Pulsenmore™

Pulsenmore ES
User Manual

Scan QR code to download the app

Federal (USA) law restricts this device to sale by or on the order of a physician.

Disclaimer

The Pulsenmore™ ES Ultrasound Device utilizes a smartphone to transmit an ultrasound image remotely to a clinician and/or qualified sonographer, via cloud services.
The device is neither certified nor intended to detect defects, replace a routine scan and/or pregnancy tests of any kind, or replace a medical consultation or a visit to the emergency room/clinic.
The decision of whether the device should be used in a particular case, and the decision regarding the medical consequences of the use is the physician's alone.
Do not use the device without a physician's prescription, as this may lead to an incorrect diagnosis or interpretation of the test findings.
Do not draw conclusions and/or act independently based on the findings of the ultrasound scan unless under direct medical supervision.
In any case of pain, bleeding, preterm rupture of membranes, suspicious vaginal discharge, fear of absence of fetal movements and/or change in fetal movements, deterioration of physical condition, or any other case that requires it, seek medical attention immediately.
Pulsenmore Ltd. is not responsible for any medical service provided as an accompaniment to the device, nor is it responsible for any clinical decisions (e.g., misdiagnosis, follow-up, and treatment) and instructions regarding the use of the device and the tests conducted on it.
Pulsenmore Ltd. is not responsible for any use of the ultrasound device, contrary to the indications and limitations provided herein.
The device is neither expected nor intended to function once the service provided by Pulsenmore has ended and continued use beyond this period may pose increased cybersecurity risks due to the absence of software updates or support.
This device is protected by patents listed at http://www.pulsenmore.com/patents

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Overview

Ultrasound scans are recommended for fetal assessment during pregnancy. Over the years, this technology has become the gold standard for routine check-ups, surveillance, and intervention for pregnant women worldwide.
The **Pulsenmore ES** ultrasound system is designed to enable the healthcare professional to review fetus ultrasound scans performed in the comfort of your home.

About this Manual

This manual is intended for the user of the **Pulsenmore ES** ultrasound system. It describes the system and its principles of operation. This manual provides instructions for using the device and the dedicated software application (mobile app) to perform ultrasound scanning at home.
This **Pulsenmore ES** User Manual includes:

- Important safety information about the **Pulsenmore ES** ultrasound device
- Instructions for how to set up, operate, and maintain the **Pulsenmore ES** ultrasound device
- Instructions for how to use the **Pulsenmore ES** user's mobile application (mobile app) software
- Troubleshooting information
- Maintenance information

Be sure to review this User Manual, including all safety information, before using the **Pulsenmore ES** ultrasound device. If you have any questions, contact your treating clinician (Service Provider).
All images are for illustration purposes only; actual products might differ from the pictures below.

Types of Notes

This User Manual is intended to assist in the safe and effective operation of the **Pulsenmore ES** ultrasound device. It is important that all users review and understand all instructions before operating the device, paying careful attention to the warnings and cautions throughout the manual. The following types of notes are used throughout this manual:

WARNING

Conditions, hazards, or unsafe practices that may result in serious personal injury or death.

CAUTION

Conditions, hazards, or unsafe practices may result in minor personal injury, damage to the device, or loss of data.

Note

Important information, emphasizing or supplementing the main text. The information does not relate directly to issues that may cause injury to patients or users, or damage to the system.

Intended Use/Indications for Use

The Pulsenmore ES ultrasound system is intended to enable the acquisition of ultrasound images that allow interpreting healthcare providers to determine fetal heart rate.
The Pulsenmore ES Ultrasound System is intended for limited diagnostic ultrasound imaging in B- Mode and M-Mode in Fetal/Obstetric applications, when traditional scanning at a health clinic is impractical or when the use of telehealth (clinician-guided mode) or software-guided self-scanning (App-guided mode) is in the best interests of the patient.
The device is intended to be used by pregnant women with a singleton pregnancy at the gestational age of 14-38 weeks, when clinically indicated to determine the heart rate on the order of a physician in non-clinical environments. When directed by their physician, the patient can either follow the steps specified by the ES software application (app-guided mode) or under the direction of a healthcare professional (clinician-guided mode).
A physician interprets the images acquired with the device in a remote access setup.
Access to the device operation must be granted by healthcare professionals.

Safety Information

This section provides you with safety instructions for operating the **Pulsenmore ES** ultrasound device.

General

The **Pulsenmore ES** ultrasound device is designed to be used in a home environment/ hospital/ professional healthcare facility.
The **Pulsenmore ES** ultrasound device is designed for single-patient use, to prevent cross contamination.
The **Pulsenmore ES** ultrasound system is designed to be used by patients with Body Mass Index under 40.
The **Pulsenmore ES** Type C and Tera ultrasound device has no internal power supply, buttons, or screen of its own.
The **Pulsenmore ES** Type iOS ultrasound device has an internal power supply and an ON/OFF button. It has no screen of its own.
When a smartphone is connected and a scan is performed, the ultrasound images can be displayed on the smartphone screen.
The **Pulsenmore ES** ultrasound system applies the ALARA (As Low As Reasonably Achievable) principle as follows:

- The system provides only 2D imaging which provides anatomical imaging
- The system supports only low frequency (2-5 MHz)
- The App-Guided scan duration is approximately 3 minutes
- The Clinician-Guided scan duration is at the clinician's discretion and intended not to exceed 30 minutes
- Each scan is enabled only upon the approval of a medical professional
- Follow the pre-defined scan protocol to ensure an optimized procedure
- Only your clinician can modify the ultrasound parameters (i.e., depth, gain, frequency, etc.)

The images and data acquired through the **Pulsenmore ES** ultrasound device are to be interpreted only by a qualified medical professional. You are not expected to interpret or diagnose ultrasound. It is the sole responsibility of your physician.
Any change in your prenatal condition, including a change in fetal movements, contractions or pain, the appearance of bleeding; dehydration; or any other change in your medical condition should be communicated to your physician.
Electromagnetic emissions from other equipment (i.e., computer printers, TVs, routers, kitchen appliances, etc.) may affect the **Pulsenmore ES** ultrasound device. If such disturbance is observed, stop the scan and move away from the interfering equipment. The device is not intended to be used in the MR environment or in the presence of strong magnetic fields.

Note

The Type iOS device is not operable while in charging mode. Connecting the charger during the scan will shut down the device. The device cannot be turned on while in charge mode.

Ultrasound Risks

Ultrasonic waves can slightly heat body tissue. While some warming may be normal, we recommend that if the device becomes warm during the scan, allow it to cool before use.

Warnings

Before using the system, read these warnings:

- Do not use the system for purposes other than those intended and expressly stated by Pulsenmore. Use the device according to the provided instructions.
- The **Pulsenmore ES** device is not intended to be used outside of your prescription, be aware of the use limits as instructed by your healthcare professional.
- Do not operate this system in the presence of flammable gases or anesthetics as this can increase the risk of explosion.
- Do not dispose of the device (or any parts of it) with industrial or domestic waste. Contact your service provider for your local disposable method.
- Avoid using the device in any case of damaged device/package.
- The device is limited to a singleton pregnancy only.
- Do not modify or repair this device, including its components, software, cables, etc. Do not disassemble or remove the battery from the device. User modification or repair attempts may cause a safety hazard and degradation in the device performance.
- Type iOS – In the unlikely event the device emits smoke or fumes discontinue use immediately. Do not place the device near a heat source or open flame as this may cause leakage of corrosive fluid, electrical shock, or fire. Avoid liquid encountering the eye. If occurs, immediately wash with water, and seek medical attention.

Precautions

- If the system was placed in an environment above 35°C (95°F) or below 0°C (32°F), allow it to reach operating (room) temperature before connecting and using the system.

- Do not allow the system to contact the skin if the temperature of the transducer exceeds 43°C (109°F).
- For external use only- The **Pulsenmore ES** device is to be used for obstetric ultrasounds only. Avoid contact with mucous membranes (e.g., eye, nose, mouth) and non-intact areas of the skin that have been opened by cuts, abrasions, dermatitis, chapped skin, etc.
- Only the area of the transducer is watertight. Do not immerse the system in water.
- Do not use abrasive cleaners, acetone, MEK, paint thinner, or other strong solvents, as they may damage the device.
- The device must be disposed of after the end of each patient's pregnancy duration. Please follow the Device Disposal instructions.

Note

For "Safety - Declarations, recommendations, and test specifications" refer to the "Appendix 1 – Declarations, Guidance, and Test Specifications"

Note

The device should not be used outside of your clinician's region for medical liability reasons.

Product Lifecycle

The device can be stored under conditions detailed in Environmental Conditions up to 2 years from the date of manufacture before the first use. The date of manufacture can be found on the device (see the Symbol Glossary).
The device is designed for use during 6 months from the first activation or for 150 minutes of scanning, the earlier of the two. The total scan time counter can be found on My Scans screen of the Mobile App.

Note

The device use is limited to 50 times over the period of your patient's pregnancy (up to 6 months).

You can check the scans number in the mobile app – Menu -> My Scans

Symbol Glossary

Symbol	Description	Symbol	Description
	Warning Information essential to your safety.		Caution Information needed to protect or avoid damaging the product (hardware and software).
	Type BF Applied Part(s) To identify a type BF applied part complying with IEC standards.		Date of Manufacture Identifies the date of manufacture (in the form of year, year/month, or year/month/day, as appropriate)

Symbol	Description	Symbol	Description
	Manufacturer Identifies the legal manufacturer.	EU REP	European Authorized Representative Indicates the Authorized European Representative.
	Refer to instruction manual/booklet Indicates that the user should refer to the "User Manual" for safety information.	SN	Serial Number Indicates the manufacturer serial number so that a specific medical device can be identified.
	Single Patient – Multiple Use To indicate that the medical device may be used multiple times (multiple procedures) on a single patient, to prevent cross-contamination.	REF	Catalogue Number Indicates the manufacture's catalogue number so that the medical device can be identified. Type C – 400-0001 Type iOS – 400-0003
IP22	Ingress protection rating Protected against solid foreign objects of 12.5 mm diameter and greater. Protected against vertically falling water drops when enclosure tilted up to 15°.		Separate waste collection and disposal Indicates the need for separate collection and disposal of electrical and electronic equipment. The device must not be disposed of with other household waste.
	Humidity Limitations Indicates the range of humidity to which the medical device can be safely exposed.		Temperature Limitations Indicates the temperature limits to which the medical device can be safely exposed.
	Atmospheric Pressure Limitation Indicates the range of atmospheric pressure that the device can be safely exposed to.		Fragile; Handle with Care Indicates the contents are fragile and should be handled with care.
	Keep Away from Rain Indicate that the transport package shall be kept away from rain and in dry conditions.	CE	European Conformity Indicates that the product complies with EU regulations.
	Consult instructions for use Indicates the need for the user to consult instructions for use.	#	Model Number Indicates the model number of type number of a product.

Symbol	Description	Symbol	Description
	This Way Up To indicate the correct upright position of the transport package.		General Symbol for Recovery/Recyclable To indicate that the marked item or its material is part of a recovery or recycling process.
	Importer To indicate the entity importing the medical device into the locale.		Direct Current
	Rated Input Power DC To indicate a DC rated power input. In the application of this symbol, the rated value(s) should be accompanied with this symbol.		ON/OFF (push-push) To indicate connection to or disconnect from the mains, at least for mains switches or their positions, and all those cases where safety is involved. Each position, "ON" or "OFF", is a stable position.
	FCC Conforms to US Federal Communications Commission. For Pulsenmore ES Type iOS: FCC-ID Z64-256N		WPA2 An encrypted security protocol that protects internet traffic on wireless networks.
	Prescription only Indicates that the product is a medical device and Federal Law (USA) restricts this device to be sold without the order of a physician.		Medical device Indicates the item is a medical device
	Unique device identifier Indicates a carrier that contains unique device identifier information		Indicates the manufacturer's batch code so that the batch or lot can be identified

Cybersecurity Recommendations

- It is recommended to lock your smartphone when not in use, using pin code or biometric lock
- When using Pulsenmore ES Type C device, do not install Android Package Kit or any unofficial apps on your mobile phone
- Use only trusted apps from official app stores
- When using Pulsenmore ES device, do not connect to unsecured, open Wi-Fi networks, as they can expose your data to potential risks. Use trusted, password-protected networks whenever possible
- Make sure your smartphone is running the latest Operating System

- Be aware of your environment—protect screens and data from unauthorized viewing or access
- The device includes a USB Type C connector
    - For Pulsenmore ES Type C and Tera, use only for supported smartphone models with Pulsenmore ES App, and do not try to connect it to a PC or other devices (charges, etc.)
    - For Pulsenmore ES Type iOS, use it only to charge the Pulsenmore ES device, and do not try to connect it to a PC or other devices
- In any case of suspicious behavior or Privacy Breaches of the Pulsenmore software, please contact Pulsenmore support immediately. In the Pulsenmore ES mobile app, tap the Menu icon, then tap About. Then tap the Copy icon next to the Application ID and send an email that includes the Application ID and description of the issue to cvd@pulsenmore.com.
- Pulsenmore releases software versions from time to time to the App Store® or Google Play Store. Pulsenmore might notify the user that a newer version is available in the store and is needed to update the software from the store. Any software release will be accompanied by a release note on the app page. The software version number can be found under Menu -> About.
- Pulsenmore ES App and device do not store any sensitive, confidential, or proprietary data. Additionally, Pulsenmore Mobile App automatically removes all data as part of uninstallation process. Therefore, no additional data removal is required when decommissioning the app.
  To help protect your information and support security investigations if needed, Pulsenmore saves system activity logs (telemetry) securely in the Pulsenmore cloud for 6 months. Contact Pulsenmore via cvd@pulsenmore.com for more information or to request access to your data.

The **Pulsenmore ES** Ultrasound System

The **Pulsenmore ES** ultrasound system consists of an ultrasound device, a mobile application, and the Clinician Dashboard. The device captures the ultrasound images and transfers them to the Clinician Dashboard via a designated mobile app (see figure below).
The **Pulsenmore ES** device consists of an ultrasound device for your smartphone. The device has 3 types:

1. Type C – for Android Phone
2. Type iOS – for iPhone®
3. Tera – for iPhone with USB-C port

Type C/Tera

This device is comprised of an ultrasound transducer and is connected to the Android phone or iPhone with USB-C port through a USB connector (see figure below).

Type iOS

This device is comprised of an ultrasound transducer and is connected to the iPhone through a wireless connection (see figure below).

Setup and Training Instructions

Compatible Smartphone Models

To ensure the Pulsenmore ES ultrasound system can be used with your smartphone, refer to Appendix 3 - Compatible Smartphones.

Downloading and Installing the Pulsenmore ES Mobile App

Download the Pulsenmore ES App from the relevant app store and install it on your smartphone.
Once the app is installed, the Pulsenmore icon will appear on the smartphone's home screen or on the smartphone's downloaded apps screen.

Note

The **Pulsenmore ES** ultrasound system utilizes internet connection for uploading scans. Make sure you have a stable internet connection throughout the entire process. Make sure you are using a password protected Wi-Fi network (WPA2).

Connecting your smartphone to Type C or Tera Device

Insert the smartphone into the device holding the adjustable brackets open, until the smartphone docked into the USB connector. Please make sure you allow the device access to your mobile phone.

Connecting the iPhone to the Type iOS Device

Before connecting the device with your iPhone, make sure the device is fully charged (using Type C charger). Please make sure a USB Type C charger is available prior to the use of the device.
Charging instructions: Use a 5 VDC 1.2 A USB Type C connector (not included). See also Type iOS Internal Battery Specification. While charging, the orange LED indicator will remain illuminated. When the device is fully charged, the LED indicator will turn green.
If you are using **Wi-Fi (2.4 GHz):**

1. Turn on the device by pressing the ON/OFF button. The LED indicator will be lit white. The device will take about 30 seconds to fully start up. The fast-blinking blue LED will indicate that the device is turned on but not connected to the network.
2. Once the device starts searching for a network, open the Pulsenmore ES App. On the first time opening the app, you will be required to input your local Wi-Fi password.
3. The LED indicator will remain steady blue once connected to the network.

If you are using a **cellular network:**

1. Turn on the device by pressing the ON/OFF button – as the device is turning on, the indication LED will be lit white. The device will take about 30 seconds to fully start up. The fast-blinking blue LED will indicate that the device is turned on but not connected to the network.
2. Once the device starts searching for a network, open the Pulsenmore ES App. On the first time opening the app, you will need to input your hotspot password and turn it on. To find and turn on your hotspot password:
   a. Navigate to **Settings.**
   b. Locate **Personal Hotspot.**
   c. Tap **Allow Others to Join.**
   d. Input your **Wi-Fi Password** in the app**.**
3. The LED indicator will remain steady blue light once connected to the network.

Note

The setup requires a cellular network connection as well as Wi-Fi connection.

iOS Device Shutdown

Auto Shutdown

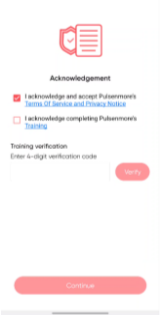
- If the device is not paired with the smartphone, it will shut down automatically after 7 minutes
- If the device is paired with the smartphone, the app will keep it powered (sending a control message every minute) and the 7-minute auto shutdown will not be activated

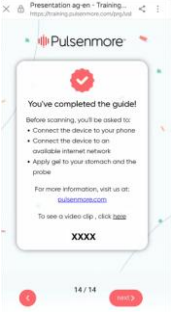
Shutdown by the App

- If the scan is completed successfully, the app will automatically shut down the device (without message to the user)
- To pair again, start the device. If the app is open on the smartphone, automatic pairing is performed

Training and Acknowledgement

To proceed with scanning, mandatory training and learning videos that simulate App-Guided and Clinician-Guided scans must be viewed. Click the Training link as seen below to access the training web site. A 100% passing of the assessment must be achieved to acknowledge training has been completed. At the end, you'll receive a unique 4-digit code - enter this code to activate the device and begin scanning. This unique code is intended for the sole purpose of successful training completion, it will not be needed again throughout the use of the device. If you choose to repeat training and assessment, you may scan the below QR codes and repeat as needed. A verification code is only provided when completing the training via pressing the link in the mobile app.





App-Guided

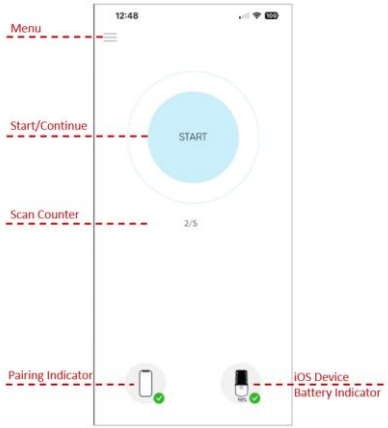
Clinician-Guided

Note

You cannot start scanning until you finish the training and pass the quiz.

Home screen

Before performing scans with the **Pulsenmore ES** ultrasound device, it is best to familiarize yourself with the Pulsenmore ES mobile app's home screen and menu options:



- **Menu** button – tap to access to the following screens:
  - **Tutorials** – select to view videos instructing you on how to perform each of the five steps in an App-Guided scan.
  - **Uploads** – select to view the recent upload status.
  - **Language** – select to choose your preferred language in the app.
  - **About** – select to view software information.
- **START/CONTINUE** button – tap to start a scan. In case of a scan interruption (scan paused), pressing this button (within a 1-hour timeframe) will resume the scan from the beginning of the step where it was paused.
- **Scan Counter –** indicates the remaining number of scans per Key, when applicable.

System Status Bar – all icons should be black. If one of them is red, you will need to resolve the relevant issue before you can tap **START/CONTINUE** (see "Verifying Scan Conditions" for further information).

Entering a Key

Your personal Pulsenmore ES device requires a valid scan key to work. The scan key is a prescription provided by your physician for ultrasound scanning. The key usage limits include an expiration date (how long your key is valid) and scan quota (the number of scans allowed before renewal, as shown in the "Scan Counter" on the home screen). This key will be provided by your prescribing physician, and it can be in form of a QR code or a link.

To scan a QR code:

1. Download and install the Pulsenmore ES Mobile App.
2. Open your smartphone camera app and Scan the QR code, or tap Scan QR Code from the Pulsenmore ES mobile App.

To follow the link:

1. Download and install the Pulsenmore ES Mobile App.
2. Tap the link that has been provided.

Upon successful completion of loading the key, you will be directed to the mobile app's home screen. The mobile app will notify you that the Key has been properly inserted. Once activated, it will allow you to conduct clinician-guided or App-guided scans within specified limits.

Note

Use your Pulsenmore ES device only as prescribed by your physician, including the recommended frequency of use.

Note

Your activation key is personal and should not be shared. It connects your device to your medical records and is meant only for your use.

Note

If your key or link is lost or expired, your physician can issue a new one. The old key will no longer work once a new one is activated.

Verifying Scan Conditions

For the best ultrasound results, connect to a local Wi-Fi network. If Wi-Fi is unavailable, use your cellular network.
Ensure that the following technical requirements are met – as indicated on the **System Status Bar:**

The device and smartphone are successfully connected and ready to use. Type iOS – device battery level indication

The device has been disconnected. To determine the reason, please refer to the error message you received.

The device has been disconnected. To determine the reason, please refer to the error message you received. Please check your internet connection, battery level, and disk space.

Additional Information

As part of the Pulsenmore™ app, tutorial videos demonstration how to complete each step of the scan are available in the "tutorials" menu section.
The tutorial includes:

1. Instructions before scanning
2. Scanning step procedures

Note

All users will go through the same tutorial steps for an App-Guided scan. Audio-video tutorials for the 5 steps are provided for this mode only. (See the 5 scanning steps). During a Clinician-Guided scan, the clinician will guide you on how to perform the scan.

Using the **Pulsenmore ES** Ultrasound Device

Using the device for ultrasound scanning includes the following steps:

1. Before scanning:
   a. Make sure that your batteries are charged before every use
      - Smartphone: at least 50%
      - Type iOS Device: at least 65% or until the battery LED indicator becomes green
   b. Check that you have a steady internet connection (Wi-Fi or cellular network) on your smartphone. If possible, Wi-Fi connection is preferable.
   c. Check that you have received a Key from your clinician.
      - This is generally a QR code or link, that you will need to begin using the **Pulsenmore ES** ultrasound device.
   d. Connect your smartphone to the device.
      - For Type iOS, refer to "Connecting the iPhone to the device".
      - For Type C, slide the smartphone into the device's adjustable brackets.

Note

You may need to remove your smartphone cover to enable proper connection with the device's USB Type C connector.

2. Launch the mobile app (Refer to "Setup and Training Instructions")
3. Make sure you have single-use sachets ultrasound gel to use on the device and skin when scanning.
4. Scanning:
   - For an App-Guided scan refer to "App-Guided Scan"
   - For a Clinician-Guided Scan refer to "Clinician-Guided Scan"
5. After scanning:
   - Make sure that an upload confirmation message has been received, then exit the app and disconnect the smartphone from the device.
   - Follow the cleaning instructions provided in "Cleaning the Device".

Gel Application

Ultrasound gel is a prescription used device, your prescribing physician shall provide you with an appropriate prescription. Use only the prescribed single-use sachets of water-based ultrasound gel with FDA marketing authorization.

1. Before starting a scan, hold the device in one hand and apply a generous amount of gel to the transducer's surface – the dark area at the bottom of the device. Make sure the gel fully covers the area, as shown in the illustration below.

2. If you feel that the device is not gliding easily over your skin while scanning, you may apply more gel on the skin.

3. If you detect that the image of the scan displayed on your smartphone is not sharp and/or includes dark zones – apply more gel on the transducer as described in Step 1.

App-Guided Scan

General

On your very first App-Guided use of the device, you will be granted an initial use session. The initial use session is identical to the App-Guided scan. To begin the initial use session, tap the Start button (you will see a label next to it indicating an initial use session). Once the initial use session is complete, the app Home Screen will be displayed. The user conducting a initial use session must be instructed or supervised by a licensed clinician.

Note

If your clinician has assigned a Clinician-Guided scan, refer to Clinician-Guided Scan section.

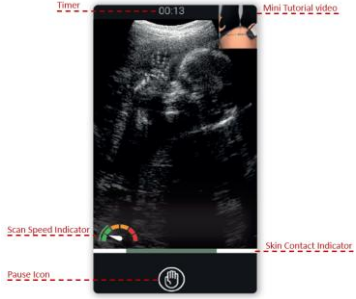
- As part of the scan, a short video will play, explaining and demonstrating how to perform the first step of the scan. To obtain the best results, follow the instructions carefully for each step.
- When the video ends, perform the scan according to the instructions and guidelines in the "App-Guided Scan Instructions" section below (Also refer to "Gel Application")
- Each step has a time limit. (The time remaining for you to perform each step is indicated by a timer on the app.) The software will automatically stop scanning when a step is completed.

Scan Screen

App screen components when scanning:

- **Timer** - Indicates the remaining scanning time.
- **Pause button** – Press to pause the scan.

- **Mini Tutorial video** – Video demonstration for your current scan step, which plays while you scan (in App-Guided scan only).
- **Skin Contact Indicator** – Indicators regarding contact.
- **Scan Speed Indicator** – Indicators regarding speed.



Skin Contact Indicator

The Skin Contact Indicator is enabled during an App-Guided scan and Clinician-Guided scan. When this feature is enabled, the Pulsenmore ES App will alert you if skin contact with part of the device's transducer is not optimal.

Red on both sides	Poor skin contact sides of the transducer
Red on the right	Poor skin contact right side of the transducer
Red on the left	Poor skin contacts on the left side of the transducer
Green in the middle	Good skin contact

To ensure quality of the images when scanning:

- Perform a correction in the required direction until the bar turns green.
- Use slow and constant movements.
- Make sure there is always a sufficient gel layer between the device and your skin.
- Ensure you are applying enough pressure to maintain good contact between the gel-covered transducer and your skin.

Note

To verify the indicators are working properly, make sure both indicators are responsive to the way you scan and not static.

Scan Speed Indicator

During the scan, you will be instructed where to place the device and how to move it. You must maintain slow and constant movement of the device over your abdomen. The Scan Speed Indicator at the bottom of the screen will point to the red/orange bars if you are moving too fast, signaling that you should move the device slower.

App-Guided Scan Instructions

1. Spread a generous amount of ultrasound gel on the bottom of the device (the transducer).
2. Tap **Start** to start the scan.
3. Press and glide the device over your skin, making sure that good contact is maintained between the transducer and your skin.
4. An ultrasound image will be displayed on the app screen.
5. Move the device slowly and consistently. Alerts on the screen during a scan will notify you if you need to move the device slower.
6. Verify that a good, sharp image is displayed on the application screen.
7. The system will alert you if there are too many dark zones in the image and you need to improve the contact between the device and your skin. Try adding gel to your skin or the transducer and moving the device a bit more slowly.
8. You can pause the scan at any time by tapping the **Pause** icon and resume by tapping the **CONTINUE** button on the home page.
9. Make sure you hold the device in a way you can see the displayed image and instructions.

The 5 Steps of a Scan

Step One	
Scan directions:	Tilt
Scanning zones:	Lower abdomen
Starting position:	Straight
Scan time:	15 seconds

Step Two	
Scan directions:	Bottom to top
Scanning zones:	Center, left, right abdomen
Starting position:	Straight, angled
Scan time:	55 seconds

Step Three	
Scan directions:	Bottom to top
Scanning zones:	Right-center-left abdomen
Starting position:	Straight
Scan time:	55 seconds

Step Four	
Scan directions:	Right to left
Scanning zones:	Above and below the navel
Starting position:	Angled
Scan time:	25 seconds

Step Five	
Scan directions:	Right to left
Scanning zones:	Above and over the navel
Starting position:	Angled
Scan time:	30 seconds

After completing all scan steps, the videos of the ultrasound scan will be automatically uploaded and sent to a clinician for review.
Refer to the After a Scan Is Competed section for further instructions.

Clinician-Guided Scan

General

The following instructions apply when your clinician has been assigned a Clinician-Guided scan. For App-Guided Scan instructions, refer to "App-Guided Scan."

Note

For all device types, you will need to allow the app's request to use your microphone, camera, and media files to let your clinician hear and see your scan in real time.

Starting a scan

After entering a Clinician-Guided Key (as described in "Setup and Training Instructions"):

1. When scheduled with your clinician, open the Pulsenmore™ app and press **Start.**
2. Click Waiting Room.
3. Wait for your clinician to connect to the call.
4. When your clinician connects to the call, the app will display the "Real-time Interactive Procedure" screen. You will be able to hear and speak with your clinician.
5. Carry out the scan following your clinician's guidance. The ultrasound scan is streamed directly to your clinician for real-time review.

Note

For components of the scan screen refer to "Scan Screen".

Clinician-Guided scanning

1. Spread a generous amount of the ultrasound gel on the bottom of the device (the transducer) (Refer to "Gel Application").
2. Your clinician will guide you on when to start moving the device and where to scan.
3. Press and glide the device over your skin. The device should always be in contact with the skin.
4. You can enable/disable your camera, microphone, or hang up the call at any time, if necessary.
5. Your clinician can start/stop the ultrasound transmission and change the ultrasound parameters.
6. The clinician controls the view on your screen and selects whether you see the ultrasound scan or the video stream.
7. Camera: Depending on the settings, you may see yourself and/or your physician on the screen during a Clinician-Guided scan.
8. If you have the ultrasound scan showing on your screen, the system will alert you if you need to improve the contact between the device and your skin. Try adding gel and moving the device a bit more slowly.
9. Your clinician will end the scan and any videos that were recorded will be automatically sent to your clinician for review and documentation.

Note

If the following symbol appears during the scan  , clicking it will present details about the issue(s) you are having, and instruct how to solve them.

After completing all scan steps, the videos of the ultrasound scan will be automatically uploaded and sent to a clinician for review.
Refer to the After a Scan Is Competed section for further instructions.

After a Scan Is Competed

After completing all scan steps, the videos of the ultrasound scan will be automatically uploaded and sent to a clinician for review.

1. Before exiting the app, make sure that an upload confirmation message has been received.
2. Close the app.
3. Carefully disconnect the smartphone from the device to avoid damaging the USB connector.
4. Clean the device as described in "Cleaning the Device".

Troubleshooting

Issue	Solution(s)
Alert message: To perform an ultrasound scan, your smartphone should be sufficiently charged (50% or more) 1. Type C – The device is powered by the smartphone's battery 2. Type iOS – The device needs to be fully charged	1. Charge your smartphone 2. Type iOS Device – Charge your device (using a USB Type C charger)
Alert message: To perform an ultrasound scan, your smartphone should be inserted into the Pulsenmore ES ultrasound device The ultrasound procedure requires the device to be connected	Perform one or more of the following steps to resolve the issue: 1. Disconnect your smartphone from the device and connect it again 2. Disconnect your smartphone Pulsenmore™ app 3. Remove smartphone cover
Alert message: Insufficient available memory The ultrasound scan requires a minimum of 1GB of available storage on your smartphone	Free up space in your smartphone storage so that you have at least 1GB available
Alert message: Please make sure the power saving mode is disabled In power-saving mode, the smartphone does not provide enough power for the ultrasound device to work. Scanning cannot be started	Disable power saving mode in your device's operating system
Alert message: No Key was entered To start a scan, a Key must be entered	Contact your healthcare provider to learn how to get a Key
Alert message: To perform an ultrasound scan, your smartphone should be connected to the internet No/poor internet connection	1. Connect to Wi-Fi or cellular network 2. Check to ensure you have adequate signal strength
Alert message: All the scans for this device were already used Your Key allows a limited number of scans. All the scans allotted in the Key have been used	Contact your provider for a new Key to be able to perform more scans

Issue	Solution(s)
Alert message: Ultrasound functionality is currently disabled – there is a limit on the number of daily scans **The healthcare provider determines the maximum number of scans that can be performed with your device over a period (per day or hour)**	1. Wait for the next time you are permitted to perform another scan 2. Contact your healthcare provider
Image cannot be viewed	• Make sure the device's USB connector is properly inserted into the smartphone's USB port. • Close and re-open the app. • Spread additional gel over the skin where the scan is being performed. This may also occur during a Clinician-Guided scan if the clinician's settings do not enable you to view the scan
App does not start	• Close the app and re-open it. • Close all open app and re-open Pulsenmore app • Turn off and restart the smartphone
Poor image quality	• Make sure there is sufficient gel on the transducer and on the skin where you are scanning. • Move away from transmitting equipment (i.e., computer printers, TVs, routers, kitchen appliances, etc.)
Videos are not sent to the clinician	• Make sure your smartphone is connected to Wi-Fi or cellular network. The app will continue to try and upload the scans when the smartphone connection is restored
Image interference	• Move away from transmitting equipment (i.e., computer printers, TVs, routers, kitchen appliances, etc.) • Turn off NFC on your smartphone. • Switch your smartphone to airplane mode (make sure you are still connected to the Wi-Fi network)
The device does not turn on	For iOS – If the battery of the device is not sufficiently charged, charge the device fully. If the device is inserted into the charger but no LED indicator, contact your Service Provider

If the device is not functioning despite the troubleshooting, contact your Service Provider to replace the device.

Clinical Study Summary – Pulsenmore Hola US Study

Title	Pulsenmore HOLA US Study (Home Ultrasound Assessment)
ClinicalTrials.gov	NCT05329077
Name of Investigational Product	Pulsenmore ES
Methodology	Prospective, multicenter investigational device study
Study Center(s)	• Center for Fetal Medicine and Women's Ultrasound, Los Angeles, California • University of Florida, Gainesville, Florida • Mount Sinai Hospital System Faculty Practice: Maternal Fetal Medicine, New York, New York

Title	Pulsenmore HOLA US Study (Home Ultrasound Assessment)
	• Brigham and Women's Hospital, Boston, Massachusetts
Objectives	Demonstrate the safety and effectiveness of the Pulsenmore ES device

Study Design	• The study consisted of two to three ultrasound study sessions over three consecutive weeks
	• Each study session consisted of three ultrasound scans:
	  • App-guided (AG) scan performed by the subject at home
	  • Clinician-guided (CG) scan performed during a telehealth visit at the subject's home
	  • In-clinic (IC) scan using a standard of care ultrasound device

Inclusion Criteria	• Female age ≥ 18 • Singleton gestation • Gestational age ≥ 14 weeks with a prior scan demonstrating fetal viability and confirming dates • No known fetal or genetic anomalies, with the exception of subjects with abnormal amniotic fluid volume • English or Spanish speaking • Ability to understand and sign the informed consent (available in English and Spanish) • Ability to read and understand instructions that are required for equipment use (instructions available in both languages)
Exclusion Criteria	• Multiple gestation • BMI >40 • Known fetal and genetic anomalies, with the exception of subjects with abnormal amniotic fluid volume. • Subjects with skin problems in the abdominal area (such as wounds, cuts in the skin and skin rash) • Subjects allergic to the ultrasound probe materials • Non-English/ non-Spanish speaking • Unable to provide consent
Safety Endpoints	• Primary: Serious Adverse Events (SAEs) device or procedure related • Secondary: All Adverse Events (AEs)
Primary Effectiveness	• Family 1: The proportion of cases in which readers using the clinician-guided mode can correctly visualize the fetal cardiac activity and pass the M-mode line through the fetal heart. • Family 2: The proportion of cases in which readers using the app guided mode can correctly visualize the fetal cardiac activity and pass the M-mode line through the fetal heart.
Reader Interpretation for Effectiveness Analysis	• CG scans: Ten study readers • AG scans: Ten study readers • IC Scans: Three expert readers, of which majority rule (two of three) was used to determine ground truth (GT) results. • Different readers per modality
Number of Subjects	• Enrolled: 188 • Per Analysis: 162
Number of Scans	• Total scans: 1370 • CG scans: 453 • AG scans: 458

Title	Pulsenmore HOLA US Study (Home Ultrasound Assessment)
	• IC scans: 458
Primary Safety Results	• 8/188 (4%) women reported 10 serious adverse events (SAE). • None of the SAEs were determined to be device or procedure-related. • The study was considered successful for the primary safety analysis.
Secondary Safety Results	• 15/188 (8%) women reported 17 non-serious adverse events (AEs). • None of the AEs were determined to be device- or procedure-related.
Primary Effectiveness Results	• Family 1: The null hypothesis was rejected, supporting the CG mode's ability to accurately visualize FCA. The percentage proportion of visualization of the fetal cardiac activity and pass the M-mode line through the heart was 99.2% (with 96.7% lower bound CI of 97.5%). In addition, the proportion of cases where CG readers agree on the presence of FCA was high, with all 10 readers agreeing on 94.3%. • Family 2: The null hypothesis was rejected, supporting the AG mode's ability to accurately visualize FCA. The percentage proportion of visualization of the fetal cardiac activity and pass the M-mode line through the heart was 97.2% (with 94.3% lower bound CI of 97.5%). In addition, the proportion of cases where AG readers agree on the presence of FCA was high, with all 10 readers agreeing on 90.8%.
Subgroup Analysis	• The primary effectiveness analysis was conducted on subgroups stratified by clinical site, HCP conducting the scan (for CG scans only), visit number, subject race/ethnicity, subject education level, BMI, gestational age at Visit 1, and comorbidities • There were no observable differences in any of the subgroups when assessing poolability for the CG or AG guided modes.
Image Quality Analysis	• For FCA visualization, 95.5% of the CG scans and 95.9% of the AG scans had an image quality of ACEP score ≥ 3.
Limitations	• Obesity data only available for BMI 30-40 kg/m^2 due to study selection criteria • For the secondary endpoints, since the hypothesis testing was not pre-planned, and the multiplicity adjustment was not taken into consideration in the study design, the statistical inference cannot be made • Long term follow-up not captured due to limited subjects' participation in the clinical study
Conclusions	• This clinical study demonstrates that Pulsenmore ES ultrasound device is safe and effective at visualizing the FCA at home, both for the CG modality and the AG modality

Maintenance

The **Pulsenmore ES** ultrasound device contains highly sensitive electronic components and is not user serviceable.
No special instructions are needed for maintaining basic safety and essential performance with regard to electromagnetic disturbances for the expected service life.
Make sure that the device is kept dry.

Ultrasound gel is a prescription used device, your prescribing physician shall provide you with an appropriate prescription. Use only the prescribed single-use sachets of water-based ultrasound gel with FDA marketing authorization.
. Keep the device and gel away from children and do not allow children to play with the device. Make sure your smartphone is charged before using it with the **Pulsenmore ES** ultrasound device (a minimum 50% battery charge is required).

Cleaning the Device

The **Pulsenmore ES** ultrasound device includes electronic components and is not waterproof. Do not immerse it in water. Avoid cleaning in the adjustable brackets (black) area or the device connector and label. Always clean it thoroughly after each use as follows:

1. Before starting the cleaning process disconnect your smartphone from the device. For Type iOS make sure the device is turned off – the indication led is turned off.
2. Acquire gauze pads measuring 10 x 10 cm (4 x 4 inches) for cleaning procedures.
3. Immediately after use, to prevent the gel from drying on the device, thoroughly wipe the device with a dry gauze to remove any visible traces of gel. Repeat if necessary.
4. Thoroughly wipe the device for at least thirty (30) seconds with a damp gauze moistened with a warm soapy solution. Use warm tap water at 30-40°C (86-104°F), containing a mild household liquid soap placed on a gauze. Use a 24% hand dishwashing solution or equivalent.
5. After cleaning, wipe the Device three (3) times with another gauze moistened with cold tap water to remove any traces of soap.
6. Wipe the Device again with a dry gauze to remove any visible traces of water, repeat if necessary.
7. Visually inspect the Device in a well-lit room to ensure that it is clean and dry. If necessary, repeat steps 3-7.

Only when the Device is visually clean, place the Device in its box supplied by the manufacturer.

CAUTION

Do not use abrasive cleaners or acetone, MEK, paint thinner, or other strong solvents as they may damage the device.

Device Disposal

CAUTION

The device must be disposed of after the end of each patient's pregnancy duration.

The device and its internal battery must not be discarded into household or unsorted municipal waste, nor destroyed by incineration. It should only be disposed of by placing it in a bin specifically designated for used electronic equipment. If necessary, you may contact your local landfill or waste disposal authority requesting a designated electronic waste drop-off location for disposal of the device when it is no longer required. The device might be contaminated, follow additional local environmental regulations when applicable.

Appendix 1 – Declarations, Guidance, and Test Specifications

Acoustic output Limits - B-Mode

Parameter	Value	Uncertainty
Mechanical Index (MI)	0.40	±18.19%
Thermal Index (TIS)	0.03	±36.01%
Intensity (Ispta.$_3$)	5.63 (mW/cm2)	±36.01%
Acoustic Power (P_{ix1})	1.92 m W	±36.01%
Peak Rarefactional Pressure ($p_{r,\alpha}$)	0.64 MPa	±18.19%
Center Frequency (f_c)	2.6 MHz	± 2%

THERMAL INDICES and MECHANICAL INDEX are less than 1.0 for all device settings. The M-Mode image is generated from the existing ultrasound data already acquired without the need to re-scan the patient.

Declaration – Electromagnetic Emissions

Emissions test - RF emissions CISPR 11

Compliance - Group1 Class B

Electromagnetic Environment – Guidance

The **Pulsenmore ES** system 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.

The **Pulsenmore ES** system 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.

Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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 the **Pulsenmore ES** ultrasound system to avoid any performance degradation of equipment.

Note

For detailed technical information, refer to your Clinician.

Testing for System Performance

Electrical safety and electromagnetic compatibility tests covering electrical safety and electromagnetic compatibility requirements.

IEC 60601-1 - Medical Electrical Equipment – Part 1: General Requirements for Safety.

IEC 60601-1-2 - Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility –Requirements and Tests.

IEC 60601-1-11 – Medical Electrical Equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

IEC 60601-2-37 – Medical Electrical Equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnosis and monitoring equipment.
The safety lab testing has been performed with the following smartphone models:

- Samsung Galaxy S24, Google Pixel 8a,iPhone 13, iPhone 16 Pro Max

Essential Performance

The essential performance of the Pulsenmore ES includes:

- The ability to display physiological images as input for diagnosis by qualified and trained healthcare professionals.
- The ability to display quantified data as input for diagnosis by qualified and trained healthcare professionals.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The **Pulsenmore ES** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Pulsenmore ES** should ensure that it is used in such an environment.

WARNING

Use of the Pulsenmore ES adjacent to or stacked with other equipment should be avoided because it could result in improper operation.

WARNING

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 the Pulsenmore ES Otherwise, degradation of the performance of this equipment could result.

Immunity test	Standard	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD)	IEC 61000-4-2	Air: ±2kV, ± 4kV, ± 8kV, ±15kV, Contact: ±8kV	Air: ±2kV, ± 4kV, ± 8kV, ±15kV, Contact: ±8kV
Power frequency (50/60 Hz) magnetic field	IEC 61000-4-8	30 (A/m)	30 (A/m)
Radiated electromagnetic fields (RF) including Proximity fields from RF wireless communications equipment	IEC 61000-4-3	10.0 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz 27V/m, 385 MHz, 18 Hz Pulse Mod. 28 V/m, 450 MHz 1KHz FM 9V/m 710/745/780 MHz 217 Hz PM 28V/m 810/870/930 MHz 18Hz PM. 28V/m 1720/1845/1970 MHz 217 Hz PM 28 V/m 2.450 MHz 217 PM 9V/m 5240/5500/5785 MHz 217 PM	10.0 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz 27V/m, 385 MHz, 18 Hz Pulse Mod. 28 V/m, 450 MHz 1KHz FM 9V/m 710/745/780 MHz 217 Hz PM 28V/m 810/870/930 MHz 18Hz PM. 28V/m 1720/1845/1970 MHz 217 Hz PM 28 V/m 2.450 MHz 217 PM 9V/m 5240/5500/5785 MHz 217 PM

Appendix 2 - Technical Specifications

Environmental Conditions

	Pressure	Temperature	Humidity
Operation	700 hPa (525 mmHg) to 1060 hPa (795 mmHg)	0°C (32°F) to 35°C (95°F)	15% to 95% non-condensing
Transportation	500 hPa (375 mmHg) to 1060 hPa (795 mmHg)	-20°C (-4°F) to 50°C (122°F)	15% to 95%
Storage	500 hPa (375 mmHg) to 1060 hPa (795 mmHg)	-20°C (-4°F) to 50°C (122°F)	15% to 95%

Product Dimensions and Weight

	Type C	Type iOS
Width	78 mm	78 mm
Height	167 mm	167 mm
Depth	38.5 mm	38.5 mm
Weight	240 g	290 g

Ultrasound

Image Display: B-mode, M-Mode*
Frequency: 2-5 MHz
Single-patient use, single-pregnancy
Pulsenmore ES Type C is powered through Type C USB 5 VDC, 1.2 A connection to the smartphone
Clinician-guided Duration - 30 minutes at default setting
* M-mode images are generated from previously acquired B-mode ultrasound data.

Mobile App and Connectivity

Network Connectivity: Wi-Fi or cellular
Data Upload: Secured cloud service

Quality of Service and Wireless coexistence

The Pulsenmore ES system uses Wi-Fi to send ultrasound images and is designed to work safely alongside other wireless devices commonly found at home. It monitors connection quality during use and alerts the user if the signal is weak, helping ensure reliable image transmission and wireless co-existence. The system checks that the data sent is complete and accurate (data integrity), and it keeps delays short so images appear smoothly without noticeable lag (low latency).

Communications and Hardware Interface

Interface type	Functionality	Interfaces usage & direction
USB Type-C Physical (Type C device)	Connects Android smartphone to ultrasound transducer	Bidirectional, connect to smartphone via USB port interfaces, used for power and data transfer.
Wi-Fi Wireless (Type iOS device)	Connects iPhone smartphone to ultrasound transducer	Bidirectional, connect to smartphone via Wi-Fi interfaces, used for data transfer.
Smartphone's Wi-Fi	Connectivity to the cloud from the mobile app	Outbound connects smartphone to the cloud via Wi-Fi.
Smartphone's Cellular	Connectivity to the cloud from the mobile app	Outbound connects smartphone to the cloud via Cellular.

Type iOS Internal Battery Specification

A full battery can support a scan time of at least 30 minutes on default settings.
The rechargeable battery allows up to 100 charging cycles.
The average charging time from a fully discharged battery is about 2 hours.
The rechargeable battery lifetime is 2 years.
Battery capacity: 1200 mAh/ Battery voltage: 3.7 V.
Battery type: Li-ion Polymer.
Battery Replacement: The battery is non-replaceable b.
Compatible charger: Samsung EP-TA800, Cable: USB Type C Xiaomi 1 meter, or similar.

Made For iPhone

Use of the Made for Apple® badge means that an accessory has been designed to connect specifically to the Apple product(s) identified in the badge and has been certified by the developer to meet Apple performance standards. Apple is not responsible for the operation of this device or its compliance with safety and regulatory standards.

Appendix 3 - Compatible Smartphones

The list of tested smartphones compatible with the Pulsenmore ES system is provided below. If you cannot find your smartphone on this list, check the updated list on our website at https://pulsenmore.com/SupportedDevices/. If the list provided herein and the one on the website do not match, follow the list on the website.

Manufacturer	Model	Compatible Pulsenmore Device
Apple	iPhone 11, iPhone 11 Pro iPhone 11 Pro Max	Type iOS
Apple	iPhone 12, iPhone 12 Pro iPhone 12 Pro Max, iPhone 12 mini	Type iOS
Apple	iPhone 13, iPhone 13 Pro iPhone 13 Pro Max, iPhone 13 mini	Type iOS
Apple	iPhone 14, iPhone 14 Plus iPhone 14 Pro, iPhone 14 Pro Max	Type iOS
Apple	iPhone 15, iPhone 15 Plus iPhone 15 Pro, iPhone 15 Pro Max	Tera
Apple	iPhone 16, iPhone 16 Plus, iPhone 16 Pro iPhone 16 Pro Max, iPhone 16e	Tera
Samsung	Galaxy A05s	Type C
Samsung	Galaxy A25	Type C
Samsung	Galaxy A26	Type C
Samsung	Galaxy A26 5G Kosher	Type C
Samsung	Galaxy A35	Type C
Samsung	Galaxy A36	Type C
Samsung	Galaxy A52	Type C
Samsung	Galaxy A52s	Type C
Samsung	Galaxy A53	Type C
Samsung	Galaxy A55	Type C
Samsung	Galaxy A56	Type C
Samsung	Galaxy S10	Type C
Samsung	Galaxy S21	Type C
Samsung	Galaxy S22	Type C
Samsung	Galaxy S23	Type C
Samsung	Galaxy S24	Type C
Samsung	Galaxy S25	Type C
Google	Google Pixel 4	Type C
Google	Google Pixel 5a	Type C
Google	Google Pixel 8a	Type C
Motorola	Motorola Edge	Type C
Motorola	Motorola Moto G Stylus 5G	Type C
OnePlus	OnePlus 8T	Type C

Pulsenmore ES
User Manual

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