HeraBEAT™

The beat of life

User Manual

Foetal & Maternal Heart Rate Monitor
By HeraMED

Foetal & Maternal Heart Rate Monitor

HERA MED

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⚠ Read the entire user manual thoroughly prior to use.

Congratulations on receiving HeraBEAT™, your personal Foetal and Maternal Heart Rate monitor.

The HeraBEAT™ unique software algorithm combines **ultrasound Doppler** used to measure the Foetal Heart Rate (FHR), an **optical sensor** to measure the Maternal Heart Rate (MHR) and distinguish between the two to prevent any confusion and a **motion sensor** used for motion detection and control. All these enable and ensure measurement accuracy.

HeraBEAT™ will assist and guide you to locate the optimal position for finding Foetal Heart Rate, measure the Foetal and Maternal Heart Rate and upload the result to a cloud-based dashboard for review by your healthcare provider.

Intended Purpose

The HeraBEAT™ hand-held doppler device is intended to detect and monitor foetal and maternal heart rate. The device is intended to be used by trained pregnant women in a home environment as part of their clinically supervised care plan. The device is to be supplied via a relevant trained healthcare professional who can access and interpret the results from the product's dashboard.

Indications for Use

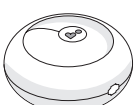
- The device is indicated for foetal and maternal heart rate detection in pregnant women starting from the 12th week into pregnancy.

Contra-Indications

The HeraBEAT™ device is NOT intended for:

- Foetal Heart Rate measurements in multiple gestation;
- Use during defibrillation, electro-surgery, applying HF surgical equipment, or magnetic resonance imaging (MRI);.
- Use during ECG measurements, on patients connected to external electrical stimulators, or with Cardiac Pacemakers.

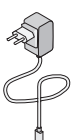
1. HeraBEAT™ device
2. HeraBEAT™ smartphone application (HeraBEAT™) (Free to download from the AppStore / Google Play.)
3. Two Ultrasound Transmission Gel
4. Power Supply
5. Carry Case
6. User Manual



(fig. 1)
HeraBEAT™ device

(fig. 2)
HeraBEAT™ application

(fig. 3)
2 Ultrasound
Transmission Gel



(fig. 4)
Power Supply

(fig. 5)
Carry Case

(fig. 6)
User Manual

Check that the box includes all items. Do not use the device if it is damaged or an item is missing.

⚠ **Always adhere to all warnings and cautions.**
As with any electrical device, you must observe certain precautions to ensure your safety

Warnings

Warnings are directions that if not followed could result in death or serious injury to a user, patient or other person, or could lead to clinical misdiagnosis, and/or loss/damage of patient-related data.

- Please ensure that you have been trained by the healthcare professional in the safe use of this device prior to use.
- Do not use the device if you are under 18 years of age.
- This device may only be used for the purposes described in this User Manual. HeraMED cannot be held liable for damage or injury caused by incorrect use. Always follow the operating procedures described in this User Manual.
- Until pregnancy week 22 - if pulse is not found after 3 attempts of 30 minutes each, please consult your physician immediately. From pregnancy week 22 onwards - if pulse is not found after one attempt of 30 minutes, please consult your physician immediately.
- Your pregnancy must be carefully followed by your treating physician.
- Use of HeraBEAT™ is not intended to replace medical advice. It is intended to be used as part of your clinical care plan.
- HeraBEAT™ does not measure foetal movements. No results can be referred to as an indication of foetal movements.
- If decreased foetal movement is noticed by the mother herself, this should be immediately reported to a healthcare provider.
- **Self-diagnosis and treatment are dangerous. In case of any doubt or concern, we recommend seeking medical assistance.**
- HeraBEAT™ is not intended to diagnose, cure, or prevent any pregnancy related medical condition, and is not intended to be used as a life saving or life preserving device.
- **Measurements made by this device are potential findings, not a professional diagnosis of foetal or maternal heart rate conditions. Interpretations should only be made by a medical professional.**
- This device is not designed or intended for the complete assessment of the foetal or maternal wellbeing or conditions
- This device should never be used as a basis for starting or modifying treatment without independent confirmation by professional medical examination.
- Efforts were made in the design and manufacture of the HeraBEAT™ device to minimize the possibility of false-detection or measurement errors. However, false detection of FHR may occur due to various types of signal interference.
- **If you have any doubt about the foetal or maternal health status after using this device, please seek medical advice.**
- Reports viewed or printed at any magnification other than 100% may appear distorted and could lead to being misinterpreted.
- False detection of foetal heart rate may occur.
- Foetal or maternal heart rate measurements may lead to false reassurance, therefore do not rely solely on HeraBEAT™ for any medical diagnosis at any stage of the pregnancy.
- FHR detection by the HeraBEAT™ device may not always indicate that the fetus is alive.
- Assume there may be measurement errors, and do not rely exclusively on measurement results.
- Recorded FHR segments of only a few seconds may be less reliable. The longer the recorded FHR segment, the more reliable it is.

- Recorded FHR with no or little change in the FHR values may be less reliable or may indicate foetal distress.
- If you suffer from an irregular heartbeat, measurements taken with this device should be evaluated with your physician.
- The sound recording is a synthesis of measured data and not the actual sound of your foetal heartbeat. Do not rely on the sound as an indication of the foetal heart rate existence.
- Do not use the device while not in static situations (For example, do not use in a car, plane etc.).
- HeraBEAT™ was not clinically validated on severely overweight or obese users.
- The HeraBEAT™ device is for personal use. It must be disinfected when transferred between different users.
- Do not use the HeraBEAT™ device on or near the eyes.
- Device must be charged only with the supplied power supply. (see Fig. 4)
- Do not charge the device under direct sun light.
- Use the device and its accessories only on intact skin.
- Do not leave the HeraBEAT™ device unattended. Store the device and its accessories in secured place to prevent access and use of the device by unintended individuals who cannot express their consent to use and especially by children.
- Do not allow water or any liquids to enter the HeraBEAT™ device or its charging connector. Do not use/store the device near any sources of water or liquids. Do not use the device if any liquids entered it or its charging connector.
- This device is not fire-resistant and cannot be used after exposure to fire or high temperatures.
- Do not drop the device. Do not use if cracked or broken, or in case of any visible malfunction. Do not touch the inner parts of the device.
- Do not disassemble, modify, remanufacture, puncture or damage the device. The device has no consumable or replaceable parts or pieces which can be replaced by the user (including batteries).
- You must check that the device is intact before use. Discontinue use of the device with any sign of damage or loss of cover integrity.
- Should the device require service, it must be serviced only by authorised and trained personnel by HeraMED Ltd. to maintain safety, and reliability.
- Use device only with the supplied gel (see Fig. 3). Using ultrasound transmission gel that is not approved by HeraMED may reduce signal quality and can lead to absence of Foetal Heart Rate (FHR) measurement or inaccurate measurement results.
- The Ultrasound Transmission Gel is for external use only. (see Fig. 3) Gel should be used only on intact, unbroken skin.
- Prior to use, verify that the Ultrasound Transmission Gel (see Fig. 3) has not exceeded its expiry date (located on the tube). Gel is valid for 5 years from month of manufacture.
- For any Doppler examination, it is essential that an adequate supply of Ultrasound Transmission Gel is used to transmit the ultrasound energy from HeraBEAT™ to the surface of the skin. Re-apply more gel if it starts to dry out or spread so thinly that an air gap occurs between the skin and the bottom of the device. Applying too much gel may impede the Maternal Heart Rate measurement.
- Incorrect placement of the device on the abdomen can lead to inaccurate measurement results.
  Follow the on-screen and voice instructions to locate the optimal position for Foetal Heart Rate (FHR) measurement.
- Do not expose HeraBEAT™ to temperatures outside the storage or operating range (Refer to HeraBEAT Specifications chapter).

- Do not expose HeraBEAT™ to direct sunlight for extended periods of time.
- Long term storage outside of acceptable conditions may permanently reduce the battery capacity or lead to failure of the device and inaccurate measurement results.
- Wash hands before the measurement procedure to avoid contamination.
- Do not use the device if your smartphone is damaged, or the app does not function properly.
- Although there are no confirmed biological effects on patients caused by exposures to ultrasound, the possibility exists that such biological effects may be identified in the future. Thus, use ultrasound in a prudent manner , as part of your clinical care plan.
- Misidentification may occur especially when the MHR is higher than normal (when it is over 100 bpm)

- **High-Risk pregnancy users:**
  High Risk pregnancies require a greater physician involvement and pregnancy management, and are more liable to pregnancy complications. Carefully follow all warnings detailed in this User Manual and in no case should you deviate from your physician's instructions due to the use of the HeraBEAT device.

Cautions

Cautions are directions which if not followed could cause damage to the equipment on which the software of the medical device is installed and/or other equipment or goods, and/or cause environmental pollution.

- External interference can cause significant noise and impede the measurements. Ensure that the environment in which the device is operated is not subject to any sources of strong electromagnetic interference, such as radio transmitters, cordless telephones, portable and mobile RF communications equipment, etc. Keep far away from the interference sources no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer.
- Do not dispose the device in the household garbage. Dispose only in accordance with local, state and/or federal regulations for electrical devices.

Notes

Notes are intended to draw your attention and aid with the use of this medical device.

- For successful measurement please verify that gel is applied and the device is gently pressed against the skin and held steady without any movement.
- There are several physiological conditions that may impair the ability to locate the Foetal Heart Rate:
  - Detection of Foetal Heart Rate in early weeks of pregnancy can be challenging since the size of the fetus' heart may be very small and might be missed.
  - Excessive or prolonged foetal, maternal or device movements can degrade the ability to locate and measure the Foetal Heart Rate (FHR). If you are experiencing frequent foetal movements during the measurement, stop the measurement and try again once foetal movements have subsided.
  - Placenta position: In cases of frontal placenta, it may take longer to detect the pulse and will require your patience during the search.

- Use device only with the supplied gel (see Fig. 3). Using ultrasound transmission gel that is not approved by HeraMED may reduce signal quality and can lead to absence of Foetal Heart Rate (FHR) measurement or inaccurate measurement results.
- The Ultrasound Transmission Gel (see Fig. 3) is for external use only. Gel can be used on intact, unbroken skin and on all patients in facilities where cross contamination is of minimal concern.
- Prior to use, verify that the Ultrasound Transmission Gel (see Fig. 3) has not exceeded its expiry date (located on the tube). The gel is valid for 5 years from month of manufacture.
- **Contraindications**

  The Ultrasound Transmission Gel (see Fig. 3) should not be used in:
  - Any invasive procedures in which a device is passed through the tissue.
  - Any procedure on or near broken skin, such as fresh surgical site or an open wound.
  - Patients with an immunodeficiency or on immunosuppressive therapy.
  - Any neonates or critically ill patients.
  - Mucous membranes.
  - Critically ill patients or patients in contact-, airborne- or droplet-transmission-based precautions.
- **Warning and precautions**

  Discard product if package is damaged or evidence of contamination is present.

  Do not use if known sensitivity to parabens exists.

  To avoid contamination, tip of the container should not come into contact with contaminating elements. Apply the gel to HeraBEAT™ surface, and not directly on your skin.
- **Storage conditions**

  Store in a cool dry place. Store away from direct sunlight.

The HeraBEAT™ measures the Foetal and Maternal Heart Rate, processes the data and transmits the information wirelessly to the HeraBEAT™ smartphone application (the HeraBEAT™ App) using safe BLE communication channel. The HeraBEAT™ App receives the digital information and displays the data to the user.

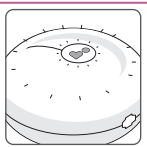
The HeraBEAT™ App guides the user step by step, to easily locate the Foetal Heart Rate (FHR), displays a Foetal Heart Rate animation, stores the Foetal Heart Rate in the smartphone's memory, uploads the result to a cloud-based dashboard for review by a healthcare provider, provides access to results history, and indicates the status of battery and connection with HeraBEAT™.

HeraBEAT™ LED Indicators

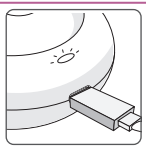
The device provides you with the following status indicators:

- Device turned OFF - light is OFF
- Device turned ON (waiting to be connected to the App) – constant white light
- Device is connected to the App – fast flashing of white light
- Device in measurement state – Ultrasound is ON– slow flashing of white light
- Device requires charging – device is flashing a white light 3 times and turns OFF
- Device is charging – orange light ON
- Device is fully charged – green light ON

Review the device lights in the following two illustrations.



White light



Orange / Green charging lights

App Home Screen

HeraBEAT™ Measurement

START — Tap on the Home Screen to start measurement session.

GO — Tap to start Foetal Heart Rate Search in every new position

END — Tap to end the Foetal Heart Rate measurement

Bluetooth Low Energy (BLE) connection

indicates that HeraBEA™ is connected to your smartphone. (BLE connected).

indicates that **HeraBEAT™** is NOT connected to your smartphone. (BLE NOT connected).

App Settings Menu

Tap on the Home Screen to access the in-app settings menu

Tutorial

Tap to access the Tutorial.

Support

Tap for Support contact details

About

Tap to view the App version

Change Language

Tap to change the App language

App Settings Menu

Advanced Settings

Tap to access the Advanced Settings.
You can edit your Personal Information, Unpair Device, Sign In to Doctor Mode , update the Measurement Duration (from 5min default to 40min) or Reset all App Private information.
Note!

- Device Unpairing will separate the connection between the HeraBEAT device and the app and will allow to connect a new device to the app.
- Reset will permanently erase your personal information and all measurements history from the App. We recommend resetting when you want to use the device for a new pregnancy.
- Instructions for Doctor Mode can be found in section 17.

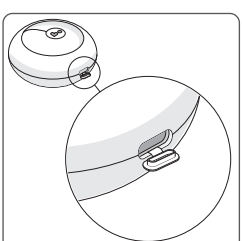
Measurements History

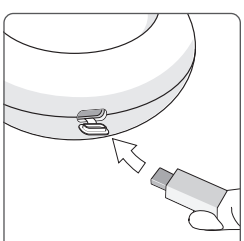
Measurement History

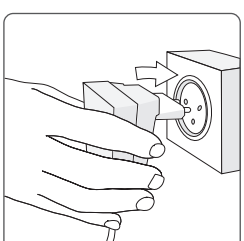
Tap on the Home Screen to access the Measurements History.
Recorded measurements will be displayed by pregnancy week.

1. Use only supplied Power Supply for charging. (fig. 4)
2. Remove the charging connector cover.
3. Connect the Power Supply Cord to the HeraBEAT™ device
4. Plug the Power Supply into an electrical outlet.
5. During charging orange light illuminates. Once fully charged, the orange light turns green.
6. Unplug the Power Supply from the electrical outlet and then disconnect its cord from the HeraBEAT™ device.

- Before you turn ON and start using the device, fully charge it.
- When the HeraBEAT™ device lights flash 3 times and the device turns OFF, it's time to charge it.
- The device cannot be used during charging.
- Do not charge the device under direct sun light.
- Full charge time is approximately 4 hours.
- It is recommended not to over-charge the device.
- When device is not in frequent use, it is recommended to periodically charge it every 3 months.





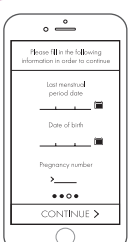


Note: The device must be operated using the smartphone application. Visit our website https://hera-beat.com.au/faq/ – 'Frequently Asked Questions' - for a list of supported devices.

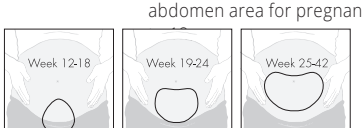
- Make sure you fully charge the HeraBEAT™ prior to first use and that the device is unplugged from the power supply.
- Install the HeraBEAT App on your smartphone: Go to AppStore / Google-Play on your smatphone. Search for 'HeraBEAT' app in the AppStore/Google-Play and install it on your smartphone.

Note: it is recommended to check the AppStore/Google Play periodically For HeraBEAT™ App updates.

- When the App starts for the first time, the Tutorial will guide you how to use the device.



Fill in your personal information: Last Menstrual Period date or Estimated Due Date (according to the app), Maternal date of birth & Number of previous pregnancies. HeraBEAT™ will optimise the guided search based on the gestational age providing 3 pre-defined search areas that consist of a number of search positions:
Week 12-18, Week 19-24 and Week 25-42.
The search will recommend the lower abdomen area for pregnancy weeks 12



- All measurement results are recorded according to your pregnancy week.
- Please make sure that you fill in your personal information accurately!

- Please note that HeraBEAT connects to a cloud system. Connection to a cloud system enables your measurement results to be automatically uploaded and shared with your healthcare provider.
  In order to enable the cloud connection, (mandatory), please use the link, username and password provided to you by the healthcare provider. Follow the instructions and login. Your personal information will be automatically filled within the HeraBEAT app. Note that the app will allow you to edit your personal information.

- Turn HeraBEAT™ ON by giving it a little shake, or by unplugging it from the power supply (fig. 4). A White light will quickly turn on.

Note: The device will turn itself off automatically 2 minutes after it is not in use and disconnected from the App.

HeraBEAT™ device pairing with the smartphone:

- The app will automatically search for and attempt to connect to a HeraBEAT™ device.
- When a device is found, the **HeraBEAT™** device flashes a white light for verification.
- This is only for first use, next time the app finds the same unique HeraBEAT™ device, it will automatically connect to it.
- If the connection to **HeraBEAT™** has not been established, verify that the **HeraBEAT™** device is turned ON (a constant white light will show), then stop the app and re-launch it.

1. Before starting a Measurement session

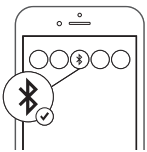
- Before you begin a search, please make sure you have available with you: HeraBEAT™ (fig. 1), your smartphone (fig. 2), the supplied ultrasound transmission gel tube (fig. 3) and a clean paper tissue/ towel.
- It is recommended that you find a comfortable position before starting any measurement session. Lean back on a pillow in bed or on a couch.

2. Measurement preparations

2.1 HeraBEAT™ preparation

Turn the HeraBEAT™ device ON by giving it a little shake, or by unplugging it from the power supply (fig. 4).
A White light will quickly turn on.
Note: The device will turn itself off automatically after 2 minutes if not used and disconnected from the App.

2.2 HeraBEAT™ US smartphone preparation



The HeraBEAT™ US device communicates with your smartphone via Bluetooth Low Energy, therefore please ensure that your smartphone's Bluetooth is turned ON (Bluetooth ON).

2.3 HeraBEAT™ App preparation

- Start the HeraBEAT™ App.
- Wait for HeraBEAT™ to connect. The App will automatically create a Bluetooth connection which will be indicated on the screen. Once connection with HeraBEAT™ is obtained, it will rapidly flash a white light.
- Please verify the device is turned ON, otherwise turn it on by giving it a little shake.

3. Applying the Ultrasound Transmission Gel:

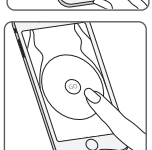
3.1 Apply a drop of supplied ultrasound transmission gel (fig. 3), about the size of your little finger, to the bottom surface of the HeraBEAT™ device.

3.2 Place HeraBEAT™ bottom side on your abdomen area and position over the bellybutton.
3.3 Hold the device in the palm of your hand and press it gently against your abdomen. Perform a circular motion to ensure a thin and even layer of gel between HeraBEAT™ and the skin.
3.4 Re-position the device over the bellybutton and make sure the bottom surface is fully touching your skin during the entire measurement.

4. Foetal Heart Rate Search

4.1 Tap the 'START' button.

To assist you with the Foetal Heart Rate Search, during the first 3 measurement sessions, the search will be guided by the app. Starting from the 4th measurement you can select the Guided Search or the Manual Search.

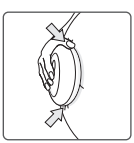


- **In Guided search** the app will guide you through several positions on your abdomen, based on the your pregnancy week, while it is searching for the Foetal Heart Rate. After placing the device on the recommended position, tap the 'GO' button and keep the device steady while waiting for the app to detect the Foetal Heart Rate. If the Foetal Heart Rate is not detected, the app will recommend moving to the next search position.
- **In Manual search**, you select where to position the device and tap the 'GO' button. The device will search for the Foetal Heart Rate in the position chosen. If the Foetal Heart Rate is not detected, the app will recommend moving to another search position.

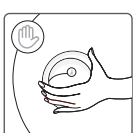
You can return to the Tutorial anytime from the App settings menu.

4.2 Follow the on-screen instructions, while maintaining the following:

1.
There is always a thin and even layer of gel between HeraBEAT™ and your skin. Note that the gel will dry after several minutes. Add gel as required to maintain a thin, moist layer.



2.
Apply a small amount of pressure on HeraBEAT™ against your skin. Verify full contact during the entire measurement.



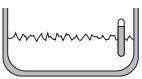
3.
Hold HeraBEAT™ steady while it is searching and measuring.

4.3 During the search

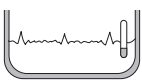
Note: The measurement is sensitive to noises which occur due to talking, eating, heavy breathing or moving. Please refrain from these actions during the measurement.
Abdominal activity or foetal movements detected may prolong the search duration, you may be requested to wait in your current position to allow the device to locate the foetal heart rate.

- At the bottom of the screen a running graph will indicate device activity.
- Next to the graph, a level bar displays the signal level.
- Understanding the running graph and signal level:

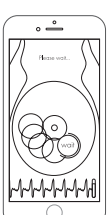
If you detect a "repetitive waves pattern" as below, it may be a foetal heart rate. Wait in this position to allow for the signal level to rise until the foetal heart rate is located:



If the running graph displays a "repetitive spike pattern" as below, it may be maternal heart rate. Move the device to search in a different position:



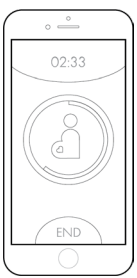
A momentary "irregular pattern" followed by a flat line may be caused by abdominal or other activity. Wait in this position to allow the data to stabilize.



- For every search position the HeraBEAT device will make sure that the maternal heart rate is not being regarded as the foetal heart rate. In such a case, it will guide you to move to the next search position.
- The search duration of every search position is indicated by a depleting ring.
- If the Foetal Heart Rate is not detected at a certain position, you will be asked to move HeraBEATTM to the next position (the new position will be displayed on the screen).
- The distance between search positions is about 2 fingers wide.
- The app will remind you to add more gel, if necessary, every 5 search positions.

5. Foetal & Maternal Heart Rate Measurement

- The HeraBEAT™ app will inform you when the Foetal Heart Rate is detected. The app will then move to the measuring screen.
- Hold steady while HeraBEAT™ is measuring the Foetal Heart Rate.



- The App will present a Foetal Heart Beat animation, play a constant Foetal Heart Beat sound and record the measurement.
- **Note:** the heart beat animation and sound are artificially generated in a predefined constant pace and only indicate that the Foetal Heart Rate has been successfully detected.
- **Note:** Measurement results of only a few seconds may be unreliable.

Hold the device steady in order to allow the measurement results to stabilise as much as possible. The longer and more continuous the measurement, the more reliable and accurate it is.

- The App will play a "Fetal Heart Located" message every 20 seconds the.
- The white depleting ring around the Foetal Heart Rate animation represents the duration of successful measurement, limited to five minutes. The time duration for the measurement session is displayed at the top of this screen.
- If foetal heart rate tracking is lost during measurement, the App will display 'Wait' instead of the foetal heart beat animation and sound. Keep the device steady until the foetal heart rate is located again. If the foetal heart rate is not located again after 20 consecutive seconds, the App will move back to the Search Screen in order to guide you to locate the foetal heart rate.

6. END Measurement Session

- Once the foetal heart rate has been recorded, the app will offer you to end the measurement. You may also choose to continue, in which case the measurement will complete a 5 minute session.
- You can always choose to end the measurement at any time by tapping the 'END' button, or by closing the App or by Switching to another App.
- The measurement will end upon an incoming call. You can start the measurement again once you return to use the app.
- The HeraBEAT™ device switches off automatically if no operation is performed for 2 minutes and the device is not connected to the smartphone.

7. Measurement Results

- Once the measurement has finished, the measurement results screen is shown. **Note:** upon measurement end, the result is automatically uploaded to a cloud-based dashboard for review by your healthcare provider. The notifications generated in the software will prompt the level of care necessary to address any concern. Escalation of care is solely dependent on the healthcare professional and local regulations.

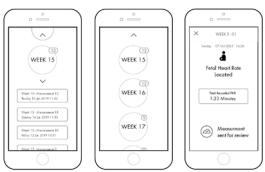
The measurement results screen includes:

- A measurement name at the top including pregnancy week, date and time.
- A 'Foetal Heart Rate Located' text message.
- Total recorded FHR .
- An indication that the measurement has been sent for review

If following the measurement Foetal Heart Rate was not located, the application will display a 'Foetal Heart Rate not found' message.

8. Measurements History

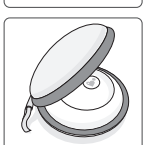
- All recorded measurements are kept and organised by pregnancy weeks in the history screen.
- Tap any week to see its measurements shown below.
- Tap a specific measurement to see its results screen.



Note: All Measurement history data saved within the HeraBEAT™ App. will be deleted should you uninstall the app or upgrade to a new smartphone.

Cleaning

1. The device should be cleaned immediately following the end of each use to remove all ultrasound gel and any other soil from all device surfaces. A delay in cleaning may result in the ultrasound gel drying on the device and being more difficult to remove.
2. Before cleaning the HeraBEAT™ device, be sure that it is unplugged from the power supply.
3. Thoroughly remove all ultrasound gel and any other visible soil from the device with a soft dry cloth or tissue, using a gentle wiping or blotting motion. Pay close attention to the LED and photodiode windows and avoid aggressive wiping or scrubbing in these areas as this may damage the lens surfaces.
4. Wipe the device with a soft cloth that has been dampened with soapy water until it is visually clean.
5. Use a soft cloth, mildly moistened with water, to remove any soap or detergent solution residuals.
6. After visually verifying that all ultrasound gel has been removed and the device is clean, thoroughly dry the device with a soft dry cloth.
7. Inspect the device to verify that the product is intact. Discontinue use if there are any signs of damage such as cracking or any other damage that may jeopardise the integrity of the device.
8. If any ultrasound gel or other soil remains on thedevice, repeat the cleaning steps 3 through 7 above as necessary.
9. Once thoroughly clean and dry, the device may be disinfected. Follow the disinfection instructions below.



Disinfection

The HeraBEAT™ device is classified as noncritical for disinfection as it only comes into contact with intact skin. Therefore, only low level disinfection is recommended according to the instructions below:

1. First follow the cleaning steps above to thoroughly remove all ultrasound gel and any other visible soil from the device.
2. Then use a soft cloth, moistened with 70% medical grade alcohol, to disinfect the device for at least 1 minute. Be sure that the alcohol is in contact with all surfaces of the device for at least 1 minute. Do not use a spray or immersion method for disinfection as this may result in liquids entering the device housing and damaging the device.

Care and Maintenance

3. Use a soft, dry cloth to thoroughly dry the device.
4. Verify the device is intact. Discontinue use with any signs of damage such as cracking or any other damage that may jeopardise the integrity of the device.
5. Once thoroughly clean and disinfected, store the device in its carry case and locate it with its accessories in a safe cool and dry place, away from direct sunlight.

Warning: Never submerge the device in liquids. Do not allow any liquid to enter the device and especially the charging connector.
Do not use strong solvent, for example, acetone. Never use an abrasive such as steel wool or metal polish.
The device is not intended to be sterilised.

Troubleshooting

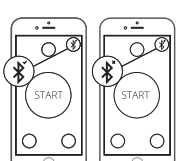
Problem: The HeraBEAT™ device is not connected or the app and device frequently disconnect.
Details: The 'No connection' message or icon is displayed.

Solution:

1. Verify that HeraBEAT™ is located within 3 meters from your smartphone.

2. Ensure that Bluetooth on the smartphone is turned ON.

3. Ensure that HeraBEAT™ is ON.
Turn HeraBEAT™ ON by giving it a little shake, or by plugging and unplugging it from the power supply after charging (fig. 4). The white light ring on the top part of the device will quickly turn on.
Note: The device will turn itself off automatically after 2 minutes if not in use and disconnected from the App.



4. Close the HeraBEAT™ app and restart it.

Problem: The device failed to detect the Foetal Heart Rate, or measured rate is inconsistent.
Details: The device failed to detect the Foetal Heart Rate at all recommended locations.
Solution:

1. Measurement is fully effective when:
   a. There is always a thin and even layer of gel between HeraBEAT™ and your skin. Note that the gel might dry after several minutes. Add gel as required to maintain a thin, moist layer.
   b. Apply a small amount of pressure on HeraBEAT™ against your skin. Verify full contact during the entire measurement.
   c. Hold HeraBEAT™ steady while it is searching and measuring.
   d. Carefully follow the step-by-step guidance as the App suggests.
2. Excessive or prolonged foetal, maternal or device movements can degrade the ability to locate and measure the Foetal Heart Rate (FHR). If you're experiencing frequent foetal movements during the measurement, stop the measurement and try again once foetal movements have stopped.
3. Detection of Foetal Heart Rate in early weeks of pregnancy can be challenging in some cases. The size of the fetus' heart can be very small and it might be missed.
4. It is recommended to perform measurements at least 1 hour after major meals as these may cause abdominal noises that may interrupt the measurement.
5. Consult with your physician.

Problem: The device does not turn ON or the device's battery is low.
Details: The 'low battery' message is displayed.
Solution:

1. Stop the current measurement using END button.
2. Charge the device.

Note: If the battery does not charge or does not hold a charge, please contact Service. (support@hera-med.com)

Problem: Device is flashing a white light 3 times and turns OFF.
Details: Device may require charging
Solution:

1. Charge the device.
2. If error persists, contact service. (support@hera-med.com)

Problem: App crashes.
Details: A general error may have occurred.
Solution:

1. Close and restart the app.
2. If error persists, restart the smartphone.
3. If error persists, contact service. (support@hera-med.com)

Problem: Charge light is flashing both orange and green lights.
Details: An error with the charge circuit has occurred. This may be due to a depleted battery.
Solution:

1. Contact service. (support@hera-med.com)

The product software installed and the information stored on the smartphone should be protected from unauthorised access and from external threats.
We recommend the following security measures:

- The physical protection of the device:
  - Do not leave the device and your smartphone unattended;
  - Do not allow others to use your devices.
- Use only official Operating System versions. Do not jailbreak or root smartphones;
- Avoid installing untrusted apps on the smartphone; Download apps only from trusted sources such as the Google Play store.
- Minimise installation of unnecessary Apps;
- Install latest software versions and apply security patches on the smartphone;
- Beware of wireless connections: avoid connection to untrusted services, and disable auto-connect to Wi-Fi signals;
- Avoid making your smartphone avaible in networking (Bluetooth or Wi-Fi);
- Hide the network SSID (network name);
- Avoid use of untrusted information services, web services and web apps (do not follow links sent in suspicious emails or text messages);
- Access controls: use of screen lock and secured unlock option is recommended (numeric PIN code, password or finger print);
- Security software including malware protection is recommended;
- Use official ;antitheft services;
- Backup smartphone data.
- Log out of any website that you conduct financial transactions on.

Special care should be taken when using smartphones in public places and other unprotected areas. Protection should be in place to avoid the unauthorised access to or disclosure of the information stored and processed by the smartphone, e.g. using cryptographic techniques and enforcing use of secret authentication information.

The smartphone should also be physically protected against theft especially when left, for example, in cars and other forms of transportation, hotel rooms, conference centers and meeting places. Devices carrying important, sensitive or personal health information should not be left unattended and, where possible, should be physically locked away, or special locks should be used to secure the devices. Use of a home Wi-Fi system with secured access (via Wi-Fi WPA2 standard) is strongly recommended.

The practical implementation of technical security elements varies by model of smartphone and version of operating system and security software used, and may employ several technologies, including virus scanning software, authentication technologies, etc.

The information recorded by the app is stored on your smartphone. If someone gains access to your smartphone, they can be exposed to this information.
Sharing the information via the app, is at your own risk and discretion.

Safety

Complies with	IEC/EN 60601-1, 60601-1-2, 60601-1-11, 60601-2-37

Classification

Anti-electric Shock Type	Internally powered equipment
Anti-electric Shock Degree	Type BF equipment
Degree of Protection against Harmful Ingress of Water	IP22 Protection against falling drops of water when unit is tilted 15o

Physical Characteristics

Device size	88 x 37 mm, 3.5 x 1.5 inch (Diameter × Height, ±2mm)
Device weight	Approximately 130g (.29 lb.)

Operating Environment

Temperature	From 5°C to 40°C (41°F up to 104°F)
Humidity	From 5% up to 90% RH (non-condensing)

Storage/Transport Environment

Temperature	From -20°C to +60°C (-4°F up to 140°F)
Humidity	From 5% up to 95% (non-condensing)
Light intensity	No direct sun light

FHR Performance

Pregnancy Week	12 to 42
FHR Measuring Range; Accuracy; Resolution	50 to 240 BPM; ±2BPM; 1 BPM

MHR Performance

MHR Measuring Range; Accuracy; Resolution	45 to 240 BPM; ± 2% or 1 BPM, whichever is greater ; 1BPM

Auto Acquisition stop

5 minutes of successful measurement

Recommended Ultrasound Transmission Gel

Water soluble hypoallergenic ultrasonic gel

Power consumption

< 2 W

Rechargeable Li-ion Battery

Nominal Capacity	3.7VDC, 1250 mAh
Continuous Work Time	4 hours (with a new battery)
Power Input	5 V DC, >0.3A
Charge Time	4 hours

Ultrasound

Nominal Frequency	2 MHz ±10%
Ultrasonic Output Power (P)	70 mW
Peak acoustic pressure (pr, α at Z MI)	0.03 MPa
Ultrasonic Output Intensity (Isat)	<20 mW/cm^2
Mechanical Index (MI)	0.02
Thermal index (TIS; TIB)	0.26; 0.7
Measurement Mode	Continuous Wave Ultrasound Doppler
Effective Radiating Area of Transducer	4.9±0.5 cm^2

Below are the HeraBEAT™ label and symbols used on the device and packaging.
When contacting Service, have readily available the device Serial Number colored pink.

	Manufacturer
	Date of Manufacture
SN	Serial Number
IP22	Ingress Protection
	Caution - Consult Accompanying Documents
	Type BF applied part (Degree and type of protection against electric shock)
	Waste of Electrical and Electronic Equipment (WEEE) compliance symbol
	Caution - Refer to instruction manual/booklet
	Bluetooth
CE 2797	BSI CE mark
Rx Only	Caution: USA Federal law restricts this device to sale in the US by or on the order of a physician.
	Class II medical electrical equipment (Double insulation).

Note: Intended for the healthcare professional, patients cannot purchase the product directly. Patients are requested to contact their healthcare professional for any warranty and service related queries)

Congratulations on your purchase of the "HeraBEAT™" medical grade home foetal monitor (the "**Product**"), which is manufactured by HeraMed Ltd. (the "**Company**").

Please read this document carefully as, amongst other things, it apprises you of certain rights with respect to the Product, and instructs you on how to take advantage of the limited warranty provided to you.

1. RETURN POLICY

You may return the Product to the authorised retailer or distributor of the Company from whom you purchased the Product (the "**Distributor**") within 30 days of purchase (the "**Purchase Period**"). In the event that the jurisdiction in which you purchased the Product requires, by law, a longer period for return of the Product, then upon your request, the Distributor will respect such requirement, and the Purchase Period shall be adjusted accordingly. In order for a refund to be granted, you must request a Return Merchandise Authorization (RMA) number within the Purchase Period. You may request an RMA number by submitting a request at support@heramed.com ("Customer Support"). The Product must be received by the Distributor within 3 weeks from the date on which the RMA was issued, in order for you to receive a refund.

If the Product is returned to the Distributor in accordance with this Return Policy, it will refund you the full purchase price for the Product minus any shipping and handling charges paid by you upon purchase of the Product. You are responsible and must pre-pay all return shipping charges and you assume all risk of loss or damage to the Product while in transit back to the Distributor.

The time to credit your account may vary, depending on processing time.

2. LIMITED WARRANTY

The Product will materially conform to its published specifications and shall be materially free from defects in materials and workmanship for a period of **two years from purchase** (the "**Warranty Period**"). In the event that the jurisdiction in which you purchased the Product requires, by law, a longer warranty period, then the Warranty Period will be adjusted accordingly. The warranty is provided only when the Product is purchased from a Distributor.

A. HOW TO OBTAIN WARRANTY SERVICE

If the Product proves defective during the Warranty Period, please contact the Distributor directly and follow its instructions for returning the Product. If it is determined that you are eligible under the limited warranty, the Distributor will ensure that the Product will be repaired or replaced with a Product that is the same or equivalent to the Product which you purchased.

If it is determined that the Product is eligible under the warranty, the Distributor shall bear the costs associated with returning a Product under Warranty. The Distributor shall not be responsible for items damaged or lost in transit.

A repaired or replaced Product will only be provided to addresses in jurisdictions where the Product is sold, by the Distributor from whom it is purchased.

For warranty coverage, proof of purchase must be supplied.

The Company shall have no direct responsibility toward you under the warranty, and you agree that any claims under the warranty shall

be brought by you to the Distributor only.

B. EXCEPTIONS TO WARRANTY COVERAGE

The limited warranty does not apply to consumable parts, such as batteries or protective coatings that are designed to diminish over time, unless failure has occurred due to a defect in materials or workmanship.

The warranty is not valid when:

i. The Product has been subjected to any use which is inconsistent with the instructions or warnings included with the Product.
ii. The Product has been opened, serviced, modified or repaired, except by the Company or its subcontractor's qualified representative.
iii. The Product has been damaged by the presence of liquids or other foreign bodies within the Product, or by the use of unapproved accessories with the Product
iv. The Product has been damaged by natural disasters (such as earthquakes, floods, fire, lightening, etc.), force majeure or accident.
v. The Product has been subjected to high dust environments, humidity or application of excessive voltage from the power supply.
vi. The Product's battery is damaged by overcharging, usage of an unauthorized charger, or other charging not in accordance with the Product's user manual.
viii. Any of the seals on the Product's battery enclosure is broken or tampered.
ix. The Product has been subjected to any other misuse, abuse, neglect, accident or external forces.

C. WARRANTY DISCLAIMER

TO THE MAXIMUM EXTENT ALLOWED BY APPLICABLE LAW, THIS LIMITED WARRANTY CONSTITUTES THE ONLY WARRANTY PROVIDED WITH RESPECT TO THE PRODUCT AND ANY SERVICES WITH RESPECT THERETO, AND SPECIFICALLY EXCLUDES ALL OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, EXPRESS OR IMPLIED, STATUTORY, CONTRACTUAL, IN TORT OR OTHERWISE, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF DESIGN, MERCHANTABILITY, SATISFACTORY QUALITY, FITNESS FOR A PARTICULAR PURPOSE (EVEN IF YOU HAVE INFORMED THE DISTRIBUTOR OR THE COMPANY OF SUCH PURPOSE), OR WARRANTY AGAINST INFRINGEMENT.

IF ANY IMPLIED, STATUTORY OR OTHER WARRANTY MAY NOT BE EXCLUDED UNDER APPLICABLE LAW, THEN SUCH WARRANTY SHALL BE LIMITED IN DURATION TO THE MINIMUM PERIOD ALLOWED BY SUCH LAW.

3. LIMITATION OF LIABILITIES AND REMEDIES

THE REMEDIES IN THIS LIMITED WARRANTY ARE YOUR SOLE AND EXCLUSIVE REMEDIES IN CONNECTION WITH THE PRODUCT AND ITS PURCHASE.

NEITHER THE DISTRIBUTOR, NOR ANY THIRD PARTY ARE AUTHORISED TO MAKE ANY MODIFICATION, EXTENSION OR ADDITION TO THE MATTERS COVERED HEREIN, INCLUDING, BUT NOT LIMITED, THE LIMITED WARRANTY AND LIMITATION OF LIABILITY.

YOU ACKNOWLEDGE THAT USE OF THE PRODUCT IS NOT INTENDED TO REPLACE MEDICAL DIAGNOSIS OR TREATMENT, AND THAT YOU SHALL NOT USE THE PRODUCT AS A REPLACEMENT FOR DOCTORS' VISITS, MEDICAL DIAGNOSIS OR TREATMENT. IT IS YOUR RESPONSIBILITY TO SEEK EXPERT MEDICAL ADVICE WITH REGARD TO PREGNANCY OR ANY OTHER CONDITIONS IN CONNECTION WITH WHICH THE PRODUCT IS USED, AND NEITHER THE COMPANY NOR THE DISTRIBUTOR SHALL BE RESPONSIBLE FOR YOUR FAILURE

TO DO SO.

YOU ALSO ACKNOWLEDGE THAT THE PRODUCT USES ULTRASOUND TECHNOLOGY, THAT YOU ARE AWARE OF THE RISKS WITH RESPECT THERETO AND THAT NEITHER THE COMPANY NOR THE DISTRIBUTOR SHALL HAVE ANY LIABILITY WITH RESPECT THERETO.

TO THE GREATEST EXTENT PERMITTED BY APPLICABLE LAW, NEITHER THE COMPANY NOR THE DISTRIBUTOR (I) ASSUMES ANY LIABILITY FOR ANY INDIRECT, CONSEQUENTIAL SPECIAL OR PUNITIVE LOSS OR DAMAGE, OR FOR ANY LOSS OF OR DAMAGE TO, OR CORRUPTION OF, DATA, LOSS OF PROFIT, LOSS OF BUSINESS, LOSS OF REVENUES, OR LOSS OF ANTICIPATED SAVINGS, (II) SHALL INCUR ANY AGGREGATE LIABILITY IN EXCESS OF THE PURCHASE PRICE OF THE PRODUCT.

TO THE GREATEST EXTENT PERMITTED BY APPLICABLE LAW, NEITHER THE COMPANY NOR THE DISTRIBUTOR SHALL INCUR ANY AGGREGATE LIABILITY IN EXCESS OF THE PURCHASE PRICE OF THE PRODUCT.

THE PRODUCT MAY ONLY BE USED IN THE JURISDICTION WHERE PURCHASED, AND NEITHER THE COMPANY NOR THE DISTRIBUTOR SHALL HAVE ANY LIABILITY FOR USE OUTSIDE OF SUCH JURISDICTION.

THE PRODUCT IS INTENDED FOR PERSONAL USE ONLY AND COMMERCIAL USE OF THE PRODUCT IS STRICTLY FORBIDDEN. NEITHER THE COMPANY, NOR THE DISTRIBUTOR SHALL HAVE ANY LIABILITY RESULTING FROM ANY SUCH COMMERCIAL USE. YOU AGREE TO INDEMNIFY AND HOLD HARMLESS THE COMPANY, THE DISTRIBUTOR AND THE DIRECTORS, SHAREHOLDERS AGENTS AND AFFILIATES THEREOF FOR ANY DAMAGE OR LIABILITY RESULTING FROM COMMERCIAL USE OR ANY OTHER USE WHICH WOULD INVALIDATE THE LIMITED WARRANTY PROVIDED HEREIN.
NEITHER THE COMPANY NOR THE DISTRIBUTOR SHALL HAVE ANY LIABILITY FOR THE OPERATION, AVAILABILITY COVERAGE, SERVICES OR RANGE OF THE CELLULAR OR OTHER NETWORK OR SYSTEM WITH RESPECT TO WHICH THE PRODUCT OPERATES.

THE LIMITATIONS SET FORTH HEREUNDER ARE INTENDED TO LIMIT THE LIABILITY OF THE COMPANY AND THE DISTRIBUTOR, AND SHALL APPLY NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY.

4. OTHER IMPORTANT NOTICES

The rights provided to you hereunder do not derogate from any legal (statutory) rights applicable to your purchase of the Product under relevant national law.

The jurisdiction applicable to you may not allow all or some of the limitations of liability or damages set forth herein, in which case such limitations shall only apply to the extent allowed in such jurisdiction.

5. SERVICE & CUSTOMER SUPPORT

When reporting to local service center, please have the device serial number ready. The serial number can be found on the device.
Customer satisfaction is our top priority. To help us provide you with the best support possible, please send us your comments and suggestions.
Contact our service: support@hera-med.com

EMC Information-Guidance and Manufacture's Declaration

1. Electromagnetic Emissions - for all Equipment and Systems

Guidance and manufacture's declaration – electromagnetic emission		
The HeraBEAT™ device is intended for use in the electromagnetic environment specified below. The user of the device should assure that it is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The HeraBEAT™ device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The HeraBEAT™ device 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.

2. Electromagnetic Immunity - for all Equipment and Systems

Guidance and manufacture's declaration – electromagnetic immunity			
The HeraBEAT™ device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, 15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, 15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%. The manufacturer may recommend the ESD precautionary procedures to user.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	30 A/m, 50 or 60 Hz	30 A/m, 50 or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

3. Electromagnetic Immunity - for all Equipment and Systems that are not Life-supporting

Guidance and manufacture's declaration – electromagnetic immunity

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

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the HeraBEATTM device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site surveya, should be less than the compliance level in each frequency rangeb. 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 HeraBEAT™ device is used exceeds the applicable RF compliance level above, the HeraBEAT™ device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the HeraBEAT™ device.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

4. Recommended Separation Distances

Guidance and manufacture's declaration – electromagnetic immunity		
The HeraBEAT™ device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment		
	Separation distance according to frequency of transmitter (m)	
Rated maximum output power of Transmitter (W)	**80 MHz to 800 MHz** $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.04	0.07
0.1	0.11	0.22
1	0.35	0.70
10	1.11	2.21
100	3.50	7.00

For transmitters rated at a maximum output power not listed above, the recommended separation distances in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

5. Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Service	Modulation	Max Power (W)	Distance	Test Text Level (V/m)	Compliance Level
385	380 – 390	TETRA 400	Pulse 18 Hz	1.8	0.3	27	27
450	430 – 470	GMRS 460, FRS 460	FM ±5 kHz 1 kHz sine	2	0.3	28	28
710 745 780	704 – 787	LTE Band 13, 17	Pulse 217 Hz	0.2	0.3	9	9
810 870 930	800 – 960	GSM 800/900; TETRA 800; iDEN 820; CDMA 850; LTE Band 5	Pulse 18 Hz	2	0.3	28	28
1,720 1,845 1,970	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse 217 Hz	2	0.3	28	28
2,450	2400 – 2570	Bluetooth; WLAN; 802.11b/g/n; RFID 2450; LTE Band 7	Pulse 217 Hz	2	0.3	28	28
5,240 5,500 5,785	5100 – 5800	WLAN 802.11a/n	Pulse 217 Hz	0.2	0.3	9	9

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the device may be reduced to 1m. The 1m test distance is permitted by IEC 61000-4-3.

a For some services, only the uplink frequencies are included.
b The carrier shall be modulated using a 50% duty cycle square wave signal.
c As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

HeraMED Ltd. reserves the right to make changes without notice to its products or specifications to improve performance, reliability, or manufacturability.
In case of device modifications, the information contained in this document is subject to change without notice.

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HeraBEAT™

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User Manual

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Foetal & Maternal Heart Rate Monitor

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