

Moyo

Fetal Heart Rate Monitor

User Guide



Intended Use

The "Moyo - Fetal Heart Rate Monitor" by Laerdal Global Health is intended for healthcare professionals to monitor fetal heart rate during labor. Moyo uses a Doppler ultrasound sensor to measure and analyze the fetal heart rate. The calculated fetal heart rate is presented on the display together with an audible (doppler) sound. Moyo provides an alarm in the case of prolonged abnormal fetal heart rate.

Intended medical indication is to screen for or monitor fetal distress on pregnant women - particularly in the setting of labor.

There are no known contraindications to the use of Moyo.

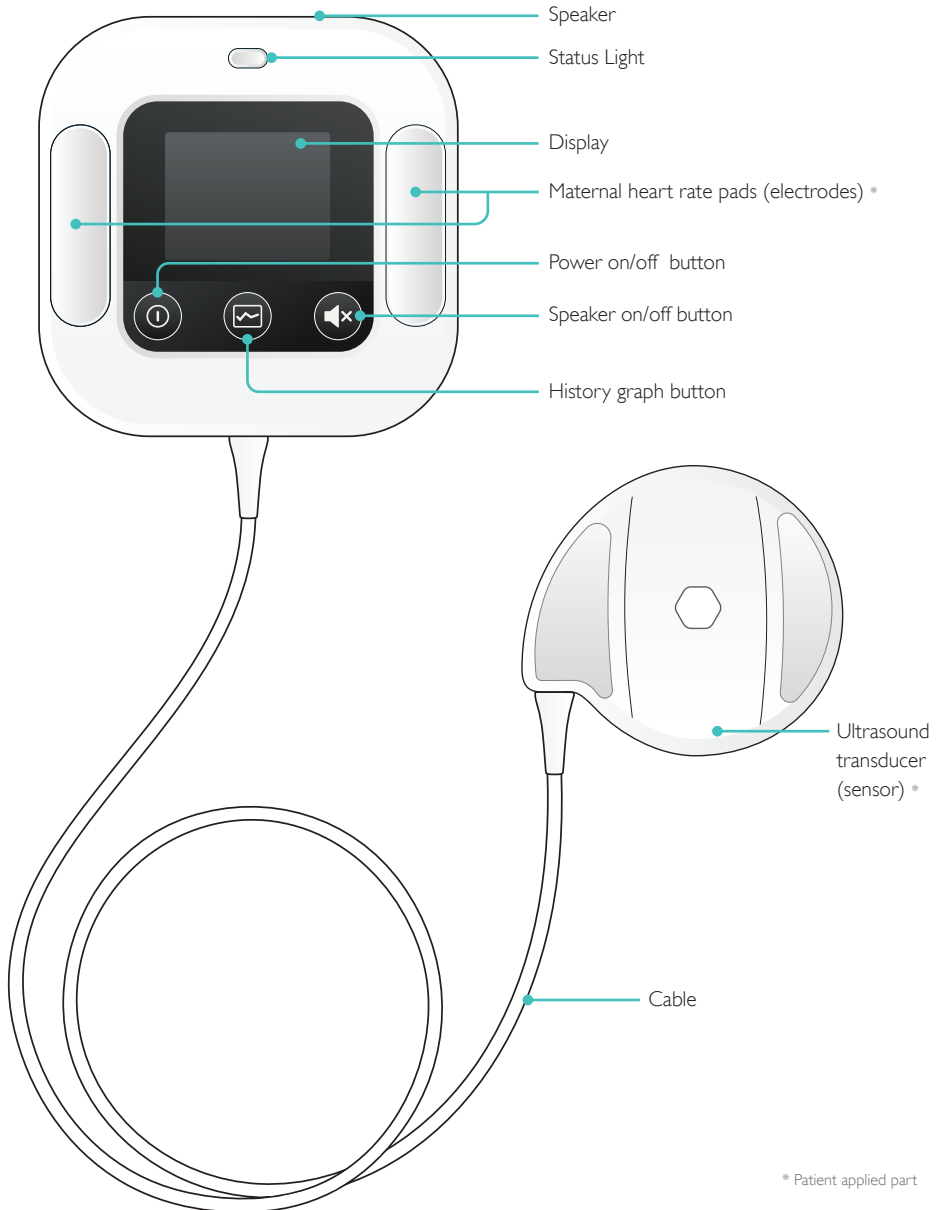


Illustrations in this User Guide may vary from actual product.

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Overview

Items included: 1 Moyo main unit with ultrasound sensor, 1 neck strap, 3 reusable abdominal transducer belts, 1 charger, 1 charger cable and this User Guide.



* Patient applied part

Please ensure that following precautions are taken to ensure that Moyo functions properly during use.



This product is intended for use by authorized healthcare professionals only.



Read this User Guide and become familiar with the operation of the device prior to use.



The device is intended for monitoring only one fetus at a time. In case of monitoring of multiple fetuses, alternative devices/methods should be used.



In case the device displays erratic or unreliable FHR, try to reposition the ultrasound transducer or use alternative monitoring devices/methods.



Excessive handling and movement of the product may cause lost or erroneous heart rate readings.



Do not connect the charger to Moyo while in use with a patient.



Turn off device and clean/disinfect between patient uses.



Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (e.g. IEC 60950 for data processing equipment). Furthermore all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1-1 or clause 16 of the 3rd ed. of IEC 60601-1, respectively). Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult your local representative or the technical service department.



Do not modify this equipment without authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe operation.



Do not immerse this product in liquid.

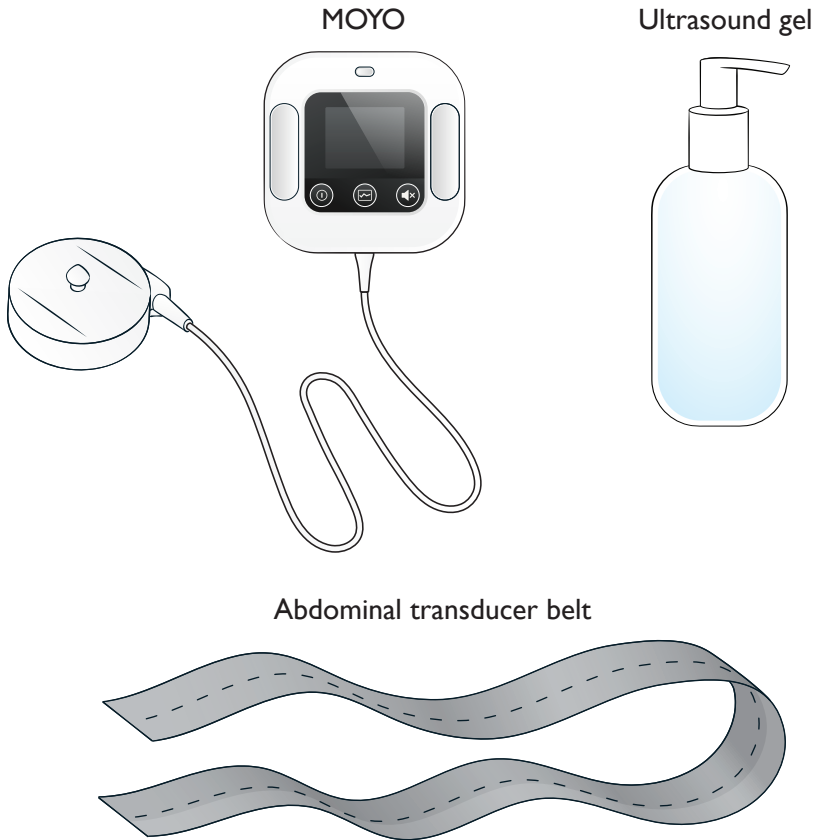



Use of Moyo does not replace clinical supervision.

Getting Started

To get started, this manual will take you through a few simple scenarios where you will learn the main functions of Moyo.

What you need:



 Only water-based ultrasound gel should be used. If ultrasound gel is not available, water can be used for short time monitoring.

 You should charge Moyo's battery regularly to ensure that it is always ready for use. To learn more about how to charge Moyo, refer to page 24.



To start using Moyo, press and hold the power button



PRACTICE

Turn on Moyo.

OBSERVE

Do you see the display turning on?
Do you hear the startup sound?

If you encountered a problem, go to
Troubleshooting on page 38.

Getting Started

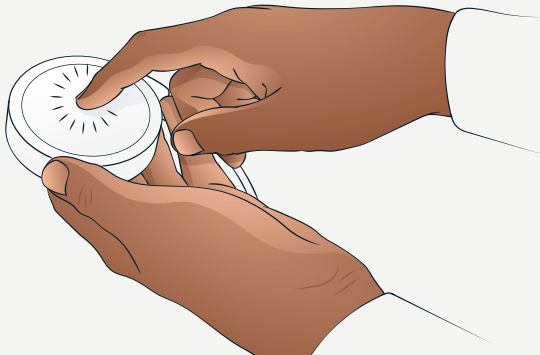


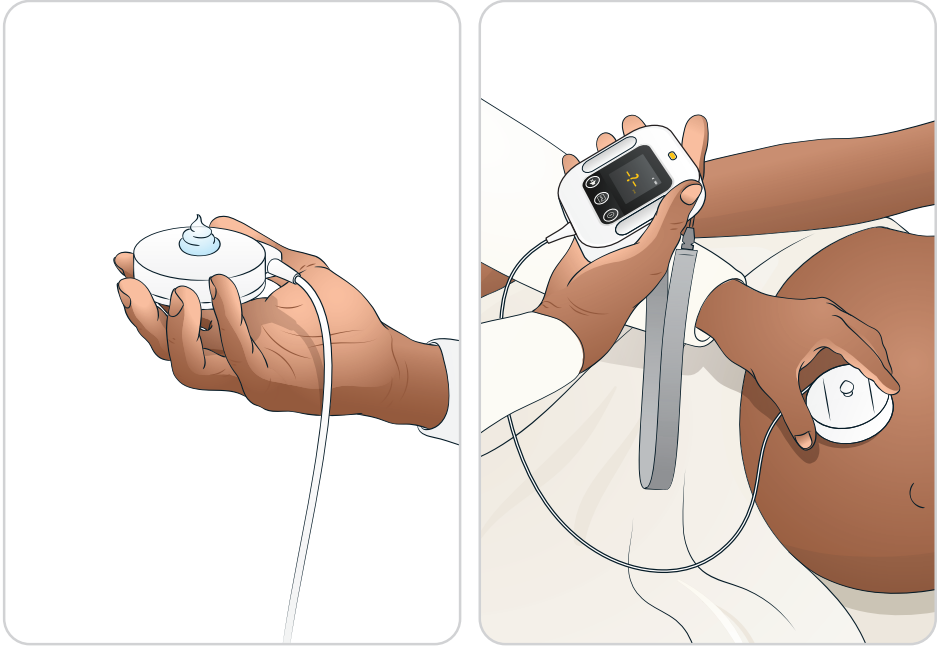
— ? — means that no heart rate (HR) is found by the sensor.



SIMULATION NOTE

You can tap on the sensor to manually simulate a HR when there is no dedicated FHR simulator available.





To measure fetal heart rate (FHR), you first need to apply gel on the ultrasound sensor and place it on the mother's abdomen (if possible over the fetal back). If no HR sound is heard, reposition the ultrasound sensor until you hear the rhythmic HR sound.



Palpate to identify fetal position. Best results will be achieved with the ultrasound sensor placed over the fetal back.

PRACTICE

Apply gel on the ultrasound sensor.

Place the ultrasound sensor on the mother's abdomen.

(Reposition the ultrasound sensor if you do not hear a rhythmic HR sound)



Moyo shows a HR number:
Green color means that HR is in the normal range for a fetus.
You can hear rhythmic HR sound from the speaker.

- Notice when FHR is shown, the status light blinks at the same rate as the FHR together with the rhythmic HR sound.
- To silence the Doppler sound, press "speaker on/off" button. Note that audible alarms will still be provided.

OBSERVE

Do you hear the rhythmic HR sound?
Do you read the numbers on the display?



If you are not sure that the found heart rate is the *fetal*, you can instruct the mother to hold the pads to measure mother's HR. If the two numbers are similar, then the HR found by the ultrasound sensor might be the maternal HR.



The ultrasound sensor might measure or be affected by mother's HR, a twin (multiples) or excessive patient movement/handling. In case the device displays unreliable or erratic FHR, try to reposition the ultrasound transducer or use alternative monitoring devices/methods.

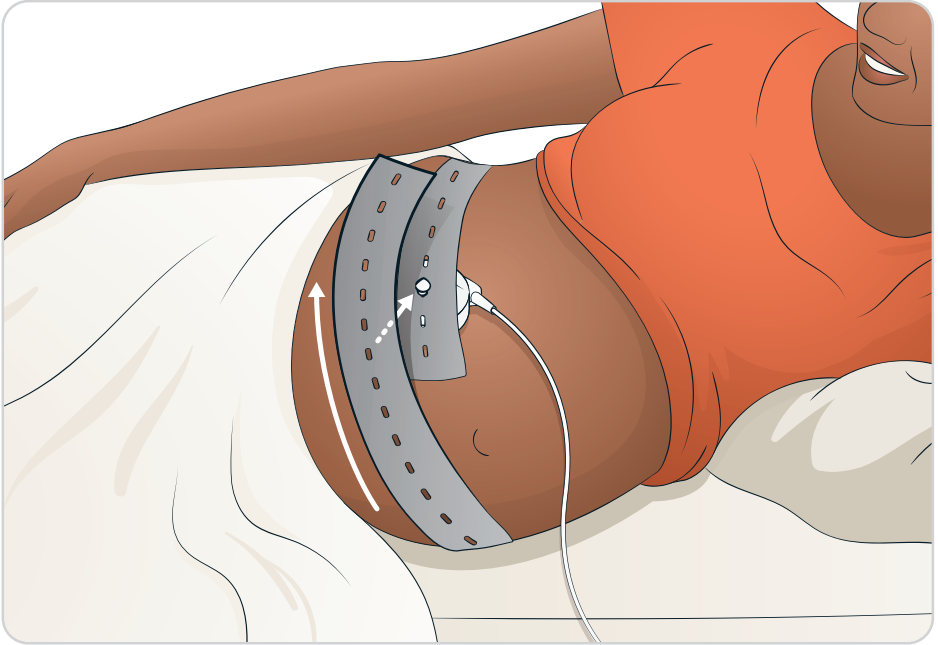


Refer to page 28 for details about the maternal HR display.

PRACTICE

Instruct the mother to hold the pads.

Compare the HR found by the ultrasound sensor with the maternal HR.



When you are sure that you have found the FHR, tighten the abdominal transducer belt around the mother to secure the ultrasound sensor in place.


PRACTICE

Keep the sensor in place using the abdominal transducer belt.

Lost FHR alarm



Moyo will give an alarm if the ultrasound sensor has not picked up any HR for 60 seconds. You will see the **— ? —** blinking, and hear an alarm sound.

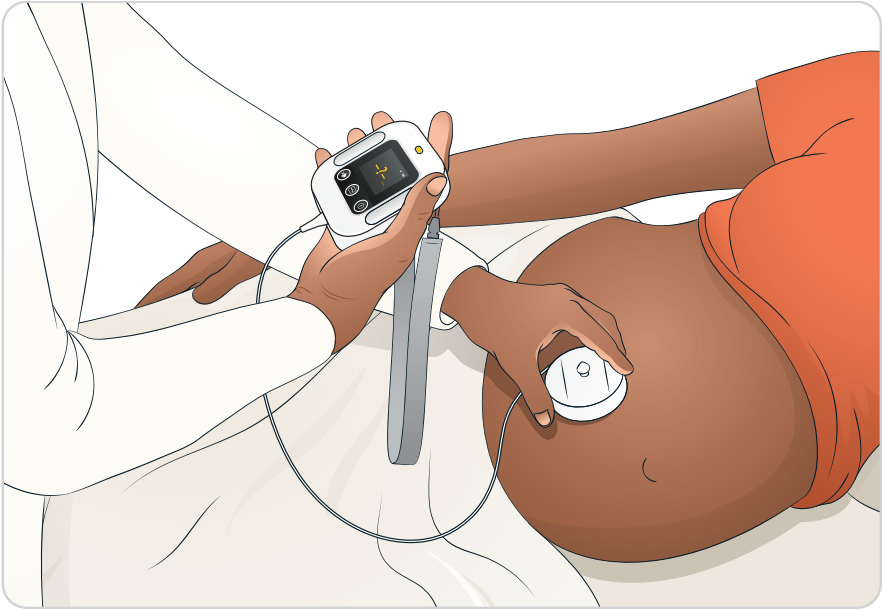
If you hear the alarm, press the speaker button  to silence (acknowledge) the alarm.

PRACTICE

Remove the ultrasound sensor from the mother, or stop simulating FHR, and wait more than 60 seconds.

OBSERVE

Did you hear the alarm sound?
Did you silence the alarm?



When **— ? —** is shown, reposition the ultrasound sensor to find the FHR.



If FHR is not found after repositioning the sensor, continue monitoring according to your medical procedures, e.g. using alternative devices to obtain FHR.



If you are not sure that the detected heart rate is the fetal, you can instruct the mother to hold the pads to obtain the maternal HR for comparison.

PRACTICE

Search and find the FHR.

Alarms

Abnormal FHR alarm

Moyo is designed to monitor FHR, and provide visual and auditory alarm when abnormal FHR is present over a prolonged period.

Moyo shows the number and status light in 3 different colors as shown below:

Abnormally high FHR (yellow and red)	More than 160 bpm
Normal FHR (green)	Between 110 - 160 bpm
Abnormally low FHR (yellow and red)	Less than 110 bpm



Yellow color turns red when abnormal FHR is present for a period of time.



To learn more about abnormal FHR alarm rules, refer to pages 35 and 40.


PRACTICE

Simulate / tap on the sensor for 3 minutes at the rate of e.g. 80 bpm (beats per minute) to trigger an abnormal FHR alarm.

After you have triggered the alarm, continue to the next page.



Moyo will give an alarm when the FHR has been abnormal for a prolonged time. You will see the status light and number in red color; and hear the alarm sound.

If you hear the alarm you can press the speaker button  to silence (acknowledge) the alarm.

OBSERVE

Did you hear the alarm sound?

Did you silence the alarm?

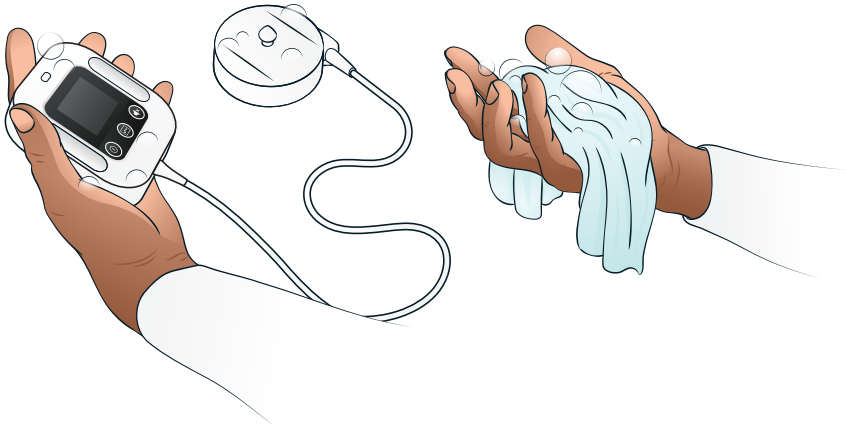
Continue standard procedures - respond in a timely and appropriate manner.

Reprocessing

Clean and disinfect Moyo and its accessories between patient uses to minimize the risk of cross-contamination. Inspect Moyo for damage between patient uses. Turn off Moyo before starting the cleaning process.

Main unit, cable and sensor

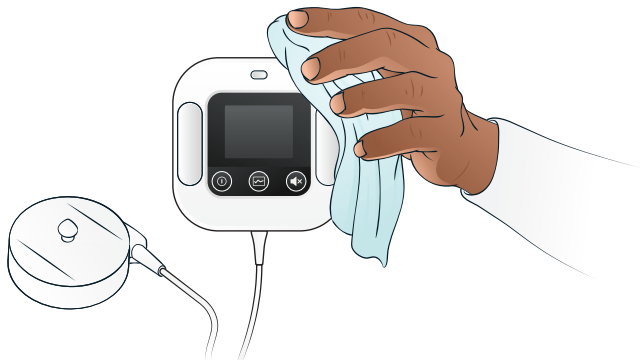
Cleaning



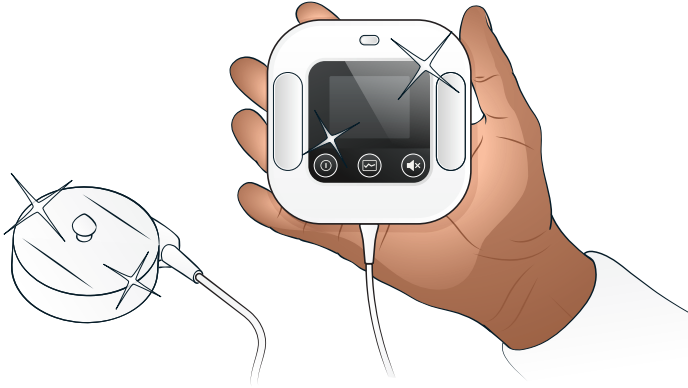
Thoroughly clean all surfaces using a cloth dampened with soapy water. A toothbrush dipped in soapy water can be used to remove difficult soil from the sensor.



The main unit must not be scrubbed with a brush to avoid getting water into the device.



Wipe Moyo with a clean cloth dampened with clean water; then leave to dry.



Inspect Moyo to confirm that it is clean and dry.
Repeat cleaning process until all visual soil has been removed.

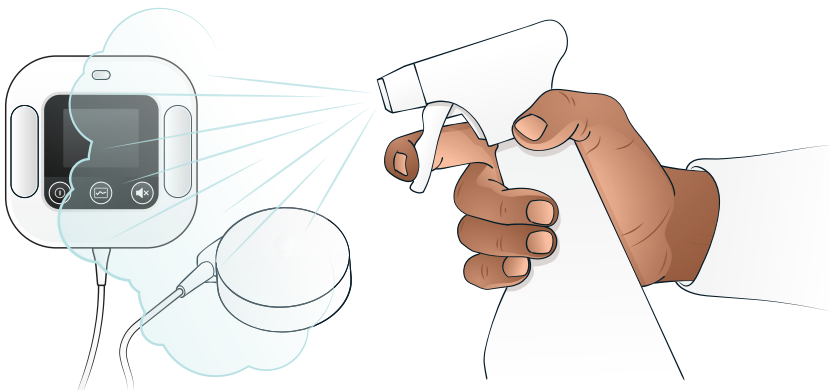
Disinfecting



Effective disinfection is not possible without first performing a thorough cleaning.

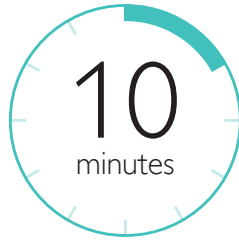


Care should be taken while handling the product between cleaning and disinfection.

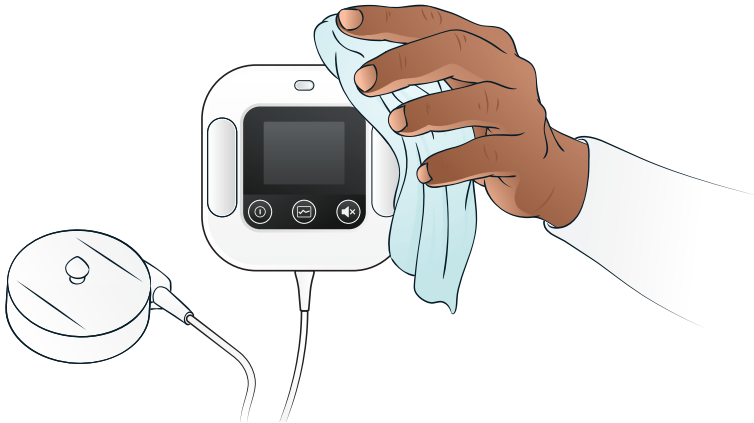


Spray 70% ethanol on the surface of Moyo, or wet Moyo with a clean cloth dampened with 70% ethanol.

Reprocessing



Let it stay for a minimum of 10 minutes.



Wipe Moyo with a clean cloth dampened with clean water, then let dry.



Do not dry this product using heating devices such as ovens or hair dryers.

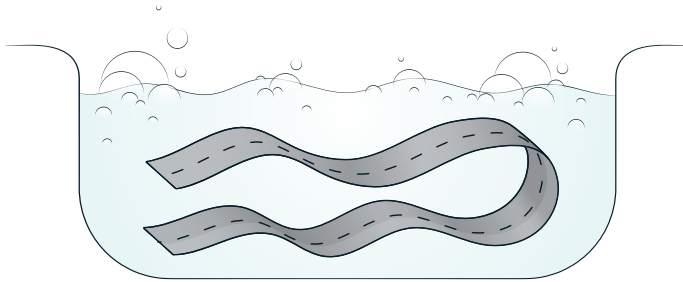
Inspection

Inspect Moyo main unit, the sensor and the cable after each use for cracks or damages. If there is any damage, refer to Troubleshooting section.

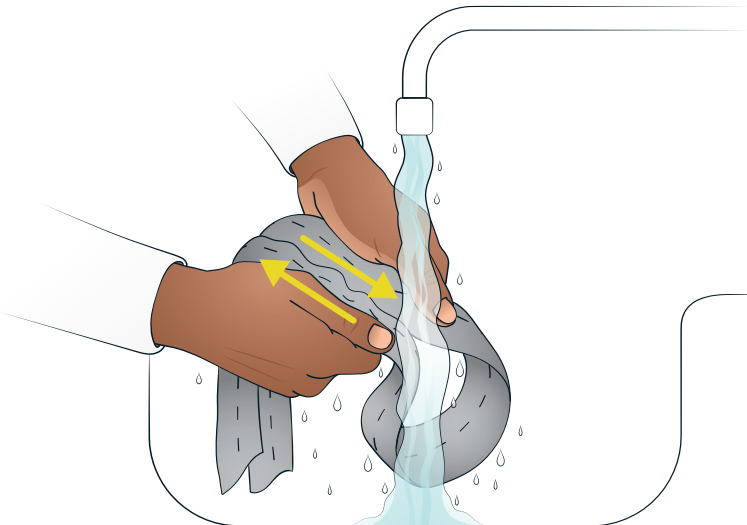
After you confirm that Moyo has no visual damage, turn on Moyo to verify that you hear the startup sound, and see that the display turns on as normal without any error message. Refer to Troubleshooting section if there is any error.

Abdominal transducer belt

Cleaning & Disinfecting

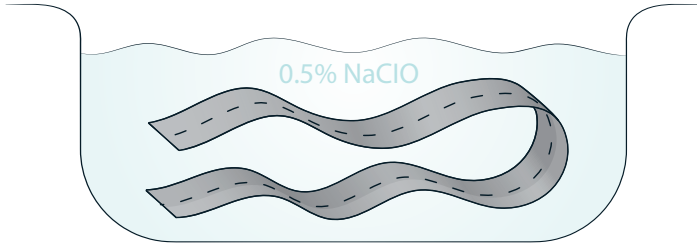


Submerge the belt in soapy water (10-40 °C), and keep for a minimum of 10 minutes.

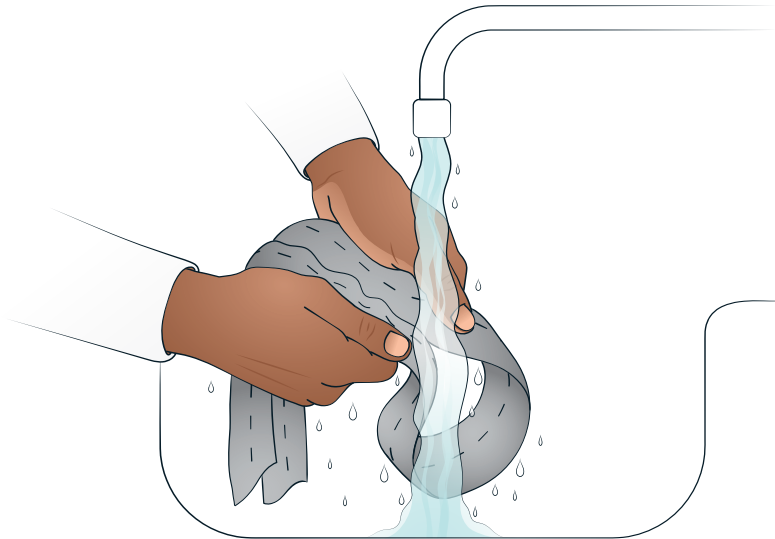


Rinse and scrub the belt by rubbing parts of the belt against each other under running tap water (10-40 °C) for a minimum of 2 minutes.

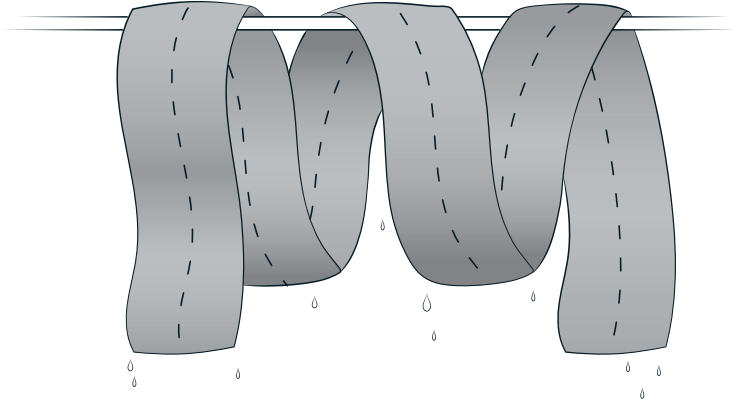
Reprocessing



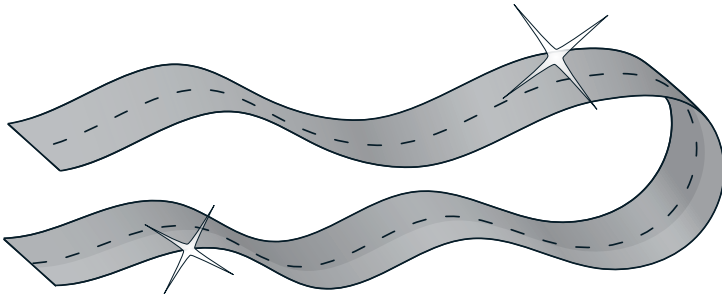
Submerge the belt in bleach containing 0.5% sodium hypochlorite (**NaClO**), and keep for a minimum of 30 minutes.



Rinse the belt under running tap water (10-40 °C) for a minimum of 2 minutes.



Let the belt air-dry.

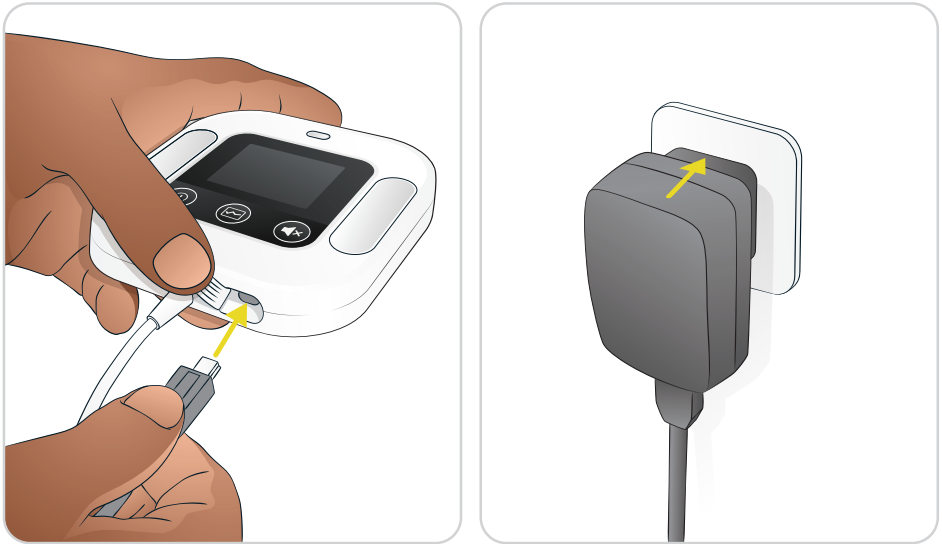


Inspect to confirm that belt is clean and dry.

Reprocessing

Charging


Moyo uses an internal rechargeable battery, which should be charged between patient uses or if the battery is low/empty. Use provided charger, model PSAI05R-050QL6-R, to charge the battery.




Open the rubber cover on Moyo and connect the power adaptor to it.


During charging, Moyo shows the battery status on the display:







 The device cannot be used clinically during charging.

 Charging time can be up to 5 hours when the battery is empty.

Power on/off

To turn on Moyo, press and hold the "power on/off" button  for at least 0.5 seconds. If Moyo is turned on using the "power on/off" button, Moyo beeps once and the LED blinks in green color to allow users to verify audio/speaker and light functionality.

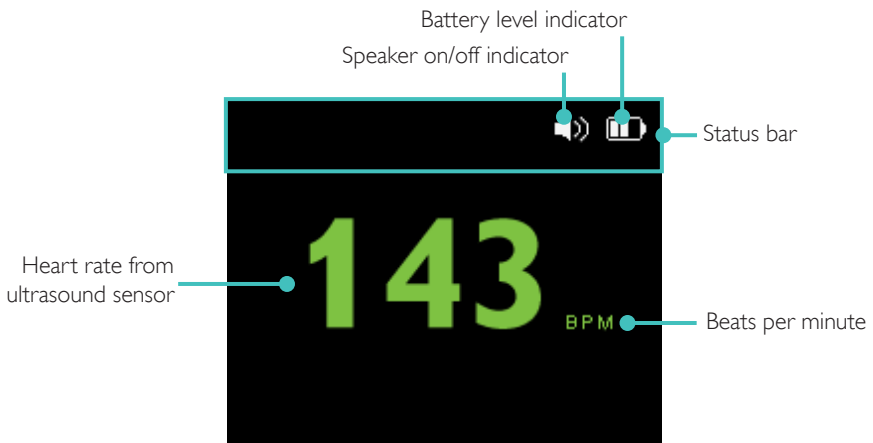
To turn off Moyo, press and hold the "power on/off" button  for at least than 1.5 seconds.

 **Technical / verbose startup:** If the "history graph" button  is pressed while turning on  Moyo, technical information including the software version will be shown on the display.

 Moyo will turn off automatically after 5 minutes of inactivity.


Display

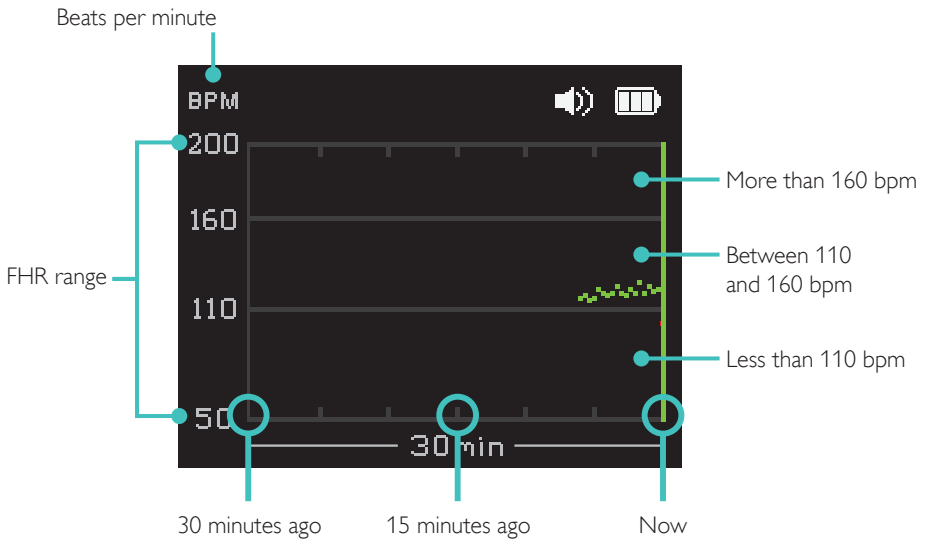
The default display providing FHR is shown below:



As an addition to the default display, there are two functions in Moyo that enable the user to view additional information on the display. These displays are only shown momentarily when the associated functions are enabled.

1. History Graph display

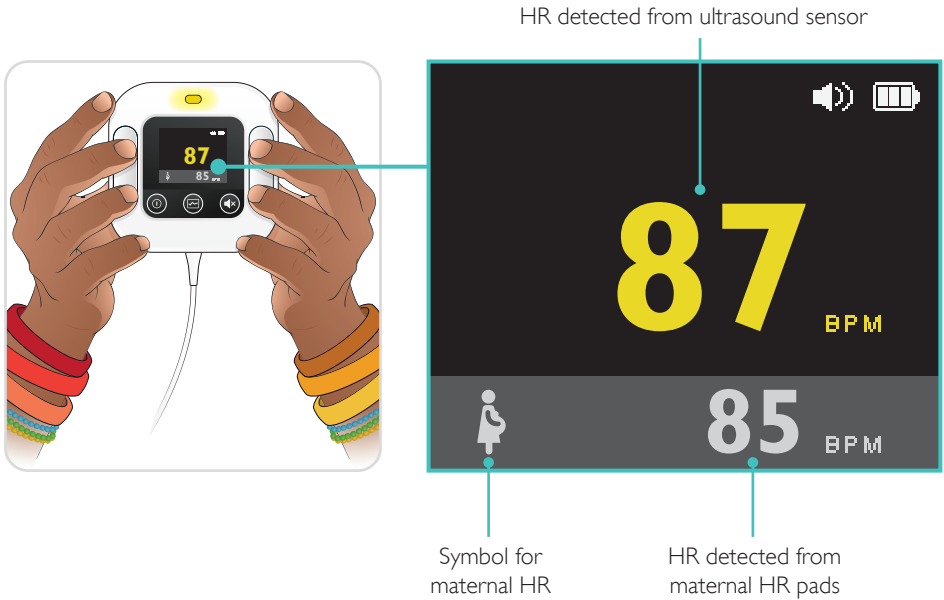
The HR that has been obtained from the ultrasound sensor during the last 30 minutes can be viewed on the History Graph. To view the History Graph, press and hold the "history graph" button  during use. The FHR range shown on the History Graph is between 50 to 200 bpm. See example below:



Features

2. Maternal HR display

When the pads are held by the mother, the display simultaneously shows the HR from the ultrasound sensor and the maternal HR. See illustration below:

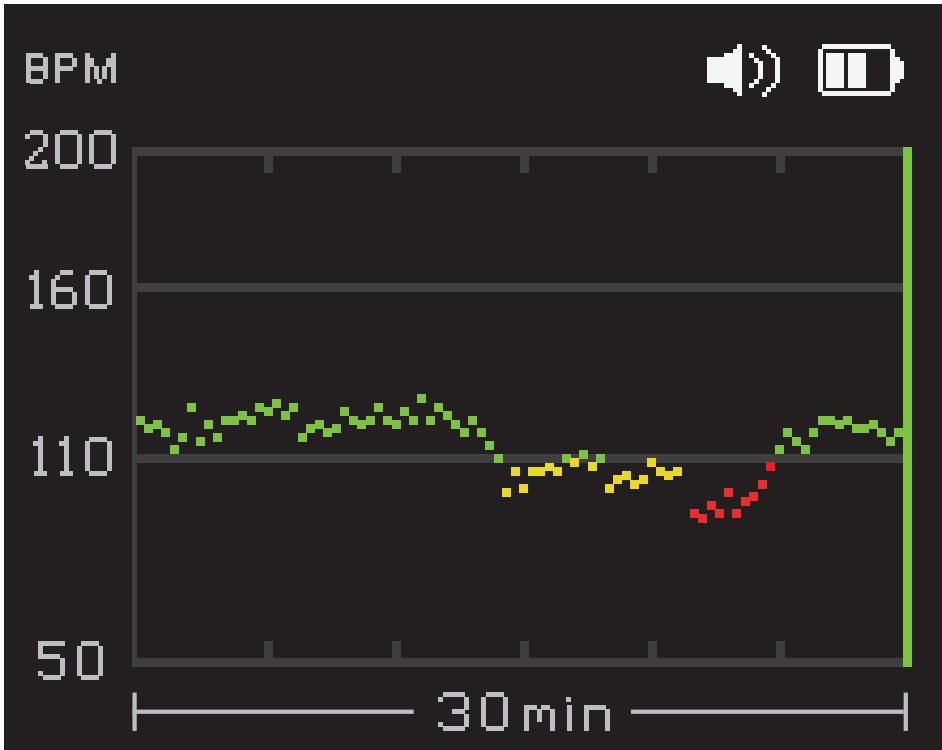


It is possible to pick up maternal signal sources, such as the aorta or other large vessels. When unsure if you are picking up the FHR or the maternal HR, check maternal HR to compare the two. This is especially relevant when you initially pick up a low HR from the ultrasound sensor which could be the mother's own HR.

While showing maternal heart rate, audio and blinking status light continues as in the previous state, i.e. corresponding to the FHR. To learn more about the status light, refer to page 35.

Colors

FHR is communicated with 3 different colors: green, yellow, red. Green is used when FHR is normal (between 110 - 160 bpm). Yellow and red are used when FHR is abnormal (less than 110 bpm or more than 160 bpm). Yellow color turns red when abnormal FHR is present for a period of time. These three different colors are used both on the FHR number and the history graph.



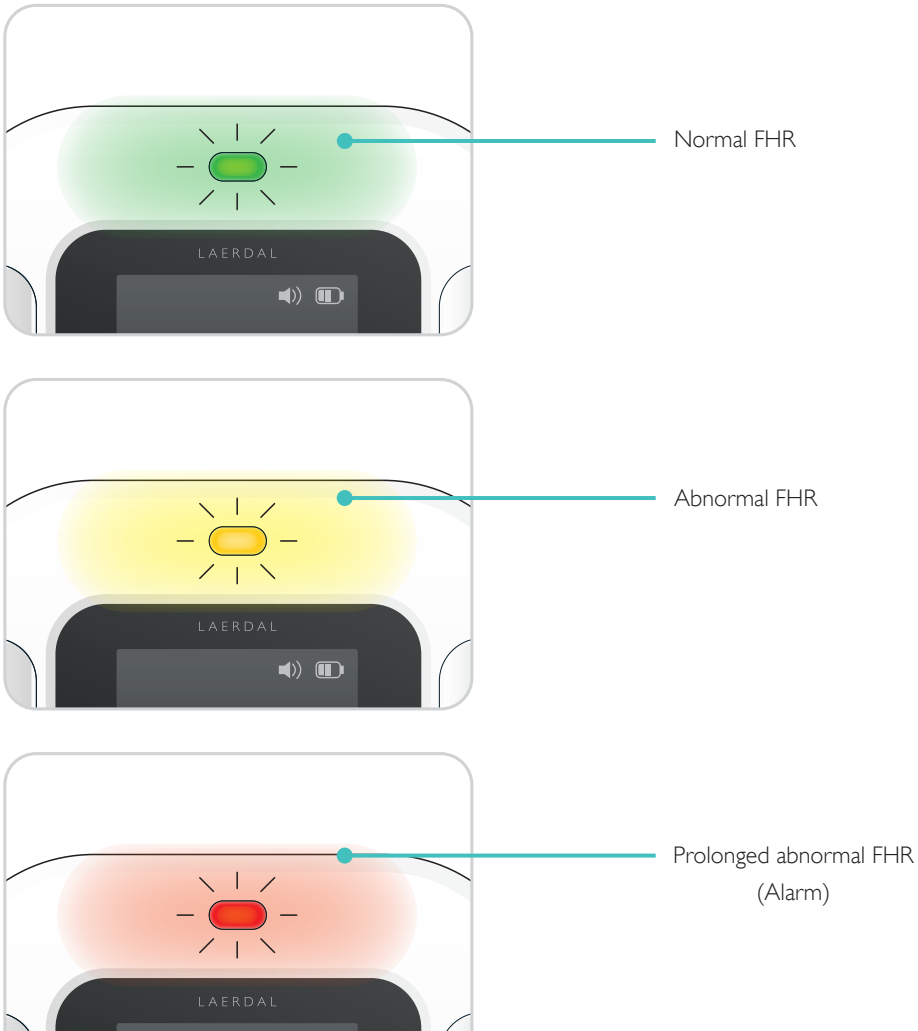
Each point on the History Graph represents a 20 second average of FHR recorded.



 Above numbers are used only for illustration purposes.

Status light

Together with the display, fetal heart rate is indicated with the status light. The status light on Moyo blinks with the same rate as the heart rate detected by the ultrasound sensor. The color of the light changes based on the FHR value as shown below:

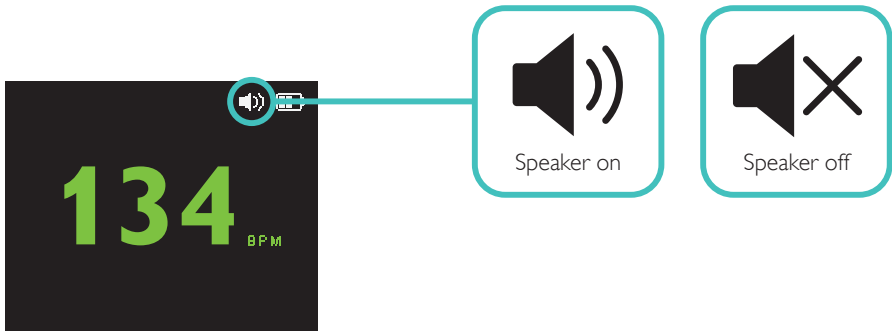


If there is no blinking light, it means that Moyo is unable to detect FHR.

Doppler sound

Moyo provides a Doppler sound, which can be silenced by pressing the speaker on/off button.

The speaker status is indicated with a symbol on the display as shown below:



When an alarm is triggered, the speaker is set to "on" automatically.



The Doppler sound continues after alarm is silenced. Press the "speaker on/off" button again to turn the speaker off.

Alarms

Moyo provides two types of alarms: soft alarm and abnormal FHR alarm. Soft alarm can be triggered for different reasons whereas the abnormal FHR alarm is only triggered when there is a prolonged abnormal FHR. See below for more detail:

Soft alarm

Triggered by: **Lost FHR or low battery**

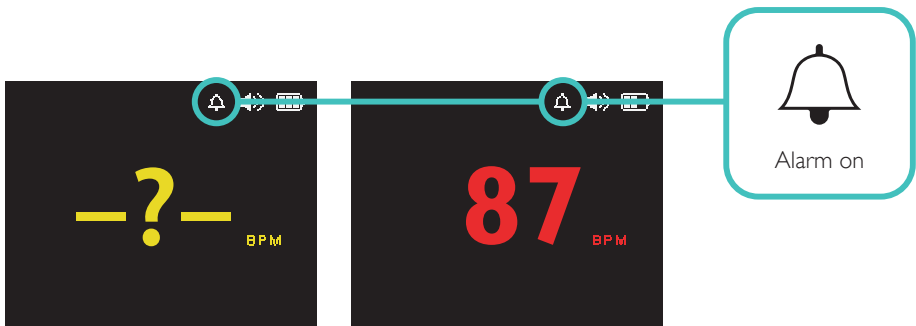
During soft alarm, a “ding-dong” sound is played every 30 seconds. Status light is off, and the icon associated with the alarm is shown on the display.

Abnormal FHR alarm


Triggered by: **Abnormal FHR over time**

During abnormal FHR alarm, three fixed-pitch pulses are played every 5 seconds. Heart rate numbers/history graph and status light are displayed in red color:

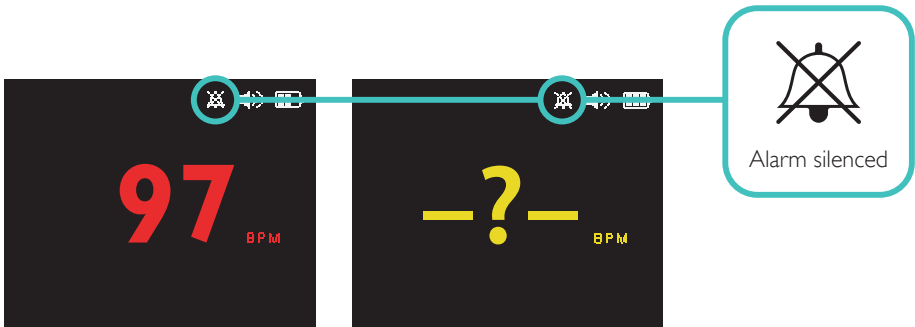
During an alarm, a “bell” icon is displayed on the status bar as shown below:



Silence/acknowledge alarm:

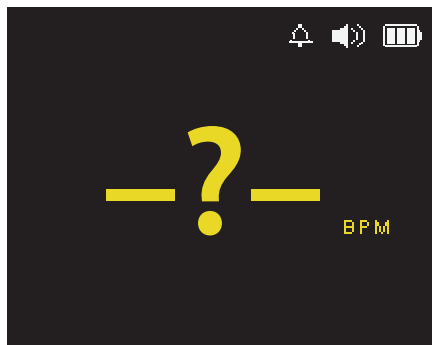
During an alarm, alarm sounds can be silenced if the “speaker on/off” button  is pressed. The silent state of the alarm lasts until current alarm is over (i.e. not time limited).

When an alarm is silenced, the alarm silenced symbol is shown on the display. This symbol will remain on the display until the alarm is over. See below:



Lost FHR alarm:

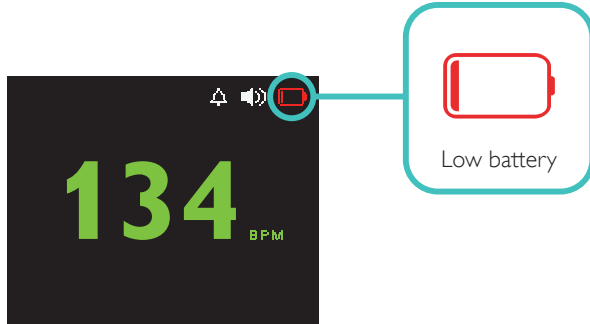
If FHR is lost for 60 seconds, a soft alarm is triggered. The soft alarm remains until a new FHR is detected. During a lost FHR alarm, a “ding-dong” sound is played every 30 seconds. The status light is off and the icon associated with the alarm is shown on the display.



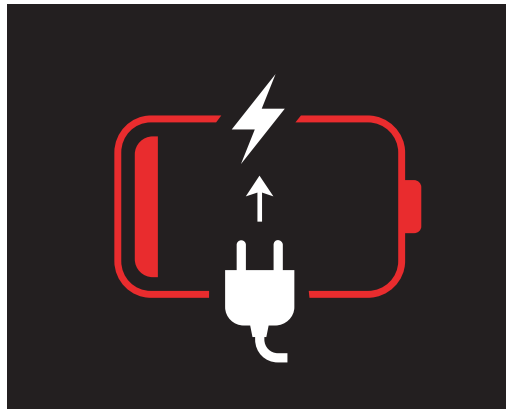
Features

Low battery alarm:

The low battery alarm is triggered when the battery status is low. A “ding-dong” sound is played every 30 seconds, and a blinking empty battery icon in the display status bar is shown as illustrated below:



If the battery drops to below critical level, Moyo will show the “battery empty” symbol on the display for three seconds, and then turn off automatically. See illustration below:



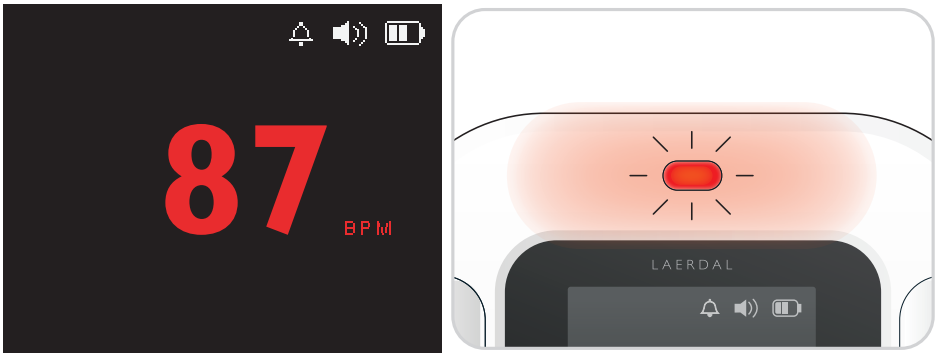
Battery empty





No other functionality is on/available when the battery is empty.


Abnormal fetal heart rate alarm:


When abnormal FHR is present over a prolonged period, the abnormal FHR alarm is activated. During abnormal FHR alarm, three fixed-pitch pulses are played every 5 seconds. The heart rate number and status light are displayed in red color.



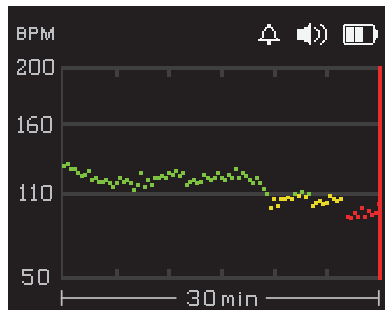
- 

More than 5 seconds of normal heart rate is required to end the abnormal heart rate alarm.
- 

If the HR is lost during abnormal FHR alarm, **— ? —** is displayed red. Status light will keep blinking at the most recent heart rate obtained. If the alarm is not silenced, three fixed-pitch pulses will continue to signal.
- 

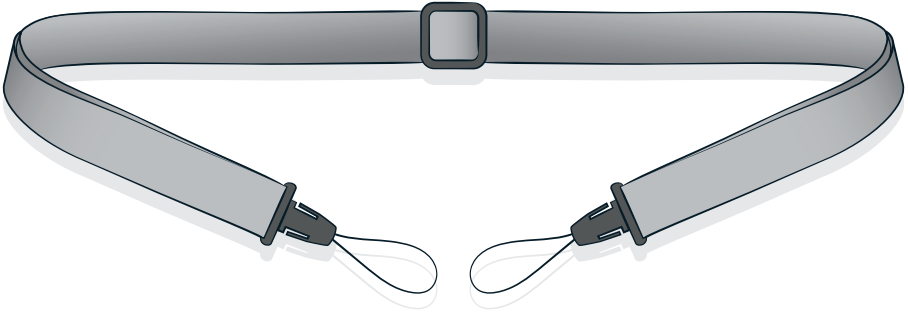
If the abnormal FHR alarm is silenced and no HR is detected within 60 seconds, the soft alarm will be activated, turning the **— ? —** into yellow.
- 

When the History Graph is shown, the points outside the "normal FHR range" are colored red during the abnormal FHR alarm. See example below:

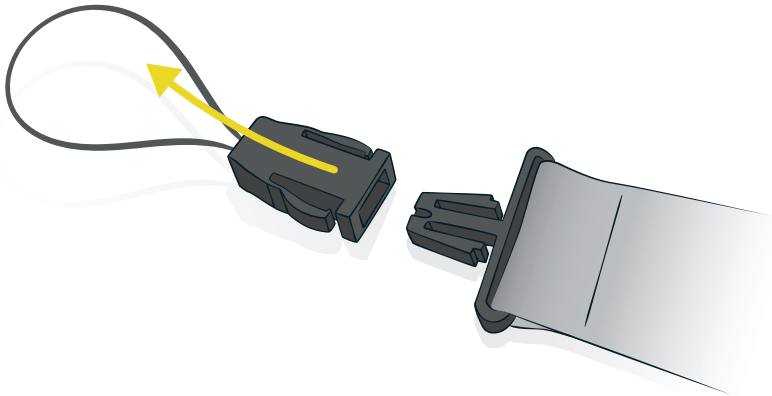


Neck strap

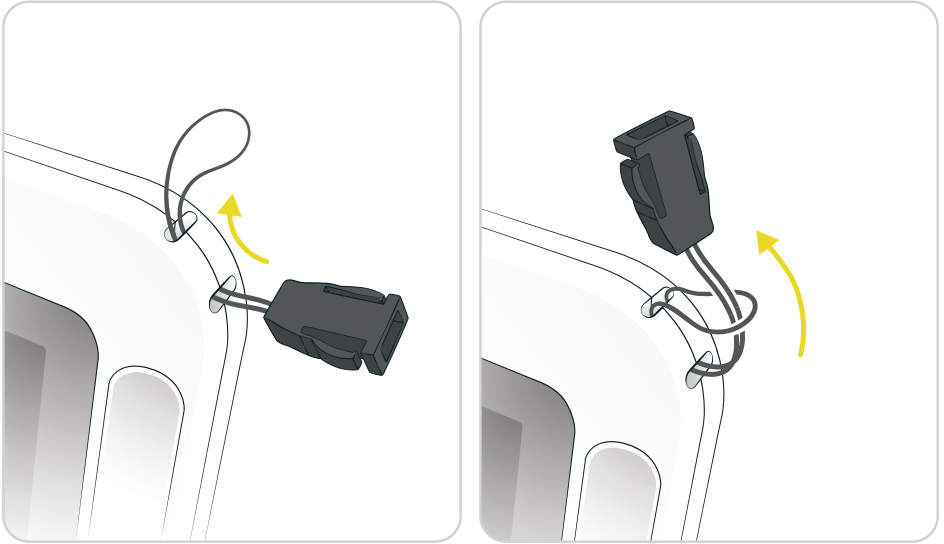
The provided neck strap is designed to enable mobility of the mother during continuous FHR monitoring. Attaching the neck strap to Moyo is explained below:



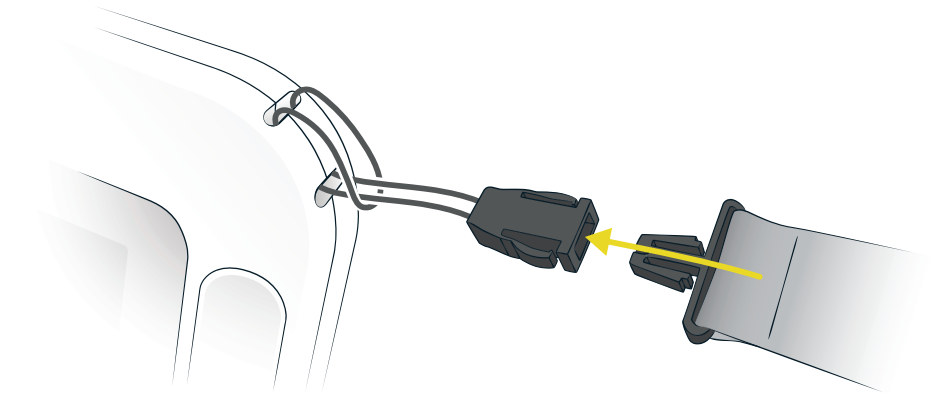
Inspect that the neck strap is undamaged and clean.



Remove the ends of the neck strap by squeezing the tabs.



Thread the neck strap to Moyo.




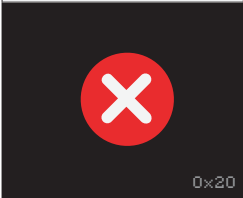
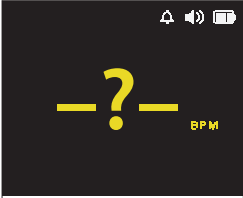
Reconnect the neck strap.

 When needed, the neck strap can be cleaned and disinfected following the same procedure as the abdominal transducer belt (see page 21).

Troubleshooting

The following table lists symptoms and messages that you may encounter, along with possible causes of the problem, and potential solutions. Symptoms are characterized by functionality.

 **In the case of device problems, continue your medical procedure. Do not allow long pauses while troubleshooting.**








SYMPTOM	POSSIBLE CAUSE	POSSIBLE SOLUTION
 <p>Critical Error</p>	<ul style="list-style-type: none"> • Critical technical error: Error code is shown in lower right corner of the display. See below for description of error codes: <ul style="list-style-type: none"> • 0x01 - Program memory checksum error • 0x02 - Calibration memory checksum error • 0x04 - Voltage regulator error • 0x08 - RTC crystal error • 0x10 - Display communication error • 0x20 - Ultrasound transducer communication error • 0x40 - Fuel gauge error • 0x80 - SD card error 	<ul style="list-style-type: none"> • Continue standard procedure without use of the device. • Use alternative means of measuring fetal heart rate, e.g. a pinard fetoscope. • Restart the Moyo, if the problem persists, the device is broken and should not be used. • If under warranty, contact Laerdal Global Health.
 <p>Heart rate is not detected.</p>	<ul style="list-style-type: none"> • Ultrasound transducer is misplaced or not on the indirect patient (mother). • Stimulation/movement/handling of patient temporarily generating too much noise. • Heart rate below 50 bpm. 	<ul style="list-style-type: none"> • If persistent question mark on screen: <ul style="list-style-type: none"> - Palpate to find fetal back and place ultrasound sensor. - Check if enough gel is used. - Check if abdominal transducer belt is tight. • If the problem continues, use alternative means of measuring fetal heart rate, e.g. a pinard fetoscope.

SYMPTOM	POSSIBLE CAUSE	POSSIBLE SOLUTION
<p>Device does not start up or there is power loss during use.</p>	<ul style="list-style-type: none"> • Battery depleted. 	<ul style="list-style-type: none"> • Continue standard procedure without use of the device. • After the standard procedure: connect the charger cable to the device, and charge. • If the problem persists, the device is broken and should not be used. • If under warranty, contact Laerdal Global Health.
<p>Nonfunctional or damaged part detected during equipment inspection.</p>		<ul style="list-style-type: none"> • If under warranty, contact Laerdal Global Health.
<p>No startup sound is audible.</p>	<ul style="list-style-type: none"> • Speaker is not functioning. 	<ul style="list-style-type: none"> • Continue standard procedure without use of the device. • Restart the Moyo, if the problem persists, the device is broken and should not be used. • If under warranty, contact Laerdal Global Health.

Technical Description

Symbol Glossary

CE₂₄₆₀ This product is in compliance with the essential requirements of EU Council directive 93/42/ EEC as amended by EU Council directive 2007/47/EC, and EU Council directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

	Manufacturer
	This product is marked according to the European directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE). Dispose of in accordance with your country's requirements.
	Meets IEC type BF applied part leakage current requirements.
	Protected against ingress of solid foreign objects >1.0 mm in diameter and vertically dripping water.
	Follow instructions for use.
	Note symbol
	Warning / Caution symbol

Specifications

HEART RATE MEASUREMENT
ULTRASOUND TRANSDUCER
Display range: 50 – 250 bpm; no detectable heart rate or heart rate <50 bpm displayed as “-?-”
Accuracy: short term average ± 5 bpm, in the range 50 – 200 bpm
MATERNAL HR ELECTRODES
Display range: 30 – 250 bpm; no detectable heart rate or heart rate <30 bpm displayed as “-?-”
Accuracy: short term average $\pm 5\%$ or ± 5 bpm, whichever is greater; in the range 50 – 150 bpm
FHR ALARM ALGORITHM
LOST FHR ALARM
No FHR or <50 bpm is detected by the ultrasound sensor lasting for 60 seconds. NOTE To enable this alarm, the device must have first measured good quality FHR for at least 10 seconds.
ABNORMAL FHR ALARM
<100 bpm or >180 bpm is detected by the ultrasound sensor for >3 minutes
Between 100 – 110 bpm or 160 – 180 bpm is detected by the ultrasound sensor for >10 minutes
Alarm sound pressure level: 72 dB(A)

POWER
Internal rechargeable battery, Lithium-ion, 3.7V, 2400 mAh
Battery run time (full charge on fresh battery): >10 hours
Battery charger: Model PSAI05R-050QL6-R. Input 100-240V AC, 50-60 Hz, 0.3 A. Output 5V DC, 1 A. USB connector:

ULTRASOUND TRANSDUCER TECHNICAL DATA
Mode: Nine-crystal Pulsed Wave Doppler Ultrasound
Frequency: 1 MHz
Thermal index (TI) and mechanical index (MI) are always below 1.0.

ENVIRONMENTAL
Operating temperature: 0 °C to 40 °C
Operating atmospheric pressure: 800 hPa – 1060 hPa
Storage/shipping temperature: -30 °C to 70 °C
Storage/shipping atmospheric pressure: 550 hPa – 1060 hPa
Operating/storage/shipping humidity: Up to 95% relative humidity, non-condensing
Ingress protection: IP41

MATERIALS
Main unit: ABS/PC, stainless steel
Ultrasound transducer: ABS
Abdominal belt: high elastic polyester; non-latex
Neck strap: Polyester; non-latex

DIMENSIONS
Size: 96 × 96 × 24 mm (W × H × D, without cable and ultrasound transducer)
Weight: 300 g (main unit + ultrasound transducer)

Maintenance

Moyo does not have any replaceable or serviceable parts, including the battery.

Technical Description

Electromagnetic Conformity

Moyo is intended for use in the following environments: Health care facilities except for near HF surgical equipment and the RF shielded room for magnetic resonance imaging.

List of cables and battery charger with which Moyo is in compliance with the IEC 60601-1-2 EMC standard:

- Charger PSAl05R-050QL6-R and USB cable, type A to mini type B, 1.5 m

No particular actions are required to maintain safety and performance with regard to electromagnetic disturbances for the expected service life.



Warnings

- *Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.*
- *Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.*
- *Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of Moyo, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.*

Electromagnetic Emissions Tests

EMISSIONS TEST	STANDARD OR TEST METHOD	COMPLIANCE
RF emissions	CISPR 11	Group 1 Class B
Harmonic emissions	IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions	IEC 61000-3-3	Complies

Electromagnetic Immunity Tests

IMMUNITY TEST	STANDARD OR TEST METHOD	COMPLIANCE LEVEL AND IMMUNITY TEST LEVEL
Electrostatic discharge	IEC 61000-4-2	± 2 kV, ± 4 kV, ± 6 kV contact ± 2 kV, ± 4 kV, ± 8 kV air
Radiated RF EM fields	IEC 61000-4-3	3 V/m 80 MHz – 2.5 GHz 80% AM at 2 Hz & 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Not tested
Rated power frequency magnetic fields	IEC 61000-4-8	3 A/m 50 Hz or 60 Hz
Electrical fast transients / bursts	IEC 61000-4-4	± 2 kV 5 kHz repetition frequency
Surges: Line-to-line	IEC 61000-4-5	± 0.5 kV, ± 1 kV
Surges: Line-to-ground	IEC 61000-4-5	± 0.5 kV, ± 1 kV, ± 2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V; 0.15 MHz – 80 MHz 10V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Voltage dips	IEC 61000-4-11	$<5\% U_T$ ($>95\%$ dip in U_T) for 0.5 cycle $40\% U_T$ (60 % dip in U_T) for 5 cycles $70\% U_T$ (30 % dip in U_T) for 25 cycles
Voltage interruptions,	IEC 61000-4-11	$<5\% U_T$ ($>95\%$ dip in U_T) for 5 s

U_T is the a.c. mains voltage prior to application of the test level.

Accessories and spare parts

CAT.NO	DESCRIPTION
510-10150	Abdominal transducer belt (package of 3)
510-10250	Neck strap (package of 3)

Technical Description

Waste Handling



European Directive 2012/19/EU (WEEE)

WEEE: this appliance is marked according to the European directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE). By ensuring this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this product.

Moyo contains electronic components. Dispose of it at an appropriate recycling facility in accordance with local regulations.

Global Warranty

See www.laerdal.com

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US and International patents pending.
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