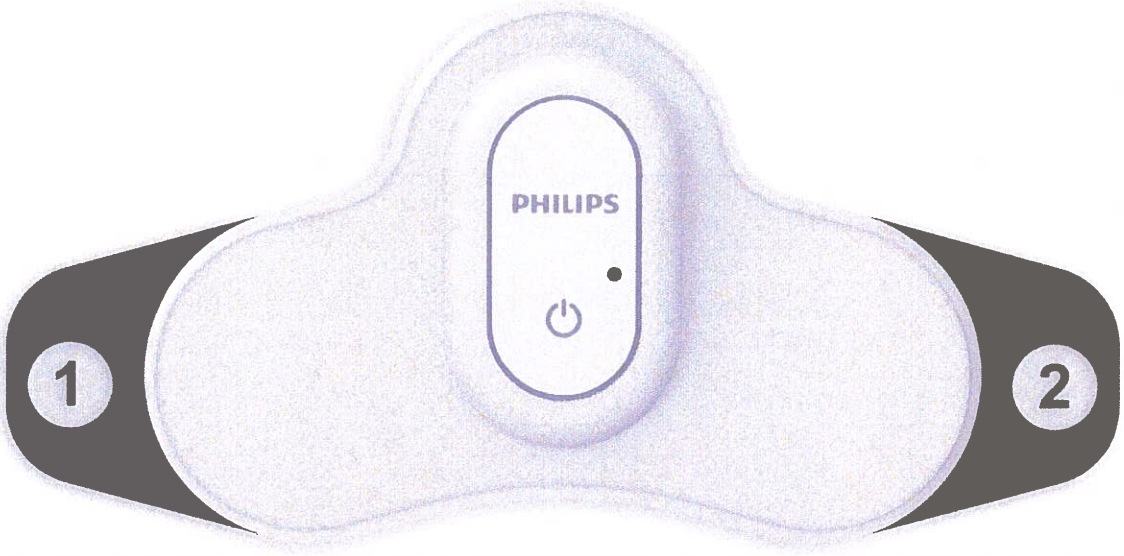
PHILIPS

Biosensor BX100

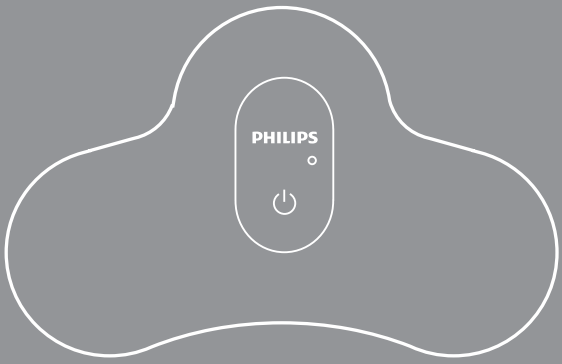
Wearable biosensor



Instructions for use

Release B

14 MAR 2019



Instructions for use

English

Contents

Conventions

Text Formatting

The following typographical conventions are used in this guide.

Typeface	Usage	Example
Bold	System keys, user interface text	Press the **Main Screen** key
Italic	Section titles, document titles	*Assigning and Applying the Biosensor*

Notes, Cautions, and Warnings

Note—A Note **calls attention to an important point in the text.**

Caution—A Caution **calls attention to a condition or possible situation that could damage or destroy the product or the user's work.**

Warning—A Warning **calls attention to a condition or possible situation that could cause injury to the user and/or patient.**

Rx Only

Caution—Investigational Device: limited by Federal Law to Clinical Investigations and investigational use (USA).

Intended Use

Philips Biosensor BX100 is a chest-worn sensor that is intended to periodically collect, store, and transmit physiological data to a qualified system for use by healthcare professionals. The physiological data measured by the biosensor includes respiration rate and heart rate. In addition, the biosensor is intended to measure and wirelessly transmit contextual parameters: activity level, activity type, and posture.

Indications for Use

The biosensor is indicated for single use in the general care areas in the hospital. The biosensor is intended for patients who are 18 years of age or older. Philips Biosensor BX100 is indicated for use as a physiological measurement device to aid in the treatment and management of patient conditions by a healthcare professional.

Warnings—

- PACEMAKER PATIENTS: The biosensor may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon biosensor. Keep pacemaker PATIENTS under close surveillance. See this manual for disclosure of the pacemaker pulse rejection capability of this instrument.
- Do not use the biosensor on a patient with a known or suspected allergy to adhesives.
- Apply the biosensor to healthy, intact skin only. Do not apply the biosensor to open wounds or to infected, irritated, scarred, or inflamed areas.
- Do not use the biosensor when signs of skin irritation are present.
- Do not use isopropyl alcohol to clean the skin prior to applying the biosensor. Alcohol dries the skin, increases the possibility of skin irritation, and can diminish electrical flow.
- Do not use on patients with suspected or known cardiac arrhythmias because their actual heart rate value may be lower or higher than reported by the biosensor.

Cautions—

- If the Philips Biosensor BX100 and cardiac monitors are used simultaneously, there is potential for interaction that could lead to inaccurate measurements.
- Inaccuracies in the measurement of heart rate and respiration rate may occur during pacing events.
- Do not use the biosensor if the pouch appears to have been opened or shows signs of tampering.
- When patient condition does not match the biosensor's measurements, manually check the patient's vital signs and take a 12-lead ECG.
- Discard the biosensor if the hydrogel on the back of the biosensor is dry.
- Do not open the biosensor pouch until you are ready to use the biosensor.
- The biosensor is for single-use only.
- Dispose of the biosensor immediately after use.

- The biosensor will not operate outside of the following rhythms: normal sinus rhythm, sinus tachycardia, sinus bradycardia, supraventricular tachycardia, and sinus rhythm with premature (<6 per minute) ventricular complexes.
- The biosensor is not intended to discern cardiac arrhythmias or to alarm when arrhythmias are present.
- Heart rate values may be inaccurate when pacemaker pulses are present outside of the disclosed pacemaker range.
- Do not modify the biosensor.
- Do not attempt to reposition the biosensor or secure it with tape or other adhesive.
- Remove the biosensor prior to MRI procedures.
- The biosensor is not intended for use in an operating room environment.
- Do not use the biosensor with high frequency surgical equipment.
- To prevent obstructing an x-ray image of the left chest, remove the biosensor prior to performing x-rays unless otherwise directed by a qualified healthcare provider.
- Activity type, activity level, and posture are not precisely classified when the patient is walking at an extremely slow pace.
- Remove the biosensor if it is located in an area where defibrillation pads will be applied.
- Assess the biosensor's connectivity to the backend system at least every eight hours. If connectivity is lost, the biosensor can store up to four hours of data.
- Do not use scissors or other sharp objects to open the biosensor pouch.
- Do not exceed periods of wear greater than 96 hours.
- Do not turn on the biosensor while it is still enclosed in the packaging.
- Do not submerge the biosensor under water.
- Do not twist, bend, or pull the biosensor.
- When wearing the biosensor, patients should abstain from activities that would cause excessive perspiration.
- Disregarding the information contained therewith is considered Abnormal Use.

Note—Read these Instructions for Use *first*, then follow the Quick Start Guide on the Philips Biosensor BX100 package to apply the biosensor to the patient.

Introduction to the Philips Biosensor BX100

The Philips Biosensor BX100 is a small, lightweight, disposable chest-worn biosensor that collects, stores, and wirelessly transmits physiological data to a qualified backend system.

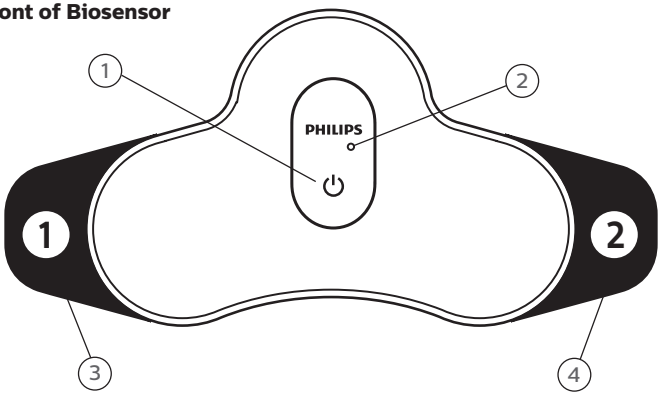
The biosensor measures five parameters:

- Heart rate between 30 and 220 beats per minute
- Respiration rate between 3 and 40 breaths per minute
- Activity level (at rest, moderate activity, high activity)
- Activity type (ambulating/not ambulating)
- Posture (left side lying, right side lying, supine, prone, leaning/reclining, and upright)

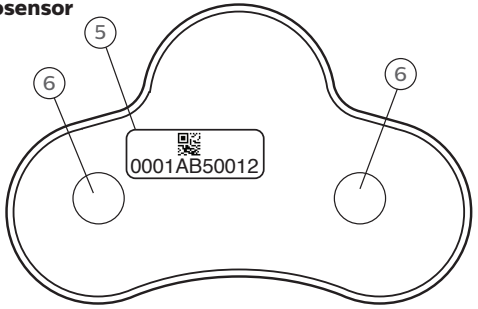
The Philips Biosensor BX100

1. Power Button
2. LED
3. Release Liner 1
4. Release Liner 2
5. Unique Biosensor ID number
6. Electrodes

Front of Biosensor



Back of Biosensor



LED States

The following table describes the states of the Philips Biosensor BX100's LED:

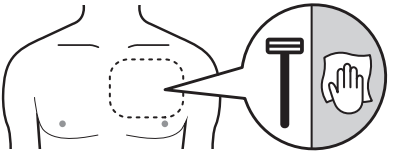
	LED indicator	State	Indication
●	Steady green for one second	Power on	The biosensor was turned on.
☀ green	Flashing green	Setup in process	The biosensor is attempting to connect with the backend system. If the biosensor is not applied to the patient within five minutes, the biosensor automatically turns off.
◉ 20 sec	Steady green for 20 seconds	Ready	A connection with the backend system has been established.
☀ red	Flashing red	Error or Leads off	Either the biosensor has encountered a non-recoverable error or the biosensor's electrodes have detached from the patient's skin.
☀ green for 7 sec	Flashing green for 7 seconds	Working	The biosensor's power button was pressed during a routine check. It is operating and maintains a connection to the backend system.
○	None	On or Off	Either the biosensor is on or off. To determine the current state, press the power button.

Assigning and Applying the Biosensor

Before you can begin collecting measurement data, you must first pair the biosensor with the backend system and apply the biosensor to the patient's skin.

To assign and apply the Philips Biosensor BX100:

1. Scan or input the patient ID and then the biosensor ID on the biosensor pouch to associate the biosensor with the patient on your backend system.

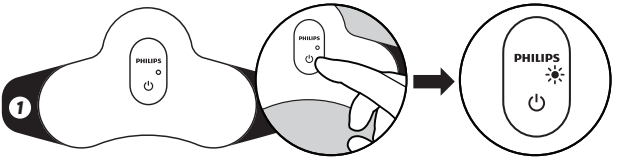


2. Prepare the patient's skin for application. Remove any excess hair on the upper left chest according to your institution's protocol and thoroughly clean the area using soap and water or a non-alcohol based cleanser. When the area is dry, gently abrade the area with ECG skin prep paper or pad.

Note—Do not use isopropyl alcohol to clean the skin. Alcohol dries the skin, increases the likelihood of skin irritation, and can diminish electrical flow.

3. Open the biosensor package and carefully remove the biosensor. Do not use sharp objects to open the package or you risk damaging the biosensor. If the biosensor appears damaged or if the hydrogel on the back of the biosensor is dry, discard the biosensor and open a new package.

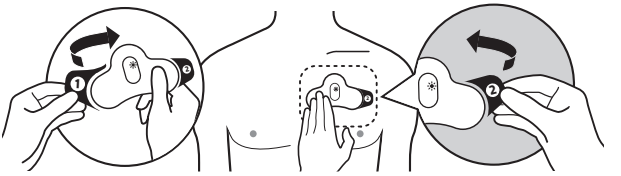
Note—Do not open the biosensor package until you are ready to use it.



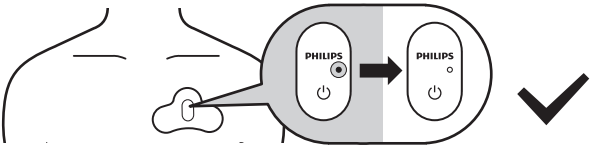
4. Depress the power button for approximately one second to turn on the biosensor. You will feel a "click" when the button is depressed. The LED flashes green, indicating that the biosensor is undergoing the setup process.

Notes—

- If the LED does not flash green after 2-3 tries, discard the biosensor and open a new package.
- If you do not apply the biosensor to the patient within five minutes of pressing the power button, the biosensor automatically turns off. To turn on the biosensor again, depress the power button for approximately one second.



5. Ensure the skin is completely dry. Remove release liner (1) and apply the left side of the biosensor to the patient's upper left chest ***without touching your fingers to the adhesive***. Press lightly on the surface to adhere the biosensor to the skin.
6. Remove release liner (2) and apply the right side of the biosensor to the patient's chest ***without touching your fingers to the adhesive***. Press lightly across the entire surface, avoiding the power button, to adhere the biosensor to the skin. If the biosensor does not adhere to the patient's skin, do not attempt to secure it with tape or other adhesive. Remove the biosensor (see *Removing the Biosensor*) and begin again with a new biosensor.



7. When the biosensor is attached to the patient, the LED displays a steady green light for 20 seconds indicating that the biosensor is communicating with the backend system and is ready for use. If the LED does not display a steady green light, refer to *Troubleshooting*.

Note—If the LED flashes red, the biosensor has experienced a non-recoverable error. Discard the biosensor and open a new package.

Displaying and Storing Biosensor Data

For information on how to display and/or store the data generated by the Philips Biosensor BX100 on backend systems, refer to your backend systems' product documentation.

Performing Biosensor Checks

Perform a check of the Philips Biosensor BX100 at least every eight hours to ensure that it is operational. In addition, periodically check the backend system to verify that connectivity with the biosensor is maintained. The biosensor can store up to four hours of data if it is disconnected from the backend system.

To perform a biosensor check:

Gently depress the power button for approximately one second while the biosensor is adhered to the patient. You will feel a "click" when the button is depressed. The biosensor LED flashes green for seven seconds, indicating the biosensor is operational.

Note—If the biosensor LED does not flash green after 2-3 tries, apply a new biosensor (see *Assigning and Applying the Biosensor)*.

Determining the Biosensor's End of Life

When the biosensor is two hours or less away from its end of life, it sends a notification to the backend system. For more information, refer to your backend systems' product documentation.

Removing the Biosensor

Remove the Philips Biosensor BX100 when:

- The patient has worn the biosensor for 96 hours or more.
- The biosensor indicates to the backend system that it is two hours or less away from its end-of-life shutdown.
- The biosensor's LED is flashing red.
- The biosensor's LED does not flash green after you press the power button.
- The biosensor does not properly adhere to the patient's skin.
- The patient's skin appears irritated.
- The patient will undergo an MRI or x-ray procedure.
- The biosensor is not operational.

To remove the biosensor:

Gently separate the biosensor from the skin as if you were removing an adhesive bandage. Remove any residual adhesive using soap and water or a mild cleanser.

Caution—Use care when removing the biosensor to prevent skin irritation. Do not pull the hair or skin.

Disposing of the Biosensor

The biosensor is considered non-biohazardous waste. Dispose of the biosensor according to your hospital's guidelines and local laws for disposable electronic devices.

Storing the Philips Biosensor BX100

Store biosensors in their sealed pouches until ready for use. Do not open the pouch until you are ready to apply the biosensor. Use immediately after opening to prevent the gel on the back of the biosensor from drying. Do not attempt to reseal the pouch after opening.

Store biosensors at:

- Temperatures between 10-40 °C
- Relative humidity (non-condensing) between 5-95%

Do not store biosensors in direct sunlight.

Troubleshooting the Biosensor

Biosensor LED flashes red

A red flashing LED indicates that the biosensor has experienced a non-recoverable error. Discard the biosensor and open a new package. See *Assigning and Applying the Biosensor* and *Removing the Biosensor.*

Biosensor LED does not flash green when power button is pressed

If the LED does not flash green after 2-3 tries, discard the biosensor and open a new package. See *Assigning and Applying the Biosensor* and *Removing the Biosensor.*

Biosensor data does not display/update data in the backend system

1. Ensure that the biosensor is evenly adhered to the patient's skin. Press lightly across the entire surface area, avoiding the power button, to adhere the biosensor to the skin. If the biosensor is properly adhered, continue with Step 2.

   If the biosensor does not adhere, do not attempt to secure the biosensor with tape or adhesive. Remove the biosensor and apply a new one. See *Assigning and Applying the Biosensor* and *Removing the Biosensor.* Then ensure that the new biosensor's data displays in the backend system.
2. Ensure that the biosensor is functional. Gently press the power button while the biosensor is adhered to the patient. You will feel a "click" when the button is depressed and the LED will flash

green for 7 seconds. If the LED flashes green, continue with Step 3.

If the biosensor LED does not flash green after 2-3 tries, remove the biosensor and apply a new one. See *Assigning and Applying the Biosensor* and *Removing the Biosensor*.

3. Ensure that the patient wearing the biosensor is within 25 feet of a Bluetooth router. The biosensor will automatically reconnect within 60 seconds when it is within range of a router. Ensure the biosensor's data properly displays in the backend system.

   If the patient is within 25 feet of the Bluetooth router but the data still does not display or update in the backend system, contact your system administrator.

Biosensor is partially adhered to the patient's chest

1. Press down gently on both sides of the biosensor to attempt to adhere it to the patient's skin.
2. If the biosensor does not adhere, do not attempt to secure it with tape or other adhesive. Instead, carefully remove the biosensor (see *Removing the Biosensor*), ensure that the patient's skin is free of any oil, lotion, debris, residue or moisture, and apply a new biosensor (see *Assigning and Applying the Biosensor*).

Biosensor appears to cause skin irritation

1. Gently remove the biosensor (see *Removing the Biosensor*) and assess the patient's skin. Treat the skin per your institution's protocol.
2. If indicated, apply a new biosensor (see *Assigning and Applying the Biosensor*) in a different area of the upper left chest.
3. If skin irritation persists, discontinue using the biosensor.

Specifications

Notice

Trademark Acknowledgments

Philips Biosensor BX100 is a registered trademark of Koninklijke Philips Electronics N.V. Other product names may be trademarks of their respective owners.

Manufactured for

Philips Medical Systems
2 Canal Park
Cambridge, MA 02141
(800) 225-0230

Document Number A-453564752821-2 Rev B
Part Number 453564752821

For more information or to reorder, go to www.philips.com/healthcarestore
Locate your local Philips sales office at www.healthcare.philips.com

EC REP

Authorized EU Representative

Philips Medizin Systeme Böblingen GmbH
Hewlett-Packard Str. 2
71034 Böblingen
Germany

Warranty Disclaimer

The information contained in this document is subject to change without notice. Philips Medical Systems makes no warranty of any kind with regard to this material, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose. Philips Medical Systems shall not be liable for errors contained herein or for incidental or consequential damages in connection with the furnishing, performance, or use of this material.

Printing History

New editions of this document incorporate all material updated since the previous edition. Update packages may be issued between editions and contain replacement and additional pages to be merged by a revision date at the bottom of the page. Pages that are rearranged due to changes on a previous page are not considered revised.

The documentation printing date and part number indicate its current edition. The printing date changes when a new edition is printed. (Minor corrections and updates that are incorporated at reprint do not cause the date to change.) The document part number changes when extensive technical changes are incorporated.

First Edition October 2018

Symbols

This section explains the symbols that appear on the biosensor and its packaging.

Symbol	Description	Symbol	Description
	Do not reuse		Read instructions for use
	Non-ionizing radiation		Do not use if package is damaged
	Use by date		Prescription use only
	Batch code		Catalogue number
	Caution		Storage humidity range limits
	MR unsafe		Storage temperature range limits
	Defibrilation Proof Type CF Applied Part (entire Philips Biosensor BX100 is an applied part)		Storage ambient pressure range limits
	WEE Disposal		Box of 10
	CE Mark	IP 27	Protected against access to hazardous parts and the ingress of solid foreign objects greater than 12.5 mm (0.5"); and, protected against effects of temporary immersion
	Not manufactured with natural rubber latex	EC REP	Authorized EU Representative
	Manufacturer		

Regulatory and Safety Specifications

This Philips product has been tested in a typical configuration as described in these Instructions for Use, and is fully compliant with the standards listed below.

EMC and Radio Regulatory Compliance

This Philips product complies with relevant international and national law and standards on EMC (electromagnetic compatibility) for this type of product when used as intended. Such laws and standards define both the permissible electromagnetic emission levels from product and its required immunity to electromagnetic interference from external sources.

Other electronic products exceeding the limits defined in such EMC standards could, under unusual circumstances, affect the operation of the product.

- Medical electrical products require special precautions regarding EMC and must be installed and placed into service according to EMC information provided in these Instructions for Use.
- The use of accessories and cables other than those specified may result in increased emission or decreased immunity levels.
- The product should not be used adjacent to or stacked with other products and that if adjacent or stacked use is necessary, it should be observed to verify normal operation.

FCC compliance statement

This device complies with FCC CFR47 Part 15 Subpart C, Federal Communication Commission Rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference
- This device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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 moving the equipment away and back, 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
- Consult the dealer or an experienced radio/TV technician for help

Equipment Classification (according to IEC 60601-1)

According to the type of protection against electrical shock:	Internally powered ME equipment
According to the degree of protection against electrical shock:	Defibrillation Proof Applied Part TYPE CF
According to the degree of ingress protection:	IP27, Protected against access to hazardous parts and the ingress of solid foreign objects greater than 12.5 mm (0.5 inch); and, protected against the effects of temporary immersion.
According to the mode of operation:	Continuous operation
ME equipment Type	Body-worn

The device is intended for use in the electromagnetic environment specified below. Given the device's electromagnetic emissions and immunity characteristics, the customer or user should assure that the device is used within such an environment. The following information is mandated by IEC 60601-1-2, the international standard for the electromagnetic compatibility (EMC) of medical electrical equipment.

Electromagnetic Capability

Guidance and Manufacturer's Declaration—Electrostatic Discharge

The Philips Biosensor BX100 shall resume normal operation in the previous operating mode within 10 seconds after an ESD event, without loss of operator settings or stored data, and shall continue to perform its intended functions.

Guidance and Manufacturer's Declaration—RF Immunity

The Philips Biosensor BX100 shall be designed to meet RF immunity requirements per EN 60601-1-2:2015, IEC 60601-1-2:2014, ANSI/AAMI/IEC 60601-2-47:2012 202.6.2.3 and IEC 60601-2-27:2011 201.12.1.101.11.

Guidance and Manufacturer's Declaration—RF Emissions

The Philips Biosensor BX100 shall be designed to meet RF emissions requirements per EN 60601-1-2:2015, IEC 60601-1-2:2014, ANSI/AAMI/IEC 60601-2-47:2012 202.6.2.3 and IEC 60601-2-27:2011 201.12.1.101.11 Guidance and Manufacturer's Declaration – Electromagnetic Immunity.

Electrical Safety

ECG Leakage Current

The Philips Biosensor BX100 shall utilize isolated electrode connection. The risk currents flowing to or from the patient through the patient electrode connections, chassis, or controls shall not exceed the limits specified in IEC 60601-1 8.7.

Currents Intentionally Applied to Patients

The currents intentionally applied to the patient for purposes of respiration, leads-off sensing, or active noise suppression shall not exceed the maximum risk currents specified in IEC 60601-1 8.7. The direct current through any patient electrode connection, with all remaining patient electrode connections attached to a common node, shall not exceed 10.0 µA for any active patient electrode under normal connection (i.e., any connection that serves as an input to an amplifier for measurement of ECG potentials). The alternating current through any patient electrode connection, with all remaining patient electrode connections attached to a common node, shall not exceed 100.0 µA for any active patient electrode under normal connection (i.e., any connection that serves as an input to an amplifier for measurement of ECG potentials).

Interference

- If the Philips Biosensor BX100 and cardiac monitors are used simultaneously, there is potential for interaction that could lead to inaccurate measurements. Philips recommends that your institution evaluate the potential interaction.
- Maintain a minimum separation distance as described in the EMC section, between portable radiofrequency communications equipment and the biosensor to avoid potential performance degradation.
- If interference problems occur, try moving the biosensor away from the source of the interference. You can also move the electronic device or its antenna to another location to solve the problem. These guidelines help ensure that the biosensor will not affect the operation of other nearby electronic devices. Additionally, other electronic devices should not affect the use of the biosensor.

Security and Privacy Recommendations

Customer's Role in the Product Security Partnership

The security of Philips products is an important part of each facility's overall security strategy. However, these benefits can only be realized in combination with a comprehensive, multi-layered strategy that includes policies, procedures, and technologies to protect information and systems from external and internal threats. Outlined below are some of the security measures adopted and/or recommended by Philips. For our product security policy statement and additional information, see the Philips Healthcare product security website at http://www.philips.com/security.

- Using 128-bit Advanced Encryption Standard (AES), data is encrypted on the Philips Biosensor BX100, during transit, and during export.
- Follow industry best practices for securely configuring, maintaining, and using the biosensor in order to prevent malware or other compromise.
- Use procedural security such as termination checklists and risk management (for example, performing risk assessments and mitigating identified risks).
- Follow industry best practices for protecting systems and data by maintaining a security risk management program and implementing administrative, technical, and operational policies.
- Periodically back up any data that is exported onto a PC or other device.

Philips Biosensor BX100 Specifications

Physical	
Size (W x H x D)	96 mm x 61 mm x 6.2 mm ±5% (without release liners)
Weight	10 g ±10%
Battery	CR2032, 3V primary cell
Memory	1 MB non-volatile flash
Robustness	Survives shock, vibration, free fall (IEC TR 60721-4-7 Edition 1.1; Class 7M3), and bump (IEC 60068-2-27)
Water Ingress Protection	IP 27 (IEC 60529: 2013)
Not manufactured with natural rubber latex	Yes
Use	
MRI Safe	No
Single Use	Single use only
Disposable	Yes
Serviceable	No
Performance	
Heart Rate Measurement Range	30–220 bpm
Heart Rate Accuracy	10% or ±5 bpm (whichever is greater)
Heart Rate Resolution	1 bpm
Heart Rate Calculation	• Takes into account last 10 beat-to-beat intervals • Excludes the minimum and the maximum intervals • Averages the remaining eight intervals to compute "mean interval" • Computes 60/mean_interval in seconds to convert to bpm
ECG Sampling Rate	250 samples per second
Heart Rate Meter Accuracy and Response to Irregular Rhythm	TBD
Response time of heart rate meter to change in heart rate	TBD
Applied Part Classification	Defib-proof CF applied part
Applied Current	16 µA (max), 40 kHz current pulse is applied to the patient

Pace Pulse Detection	Pacemaker pulses are detected with amplitudes from ±2 mV to ±700 mV; pulse widths from 0.1 ms to 2 ms; and rise time of 10% of the pulse width but not greater than 100 µs are present
Algorithm Performance	Meets IEC 60601-2-27:2011 and AAMI EC57 for Heart Rate measurements
Respiration Rate Measurement Range	3-40 rpm
Respiration Rate Accuracy	3-10 rpm (±1 rpm); 11-20 rpm (±2 rpm); 21-30 rpm (±3 rpm); 31-40 rpm (±4 rpm) excluding periods of undefined respiration rate as a result of subject talking, eating, or coughing for example.
Respiration Rate Resolution	1 rpm
Activity Level	Ambulating or Not Ambulating
Activity Type	0 (at rest); 1 (low activity); 2 (moderate activity); 3 (high activity)
Posture	Lying on the left side; Lying on the right side; Supine; Prone; Leaning/Reclining; Upright
Wireless	
Radio	Bluetooth Low Energy (4.2)
Transmission	1 minute
Local Storage	4 hours
Battery Life	5 days
Frequency Band	2402-2480 MHz
RF Radiate Power Output	Transmit Power 0 dBM (1 mW)
Operating Range	10 meters, line of sight
Environmental	
Operational Temperature Range	+10 to +45 °C
Operational Humidity Range	10-85 % relative humidity (non-condensing)
Operational Atmospheric Pressure Range	70 to 101 kPa
Shipping Temperature Range	-30 to +65 °C
Shipping Relative Humidity Range	5-95% relative humidity (non-condensing)
Shipping Atmospheric Pressure	70 to 101 kPa
Storage Temperature Range	+10 to +40°C
Storage Humidity Range	5-95% relative humidity (non-condensing)
Storage Atmospheric Pressure Range	70 to 101 kPa
Shelf Life	12 months in individually sealed pouch

Printed in the United States of America.
First Printing: December 2018.

Part number: 453564752821
Document number: A-453564752821 Rev B

www.philips.com