

# Pulsenmore ES: Data Management Document



**Pulsenmore is a home ultrasound solution for remote clinical diagnosis**



**It is prescribed by a healthcare provider (HCP)**



**Pulsenmore scans are complimentary to routine prenatal diagnostic procedures**

## Workflow



**1**

The HCP prescribes the Pulsenmore remote ultrasound, then selects the Pulsenmore ES mode (Clinician or App Guided).



The HCP or admin generates a scan key code (QR or link) to share with the patient.



### Clinician Guided

**Synchronous remote ultrasound consultation**  
A comprehensive tele-ultrasound consultation guided & controlled by the HCP.

### App Guided

**Asynchronous remote ultrasound**  
Patient follows 5 self-scan steps using the instructional video, and gets diagnostic feedback via sms or phone call.



**2**

The patient purchases the device, downloads the app and activates the scan key code according to planned protocol.



**3**

The HCP reviews the scans through a clinical dashboard interface, diagnoses, documents, and when required, downloads the scans to the patient's file.

To see a demonstration of this workflow, please visit the [Clinician Dashboard](#) [Pulsenmore Desktop Demo](#)



**Nontransferable and Single Patient Use**



**Single Fetus Pregnancy Use**


## Data Policy

At Pulsenmore, we prioritize the privacy and security of data. We adhere to strict data protection regulations and employ the industry's standard security measures to safeguard the information.


Pulsenmore is GDPR Compliant, our systems comply with the following security standards:


- ISO 27001: Information security management system
- ISO 27799: Health informatics – Information security management in health.
- ISO13485: Medical device QMS


## Data Protection:


-  **What data does Pulsenmore collect?**

Pulsenmore collects four types of data:

  - **Service logs:** Application usage logs, such as performance logs and errors.
  - **Technical information about the smartphone:** Smartphone capabilities, application version, language, etc.
  - **Clinical information:** Ultrasound clips, scan time, scan measurements and last menstrual period (LMP).
  - **Interpreter Data:** The identifiers of the clinicians that interpret the scans.
-  **Does Pulsenmore use the data for its own purposes?**


Pulsenmore utilizes service logs and technical information to improve services and enhance user experience. Pseudonymized clinical data (also referred as de-identified data in the US) is used for clinical education, training, research and development purposes only.
-  **What data does Pulsenmore store?**


We securely store the scans and clinically relevant data (such as the LMP).
-  **Is the data stored on the platform pseudonymized?**


Yes, the pseudonymized ultrasound scans are uploaded to Azure – a cloud computing platform run by Microsoft. Scans are encrypted in transit and stored in the encrypted format on the platform.
-  **Data Sharing:**


Pulsenmore does not share your personal data or scans with any third parties unless explicit consent is given by the patient.

## Usability:

-  **How does the patient receive her Pulsenmore Scan Key Code?**

The Pulsenmore Scan Key Code is generated by the HCP or admin within the clinician dashboard interface. It has unique identifiers based on the patient de-identified ID, selected mode (Clinician-Guided or App-Guided), and prescription details (frequency and time of use). The key is automatically transformed into a QR code and shared with the patient via email or SMS.
-  **Can anyone access the dashboard?**

No, the Clinician-Dashboard interface is an online web application that utilizes an active directory access technology (permission management tool).
-  **How long can scans be viewed on the interface?**

Data is available for review for 30 days. During this time, the HCP can download and save the scans onto the patient file. More information is available in our [Terms of Use](#).
-  **What is the size of the generated clips?**

In the App-Guided mode, the size of the zip file is about 20MB.  
The Clinician-Guided recorded scan is usually smaller, depending on the amount and length of clips.

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The data is classified as personal data with a lower-level of Protected Health Information (PHI). For more details you are invited to check Pulsenmore End-User: [Privacy Policy](#) & [Terms of Use](#). MDS2 is available upon request.



Please feel free to reach out if you require any further information or have specific inquiries. We are committed to ensuring the utmost privacy and security of your data throughout your experience with Pulsenmore ES.