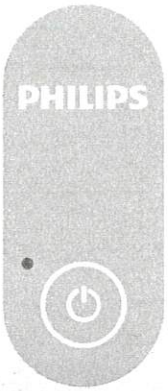
PHILIPS

G5 Solution

Wearable biosensor



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Instructions for use

989803199491

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PHILIPS

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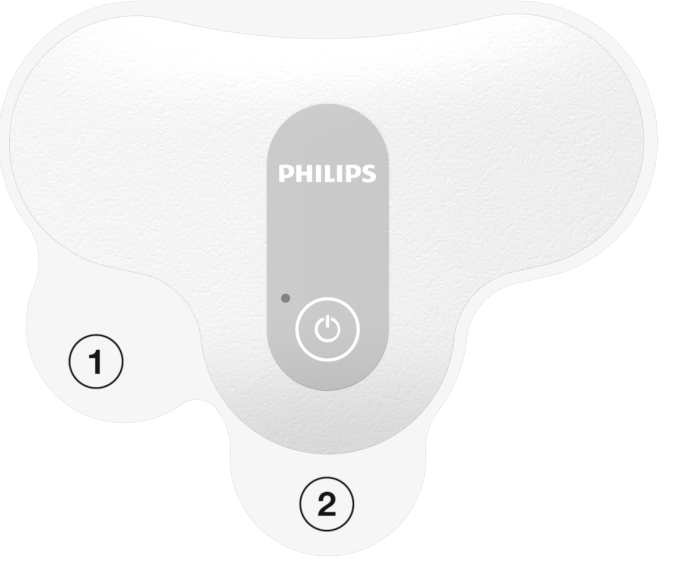

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Introduction

Intended use

Philips wearable biosensor-G5 solution is a single-location, chest-worn heart rate monitor. The wearable biosensor-G5 solution includes a wearable biosensor-G5 and software application. The wearable biosensor-G5 is a single-use device measuring heart rate by continuously acquiring surface electrical waveforms related to cardiac excitations and measuring beat-to-beat intervals when a patient is stationary or ambulatory. The biosensor functions by capturing and then sending physiological data wirelessly to the software application. The biosensor's frequency of data collection and transmission is configurable.

The software application is a single-patient use device, intended as an accessory to the biosensor to display and store physiological and operational data. The software application receives and displays data from the biosensor providing a user interface and exportable file for retrospective review and analysis. The application allows configuring the biosensor frequency of data collection and transmission.

Indications for use

The Philips wearable biosensor-G5 is indicated for single patient use whenever heart rate measurement is needed in non-critical hospital settings. The Philips wearable biosensor-G5 solution is used as a higher resolution heart rate log by nurses or physicians retroactively as an aid in making non-critical or non-life threatening therapeutic decisions. The biosensor is intended for patients who are 18 years of age or older.

Note

Before using this product to obtain heart rate, carefully read the instructions for use and the quick start guide on the G5 biosensor package.

Product description

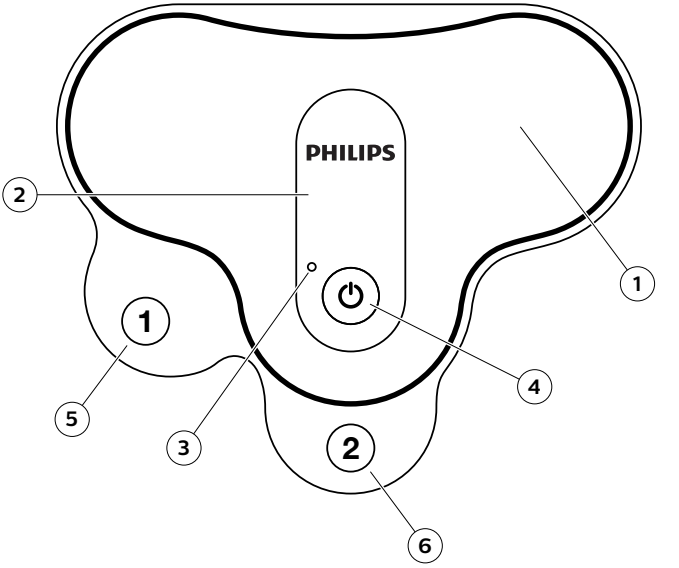
Biosensor

Philips wearable biosensor-G5 solution is a patient heart rate sensing system – comprised of a *Philips wearable biosensor-G5* and a software application *G5 application* – which gathers, stores and displays a patient's heart rate. The biosensor G5 is designed to connect with the G5 application to let clinicians review and export patient heart rate. Heart rate measurements are sent to a compatible device using a USB cable for offline review and analysis.

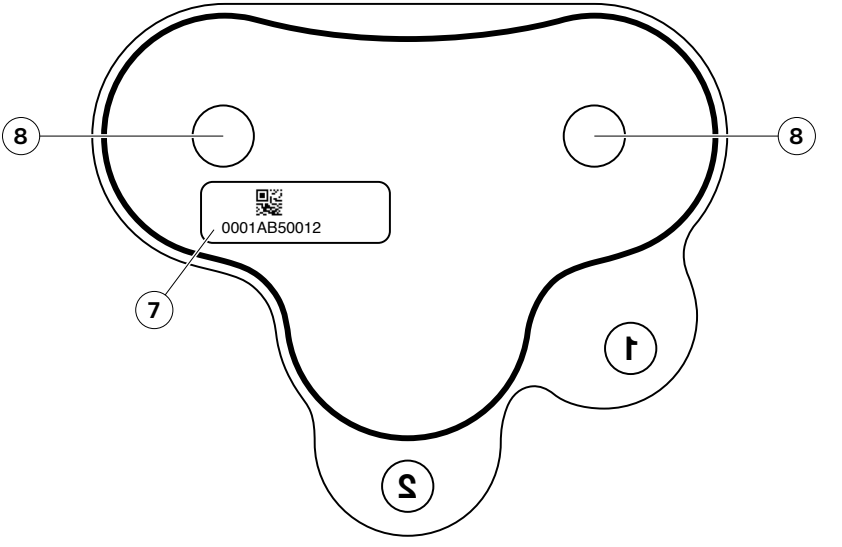
Philips wearable biosensor-G5 is a wireless, single-use, single-location chest-worn device that acquires surface electrical waveforms related to cardiac excitations, and measures beat-to-beat intervals. The biosensor calculates patient heart rate based upon a combination of patient's single-vector ECG and their motion data. The biosensor has two days of wear life, after which it turns off automatically.

1. **Biosensor top cover**
2. **Biosensor label**
3. **LED light**
4. **ON button**
5. **Release liner 1**
6. **Release liner 2**
7. **Biosensor ID on the back of the release liner**
8. **Electrodes**

Front of biosensor



Back of biosensor



Product description

Application

G5 software application is an Android-based application for mobile devices. The app receives patient's heart rate data, exports data into a password-protected file and displays the following:

9 **Menu**

- Disconnect biosensor and exit
- Clear all data and exit

10 **Heart rate (instantaneous)**

Instantaneous heart rate is measured every beat over the reporting interval, which is user-configurable between 1 to 30 minutes

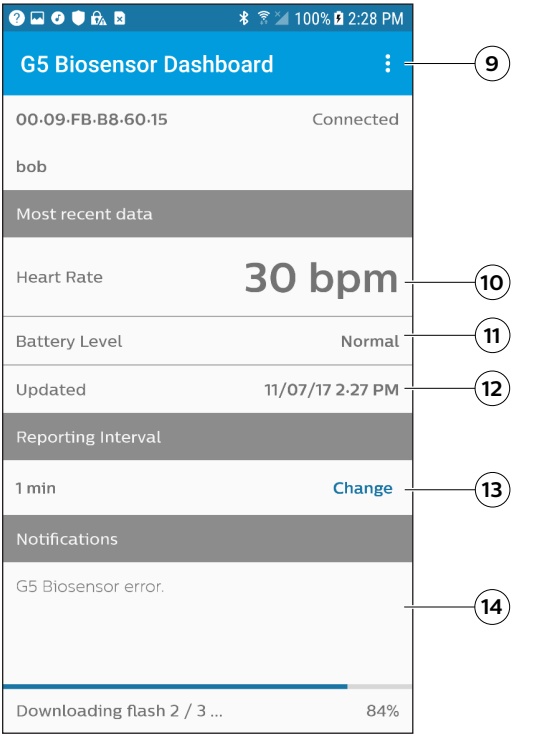
11 **G5 biosensor battery level**

12 **Date and time**

13 **Reporting interval**

14 **Notifications log**

Application dashboard



General warnings and precautions

Warnings

- Do not use the biosensor during MRI procedures. The biosensor is MRI unsafe.
- Do not use the biosensor during X-ray. The biosensor will obstruct the view of an X-ray of the chest.
- The biosensor should only be used under direct supervision of a licensed physician or healthcare provider, according to the hospital standard of care.
- Do not use for more than 48 hours. Replace biosensor if it no longer sticks firmly to the skin. The biosensor must be properly adhered to the patient to obtain signal from the body.
- Do not use if hydrogel is dry. Keep biosensor in sealed package. Only open immediately before use to prevent hydrogel from drying.
- Biosensor is for single use only. Do not reuse due to risk of cross-infection, degradation of adhesive or electrical performance.
- Do not apply over open wounds, lesions, infected, irritated, scarred or inflamed areas. The biosensor should only be applied to intact skin.
- Do not apply to patients with a history of known tape or adhesive allergy. The biosensor contains an adhesive which adheres to the skin.
- ***Warning pacemaker patients:*** Biosensor can detect a patient's pacemaker pulses. 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 the G5 application interface section of this manual for disclosure of the pacemaker pulse detection capability of the biosensor.
- ***Warning pacemaker patients:*** Biosensor can detect a patient's pacemaker pulses. Do not use the biosensor for rejecting pace pulses. A 'pace-pulse detected' notification will appear whenever interrupted measurements occur. The heart rate value will not display during a detected pacing event.
- Do not use the biosensor simultaneously with the cardiac monitors or cardiac

telemetry devices. Cardiac monitors or cardiac telemetry devices in direct contact with the thorax may degrade the biosensor signal quality or produce erroneous results. This potential interaction has not been evaluated.

- Do not use the device for diagnosis. Whenever patient condition does not match values, take a confirmatory, independent check of vitals (including 12-lead ECG).
- Do not use the device to discern abnormal rhythm patterns or for alarms.
- Do not use the biosensor with high frequency surgical equipment.
- No modification of this equipment is allowed.

Precautions

- Only apply the biosensor over clean and dry skin. Do not apply the biosensor over body hair. Remove any oil, lotion, residue, or debris from skin before application.
- Use caution when removing biosensor to prevent skin irritation. Gently swab area under the biosensor with water as you are removing the sensor.
- To frequently collect instantaneous heart rate, assess the biosensor connectivity to the G5 application every 8 hours. If connectivity is lost, the biosensor will store up to 4 hours of data.
- Keep your mobile device charged at all times.
- The biosensor is defibrillation proof. Remove the biosensor from the chest if the biosensor is located on the area where defibrillation pads need to be applied.
- Heart rate value may be lower or higher with patients with arrhythmia.
- Heart rate value may be higher when pacemaker pulses are present outside of the disclosed pacemaker pulse range.

Use environment

- The G5 solution is intended for non-critical care hospital environments.
- Maintain a minimum separation distance as described in the EMC section, between portable radiofrequency communications equipment and biosensor to avoid potential performance degradation.

General warnings and precautions

Use environment continued

- **Keep biosensor pouch sealed until the biosensor is ready for use.**
- **The biosensor should not be exposed to more than three showers. Each shower should not be longer than 10 minutes long, and the water temperature should not be higher than 105°F.**
- **The biosensor should not be worn during baths or submerged under water.**
- **The biosensor's adhesive should not be handled directly with the fingers once the liners have been removed.**
- **The biosensor should not be subjected to aggressive mechanical handling (e.g. twisting, pulling, etc.) during setup.**
- **The biosensor should be disposed according to hospital's disposable electronic devices guidelines after its use.**

Radiofrequency interference

If interference problems occur, try moving 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

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. In accordance with security and industry best practices, security strategies should address:

Data encryption

- Heart rate data is encrypted on the biosensor using 128-bit AES and sent via Short Range

Wireless to the compatible mobile device.

Customer network security and importance of security policy

- Ensure there are sufficient intrusion prevention and detection measures as part of the IT security policies.
- The mobile device should not be connected to the hospital network.
- It is recommended to have anti-virus or malware on the mobile device.
- Philips recommends operating Biosensor in secure network by turning off the Wi-Fi connectivity on the mobile device running the G5 App. Connectivity of G5 app with biosensor shall only be established on Bluetooth protocol (Version 4.2).
- If Wi-Fi cannot be disabled on the mobile device, it is advised to connect on a highly secure wireless network (e.g. WPA2) with strong password enabled.

User account maintenance

- Do not share the G5 App password with any unauthorized personnel.
- Use physical security; for example, locks, cameras, keycards, sensors, and so on, to restrict unauthorized access of mobile device.
- Use procedural security; for example, unattended mobile device locking, no sharing of access credentials, termination checklists, risk management (that is, performing risk assessments and mitigating identified risks), and so on.
- Operational security; for example, access/authorization controls, change management, and network segmentation based on data classification.

Auto-lock settings

- Philips recommends that you configure the mobile device auto-lock time to match the security policies (Permissible is between 1-9 minutes).

Application

- Philips recommend that G5 application should only be used with a compatible mobile device. – Any unnecessary applications should be removed from the compatible device.
- For optimal performance, only the G5 app should be running on the device

Product operation

Product setup

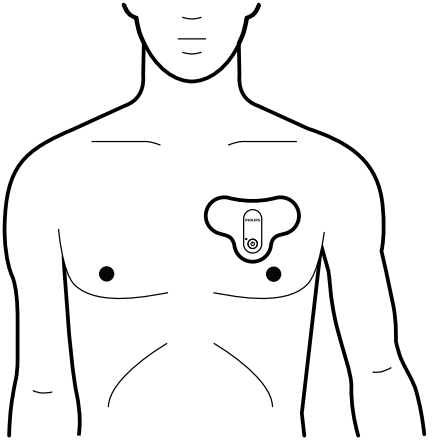
1 Gather required materials

a Materials needed to prep the skin and trim excessive body hair.

b G5 biosensor.

c Mobile device with G5 software application (app) installed.

Preparing skin and applying biosensor



Warning

- **Do not use the biosensor during MRI procedures. The biosensor is MRI unsafe.**
- **Do not use alcohol for cleaning purposes because it dries the skin and may diminish electrical flow. Alcohol may also increase likelihood of skin irritation.**
- **Do not apply the biosensor to patients with skin integrity issues. Only apply the biosensor to intact skin.**
- **Do not apply the biosensor over visible scars.**
- **Do not apply the biosensor to patients with known allergies to tape or adhesives.**

2 Prepare patient's skin

a Locate the upper left chest area (over the heart) for biosensor application.

b Shave or cut hair from electrode sites since excessive hair prevents good electrode contact.

c Clean each site thoroughly with soap and water or use an alcohol-free wipe to improve electrical flow.

d Let skin dry.

Note: Thorough cleaning and drying of the skin can improve biosensor adhesion.

Note: Skin prep solution may be applied to patients with delicate skin to make removal easier later.

3 Prepare biosensor

a To open the package, pull the two silver layers apart.

b Carefully remove the biosensor from the package.

c Examine biosensor for physical damage and liner integrity before setup.

Note: Discard the biosensor and use a new one if the biosensor foam is not intact, if the ON button appears damaged, or if a liner is missing.

d Turn on the biosensor by pressing the ON button ⏻.

e A green light will flash, indicating the biosensor is ready for placement on the patient.

Note: If the light does not turn on, use a new biosensor and repeat the previous steps.

Product operation

4 Apply biosensor

- **a** Without touching the adhesive, remove release liner (1).
- **b** Apply the biosensor to the patient's upper left chest, over the heart.
- **c** Apply pressure on the biosensor evenly across the applied side.
- **d** Without touching the adhesive, remove release liner (2).
- **e** Press firmly over the entire biosensor to ensure it is fully adhered to the skin.

Note: If the biosensor does not adhere properly or if it falls off after application, remove it and replace with a new one.

Note: A quick start guide with instructions for correct biosensor placement is located on the outside of the package.

Connecting to the G5 application

5 Connect G5 biosensor to G5 software application

- **a** Open the app on the mobile device by tapping the icon for the G5 software app.

Note: G5 app will be loaded on the customer supplied mobile device by Philips Field Service.

Note: The app will prompt you to enter your password after logging in for the first time.

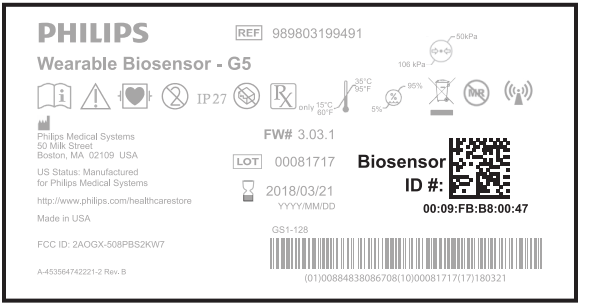
- **b** Enter the new password in the New Password and Confirm New Password fields. During login, the app will offer 4 opportunities to enter the correct password before the app terminates itself.

Note: Do not forget your password, as without it any data collected with the app will not be recoverable.

- **c** Enter patient ID (required) and patient assignment information (optional). Select *Save and Connect to G5 Biosensor.*

Note: Do not enter patient's medical record number (MRN) or patient's name as patient ID.

d Select the patient's Biosensor ID from the list of biosensors displayed. Scroll down, if applicable, to ensure all biosensors in the range are visible. If the biosensor does not appear, proceed to the troubleshooting steps (page 24).



Note: The alphanumeric Biosensor ID can be found on the biosensor package, underneath the square QR code labeled Biosensor ID.

e Tap *Connect* if G5 biosensor ID and patient ID are correct. If not, tap *Cancel*.

Note: If the patient ID or Biosensor ID is incorrect, select Cancel to return to the biosensors in the range screen.

Note: The biosensor pairing process is not instantaneous. It may take a little time.

Note: If the app could not connect to the selected biosensor, verify whether the correct biosensor was selected. If not, select the correct biosensor.

f Once the biosensor has successfully connected with the app, the app dashboard will be displayed. The green light on the biosensor will become steady and will stay on for 20 seconds, and then turn off automatically.

g Visually confirm that the heart rate measurement is displayed on the app. Now the biosensor is properly set up.

h The default reporting interval is heart rate every 1 minute. Change the reporting interval by clicking *Change*.

Note: If the app doesn't display heart rate, review the troubleshooting steps.

Note: In the event the biosensor is out of range of the app, it will automatically reconnect with the app when it is in range again.

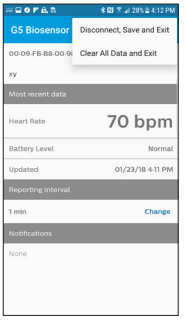
Product operation

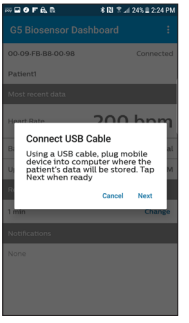
Disconnecting biosensor and saving patient data

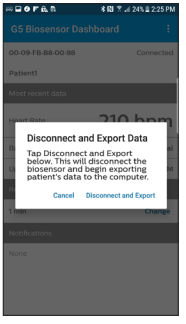
Note: Use caution when removing biosensor to prevent skin irritation. Take care not to pull the hair or skin. An adhesive tape remover may help with removal.

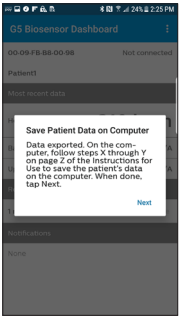
Note: Dispose of the biosensor according to local laws for battery operated electronics and hospital guidelines.

1 Disconnect biosensor and begin exporting patient data









a Tap menu on top right of the app dashboard screen. Select *Disconnect, Save and Exit*.

b Using a USB cable, plug the mobile device into the computer where patient data will be stored. Click *Next* to proceed.

c Tap *Disconnect and Export Data* on app screen. This will disconnect the G5 biosensor, if one is paired, and begin the process of exporting the patient's data.

Note: You must continue with step 2 in order to save the patient's data.

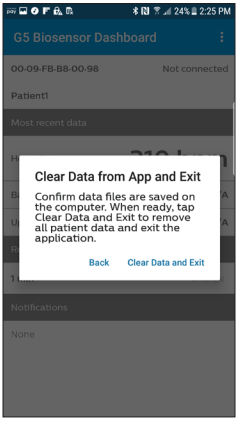
2 Save patient data on computer

- On the computer, click on the folder icon in the toolbar.
- On the left hand side of the window, click on "Samsung"
- Navigate through the folders: Android > Data > com.philips.cs.g5.android > Files > Export

- If this folder is empty, wait until the file export has completed.
- Click on the zip file. This will open a new window.
- Click on the ‘export’ folder.
- This will display a few Excel files. **Highlight the Excel file that starts with “G5_RAW”**
- Click “extract to”
- Click “OK”
- Enter the password that you created for the app

The files are now saved to the computer’s desktop for future review.

Note: Use the app login password to open the .zip files for viewing on the computer. See the ‘Reviewing data’ section on page 22 for additional instructions for viewing patient data.



3 Clear data from app and exit

Note: Be sure to exit the app to delete the patient’s files on the mobile device.

a Tap *Clear Data and Exit*. This will clear out all patient data from the app and exit the application.

4 Remove biosensor from patient

a Gently peel each side of the biosensor one at a time, leaving the center adhered. Gently swab with water while removing the device.

b Gently peel the center of the biosensor from top to bottom, until the entire surface becomes loose and comes off.

c Use adhesive tape remover if necessary.

Note: If the same patient requires another biosensor, repeat steps on page 12 for setup and connection of new biosensor.

Biosensor interface

The biosensor interface consists of a one-time ON button and LED light. The LED light indicates the status of the device.

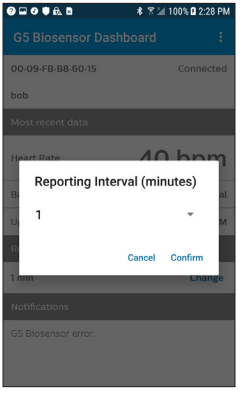
LED Behavior	Meaning	Action Required
Green flashing	Biosensor ON/Setup in process	Continue with setup
Steady green for 20 seconds	Setup complete	None. Biosensor is operating correctly
Flashing red	Error	Remove and replace biosensor
No light (biosensor broadcasting to app)	Biosensor is operational	None
No light (biosensor not broadcasting to app)	Biosensor is not functional	Remove and replace biosensor

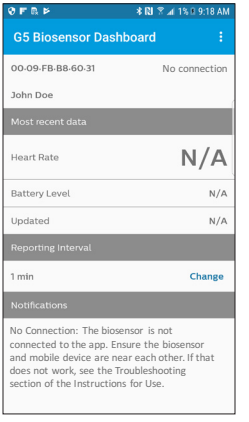
If the light on the biosensor flashes red at any time during use, remove the biosensor (see *Remove biosensor from patient*) and replace it with a new one.

G5 application interface

The app dashboard will display the following in addition to the heart rate:

- Biosensor ID of connected G5 biosensor
- Patient ID of assigned patient
- (Optional) patient assignment information of assigned patient
- Date and time of displayed heart rate
- Biosensor battery status
- Notifications





Heart rate transmission configuration

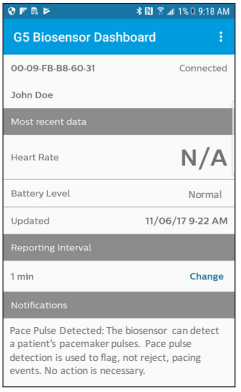
The frequency of data collection and transmission is clinician-configurable. Transmission intermittence period can be adjusted from 1 minute to 30 minutes. The biosensor will store data locally up to 4 hours.

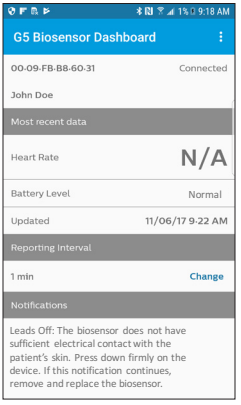
Notifications

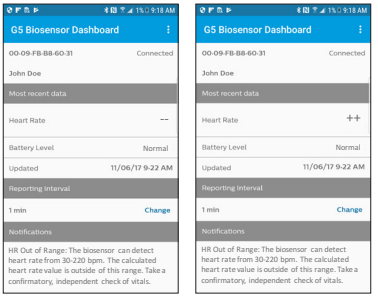
'No connection'

No Connection notification will be displayed whenever biosensor is not connected with the app.

G5 application interface







Notifications continued

'Pace pulse detected'

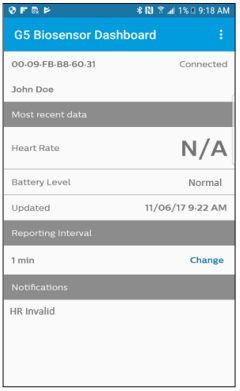
The Philips biosensor-G5 can detect a patient's pacemaker pulses. Pace pulse detection is used to flag, not reject, pacing events. Pacemaker pulses are detected when amplitudes from ±2mV to ±700mV; pulse widths from 0.1ms to 2ms; and rise time of 10% of the pulse width, but not greater than 100µs are present.

'Leads off'

Leads off notification is displayed on the app when the biosensor does not have appropriate electrical contact with the skin. Press down firmly on the device to see if the notification is resolved. If the notification continues, remove and replace the biosensor following the instructions in the Basic operation section.

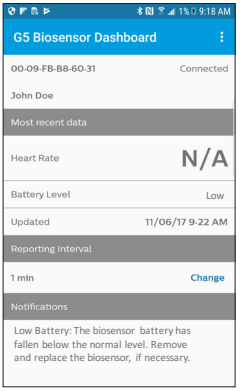
'Heart rate out of range'

The biosensor can detect heart rate from 30-220 bpm (beats per minute). Whenever the heart rate value calculated outside of this range, a notification will indicate *Out of Range*.



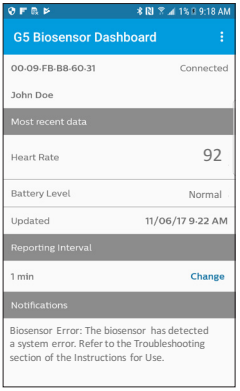
‘Heart rate invalid’

The biosensor may detect a noise in the signal or another error which may cause the heart rate to be invalid. This may occur when a patient is moving, and the activity could impact the heart rate value.



‘Low battery’

The biosensor will send low battery notification in the event the battery level falls below the normal level.



‘Biosensor error’

The biosensor has detected system error that will be displayed under notification log. Refer to biosensor troubleshooting section for next steps.

Reviewing data

The G5 software application provides the ability to export a file for retrospective review and analysis on a computer.

The file must be unlocked (using the same password that was used on the G5 biosensor app) to review and analyze the data. Time-stamped heart rate data and notifications are listed in the file. Files are named using patient ID and date. Use any data analysis software program to sort the data by date, as needed.

Maintenance

Cleaning and disinfection

The biosensor is a disposable, single use device. Do not reuse the biosensor. After use, the biosensor is considered non-biohazardous waste and should be discarded according to hospital guidelines and local laws for battery operated electronics.

Refer to the instructions for use for the mobile device for cleaning and disinfection procedures.

Storage

Biosensors must be stored in their sealed pouch. The pouch cannot be resealed after opening. The biosensor should be used immediately after opening the pouch to prevent the hydrogel from drying.

Biosensors should be stored at:

- Temperature between 15 and 35 °C (59 and 95°F)
- Humidity between 5 and 95%

Biosensors should not be stored in direct sunlight.

Troubleshooting

The patient's heart rate is not displayed in the software app

- Press the ON button ⏻ on the biosensor. If the green light flashes, the biosensor was not previously turned on.
- If no light flashes,
  - Ensure the biosensor and the mobile device are next to each other.
  - Close the app, turn the mobile device Short Range Wireless off and on and re-launch the app and proceed to connect biosensor to the app.
  - If this does not resolve the issue, close the app, restart the mobile device and attempt to connect to the biosensor.
  - If this does not resolve the issue, remove the biosensor and replace with a new one.

The biosensor won't properly adhere to the patient's chest

- If you touched a large area of the adhesive, you may need to dispose of the biosensor and apply a new one.
- Before applying a new biosensor to the patient's chest, ensure the skin is clean of any oil, lotion, debris or residue and the area is completely dry.
- Press firmly to adhere the sensor to the patient's skin.

The patient's heart rate does not seem to be updating

- Ensure the biosensor and the mobile device are next to each other.

The Biosensor ID is not found

- Press the ON button ⏻ on the biosensor. If the green light flashes, the biosensor was not previously turned on.
- If no light flashes,
  - Ensure the biosensor and the mobile device are next to each other.
  - Close the app, turn the mobile device Short Range Wireless off and on and re-launch the app and proceed to connecting biosensor to the app.

- If this does not resolve the issue, close the app, restart the mobile device and attempt to connect to the biosensor.
- If this does not resolve the issue, remove the biosensor and replace with a new one.

The red light is flashing on the biosensor

- The biosensor has a low battery or has an error.
- Remove and discard the biosensor and replace it with a new one.

The biosensor appears partially adhered to the patient

- Check to see if the biosensor has a red flashing light.
- If the red light is flashing, remove and replace the biosensor.
- If there is no red light flashing, press down firmly on the biosensor to adhere.
- If the biosensor still does not adhere, remove and replace the biosensor.

The G5 app shows “Could not connect to G5 biosensor” message

- Tap *Cancel* to return to the biosensors in the range screen.
- Enter the patient information and select correct Biosensor ID.

The biosensor is causing skin irritation

- Gently remove the biosensor and assess the skin irritation. Treat the area per clinical practice, if needed.
- Replace the biosensor with a new one, selecting a different area of the upper left chest to avoid further irritating the patient’s skin.
- If skin irritation persists, discontinue use.

Specifications

Symbols

Do not reuse

Read instructions for use

Non-ionizing radiation

Do not use if package is damaged

Manufacturer

Prescription use only

Use by date

Catalogue number

Batch code

Storage humidity range limits

Caution

Storage temperature range limits

MR unsafe

Storage ambient pressure range limits

Defibrillation Proof Type CF Applied Part (Entire G5 biosensor is an applied part)

Box of 5

IP27

Protected against access to hazardous parts and the ingress of solid foreign objects greater than 12.5mm (0.5 inch); and, protected against effects of temporary immersion.

Manufacturer's information

Connected Sensing – Division of Philips Medical Systems
50 Milk Street
Boston, MA 02109, USA
(800) 225-0230

For more information or to reorder, go to
www.philips.com/healthcarestore

Locate your local Philips sales office at
www.healthcare.philips.com

Open source software

Following is a list of software used for the development of G5 Application.

Title	Description	Version	Vendor
Zip4j	Password protect the exported data	1.2.4	net.lingala
OpenCSV	Library to create CSV files	4.0	OpenCSV
Android SDK	Platform to build and run Android apps	API25	Google
Butterknife	Annotation processing	8.8.1	Square

Regulatory and safety specifications

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

- EN IEC 60601-1:2006, EN IEC 60601-1:2006/A1:2013, General requirements for basic safety and essential performance.
- EN 60601-1-2:2015, IEC 60601-1-2:2014, General requirements for basic safety and essential performance.
- Collateral standards: Electromagnetic Compatibility requirements and test.
- EN IEC 60601-1-6:2010, General requirements for basic safety and essential performance.
- Collateral standards: usability.

Specifications

Regulatory and safety specifications continued

- EN ISO 10993-1:2009, EN ISO 10993-1:2009/AC:2010 ISO 10993-1 and Biological Evaluation of Medical Devices
- EN ISO 10993-5:2009 Biological Information of Medical Devices-Part 5: Test for cytotoxicity
- ISO 10993-10:2010 Biological Information of Medical Devices-Part 10: Test for irritation and skin sensitization
- ANSI/AAMI/IEC 60601-2-47:2012, EN 60601-2-47:2001 Particular requirements for the basic safety and essential performance and ambulatory electrocardiographs system.
- ANSI/AAMI/IEC 60601-2-27:2011, IEC 60601-2-27 Ed 3.0 2011-03 Particular requirements for the basic safety and essential performance of Electrocardiographic Monitoring Equipment
- ANSI/AAMI/ISO EC57:1998(R)2008, Testing and reporting performance results of cardiac rhythm and st-segment measurement algorithm.
- ANSI/AAMI/ISO EC12:2000/®2010 Disposable electrodes

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 needs special precautions regarding EMC, and needs to be installed and put into service according to EMC information provided in this 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

Caution: Changes or modifications not expressly approved could void your authority to use this equipment.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. this device may not cause harmful interference and
2. this device must accept any interference received, including interference that may cause undesired operation.

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

Specifications

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 BF
According to the degree of ingress protection:	IP27, Protected against access to hazardous parts and the ingress of solid foreign objects greater than 12.5mm (0.5 inch); and, protected against 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.

Guidance and manufacturer's declaration- electromagnetic emissions

The Philips wearable biosensor-G5 Solution is intended for use in the electromagnetic environment specified below, and the customer or the user should assure that it is used in such an environment.

Emission Test	Compliance	Electromagnetic Environment Guidance
RF Emissions, CISPR 11	Group 1	The Philips wearable biosensor-G5 Solution uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions, CISPR 11	Class A	The Philips wearable biosensor-G5 Solution is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.

Specifications

Guidance and manufacturer's declaration- electromagnetic immunity

The Philips wearable biosensor-G5 Solution is intended for use in the electromagnetic environment specified below. The customer or the user of the Philips wearable biosensor-G5 Solution should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level
Electrostatic discharge (ESD) IEC 61000-4-2	± 8kV contact ± 15kV air	± 8kV contact ± 15kV air
Electromagnetic Environment Guidance		
Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.		

Immunity Test	IEC 60601 Test Level	Compliance Level
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m
Electromagnetic Environment Guidance		
Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.		

Immunity Test	IEC 60601 Test Level	Compliance Level
Radiated RF IEC 61000-4-3	3 V/m 80-2700 MHz plus intentional radiator requirement Table 9 from 60601-1-2: 2014	3 V/m 80-2700 MHz plus intentional radiator requirement Table 9 from 60601-1-2: 2014
Electromagnetic Environment Guidance		
Portable and mobile RF communications equipment should not be used no closer to any part of the Philips wearable biosensor G5-Solution, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance is 30cm. 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. Interference may occur in the vicinity of equipment marked with the symbol.		

- 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 Philips wearable biosensor-G5 Solution is used exceeds the applicable RF compliance level above, the Philips wearable biosensor-G5 Solution should be observed to ensure normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Philips wearable biosensor-G5 Solution.*

Specifications

Biosensor specifications

Hardware	
Size (W x H x D)	100mm x 69mm x 6.2mm ±5% (without the release liners)
Weight	12 g ±10%
Battery	CR2032, 3V primary cell
Memory	1MB non-volatile flash
Robustness	Survives shock, vibration, free fall, and bump
Ingress Protection	IP27
Manufactured with Latex	No
Use	
MRI Safe	No
Singe Use	Yes
Disposable	Yes
Serviceable	No
Performance	
Heart Rate Measurement Range	30-220 bpm (beats per minute)
Heart Rate Accuracy	10% or ±5bpm (whichever is greater)
Heart Rate Resolution	1 bpm
Heart Rate Calculation	Heart Rate is calculated: • Taking into account last 10 beat-to-beat intervals • Excluding the minimum and the maximum intervals • Averaging the remaining eight intervals to compute “mean_interval” and • Compute 60/mean_interval (in seconds) to convert to bpm
Heart Rate Sampling Rate	250 samples per second
Heart Rate Meter Accuracy and Response to Irregular Rhythm	Provides correct heart rates (60, 80, 90, 120 bpm) using test waveforms as indicated in ANSI/AAMI EC13 Sec. 4.1.2.1(e). All QRS are counted with test waveforms within HR accuracy defined above
Response time of heart rate meter to change in heart rate	Inside a reporting interval, instantaneous heart rate change from 80 bpm to 120 bpm shall be captured within 8 seconds (margin of +2 sec)

Defibrillator-Proof	Defibrillator has no adverse effects on biosensor
Applied Current	29.1 µA (max), 32 kHz current pulse is applied to the patient
Tall T Wave Rejection	Up to 1mV peak to peak will be rejected
Wireless	
Radio	Bluetooth Low Energy (4.2)
Transmission	1-30 minutes (programmable)
Local Storage	4 hours
Battery Life	4 days
Frequency Band	2402-2480 MHz
RF Radiate Power Output	Transmit Power 0dBm(1mW) Maximum power 8dBm (6.31mW)
Operating Range	10 meters, Line of Sight
Environmental	
Operating Temperature Range	15-35 °C
Operating Humidity Range	20-85 %
Operating Atmospheric Pressure Range	10-106 kPa
Storage Temperature Range	15-35 °C
Storage Humidity Range	5-95%
Storage Ambient Pressure Range	50-106 kPa
Shelf Life	3 Months

Software application specifications

Mobile device	
Operating System	Android OS 7.0 or higher
Compatible Device	Smartphone with Bluetooth Low Energy (4.2) 8 GB Storage 1GB RAM
Dashboard screen	
Heart Rate (Instantaneous)	bpm (beats per minute)
Reporting Interval	1, 2, 3, 4, 5, 10, 15, 30 minutes

Part Number: 453564741671
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