



User Manual

USER MANUAL

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1. INTENDED USE

The Keikku device is a digital stethoscope (hereafter referred to as “Keikku”) that enables amplification, filtering, and transmission of auscultation data of the patient (heart, lungs, bowel, arteries, and veins), whereby a clinician at one location on network can listen to the auscultation data of a patient on site or at a different location on the network. Keikku is intended for use on pediatric and adult patients. Keikku is intended to be used by professional users in a clinical environment or by lay users in a nonclinical environment. Keikku is not intended for self-diagnosis.

Only healthcare professionals should use Keikku for diagnosis purposes.



Figure 1 Keikku

2. INTRODUCTION

Keikku is designed to support healthcare professionals to listen to sounds produced by the body, primarily lung, heart, and bowel sounds. Keikku enables regular users to record, save and share their body sounds with a healthcare provider. The Keikku system includes an application, the Keikku App.

Keikku features sound amplification and audio transmission to a smartphone through Bluetooth connectivity. This enables users to access and play sounds via a dedicated mobile app on iOS and Android devices. The app allows users to save sound files, share recordings, and includes the option to trim and add annotations to captured audio.

3. FOR HELP AND ASSISTANCE

Please contact Lapsi Health if you need assistance or any product related concerns.

For more information and full electronic instruction for use please visit: <http://keikku.health/>

Direct Contact: support@keikku.health

4. SYMBOLS

	Manufacturer – Name and the address of the manufacturer.		Serial Number - every Keikku has a unique serial number.
	Fragile - handle with care.		Keep dry
	Temperature limitations – Keikku has operational, storage and transportation temperature limits.		Humidity limitations - Keikku has humidity limitations.
	Atmospheric limitations - Keikku has atmospheric limitations.		Type BF applied part - Degree of protection (applied part) against electric shock: classified as of type BF. Parts in physical contact with the patient comply with IEC 60601-1.
	Disposal information		Non-ionizing electromagnetic radiation – Keikku has wireless connectivity.
	Caution - Indicates a situation which could result in device harm, damage or malfunction if the appropriate precautions are not followed.	IP44	protected against harmful effects of dripping water as per IES 60529. First number 4: the product is protected against ingress by small solid bodies of 1mm diameter or

			more. Second number 4: the product has effective protection against splashing water from any direction or angle, including vertical drops or sprays of droplets
	WARNING - There are some warnings when using Keikku, read them carefully before using the device.		CAUTION - There are some cautions and precautions when using Keikku, read them carefully before using the device.
	Wireless Bluetooth communication- Bluetooth LE 5.2		MR Unsafe
	Quantity		Read the instructions for use before using the device
	UDI code: (01) Device identified (21) Serial number (11) Manufacturing date		FCC certification

5. CAUTIONS AND WARNINGS

It is important to read the safety issues before using the Keikku system. Keikku lifetime is 2 years and to ensure that the device withstands the usage during its lifetime it is important to follow instructions provided in this manual.

Rx only: Federal (USA) law restricts this device to sale to or on the order of a clinician.

The device is intended to be used by or under the supervision of licensed medical professionals. The device may be used on patients during a physical assessment in a clinical setting or by patients under the supervision of a clinician. The system provides one source of data that is significant only when used in conjunction with clinician oversight and consideration of other relevant patient information.

This device should be used only by qualified clinicians or by patients with an adequate understanding of the device. This device is intended for use on patients that can be auscultated normally with an acoustic stethoscope.

Maintenance while the device is in use is not allowed. When maintenance is ongoing the device should not be charging.

There are no user serviceable parts. The device should be serviced by authorized personnel only.

Service performed by non-authorized personnel may affect the recorded data and result in possible incorrect usage. The warranty is void if the Keikku is opened for any other purpose other than for the membrane replacement.

Only properly trained persons are allowed to perform maintenance operations.

Make sure that Keikku and its parts are not damaged. Using a damaged Keikku or its parts may cause wrong diagnosis.

Do not use Keikku and/or its parts during radiography/X-ray studies.

Check the approved environmental conditions before transport / usage. Make sure to use a storage box when transporting Keikku. Box provides protection for the Keikku device.

Do not destroy the sales box, it contains important information about the device.

When using the Keikku in the home, avoid exposing it to lint and dust.

When using Keikku in the home, keep it away from pets.

Device has no alarm function

The Keikku device is compliant with biocompatibility IEC 10993-1 but using the device may cause temporary allergic reaction, rash or irritation. If symptoms persist, contact your healthcare professional. To avoid rash, make sure that patient skin is clean and free from cream before use.

Extreme Heat or Cold Conditions and Battery Functionality

Follow defined environmental conditions and avoid using Keikku when the device is overheated. In case of overheating please contact your distributor.

To mitigate the risks associated with extreme temperature conditions, please adhere to the following precautions:

- **Operational Temperature Range:** Ensure that the device and battery are used within the specified operational temperature range provided in the user manual or manufacturer's guidelines.
- **Avoid Prolonged Exposure:** Minimize exposure to extreme heat or cold conditions. Do not leave devices or batteries in direct sunlight, near heaters, or in

freezing environments for extended periods.

- **Storage Guidelines:** When storing devices or spare batteries, choose a cool and dry location, avoiding extreme temperature fluctuations. Follow recommended storage conditions provided by the manufacturer.
- **Warm-up or Cool-down Periods:** If your device has been exposed to extreme temperatures, allow it to acclimate to a moderate temperature before use. This helps stabilize battery performance and ensures optimal functionality.
- It is essential to understand that extreme temperature conditions can significantly impact battery performance, lifespan, and safety. Adhering to the guidelines outlined in this warning will help maintain the reliability and longevity of your device's battery.

To reduce the risks associated with very strong electromagnetic fields avoid using the stethoscope near strong radio frequency (RF) signals or portable and/or mobile RF devices and/or specific RF emitters that are known sources of electromagnetic disturbance such as diathermy, electrocautery, RFID, security systems (e.g., electromagnetic anti-theft systems, and metal detectors). Interference from hidden RF emitters like RFID might cause packet loss and this will be visible as connection lost in the Keikku app. Move away from the hidden RF emitter if this happens. If sudden or unexpected sounds are heard, move away from any radio transmitting antennas. Using accessories, transducers, and cables not produced by Lapsi Health Holding B.V may result in increased RF emissions or decreased immunity of the Keikku.

Keikku contains a Bluetooth wireless data link. The maximum radio frequency field strength generated by the stethoscope is below three volts per meter, a level that is considered safe to use with other medical devices. However, audio, video, and other similar equipment may cause electromagnetic interference. If such devices are encountered and cause interference, immediately move Keikku away from that device and/or turn the Bluetooth feature OFF.

To improve Bluetooth connection, reduce the distance and/or allow a line of sight between Keikku device and mobile device. The Bluetooth range will be reduced when objects (walls, furniture, people, etc) are between the Keikku device and a paired mobile device

To ensure high quality sounds location and position of Keikku placement should be taken into consideration when auscultating

To reduce risk of asphyxiation and strangulation, ensure that all components are properly attached and stored. Keep away from children.

Please be aware of the potential risks associated with using Bluetooth-enabled devices in close proximity to heart pacemakers. This warning aims to inform you about the precautions necessary to avoid any adverse effects on pacemaker functionality and your overall health.

Bluetooth technology utilizes electromagnetic signals to establish wireless connections between devices. While generally safe for most individuals, it is essential to exercise caution when using Bluetooth devices if you have a heart pacemaker or any other

implanted medical device. Interactions between Bluetooth signals and pacemakers can result in unwanted consequences, including potential interference with the pacemaker's normal operation. If you have any concerns or questions regarding the use of Bluetooth devices with your pacemaker, consult with your healthcare provider or cardiologist.

Do not operate this system in proximity to substantial emitters, such as:

- Military areas (e.g., submarines, radar installations, weapons control systems)
- Heavy industrial areas (e.g., power plants, steel and paper mills, foundries, automotive and appliance manufacturing, smelting and mining operations, oil and gas refineries)
- Aircraft environments (e.g., planes, helicopters)
- Public security systems (e.g., metal detectors, electronic article surveillance, electromagnetic anti-theft systems).

Do not operate this system in medical treatment areas with high powered medical equipment, such as: high-frequency surgical equipment, short-wave therapy equipment, MRI system, and unique medical emitters such as electrocautery, electrosurgical units, and diathermy equipment.

To enable best audio quality make sure that you have a quiet surrounding when auscultating. We recommend only performing an exam in a quiet, closed room. Try to avoid recording data in a hallway or an area with music, other people talking, or other background noise.

To reduce the risks associated with infection, follow all cleaning instructions included in this manual . Establish and follow a cleaning schedule after each use. Standard stethoscope hygiene practices apply to the Keikku device.

6. EMC COMPLIANCE

FCC International Radiator Certification

Contains FCC ID: XPYNORAB1

47 CFR Part 15.105 required statement for class B:

This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide

reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

NO MODIFICATION

Modifications to this device shall not be made without the written consent of Lapsi Health Holding B.V. Unauthorized modifications may void the authority granted under Federal Communications Commission rules permitting the operation of this device.

7. CONTENTS AND OPERATION

The following section details the steps involved in going from the opening of the sales package for the first time to getting the system ready for use. Do not throw the package away, use it for storing the Keikku device when it is not in use.

Contents of the package

- 1 Keikku Digital Stethoscope
- Quick Instruction guide

1. Unpacking the Keikku

Keikku comes in a shrink-wrapped sales cardboard box.



Figure 2 Keikku device package

2. System Overview and requirements

The system consists of a chest piece and an application for use with the chest piece.

An application that is available for iOS and Android.

The application can be downloaded from the Apple App Store for iOS and from the Google Play Store for Android.

The versions of those OS supported are the following:

- iOS: Version 16 and above
- Android: Version 12 and above

Headphones are not provided with Keikku: Any third-party headphones or Pods, that support Bluetooth, can be connected to the iOS or Android device wirelessly. If the headphones support connection to the mobile device with a cable that can also be used.

Please note - the usage mode of the headphones or Pods being used should be placed in an optimized mode for usage with Keikku if different modes of operation exist. In case of doubt please contact the headphone manufacturer and/or refer to the relevant documentation.

3. Operating overview

Keikku is intended to be used by healthcare professionals to electronically amplify, filter, and transfer body sounds. The Keikku is also suitable for use by lay persons as long as they are using it under the supervision of a healthcare professional. The system includes a mobile application that is used for recording, editing, storing and sharing sound files.

The device is used to record different body sounds including heart sounds (cardiac murmurs, etc), respiratory sounds, and abdominal sounds during physical examination in normal patients or those with suspected diseases of the cardiac, vascular, pulmonary, or abdominal organ systems. The device can be used on adults and pediatrics.

The data received by using the Keikku system should **only be interpreted** by a qualified healthcare professional.

The Keikku chest piece is a wireless digital stethoscope that transmits body sounds to the Keikku app that is installed on a mobile device such as a mobile phone. The app in turn transmits the sound to a headset or speaker to be listened to. The Keikku app also allows for the annotation of the collected sounds files and for these files to be shared with other persons who have the Keikku app installed. The following diagram illustrates the data flow in the system.



Figure 3 Keikku system data flow during operations

Bluetooth and Data connection

In order to transmit sounds to the Keikku App, the stethoscope and mobile device must be connected via Bluetooth, and in order to fully use certain functions, the mobile device must be connected to the internet via cellular data connection or Wi-Fi. Please keep Keikku and the Keikku App within 15 feet of each other for optimum Bluetooth connection.

4. Prepare for App Setup

To ensure that the app setup goes as smoothly as possible, please have the following available:

- An internet connection through a WiFi or cellular network connection.
- Your Apple ID and password or Google Play username and password, if registering with your Apple or Google accounts.
- Ensure that Bluetooth is enabled on the iOS or Android device.
- It is recommended that the headphones being used are connected to the iOS or Android device.

NOTE: Check that you have enough storage space available on your device. To check this please refer to the documentation of your device. The Keikku app uses approximately 100 MB of space.

8. USAGE OF THE KEIKKU



Caution: Ensure the safe and effective use of your device by following the cleaning and maintenance guidelines provided in this manual. Failure to adhere to these instructions may result in potential harm to the patient.

Improper Cleaning Risk:

- Failure to clean the device as instructed may lead to potential damage.
- Potential damage to the device can impact its safe and effective use.
- Adverse health effects, such as skin infections, may result from inadequate cleaning.

It is crucial to strictly adhere to the cleaning guidelines outlined in this manual to mitigate these risks.

The Keikku is a multiple patient, multiple use device.

Processing between uses

The Keikku device should be sufficiently cleaned between uses following instructions provided in this manual. Keikku should be charged every time the battery level is low. The Keikku does not perform nor require periodic self-check maintenance activity to maintain functionality. Ensure the Keikku is within the specified continuous operating conditions prior to use. There is no warm-up or cool-down period required between uses. There are no known adverse effects of lint, dust, or direct sunlight on the functionality of Keikku. However, the device should be stored in a clean location. The device should be stored away from children and pets to prevent unintended tampering.

To ensure the device's continued effectiveness and safety, perform visual inspections at regular intervals. During cleaning ensure Keikku functionality by visually checking that surfaces are intact and seals are not cracked. In case deviation found during the visual check, stop using the device and contact Lapsi Health customer support.

Cleaning instructions

NOTE: DO NOT immerse the Keikku device in any liquid or subject it to any high-pressure/autoclave sterilization processes.

The Keikku device should be disinfected between uses following instructions provided in this manual. The Keikku does not perform nor require periodic self-check maintenance activity to maintain functionality. Standard stethoscope hygiene practices apply to the Keikku device.

Clean Keikku after usage by using 70% isopropyl alcohol wipes.

Ensure all external surfaces are dry prior to use.

After cleaning, examine the device for any remaining contaminants. Pay particular attention to the membrane area which contacts the patient's skin. If residual contaminants are observed, repeat the relevant cleaning steps outlined in this manual. Ensure that all visible soil is removed before

Charging the Keikku Device

NOTE! Charger is not included in the Keikku package.

When the device is taken from its package, it has to be charged before use. The Keikku device is charged using a wireless charger.

1. Plug-in the wireless charger to an energy source using the supplied cable.
2. Place the Keikku device on the wireless charger. A light will appear on the device to indicate that it is charging. NOTE! Make sure to place the membrane side on the charger.
3. When the device is fully charged a light appears indicating that the device is now ready for usage.



Connecting the headphones

Ensure that your headphones are connected to your mobile device prior to setting up, or starting the Keikku app.

Download the App

The app is downloaded from the Apple App Store or Google Play store. An Apple / Google Play store account is required for this purpose.

Once downloaded, the app is started by tapping the Keikku icon.

NOTE! Do not prevent app to send notifications because the state of the device is sent via the app

Registration

Registration, and completion of user information, must be done only once.

The first time the Keikku app is started, a wizard will take you through the device registration and initial setup.

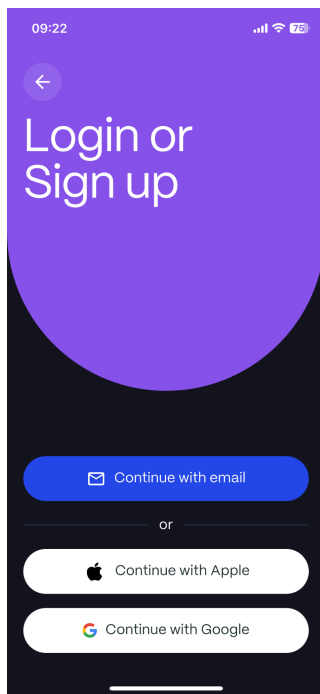


Figure 4 Registration

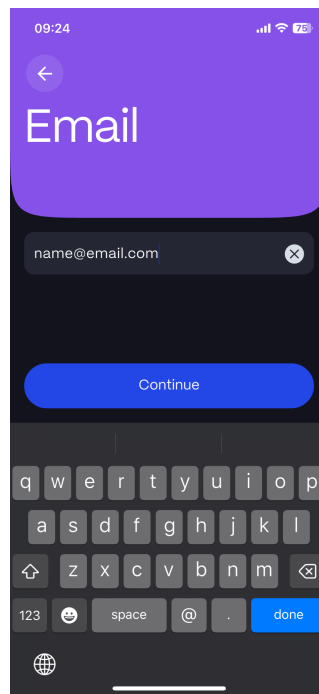


Figure 5 Email Login

On **Figure 4**, tap “Register” to start the wizard to create an account using your email and selecting a password. An activation email is sent to the email address provided. (**Figure 5**)

Alternatively, you can select one of the Google or Apple login options to login with those existing credentials.

After the first login you will select your login method or tap “Login”, if an account using username or password has been created.

After the first login the credentials can be associated with a FaceID profile to allow for subsequent login using FaceID.

Device Pairing

Note! There is no power button on the Keikku.

Keikku device will power on when it is picked up.

Make sure that Bluetooth is enabled on the selected mobile device.

Following registration, a Keikku device should be selected, for use with the app, and certain user information must be filled in. A wizard procedure is available to walk you through the process.

These steps can also be completed at a later stage and the information form is accessible via the **Settings Menu**.

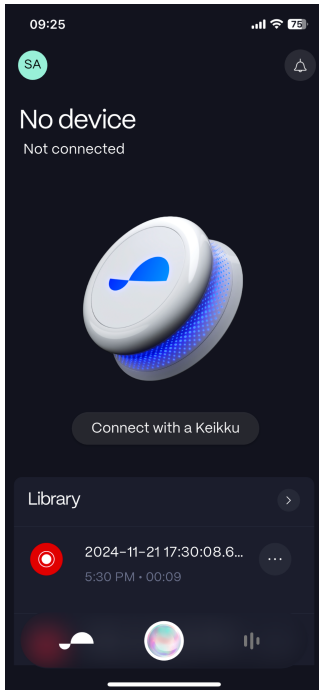


Figure 6 Connect with a Keikku devices

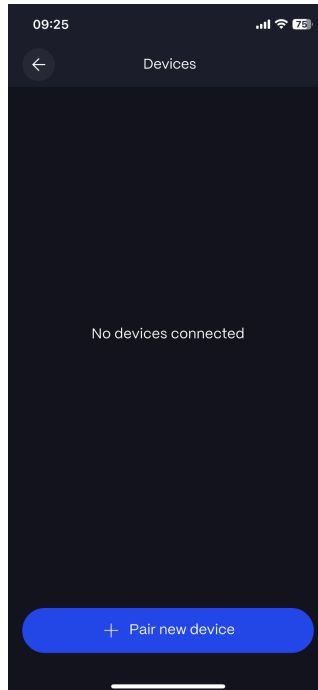


Figure 7 Connecting to the Keikku device

Once logged in, tapping the “Connect with a Keikku” (Figure 6) icon will bring you to the pairing screen where you can choose to pair a new device.

Click on “Pair new device”.

You will see the available Keikku devices available for pairing.

If you do not see the Keikku device(s) listed, please refer to Section troubleshooting.

Please note that when you receive your Keikku it is in “Shipping Mode” and must be activated by placing the device on a charger.

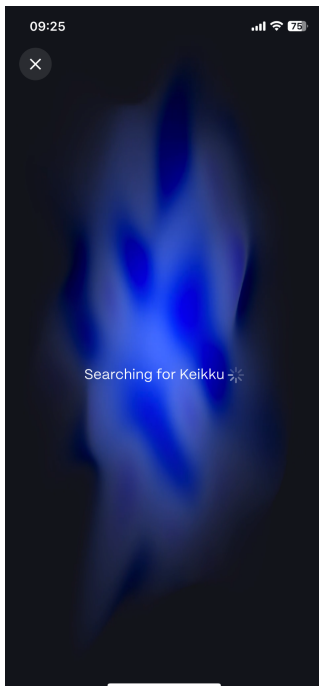


Figure 8 The Keikku app will scan for available devices



Figure 9 Choosing to Pair with a Keikku



Figure 10 Pairing is complete

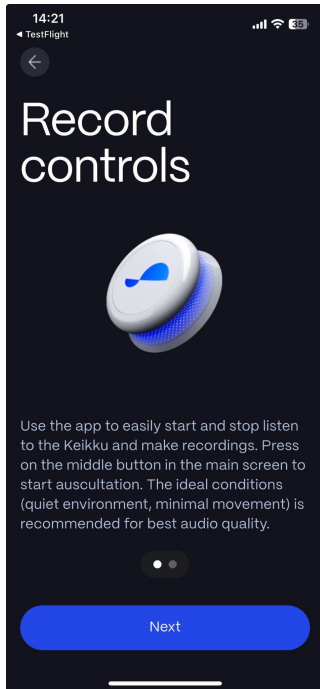


Figure 11 Information on starting auscultation

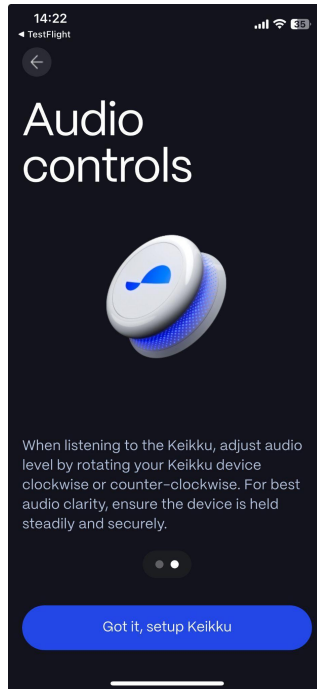


Figure 12 Information on gesture control to increase and decrease volume

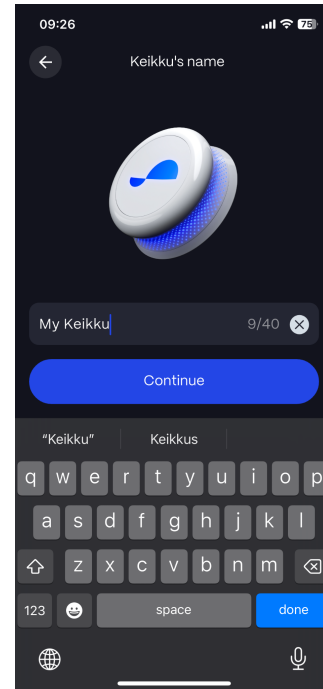


Figure 13 Naming your Keikku device

You can give your Keikku a name and proceed to tell us some details about yourself (**Figure 12**). You also have the option to subscribe to our newsletter and receive updates regarding your Keikku.

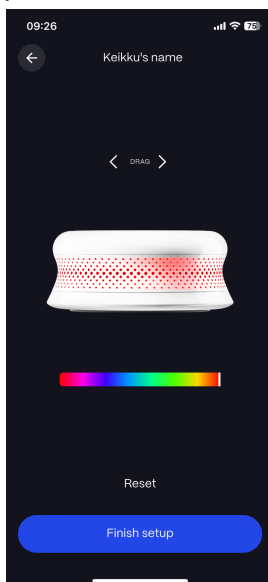


Figure 14 Select the default color for LED lighting

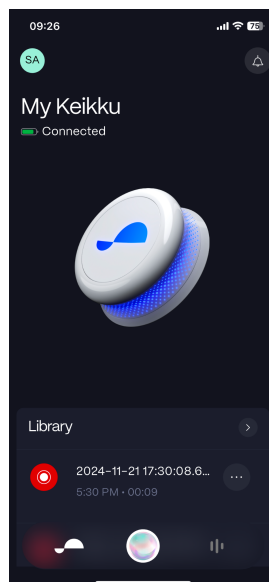


Figure 15 Keikku is ready for use

Tapping “Finish” ends the setup wizard and allows you to start using your Keikku (**Figure 15**).

Starting a recording

Once you have logged into Keikku, the main Home Screen appears.

The Home Screen allows access to the device settings menu, the Notifications Screen, the Auscultation Screen, and the library of saved sound files.

Below the name of the device and indicator of the remaining battery lifetime is shown.

The animated icon on the bottom of the screen allows you to enter the Auscultation Screen.

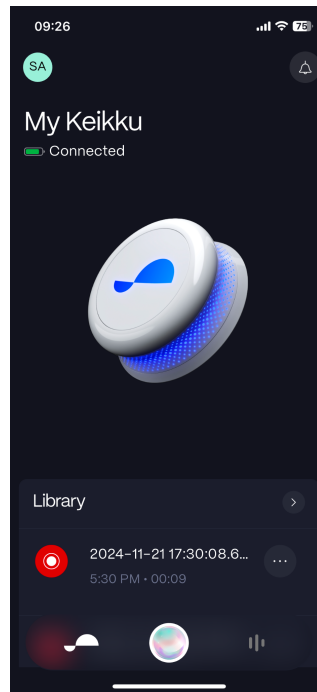


Figure 16 The Home Screen

Icon explanations:



This icon shows the initials of the user. Clicking brings you to the User Profile screen where user and device information is accessible.



This icon links to the Notifications screen.



Clicking the Keikku icon brings you back to the Home Screen.



Clicking this icon brings you to the sound files library.



Clicking this animated icon brings you to the Auscultation Screen.

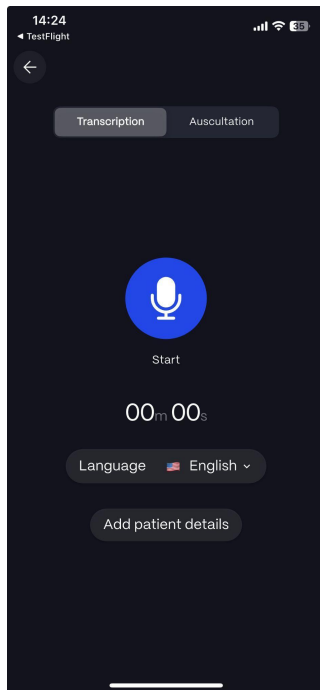


Figure 17 The Transcription Screen

Keikku offers the possibility to transcribe conversations. This feature is available if a subscription for transcription has been purchased. The description of the transcription feature is outside the scope of this guide.

Separate User Guides are available for features available with subscription.

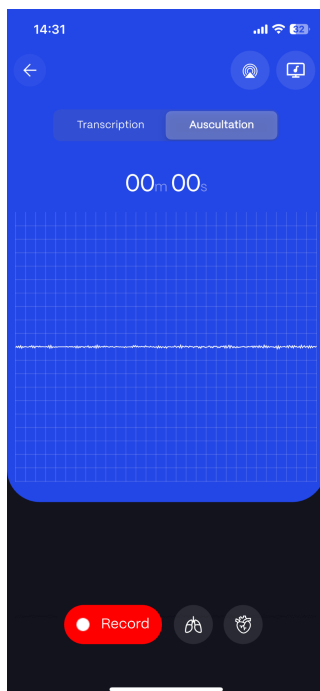


Figure 18 The Auscultation Screen

Tap “Record” to start using the Keikku device to gather auscultatory sounds.



With this option selected the sounds heard are filtered to highlight cardiac sounds.



With this option selected the sounds heard are filtered to highlight pulmonary sounds.



Allows you to share your session and enables others to listen to the Keikku audio stream. Sharing the QR code will enable others to listen to the audio over the internet.



Allows you to choose which bluetooth device the sound should be streamed to.

9. APP OVERVIEW

Recording, Editing, Listening to, and Sharing Auscultatory sounds

This section describes how to use the Keikku and make auscultatory sound recordings.

Note: Before starting please ensure that both the Keikku device and headphones/speakers are connected to the iPhone/Android device via bluetooth.

Warning: The device is not intended to be used while the person being auscultated is moving. Please ensure that the person is standing still, sitting or lying down, before starting to take sound recordings.

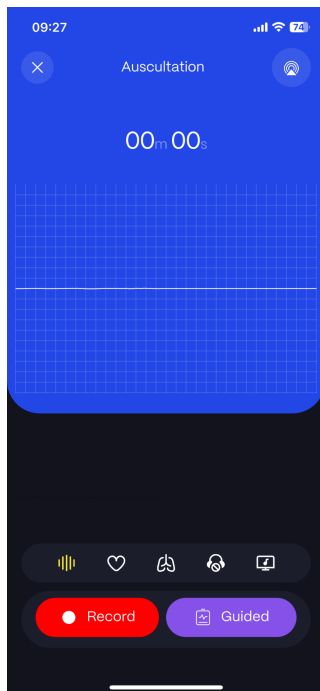


Figure 19 Recording

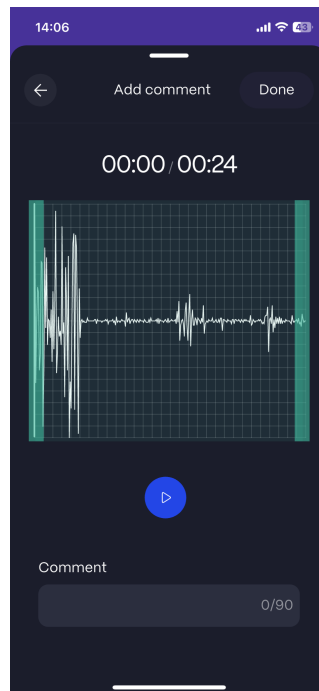


Figure 20 Annotating Sound Files

On **Figure 19**, press “**Record**” to start listening and recording the sound of the patient, when the device is pressed to the skin of the patient.

Previous recordings are available in the library and can be selected, edited, shared and played.

When a file is tapped on to select it for listening to or editing, information can be added. This information includes:

- Assigning patient information (name and patient ID)
- Adding information about findings (murmur, wheezing, crackles, rales, stridor)
- Comments can be added and the file cropped to include only that part of the file where the comments are applicable to
- The auscultation points that have been listened to can be added by tapping on “+ Add

Auscultation Points”.

- Certain parts of a file can be selected with the remainder of the file being discarded. Auscultation points can be added following the trimming.

Notes can be added to describe what is being heard in the file - or any other information that is deemed relevant.

Warning: If the mobile device memory is full, then recordings cannot be saved to the device or uploaded to the Cloud. Please refer to the device manual on how to free up storage space if this is the case.

Sharing Files

Recorded files can be shared with other Keikku users.

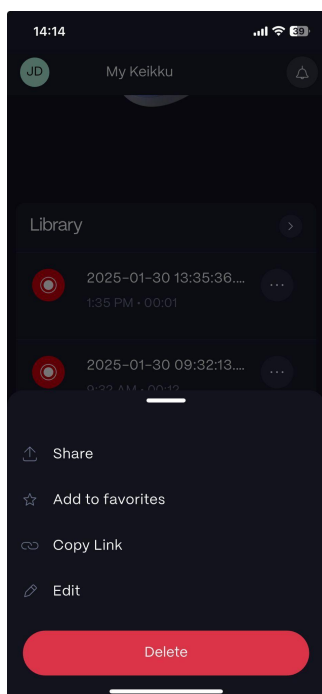


Figure 21 Sharing a saved sound file

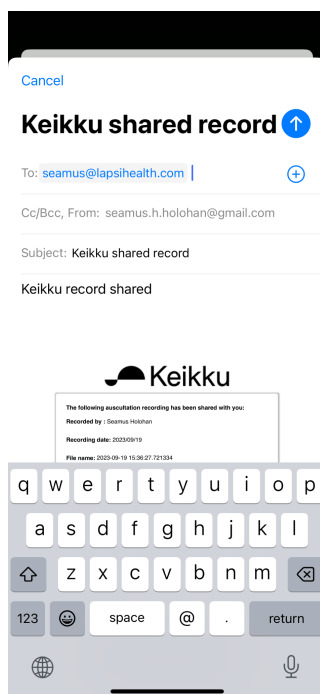


Figure 22 Sharing the sound file via email

The file to be shared is selected by tapping the three dots beside the file name in the library and then selecting “Share”..

The method to share the file is then selected. In the example email is used and the email address of the recipient is entered.

The file can also be shared using the normal file sharing options that are available to the operating system being used, e.g. AirDrop.

Password Management

Keikku includes a password management feature that allows for a password to be reset if forgotten.

This process is available for an Account created with a Keikku username and password. If other methods are used, such as Google, please refer to the documented procedures on how to reset the password from within their system.

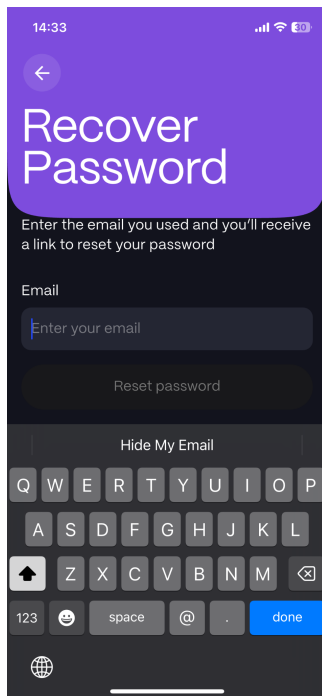


Figure 23 Forgot password

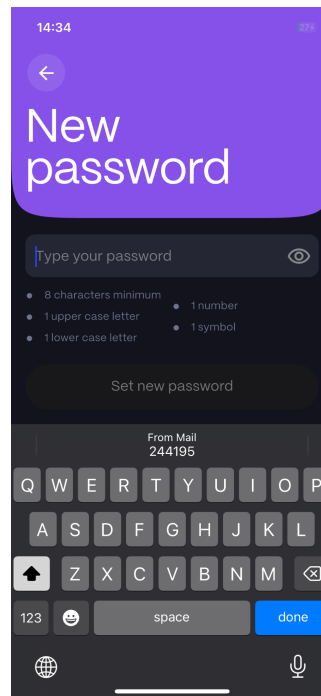


Figure 24 Password changing

The Recover password screen is accessed by tapping on “Recover Password” that is shown above the field for entering the password.

As shown in **Figure 23**, enter the email address associated with the Keikku account.

To recover the password (**Figure 24**):

1. Enter the email address associated with the account.
2. Tap the “**Reset password**” button.
3. Check email to receive the verification code.
4. Enter the verification code in the field provided.
5. Enter a new password.
6. Tap the “**Set new password**” button to confirm the password change.

Notification Center

The Notification Center is accessed by tapping on the bell icon on the Home Screen. The Notification Center provides certain information, including:

1. Information when battery life remaining on the Keikku device is below 20%.
2. Alerts sent to the users by the device manufacturer (for example an alert may be sent when a new software or firmware version is available for download).

-
3. When some other Keikku user shares a recording with you.

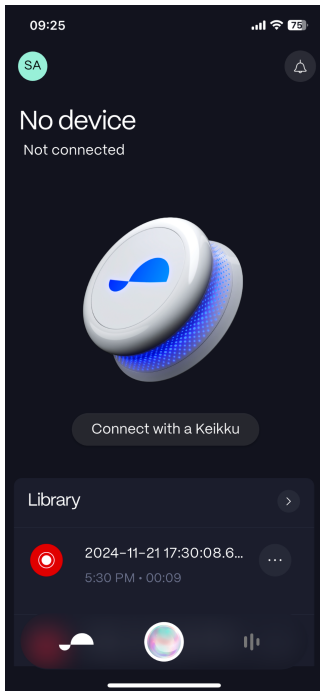


Figure 25 Accessing the Notification from the Home Screen

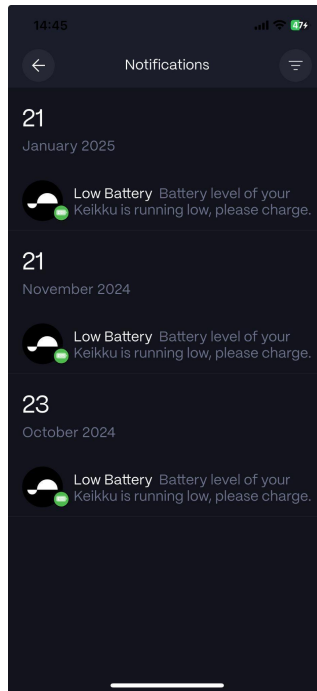


Figure 26 Notifications

Settings

The Settings screen is accessed by tapping the User Profile picture from the Home Screen menu.

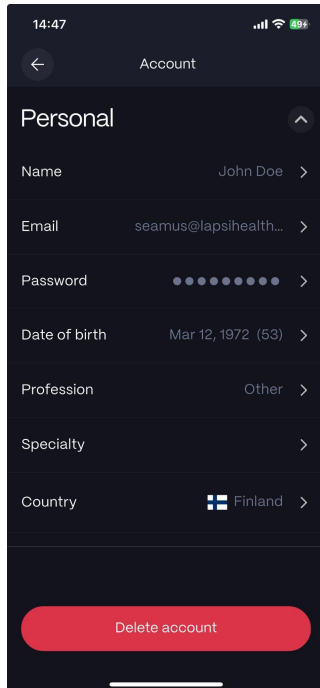


Figure 27 Personal Information

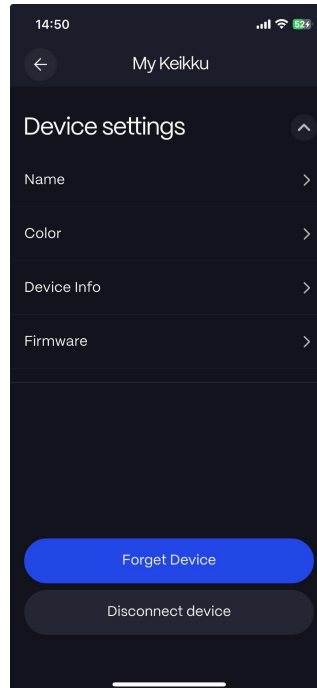


Figure 28 Device Settings

Within Settings, there is the possibility to enter the personal information about the device owner or user (**Figure 27**).

From the Settings screen, the Device Setting screen can be accessed.

Device information including battery charge remaining, software version and firmware version is shown.

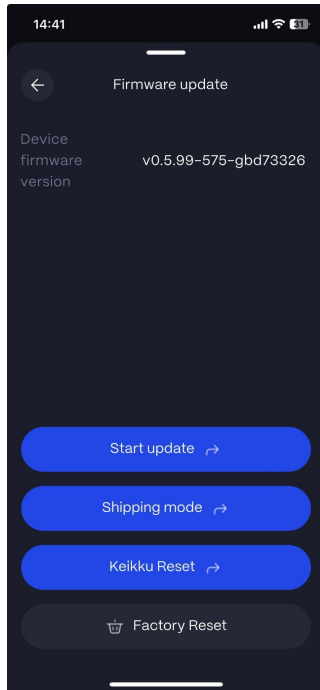
From this screen you can:

- Change the device name
- Control the LED lighting settings
- Check the device info including retrieving the device serial number
- Setup a new Keikku device
- Forget the device
- Update the device firmware
- Update the device software
- Conduct a factory reset

NOTE: If Google or Apple accounts are used for login, then the “Change Password” option is not available and the passwords are changed via Google or Apple.

Updating the Keikku Firmware

A notification is sent to the notification center when a new version of the Keikku firmware is available for download and installation. You can check for updates via the Device settings screen.



Tap **“Start update”** button to check for and install a new version of the device firmware.

Tap **“Shipping mode”** to place the device in shipping mode. Shipping mode is exited by placing the device on a charger.

Tap **“Keikku Reset”** to reset the software.

Tap **“Factory Reset”** to revert to the original factory settings.

Figure 29 Updating the Device Firmware

10. SPECIFICATIONS AND ELECTRICAL SAFETY

Technical Specifications

Model: Keikku digital stethoscope

Connectivity: Bluetooth LE 5.2

Diameter: 59,6mm Height: 25,3mm

Weight: 67 g

Battery: Internal Li-Ion Polymer 4,35V and 325 mAh. Not replaceable.

Recording time: 70h

Charging time: 12h

Materials: PVC and medical-grade silicone

Service lifetime: 2 years

Frequency Band: 2.402 GHz – 2.480 GHz

Power: Max transmission output power 0 dBm

Environmental Conditions

Temperature:

Operational: -4°F to +140°F (-20°C to +60°C)

Transport and Storage: -13°F to +140°F (-25°C to +60°C)

Charging: 32°F to +113°F (0°C to +45°C)

Humidity:

Operational: 15% to 90% (non-condensing)

Transport and Storage: 10 to 90% (non-condensing)

Atmospheric pressure:

Operational: 700hPa to 1060hPa

NOTE!

Please note that when the environmental temperature is +20°C (+60°F), the time required for the device to warm from the minimum storage temperature between uses, until it is ready for its intended use, is approximately 20 minutes.

NOTE!

Please note that when environment temperature is 20°C (+60°F), the time required for device to cool from the maximum storage temperature between uses until it is ready for its intended use is approximately 30 minutes

Disposal Instructions

When the Healthcare Professional wishes to discard the product or its parts, it must be sent to separate collection facilities for recovery and recycling. Please contact the relevant authorities to determine the proper method of disposal of potentially biohazardous parts and accessories.

Lifetime

Normal battery service life is expected to be 2 years when used as described in this manual. When the battery is at the end of its service life, the usage time of the device is reduced.

Service and Repair



CAUTION!

If repair is needed, only an authorized repair service should be used. Please refer to our website: [keikku.com/support](https://www.keikku.com/support) for further information and to find your nearest authorized service center.



CAUTION!

The battery is not replaceable, if the battery is not working then please contact

support or your distributor.



WARNING!

The development, production and maintenance of this device, together with associated risks, are based on an expected device life time of two years. Modifications to the product or failure to follow the manufacturer's instructions may substantially reduce the expected service life and significantly increase the risks associated with the use of this device.

Warranty

Lapsi Health provides a 12-month warranty for the Keikku device and parts. The warranty is void if:

- The chestpiece module has opened or modified
- Negligence of instruction for use
- Device is used in an environment that is not approved under the instructions for use
- The device has been deliberately broken

Compliance to Standards

The Keikku device is compliant with standard IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

The performance of the Keikku stethoscope can be generally described as to monitor human body sounds. It is primarily designed for capturing and transmitting audio signals from the patient's body to a digital platform for analysis, recording, or sharing.

This functionality can fail in two distinct ways:

- Measured data from the Keikku device is bad or inaccurate
- Data from the device is lost

Intended use excludes usage of the device for critical and/or life-supporting situations, the possible risk is limited to failure in obtaining (accurate) signal data. And in both cases the user is notified whether signal quality is unacceptable (device is not transmitting the data) and / or no data is transmitted or lost. It is important to operate the device within this specified environment to ensure proper functionality.

The measurement must be repeated, with repaired or replacement Keikku device, to get accurate signal data. In both cases the risk is considered acceptable.

The Lapsi Health Keikku device has no essential performance.

Electromagnetic compatibility (EMC) information

The Keikku device needs special precautions regarding Electromagnetic Compatibility (EMC), and needs to be installed and put into service according to the EMC information detailed in the section “Electromagnetic Compatibility (EMC) Information” of this manual.



WARNING!

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.



WARNING!

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emission or decreased electromagnetic immunity of this equipment and result in improper operation.



WARNING!

Portable and mobile RF (radio frequency) communications equipment (for example mobile phone), (including peripherals such as antenna cables and external antennas) can cause Keikku device performance degradation. Portable and mobile RF devices should be used no closer than 30cm (12 inches) to any part of the Keikku, including cables specified by the manufacturer.



CAUTION!

Replacement cables may be purchased only from Lapsi Health or an authorized distributor. Using other cables than specified may cause degradation of the performance of this equipment.



CAUTION!

This product complies with current required standards for electromagnetic interference and should not present problems to other equipment or be affected by other devices. As a precaution, avoid using this device in close proximity to other equipment.



CAUTION!

To reduce the risks associated with very strong electromagnetic fields avoid using the stethoscope near strong radio frequency (RF) signals or portable and/or mobile RF devices and/or specific RF emitters that are known sources of electromagnetic disturbance such as diathermy, electrocautery, RFID, security systems (e.g., electromagnetic anti-theft systems, and metal detectors). Interference from hidden RF emitters like RFID might cause packet loss and this will be visible as a “Poor Bluetooth Signal” message on the mobile application. Move away from the hidden RF emitter if this happens. If sudden or unexpected sounds are heard, move away from any radio transmitting antennas. Using accessories, transducers, and cables not produced by The Lapsi Health may result in increased RF emissions or decreased immunity of the Keikku.

**CAUTION!**

In case this product is used around other wireless devices including microwave and wireless LAN, which operate on the same frequency band as this Product, there is a possibility that interference may occur between this Product and other such devices. If such interference occurs, please stop the operation of the other devices or relocate this Product before using this Product or do not use this product around the other wireless devices.

**CAUTION!**

The use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emission or decreased electromagnetic immunity of this equipment and result in improper operation.

Guidance and manufacturer's declaration – electromagnetic emissions		
The Keikku device is intended for use in the electromagnetic environment specified below. The customer or the user of the Keikku device should assure that it is used in such an environment.		
RF emissions CISPR 11	Group 1	Keikku uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Voltage fluctuations and flickering IEC 61000-3-3	Complies	
Harmonic current emissions IEC 61000-3-2	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Keikku device is intended for use in the electromagnetic environment specified below. The customer or the user of the Keikku device should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±2 kV, ±4 kV, ±8 kV Contact discharge ±2 kV, ±4 kV, ±8 kV, ±15 kV Air discharge	±2 kV, ±4 kV, ±8 kV Contact discharge ±2 kV, ±4 kV, ±8 kV, ±15 kV Air discharge	Floors should be wood, concrete or ceramic tile. If floor is covered with synthetic material humidity should be at least 30%
Rated power frequency (50/60 Hz) magnetic fields IEC 61000-4-8	30A/m, 50/60Hz	30A/m, 50/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% Ut: 0,5 cycle At 0°, 45°, 90°, 180°, 0% Ut: 1 cycle And 70% Ut: 25/30 cycles Single phase: at 0° 0% Ut: 250/300 cycle	0% Ut: 0,5 cycle At 0°, 45°, 90°, 180°, 225°, 270° and 315° 0% Ut: 1 cycle And 70% Ut: 25/30 cycles Single phase: at 0° 0% Ut: 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment.
Conducted RF ^{a)} IEC 61000-4-6 Radiated RF EM fields IEC 61000-4-3	3Vrms, 0.15 MHz – 80 MHz and 6Vrms, in ISM and amateur radio bands between	3Vrms, 0.15 MHz – 80 MHz and 6Vrms, in ISM and amateur radio bands between	Portable and mobile RF communications equipment should be used no closer to any part of the Keikku device than the

	0,15 MHz and 80 MHz	0,15 MHz and 80 MHz	recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80MHzto800M Hz $d=2.3\sqrt{P}$ 800MHzto2.7G Hz, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Radiated RF EM fields IEC 61000-4-3	10V/m Home healthcare at 80 MHz – 2700 MHz, AM Modulation 3V/m at 2.7GHz–6GHz,AM Modulation	10V/m Home healthcare at 80 MHz – 2700 MHz, AM Modulation 3V/m at 2.7GHz–6GHz,AM Modulation	
Immunity to proximity magnetic fields IEC 61000-4-39	8A/m at 30 kHz, 65A/m at 134.2 kHz 7.5A/m at 13.56 MHz	8A/m at 30 kHz, 65A/m at 134.2 kHz 7.5A/m at 13.56 MHz	NA
a) The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are: 6.765 MHz to 6.795 MHz; 13.553 MHz to 13 13.567 MHz; 26.957 MHz to 27.283 MHz and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are: 1.8 MHz to 2.0 MHz; 3.5 MHz to 4.0 MHz; 5.3 MHz to 5.4 MHz; 7 MHz to 7.3 MHz; 10.1 MHz to 10.15 MHz; 14 MHz to 14.2 MHz; 18.07 MHz to 18.17 MHz; 21.0 MHz to 21.4 MHz; 24.89 MHz to 24.99 MHz; 28.0 MHz to 29.7 MHz and 50 MHz to 54 MHz.			

Proximity fields test frequencies and test levels

Test frequency (MHz)	Band (MHz)	Modulation	Test level (V/m)	Compliance level (V/m)
385	380-390	Pulse modulation 18 Hz	27	27
450	430-470	Pulse modulation 18 Hz	28	28
710 745 780	704-787	Pulse modulation 217 Hz	9	9
810 870	800-960	Pulse modulation 18 Hz	28	28

930				
1720 1845 1970	1700-1990	Pulse modulation 217 Hz	28	28
2450	2400-2570	Pulse modulation 217 Hz	28	28
5240 5500 5785	5100-5800	Pulse modulation 217 Hz	9	9

Separation distances

The Keikku device maintains basic safety and essential performance when used in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of The Keikku device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and The Keikku device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	From 150 kHz $1.2 \sqrt{P}$	From 80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	From 800 MHz to 2.7 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

11. CYBERSECURITY INFORMATION

Cybersecurity

Lapsi Health Holding B.V uses industry-standard instructions to protect the device, including its hardware, system development servers, and the data on those servers by using access enforced firewalls, and SSH secure communications. In addition, the company maintains regular security patches for firmware, applications, and modules used. User should strictly follow the instructions and technical notes listed in this section to reduce any cyber security risk to the system.

Device Security

It is the responsibility of the authorized user to ensure that the Mobile application is not left unlocked, or otherwise unsecured when not in use, to ensure that non-authorized medical, professional, or otherwise unapproved personnel are not exposed to, or gain access to, ePHI.

User Responsibility

Administrators have access to patients' ePHI and must not take snap-shots, screenshots or pictures (e.g. using another device) of any information viewed through the device.

Operators should not enter identifying data into the device. All the data on the device should be de-identified and relate to the sample id and not to the patient.

Reporting Device Security or Privacy Breaches

Operators must contact Lapsi Health Holding B.V support team and disclose any suspected or confirmed privacy or security breaches.

Recovering from Compromised Accounts or Devices

When devices are lost, or unauthorized access is discovered or suspected, Lapsi Health Holding B.V support team should be contacted.

Unavailable Service

Users should report unavailable service or prohibited access to information to the Lapsi Health Holding B.V support team.

Cybersecurity system description

The device does not interface with other devices using connectors or any physical means.

Device may interface with the devices via secured Bluetooth low energy (BLE) interface. Never try to connect the device with devices other than devices recommended by Lapsi Health Holding B.V.

The device, mobile application and cloud system are designed to provide several features that protects the system against cyber threads:

- Device firmware is encrypted to prevent any changes in firmware by uncertified personnel.
- The communication between the mobile and cloud is encrypted by several means.

The device cloud provides several means of device data backup

- All device logs and data are stored in the cloud system and not locally on the device.
- Device firmware is always backedup by Lapsi Health Holding B.V.
- The nature of the system is constant backup in the cloud system.

The system is ready for use. No system settings are required either for system operation or connection with system cloud.

The device firmware is not accessible for the user, therefore no access to any system log files is permitted for the user.

12. TROUBLESHOOTING

Access to customer support, including contact information, and our FAQ is found via our website <http://keikku.health>

The following are descriptions of the most common errors encountered and how to solve them.

Battery is out of charge

Device has not been charged prior to use. Charge the device using a wireless charger.

The Keikku device is not visible on the phone even when charged

Ensure that bluetooth is enabled on your mobile device. This can be checked under “**Settings**” on the device. For more detailed information, please refer to the user guide for the mobile device you are using.

Everything appears to be working but I can’t hear anything

Increase the volume on the mobile device that is connected to the Keikku device.

Devices are out of bluetooth range

Bluetooth operates within a specified range, typically up to 100 meters (or 330 feet) in open spaces. However, this range can be significantly reduced depending on the environment. Obstacles like walls, furniture, or other electronic devices can impede the signal strength and reduce the effective range. It is essential to maintain an awareness of the physical environment when using the Keikku device to avoid potential connectivity issues.

If you encounter connectivity problems, ensure that the devices are within the recommended range and attempt to re-establish the connection. If issues persist, consult the user manual or contact customer support for further assistance.

If the Keikku device is too far away from the phone and the operational range exceeded, the following consequences may occur:

- **Signal Degradation or Loss:** As the distance between the devices increases beyond the recommended range, the Bluetooth signal strength weakens. This can result in a degraded connection or complete signal loss, leading to intermittent or non-existent communication between the devices.
- **Audio/Video Quality Issues:** In the case of audio or video streaming applications, moving beyond the recommended Bluetooth range can cause audio or video interruptions, poor quality, or lag. These issues can significantly impact your listening or viewing experience.
- **Data Transfer Failures:** When transferring data files between devices, exceeding the Bluetooth range may result in incomplete or failed transfers. It can lead to data corruption, loss of information, or an inability to establish a connection altogether.
- **Increased Power Consumption:** In an attempt to maintain a connection outside the optimal range, devices may consume additional power, leading to faster battery drain. Extended distances between devices can strain their battery life, reducing overall usage time.

I can't upload my recordings to the cloud

Ensure that the mobile device is connected to the Internet. Please refer to the device's user manual or manufacturer's support resources for device-specific instructions.

13. ABOUT THIS MANUAL

This manual is provided in electronic format. It is available from Keikku's website at <http://keikku.health>

Electronic versions are provided as PDF documents and a PDF reader is required to open the documents. PDF readers are commonly available at no cost for users.

Printed versions of the instructions are available at no additional cost via <http://keikku.health>. The printed version will be sent within 7 calendar days.

Any serious incident that has occurred in relation to the Keikku device should be reported to the manufacturer via email: support@keikku.health and the competent authority of the Member State in which the user and/or patient is established. Serious incident means any incident that directly or indirectly led, might have led or, in case of recurrence, could lead to any of the following: the death of a patient, user or other person, the temporary or permanent serious deterioration of a patient's, user's, fetus or other person's state of health, or a serious public health threat.



Contact and Manufacturer Information

Lapsi Health Holding B.V.,
Matrix ONE
Science Park 301 unit 1.53
1098 XH Amsterdam
The Netherlands

<http://keikku.health>

The manufacturer is responsible for the safety, reliability and performance of this product providing the following conditions are observed and followed:

- All product expansions, changes, modifications, and repairs of this product are conducted by the manufacturer or by manufacturer authorized personnel.
- The product is operated under strict observance of the instructions in this manual.
- Lapsi Health B.V. does not accept any liability for the use or misuse, whether direct or indirect, of the products, or for damages arising out of the use of or the inability to use the product.

All clinical conclusions and decisions that are based on the use of this product are the responsibility of the medical specialist.

Help Desk

Help desk information is available via the Keikku website at keikku.health.