Braemar Telemetry Patch System BTPS-1000 User Manual

Should the prescriber, or patient using the Braemar Telemetry Patch System need assistance in setting up, or using any element of the system, or should they wish to report unexpected operation or events, please contact the manufacturer below:

Manufacturer:
Braemar Manufacturing, LLC
1285 Corporate Center Drive
Suite 150
Eagan, MN 55121 USA
651-286-8620

	Read this manual before use. Keep it for future reference.

Braemar Limited Warranty

Braemar products are warranted to be free from manufacturing and material defects for a period of one (1) year from the date of shipment from Braemar to the original purchaser.

Excluded from this warranty are expendable supply items including, but not limited to, electrodes, lead wires, patient cables and batteries. This warranty does not apply to any product which Braemar determines has been modified or damaged by the customer.

Except for the express warranties stated above, Braemar disclaims all warranties including implied warranties of merchantability and fitness. The stated express warranties are in lieu of all obligations of liabilities on the part of Braemar for damages, including but not limited to, special indirect or consequential, arising out of or in connection with the use or performance of Braemar products.

Device is to be serviced by Factory Authorized Technicians only. Do not attempt to repair, modify, or service any Braemar device. Opening case will void product warranty.

Any action for breach of warranty shall be commenced within one (1) year of said breach or be forever barred. Any repairs made to the product which are not covered by the warranty shall be billed to the customer.

The BTPS-1000 system is used for measuring, recording, and analyzing heart rhythms on patients. This system is not an emergency response service. If a medical emergency is identified, call immediately a medical emergency number such as 911. Please read this entire manual completely prior to using the system to ensure reliable and safe operation.

Table of Contents

1. Warnings

NOT AN EMERGENCY RESPONSE SERVICE
WARNING: The Braemar Telemetry Patch System is not an emergency response service. If you experience any symptoms that concern you, seek medical help.

EXTERNAL DEFIBRILLATOR
WARNING: Remove Braemar Telemetry System Patch and Sensor before using an external defibrillator.

INFANTS and SMALL CHILDREN
WARNING: The Braemar Telemetry Patch System should not be used on infants weighing less than 22 lbs (10 kg). The system should be kept away from infants and small children due to the following potential hazards.

- Cords can be a strangulation hazard to infants and children, keep cords away from infants and children.
- Small components which may fit in the mouth, such as the Sensor, may be a choking hazard.
- Never apply the Patch to the face or cover nose or mouth.

2. Precautions

DO NOT TAMPER WITH DEVICE
CAUTION:

- Do not use Patch or Electrodes if package is tampered with, damaged or defective.
- There are no serviceable parts in the Sensor or any of its accessories. Disassembling the Sensor or any accessory will void warranty and may alter performance.
- There are no serviceable parts in the Monitor. Disassembling the Monitor will void warranty and may alter performance.

DO NOT TAMPER WITH MONITOR OR SENSOR BATTERY
CAUTION: The Monitor and Sensor batteries of the Braemar Telemetry Patch System can present a fire or chemical burn hazard if mistreated. Do not disassemble heat, incinerate, or recharge using any device other than the supplied power cords and chargers.

USE POWER CORDS IN SINGULAR OUTLET

CAUTION: A multiple, portable socket outlet or extension cord should not be used with the equipment.

USE ONLY MANUFACTURER APPROVED EQUIPMENT

CAUTION:

- Do not use any cables, power cords or other accessories other than the ones provided or replaced from the manufacturer.
- Usage of accessories or components other than the ones provided may result in increased Radio Frequency (RF) emissions or decreased immunity to electromagnetic interference of the system.
- Only use wall adapters to charge the Monitor that have undergone appropriate safety tests as indicated by a CE or UL marking on label. Use of other wall adapters may damage devices or impact performance.

SINGLE USE / MULTIPLE USES

CAUTION: The Patch is a single use item as are surface electrodes; do not reuse the Patch or surface electrodes. All other system components are reusable.

CONNECTION TO COMPONENTS

CAUTION: Only connect the components as described in this manual. Never connect any accessory to any external electrical item other than the supplied Sensor.

DO NOT STACK

CAUTION: The BTPS-1000 system should not be stacked with other equipment. Stacking other equipment on top of the devices may damage enclosure or inner components.

PATCH STORAGE TEMPERATURE AND SHELF LIFE

CAUTION: Shelf life of 18 months from Date of Manufacture has been tested and is within the range of +41ºF to +80ºF (+5ºC to +27ºC). Storage of Patch outside these limits may affect longevity of shelf life.

ASSEMBLED DEVICE

CAUTION: Do not attempt to charge Sensor while assembled into any accessory. The sensor should be charged on its own as an isolated unit.

FOR USE WITHIN CELLULAR DATA COVERAGE AREA

CAUTION: The device is not designed for high-risk patients and ECG analysis is not meant to be real-time.

- A loss of cellular data coverage may prevent Monitor from sending medically significant events to Remote Site for review. For optimal monitoring service please stay in an area with cellular coverage.

NOT AN APNEA MONITOR

CAUTION: The Braemar Telemetry Patch System is not to be used as an apnea monitor.

AVOID ELECTROMAGNETIC INTERFERENCE

CAUTION: For the best recording results, you should avoid close proximity to heavy equipment or other sources of electromagnetic interference such as electric blankets, heating pads, water beds, etc. In addition, sources of strong magnetic fields, such as MRI rooms, should also be avoided.

POTENTIAL FOR ELECTROMAGNETIC INTERFERENCE

CAUTION: There is a potential for electromagnetic interference to other devices while using the Braemar Telemetry Patch System Model BTPS-1000. If the user needs to completely shut down all devices generating an electromagnetic signal, then turn the Monitor OFF. The Bluetooth radio in the Sensor CANNOT be turned OFF. Additionally, enabling Airplane Mode disables cellular modem but Bluetooth radio for both Monitor and Sensor will still be active.

USE WITH IMPLANTED PACEMAKERS

CAUTION: If you have an implanted pacemaker, the manufacturer may have recommended certain precautions when using a cellular phone. Since the Braemar Telemetry Patch System Monitor contains a cellular phone, you should take the same precautions when carrying and using the Monitor. In general, most pacemaker manufacturers recommend the following:

- You should keep a distance of at least 6 inches (15 cm) between the cellular phone and a pacemaker.
- You should hold the cellular phone on the opposite side of the body from the pacemaker.
- Do not carry a cellular phone in a breast pocket or on a belt if that would place the phone within six inches of the pacemaker.
- You should refer to the manufacturer's information for guidance regarding your pacemaker and interference issues.

PACEMAKER DETECTION

CAUTION: Pacemaker detection is in accordance with AAMI 60601-2-47.

IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (ICD)

CAUTION: The Braemar Telemetry Patch System is not protected against defibrillator, no functional earth terminal.

RADIOGRAPHIC USE

CAUTION: The Braemar Telemetry Patch System is not intended for use in radiographic, x-ray, or Magnetic Resonance Imaging (MRI).

ADDITIONAL EQUIPMENT CLASSIFICATION INFORMATION REQUIRED BY EN 60601-1

CAUTION:

- EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE.
- The water resistance rating of IP24 only applies to the configuration of the Sensor with Patch when properly inserted. All other configurations (Lead Wire Adapter and Flex Adapter with Sensor) are not water resistant.
- Internally Powered Equipment.
- Mode of Operation – Continuous Operation.

CHANGES OF PERFORMANCE

CAUTION: In the event there's a change in performance of the BTPS-1000 system, reference TROUBLESHOOTING in chapter 28.

EXPOSURE TO ENVIRONMENTAL CONDITIONS

CAUTION: In the event the system is subjected to environmental conditions which may affect performance, such as high magnetic fields, as is the case in an MRI room, external electrical influences, electrostatic discharge (ESD), or other similar situations the user is requested to follow the instructions in the *TROUBLESHOOTING* section from chapter 28.

PHYSICAL ACTIVITIES AND EXPOSURE TO ENVIRONMENTAL EFFECTS SHOULD BE LIMITED

CAUTION: Physical activities leading to involuntary muscle spasm may cause artifacts while recording ECG signals. These activities should be avoided for the duration of use. Additionally, environmental effects, such as cold ambient temperature, may also generate muscle tremors and should also be avoided.

WHEN USING THE BTPS LEAD WIRE ADAPTER

CAUTION: Take precaution when using the lead wires as they can be a strangulation and choking hazard.

DO NOT TAKE THE MONITOR INTO THE SHOWER

CAUTION: The Braemar Telemetry Patch System Monitors (cell phones) are water resistant, not waterproof; do not take the Monitor into the shower.

DO NOT LIE DIRECTLY ON THE SENSOR

CAUTION: Do not lie or sleep directly on top of the Sensor as damage may result.

CHARGING THE MONITOR

CAUTION: Do not touch pins on the charger while connected to power outlet.

℞ Only **U.S. Federal law restricts this device to sale by or on the order of a physician.**

3. Indications for Use

The device is designated as Rx only. Its indications for use are as follows:

1. Patients who have a demonstrated need for cardiac monitoring. These may include but are not limited to patients who require monitoring for:
    a) non-life threatening arrhythmias such as supraventricular tachycardias (e.g. atrial fibrillation, atrial flutter, PACs, PSVT) and ventricular ectopy;
    b) evaluation of bradyarrhythmias and intermittent bundle branch block, including after cardiovascular surgery and myocardial infarction; and
    c) arrhythmias associated with co-morbid conditions such as hyperthyroidism or chronic lung disease.
2. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as:
    a) dizziness or lightheadedness;
    b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and
    c) dyspnea (shortness of breath).
3. Patients with palpitations with or without known arrhythmias to obtain correlation of rhythm with symptoms.
4. Patients who require outpatient monitoring of antiarrhythmic therapy:
    a) monitoring of therapeutic and potential proarrhythmic effects of membrane active drugs,
    b) monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation).
5. Patients recovering from cardiac surgery who are indicated for outpatient arrhythmia monitoring.
6. Patients with diagnosed sleep disordered breathing including sleep apnea (obstructive, central) to evaluate possible nocturnal arrhythmias.
7. Patients requiring arrhythmia evaluation of etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation or atrial flutter.
8. Patients requiring measurement, analysis and reporting of QT interval, excluding patients with a documented history of sustained atrial fibrillation or atrial flutter.

9. Patients who require monitoring for potential arrhythmias based on risk factors (e.g. atrial fibrillation).
10. Patients requiring measurement of ST segment changes. The device is not intended to sound any alerts for ST segment changes.

4. Contraindications

The BTPS-1000 is contraindicated as follows:

1. Patients with potentially life-threatening arrhythmias who require inpatient monitoring.
2. Patients who the attending physician recommends should be hospitalized for ECG monitoring.
3. This device should not be used for monitoring of QT interval during the initiation of antiarrhythmic therapy, where in-hospital monitoring is required by the labeling of that drug.
4. The device does not replace the QT interval measurement by a trained observer using diagnostic 12 lead ECG in a clinical environment. This device is not intended to sound any alerts for QT interval changes.
5. The device does not annotate QT interval for QRS durations >160ms or for T wave amplitudes ≤5% of the peak QRS amplitude.

5. Overview

The Braemar Telemetry Patch System Model BTPS-1000 (BTPS-1000 system) is meant to be used/worn by the patient at home, in the office and during most activities. Activities such as showering, swimming and the like require special precautions as described in chapter 23, "Showering, Bathing and Swimming," of this Manual. The BTPS-1000 system continuously collects ECG data from the patient. The Sensor acquires the ECG data and transmits the data to the Monitor. The Monitor continuously and automatically analyzes the ECG data using a proprietary onboard algorithm. The data is algorithmically processed and transmitted via the Monitor to a remote site for further processing.

The BTPS-1000 system is intended for use on adults and children weighing more than 22 lbs (10 kg).

The BTPS-1000 system is not intended as an emergency response system.

The BTPS-1000 system, which provides continuous ECG recording and automated analysis is comprised of several components. The system will be able to operate in a mode called MCOT®, which stands for **M**obile **C**ardiac **O**utpatient **T**elemetry. In this mode, the system performs the following functions:

1. Records ECG signals
2. Analyzes acquired ECG signals
3. Reports detected arrhythmias via cellular service to an external monitoring service

The following illustrates the basic operation of the system:

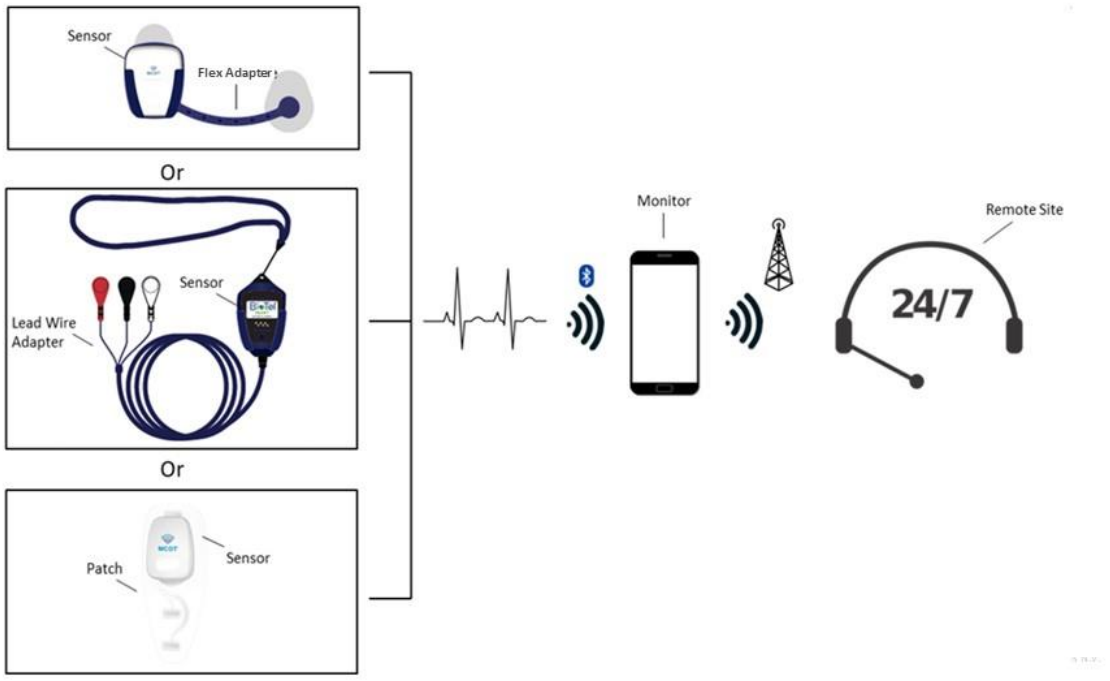
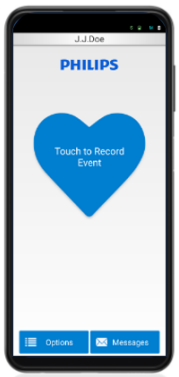


Figure 5-1 BTPS-1000 Basic Operation

6. System Components

The BTPS-1000 system consists of the following components. Materials for cleaning the skin to apply the Patch are not supplied with this product.

#	Image	Name	Part Number	Description
1		Sensor (BTP-1000S)	02-01606 02-01846 02-01889 02-02124	**What it does:** The Sensor is a device that acquires ECG data and stores the data in non-volatile memory. The Sensor can store up to 30 days of ECG data and operates on one rechargeable battery. The Sensor will wirelessly transmit data to a portable Monitor device over a Bluetooth link. For minimum signal amplitude, see NOTE 1 below. **Battery:** See NOTE 3 below.
2	 To be used with Sensor ONLY	Charge Adapter (BTP-1000S-CA)	02-00109	**What it does:** Connects to the Sensor AC Adapter or a USB port on a computer to charge the Sensor that is plugged into the Charge Adapter. * Has black cable
3	 Example of AC Adapter To be used with Sensor Charge Adapter or Purge Adapter ONLY	Sensor AC Adapter	01-02038	**What it does:** Connects to wall electricity outlet to charge the Sensor (when using the Charge Adapter) or to purge the Sensor (when using the Purge Adapter).

#	Image	Name	Part Number	Description
4	 Samsung J3 2017  Samsung J3 2018	Monitor (BTP-1000M)	02-00106- J3 Emerge (2017) 02-01548- J3 Verizon (2018) 02-01549 J3 (Sprint/T-Mobile 2018)	***All supported models are illustrated. The patient will receive either one of the Samsung models, not all.*** **What it does:** The Sensor transmits ECG, PIE events, system logs and other related data to this cellular phone, henceforth called Monitor. The Monitor performs data analysis using an FDA-cleared arrhythmia detection algorithm and transmits the data to the remote site via cell modem for further post-processing and reporting. **Battery:** See NOTE 3 below.
4	 Samsung Galaxy A10e		02-01800 Samsung A10e (Sprint/T-Mobile) 02-01804 Samsung A10e (Verizon) 02-01894 Samsung A10e (Verizon)	
	 Samsung Galaxy A13		02-02119 Samsung Galaxy A13 (T-Mobile) 02-02118 Samsung Galaxy A13 (Verizon)	

#	Image	Name	Part Number	Description
5		Monitor Charging Cable	01-01882 (Cable USB-A to Micro-B BK) used with Samsung J3 01-01970 (Cable USB-A to USB-C RD) used with Samsung A10e/A13	**What it does:** Connects to the Monitor AC Adapter on the USB-A side and the Monitor on the other end, in order to charge the Monitor.
6	 Example of Monitor AC Adapter	Monitor AC Adapter	01-02034 (AC/DC USB Dual)	**What it does:** Connects to wall electricity outlet to charge the Sensor (when using the Charge Adapter) and/or charge the Monitor (when using the Monitor Charging Cable).
7	 Example of Patch	ECG Electrode Patch (Patch) (BTP-1000P)	02-01609 (Single) 02-01615 (Box of 40)	**What it does:** The Sensor is connected to the patient via four integrated electrodes, built into the Patch. The electrodes are not removable from the Patch by the patient and are hardwired to the Sensor within the Patch. Upon removal of the Sensor from the Patch, the Patch is destroyed, and a new Patch must be used with the Sensor.
8		Lead Wire Adapter (BTP-1000L-2)	02-00139	**What it does:** The Sensor is connected to the Lead Wire Adapter, which is then attached to three surface electrodes. The patient can then place the device on their chest. The surface electrodes can be changed by the patient, and it is recommended that they be changed every other day.

#	Image	Name	Part Number	Description
9		Flex Adapter (BTP-1000A)	02-00143	**What it does:** The Sensor is connected to the Flex Adapter which is then attached to two surface electrodes. The Patient can then place the device on their chest. The surface electrodes can be changed by the patient, and it is recommended that they be changed every other day.
10	 Example of a Surface Electrode	Surface Electrode	01-02108 (Pack of 3) 01-02159 (Pack of 30) 01-02160 (Sensitive Pack of 10)	**What it does:** Connects to leads on Flex Adapter or Lead Wire Adapter. Once connected to accessory, patient can place it on their chest.
11		Purge Adapter (BTP-1000S-PA)	02-01693	**What it does:** Connects to the Sensor AC Adapter or a USB port on a computer to purge/erase patient data from the Sensor that is plugged in to the Purge Adapter. When data has been purged, it will charge the Sensor. This component is to be used with Sensor AC Adapter or Monitor AC Adapter only as described in Note 2, below. * Has white cable

NOTE 1: *The device does not have a set minimum amplitude or value for ECG measurement. Minimum requirements are to maintain leads attachment to the skin. When this condition is not met, a 'Leads-OFF' event is triggered and results in ECG data being flagged as 'leads-off', which is not used for ECG analysis. See chapter 29, 'Monitor Screen Alerts and Warning Screens'.*

NOTE 2: *The use of power adapters or other accessories other than the ones listed above may result in increased electromagnetic (EMC) emissions or decrease EMC immunity to the devices.*

NOTE 3: *The battery from Monitor and the battery inside the Sensor are only serviceable or replaceable by the manufacturer or by approved trained personnel. Each can only be charged by the charger identified in the table above and provided with the device.*

ESSENTIAL PERFORMANCE

The system is designed with the following safety-related functions:

- The Patch is designed to be used only once. Upon removal of the Sensor, it will break and prevent reuse.
- The system detects when the electrodes from the Patch are not making an acceptable contact with the skin. A "Leads-OFF" alert will be triggered in the Monitor. Reference chapter 29, Monitor Screen Alerts and Warning Screens.
- Identifiable patient information is securely saved in the Monitor and is encrypted when transmitted to the remote site. All patient information is controlled and protected throughout every step of data acquisition, processing, and transmission to remote site.
- Both the Sensor and Monitor are powered by a rechargeable internal battery, which is protected using various mechanisms to ensure a safe operation for the duration of use. For continued protection only use approved accessories provided with the device.
- The Sensor is designed to be recharged only when not attached to the Patch or patient.
- Communication between the Sensor and Monitor via Bluetooth technology is protected by using a proprietary communication protocol.
- The Monitor is protected against unauthorized installation of software packages or modification of settings by an internal software process.
- ECG noise generated by the system or various other external sources is possible and effects are mitigated by internal processes. At a minimum, the Sensor will continuously record ECG data and transmit it to the Monitor for processing.
- In the event the Sensor cannot transmit the collected ECG data to the Monitor, it will indefinitely continue to search for the paired Monitor until the communication link has been re-established.

SERVICING AND INQUIRIES

Please contact Customer Service for any questions regarding the product, servicing request, disposal needs or to report any unexpected operation or events. Customer Service can be reached at 1-866-426-4401.

The manufacturer can be reached via the following contact information:

Braemar
a BioTelemetry company

Phone: 800.328.2719 *Fax:* 651.286.8630 *E-Mail:* sales_braemar@philips.com
1285 Corporate Center Drive, Suite 150, Eagan, MN 55121 USA

7. Proper Care of the BTPS-1000

SHOWERING:

- Lead Wire Adapter and Flex Adapter must be removed prior to shower. They are not intended to be waterproof and may stop functioning if used in the shower.

  The Patch with Sensor is water resistant, not waterproof. The Patch with sensor may be worn in the shower. However, the patient must avoid spraying water directly onto the Sensor by keeping it away from all direct water flow and deflecting/shielding with body, a hand, or towel, when showering.

AVOID DUSTY ENVIRONMENTS

While wearing the Braemar Telemetry Patch System components avoid areas that have a high degree of airborne dust and other contaminates.

CLEANING

Follow instructions from chapter 22, “Cleaning, Maintenance and Purging”.

LIMITATIONS OF COVERAGE

The ability of the Braemar Telemetry Patch System to obtain and transmit information regarding a cardiac event is limited by a number of factors including:

- Transmission of information about a cardiac event to the provider remote site is potentially limited by the availability of cellular phone coverage.
- There is an inherent time delay from the time that an event is detected to when the events are transmitted and analyzed.

DISPOSAL

The Patch and surface electrodes are single use. Dispose of the Patch and Electrodes properly in accordance with local ordinances or the instructions of the prescribing physician. The Patch and Electrodes may need to be recycled in accordance with local laws.

All other items provided, including Lead Wire Adapter and Flex Adapter are reusable and should be returned to the provider at the end of the monitoring period.

8. Step-by-Step Walkthrough

The system needs to be installed and put into service in accordance to the instructions provided in this manual. The steps for installation, configuring and final set up of the system are broken down as follows:

1) Check completeness of equipment
    a. Reference component list from chapter 6, “System Components”.
    b. Don’t use if broken, damaged, tampered or otherwise impacted. Contact Customer Service for further instructions.

2) Monitor start up and initial power ON
    a. Follow provided instructions from chapter 12, “Starting the Monitor”

3) System setup
    a. Follow provided instructions from chapter 13, “Initial Set Up” to set up the monitor.
    b. Apply Patch or other electrode options to body
        i. Continue instruction from chapter 9, “Patch: Skin Preparation, Set-up and Application to Skin” or chapter 10 “Lead Wire Adapter: Skin Preparation, Set-up and Application to Skin. Use chapter 11, “Flex Adapter: Skin Preparation, Set Up and Application to Skin,” for use with Flex Adapter option.
        ii. If considerable skin irritation occurs during the course of the patient’s ECG monitoring, contact Customer Service for further instructions.

NOTE: *Minor discomfort can occur when the Patch or surface electrodes used with the Lead Wire Adapter or Flex Adapter are attached to the skin. The materials selected for these accessories are biocompatible and are purposed for this use, however, if severe skin irritation does occur and becomes uncomfortable for continued use then remove Patch, Lead Wire Adapter with electrodes or Flex Adapter and contact your medical practitioner or Customer Service department.*

To replace the Patch, follow instructions from chapter 18, “Removing Patch”

4) To turn the devices OFF, follow the instructions from chapter 21, “Removal and Turning OFF“

5) Respond to any alerts or warnings displayed on the Monitor, see chapter 29, “Monitor Screen Alerts and Warning Screens”.

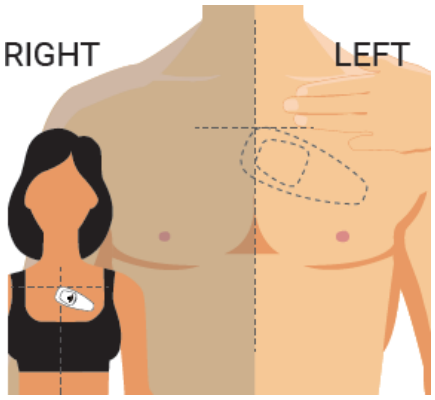
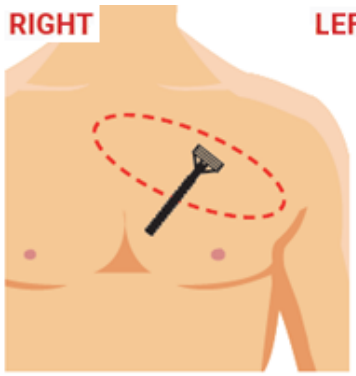
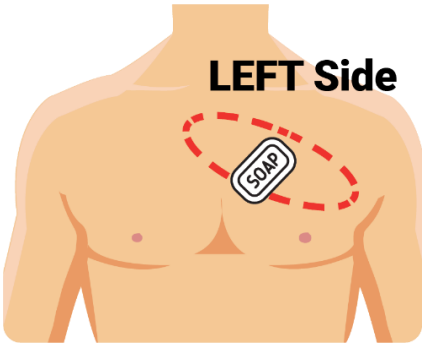
6) Once it is set up, ECG recording is automated. No other action is required.

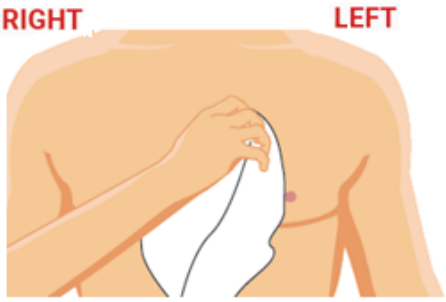
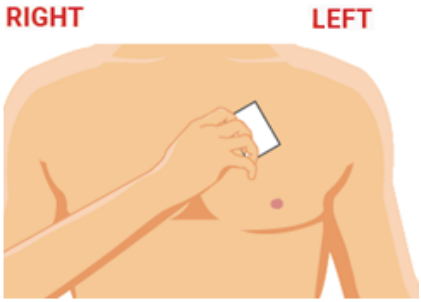
If any questions or concerns arise, contact Customer Service referenced under, “Servicing and Inquiries” in chapter 6.

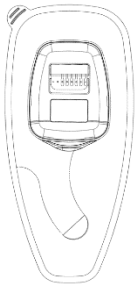
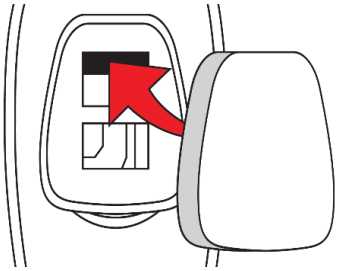
9. Patch: Skin Preparation, Set-up and Application to the Skin

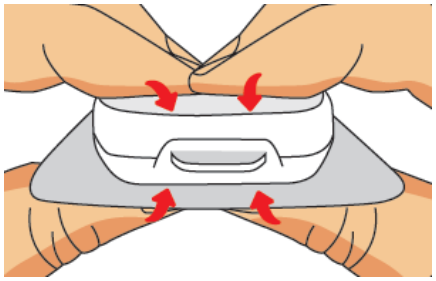
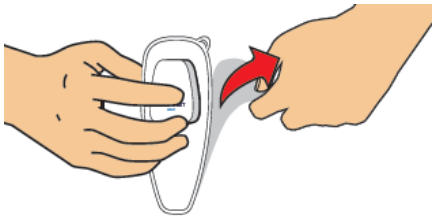
Follow the instructions below to prepare skin for the Patch. The supplied Patch may not look exactly like what is pictured below, but the steps to follow are the same.

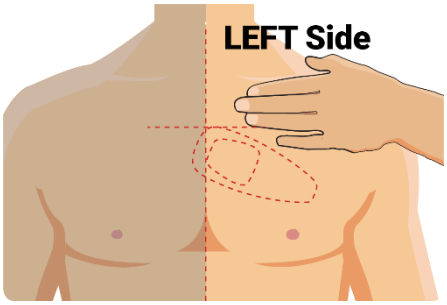
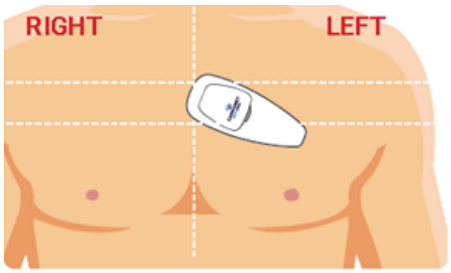
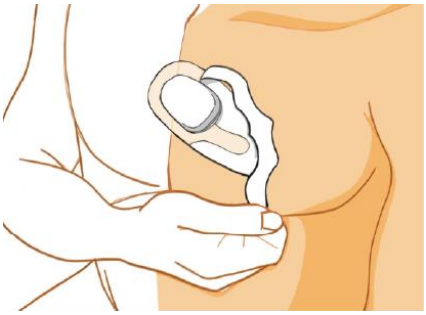
NOTE: If you are the healthcare professional, perform these actions on the patient. If you are the patient, follow the guidance and perform on yourself.

Step	Illustration	Description
1		**Proper Placement / Positioning the patch** **1.** Determine the area of your chest to prepare by referring to the diagram. **2.** Locate your collarbone on the left side of your body and measure three finger widths below it.
2		**Shave** It is important to prepare your skin before applying the device. If hair is on your chest in the indicated area (red circle), shave hair using a razor.
3		**Skin Prep** Wash the area with soap and water. **Do not apply lotions or oils.**

4		**Dry Skin thoroughly using a towel**
5		**Abrade Skin** Remove the Scrub Pad / Skin Preparation Pad from your kit. Scrub the cleaned area with firm pressure in a circular motion for one minute. This important step will improve the quality of the recording. **Do not apply lotions or oils to the shaved area.**
6		**Wait 2-3 Minutes** It is important to wait for a minimum of 2-3 minutes until your skin is completely dry before applying the Patch. While you wait, continue with the next steps.
7		**Locate the Sensor in your kit** The Sensor is shipped fully charged. During transport, the Sensor is in a deep sleep state, where minimal energy is used. Once assembled with the Patch, a green LED will light up momentarily to indicate that self-test has been successfully completed.
8		**Remove Patch from pouch** Tear open a pouch and remove a patch.

9	 Example of patch	**Place patch on flat hard surface in the orientation shown to the left**
10		**Place Sensor in the Patch**
11		**Reassure Sensor is in place** While standing, place the palm of your hand on top of the Sensor and apply pressure to snap the Sensor into the patch.
12		**Rotate the Patch 180 degrees**
13		**Sensor placement** With the Patch rotated, again place the palm of your hand on top of the sensor and apply pressure to further snap the Sensor into the Patch.

14		**Inspect Sensor** Inspect all four sides of the Sensor for gaps. The Sensor is attached correctly if there are no visible gaps.
15		**Correct- No Gap**
16		**Incorrect- Gap**
17		**Seal Gap** Apply pressure to any gaps to fully seal the gap.
18		Ensure that sensor is sealed to the Patch and that there are no gaps. It is very important that all gaps are closed or damage to the Sensor could occur.
19		**Watch for the green light** Once the gaps are closed and the Sensor is fully connected to the Patch, check for a green LED light to ensure the device is working. This will take up to 15 seconds.
20		Pick up the Patch with the attached Sensor and peel off the clear plastic backing.

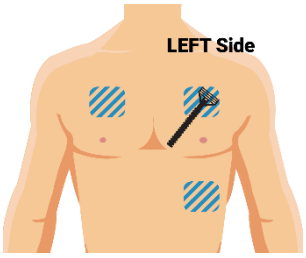
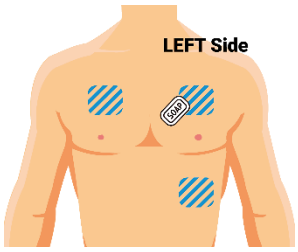
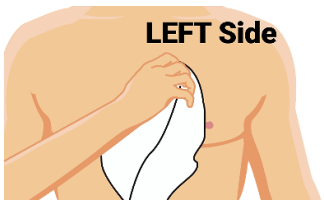
21		**Position the Patch as follows:** 1. The top of the Patch should be three finger widths down from your collarbone in the center of your chest. 2. Place Patch on chest as illustrated. The right corner (widest part) of the Patch (near the sensor) should be closest to the center of your chest. The other end of the Patch should be on a slight angle down as shown in the illustration.
22		Press all sides of the Patch firmly against skin to assure adherence.
23		**Remove the top white paper from the Patch** Gently peel off the top white liner paper by starting with the raised tab. 1. After the top liner is removed, press firmly around all of the edges of the Patch and on the Sensor so that the Patch will firmly adhere to your skin. 2. Smooth any wrinkles by pressing around the entire Patch. Now that the Sensor and Patch are attached to your chest, continue with turning on your Monitor in chapter 12.
24		**<u>Pairing Monitor with Sensor</u>** Now that the Sensor is attached to the Patch continue with chapter 12, “Starting the Monitor,” and chapter 13, “Initial Set up”.

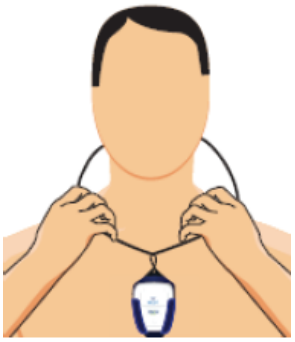
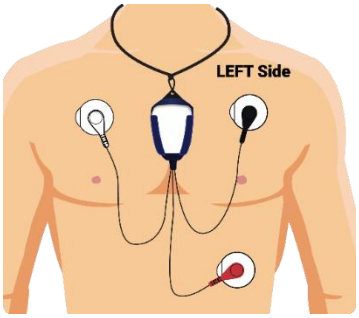
10. Lead Wire Adapter: Skin Preparation, Set-up and Application to Skin

The Lead Wire Adapter is an alternative to the Patch. Before you continue to the next steps, locate the Lead Wire Adapter, packets of electrodes and the Quick Start guide to assist you with set-up and questions.

NOTE: The instructions provided by this chapter can be performed when you require replacing (applying new) surface electrodes.

NOTE: If you are the healthcare professional, perform these actions on the patient. If you are the patient, follow the guidance and perform on yourself.

Step	Illustration	Description
1		**Proper Placement and Preparing the Skin:** It is important to prepare your skin before applying the device. If hair is on your chest in the indicated areas, you will need to shave using a razor.
2		**Skin Prep:** Wash the three shaded areas in the graphic to the left with soap and water. **Do not apply lotions or oils.**
3		**Dry Skin:** Dry skin thoroughly using a towel.
4		**Insert the Sensor into the Adapter:** Locate the Sensor. Push the Sensor through the top of the Lead Wire Adapter until it is firmly in place.

Step	Illustration	Description
5		**Green Light:** Approximately 15 seconds after the Sensor has been properly inserted into the Lead Wire Adapter, a green light should flash intermittently.
6		**Attaching the Electrodes:** Place the lanyard over your head and around your neck. Remove a packet of surface electrodes from the kit. Open the surface electrode pouch. Keep the plastic backing on the electrodes. Remove three surface electrodes and snap each of the three lead wires into the electrodes. NOTE: Surface electrodes should be changed out every other day.
7		**Attach the Leads to Your Body:** **When you remove the plastic backing, be careful not to touch the surface electrode adhesive.** Start with the white lead. Peel the adhesive off the back and place the white lead approximately three fingers below collarbone on your right side. Next, you will attach the black lead to the upper left side of your chest. Peel the adhesive off the back of the electrode and place approximately three finger widths below your collarbone on the left side. Lastly, peel the adhesive and place the red lead on your lower rib on the left side of your body.

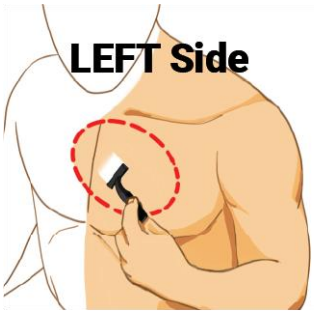
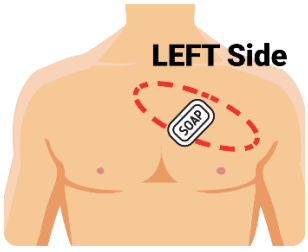
Step	Illustration	Description
8		**Pairing Monitor with Sensor:** Now that the Sensor is attached to the Lead Wire Adapter, continue with chapter 12, "Starting the Monitor" and chapter 13, "Initial Set up," to pair the Sensor to the Monitor.

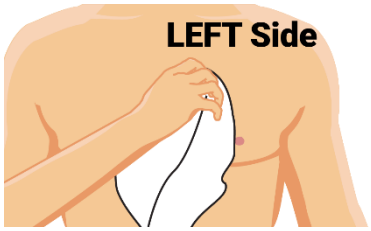
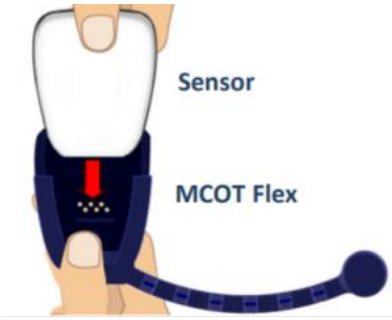
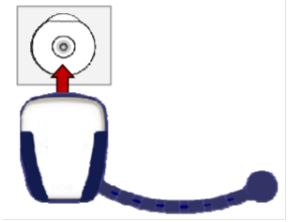
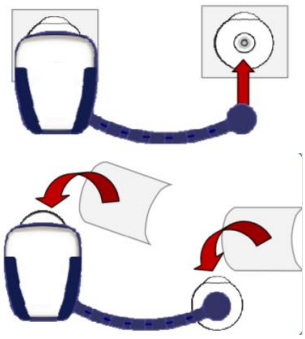
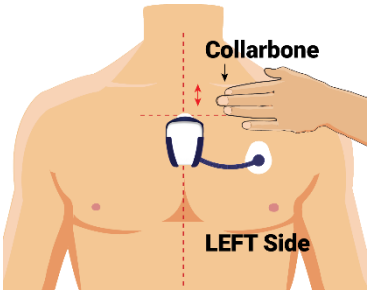
11. Flex Adapter: Skin Preparation, Set Up, and Application to Skin

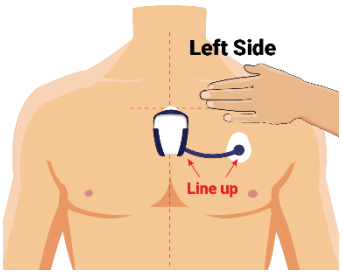
The Flex Adapter is an alternative to the Patch. It is located in the BTPS-1000 kit, along with packets of electrodes and a Quick Start Guide to assist you with set-up and questions. Before you continue to the next steps, locate the Flex Adapter and kit.

NOTE: The instructions provided by this chapter can be performed when you require applying a new Flex Adapter.

NOTE: If you are the healthcare professional, perform these actions on the patient. If you are the patient, follow the guidance and perform on yourself.

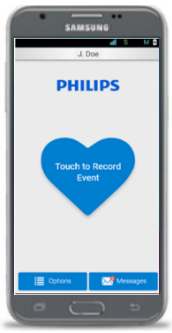
Step	Illustration	Description
1		**Proper Placement and Preparing the Skin:** It is important to prepare your skin before applying the device. If hair is on your chest in the indicated areas, you will need to shave using a razor.
2		**Skin Prep:** Wash the area with soap and water. **Do not apply lotions or oils.**

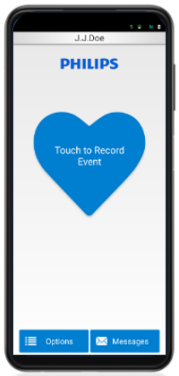
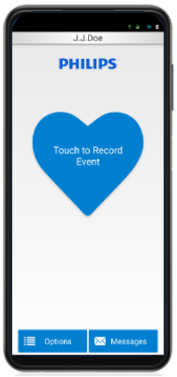
Step	Illustration	Description
3		**Dry Skin:** Dry skin thoroughly using a towel.
4		**Insert the Sensor into the Flex Adapter:** Insert the Sensor into the Flex Adapter Once the Sensor has been properly inserted into the Flex Adapter, after approximately 15 seconds, a green light should flash intermittently.
5	 	**Attaching the Flex Adapter:** Remove the surface electrode strip from the pouch. Leave the plastic backing on the surface electrodes. Use the perforations to separate two Electrodes from the strip. While the electrode is still on the plastic backing, snap it into the connector on the back of the Flex Adapter. NOTE: Refer to the information provided with the surface electrodes for replacement instructions.
6		**Attach Flex Adapter:** **When you remove the plastic backing, be careful not to touch the surface electrode adhesive.** Place your left hand on the left side of your chest so that your index finger is just below the collarbone. Position the Flex Adapter so that it is lined up with your chin and three finger widths below your collarbone. Press the Flex Adapter firmly against your chest.

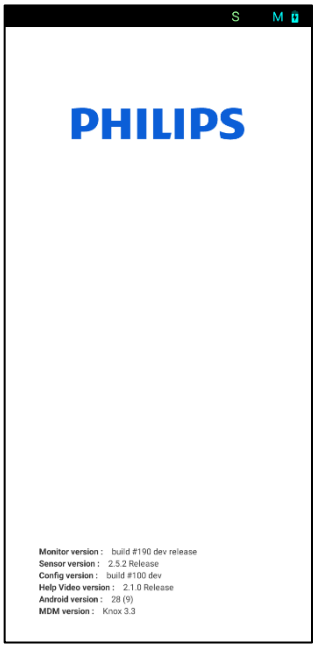
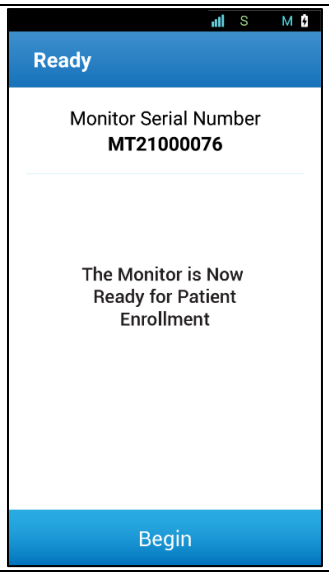
Step	Illustration	Description
7		Line up the second electrode so that the arm lays flat against your chest and the button snap is lined up with the bottom of the Flex Adapter Be careful not to straighten the arm. Keep a bend so it looks like a smile. Press the second electrode firmly against your chest.
8		**Pairing Monitor with Sensor:** Now that the Sensor is attached to the "Flex Adapter" continue with chapter 12, "Starting the Monitor," and in chapter 13, "Initial Set up".

12. Starting the Monitor

NOTE: If you are the healthcare professional, guide the patient accordingly. If you are the patient, follow the instructions.

Step	Illustration	Description
1	 Samsung J3 phone (Representative)	The Monitor can be turned ON by pressing and holding the ON/OFF button for approximately 3 seconds. The screen will illuminate, and the Monitor will begin its start-up sequence. The screen saver in the Monitor will turn OFF the screen after a short period of time. To illuminate the

	 Samsung A10e phone (Representative)	screen again, press the ON/OFF button. NOTE: External buttons, such as camera, volume, return, and home are disabled, with the exception of power ON/OFF.
	 Samsung A13 phone (Representative)	

2		Once powered on, the Monitor will momentarily display a brief splash screen, followed by a screen indicating the currently installed version number. The Sensor and Monitor will wirelessly link to each other via Bluetooth. Make sure they are no more than 3 feet apart and in line-of-sight of each other. At this point, the Monitor is also communicating with external services via cellular network to receive information. The instructions for initial set up are described in the next chapter.
3		Once you have successfully turned ON the Monitor and the Bluetooth and cellular connections are established, the set-up process will continue. The text on this screen confirms the monitor is ready for you to begin the initial set-up in chapter 13.

13. Initial Set Up

NOTE: If you are the healthcare professional, guide the patient accordingly. If you are the patient, follow the instructions.

13.1. Ready for Patient

On start-up, the Monitor will display the *Ready* screen. (See Figure 13.1-1). For the initial start-up it will ask you to select from the available languages. (See Figure 13.1-2).

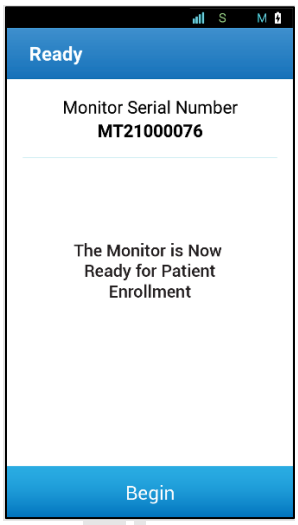


Figure 13.1-1 Ready Screen

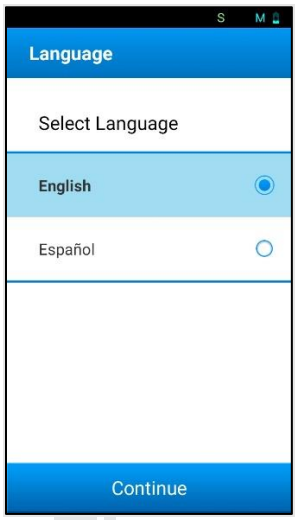


Figure 13.1-2 Language Selection

13.2. Pairing Monitor to Sensor

After pressing 'Continue' on the *Language* screen, the Monitor will display the *Insert Sensor* screen prompting you to install the sensor (See Figure 13.2-1). Refer to chapters 9-11 for desired configurations.

Figure 13.2-1 Insert Sensor

While displaying the *Insert Sensor* screen, the Monitor will look for the Sensor, perform some basic operations, and link to it, which is also called "paired".

The Monitor may ask for a pairing request (See Figure 13.2-2). Press 'OK' to pair with the Sensor. The Monitor will display the following screens while pairing (See Figure 13.2-3, Figure 13.2-4). Once pairing is completed, the *Paired Complete* screen will display (See Figure 13.2-5).

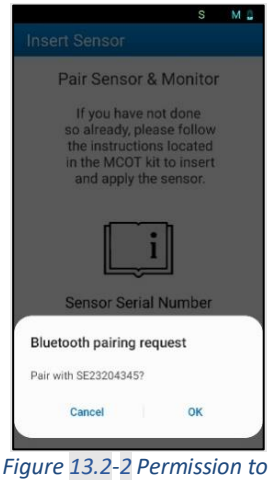


Figure 13.2-2 Permission to Pair

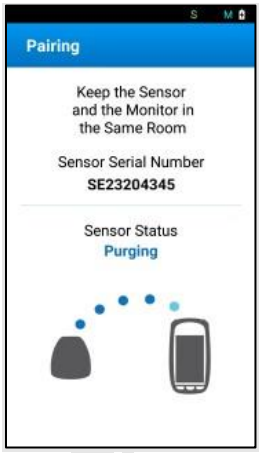


Figure 13.2-3 Pairing with Sensor

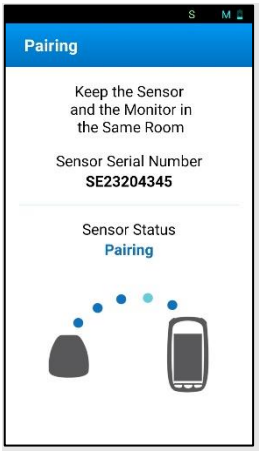


Figure 13.2-4 Pairing

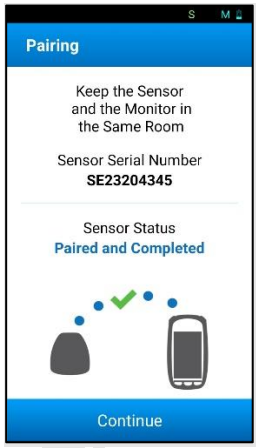


Figure 13.2-5 Pairing Complete

Once pairing is complete and the 'Continue' button on the *Pairing Complete* screen is pressed, the Monitor will display the *Welcome* screen (See Figure 13.2-6).

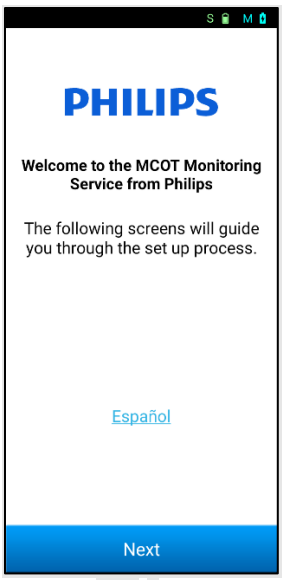


Figure 13.2-6 Welcome

13.3. Patient Consent

After pressing 'Next' on the *Welcome* screen, the Monitor will display a series of Consent screens. The *Confirm Identity Consent* screen (See Figure 13.3-1) allows you to confirm your prescription. Verify that the name written on the Monitor is yours, but do not press the 'Yes' button until you have read the important NOTE below.

NOTE:

- If you as the patient are the named individual, select 'Yes' to confirm the identity screen then follow instructions to continue with setup.
- If the information on-screen does not identify you as the patient prescribed use of the system, then select **'No'**.
- If 'Yes' was mistakenly pressed on the Confirm Identity screen and the wrong identity is confirmed, you need to call your prescribing physician or Customer Service.
- If 'No' was mistakenly pressed on the Confirm Identity screen when you as the patient were identified on that screen, press 'OK' on the *Contact* Support screen, and select 'Yes' when the *Confirm Identity Consent* screen appears. If any issues persist, call your prescribing physician or Customer Service (See Figure 13.3-2).

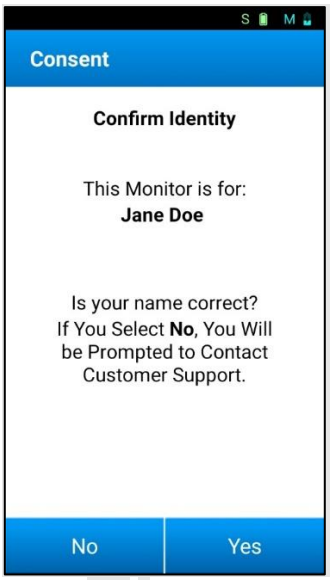


Figure 13.3-1 Confirm Identity

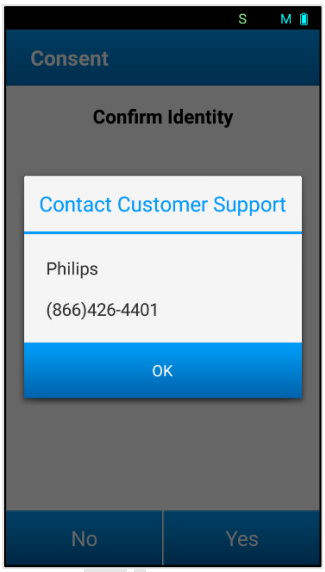


Figure 13.3-2 Contact Support

Once the patient's identity has been confirmed, the *Patient Consent* screen will display (See Figure 13.3-3). This screen covers a legally binding consent in which you, as the user of the BTPS-1000 system, agree to the Terms & Conditions. Terms & Conditions can be read by clicking on the hyperlink. Press 'Accept' to agree to the Terms & Conditions and to continue setting up the Monitor. If you select 'Decline' the *Contact Support* screen will display (See Figure 13.3-4).

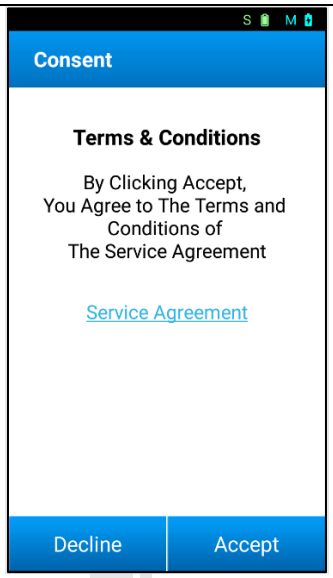


Figure 13.3-3 Patient Consent

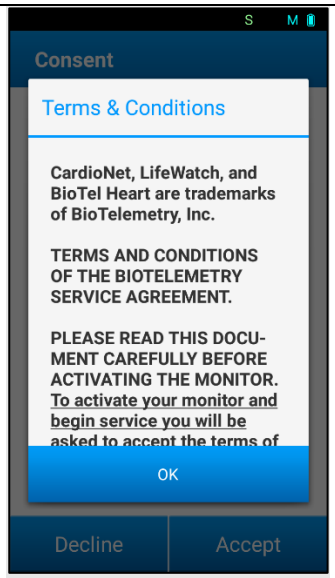


Figure 13.3-4 T&C Customer Support

Next, the *Data Terms Consent* screen (See Figure 13.3-5) will display, asking for the patient's permission to allow the Remote Site to use non-identifiable monitored data for research purposes. This information is used to improve the performance of the BTPS-1000 Patch system. The answer will be saved in the Monitor and sent to the Remote Site for storage in a database. The data of a

patient who chooses ‘Disagree’ on the *Data Terms Consent* screen is flagged at the Remote Site for specific exclusion from use in any research studies.

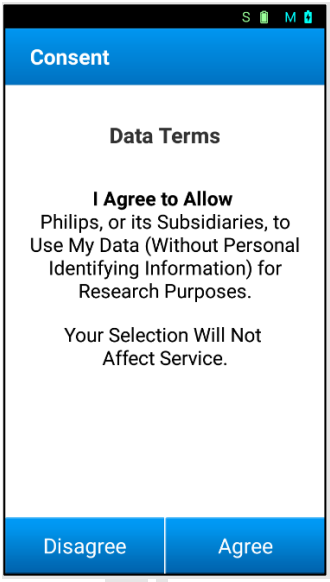


Figure 13.3-5 Data Terms

All data on the Monitor is stored in a secure memory area and is only accessible by authorized personnel. Additionally, all data is purged from the Monitor after each prescription. Industry standard computer security practices are utilized to prevent unauthorized access to the data stored in the Remote System’s database and your response to privacy will be respected. In all cases, security measures are in place to prevent third party access to patient’s data.

Please note: Your answer on the Data Terms screen does not affect the service provided to you. This is strictly an option.

13.4. Implantable Pacemaker Question

Next, a question will be asked on the presence of an implantable pacemaker. If you have an implanted Pacemaker choose 'Yes'. If you do not have an implanted Pacemaker or are not sure if you have one, then choose 'No/Unsure'. Your answer selection will not affect your ECG recording service.

Figure 13.4-1 Pacemaker

13.5. Wear & Care

Next, the Monitor will display one of the three *Wear & Care* screens pictured below, depending on which electrode type the sensor is in (See Figure 13.5-1, Figure 13.5-2, Figure 13.5-3). Press 'OK' to complete the set up and to begin Monitoring. The Monitor will advance to the *Home* Screen, see the *Activated & Monitoring* section below.

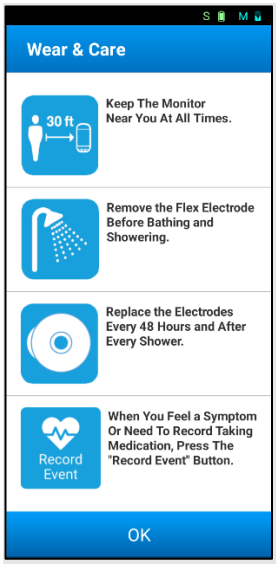


Figure 13.5-1 Flex Adapter

Figure 13.5-2 LWA

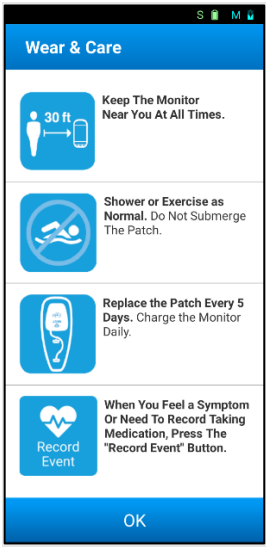


Figure 13.5-3 Patch

13.6. Activation without Connection

The Monitor can be activated and record ECG data without cellular connection. Upon start up, if the monitor cannot establish a connection, the Sensor and Monitor will pair as described in the *Pairing Monitor to Sensor* section (see Figure 13.6-1).

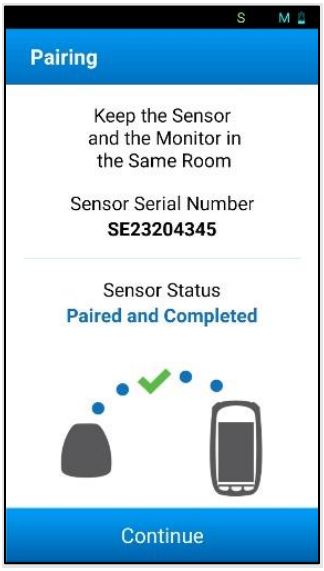


Figure 13.6-1 Pairing Completed

After pairing, the *Welcome ECG Recording* screen (See Figure 13.6-2) will display.

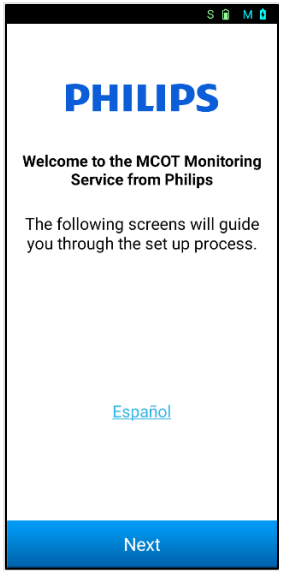


Figure 13.6-2 Welcome - ECG Recording

Pressing 'Next' will display one of three Wear & Care screens as described in the *Wear & Care* section (see Figure 13.5-1, Figure 13.5-2, Figure 13.5-3).

After pressing 'OK' on the *Wear & Care* screen, if the connection still has not been established, the *Waiting for Prescription Home screen* will display (See Figure 13.6-3). "Waiting for Prescription" will be visible on the top of the *Waiting for Prescription* Home screen.

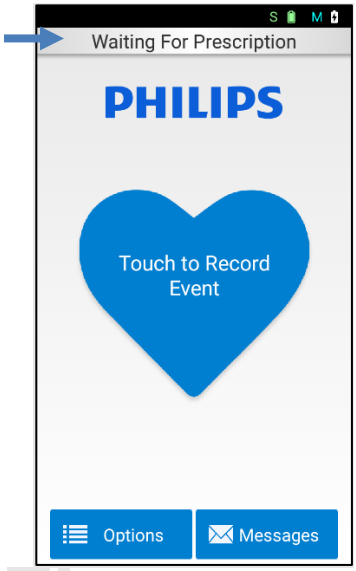


Figure 13.6-3 Waiting for Prescription Home Screen

Once the connection has been established, the *Prescription Received* screen (See Figure 13.6-4) will display to inform you that the connection has been established and that the prescription has been received. An alert sound will accompany the screen when displayed, until the <NEXT> button is pressed. Now the Monitor can complete the set up.

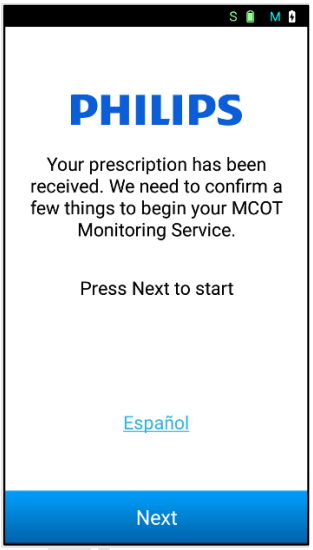


Figure 13.6-4 Prescription Received

After pressing 'Next' on the *Prescription Received* screen, the *Patient Consent* screens display as described in the "Patient Consent" section (see Figure 13.3-3, Figure 13.3-4, Figure 13.3-5). After completing the Consent screens, the *Home* Screen displays, and the patient is fully activated and is being monitored.

If the Monitor fails to receive a prescription after a configured amount of time, the Monitor will display a warning or an error. See chapter 29 Monitor Screen Alerts and Warnings screens.

13.7. Activated & Monitoring

The *Home screen* of the Monitor is displayed as shown below.

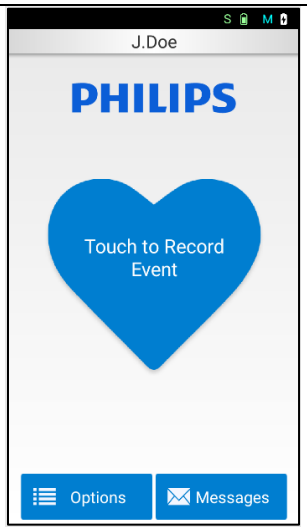


Figure 13.7-1 Home screen

From this screen, you can record an event, view messages, and access the 'Options' menu (See Figure 13.7-1). The "Touch to Record an Event" button is discussed in chapter 14.

13.8. Options Menu

The 'Options' menu allows changing Monitor options, sending an ECG test to the Remote Site, testing the cellular connection, watch the Help Video for installation instructions, or contacting Customer Service (see Figure 13.8-1). The 'Monitor Options' sub-menu also allows you to change volume, turn vibration on/off, select language, and change Monitor to Airplane Mode.

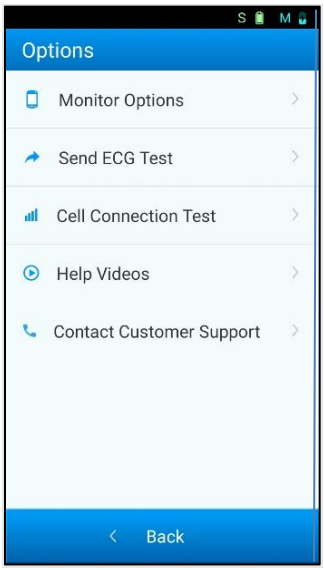


Figure 13.8-1 Options

13.9. Messages Screen

The Messages screen displays messages sent to you from Customer Service (see Figure 13.9-1) Unread messages are indicated by a number next to the envelope symbol in the button on the Home Screen (see **Error! Reference source not found.** Each message can be viewed by selecting it. P lease note you cannot reply to the text message, you can only view it.

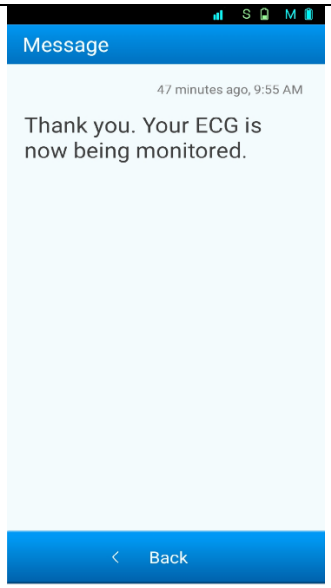


Figure 13.9-1 Message

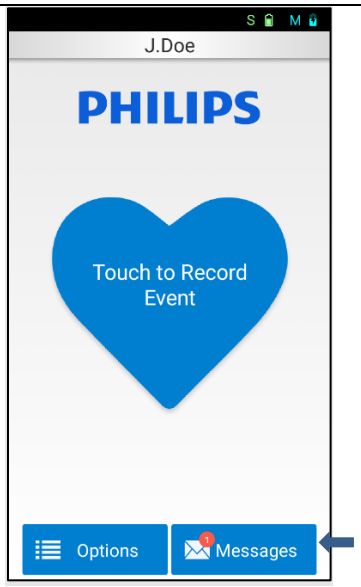


Figure 13.9-2 Unread Messages Indication

13.10. Changing languages

You can change default languages by performing the following operation:

1. From HOME screen, select Options
2. From Monitor Options screen, select Language
3. Select the language, then click OK.

Please reference representative screen shots (Figure 13.10-1 and Figure 13.10-2).

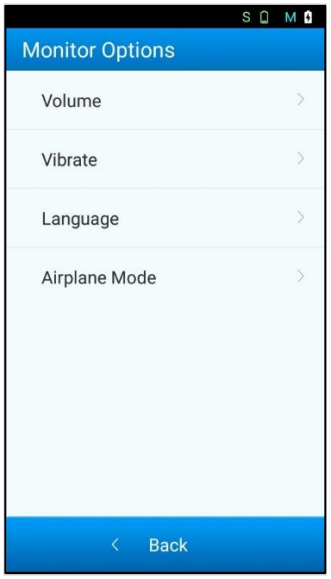


Figure 13.10-1 Monitor options

Figure 13.10-2 Language

13.11. Enabling or disabling Airplane Mode

Airplane Mode is used to disable only the Monitor's wireless cell radio frequency transmission. Bluetooth radios for both the Monitor and Sensor will remain on. Under special environments, such as boarding an airplane or in a hospital with sensitive equipment, you can enable Airplane Mode by performing the following:

To Enable/Disable:

1) From Home screen, select Options (Figure 13.11-1)
2) Select Monitor Options.
3) Select Airplane Mode then select 'On' to enable (Figure 13.11-2) and 'Off' to disable (Figure 13.11-3)
4) When Airplane Mode is enabled/disabled, a pop-up screen will display indicating it is enabled/disabled. In the enabled mode, an airplane icon on the Status Bar will appear. See Figure 13.11-4 and Figure 13.11-5.

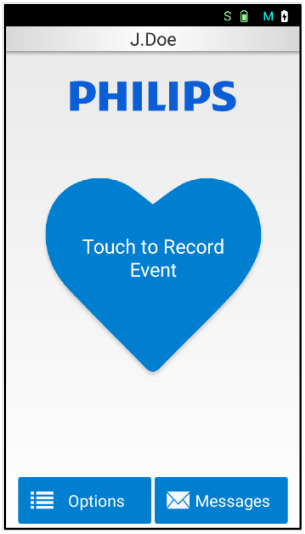


Figure 13.11-1 Options on Home Screen

Figure 13.11-2 Enabling Airplane Mode

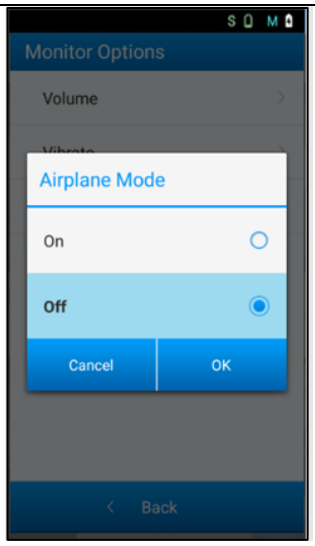


Figure 13.11-3 Disabling Airplane Mode

Airplane mode is enabled

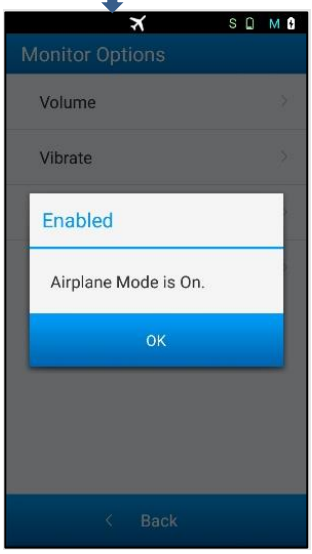


Figure 13.11-4 Airplane Mode Enabled

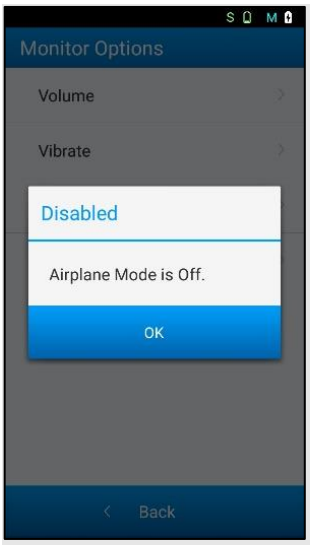


Figure 13.11-5 Airplane Mode Disabled

14. Recording Symptoms and Events

NOTE: If you are the healthcare professional, guide the patient accordingly. If you are the patient, follow the instructions.
NOTE: This system is not an emergency response service. If a medical emergency is identified, call immediately a medical emergency number such as 911.

It is important for you to record any symptoms you may feel or any medications you have taken. When you feel a symptom, you may record it on the Monitor. You can also record times when you are taking medication as instructed by your prescribing physician.

1. From the *Home screen*, press the "Touch to Record an Event" button
2. The *Select an Event* Screen will display (see Figure 14-1)
3. To go back to the *Home Screen* without recording an event, press 'Cancel'
4. When recording an event that is a symptom, you must remain still for an optimal recording of an ECG signal. It is preferable to be sitting down during the entire process. The total time normally required for a good ECG recording is approximately 90 seconds.
5. On the *Select an Event* screen, select all that apply and then press 'OK'
6. If "fainted" was selected, another dialog box will open to request confirmation of the selection. Selecting 'No' will return you to *Select an Event* while selecting 'Yes' will continue the process.
7. If you select at least one symptom event, the next screen that displays is the *Select Activity* screen (See Figure 14-2). This allows an indication of the level of activity performed when the event occurred. Press 'Done' to finish the process, or 'Back' to return to the *Select an Event* screen. Determination of what constitutes light, medium, and heavy activity depends on your personal analysis.

The following may be used as guidance:

a) Resting: This can include lying down on the bed or sitting down on a chair.
b) Light: This can include slow-paced walking and light house chores like cooking and washing dishes.
c) Medium: This can include biking on ground level, general gardening and carrying small children.
d) Heavy: This can include jogging, fast dancing, heavy gardening such as continuous digging and hoeing, playing sports such as basketball or soccer.

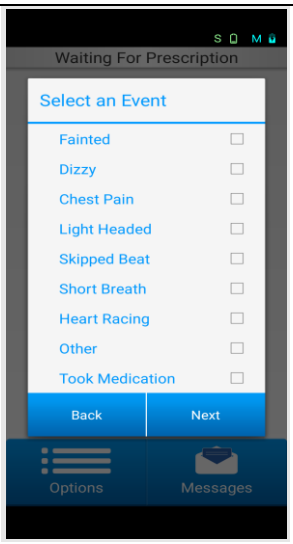


Figure 14-1 Select an Event

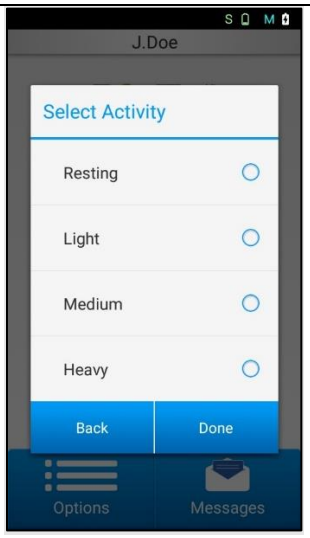


Figure 14-2 Select Activity

e) If "Took Medication" was the only selection from the *Select an Event* screen, the *Select Activity* screen will be bypassed, and there will be no requirement to enter an *Activity*.
f) A final screen will confirm the event was recorded (see Figure 14-3). Press 'OK' to return to *Home* screen.

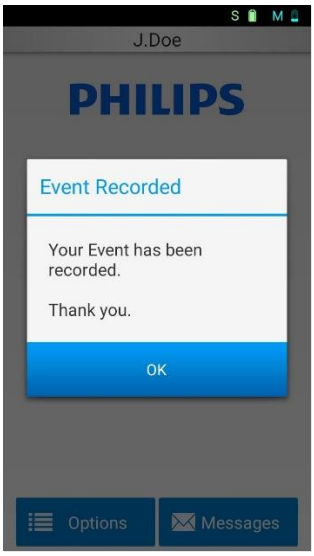


Figure 14-3 Event Recorded screen

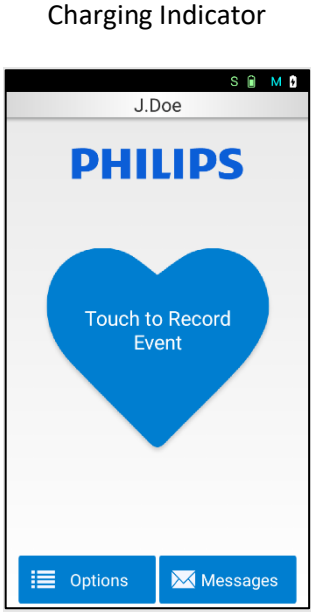
15. Charging the Monitor

NOTE: If you are the healthcare professional, guide the patient accordingly. If you are the patient, follow the instructions.

Charge the Monitor every night. It may take up to 4 hours to fully charge the Monitor. Only use supplied charger to charge the Monitor.

CHARGING THE MONITOR
NOTE: Do not touch pins on the charger while connected to power outlet.

Step	Illustration		Description
1	 Samsung J3	 Samsung A13 and A10e	Insert the small end of the charging cable into the Monitor as shown. Insert the other end of the cable into the charger. Insert the charger into a wall outlet.

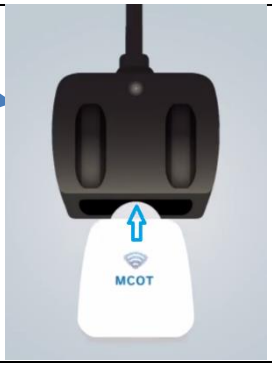
2	Charging Indicator  *Figure 15-1 Monitor Charging indicator icon*	The Monitor battery status indicator can be found on the top right corner of the screen as seen in Figure 15-1.

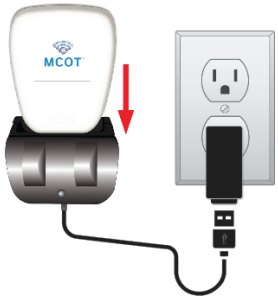
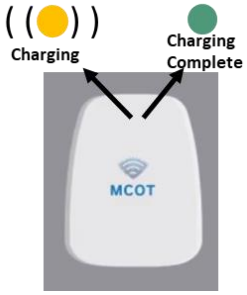
16. Charging the Sensor

NOTE: If you are the healthcare professional, guide the patient accordingly. If you are the patient, follow the instructions.

The Sensor should be charged each time you remove and replace the Patch or surface electrodes for the Lead Wire Adapter or Flex Adapter. It may take up to 90 minutes to fully charge the Sensor. Only use the charger supplied with the Sensor.

NOTE: DO NOT use a purge adapter as this will erase all patient data and pairing information.

Step	Illustration	Description
1	Black Cable  	Insert Sensor into the charge adapter (BLACK CABLE) in the direction shown. The sensor has to be removed from the Lead Wire Adapter, Flex Adapter or Patch before being placed in the charge adapter.

2	With Charge Adapter:  	Insert the other end of the cable into the wall charger and insert the wall charger into a wall receptacle.
3	 With Charge Adapter:  	While charging, the Sensor and Charge Adapter will emit a flashing light orange colored light. Once fully charged, the Sensor will emit a green light.

17. Checking the Battery Charge of the Monitor and Sensor

NOTE: If you are the healthcare professional, guide the patient accordingly. If you are the patient, follow the instructions.

The strength of the Sensor battery and the Monitor battery can be checked by reviewing the on-screen icons on the *Home* screen (see Figure 17-1).

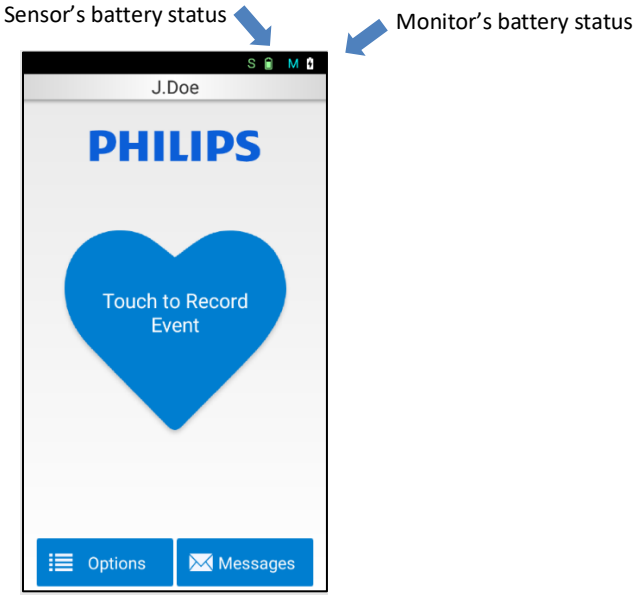


Figure 17-1 Battery Status

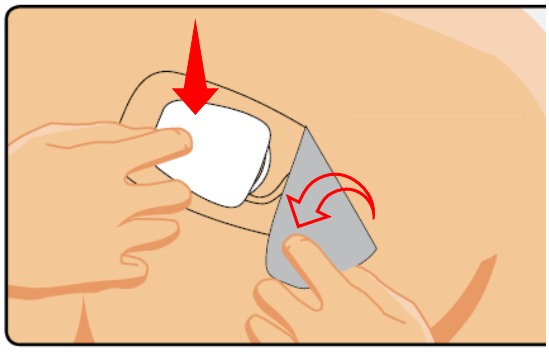
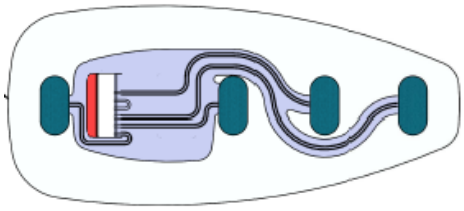
18. Removing Patch

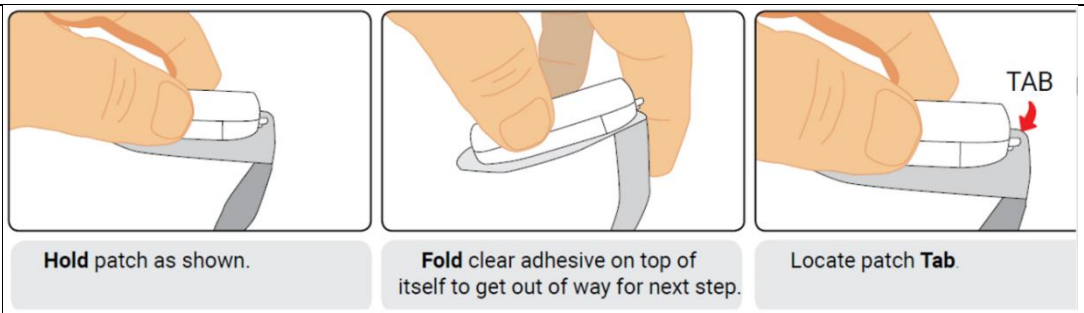
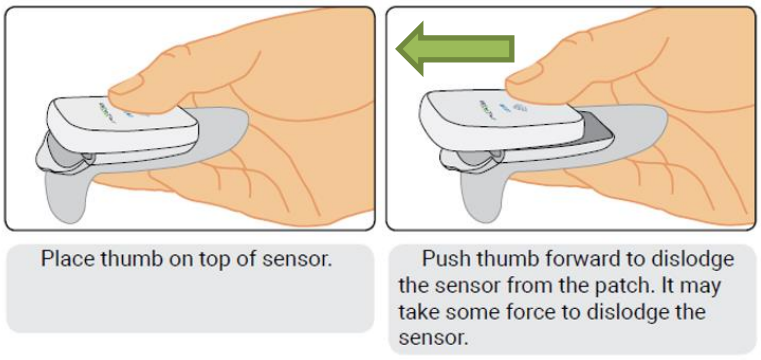
NOTE: If you are the healthcare professional, guide the patient accordingly. If you are the patient, follow the instructions.

Before removing the Patch, power off the monitor (by pressing the on/off button for 3 seconds) to avoid any disconnection alerts.

Removing the Sensor and Patch assembly requires several steps. Please read through all the steps first before attempting to perform these activities. Do not continue to use Patch beyond the time indicated by your physician, as skin irritation may occur.

If your Patch comes loose, falls off, or becomes damaged prior to the alert provided by the Monitor, contact your prescribing physician.

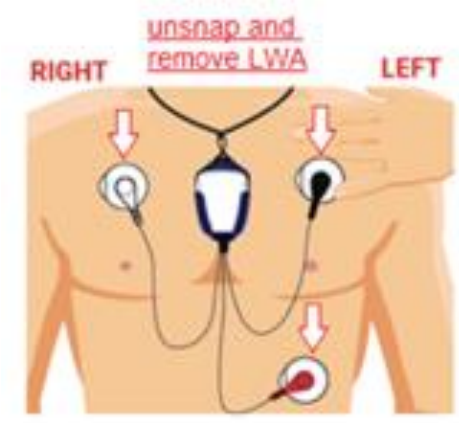
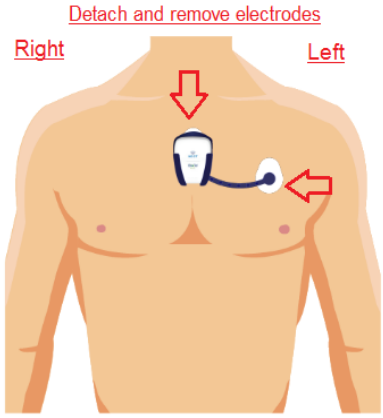
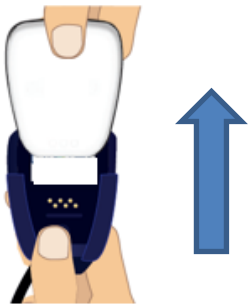
Step	Illustration	Description
1		Firmly press the Sensor with your fingers against your chest as shown with the red arrow. With the other hand pull the Patch clear adhesive material away from the body. Careless removal of the Patch may result in damage to the skin. Once the tail of the Patch is lifted from the skin, continue to pull the Patch off the skin away from the body.
2		During removal, the Patch's film or traces may tear apart. The Patch is designed as a single-use item, therefore this behavior is a mechanism to ensure Patches are not reused.

3	 The first step to remove the Sensor from the Patch is breaking the Patch, by pressing down the Patch Tab. Force needs to be applied in direction of the red arrow. The plastic frame holding the Sensor should break.
4	 Remove the Sensor from the Patch by holding the Sensor and Patch as shown above and sliding your thumb towards you (in the direction of the green arrow) while simultaneously pushing your fingers away from you. The Sensor will slide off. Dispose of the Patch properly in accordance with local ordinances. The Patch may need to be recycled in accordance with local laws.

NOTE:
Do not discard the Sensor. It is to be returned with your device.

19. Removing Lead Wire Adapter or Flex Adapter

NOTE: If you are the healthcare professional, guide the patient accordingly. If you are the patient, follow the instructions.

Step	Illustration	Description
1		**For the Lead Wire Adapter**: Unsnap the leads from the electrodes and gently remove the electrodes from the body.
2		**For the Flex Adapter:** Unsnap both the Flex Adapter device and the lead and gently remove the electrodes from the body.
3		Slide out the Sensor from the Lead Wire Adapter or Flex Adapter.

20. Switching the Patch to a Lead Wire Adapter or Flex Adapter

NOTE: If you are the healthcare professional, guide the patient accordingly. If you are the patient, follow the instructions.

If instructed to switch from the Patch to the Lead Wire Adapter or Flex Adapter, remove the Patch as described in chapter 18.

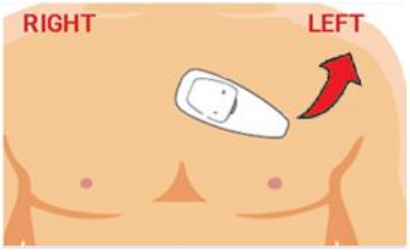


Figure 20-1 Remove Patch

If switching to the Lead Wire Adapter, apply as described in chapter 10.

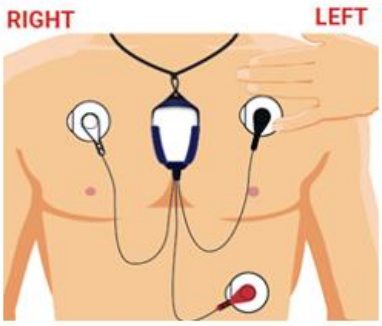


Figure 20-2 Apply Lead Wire Adapter

If switching to the Flex Adapter, apply as described in chapter 11.

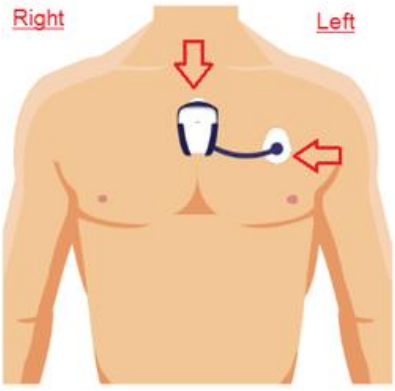
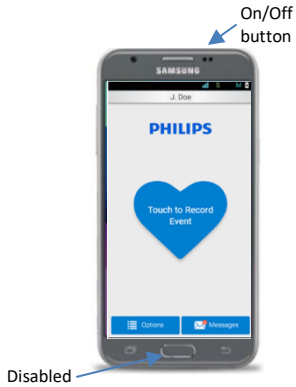


Figure 20-3 Apply Flex Adapter

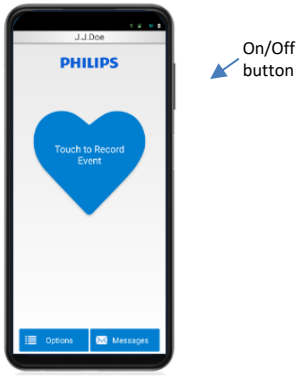
21. Removal and Turning OFF

NOTE: If you are the healthcare professional, guide the patient accordingly. If you are the patient, follow the instructions.

In the event that the Monitor needs to be powered off, press the on/off button for approximately 3 seconds and follow the instructions on the monitor. Please reference the example figures below.



Samsung A13 and A10e



Samsung A13 and A10e

Figure 21-1 Power button locations

This action will power off the Monitor only. To power off the Sensor, detach it from the patch by following instructions from chapters 18 or 19, as applicable. Once the Sensor is completely detached from the Patch, Lead Wire Adapter or Flex Adapter, it enters into deep sleep mode.

NOTE: ECG acquisition will cease recording until the Sensor is re-attached to a patient via a new Patch, Lead Wire Adapter or Flex Adapter.

22. Cleaning, Maintenance and Purging

The Patch and surface electrodes are provided in sealed pouches; no cleaning is required. There is no maintenance required for the Patch and surface electrode as these are single use devices.

Cleaning is the only recommended maintenance of the Lead Wire Adapter, Flex Adapter, Monitor and Sensor. There are no serviceable parts on these items.

Figure 22-1 Cleaning the Sensor

22.1. Cleaning the Sensor

Clean the Monitor, Sensor, Lead Wire Adapter, or Flex Adapter using disinfectant towelette listed below. This must be performed prior to use on a new patient to prevent cross contamination. Do not use other chemical products or detergents for cleaning that are not listed below. Wear proper protective equipment when cleaning.

Compatible cleaning materials (not supplied with the product):

1. Sani Professional Disinfecting (Ammonium Chloride based) disinfectant towelette or equivalent

22.2. Purging

To remove patient data from the device and return the Sensor configuration to default:

1. Plug the Purge Adapter into the included Sensor AC Adapter.
2. Insert the Sensor into the Purge Adapter and wait five minutes for the pulsing pink LED to pulse blue. This marks the end of the purge data phase and the beginning of the charge phase.
3. Wait for the Purge Adapter to display a solid blue light indicating charging is complete.

Figure 22.2-1 Pulsing Pink LED indicates purging device

Figure 22.2-2 Pulsing Blue LED indicates charging. Solid Blue indicates charge complete

⚠ **Caution:** The Purge Adapter (BTP-1000S-PA) will erase data from the sensor.

⚠ **Caution:** Only use the Purge Adapter Fixer with the supplied USB Charger.

23. Showering, Bathing and Swimming

NOTE: If you are the healthcare professional, guide the patient accordingly. If you are the patient, follow the instructions.

Monitor: The Monitor must be set aside, and powered off when showering, bathing, or swimming. The Monitor may be resistant to water, depending on the model provided to you, but as a precautionary measure do not immerse the Monitor in water.

A "Do not wet" symbol on the Monitor means it should not be exposed to any water.

Stand Alone Sensor: The Sensor is not resistant to water when not connected to the Patch. Submersion to any liquid may render the Sensor inoperable. Contact Customer Service if Sensor is not functioning.

Lead Wire Adapter / Flex Adapter**:** The Sensor is NOT water-resistant when worn with the Lead Wire Adapter or Flex Adapter; therefore, showering, swimming, and bathing must be avoided when wearing these devices. Before these activities, power off the monitor. Remove the surface electrodes, all accessories, and the Sensor. Proceed with water activities and replace electrodes after any activities involving water.

Patch: The Patch component is water-resistant, not waterproof. When the Sensor is properly inserted into the Patch, testing has shown that the system can meet the standard test requirements of IP24. This assures that water splashing against the enclosure from any direction shall have no harmful effect. **While showering**, it is recommended to face away from the shower head. It is

recommended to deflect any direct showering water from impinging on the Sensor by shielding the Sensor away from the direct spray of the shower with your hand or cloth. See “Swimming and/or Bathing” section below (23.1).

NOTE: *Meeting IP24 rating means the device is resistant to water splashes from any direction. The Sensor must be fully assembled into the Patch to protect against water splashes.*

23.1. Swimming and/or Bathing

CAUTION: Do not swim while wearing the device and any accessories. Do not submerge Sensor or Monitor in any form of liquid as device functionality may be impacted or this may render the device inoperable.

24. Device Inspection

NOTE: If you are the healthcare professional, guide the patient accordingly. If you are the patient, follow the instructions.

Inspection of both the Sensor and Monitor should be performed if any of the following events occur:

- Devices were dropped
- Exposed to liquids like in the case of showering or dust
- Heavy objects fell on top of the devices

If damage is detected, please stop use and contact Customer Service or your prescribing physician.

25. Deactivation/Re-Activation

NOTE: If you are the healthcare professional, guide the patient accordingly. If you are the patient, follow the instructions.

25.1. Deactivation

Upon completion of prescription, the remaining data will be sent to the data monitoring center. The Monitor will display a *Monitoring Complete* screen and will notify the User to return the Monitor, Sensor, and Chargers using the return envelope.

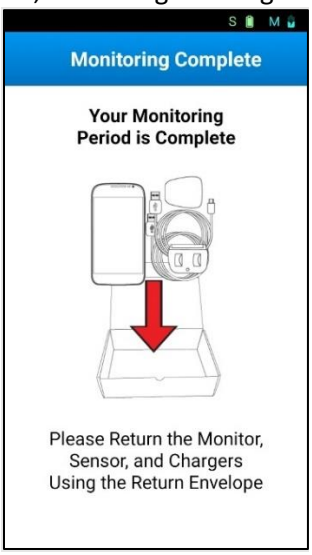


Figure 25.1-1 Deactivation - Monitoring complete

Deactivation: Please follow instructions to return the Monitor, Sensor, and Chargers.

25.2. Reactivation:

If the monitor is deactivated but the patient wants to resume the current prescription, or if the prescription needs to be changed, the monitor can be reactivated. The updating screen service will be displayed.

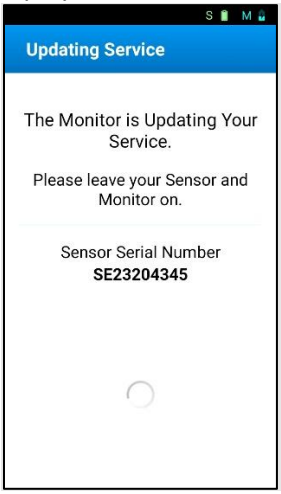


Figure 25.2-1 Updating Service

26. Tutorial for Patients

This chapter is aimed for medical physicians who provide a tutorial to patients on the use of this system, in the case that a medical practitioner installs the device and runs thru the setup procedure with the patient. At a minimum, the following list of instructions should be clearly explained and understood by the patient using the BTPS-1000 system.

- Chapter 1, Warnings
  - Especially instructions for not tampering and the fact that this is not a first responder device
- Chapter 2, Precautions
  - Inform patient of all cautions listed in this manual
  - In the event of changes to performance, advise patient to reference listed precautions in this chapter and chapter0, TROUBLESHOOTING.
- Chapter 14, Recording an Event
- Chapter 15 and 16, Charging the Monitor and Sensor
- Chapter 17, Checking the battery status of Monitor and Sensor
- Chapter 18, Removing Patch
- Chapter 19, Removing Lead Wire Adapter or Flex Adapter
- Chapter 21, Removal and turning devices OFF
- Chapter 22, Cleaning and Maintenance
- Chapter 23, Showering, Bathing and Swimming
- Chapter 24, Device Inspection
- Chapter 25, Deactivation/Re-Activation

BTPS-1000 also provides a Help Video with useful reminders of how to perform basic functions. The menu of this video is available from the status bar, which you access from the *HOME screen* and tap on the top of the screen or from the *Options* screen (see Figure 13.81.

Other icons are also viewable from the status bar (see Figure 26-1), such as battery level for Sensor and Monitor, and Cell signal strength. Information on the device can be viewed from clicking on the 'Info' button from the status bar (Figure 26-2).

Click here for Help Video

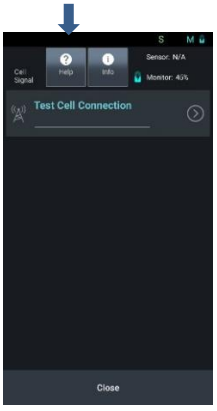


Figure 26-1 Status Bar

Figure 26-2 Device Information

The menu items are the name of the corresponding chapters for the Help video topics (See Figure 26-3). Pressing 'Next' will list the next list of chapters. To view any particular chapter simply click on the name of the chapter.

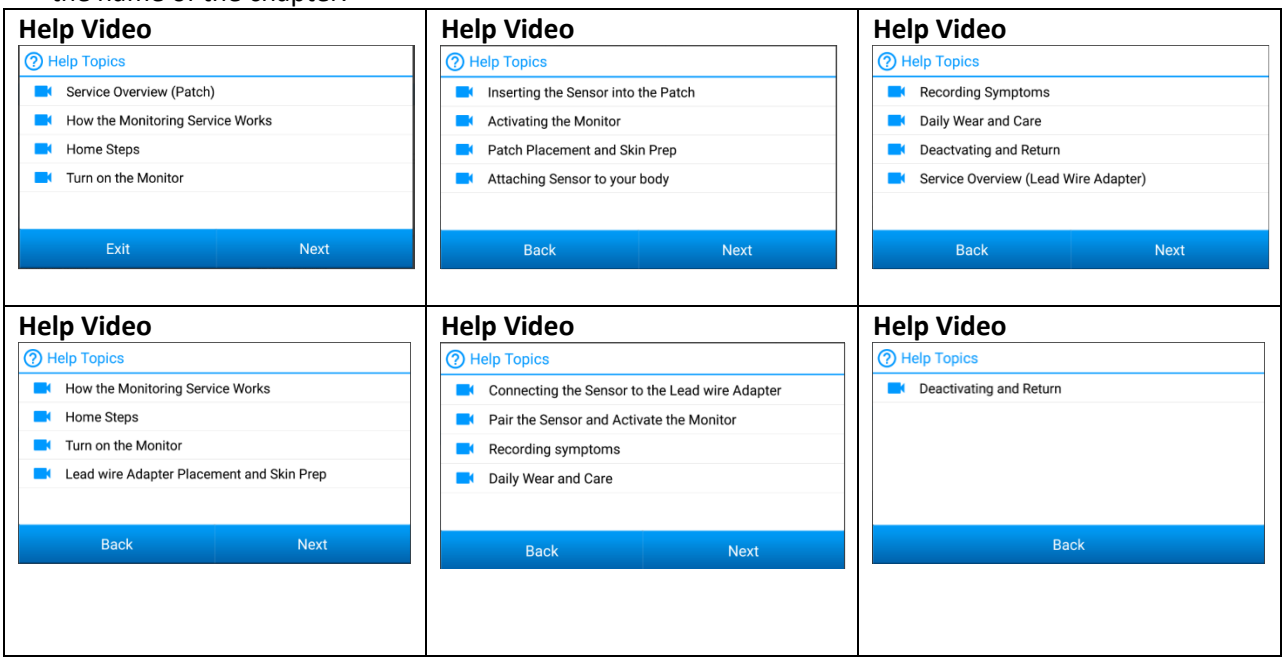


Figure 26-3 Help Video Topics

Pressing 'Exit' will return you to *Home screen*

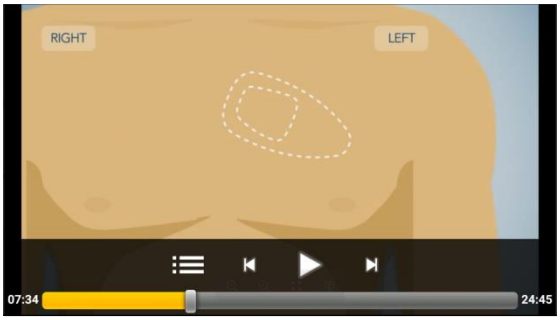


Figure 26-4 Video Controllers

Video controllers are available by tapping the middle of the screen.

NOTE:
If headphones are connected to the Monitor, the audio level defaults to Medium and is not changeable.

NOTE:
For the hearing impaired or with other disabilities preventing them from hearing the explanations from these videos, please consult with your medical practitioner for clarifications.

27. Symbols

27.1. Symbols for Sensor

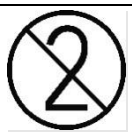
	Manufacturer
	Prescription use
	Non-Ionizing Radiation
	Type BF Applied Part
	Refer to instruction manual
IPX4	Ingress Protection Mark number 4 – Protected against splashing water (when connected to an ECG Electrode Patch)
	Wireless

27.2. Symbols for Monitor

	Type BF Applied Part
	Refer to instruction manual
	Prescription use
	Non-Ionizing Radiation

	Keep dry
	Serial Number
V	Monitor connected to the Verizon cellular carrier
S	Monitor connected to the T-Mobile (Sprint) cellular carrier
T	Monitor connected to the T-Mobile (Sprint) cellular carrier
	Wireless

27.3. Symbols for Patch

	Manufacturer
	Refer to instruction manual
	Do Not Reuse, Single Use Only
	Use By Date
	Batch Code
	Temperature Limitations
	Does Not Contain Natural Rubber Latex

	Does Not Contain PVC
	Prescription use
	Catalogue number
	Complies with the Medical Device Directive of the European Union
	Humidity Limitation

27.4. Symbols for Charge Adapter and Purge Adapter

	Manufacturer
	WEEE (Waste Electrical and Electronic Equipment) Directive (2002/96/EC)
	Refer to instruction manual
	Keep dry
	Catalogue number
	Indication of a chance of slight to moderate harm

28. Troubleshooting

NOTE: If you are the healthcare professional, guide the patient accordingly. If you are the patient, follow the instructions.

Precautions or things to check in the event there is a change in the performance of the BTPS-1000 system.

Problem	Possible Solution
Monitor battery low	Recharge the Monitor for a minimum of 4 hours
Sensor battery low	Recharge the Sensor for a minimum of 90 minutes
Blank Monitor screen	The Monitor may be asleep. Wake up the Monitor by pushing down and quickly releasing the on-off button. The Monitor may be powered off. Turn on the monitor by pressing and holding down the on-off button until the screen illuminates.
Skin Irritation	Ensure that you properly clean and dry skin before applying the Patch or surface electrodes. Do not touch the adhesive backing of the Patch or surface electrodes. If skin is irritated or reddened, you may be experiencing an allergic reaction to the Patch adhesive or surface electrodes used with the Lead Wire Adapter or Flex Adapter. If you experience irritation worse than minor itching, call your prescribing physician or Customer Service.
No communication between the Sensor and Monitor	Your Monitor and Sensor may be too far apart, relocate them within 3 feet of each other. Move any RF devices such as cell phones or Bluetooth headphones away from the Sensor and/or Monitor. Verify that both the Sensor and Monitor have sufficient battery charge.
Patch, Flex Adapter or surface electrodes come loose from skin	Stick the accessory back on by pressing around the edges. If that does not work, contact your prescribing physician or Customer Service, you may need replacement accessories.
Sensor or Monitor are very hot	It is normal for the Sensor and Monitor to occasionally feel warm. If you are concerned about the temperature of the Sensor or Monitor, turn off the Monitor by pressing and holding the on/off button and remove Sensor from accessory by following instructions from chapters 18 or 19. Then contact Customer Service.
Sensor LED is red	This status light indicates an internal error in the Sensor. Please call Customer Service for assistance.

Problem	Possible Solution
Sensor is not Charging	Charging is indicated by a flashing orange colored light in a Charge Adapter and by a pulsing blue light in a Purge Adapter. If you are using the Patch accessory, ensure the Sensor has been removed from the Patch Socket completely (see chapter 18). Ensure contact between the Sensor and charger. If charging is still not occurring, contact Customer Service.
Purge Adapter is flashing light orange colored light	Charging is indicated by a pulsing blue light in a Purge Adapter. If the Purge Adapter is flashing light orange, that indicates that the device is charging and will NOT purge patient data. Contact Customer Service.
Purge Adapter is flashing green light	Check that the Purge Adapter is plugged into a functional power source. If there are problems with the power source to the Purge Adapter, it is possible to see other colors on the Purge Adapter. If the power source is functional and the Purge Adapter still blinks green contact Customer Service.

If you experience any other problems or changes in performance with your BTPS-1000 system, or if you have any questions regarding its operation, please contact Customer Service listed at the end of chapter 6 under “SERVICING AND INQUIRIES”.

28.1. System test

The Monitor is designed to run a sequence of tests during patient setup phase. The tests are meant to verify correct operation of the device and ensure safety. When a test fails it will be evidenced by the Monitor not turning ON or an alert message displayed on the screen.

To run the sequences of tests, turn the Monitor OFF and ON again, as described in chapter 21. If an alert message is displayed on-screen follow the instructions provided.

29. Monitor Screen Alerts and Warning Screens

NOTE: If you are the healthcare professional, guide the patient accordingly. If you are the patient, follow the instructions.

29.1. Alerts

Alerts appear as a new window and cannot be dismissed without addressing the issue that caused the alert. Pressing 'Silence' would temporarily silence alerts. These require immediate action to continue ECG monitoring service. The following alerts can be displayed on the Monitor. Please follow the instructions described in the message window.

Alert - Monitor Error

This error cannot be fixed by patient. Please contact Customer Service department.

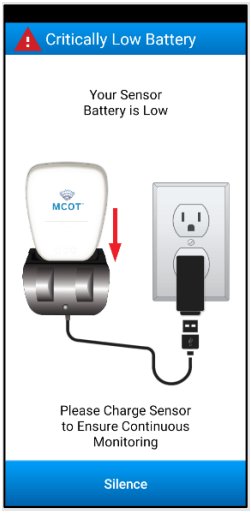
Alert – Sensor Error

This error cannot be fixed by patient. Please contact Customer Service department.

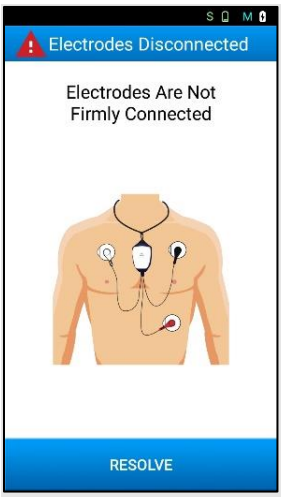
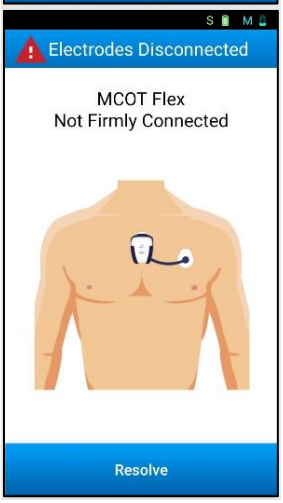
Alert – Imminent Monitor shutdown

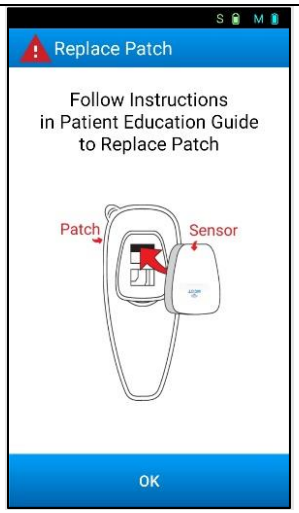
Follow instructions from Chapter 15.

Alert – Imminent Sensor shutdown



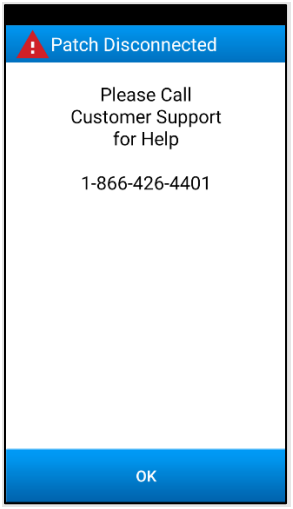
Follow instructions from Chapter 16.

Alert – Sensor/Patch Not Firmly Connected	Alert – Electrodes Are Not Firmly Connected
  Step 1 Wait 20 minutes to ensure proper connection. If not connected after guidance refer to next step.	 

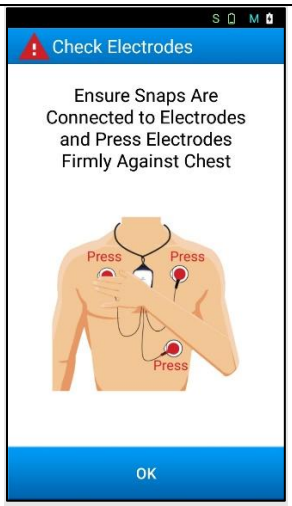


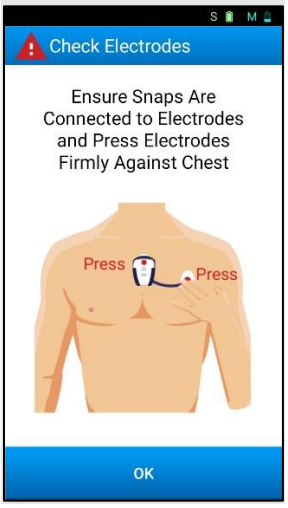
Step 2

Refer to instructions from chapter 9. After replacing the Patch, wait 20 minutes to ensure proper connection. If issue is not resolved after 20 minutes, the Monitor will display the following screen:



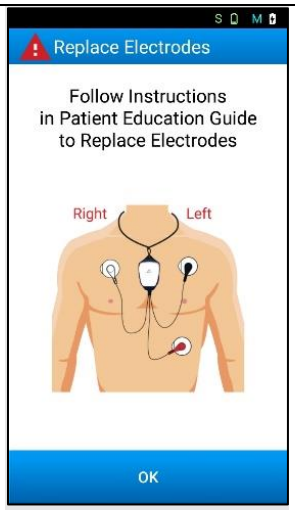
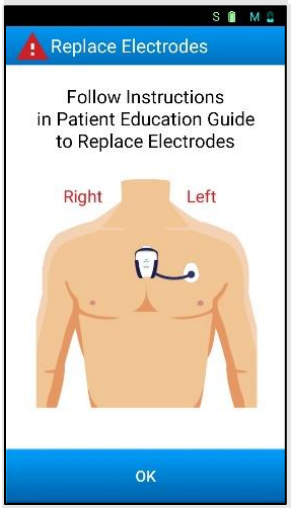
Contact Customer Support 866-426-4401.

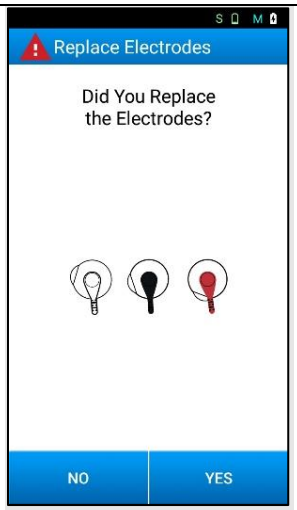
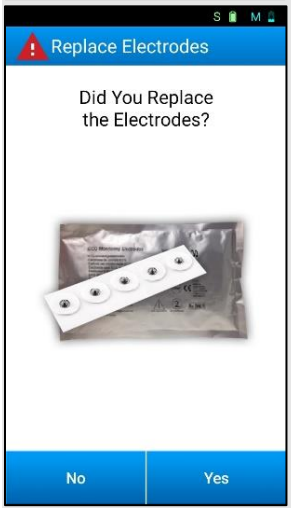


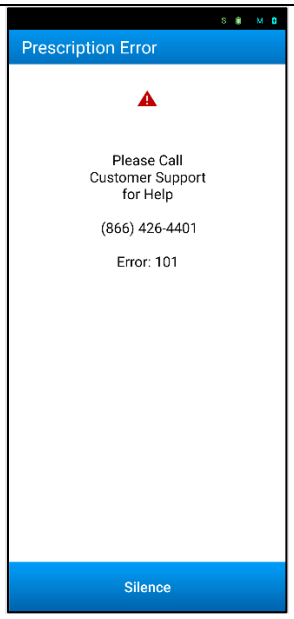
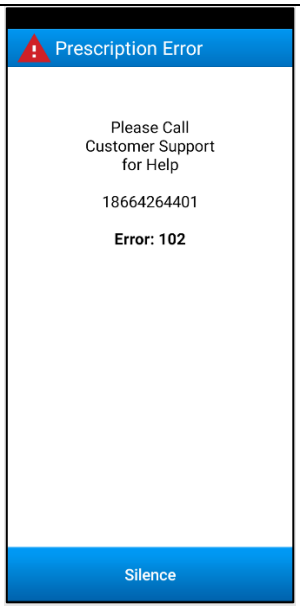


Step 1

Wait 20 minutes to ensure proper connection. If not connected after guidance refer to next step.

	  Step 2 Refer to instructions from chapter 10 or 11 to replace electrodes.

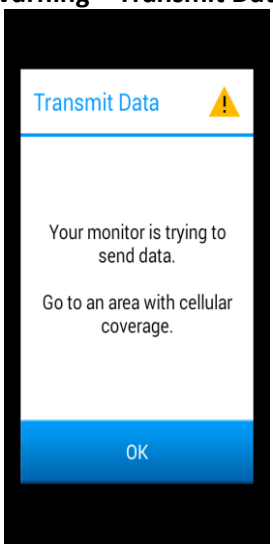
	  After replacing the electrodes, wait 20 minutes to ensure proper connection. If issue is not resolved after 20 minutes, the Monitor will display the “Please contact Customer Support 866-426-4401”.

 If the wrong Monitor has paired with the Wrong sensor, Error 101 will display. The error cannot be dismissed. Contact Customer Support 866-426-4401.	 If the Monitor does not receive an enrollment after a configured amount of time, and *Warning 102* has already displayed, then *Error 102* will display. The error cannot be dismissed. Contact Customer Support 866-426-4401.

29.2. Warning Screens

Warnings are messages that appear as a pop-up dialog window, require action, and can be dismissed by pressing 'OK'. If the situation is not remedied, the warning screen will appear again after a short period of time. The following warning screens can be displayed on the Monitor. Please follow the instructions described in the message window.

Warning – Transmit Data



Cannot find a cellular tower. Triggered when an event is pending for longer than 30 minutes. Move to an area with cellular service.

Warning – No Communication

No communication between Sensor and Monitor triggered when Monitor can no longer detect Sensor. Keep the Monitor and Sensor close together.

Warning – Monitor Low Battery

Monitor needs to be recharged. Follow instructions from chapter 15.

Warning – Sensor Low Battery

Sensor needs to be recharged. Follow instructions from chapter 16.

After a configured amount of time, if the Monitor does not receive an enrollment, Warning Error 102 will display. You can dismiss this warning.

30. Specifications

30.1. Sensor

General Functional

Channels	2 channels
Resolution	12 bits
Sample Rate	250, 500 or 1000 sps
Frequency Response	0.05 – 55 Hz
CMMR	71 dB
Input Range	+/- 7.5 mV @ Gain 70 +/- 3.75 mV @ Gain 140 +/- 3.0 mV @ Gain 175
Recording time	30 days at 250Hz, 2 Channels
Service Life	3 years
Sensitivity	The device does not have a set minimum amplitude or value for ECG measurement. Minimum requirements are to maintain leads attached to the skin. When this condition is not met, a 'Leads-OFF' alert is triggered and resulting ECG data is flagged as 'leads-off' and not used for ECG analysis.

Environmental

IPX Rating When Inserted into Patch	IP24 Resistant to water splashes from any direction
Operating Temperature *	10°C to +45°C
Non-Operating Temperature	-20°C to +70°C
Atmospheric Pressure	700 hPa to 1060 hPa
Operating Humidity	10% to 95% (non-condensing)
Non-Operating Humidity	5% to 95% (non-condensing)

Physical

Size	2" x 1.6" x 0.36"
Weight	0.69 oz
Weight (Sensor + Patch)	0.78 oz
Connection to Patch	Custom 8 terminal connector
Battery Type	Internal Rechargeable Lithium Ion 3.7 V 500 mAh with LiNiMnCoO2 (NMC) as cathode and graphite as anode.

Data Transmission

Bluetooth Radio	BT 2.0 or 2.1
USB	USB 2.0

30.2. Samsung J3 2017 and J3 2018 Monitor Specifications

General Functional

	Samsung J3 2017	**Samsung J3 2018**
Display	Super AMOLED Touchscreen	IPS LCD capacitive touchscreen
Operating System	Android	Android
Battery Type	2600 mAh Lithium Ion with $LiCoO_2$ (LCO) as cathode and graphite as anode	2600 mAh Lithium Ion with $LiCoO_2$ (LCO) as cathode and graphite as anode
Service Life	3 years	3 years
Hearing Aid Compatibility (HAC)	Samsung J3 M3 (RF Emissions Category) T3 (Signal to Noise Category)	Samsung J3 M3 (RF Emissions Category) T3 (Signal to Noise Category)

Environmental

IPX Rating	IP22 Protected from particles >12.5mm and dripping water when tilted up to 15°	IP22 Protected from particles >12.5mm and dripping water when tilted up to 15°
Operating Temperature	10°C to +45°C	10°C to +45°C
Non-Operating Temperature	-20°C to +70°C	-20°C to +70°C
Atmospheric Pressure	700 hPa to 1060 hPa	700 hPa to 1060 hPa
Operating Humidity	10% to 95% (non-condensing)	10% to 95% (non-condensing)
Non-Operating Humidity	5% to 95% (non-condensing)	5% to 95% (non-condensing)

Physical

Size	142.3 x 71.0 x 7.9mm	142.3 x 71.0 x 7.9mm
Weight	138g	152g
Battery Type	2600mA-Hr Lithium Ion	2600mA-Hr Lithium Ion

Data Transmission

Cellular Radios	LTE Cat 3, CDMA 1x EVDO, 1x Advanced	LTE Cat 3, CDMA 1x EVDO, 1x Advanced
Bluetooth	4.2, A3DP, LE	4.2, A3DP, LE

30.3. Samsung A10e specifications

General Functional

	Samsung A10e
Display	PLS TFT capacitive touchscreen
Operating System	Android
Battery Type	3000 mAh battery
Service Life	3 years
Hearing Aid Compatibility (HAC)	M3 (RF Emissions Category) T3 (Signal to Noise Category)

Environmental

	Samsung A10e
IPX Rating	IP68 dust resistant and can be immersed in 1.5 meters of freshwater for up to 30 minutes
Operating Temperature	10°C to +45°C
Non-Operating Temperature	-20°C to +70°C
Atmospheric Pressure	700 hPa to 1060 hPa
Operating Humidity	10% to 95% (non-condensing)
Non-Operating Humidity	5% to 95% (non-condensing)

Physical

	Samsung A10e
Size	147.3 x 69.6 x 8.4 mm
Weight	141g

Data Transmission

	Samsung A10e
Cellular Radios	LTE Band 13(700), 25(1900), 26(850), 41(2500) CDMA- Band 27(800)
Bluetooth	5.0, A2DP, LE

30.4. Samsung A13 specifications

General Functional

	Samsung A13
Display	6.6” FHD + LCD, 1080x2408
Operating System	Android
Battery Type	5000 mAh
Service Life	3 years
Hearing Aid Compatibility (HAC)	M3 (RF Emissions Category) T3 (Signal to Noise Category)

Environmental

	Samsung A13
IPX Rating	No IPX Rate
Operating Temperature	0°C to +35°C
Non-Operating Temperature	-20°C to +50°C
Atmospheric Pressure	4,572m, Equivalent air pressure above 57.3 kPa
Operating Humidity	00% to 95% (non-condensing)
Non-Operating Humidity	5% to 95% (non-condensing)

Physical

	Samsung A13
Size	165.1 x 76.2 x 8.8 mm
Weight	195.6g

Data Transmission

	Samsung A13
Cellular Radios	LTE Band B1(2100),B2(1900),B3(1800),B4(AWS),B5(850),B7(2600),B12(700),B13(700),B14(700),B20(800),B25(1900),B26(850),B29(700),B30(2300),B66(AWS-3),B71(600), B38(2600),B41(2500) CDMA-B1(2100),B2(1900),B4(AWS),B5(850),B8(900)
Bluetooth	5.0, A2DP, AVRCP, DI, HFP, HID, HOGP, HSP, MAP, OPP, PAN, PBAP, SAP

30.5. Patch

General Functional

Number of Electrodes	4
AC Impedance	500 ohm typical
DC Offset Voltage	2 mV
Combined Offset Instability and Internal Noise	<40 µV
Defibrillation Overload Recovery	15 mV
Bias Current Tolerance	6 mV (8 h)
Service Life	Single-use only

Environmental

IPX When Sensor is Connected to Patch	IP24 Resistant to water splashes from any direction
Storage Temperature	+5°C to +27°C
Storage Humidity	Up to 93% non-condensing
Operating Temperature	+5°C to +40ºC
Operating Humidity	15% to 93% non-condensing
Atmospheric Pressure	700 hPa to 1060 hPa
Transportation Temperature	0°C to 40°C
Transportation Humidity	Up to 93% non-condensing
Shelf Life	18 Months from Date of Manufacturer

Patch Storage temperature and shelf life

CAUTION: The Patch's storage temperature requirement is narrower than the rest of the components and temperature limits should be taken into account for storage. Shelf life of 18 months from Date of Manufacture has been tested and is within the range of +5°C to +27°C. Storage of Patch outside these limits may affect longevity of shelf life.

Physical

Size (W x H x D)	61 mm x 7 mm x 132 mm 55* mm x 6* mm x 126* mm *Without release liner
Weight (after removal from pouch)	5 g

*** Practical operating temperature range for using the system is limited by the Patch's temperature limitations. Together, operating temperature range is +10°C to 40°C.**

30.6. Lead Wire Adapter and Flex Adapter

Environmental

IPX When Sensor is Connected to Lead Wire Adapter and Flex Adapter	Tested to IP21 to ensure basic safety; devices are not water resistant
Storage Temperature	-25°C to +70°C
Storage Humidity	Up to 93% non-condensing
Operating Temperature	+5°C to +45°C
Operating Humidity	15% to 93% non-condensing
Atmospheric Pressure	700 hPa to 1060 hPa
Transportation Temperature	0°C to 40°C
Transportation Humidity	Up to 93% non-condensing

30.7. Monitor Charging Cable and AC Adapter

General Functional

Input Voltage	100-240 VAC, 50/60 Hz
Output Rating	5.0 VDC, 2.1 A (Minimum)
Plug Type Input	Standard USA 2 prong plug (Type A)
Plug Type Output	USB-A
Cable Connections	USB-A to USB-C (Samsung A10e/A13) USB-A to USB Micro-B (Samsung J3)
Service Life	3 years

30.8. Sensor Charge Adapter

General Functional

Output Rating	5.0 VDC, 0.55 A (Minimum)
Plug Output at Sensor AC Adapter	USB-A
Sensor Connection	Docking station
Service Life	3 years

30.9. Sensor Purge Adapter

General Functional

Output Rating	5.0 VDC, 0.55 A (Minimum)
Plug Output at Sensor AC Adapter	USB-A
Sensor Connection	Docking station
Service Life	3 years

31. ARRHYTHIMIA DETECTION ALGORITHM PERFORMANCE ANALYSIS

The BTPS-1000 System incorporates an arrhythmia analysis algorithm whose performance was successfully tested against AHA, MIT-arrhythmia, and NST databases, in strict accordance to ANSI/AAMI

EC57:2012. Performance results are available upon request by the manufacturer (see chapter 6 for contact information).

32. HEART RATE, PAUSE, ST ANALYSIS CALCULATIONS and CLINICAL REPORT

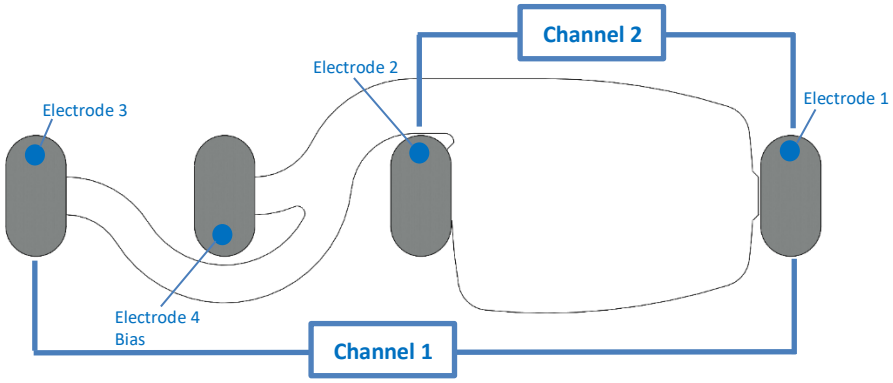
Sustained heart rate (SHR) is inversely proportional to the RR interval averaged over 10 seconds or 12 consecutive beats, whichever is shorter.

The Pause is detected if the distance between two consecutive locations is ≥ than 2 sec for moderate pause or ≥ 4 Sec for severe Pause.

The BTPS-1000 system uses data collected from 2-channel ECG electrodes for ST analysis. When used with the Flex Adapter accessory, both channels are taken from one lead configuration and therefore are identical.

Clinical report and information presented in the report do not form part of this system. This is handled by an external process identified in this manual as “remote site” (see illustration on chapter 5).

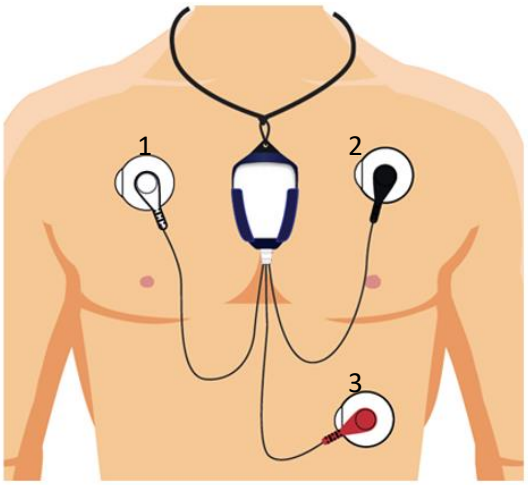
33. PATCH ELECTRODE CONFIGURATION



The Patch has four electrodes. Channel 1 is formed by Electrode 1 and 3. Channel 2 is formed by Electrode 1 and 2. Electrode 4 corresponds to the bias electrode.

Electrode 1 is the common electrode to channel 1 and channel 2.

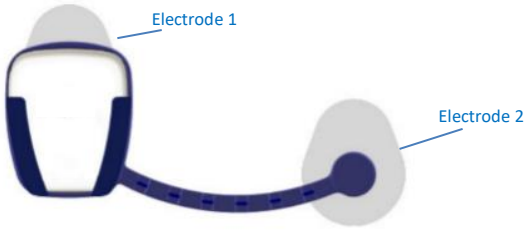
34. LEAD WIRE ADAPTER CONFIGURATION



The Lead Wire Adapter utilizes three electrodes. Channel 1 is formed by Electrode 1 and 3. Channel 2 is formed by Electrode 1 and 2.

Electrode 1 is the common electrode to channel 1 and channel 2

35. FLEX ADAPTER CONFIGURATION



The Flex Adapter utilizes two electrodes. Channels 1 and 2 are formed by Electrodes 1 and 2. Channel 1 and Channel 2 are connected in parallel.

Electrode 1 is the common electrode to channel 1 and channel 2.

Annex 1: Electromagnetic Compatibility

System Summary

The BTPS-1000 Sensor functions as the data acquisition element for the system. It collects ECG data and transmits it wirelessly via Bluetooth to the Monitor. The Monitor will perform data/arrhythmia detection analysis and transmit the data to the customer remote site via cell modem for further post-processing and reporting.

The Bluetooth network sensor-monitor does not allow for any other medical or non-medical devices to be operational in the same network. This setting is enforced by the Monitor. Rejection of other devices (in the Sensor) is guaranteed by the pairing process.

In the pairing process the Sensor and Monitor use a unique link key for communication and they can both check the MAC-address of the other device. This ensures that both devices are connected to the correct device. During the pairing process, the Bluetooth devices share a link-key. This key is used to encrypt/decrypt the messages, which allows safe data transfer.

The BTPS-1000 is neither a critical care device nor a first response emergency medical device. The device does not incorporate high-priority medical device alerts, time-sensitive continuous physiological waveform data, or provide real-time therapeutic benefit.

The BTPS-1000 system will always retry a connection loss indefinitely, so any interference will not result in lost or corrupted data, but rather potential delayed delivery of information. The BTPS-1000 relies on the underlying checksum schemes of the Bluetooth protocol for corruption detection. Any lost connection or corrupt data will be retried indefinitely.

The BTPS-1000 Sensor can buffer multiple days' worth of data if the Bluetooth connection between the Sensor and the Monitor does not allow for the transmission of data and the BTPS-1000 Monitor can also store multiple days' worth of data if the cellular connection does not allow successful transmission. The "retry design" philosophy and the extended storage capabilities of all BTPS-1000 components guarantees that all of the captured heart monitoring data is not lost so that the intended diagnostic capabilities of the device can be achieved.

The Braemar BTPS-1000 is indicated for use by patients who experience transient events that may suggest cardiac arrhythmia. It is specifically contraindicated for patients with potentially life-threatening arrhythmias who require inpatient monitoring. It is also contraindicated for patients who the attending physician recommends should be hospitalized for ECG monitoring. These aspects are an important consideration for determining possible risks associated with delayed or failed communications, because the device is not providing time-sensitive continuous physiological data intended to support real-time response. Braemar is aware of the latencies present in the wireless communications that we use, which is a reason why we advise against use for the situations described above.

Quality of Service

Quality of Service (QoS) is the idea that transmission rates, error rates, and other characteristics can be measured, improved, and to some extent, guaranteed in advance. Achieving the required QoS by managing the delay, delay variation (jitter), bandwidth, and packet loss parameters on a network becomes the secret to successful end-to-end transmission quality. Thus, QoS is the set of techniques to manage real time network resources. The BTPS-1000 does not have any real time network transmission requirements.

The standard QoS determination is not relevant for any of the radio connections in the BTPS-1000 device. The BTPS-1000 device handles most of the QoS concerns by increasing latency. As mentioned above, the BTPS-1000 product will always retry a connection loss indefinitely, so any interference will not result in lost or corrupted data, but rather a potential delayed delivery of information. The BTPS-1000 relies on the underlying checksum schemes of the protocol for corruption detection. Any lost connection or corrupt data will be retried indefinitely.

As mentioned above, the Braemar BTPS-1000 is indicated for use by patients who experience transient events that may suggest cardiac arrhythmia. It is specifically contraindicated for patients with potentially life-threatening arrhythmias who require inpatient monitoring. It is also contraindicated for patients who the attending physician recommends should be hospitalized for ECG monitoring. These aspects are an important consideration for determining QoS as appropriate to the device, because the device is not providing time-sensitive continuous physiological data intended to support real-time response. Braemar is aware that there are latencies present in the wireless communications that we use, which is a reason why we contraindicate for the situations described above. Our labeling also states that we are not an emergency response service.

The cell tower quality can be checked by looking at the signal quality bars on the Monitor.

The Sensor with its accessory should continue to be worn unless told to stop by patient's physician. The Sensor will keep storing heart signal data even if the Monitor has temporarily moved out of the range of a cell tower.

Data Rate

Bluetooth transmission rates have been measured to be an average of 55 kBps on the Sensor side. The Sensor can achieve a theoretical maximum net transfer rate close to 80 kBps according to the manufacturer and using the clock settings, UART settings and headers in the specifics of the BTPS-1000 Sensor node.

Data Flow

The Bluetooth protocol stack, RFCOMM and the SPP run on the radio module. The microcontroller in the sensor node runs a proprietary Extensible Messaging Protocol (XMP).

The extensible Messaging Protocol (XMP) is designed as a flexible and reliable message transfer protocol for embedded devices. This protocol is loosely based on the HTTP web protocol, and provides much of the flexibility provided by that protocol, but with the compactness of a binary protocol. A simple command message with no additional data can be transferred to a remote endpoint in as few as 5 bytes.

The primary features defined by XMP are the ability for messages to define custom header fields, as well as binary data payloads. The protocol design allows for a message to describe a binary

payload by defining metadata directly in custom header fields. Header fields are also allowed to specify a default value, allowing a receiver to apply a default value to any headers that are not present in the transmission.

Finally, the XMP protocol is designed to work over any stream based connection-oriented network protocol, such as TCP/IP, Bluetooth, RS232 serial, and any other protocol that guarantees order of delivery. The protocol can be extended to non-connection oriented protocols by defining custom message envelopes that facilitate message framing. These protocols may place additional restrictions on message size.

Device messaging supports session management where necessary to minimize retransmission on connection loss. Protocols such as TCP/IP and Bluetooth RFCOMM are reliable, stream-based protocols that have built-in protections against cross-transmitted data.

Protocol/Security

In the pairing process the sensor and monitor create a link-key and they can both check the MAC-address of the other device. This, as well as checking for devices serial number and correct communication protocol, ensures that both devices are connected to the correct device.

During the pairing process, the Bluetooth devices share a link-key. This key is used to encrypt/decrypt the messages, which guarantees safe data transfer.

The Bluetooth network sensor-monitor does not allow for any other medical or non-medical devices to be operational in the same network. This setting is enforced by the Monitor. Rejection to other devices (in the sensor) is guaranteed by the pairing process.

The Sensor-Monitor network is designed to be operational in a home environment, able to co-exist with other Bluetooth devices and other protocols operating in the 2.4GHz ISM band. Bluetooth technology's adaptive frequency hopping (AFH) capability was designed to reduce interference between wireless technologies sharing the 2.4 GHz spectrum. AFH works within the spectrum to take advantage of the available frequency. This is done by the technology detecting other devices in the spectrum and avoiding the frequencies they are using. This adaptive hopping among 79 frequencies at 1 MHz intervals gives a high degree of interference immunity and also allows for more efficient transmission within the spectrum. For users of Bluetooth technology this hopping provides greater performance even when other technologies are being used along with Bluetooth technology.

This product emits radio frequency energy, but the radiated output power of this device is far below the FCC radio frequency exposure limits. The level of energy emitted is far less than the electromagnetic energy emitted by wireless devices such as mobile phones SAR value of 0.541W/kg max.

Device	Type of RF	Frequency
Communication with Remote Site via cellular network **BTP-1000M (Monitor)**		
Applies to Samsung J3 2017 and 2018 part numbers	CDMA Band Class 10, 1X Advanced	800MHz
Applies to Samsung J3 2017 and 2018 part numbers	LTE Band 25 – CDMA/LTE	1.9GHz
Applies to Samsung A10e	LTE Band 13(700), 25(1900), 26(850), 41(2500) CDMA- Band 27(800)	700, 800, 850, 1900, 2500 MHz
Applies to Samsung A13	LTE Band B1(2100),B2(1900),B3(1800),B4(AWS),B5(850),B7(2600),B12(700),B13(700),B14(700),B20(800),B25(1900),B26(850),B29(700),B30(2300),B66(AWS-3),B71(600), B38(2600),B41(2500) CDMA-B1(2100),B2(1900),B4(AWS),B5(850), B8(900)	600, 700, 800, 850, 900, 1800, 1900, 2100, 2300, 2500, 2600 MHz
Communication with Sensor **BTP-1000M (Monitor)**		
Samsung J3 2017	Bluetooth 4.2 A2SP, LE	2.4GHz
Samsung J3 2018	Bluetooth 4.2 A2SP, LE 2.4GHz	2.4GHz
Samsung A10e	Bluetooth 5.0, A2DP, LE	2.4GHz
Samsung A13	Bluetooth 5.0, A2DP, AVRCP, DI, HFP, HID, HOGP, HSP, MAP, OPP, PAN, PBAP, SAP	2.4GHz
Used only by servicing personnel **BTP-1000M (Monitor)**		
Samsung J3	Wi-Fi 802.11 a/b/g/n	2.4GHz
Samsung A10e	Wi-Fi 802.11 a/b/g/n/ac	2.4GHz
Samsung A13	Wi-Fi 802.11 a/b/g/n/ac, Dual Bands	2.4GHz
Communicate to Monitor		
BTP-1000S (Sensor)	Bluetooth 2.1 + EDR	2.4GHz

Electromagnetic Emissions and Immunity Information for the BTP-1000M (Monitor)

Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The BTP-1000M 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. For intended RF emissions, such as required to communicate to cellular towers, the BTP-1000M is compliant to FCC regulations Part 15 for mobile cellular devices.
RF emissions CISPR 11	Class B	The BTP-1000M is 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.

Immunity test	**IEC 60601-1-2 4th (Professional Healthcare & Home Healthcare)** **Test level**	**BTP-1000M Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 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%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50/60 Hz	30 A/m 50/60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial, hospital, or residential environment.
Conducted RF Immunity IEC 61000-4-6	3 V (0.15 – 80 MHz) 6 V (ISM & Amateur)	Test not applicable to Monitor. Device is battery operated during normal use.	Portable and mobile RF communications equipment should be used no closer to any part of the unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance: $d = 1.2\sqrt{P}$ 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).
Radiated RF Immunity IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80% @ 1kHz	10 V/m 80 MHz – 2.7 GHz 80% @ 1kHz	

	AM Modulation Home Healthcare environment considered worse-case.	AM Modulation	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 unit is used exceeds the applicable RF compliance level above, then the unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the unit. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

The internal wireless radio operates within guidelines found in radio frequency safety standards and recommendations, which reflect the consensus of the scientific community. Braemar Inc. therefore believes the internal wireless radio is safe for use by consumers. The level of energy emitted is far less than the electromagnetic energy emitted by wireless devices such as mobile phones SAR value of 0.541W/kg max. **However, the use of wireless radios may be subject to governmental and business restrictions, including but not limited to air travel and hospital visitations.** If you are unsure of restrictions, you are encouraged to ask for authorization before turning on the wireless radio.

Radio frequency radiation exposure Information

For body worn operation, the phones have been tested and meet the FCC RF exposure guidelines when used with the supplied accessories which are designated for this product. Use of other accessories may not ensure compliance with FCC RF exposure guidelines.

NOTICE: This device complies with part 15 of the FCC rules and with RSS-210 of Industry Canada. Operation of this device is subject to the following two conditions: (1) This device may not cause harmful interference; (2) This device must accept interference received including interference that may cause undesired operation.

Changes or modifications made to this equipment not expressly approved by Braemar may void the FCC authorization to operate this equipment.

NOTE: 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 equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

Reorient or relocate the receiving antenna.

Increase the separation between the equipment and receiver.

Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

Consult the dealer or an experienced radio/TV technician for help.

Electromagnetic Emissions and Immunity Information for the BTP-1000S (Sensor)

Electromagnetic Emissions

The sensor is intended for use in the electromagnetic environment specified below. The customer or user of the sensor should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The sensor limits unintentional emitted RF energy to 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 sensor is 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.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Electromagnetic Immunity

The sensor is intended for use in the electromagnetic environment specified below. The customer or the user of the sensor should assure that it is used in such an environment.

Immunity Test	IEC60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 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	Not applicable to Sensor	Battery-powered device
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not applicable to Sensor	Battery-powered device
Voltage dips, short interruptions, and voltage variations on power supply input lines. IEC 61000-4-11	<5% UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT)	Not applicable to Sensor	Battery-powered device

Immunity Test	IEC60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Tested to recommended test levels for hospitals, office, and residential use.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	6 Vrms (in ISM bands and amateur radio RF bands) Frequency: 0.15 MHz-80 MHz Modulation: AM: 80%, Sinusoidal 2Hz Pass with Lead Wire Adapter accessory.	Portable and mobile RF communications equipment should be used no closer to any part of the sensor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80% @ 1kHz AM Modulation	10V/m 80 MHz to 2.7 GHz 80% @ 2Hz AM Modulation 2 Hz modulation frequency selected as a worse case frequency for a cardiac ambulatory device as required by IEC 60601-2-47.	**Recommended separation distance** d = (1.17)√P 80 MHz to 800 MHz d = (2.33) √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			

Immunity Test	IEC60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
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 sensor is used exceeds the applicable RF compliance level above, the sensor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the sensor. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Sensor

The sensor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Sensor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the sensor as recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to frequency of transmitter (m)		
Rated maximum output power of transmitter (W)	**150 kHz to 80 MHz** $d = (1.17)\sqrt{P}$	**80 MHz to 800 MHz** $d = (1.17)\sqrt{P}$	**800 MHz to 2.5 GHz** $d = (2.33)\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30