 423-2929, Laguna Hills, CA.

Transport

The HPP recorder, Smart Dock and accessories should be stored and transported between 10^{o}-70^{o}C (50^{o}-158^{o} F) and 10% to 95% Relative Humidity (non-condensing).

Section 7: Holter Performer PLUS Specifications

General Specifications:

· Input impedance: ≥ 10 MΩ

· AC signal range: ± 5mV

· Bandwidth: 0.05 –40 Hz.

· Resolution: 10 bits (1024 SPS or greater)

· Memory type: Flash

· User alerts: LED indicators and/or audible alerts

· Operating temperature range: 0–60° C (32°-140° F)

· Operating humidity range: 10–95% R.H. (non-condensing)

· CMRR: > 60 dB

· DC signal range: ± 300mV

· Sampling rate: 256 samples/sec.

· Battery: Lithium-Polymer, rechargeable

· Lead status: Automatic lead-off detection

· Wireless link option: Bluetooth Low Energy

· Weight: 42 gr. (1.5 Oz.) excluding cable.

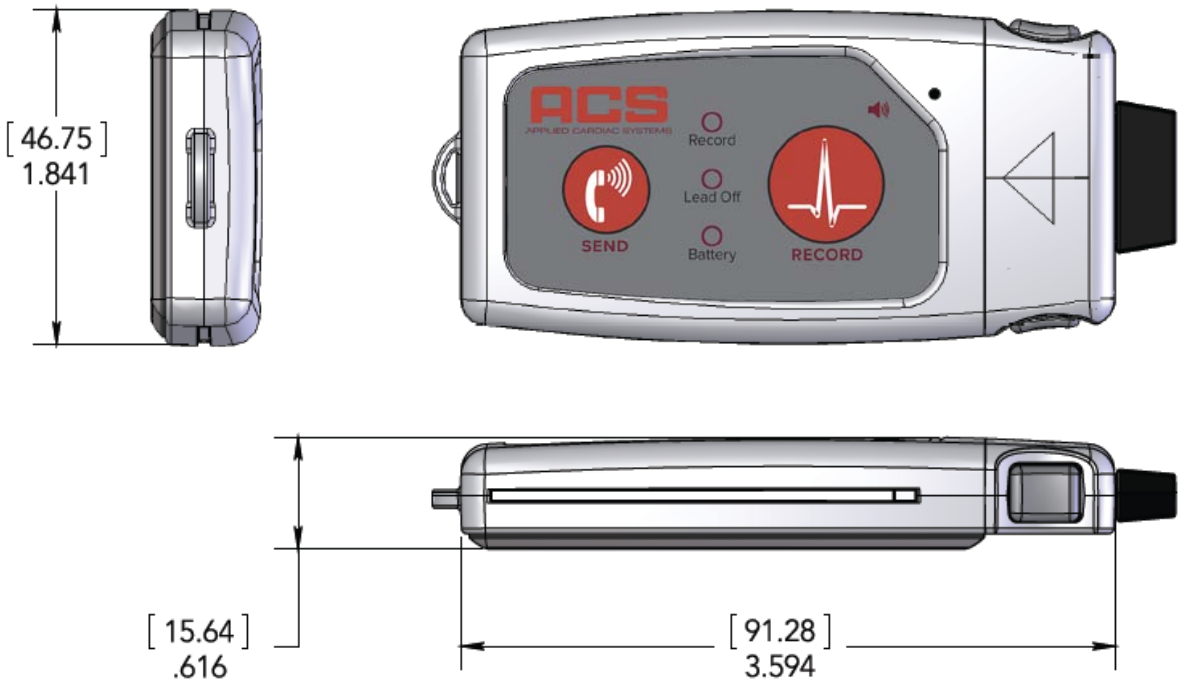


Figure 7-1. Holter Performer PLUS Mechanical View with Dimensions

Holter Monitor Specifications:

· 2 or 3 channel recording (depending on cable)

· 1 - 7 day recording length

· Upload to PC via Smart-Dock (USB 2.0 accessory)

Event Recorder Specifications:

· 1 or 2 channels (depending on cable)

· Pre-trigger length: 30 and 45 seconds

· Post-trigger length: 30, 45, 60, 90, 120 and 300 seconds

· Maximum number of events: 500+

· TTM event data transmission (for Manually recorded events only)

· Automatic recorded (Auto Trigger) events can be downloaded via USB Smart Dock only (not via TTM) at the end of the recording period.

· Typical battery life: up to 30 days between charges

The HPP recorder is compliant with IEC 60601-1 as a Type BF, internally powered device designed for short time operation. The equipment is not suitable for AP or APG category environments.

The HPP recorder complies with Part 15 of the FCC rules.

Holter Performer PLUS Accessories

ACS HPP Recorder Accessories List	
Description	**ACS Part Number**
3 Wire 2-Channel Holter/Event Cable 20"	22091214
3 Wire 2-Channel Holter/Event Cable 39"	22091222
5 Wire 3-Channel Holter Cable 20"	22091223
5 Wire 3-Channel Holter Cable 39"	22091224
Smart Dock	22091219
USB Cable for Smart Dock	22091220
USB Charging Cable	22091215
AC Charging Adapter	22091216
Lanyard	22091212
Belt Clip	22091213
Power Off Plug	22091217
USB Bluetooth LE (BLE) Dongle *(Optional)*	22091221

Table 7-1: HPP Accessories List

Service/Technical Support Please call:

(800) 423-2929

Applied Cardiac Systems, Inc.
22912 El Pacifico Drive
Laguna Hills, CA. 92653

Manufactured by IntriCon Datrix; Distributed by Applied Cardiac Systems, Inc.:

IntriCon Datrix
340 State Place
Escondido, CA 92029

EC REP

CEpartner4U
Esdoornlaan 13
3951 DB Maarn, Nederland

Warning: THE HOLTER PERFORMER PLUS SHOULD NOT BE USED ADJACENT TO OR STACKED WITH OTHER EQUIPMENT. IF ADJACENT OR STACKED USE IS NECESSARY, THE HOLTER PERFORMER PLUS SHOULD BE OBSERVED TO VERIFY NORMAL OPERATION IN THE CONFIGURATION IN WHICH IT WILL BE USED.

Section 8: Certification Declarations

Guidance and manufacturer's (IntriCon Datrix) declaration - electromagnetic emissions		
The HPP recorder is intended for use in the electromagnetic environment specified below. The customer or user of the HPP recorder should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The HPP recorder uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The HPP recorder is suitable for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

Table 8-1: Guidance and manufacturer's (IntriCon Datrix) declaration - electromagnetic emissions

<table>
<tr><th colspan="4">Guidance and manufacturer's (IntriCon Datrix) declaration - electromagnetic immunity</th></tr>
<tr><td colspan="4">The HPP recorder is intended for use in the electromagnetic environment specified below. The customer or user of the HPP recorder should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>Conducted RF

IEC 61000-4-6

Radiated RF

IEC 61000-4-3</td><td>3 Vrms

150 kHz to 80 MHz

3 V/m

80 MHz to 2.5 GHz</td><td>N/A

3V/m

80 MHz to 2.5 GHz</td><td>Portable and mobile RF communications equipment should be used no closer to any part of the HPP recorder, including cables, than the recommended separation distance calculated for the equation applicable to the frequency of the transmitter.

Recommended separation distance.

$d = 1.17\sqrt{P}$

$d = 1.17\sqrt{P}$ 80 MHz to 800 MHz
$d = 2.33\sqrt{P}$ 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 on each frequency range.[b]

Interference may occur in the vicinity of equipment marked with the following symbol:  </td></tr>
<tr><td colspan="4">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.</td></tr>
<tr><td colspan="4">[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 access 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 HPP recorder is used exceeds the applicable RF compliance level above, the HPP recorder should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the HPP recorder.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.</td></tr>
</table>

Table 8-2: Guidance and manufacturer's (IntriCon Datrix) declaration - electromagnetic immunity

Guidance and manufacturer's (IntriCon Datrix) declaration - electromagnetic immunity			
The HPP recorder is intended for use in the electromagnetic environment specified below. The customer or user of the HPP recorder 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	N/A	N/A
Surge IEC 61000-4-5	+/- 1kV line(s) to lines(s) +/- 2kV line(s) to earth	N/A	N/A
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	N/A	N/A
Power frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic if 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			

Table 8-3: Guidance and manufacturer's (IntriCon Datrix) declaration - electromagnetic immunity

Recommended separation distances between portable and mobile RF communications equipment and the HPP			
The HPP is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the HPP can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the HPP 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 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	7.3
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.			

Table 8-4: Manufacturer's (IntriCon Datrix) Recommended separation distances between RF sources and the HPP Recorder

APPENDIX A: Holter Performer PLUS Configuration Settings

Revised: 4-22-2015

HPP Holter Mode Configuration Settings:

Setting	Default Settings	Selection Range	Explanation of Setting	Setup9 3092	Setup9 3108	M9 90.53	Setup9 3591	M9 90.55	Setup9 3870	M9 90.56	M9 90.57.4	M9 90.57.6 & Up
Holter Recording Duration:	24 Hours	24 - 168 Hours	Range of hours (days) for Holter Study	✓	✓	✓	✓	✓	✓	✓	✓	✓
Recording Start Timeout (min):	5 minutes	0 - 300 Minutes	Minutes before Study Auto-Starts			✓		✓		✓	✓	✓
Live ECG Transmission Timeout (sec):	300 seconds	None - 600 seconds	How long BLE is active	✓	✓	✓	✓	✓	✓	✓	✓	✓
Event Pre-Trigger:	30 seconds	30 - 45 seconds	Pre-Trigger recording time	✓	✓	✓	✓	✓	✓	✓	✓	✓
Event Post-Trigger:	30 seconds	30 - 90 seconds	Post-Trigger recording time	✓	✓	✓	✓	✓	✓	✓	✓	✓
Audible Alert	Enabled	Enabled or Disabled	Enables TTM Queue Alert	✓	✓	✓	✓	✓	✓	✓		

HPP Event Mode Configuration Settings:

Setting	Default Settings	Selection Range	Explanation of Setting	Setup9 3092	Setup9 3108	M9 90.53	Setup9 3591	M9 90.55	Setup9 3870	M9 90.56	M9 90.57.4	M9 90.57.6 & Up
Live ECG Transmission Timeout (sec):	300 seconds	None - 600 seconds	How long BLE is active	✓	✓	✓	✓	✓	✓	✓	✓	✓
Event Pre-Trigger:	30 seconds	30 - 45 seconds	Pre-Trigger recording time	✓	✓	✓	✓	✓	✓	✓	✓	✓
Event Post-Trigger:	30 seconds	30 - 90 seconds	Post-Trigger recording time	✓	✓	✓	✓	✓	✓	✓	✓	✓
TTM	Enabled	Enabled or Disabled	Transmit Events via TTM	✓	✓	✓	✓	✓	✓	✓	✓	✓
TTM Timeout (min):	15 minutes	0 - 100 minutes	Minutes to resend TTM Data			✓	✓	✓	✓	✓	✓	✓
TTM Speed:	1x	1x or 3x	TTM transmission speed			✓	✓	✓	✓	✓	✓	✓
Channel Transmitted via TTM	Channel 2	Chnl 1, Chnl 2 or All	Which Channels are transmitted via TTM				✓	✓	✓	✓	✓	✓
TTM Audible Alert:	Off	(Check Box)	Enables TTM Queue Audio Alert						✓	✓	✓	✓
Event Count Alert (LED) Threshold:	5 Events	1 - 500+	How many events queued until LED Alert	✓	✓	✓	✓	✓	✓	✓	✓	✓
Event Auto-Trigger:	Off	(Check Box)	Enables Auto-Triggered events						✓		✓	✓
Detect Tachycardia:	On	(Check Box)	Enables Tachycardia Detection						✓		✓	✓
Tachycardia Threshold (BPM):	120 BPM	120 - 200	Range of BPM for Tachy Auto-Detect						✓		✓	✓
Detect Bradycardia:	On	(Check Box)	Enables Auto-Triggered events						✓		✓	✓
Bradycardia Threshold (BPM):	40 BPM	20 - 70	Range of BPM for Brady Auto-Detect						✓		✓	✓
Pause Detection:	On	(Check Box)	Enables Auto-Triggered events						✓		✓	✓
Pause Threshold (ms):	2000 ms	1,000 - 5,000	Range of ms for Pauses						✓		✓	✓
Audible Alert	Enabled	Enabled or Disabled	Enables TTM Queue Alert	✓	✓	✓	✓	✓	✓	✓	✓	