

Moyo

Fetal Heart Rate Monitor

User Guide





Contents

Clinical Indications	4
Overview	5
Important Information	6
Getting Started	7
Alarms	14
Reprocessing	18
Charging	21
Features	22
Troubleshooting	34
Specifications	36

Clinical Indications

Device description

Moyo is a fetal heart rate monitor using Doppler ultrasound technology.

Indication for use

Moyo is indicated to be used during labor to monitor the fetal heart rate.

Intended use

Moyo is intended to monitor the fetal heart rate.

Intended users

Moyo is intended to be used by healthcare professionals.

Intended Use Environment

Obstetric healthcare facilities.

Clinical Benefit

Positive effect on obstetric management by monitoring the fetal heart rate.

Clinical Outcome

Desired outcome of fetal heart rate monitoring is recognition of non-reassuring fetal status to enable appropriate obstetric interventions.

Known Side Effects

Continuous fetal heart rate monitoring may increase the rate of cesarean sections and operative vaginal deliveries.



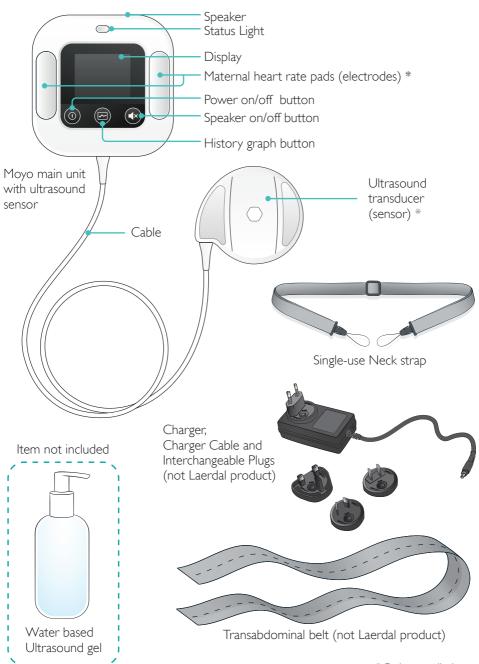
This side effect is not specific to Moyo.

Contraindications

None known

Limitations of the device

Not suitable for use on pregnancies with multiple fetuses.



Important Information

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



- Care should be taken in cases of obesity of the mother, position of the baby and/or mother and polyhydramnios or olygohydramnios, as it may be difficult to obtain a fetal heart rate.
- 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.
- Care should be taken before initiating C-section procedure. Alternative methods should be used to confirm need for C-section.



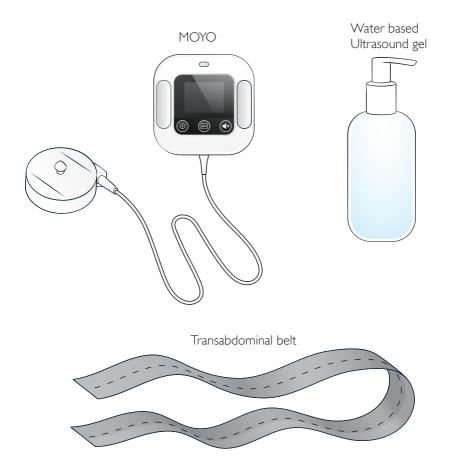
Should any serious malfunction, undesirable incident with, or deterioration in the functionality or performance of the device occur, contact Laerdal promptly. The competent authority where the incident took place and/or the device was used should also be notified.

Before Use

Clean and disinfect Moyo as described in Reprocessing. Charge Moyo as described in Charging.

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.



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 charging section.



To start using Moyo, press and hold the power button



PRACTICE

Turn on Moyo.

OBSERVE

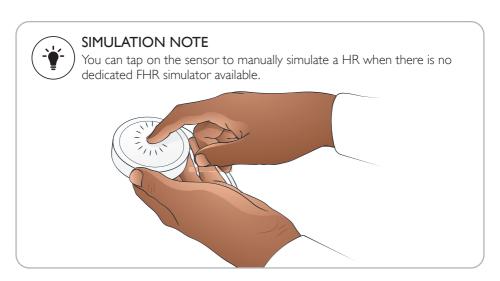
Do you see the display turning on?

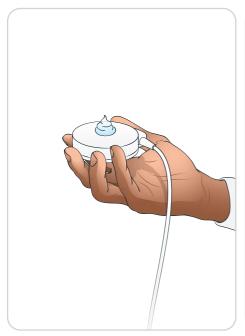
Do you hear the startup sound?

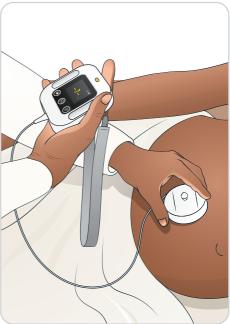
If you encountered a problem, go to Troubleshooting on page 38.



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







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.

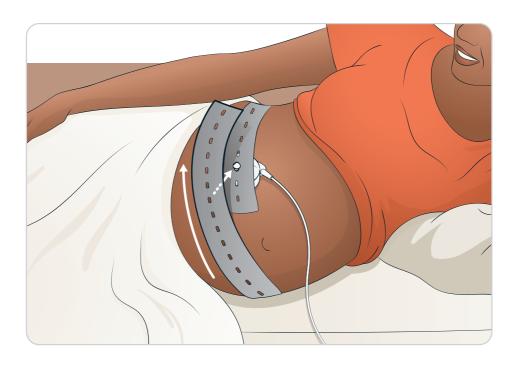


Refer to "Maternal HR display" in Features section for details about the maternal HR display.

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 transabdominal belt around the mother to secure the ultrasound sensor in place.

PRACTICE

Keep the sensor in place using the transabdominal belt.



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 (acknowledge) the alarm.



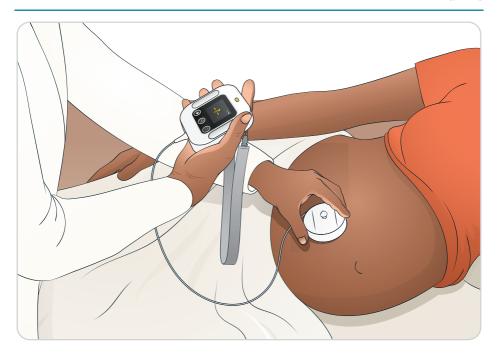
PRACTICE

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.

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 (x) to silence (acknowledge) the alarm.



OBSERVE

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

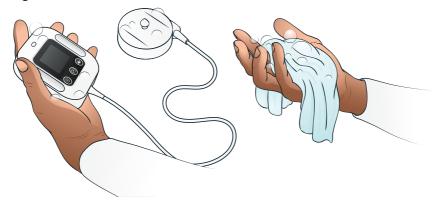
Continue standard procedures - respond in a timely and appropriate manner.

Reprocessing

Clean and disinfect Moyo after each patient use to minimize the risk of cross-contamination. Turn off Moyo before starting the cleaning process.

Main unit, cable and sensor

Cleaning



1. Clean all surfaces of Moyo main unit, ultrasound transducer and cable using a cloth dampened with lukewarm (30 to 40 °C, 86 to 104 °F) tap water with mild dishwashing detergent for 30 seconds. To remove difficult soil, use a bristled brush (e.g. toothbrush) dipped in the cleaning solution. Note; Only on front surface of Moyo main unit. Clean for a minimum of 1 minute, ensuring that all soil has been removed.



- 2. Repeat above process with new clean cloth.
- 3. Rinse Moyo main unit, ultrasound transducer and cable with a clean cloth dampened with lukewarm tap water, for 30 seconds.



4. Dry Moyo using a clean cloth or by air drying.

Disinfecting



- Effective disinfection is not possible without first performing a thorough cleaning.
- Care should be taken while handling the product between cleaning and disinfection.
- 1. Wipe all surfaces of Moyo main unit, ultrasound transducer and cable with a clean cloth dampened with 70% ethanol for a minimum of 2 minutes.



2. Spray 70% ethanol on front surface of Moyo main unit and all surfaces of ultrasound transducer and cable.



Ensure the surfaces remain wet for a minimum of 12 minutes. Repeat spraying as necessary to account for evaporation.



3. Allow to air 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.

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.

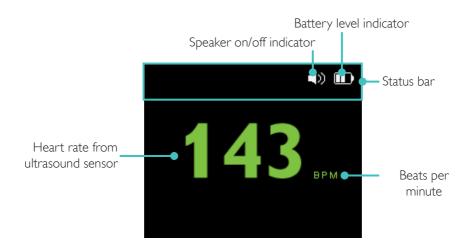
To turn off Moyo, press and hold the "power on/off" button off for at least 1.5 seconds.



- 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

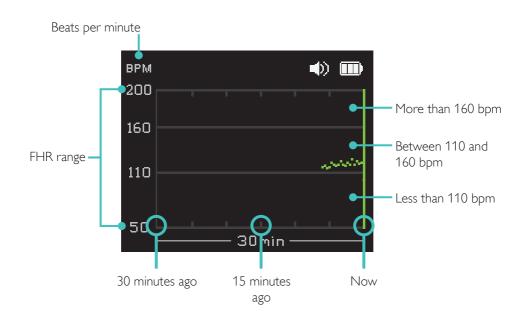
The default display providing FHR is shown below:



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.

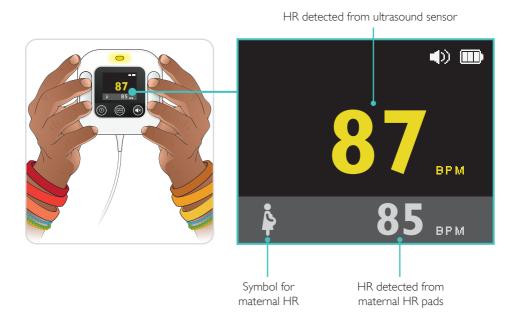
1. History Graph display

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 shown on the History Graph is between 50 to 200 bpm. See example below:



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 "Status light" section.

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.

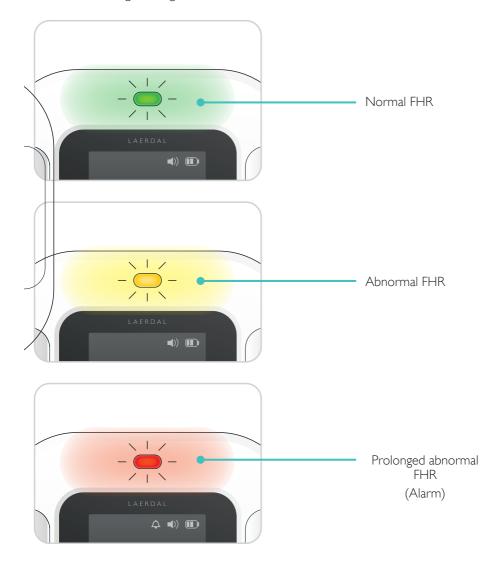




Above numbers are used only for illustration purposes.

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:



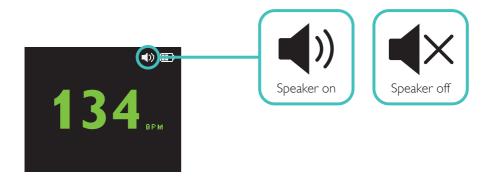
Note

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.

Features

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

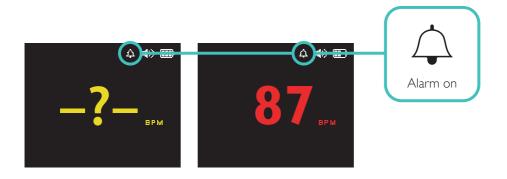
During soft alarm, a "ding-dong" sound is played every 30 seconds. Status light is off, and the icon associated with the alarm is shown on the display.

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.

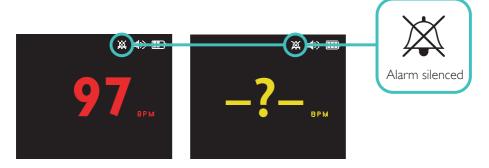
During an alarm, a "bell" icon is displayed on the status bar as shown below:



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.

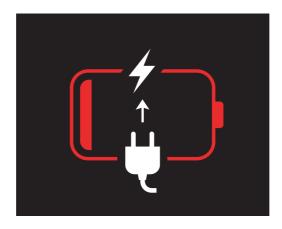


Low battery alarm:

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.





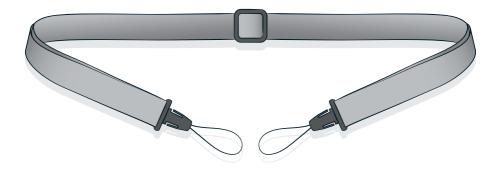
- More than 5 seconds of normal heart rate is required to end the abnormal heart rate alarm.
- If the HR is lost during abnormal FHR alarm, ? is displayed red. Status light will keep blinking at the most recent heart rate obtained. If the alarm is not silenced, three fixed-pitch pulses will continue 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:



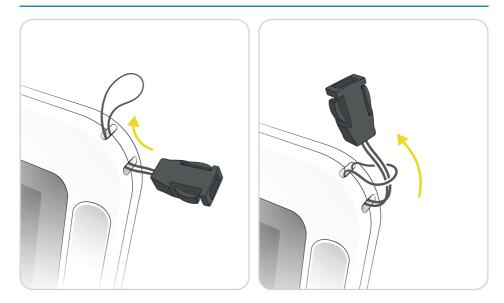
Features

Single-use Neck strap

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







Thread the neck strap to Moyo.



Reconnect the neck strap. Remove the neck strap after each patient use.



The neck strap is single-use and reuse may lead to cross-contamination.

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.



Caution

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

SYMPTOM	POSSIBLE CAUSE	POSSIBLE SOLUTION
Critical Error	Critical technical error. Error code is shown in lower right corner of the display. See below for description of error codes: Ox01 - Program memory checksum error Ox02 - Calibration memory checksum error Ox04 - Voltage regulator error Ox08 - RTC crystal error Ox10 - Display communication error Ox20 - Ultrasound transducer communication error Ox40 - Fuel gauge error Ox40 - SD card error	 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.
Heart rate is not detected.	 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. 	 If persistent question mark on screen: Palpate to find fetal back and place ultrasound sensor: Check if enough gel is used. Check if transabdominal belt is tight. If the problem continues, use alternative means of measuring fetal heart rate, e.g. a pinard fetoscope.

Troubleshooting

SYMPTOM	POSSIBLE CAUSE	POSSIBLE SOLUTION
Device does not start up or there is power	Battery depleted.	Continue standard procedure without use of the device.
loss during use.		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.
Nonfunctional or damaged part detected during equipment inspection.		If under warranty, contact Laerdal Global Health.
No startup sound is audible.	Speaker is not functioning.	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.

Specifications

LOSSARY
This medical device is in compliance with the general safety and performance requirements of Regulation (EU) 2017/745 on medical devices. This product is in compliance with Council Directive 2014/53/EU on Radio Equipment (RED) and Council Directive 2011/65/EU on restriction of the use of certain hazardous substances (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
Medical device
GTIN (Global Trade Item Number) + Serial Number
Temperature limitation
Atmospheric pressure limitation
Humidity limitation

FHR	ALARM	I ALGO	RITHM

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)

DESCRIPTION	SPECIFICATION
Heart rate measurement - Ultrasound Transducer	Accuracy: short term average ±5 bpm, in the range 50 – 200 bpm No detectable heart rate, or heart rate <50 bpm, is displayed as ''-?-''
Heart rate measurement - Maternal HR Electrodes	Accuracy: short term average $\pm 5\%$ or ± 5 bpm, whichever is greater, in the range $50-150$ bpm No detectable heart rate, or heart rate <30 bpm, is displayed as "-?-"

POWER	
Internal rechargable battery, Lithium-ion, 3.7 V, 2400 mAh	
Battery run time (full charge on fresh battery): >10 hours	
Battery charger: Model PSAI05R-050QL6-R. Input 100-240 V AC, 50-60 Hz, 0.3 A. Output 5 V 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
Short term storage/shipping (24 h): -20 °C to 60 °C
Long-term storage: Room temperature (23 °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/PC
Single-use Neck strap: Polyester; non-latex

LIFETIME PARAMETERS	
Shelf life	2 years at room temperature (23 °C)
Expected Service Life	100 cycles of reprocessing

DIMENSIONS	
Size: $96 \times 96 \times 24$ mm (W x H x 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.

Specifications

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 PSAI05R-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.



- 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
Radiated RF emissions	CISPR 11	Group 1 Class B
Conducted RF emissions	CISPR 11	Group 1 Class B
Harmonic distortion	IEC 61000-3-2	Class A
Voltage fluctuations/ flicker	IEC 61000-3-3	Complies

Specifications

Electromagnetic Immunity Tests

IMMUNITY TEST	STANDARD OR TEST METHOD	IMMUNITY TEST LEVEL
Electrostatic discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated RF EM fields	IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80% AM at 2 Hz & 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	380-390 MHz: 27 V/m 430-470 MHz: 28 V/m 704-787 MHz: 9 V/m 800-960 MHz: 28 V/m 1700-1990 MHz: 28 V/m 2400-2470 MHz: 28 V/m 5100-5800 MHz: 9 V/m
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz
Proximity magnetic fields	IEC 61000-4-39	N/A
Electrical fast transients / bursts	IEC 61000-4-4	± 2 kV 100 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 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Voltage dips	IEC 61000-4-11	0% of $U_{\rm T}$ for 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° phase angles 0% of $U_{\rm T}$ for 1 cycle and 70% of $U_{\rm T}$ for 25/30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11	0% of U_{T} for 250/300 cycles
$\rm U_T$ is the a.c. mains voltage prior to	application of the test level.	1

Accessories

DESCRIPTION	
Transabdominal belt	
Power Supply	

Consumables

CAT. NO	DESCRIPTION
510-11050 / LGH-510-11050	Moyo Single-use Neck strap

Specifications

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. $\label{eq:lambda} \mbox{Laerdal} \mbox{\otimes is a registered trademark of Laerdal Medical AS.}$



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