PATH MEDICAL

User Manual

QSCREEN

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Manual Information

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Device: QSCREEN (PM1610)

All information, illustrations, and specifications provided within this manual are based on the latest product information available at the time of publication. PATH MEDICAL reserves the right to make changes at any time without notice.

The latest revision of the user manual is available online at www.pathme.de/downloads.

Errors and omissions excepted.

Copyright Notice

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1 Overview

1.1 Introduction

Thank you for purchasing the QSCREEN. This manual is your guide for safely operating and maintaining your device.

Please read this manual carefully before using QSCREEN for the first time. We recommend taking particular note of the safety (see section *8: Notes on Safety*), intended use (see section *1.3: Intended Use*), cleaning (see section *5: Cleaning*) and maintenance (see section *4: Service and Maintenance*) instructions.

QSCREEN is a reliable, easy-to-use, and mobile medical device, which provides easy navigation via touch-screen and is intended for hearing examinations (see section *1.3: Intended Use*).

Some of the mentioned firmware modules in this manual may not be included with your license. Please contact your distributor if you would like to upgrade your license to enable more modules.

1.2 Device Overview

Your QSCREEN device is delivered with a docking station for wireless charging of the handheld device and for data transmission to the PC via USB. The handheld device and the docking station are able to exchange data via Bluetooth.

Figure 1: QSCREEN (left) and Docking Station (right)

1.3 Intended Use

The QSCREEN device is a hand-held, portable hearing screener intended for recording and automated evaluation of Otoacoustic Emissions (OAE) and Auditory Brainstem Responses (ABR). Distortion Product Otoacoustic Emission (DPOAE) and Transient Evoked Otoacoustic Emission (TEOAE) tests are applicable to obtain objective evidence of peripheral auditory function. ABR tests are applicable to obtain objective evidence of peripheral and retro-cochlear auditory function including the auditory nerve and the brainstem. QSCREEN is intended to be used in subjects of all ages. It is especially indicated for use in testing individuals for whom behavioral audiometric results are deemed unreliable.

QSCREEN is to be used by audiologists, ear-nose-throat (ENT) doctors, and other hearing health care professionals, nurses and audiologically trained personnel. It is not intended to be operated by lay users. Please consider local regulations regarding the qualification requirements for performing measurements with QSCREEN's test modules.

QSCREEN is not intended for operational use by the general public. All test procedures must be supervised or conducted by qualified personnel. In the United States of America, Federal law restricts this device to sale by or on the order of a licensed physician.

QSCREEN is intended for indoor-use only and must be operated at defined environmental conditions. See also operating conditions in section *9: Technical Specifications* and information about environmental conditions regarding electromagnetic disturbances in section *10: Electromagnetic Compatibility Information*. QSCREEN is not intended for use in oxygen-rich environments.

CONTRAINDICATIONS:

QSCREEN must not be used in cases of external otitis (outer ear canal infection) or in any case which yields to pain when inserting an ear probe or applying any other transducer.

SIDE EFFECTS:

There are no known undesirable side effects for QSCREEN.

See also section *8: Notes on Safety*.

1.4 Performance Characteristics

QSCREEN is capable of producing acoustic signals which are transmitted to the patient via an air conduction transducer, recording acoustic signals from the patient via an ear probe, and recording bio-potential signals from the patient using electrodes. Test result data is shown on the device display. In order to preserve device functionality, routine maintenance is required (see section *4.2: Routine Maintenance and Calibration*).

QSCREEN has no essential performance as related to DIN EN / IEC 60601-1.

2 Explanation of Symbols

This section explains all symbols used within this manual and on the device label.

Symbols within this manual:

Symbol	Explanation
	Important notice: please read for important information.
	Warning: please read for safety-relevant information, which may cause risk of danger to persons and/or device if not followed.

Symbols on the device and/or docking station label:

Symbol	Explanation
	Reading instructions for use is mandatory. Follow instructions in this manual.

	Consult instruction for use, i.e. this manual.
	Serial number
	Article number
	Medical device
	Manufacturer name and address, production date
	Compliance with applied part type BF (body floating) requirements according to DIN EN 60601-1
	Device with safety class II according to DIN EN 60601-1
	Direct current input
	The device is electronic equipment covered by the directive 2012/19/EC on waste electrical and electronic equipment (WEEE). When discarded, the item must be sent to separate collection facilities for recovery and recycling.
	CE mark to declare conformity with applicable European directives and regulations as stated in the declaration of conformity on the PATH MEDICAL website www.pathme.de/certificates. The number below the CE mark refers to the identifier of the notified body.
	2D code, Unique Device Identifier (UDI). Information next to the UDI represents: (01) identifier, (11) manufacturing date, (21) serial number; additional codes on other labels: (17) expiration date
	PATH MEDICAL company logo
	UKCA mark that indicates conformity with the applicable requirements for products sold within Great Britain. (UKCA = UK Conformity Assessed)

For further symbols, e.g. on accessory labels, please refer to the respective manual or data sheet of the accessory. Important symbols may include:

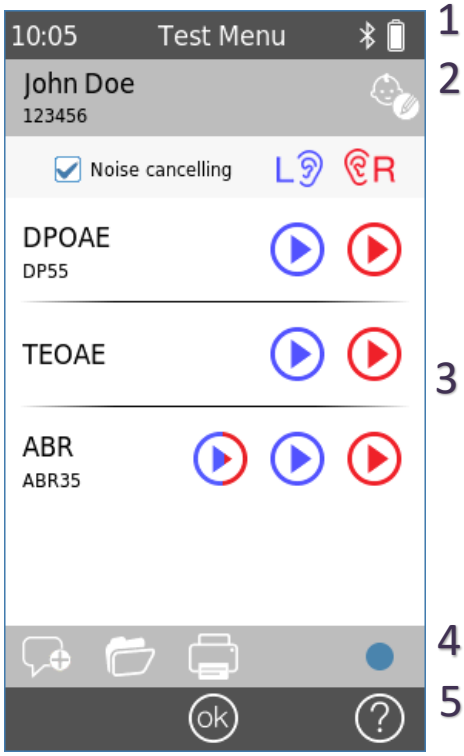
Symbol	Explanation
	Single use only. Do not reuse the respective item.
	Expiration date. Do not use the respective item after the specified date.

3 Operating Instructions

After switching on QSCREEN (see section: *3.4.1:Switching the device On/Off*), the device can be operated via a touch-sensitive display. In the following sections the most important device functions and screen elements are explained.

3.1 Screen Layout

The screen is partitioned into the following sections:



① **Header**, including the following elements:
- Device time (e.g. 12:00)
- Screen name
- Bluetooth connection status: Bluetooth connection established
- Battery status: charging; status indicator from empty to full

② **Patient header**, including patient last name, name and ID on the left and edit option on the right

③ **Main screen**, including screen-related elements (e.g. test module list, patient list, test data result view)

④ **Function Footer**, including function elements (e.g. add comment, browse measurements, print data, , To-Do state)

⑤ **Navigation Footer**, including control elements (e.g. for browsing to different screens) and online help (see section *3.2: Online Help*)

Figure 2: Device screen layout (example)

For explanation of symbols please refer to the device online help (see section *3.2: Online Help*) and for explanation of other screens see section *3.5: Device Functions*.

3.2 Online Help

Context-sensitive help screens allow an intuitive handling of the device. Automatically generated message boxes may additionally present context-sensitive warnings or information.

The context-sensitive help screens are available via the information icon , which is displayed in the navigation footer. The help screens explain the currently available symbols and their functions.

3.3 Screening Result Icons

Test results are shown with an overall test result status icon. The icons correspond to the following definitions:

Test result PASS

Screening passed successfully; no further testing necessary

Test result Incomplete

Screening incomplete (e.g. test could not be finished, test aborted by user), screening should be repeated

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Test result REFER

Screening referred. Please consult your local facility for next steps with rescreening or audiological referral.

The screening result icons are intended as a rough hearing status estimator. A screening result is not to be interpreted as a binding audiological diagnosis. A green status icon is not necessarily an indication of full auditory function. A complete audiological evaluation should be administered if concerns about hearing sensitivity persist. A red status icon should not be assumed to be an indicator of a lack of auditory function or the presence of pathology. However, it should be followed with full audiological diagnostic testing as appropriate. In all cases, the examiner needs to check and interpret result data within the context of the patient's case history, considering results from other measurements and additional influencing factors as appropriate (e.g. environmental conditions during the test, patient cooperativeness).

3.4 Device Hardware

3.4.1 Switching the device On/Off

The on/off switch is located at the top side of the device housing (see *Figure 3*). For turning on the device, press the on/off switch briefly. The boot screen appears. For turning off the device, either press the **Power** button on the bottom left corner of the screen or hold down the on/off switch for approx. 5 seconds.

*Figure 3: On/off switch (left: device on/off switch, right: screen **Power** button)*

3.4.2 Device Reset

If the device is unresponsive (i.e., no reaction when pressing the touch screen), the device can be reset by holding down the on/off switch (see *Figure 3*) for approx. 5 seconds. Restart the device afterwards. The reset does not change any device or test module settings or affect any other saved data on the device.

3.4.3 Device and Docking Station Sockets

Multiple accessories can be connected to the QSCREEN device. This includes transducers (e.g. insert earphones, ear coupler cable, ear probe) and an electrode cable.

Multiple accessories can be connected to the docking station. This includes USB-Printers, PC communication cable (USB-C), and power supply unit.

Figure 4: QSCREEN device sockets (top), docking station sockets (bottom)

For further information see section *6: Accessories*.

The accessories described in *Table 1* can be connected to the QSCREEN device sockets (see *Figure 4*).

Socket	Connectable accessory
 Blue	Insert earphones, ear coupler cable, ear probe
 Black	Electrode cable

Table 1: QSCREEN device socket overview

The accessories described in *Table 2* can be connected to the docking station sockets (see *Figure 4*).

Socket	Connectable accessory
USB-C socket (1)	USB PC Communication Cable
USB-A sockets (2)	USB Printer, Modem
Texas socket (3)	Power Supply Unit
Ethernet socket	LAN Cable (future use, not available yet)

Table 2: Docking station socket overview

3.4.4 Device Charging

3.4.4.1 Battery

The instrument is powered by a rechargeable single cell Lithium-Ion (Li-Ion) battery. The battery is charged by placing the instrument on the docking station. The battery is replaceable by authorized service personnel.

- Do not damage the battery or use a damaged battery
- Do not touch or short circuit the battery contacts
- Keep the battery away from fire and water
- The battery must be replaced by an authorized service partner only

3.4.4.2 Charging

Connect the power supply unit to the docking station (see section *3.4.3: Device and Docking Station Sockets*). Make sure to connect the power plug to a mains socket with appropriate output voltage and frequency. The indicator light defaults to white indicating the docking station is powered on and the charger is in standby mode. It turns to blue when charging is in progress and green if battery is fully charged (see *Figure 5*).

Figure 5: Docking station charging indicator light

For wireless charging of the QSCREEN device, place the device on the docking station. Please make sure that the device is well located on the docking station and the indicator light is flashing blue. When charging is complete the indicator light shows a solid green color. If the indicator light is not flashing or shows a solid red color, the QSCREEN device may be incorrectly positioned on the docking station and wireless charging is not in progress. Whilst the QSCREEN is connected to the docking station testing is disabled.

The charging process starts automatically and is finished within approximately 8 hours from 0% to 90% capacity. When fully charged, the battery will last for a full day of testing under normal test conditions when the default power save and power off is enabled. The battery status can be derived from the battery status icon symbol: fully charged; charging; status indicator from empty to full.

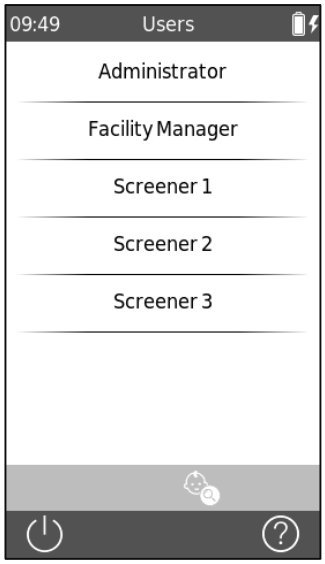
- Make sure that there are no metallic objects between the QSCREEN and the docking station during charging.
- Do not place any other object between QSCREEN and the docking station when charging
- Do not use with any other wireless charging enabled device: charger may overheat
- Use only the charger provided with QSCREEN

3.5 Device Functions

3.5.1 User Management

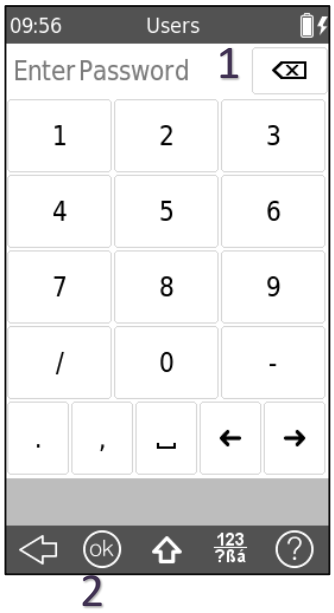
The QSCREEN can be configured to require user login on the device via QLINK (see QLINK online help for more information). When user login is enabled the User List screen is displayed after switching on the device. You will be asked to select your name and to enter your password. Please follow the on-screen instructions. If you would like to change a user you need to restart the device. If the user management is active, you are only enabled to change module parameters when logged in as administrator.

Please make sure that local data protection requirements are met. Use individual user accounts and passwords. When deactivating users on QSCREEN, the device does not provide any inherent access protection (i.e. no login with password).



When starting the device the list of available users appears. Select the correct user name. You can scroll through the user list by swiping the screen from top or bottom.

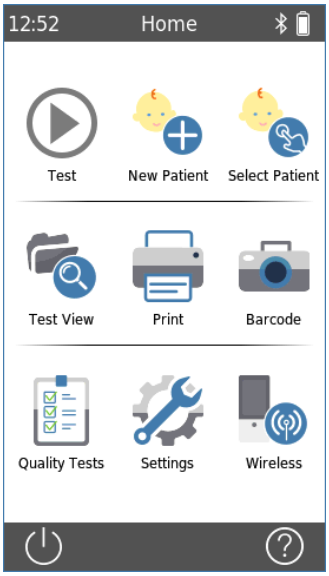
You can also search for your user name by pressing the icon in the footer.



After selecting the correct user name, the password entry screen appears. Enter the correct password in the text box (1) and press **OK** (2) afterwards.

3.5.2 Home Screen

Select any of the following start screen options (from left to right, from top to bottom):



- Test: Start test
- New Patient: Add patient
- Search Patient: Search and select patient
- Test View: Show patient test data
- Print: Print patient test data
- Barcode: Reads 1D barcodes and QR-codes where patient demographics, test data and further information is stored
- Quality Tests: Device functional checks
- Settings: Device settings
- Wireless Wireless data transmission via modem (license required)

Footer option:

- Power off: Power down device
- Question mark: Online help

3.5.3 Patient Data Handling

You can enter patient data manually, upload patient data from QLINK (see the QLINK User Manual for instructions) or import data from pathTrack.

3.5.3.1 Adding a new patient

To add a new patient, manually press the **New Patient** button. A patient can be added in **Home** menu, during or after the measurements in open session mode.
The **New Patient** screen shows a list of entries you can fill out for entering patient data. To view more fields swipe up from the bottom.

There are two types of fields for data entry: Mandatory fields ② and Optional fields ①

In mandatory fields the text “Press to edit” string is shown in red. You must always enter a value in the mandatory field.

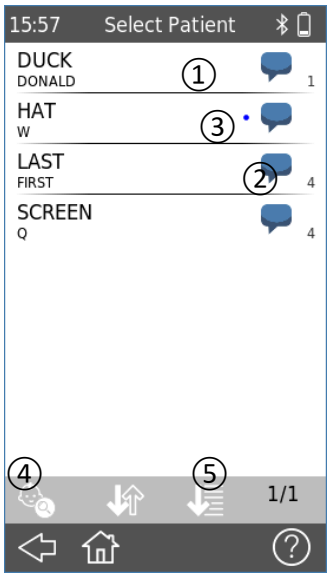
Press a field to enter patient data. When you have entered all the data, press the **OK** button to save the data. You are forwarded to the **Patient Test Menu**.

To simplify patient data entry you can scan the patient’s barcode to read in patient data ③. Proceed as follows:

- Press the **Barcode** button to turn on the camera.
- Place a Barcode or QR code in front of the camera, so it is centered in the box displayed on the screen.
- Once the barcode has been read, the patient fields are filled out automatically.
- Check the patient data after scanning
- Press the OK button to proceed to the **Patient Test Menu**.

3.5.3.2 Select a patient

To select a patient stored on the device press the **Select Patient** button. A patient can be selected in **Home** menu, during or after the measurements in open session mode.



Each entry of the patient list includes several entries:

- first and last name
- The Dot ① indicates that patient doesn't have any tests and comments (new patient).
- Button to add a comment (speech bubble ③)
- Number indicating the number of tests of the patient②

 The list is sorted by date ⑤ when called from **Select Patient** button in **Home** menu. It guarantees that new patients are on top of the list.

The list is sorted by name, when called to print data () or to review data in archive ()

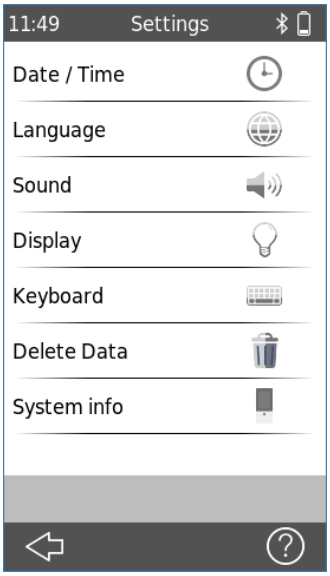
The sort sequence (e.g. A-Z or Z-A) can be changed by pressing the  button.

 You can find the desired patient by pressing the **Find Patient** button ④ or by scrolling through the list.

For further information about patient management please see device online help.

3.5.4 Device Settings

There are multiple options to configure the device.



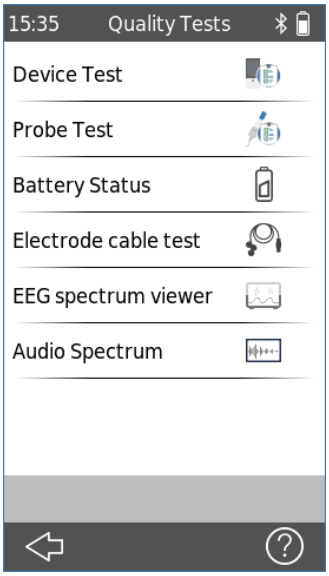
The device settings can be reached with the **Settings** button  from the **Home** menu. The following device settings are available:

- Date and time, date and time format
- Language
- Sound (key click, result sound),
- Display (brightness, power timeout)
- Keyboard
- Delete Data
- System info:
    - Firmware version,
    - Serial number,
    - Next service date,
    - Transducer status
    - Memory usage
    - License Management

For further information about device settings please see the online help.

3.5.5 Hardware and Quality Tests

The main device functions can be tested with the “Device tests” option.

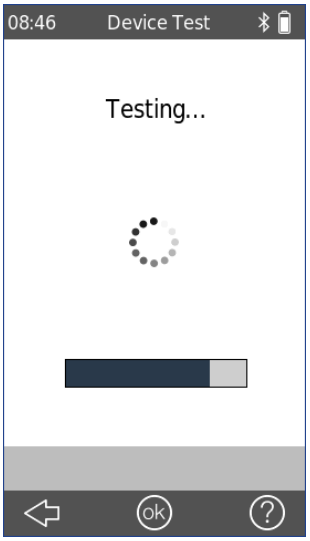


The device tests menu can be reached with the **Device Test** button  from the **Home** menu.

The following device settings are available:

- Device Test: The test includes checking the Camera, SD card and the audio functionality.
- Probe Test: examines ear probe functionality
- Battery State: displays current status of battery voltage, remaining capacity, temperature and health.
- Electrode cable test: allows testing of the electrode cable for damage. Can detect broken cables and ineffective cable shielding.
- EEG/Audio spectrum viewer: can be used for diagnostics testing, acoustic and EMI environments.

3.5.5.1 Device Test



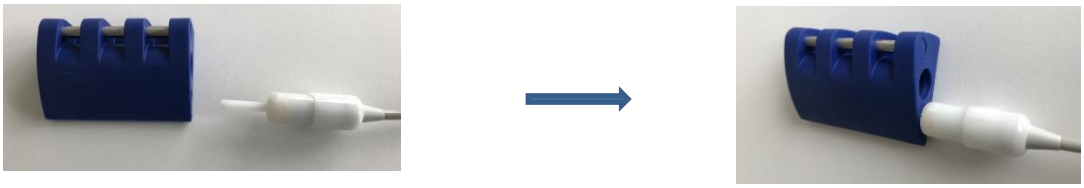
The **Device Test** examines several device properties

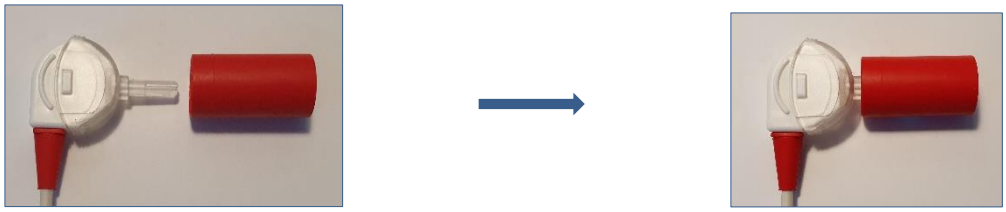
- Power supply
- Audio function
- SD Card
- Camera

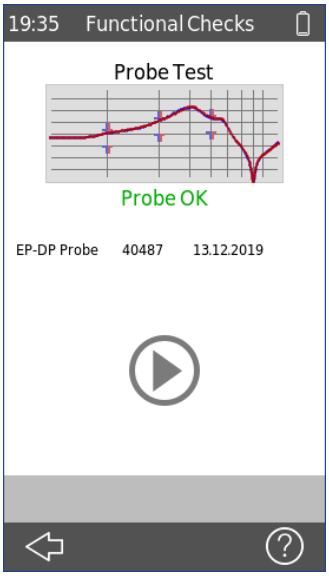
An error message is shown if the device is not properly working. Please contact your distributor for further assistance.

3.5.5.2 Probe Integrity Test

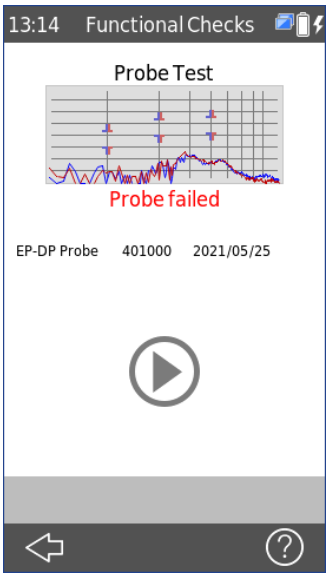
To run the probe test, insert the probe without ear tip into the probe test cavity of the check-kit for testing the small probe tip (PT-S, PT-LT). Insert the probe into the red test cavity for testing the large probe tip (PT-A). Do not use other combinations.







Select “Probe test” from the “Device tests” menu. The probe test will automatically start. If the probe functions correctly the message **“Probe OK”** appears



If the probe does not function correctly the message “Probe failed” appears

For further information on possible error messages please refer to Table 3 as below.

If the probe test fails multiple times, do not continue to test on patients. Contact your local distributor for assistance.

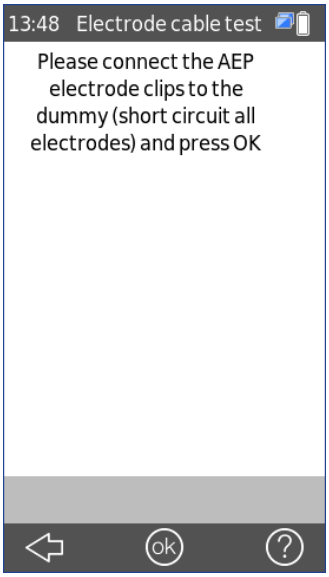
Error message	Recommended actions for troubleshooting
No probe found	Check if the ear probe is properly connected to the device. → If not, connect the ear probe to the device.
Probe failed	1) Check if the ear probe is placed in the correct test cavity. → If not, use the correct test cavity provided with the ear probe. 2) Check if the calibration curves are within the upper and lower tolerance limit markers or if both of the calibration curves are smooth lines. → If not, make sure to use the correct test cavity and check if one or both channels of the probe tip are clogged. If so, change or clean the probe tip.

Table 3: Probe test error messages and recommended actions

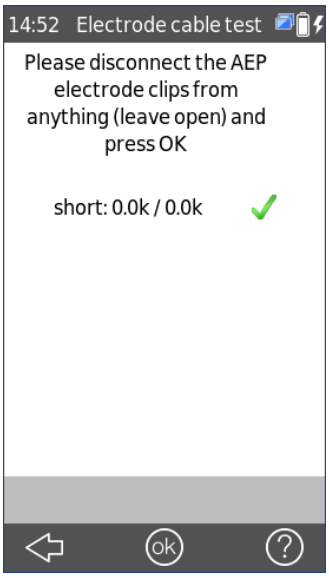
If the recommended actions in the table or in the online FAQ (www.pathme.de/faq) do not help in solving the problem, please contact your distributor.

3.5.5.3 Electrode Cable test

To perform an electrode cable test it is necessary to connect the electrode cable clips to the metal bar of the check-kit to short circuit all electrodes. Then select “Electrode cable test” from the “Device tests” menu.

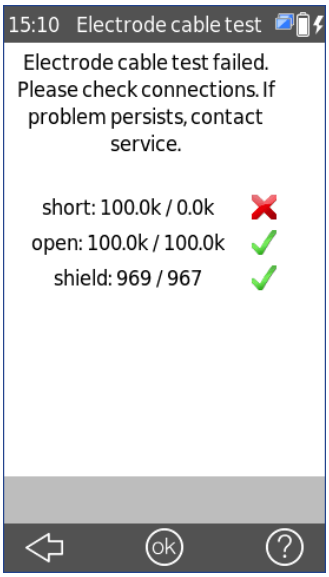


The next screen will provide the instructions.



After pressing **OK** disconnect the electrode cable clips and leave them open. Then press **OK.**

If the electrode cable is functioning correctly, the message “Electrode cable test passed” appears

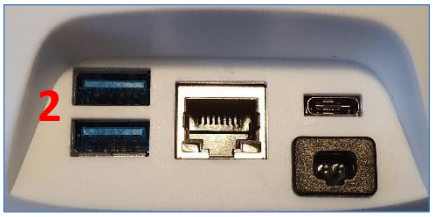


If the electrode cable does not function correctly, the message “Electrode cable test failed” appears. Press **OK** to confirm the test results.

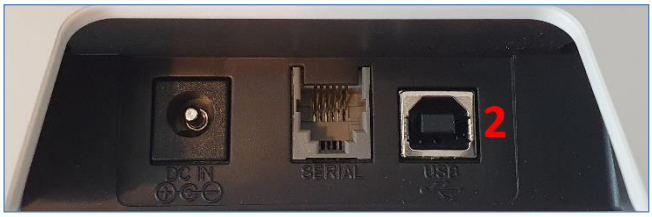
3.5.6 Printing

The connection of the QSCREEN docking station and the Seiko SLP650SE Label printer is via USB cable and for maximum user convenience the QSCREEN connects to the docking station via Bluetooth.

Seiko SLP650SE label printer



Docking station connectors



Seiko printer connectors

To connect the printer to the QSCREEN docking station, simply connect the flat blade USB connector into either of the ports **(2)** followed by the square end USB into the printer also marked **(2)**

Ensure that the label printer is connected to mains power and the green standby light is illuminated

Before the QSCREEN leaves the factory the device and its docking station are paired so no further actions are required to start printing.

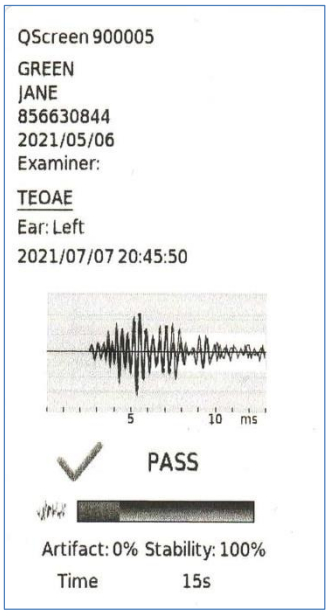
Note: *Connection between QSCREEN and the docking station is via Bluetooth within a 10m free field range.*

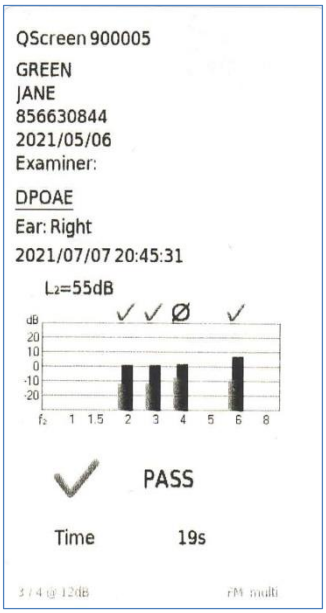
3.5.6.1 Printouts from label printer

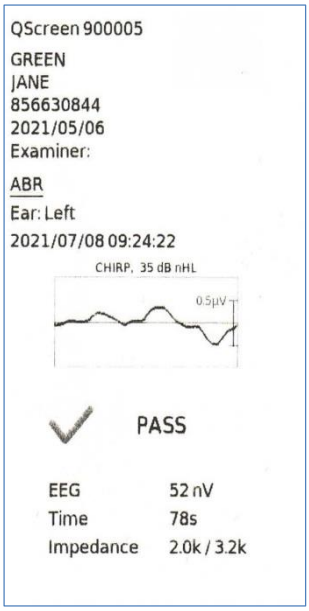
There are two types of reports: detail and summary report of a patient.
The detail report shows the result of a single measurement.

The printout contains:
The serial number of the QSCREEN device
Last name
First name
The patient's I/D number
Date of birth
Examiner:
Type of test (TEOAE, DPOAE, ABR)
Ear (left or right)
Time of print
Test data including outcome (PASS or REFER)

Single result:







The summary report shows the result of each test:

QSCREEN
SN: 900070
2022/09/27
10:11

ID: 01234567
Title:
First name: John
Last name: Smith
aka:
Gender: Male

2022/09/20

09:11	Left	DPOAE	PASS
09:14	Left	DPOAE	PASS
09:37	Left	DPOAE	PASS
09:37	Left	DPOAE	PASS
09:38	Left	DPOAE	REFER
09:39	Left	DPOAE	Incomplete

The QR code contains the patient data (ID, First Name, Last Name, Date of Birth). It can be used to speed up patient data entry in case the patient is tested again.

3.5.6.2 Different ways to perform a print

There are several ways to access the print function on the QSCREEN.

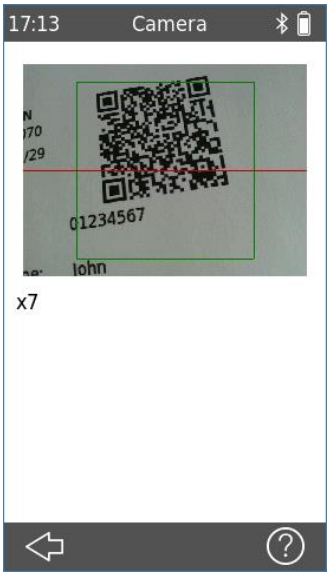
(1.) After performing a test, a print icon in the lower part of the screen will be displayed. Click on the **Print** icon to print the current test.

(2.) From the **Home** screen select the **Print** icon. The patient list will be shown, then simply select the patient that you wish to print and a list of all available tests for the patient will be displayed. If only one print is required, select the test by pressing on-screen. If multiple tests are required, use the tick box on the right-hand side to select multiple tests for printing.

(3.) From the **Home** screen, click on, **Select Patient**. The patient list will be shown, then select the patient that you wish to print and a summary of all test results is shown. By pressing the **Print** icon a summary of their test results for all tests can be printed. If a single test is required select the folder icon at the bottom of the screen and then select the required test to print from the list as shown

(4.) From the **Home** screen select the **Test View** icon. The patient list will be shown, then simply select the patient that you wish to print and a list of all available tests for the patient will be displayed. If only one print is required, select the test by pressing on-screen. If multiple tests are required, use the tick box on the right-hand side to select multiple tests for printing.

3.5.7 Barcode



The Barcode reader is launched by pressing the **Barcode** button on Home screen.

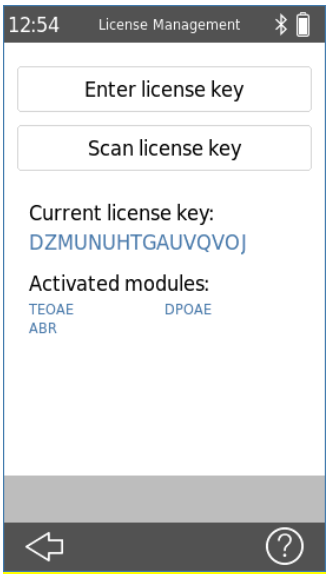
The Camera located on the underside side of the handheld device housing can be used to read 2D QR-codes or 1D linear barcodes with patient data encoded.

Linear Barcodes store a number such as the patient ID.
When the barcode is successfully decoded the result is transferred to the patient ID field.

QR code:
A compressed QR code format is supplied.
All patient data is transferred to the device when the QR code is successfully decoded. Please contact PATH MEDICAL for defining a custom QR code format according to your needs.

3.5.8 License Management

If you would like to update your device license, please follow the steps below.

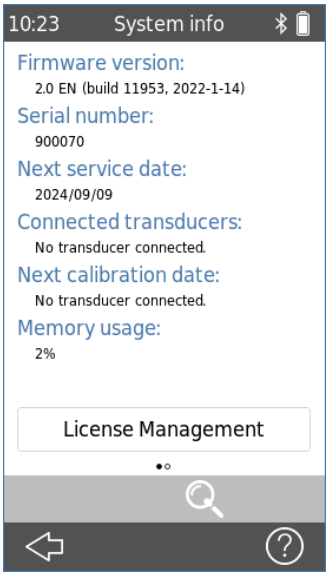


When upgrading your license, you will receive a new license (key or QR code) that needs to be entered on your device. Before entering a new license, please make sure that you keep a written note of the former license key details for potential reinstallation if needed.

In order to update your license key you need to go to the **License Management** screen *(Settings → System Info → License Management).* The activated key and modules are displayed.
You can insert the key by either entering it via keyboard or by scanning the QR code you have received via email. When correctly entered, the corresponding modules are available on the device, otherwise a message box shows up.

Please contact your distributor in case you have any troubles entering the license.

3.5.9 System Information

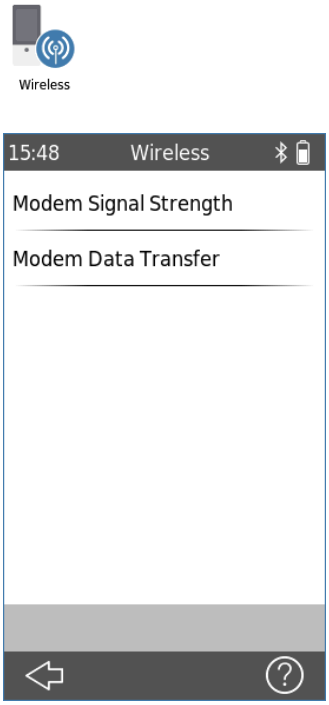


On the system information screen, general information about the device and firmware version is displayed. Press the **License Management** button to review or update your license.

Information about connected transducers is also displayed if the respective transducer has been connected before the system information screen is entered.

On the second page, the next service date of the device and the next calibration dates of the known transducers are listed. When contacting your distributor regarding any service request (e.g. error message or module update) this data should be at hand.

3.5.10 Wireless Modem Data Transmission (license required)



For exchanging data with a tracking center press the **Wireless** icon on **Home** screen

Press the **Modem Signal Strength** button to check the quality of your reception within the mobile network.

Press the **Modem Data Transfer** button to start sending patient and test data to the tracking center.

3.6 Preparing for testing

3.6.1 Preparing QSCREEN

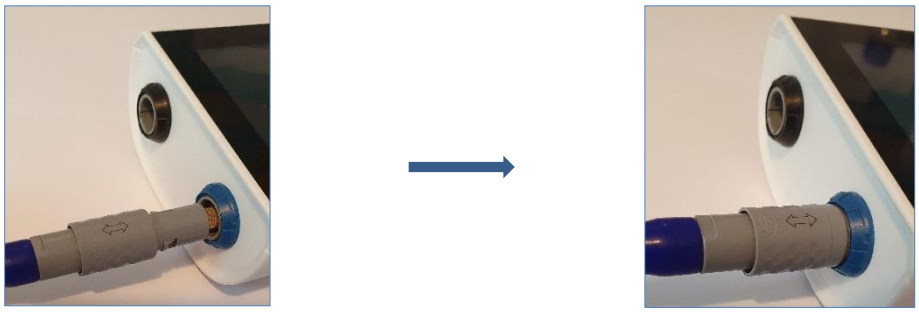
Every day before testing on patients, we recommend that you perform whichever quality tests that may be necessary to ensure that the probe, electrode cable and ear coupler cable function correctly.

3.6.2 Preparing the OAE probe

Inspect the probe for deterioration (color changes, surface changes) of the reusable probe parts before every usage. If deterioration occurs, contact your distributor.

3.6.3 Connecting the OAE probe

The OAE probe plug sleeve and the color around the probe socket are both blue. Align the ridges in the plug with the notches in the blue socket and gently insert the probe into the probe socket. A “click” is audible when the probe is fully inserted.



Disconnecting the OAE probe

When disconnecting the plug, do not twist it. Instead, hold the sleeve of the plug and release it by pulling it straight out of the socket. The probe will not be released if you pull anywhere else than the sleeve of the plug.

Note: *Do not pull the plug by the cable when you disconnect the probe. Instead, pull the sleeve of the grey connector.*

3.6.4 Connecting the electrode cable for ABR testing

The electrode cable plug sleeve and the color around the electrode plug socket are both black.
Align the ridge on the electrode cable plug with the notch in the black socket and gently insert the electrode cable plug into the electrode cable socket. A “click” is audible when the cable is fully inserted.

Disconnecting the electrode cable

When disconnecting the plug, do not twist it. Instead, hold the sleeve of the plug and release it by pulling it straight out of the socket. The cable will not be released if you pull anywhere else than on the sleeve of the plug.

Note: *Do not pull the plug by the cable when you disconnect the electrode cable Instead, pull the sleeve of the grey connector.*

3.6.5 Connecting the ear coupler cable for ABR testing

For ABR measurements you can use either the ear probe or the ear coupler cable with ear couplers. A major advantage in using the ear coupler cable is that both ears can be tested simultaneously or consecutively.

The sleeve on the plug of the ear coupler cable and the color around the probe socket are both blue. Align the ridges in the plug with the notches in the blue socket and gently insert the ear coupler cable into the socket. An audible “click” will be heard when the cable is fully inserted.

Disconnecting the ear coupler cable

When disconnecting the plug, do not twist it. Instead, hold the sleeve of the plug and release it by pulling it straight out of the socket. The cable will not be released if you pull anywhere else than on the sleeve of the plug.

Note: *Do not pull the plug by the cable when you disconnect the ear coupler cable Instead, pull the sleeve of the grey connector.*

3.7 Preparing the test environment

When conducting a measurement, please consider the following aspects:

For optimum test performance (OAE), the device must be used in a quiet environment (e.g. soundproof cabin, room with low ambient noise). For measurements with ear probes (OAE) also a sound insulation headphone can be used. For ABR measurements acoustical noise is less influential on test performance than muscle artefacts (e.g. patient movement). For ABR measurements also make sure to test in an environment with low electromagnetic disturbance from electronic devices (e.g. computers, lights, other electronic medical devices) as electromagnetic radiation may deteriorate ABR test performance. It is recommended to perform ABR tests in a shielded cabin. Please consider local regulations regarding requirements for the test environment.

OAEs are most likely not present in ears with sound-conductive hearing loss, since both the stimulus and the response amplitude are reduced due to the damping of the middle ear.

Please use only the large ear tips (ET) together with the large probe tip (PT-A) and the small ear tips (ET-S or ET-LT, respectively) together with the small probe tip (PT-S or PT-LT, respectively). An incorrect combination of ear tip and probe tip may deteriorate test performance. See also advice in the accessory box. If in doubt about what combination is correct, please contact your distributor.

If possible, do not hold the ear probe during OAE testing. This may introduce additional noise. Common sources of noise relate to room noise, patient movement (breathing, moving, talking, chewing, etc.), or ear probe movement.

Be sure to follow any established infection control procedures for the setting in which you are working. Clean probe body, probe cable and probe plug before each patient or surface is visibly contaminated. Clean the electrode cable and the electrode cable plug before measuring the patient or if surface is visibly contaminated. Use a sterile alcohol wipe to clean the surfaces and wait until the probe body, probe cable and probe plug are completely dry.

3.8 Preparing the Patient

The following instructions relate to the use of QSCREEN within a Newborn Hearing Screening program.

Newborn hearing screening with OAE and ABR is best performed when the baby is sleeping. The ideal time is after the baby has been fed and changed.

3.8.1 Preparing the Patient for fitting the ear probe

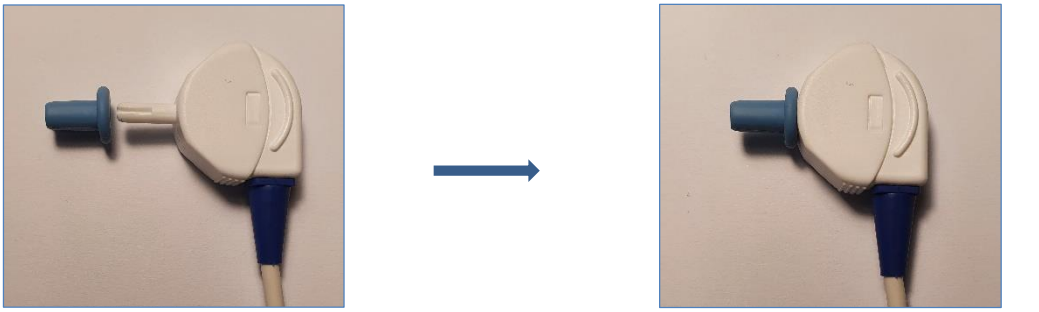
Position the patient with easy access to the ear to be tested.

Grasp the pinna and gently pull back and slightly away from the patient's head.

Inspect the ear canal. If you can see narrowing of the ear canal, it's probably not straight. Newborn ear canals are very soft and can easily pressed out of shape. If this is the case, wait until the ear canal returns to its original shape. Release the pinna and try again. Gentle massaging of the area may help opening the ear canal.

Inspect the ear canal to ensure that it is clear of vernix or debris as this could affect the outcome of the test.

3.8.2 Fitting the ear tip on the probe



Select an ear tip that fits the patient's ear canal. You may need to try several sizes before finding the most appropriate size.

Gently push the ear tip onto to the probe tip until it hit the base of the probe tip. It is much easier to attach and remove the ear tip if you turn it gently. When you do so, ensure that you hold the probe by the probe body and ***not by the cable***.

Note: *Accurate testing is only guaranteed if you use the ear tips provided.*

Note: *The ear tip can be used for both ears. If you suspect infection in one ear, change the ear tip and clean the probe tip, or replace it with a spare, before you continue testing on the other ear.*

Note: *Using a probe with an incorrect ear tip or applying excessive force may irritate the ear canal.*

3.8.3 Inserting the probe into the patient's ear canal

When you have fitted an ear tip on the probe, gently pull the pinna back and slightly down and insert the probe in the ear canal, using slight pressure. Slightly twist the probe as you insert it.

Verify visually the correct fitting.

If using the EP-DP probe, it can be inserted with the probe cable pointing either upwards or downwards, depending on which direction fits best.

Make sure that the probe fits well. Any leakage may increase the test duration due to sound leakage, excessive noise or both.
Attach the clip to the patient's clothing or bedding to secure the probe cable.

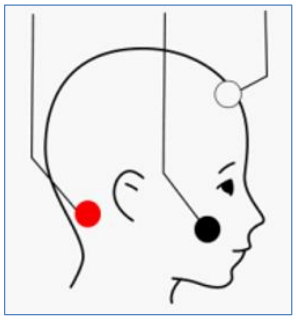
Note: *Ensure that the cable is not in contact with any vibrating surfaces during testing*

3.8.4 Placing the electrodes for ABR testing

Skin preparation

Note*: Do not use alcohol pads or other cleaning agents that contain alcohol to prepare the skin as they may cause the skin to dry out, leading to a higher skin impedance*

Place the electrodes on the patient as follows:



Red: On the nape of the neck

Black: On the cheekbone (common or ground electrode)

White: On the upper part of the forehead

Note: *Ensure that the electrodes fit tightly on the skin*

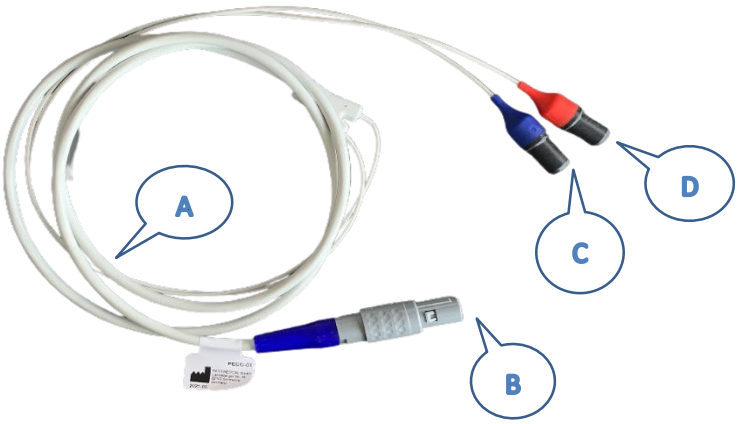
Note: *The hydrogel of the electrodes can dry out. Make sure that used packages are closed properly. Dried out hydrogel may cause high electrode impedance. If this is the case, change the electrodes.*

Note: *The black electrode (ground electrode) could alternatively be placed on the baby's chest or shoulder. The red and white electrodes must be placed as stated, i.e. on the nape of the neck and on the upper part of the forehead. Other electrode placements have not been validated.*

3.8.5 Fitting the ear couplers

Note: *Never place the red and blue ear coupler adapters directly in the ear canal. Use them only with the ear couplers fitted.*

Note: *Only use the ear couplers with the ear coupler cable - not with the ear probe.*



Ear Couplers

A. Ear coupler cable
B. Cable connector
C. Blue ear coupler adaptor for left ear
D. Red ear coupler adaptor for right ear

Place the electrodes on the forehead, neck and cheek bone of the baby, before you connect the ear couplers. See *3.6.4: Connecting the electrode cable for ABR testing*

Insert an ear coupler adapter into the tube at the top of each ear coupler, ensuring the blue connector fits to the blue ear coupler, and the red connector to the red ear coupler.

Peel off the protective film of the ear coupler and place the red ear coupler with the red adapter over the right ear of the baby, and the blue ear coupler with the blue adapter over the left ear of the baby.

The ear couplers can be placed with the cables pointing either upwards or downwards, depending on which direction fits best.

Note: *To remove the ear coupler cables, do not pull them by the cable. Instead, hold them by the ear coupler adapter*

3.8.6 Start a Test

To start any test make sure a transducer (e.g. ear probe, headphone or insert earphone) is connected to the blue socket and that the patient is prepared.

3.8.6.1 Quick Test

There are different ways to start any test:

- The easiest option to start a test is by clicking on the Test icon shown on the **Home** screen and pushing the **blue** or **red** button afterwards (open session mode).
  A simultaneous test can be started by pressing the button in blue and red (only for ABR measurement with PIEP insert earphones, headphones or PECC ear coupler cables).

- Press on the **Select Patient** button (see section: *3.5.3.2 Select a patient*) and on a certain patient. If the list is empty, you can add a patient (see *3.5.3.1 Adding a new patient*).

- When the **Test View** screen is shown, a test can be started by clicking on in the function footer.

Each example will lead to the **Test Menu** screen where a test can be started by pushing the **blue** or the **red** button.

3.8.7 Auditory Brainstem Response (ABR)

1. Prepare the patient by cleaning the skin where the electrodes will be attached and ensure that the skin is dry.
   Place the electrodes accordingly. Make sure the environment is quiet and the device is prepared with the electrode cable and the transducer plugged into the QSCREEN (see Table 1 in section *3.4.3 Device and Docking Station Sockets*).

   Place the correct size of ear tip for the patient onto the probe tip of the ear probe and place it carefully into the patient's ear canal or place the headphone or the ear coupler onto the patient's ears, respectively. Ensure correct and comfortable fitting.

   The online-help provides a short description.

2.

Press **Test** on the **Home** screen or choose one of the other options from section *3.8.6 Start a Test* .

If you want to add a patient, please refer to section *3.5.3.1 Adding a new patient*

If you want to select a patient, please refer to section *3.5.3.2 Select a patient*

Start a test by pressing either the **blue** or **red** button.

Press the button in blue/red for a simultaneous test.

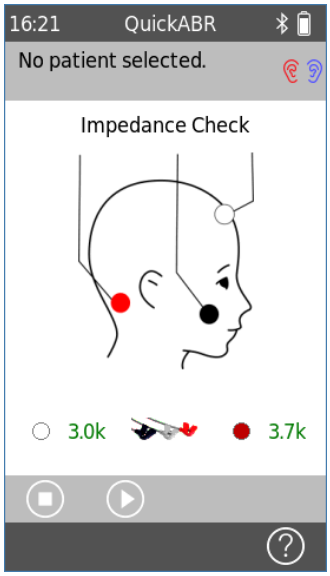
You can:

view a comment or add one

browse through already available test results

print test results

3.



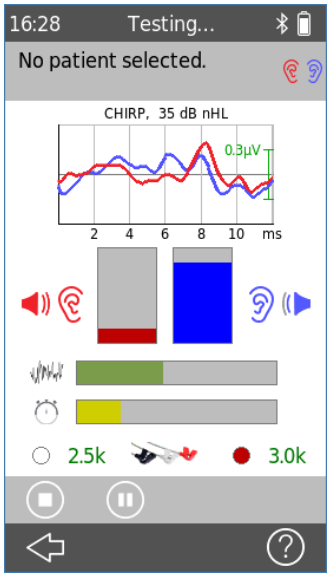
After starting an ABR test the screen will show "Checking". The device is checking if the impedances are within the limits (green letters mean accepted, red letters suggest repositioning or replacing the electrodes).

A test tone (chirp) is played.

By pressing:

the test can be aborted.

the test can be started if the impedances are acceptable.

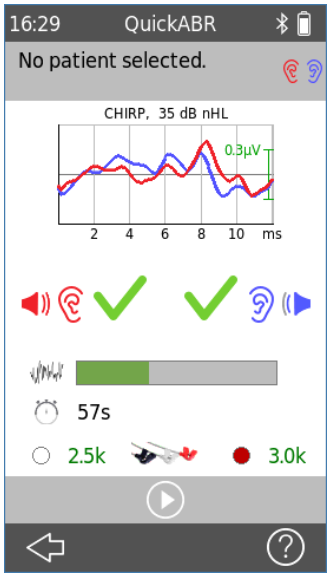
4. 

A test is conducted with a chirp stimulus at 35 dB nHL.

You can:

 stop the test to save the current the data or reject the measurement.

 Tests can be paused and resumed.

5. 

The result screen is shown after completing a measurement.

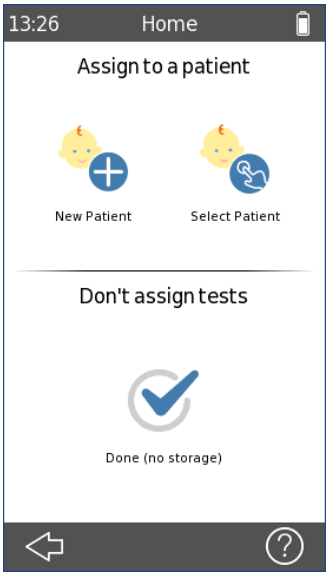
The graph shows the detected EEG-signal for each ear.

The PASS/REFER result is shown per ear.

Additional test information is:

- Noise
- Duration
- Impedances

The test can be repeated by pressing the Play button  .

6. 

In case you haven't selected a patient in the first place (see section *3.5.3 Patient Data* Handling) and you leave the Patient Test Menu the device will ask if you want to assign the test to a patient.

You can either assign the data to a new or existing patient

Alternatively you can discard the tests by pressing  button. **No data will be stored**. You will be prompted to confirm that you wish to delete the session.

In case a patient was selected in the first place you are navigated to the Home screen when leaving the Patient Test Menu.

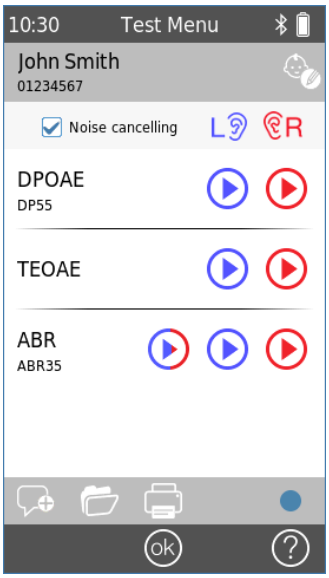
Electrode placement depends on monaural or binaural recording. In step 2 the recommended placement for monaural ABR tests is shown. This pictogram can be found on the electrode cable and on the calibration screen of the QSCREEN.
For binaural measurement place one electrode in the middle of the patient's neck on the spine near the hair line.
Applying the electrodes at the beginning of the test set-up can improve impedance due to the fact that the electrode has time to adhere to the skin properly during further preparations. A conductive gel can also be used but is not required in all cases.
It is recommended that each of the impedances are below 4 kΩ and the difference between red and white electrode is lower than 2 kΩ. If the impedances are higher, reposition or replace the electrodes for more reliable results.

3.8.8 Otoacoustic Emissions (OAE)

1. Make sure the environment is quiet and transducers are connected correctly to the device (see Table 1 in section *3.4.3 Device and Docking Station Sockets*).

   Select the correct size of the ear tip put it onto the probe tip of the ear probe. Insert the probe carefully into the patient's ear canal.

   The question mark always provides short functional descriptions.

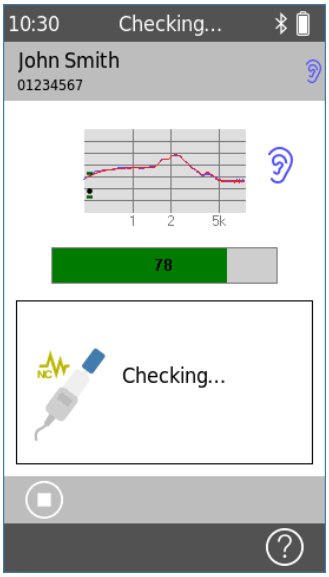
2. 

   Press **Test** on the **Home** screen or choose one of the other options from section *3.8.6 Start a Test* .
   If you want to add a patient, please refer to section *3.5.3.1 Adding a new patient*
   If you want to select a patient, please refer to section *3.5.3.2 Select a patient*

   Start a test by pressing either the **blue** or **red** button.

   You can:
   view a comment or add one
   browse through already available test results
   print test results

3.

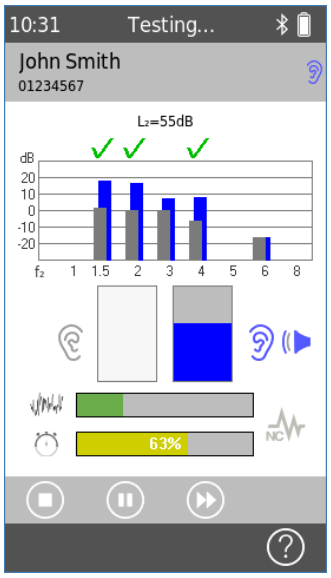


After starting an OAE test the screen will show “Checking”. The device is checking if the probe fits properly and the ear canal is sealed. A calibration tone is played.

The probe connected to the device is displayed in the box .

The test can be aborted by pressing the button. You can proceed to the OAE recording by pressing the **Skip** button (if available)

4.



DPOAE:
The test is conducted with L_2= 55dB.

The graph shows the emissions per frequency in dB SPL.

If the noise cancelling feature is active, the noise cancelling icon color changes to green.

The DPOAE response bar provides feedback about the progress for getting a PASS. A response is present if the bar is fully filled.

Left ear is tested.

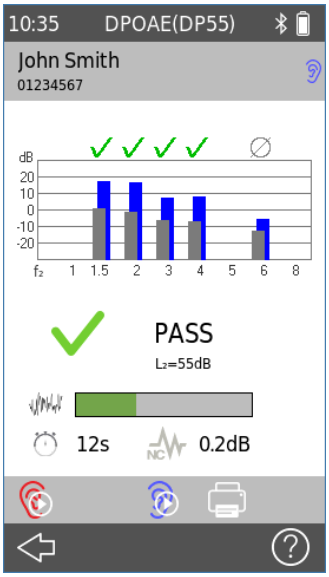
The noise bar provides feedback about the current noise level.

The progress bar shows the time elapsed.

You can stop the test. You will be asked to save the current status or to discard the measurement.

Tests can be paused and resumed again

Skip a test frequency

5. 

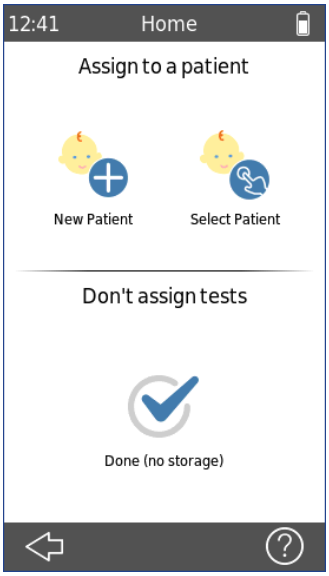
When the DPOAE test is completed, the test data is saved and the result screen is shown.

The graph shows the PASS/REFER result of each frequency.

The overall PASS/REFER result is shown below the graph.

The noise bar displays the average noise captured during the recording.

The noise cancelling icon is green if the noise suppression was active and the test time was significantly (by a factor of up to 10) suppressed.
The test can be repeated by pressing the **Test Same Ear** button  . (Note: since the left ear was tested here, the blue ear button is displayed in the middle of the footer)
The other ear can be tested pressing the **Test Other Ear** button  .
The result can be printed by pressing  .

6. 

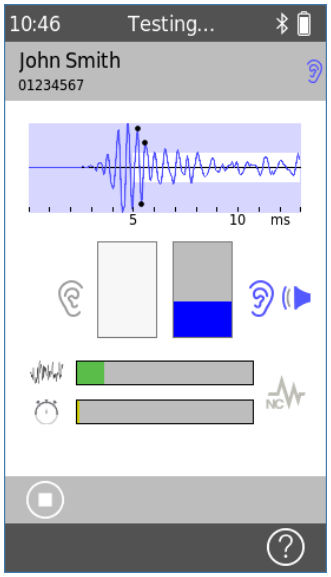
In case you haven't selected a patient in the first place (see section *3.5.3 Patient Data* Handling) and you leave the Patient Test Menu the device will ask if you want to assign the test to a patient.

You can either assign the data to a new or existing patient

Alternatively you can discard the tests by pressing 

button. **No data will be stored**. You will be prompted to confirm that you wish to delete the session.

In case a patient was selected in the first place you are navigated to the Home screen when leaving the Patient Test Menu.

7. 

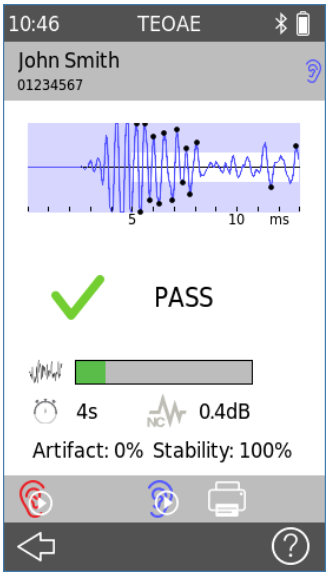
TEOAE:

The graph displays the TEOAE response and the peaks reaching a PASS. Eight significant peaks are required for reaching a PASS.

The TEOAE response bar provides feedback about the progress for getting a pass. Left ear is tested.

The noise bar provides feedback about the current noise level.

The progress bar shows the time elapsed.

8. 

When the TEOAE test is completed, the test data is saved and the result screen is shown.

The graph displays the TEOAE response and the peaks reaching a PASS.

The PASS/REFER result is shown below the graph.

The noise bar displays the average noise captured during the recording.

The noise cancelling icon is green if the noise suppression was active and the test time was significantly suppressed (by a factor of up to 10).

The artifact value shows the portion of frames rejected because of noisy conditions. The value should be lower than 20%.

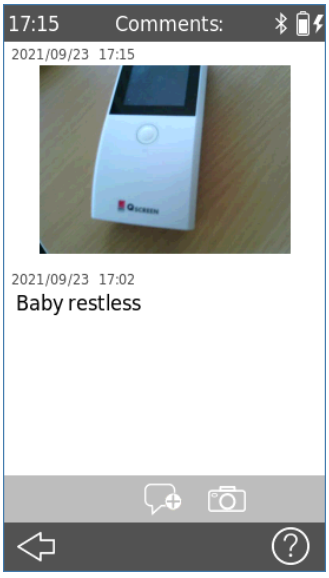
The stimulus stability indicates that the probe may have shifted during the test. The value should be higher than 80%

3.8.9 Adaptive Noise Cancelling

Your QSCREEN with the LT-probe connected performs adaptive noise cancelling (NC) throughout the OAE recording to suppress unwanted ambient noise that travels past the seal of the ear tip. To compensate for this the LT-probe contains two microphones, one pointing outwards for capturing ambient noise and the other (primary microphone) for capturing the OAE response in the ear canal. The adaptive noise cancelling system adjusts to the ambient noise signal to produce an output that is a virtual replica of the ambient noise reaching the ear canal. By subtracting this output from the primary microphone signal, ambient noise in the ear canal is suppressed without influencing the OAE response.
The adaptive filter follows changes of the noise and makes OAE recordings up to 20 times faster in noisy surroundings.

3.8.10 Adding comments to a test or patient

You can either select a predefined comment from a list of standard comments or add a free text comment of your choice.
Predefined comments can be configured in QLINK and uploaded to the QSCREEN handheld device.



To add a new comment, press the Add Comments button.

Enter one or several comments by using the keyboard.

You can also add a picture to the comments for convenience.

You can review comments of tests and patients by pressing the View Comments button .

3.9 QLINK PC Software

The latest QLINK PC software is available via download from the PATH MEDICAL homepage (see www.pathme.de/downloads). QLINK includes the latest firmware for updating the device. QLINK is supplied with integrated online help for further information about correct handling.

QLINK can be used for administering users, downloading data from the device, uploading and downloading patient information to and from the device, reviewing and archiving test data and printing test data to a standard PC printer.

Information about QLINK error handling can be found at www.pathme.de/faq.

For data privacy reasons please make sure to secure the physical and network access to computers which locally store or have remote access to personal data (e.g. patient test results). This may include e.g. the computer(s) on which QLink is running, the computer(s) on which the QLink database (or any backup of the database) is stored and the computer(s) on which relevant data files (e.g. test result exports or printouts) are stored.

Please make sure to implement an appropriate backup policy in order to avoid loss of relevant data (e.g. patient test results).

3.10 PATH Service Tool

The PATH Service Tool is only available for authorized distributors and service partners. The latest PATH Service Tool software is available via download from the PATH MEDICAL homepage via restricted area login. The PATH Service Tool is needed for servicing devices and for calibrating transducers. Service Training from PATH MEDICAL is required. For further information see separate PATH Service Tool manual or contact PATH MEDICAL (service@pathme.de).

3.11 Troubleshooting

If an error occurs with your QSCREEN device please check the below list and proceed as recommended in *Table 4*. Further information about error handling can be found in section *3.5.5: Hardware and Quality Tests* or in the online FAQ (www.pathme.de/faq).

Error	Recommended action for troubleshooting
Black display	The display is automatically deactivated after 2 minutes (time span configurable) without user activity in order to increase use time without recharging. Touch the display in order to leave the power saving mode.
No feedback, black display	After 10 minutes (time span configurable) without user activity the device automatically powers down completely. Start the device by pressing the on-switch.

Error	Recommended action for troubleshooting
No feedback, black display, device frozen	If the device does not respond to user action you might need to restart the device by pressing the On/Off switch for approximately 5 seconds (see section *3.4.2: Device Reset*). Charge the battery if necessary.
Error message: "Battery is too low for testing."	Place the device on the docking station for charging the battery. It may take a few minutes until the device is ready for starting a test module again.
Device stops test and/or shuts down during test.	Place the device on the docking station for charging the battery. If a test is stopped due to low battery and the device is shut down, the test data is saved before shut down.
Error message: "Calibration interval expired"	The error message appears if the calibration interval of a transducer has expired. Please send the transducer to your service partner.
"Error *[Error-ID]*"	Device error recognized by device self-test. Contact your service partner for more information.

Table 4: Errors and recommended actions

If the recommended actions in the table or online FAQ do not help in solving the problem, please contact your distributor.

4 Service and Maintenance

4.1 General Service Information

PATH MEDICAL is committed to customer satisfaction. Please contact your distributor for ordering supplies, obtaining information on training courses and service contracts, getting help with device-related problems, suggesting desired features, or finding answers not addressed in the device online help or associated manuals. General information on your device and on PATH MEDICAL can be found at www.pathme.de.

Updates to software, firmware and documentation (e.g. user manual) are available on the PATH MEDICAL homepage. If updates are available, PATH MEDICAL distributors will be informed. It is the responsibility of the local distributor to inform the end customer. If you are not sure whether your software, firmware, or documentation is up-to-date please check www.pathme.de/downloads or contact your distributor.

Service activities and repairs of the device and its electro-medical accessories must only be conducted by PATH MEDICAL or its authorized service partners. Authorized service partners are enabled from PATH MEDICAL with necessary documentation and training in order to conduct specified service activities and repairs.

PATH MEDICAL reserves the right to decline any responsibility for the safety in operation, reliability, and capability of the device or accessory if any service activities or repairs were conducted by a non-authorized service partner (see also section *7: Warranty*). If in doubt, please contact PATH MEDICAL (service@pathme.de) before commissioning a service activity or repair. Please send the device or accessory in its original packaging to your distributor.

4.2 Routine Maintenance and Calibration

To ensure safe operations and to keep measurements valid, it is stipulated by PATH MEDICAL to check the device and calibrate its transducers at least once a year or more frequently if required by local regulations or if there is any doubt about correct system function. A warning message is shown on the device if a transducer calibration date has expired. Please return the accessory immediately to your distributor or service partner.
The device's next service date can be consulted in *3.5.9: System Information.* The font color indicates the interval to the next device calibration or if calibration is expired. When time to calibration is more than one year the font color is black, if less than one year the font color is orange. If device calibration is expired after two years (maximum recommended service interval), font color of next service date is red. Please return the device immediately to your distributor or service partner.

Please note that for QSCREEN devices, it is easy to exchange transducers individually and recalibrate them separately. This will help you to increase uptime and availability of your device. QSCREEN electronically reads the calibration date of transducers. If the calibration date cannot be read, QSCREEN will not allow screening with that transducer. Calibration dates are read at start-up and also prior to starting the screening.

REGULATORY BACKGROUND:

The medical device operator act (MPBetreibV, Germany) requires that audiometric equipment undergoes an annual metrological inspection, which must be conducted by authorized and trained personnel. An annual inspection interval is also suggested by DIN EN 60645-6 and DIN EN 60645-7 for OAE and AEP test equipment.

EXPLANATION:

The device and especially its accessories contain parts, which may be subject to environmental impacts, contamination, and wearing. In order to ensure accurate measurements, the fault tolerance provided by the manufacturer or defined by applicable standards needs to be controlled by specifically designed instrumentation and defined procedures. Therefore, metrological inspection must be conducted by authorized service partners trained by PATH MEDICAL.

For acoustic transducers differences in environmental conditions between the point of calibration and the point of use may influence the calibration accuracy. For more information please refer to section *9.4: Storage, Transport, and Operating Conditions*.

In addition to the annual metrological inspection, a regular visual inspection and a regular check for correct operation of the device and its accessories is recommended. Guidelines for routine inspections are provided e.g. in DIN EN ISO 8253-1 for pure-tone audiometry. Please follow local regulations or guidelines.

4.3 Repair

In case a device or accessory is defective or differs in any way from its original setup, PATH MEDICAL or an authorized service partner will repair, re-calibrate or exchange the device or accessory. All repairs are subject to parts and material availability. Please contact your distributor to find out about the lead time of any repair activity.

Prior to sending any equipment for repair, please provide relevant information to your service partner (e.g. model, serial number, firmware version, contact information, shipping information, detailed description of experienced issue or defect). This may help in speeding up the repair process and failure analysis and in excluding issues that can be solved without sending the device. Additional information may be requested by your service partner.

See also sections *4.1: General Service Information* and *7: Warranty*.

5 Cleaning

Cleaning the device and its accessories is very important for compliance with hygienic requirements and to avoid any cross-infection. Please always consider local regulations and read this section carefully.

Before cleaning the device, the device must be switched off and removed from all connected components.

Wipe the surface of the device with a cloth slightly dampened with mild detergent or normal hospital bactericides or antiseptic solution. The following quantities of chemical substances are allowed:

- ethanol: 70-80%
- propanol: 70-80%
- aldehyde: 2-4%.

Do not immerse the device and make sure that no liquid gets into the device. Dry the device with a lint-free cloth after cleaning.

Disposable accessories (e.g. ear tips and other accessories marked for single use only on the package label or data sheet) must be replaced between patients (or ears of the same patient) to avoid cross-infection.
The ear probe test cavity must be used with a disinfected and clean new probe tip. In case of contamination with pathological material or suspected dirt inside the cavity, please discontinue the

use of the test cavity. For external cleaning, please use a sterile alcohol wipe, typically containing 70% isopropyl alcohol.
It is recommended that parts which are in direct contact with the patient are subject to standard disinfecting procedures between patients. This includes physical cleaning and use of recognized disinfectants.

When using a cleaning agent, please refer to the manufacturer's data sheet of the cleaning agent for the minimum time period in which the wipe has to be in direct contact with the surface of the device or accessory to ensure effectiveness of cleaning.
The device and its accessories are provided non-sterile and are not intended to be sterilized.

5.1 Cleaning and maintenance of EP-DP/LT probes

Clean the probe between each patient or if surface is visibly contaminated. Use a sterile alcohol wipe to clean the surface and wait until the probe is completely dry.

Probe accessories are for disposable, single use (1 patient) only. In case the probe tip channels are blocked by ear wax, use the cleaning tool  to clear the channels.

The filter plate of the LT-probe needs to be removed if it is damaged or soiled. Remove the probe tip and choose the empty hole to pull out the filter plate. 

5.2 Cleaning the ear coupler cable

Always connect the ear couplers on to the ear coupler adapters before use to prevent the ear coupler adapters from coming into contact with the patient. The ear couplers are disposable items and should be used only on one patient.

If there is a risk of cross-infection, clean the adapters. Otherwise, clean the adapters at the end of the day. To clean:

Disconnect the ear coupler cable from the QSCREEN.

Clean ear coupler cable and cable plug between each patient or if surface is visibly contaminated.

Use a sterile alcohol wipe to clean the surfaces and wait until the ear coupler cable and cable plug are completely dry.

Note: *A sterile alcohol wipe typically contains isopropyl alcohol 70%. It is important to have the disinfectant in contact with the surface for the time period specified by the disinfectant manufacturer to ensure its effectiveness.*

***Note**: Never immerse the ear coupler cable in liquid*

5.3 Cleaning the electrode cable

Clean the electrode cable at the end of the day. If there is a risk of cross-infection, clean it immediately

Disconnect the electrode cable from the QSCREEN for cleaning.

Clean the electrode cable and cable plug between each patient or if surface is visibly contaminated.

Use a sterile alcohol wipe to clean the surfaces and wait until the ABR electrode cable and cable plug are completely dry.

Note: *A sterile alcohol wipe typically contains isopropyl alcohol 70%. It is important to have the disinfectant in contact with the surface for the time period specified by the disinfectant manufacturer to ensure its effectiveness.*

***Note**: Never immerse the ABR electrode cable in liquid*

6 Accessories

Available accessories for QSCREEN devices include:

Type	Model examples	Applied part	Max. cable length*
Headphone	HP-[xx]: DD45, DD65 V2	yes	2.5 m (100'')
Insert earphone	IP-05: PIEP	Yes	2.0 m (79'')
Ear coupler cable	PECC-HP	Yes	2.0 m (79'')
Related accessories: ear coupler			
Ear probe	EP-DP, EP-VIP, EP-LT	yes	1.8 m (71'')
Related accessories: - probe tips (adult and baby size) - ear tips (multiple sizes and types) - red test cavity (adult probe tip of EP-DP/EP-VIP) - check-kit (for EP-LT probe and small probe tip of EP-DP/EP-VIP) - inspection/cleaning tool - fixation clip			
Electrode cable	EC-04 (mini clips), EC-05 (crocodile clips)	yes	1.8 m (71'')
Related accessories: - check-kit - electrodes			
Label printer	SLP650SE	no	---
Related accessories: printout paper rolls			
Sound insulation headphone	Peltor Optime III	no	---
Communication cable	USB-C	no	2.0 m (79'')
Modem (for pathTrack)	DGL61-W	no	---
Transportation bag / case	---	no	---
PC software	QLINK	no	---
Docking station	QDOCK	no	---
Power supply units	Friwo FW8002.1M/05 Friwo FW8000M/05 Friwo NEO006.0-I-X-05 Friwo NEO012.0-I-X-05	no	1.85 m (73'')

* Maximum cable length rounded to next 5 cm step. The actual cable length may vary dependent on the model of the accessory type. The given cable length is the maximum cable length across all models for the accessory type.

The above list of accessories may be subject to change. Accessories may be available only upon request, may be replaced by comparable equipment, or may be discontinued without prior notice. Please contact your distributor for an up-to-date list of available accessories.

7 Warranty

PATH MEDICAL warrants that the supplied device and its accessories are free from defects in material and workmanship and, when properly used, will perform in accordance with applicable specifications during the defined warranty period.

For the device a one year warranty period is provided. For the rechargeable battery pack, the touch screen and wearing parts (e.g. ear probe) a six months warranty period is provided. The warranty period starts at the date of shipment. In case longer warranty periods are defined by law, these warranty periods take precedence.

This warranty is only valid for devices and accessories purchased from an authorized distributor. This warranty is not valid in cases of breakage, malfunction due to manipulation or unintended usage, negligence, non-observance of manufacturer's instructions including cleaning instructions, crashes or accidents, damages by external causes (e.g. flood, fire) or damages due to shipment (see also disclaimer of warranty). This warranty is not valid for normal deterioration of wearing parts and cosmetic damages (e.g. scratches). Opening the device case or any accessory housing voids this warranty as well as modifications or changes in the device or accessory not approved in writing by PATH MEDICAL.

This warranty includes material and labor costs and has to be in accordance with the manufacturer specifications. PATH MEDICAL reserves the right to credit, repair or replace (with a new or refurbished product) an "in-warranty" device or accessory at its sole option.

Warranty repairs for the device and accessories are handled in the same manner as other repairs and service. When suspecting a warranty case, please inform your distributor about the defect. Send the device or accessory together with an error description to your distributor. Mailing expenses are not refundable and are to be paid by the customer. Please send the device or accessory in its original packaging to your distributor.

See also section *4.1: General Service Information*.

DISCLAIMER OF WARRANTY:

The warranty contained herein is exclusive. PATH MEDICAL disclaims all other warranties expressed or implied, including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose or application. PATH MEDICAL shall not be liable for any incidental, indirect, special or consequential damages whether resulting from the purchase, use, misuse or inability to use of the device or accessory or relating in any way to the defect in or failure of the device or accessory, including, but not limited to, claims based upon loss of use, lost profits or revenue, environmental damage, increased expenses of operation, cost of replacement goods. PATH MEDICAL's warranty and liability is directed to the distributor and limited to the regulations in the respective distribution contract and German law. The end user shall address warranty claims only to the authorized distributor from whom the device was purchased. PATH MEDICAL reserves the right to refuse warranty claims against products or services that are obtained and/or used in contravention of the laws of any country.

8 Notes on Safety

In order to allow safe performance of QSCREEN, please read the following notes on safety carefully and follow the provided instructions. If not followed, risks of danger to persons and/or the device may be the consequence. Retain this manual for later use and make sure to hand over this manual to any person who uses this device. Applicable local government rules and regulations must be followed at all times. Please report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the country in which the user and/or patient is established.

8.1 General Usage

Follow relevant regulations in your facility regarding maintenance and calibration of audiometric equipment. This includes regular servicing of the device and calibration of transducers. See section *4: Service and Maintenance*.

Do not try to open or service the device and its components yourself. Return the device to the authorized service partner for all service.

Do not use the docking station if its power supply is connected to the docking station and shows a damaged cord or plug. Likewise, this is true for any accessory with a separate power supply.

During charging, the enclosure of the device warms up on the backside and around the battery compartment. Touch the device with care.

Ensure that no metal objects or metallic material interferes with wireless charging, i.e. make sure that no conducting object is placed between docking station and device.

Do not damage the battery or use a damaged battery. Do not touch or short circuit the battery contacts. Keep the battery away from fire and water. The battery must be replaced by an authorized service partner only.

The device is not intended for use in the Magnetic Resonance (MR) environment. The device has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the device in the MR environment is unknown. Bringing or operating this device in the MR environment may result in injury or device malfunction.

If skin irritation and/or sensitization occur when using the device or any accessory, please stop using the subject device and/or accessory.

The device needs to be operated in a quiet environment, so that measurements are not influenced by ambient noises. This may be determined by an appropriately skilled person trained in acoustics. DIN EN ISO 8253-1 section 11 defines maximum ambient noise levels for audiometric hearing testing. If not followed, measurement data may not reliably represent the actual hearing status.

For ABR measurements the device needs to be operated in an environment with low electromagnetic disturbance. It is recommended to perform ABR tests in a shielded cabin. If not followed, measurement data may be deteriorated by electrical noise.

For calibrated transducers differences in environmental conditions between the point of calibration and the point of use may influence the calibration accuracy. For more information please refer to section *9.4: Storage, Transport, and Operating Conditions*.

There are no device parts, which can be serviced during use with a patient. See also section *4: Service and Maintenance*.

During data transmission via Bluetooth between QSCREEN and docking station make sure that the distance between QSCREEN and docking station does not exceed 10 m (30 ft.) and that no items are in between. If not followed the Bluetooth connection stability and data rate may be reduced or no transmission may be possible.

8.2 Handling, Transport, and Storage

Do not drop or otherwise cause undue impact to the device or any accessory. If any damage is suspected (e.g. loose parts inside device), do not use the device or accessory anymore and return it to your local service partner for repair and/or calibration.

Do not modify the device and its components in any way without written consent of the manufacturer. Failure to do so may result in a reduced level of safety of the system and/or degradation of functionality.

Do not transport, store or operate the device at environmental conditions exceeding those stated in section *9: Technical Specifications*. If the device is moved from a cold location to a warmer one, there will be a risk of condensation. If condensation occurs, the device must be allowed to achieve normal temperature before it is switched on.

Make sure that any platform, table, cart, or other surface used during the operation, transport, or temporary or permanent storage of the device and its components is adequate, sturdy, and safe. PATH MEDICAL is not responsible for any injury or damage that may result from inadequate, poorly constructed, or unapproved transports, carts, or operating surfaces.

Do not allow any fluid to infiltrate the device or the docking station. Do not immerse the device or the docking station in fluids as e.g. cleaning agents.

Do not put excessive pressure on the device display or allow any item to puncture the device display.

Do not place the device next to a radiator or any other heat source.

8.3 Electrical Safety

Do not use any power supply with the docking station other than the ones defined in section *9: Technical Specifications*. Other power supplies made for other electronic devices such as notebook computers or printers may cause damage to the docking station. Likewise, using the docking station power supply on other types of devices may cause damage to the power supply unit and to those devices, respectively.

Avoid accidental contact between connected but unused applied parts and other conductive parts including those connected to protective earth. Conductive parts of electrodes and their connectors including the neutral electrode are not allowed to contact other conductive parts and earth.

Do not use the device during the application of high-frequency surgical devices, cardiac pacemakers, defibrillators or other electrical stimulators. This may result in burns at the site of electrodes and possible damage to the applied parts.

Do not use the device in close proximity to shortwave or microwave therapy equipment as it may produce instability in the applied parts.

If the device is used during surgery, the connectors must not touch conductive items including ground.

If a connection is established from the docking station to a PC which is powered through the mains network, special precautions must be taken in order to maintain medical safety. The docking station and the PC must be located outside the patient environment (i.e. at least 1.5 m away from the patient). The PC must be either medically approved (EN 60601-1) or compliant to EN 60950.

8.4 Electromagnetic Compatibility

The use of QSCREEN devices next to other electronic equipment or with other electronic equipment in a stacked form should be avoided, as this could result in improper operation (QSCREEN: e.g. occurrence of unwanted noise). Electronic equipment may include e.g. mobile phones, pagers, walkie-talkies, or RFID systems. If such an application cannot be avoided, QSCREEN and the other electronic devices should be observed to make sure they are working properly. It may be necessary to implement suitable corrective measures (e.g. new orientation or positioning of QSCREEN or shielding). Please also refer to section *10: Electromagnetic Compatibility Information.*

Portable radio frequency communications equipment (radio equipment) including their accessories such as antenna cables and external antennas should not be used closer than 30 cm (12'') to QSCREEN and its accessories.

During testing it is recommended to keep low-power radio equipment (≤ 2 W) at a distance of at least 3 m (118'') from QSCREEN and its accessories.

It is recommended to keep very strong sources of radio frequency emissions (e.g. high-power transmitting antennas from radio or TV stations) at a distance of at least 2 km (6560 ft.) from QSCREEN (minimum required distance depends on signal power and directional characteristics of the sender).

Failure to do so may result in a reduction of device performance.

Use of other accessories than the ones specified or provided by PATH MEDICAL may result in higher electromagnetic emission or reduced immunity to interference of the device and may result in improper device operation.

8.5 Accessories

The probe tip of the ear probe must not be inserted into an ear without a disposable ear tip properly affixed to the probe tip. Make sure that the ear tip size corresponds to the patient's ear canal size.

Ear probes or insert earphones must not be used in cases of external otitis (outer ear canal infection) or in any case which yields to pain for the patient when inserting the ear probe or insert earphone.

Disposable accessories (e.g. ear tips and other accessories marked for single use only on the package label or data sheet) must be replaced after completing measurements on

the patient (or on the same patient's ear) to avoid cross-infection. Do not clean or reuse these items.

Do not connect any accessories other than those provided by PATH MEDICAL. Other accessories are not compatible with the device and may result in device damage or improper functionality of the device. If connecting accessories which do not comply with the same safety requirements as this product, this may lead to a reduction in the overall system safety level.

Cleaning the device and its accessories is very important for compliance with hygienic requirements and to avoid any cross-infection. For further information please refer to section *5: Cleaning*.

Always handle cables and transducers with care. Do not excessively bend or twist any cable. The cable may break and hence deteriorate overall device functionality or reduce the overall system safety level. Do not drop, throw or hit any transducer on a hard object. Sensitive parts (e.g. ear probe microphone and loudspeakers) may get damaged and deteriorate measurement performance. Do not use a cable or transducer if any damage is suspected.

Keep small parts (e.g. ear tips) out of patient's range (especially children) in order to prevent accidental swallowing.

No parts may be eaten, burnt, or in any other way used for purposes other than audiometry.

Inspect the transducer channels of the insert earphone and/or ear probe (including probe tip and ear tip) before use. A blocked loudspeaker channel may yield lower stimulus levels or prevent successful calibration. A blocked microphone channel may yield lower response levels or prevent successful calibration. If in doubt conduct a probe test (see section *3.5.5: Hardware and Quality Tests*).

The device or docking station sockets are intended to connect to the respective accessories (e.g. transducer, electrode cable, power supply unit, label printer). Do not connect any other item to these sockets. For correct connections see section *3.4.3: Device and Docking Station Sockets*.

Do not try to insert any plug into a device or docking station socket with excessive force. A plug fits only into the respective socket if the mechanical coding of the plug is corresponding to the socket. Color-codes help finding the correct device socket. See section *3.4.3: Device and Docking Station Sockets*.

When pulling a plug out of a socket always pull at the plug and not at the cable to avoid cable break.

Do not expose the label printout to sunlight or heat. Printing on thermal paper fades with exposure to light or heat.

8.6 Waste Disposal

The device includes a rechargeable lithium-ion battery pack. In case the battery pack cannot be charged anymore or in case of any other suspected defect of the battery pack, the battery pack must be replaced by an authorized service partner. The service partner is responsible for the correct disposal and storage of the battery pack. Do not dispose of the batteries in your normal household waste bin. Please follow your local regulations for proper disposal.

Within the European Union, the device and its accessories which are electrical or electronic equipment must not be disposed of in your normal household waste bin since electronic waste may contain hazardous substances. Electrical or electronic equipment is defined as equipment which depends on electric currents or electromagnetic fields. The device and accessories to which the definition is applicable (e.g. transducers, label printer, USB-C cable, modem) are electronic equipment covered by the Directive 2012/19/EC on waste electrical and electronic equipment (WEEE). The device and applicable accessories may be returned to your service partner or PATH MEDICAL for disposal. Please contact your service partner or PATH MEDICAL for proper disposal of the device and its accessories. Please follow your local regulations for proper disposal of the device and its accessories.

Please follow your local regulations for proper disposal of any packaging material.

Patient and test data must be erased prior to equipment disposal.

9 Technical Specifications

This section provides a summary of the most important technical specifications.

9.1 General Device Information

Dev. classification (93/42/EEC, 2017/745) (MDR Canada)	Class II a Class II
Applied part classification (60601-1) Applied parts	Type BF (body floating) Insert earphones, ear probe, ear coupler cable, electrode cable
Device safety class (60601-1)	Class II
Ingress protection rating (IP code)	IP30
Mode of operation	Continuous
Applied standards	DIN EN ISO 389-2 (transducer calibration), DIN EN ISO 10993-1 (biocompatibility), DIN EN ISO 15223-1 (manual), DIN EN 60601-1 (electrical safety), DIN EN 60601-1-2 (EMC), DIN EN 60601-1-4 (PEMS), DIN EN 60601-1-6 (usability), DIN EN 60601-2-40 (AEP equipment), DIN EN 60645-3 (short-term test signals), DIN EN 60645-6 (OAE, class 2), DIN EN 60645-7 (ABR, class 2), DIN EN 62304 (software lifecycle)

9.2 Device Characteristics

Device dimension	ca. 205 x 86 x 42 mm (8.07 x 3.39 x 1.65'')
Device weight (including battery pack)	ca. 300 g
Display properties	272 x 480 pixel, graphic LCD, 4.3''
Maximum power consumption from battery	ca. 4 V, 0.4 A = 1.6 W
Typical power consumption during charging	ca. 5 V, 1.0 A = 5 W

9.3 Power Supply

Use docking station exclusively with the power supply units Friwo FW8002.1M/05, Friwo FW8000M/05, Friwo NEO006.0-I-X-05, or Friwo NEO012.0-I-X-05

Do not use any other power supply unit. Failure to do so may reduce electrical safety and damage the docking station.

Input rating of power supply unit	Friwo FW8002.1M/05, Friwo NEO006.0-I-X-05: 100-240 V, AC, 50-60 Hz, 0.16-0.08 A Friwo FW8000M/05, Friwo NEO012.0-I-X-05: 100-240 V, AC, 50-60 Hz, 0.3-0.15 A
Output rating of power supply unit	5 V, 1.4 A (Friwo FW8002.1M/05, Friwo NEO006.0-I-X-05) 5 V, 2.2 A (Friwo FW8000M/05, Friwo NEO012.0-I-X-05)
Rechargeable battery pack	3.7 V (lithium ion)
Maximum operating time with fully charged batteries	ca. 8-10 hours (dependent on usage)
Maximum charging cycles	500-1000 (life time minimum 2 years for normal usage)
Maximum charging time:	ca. 10 hours

9.4 Storage, Transport, and Operating Conditions

For storage and transport, please keep the device and its accessories in the provided carrying case or a similar closable container in order to protect all components against external forces and environmental impacts as e.g. mechanical stress (scratches), dust or moisture. Extreme storage and operating conditions may result e.g. in breakage of the touch screen display (at extremely low temperatures) or in impairment of the device and/or transducer calibration.

If the device is moved from a cold location to a warmer one, there will be a risk of condensation. In this case, the device must be allowed to achieve normal room temperature before it is switched on. Also make sure that the below operating conditions are fulfilled.

TRANSPORT AND STORAGE CONDITIONS:

Transport temperature	-20 to 60 °C (-4 to 140 °F)
Storage temperature	0 to 40 °C (32 to 104 °F)
Relative air humidity	10 to 90 % non-condensing
Barometric pressure	70 to 106 kPa

OPERATING CONDITIONS:

Temperature	10 to 40 °C (50 to 104 °F)
Relative air humidity	20 to 90 % non-condensing
Barometric pressure	70* to 106 kPa

* In the following cases a transducer recalibration at the point of use is recommended:

Air pressure at point of calibration p_c	Air pressure at point of use p_u
98 to 104 kPa	< 92 kPa
92 to 98 kPa	< p_c – 6 kPa
<92 kPa	< p_c – 6 kPa or > p_c + 6 kPa

See also DIN EN 60645-1 5.3 and Soares et al.: “Audiometer: Correction factor for atmospheric pressure”, Inter-Noise 2016.

9.5 Test module parameters

9.5.1 TEOAE

- Noise detection: root mean square (RMS) of non-stimulus intervals
- Residual noise calculation: weighted averaging, summed weighting factors
- Artifact rejection: weighted averaging
- Response detection: 8 values with changing sign fulfilling a 3 sigma criterion (representing 99.7 % statistical significance)
- Probe check: limit of maximum sound pressure, symmetry check of both speakers, leak check.
- Calibration: in-the-ear calibration with ear canal volume adjustment
- Stimulus monitoring throughout the recording
- Sample rate: 48 kHz (stimulus), 16 kHz (response)
- Window of analysis: 5 to 13 ms post-stimulus
- Stimulus level: 85 dB peSPL
- Stimulus type: short-term stimulus without direct component (0.7-6 kHz)
- Stimulation protocol: nonlinear

9.5.2 DPOAE

- Noise detection: narrow band noise around $2f_2$-f_1
- Residual noise calculation: weighted averaging, summed weighting factors
- Artifact rejection: weighted averaging
- Response detection: phase-statistics-derived spectral SNR criterion (6, 9, 12 dB, dependent on protocol settings)
- Leak check: analysis of feedback signal (440 Hz probe tone)
- Probe check: limit of maximum sound pressure, symmetry check of both speakers, leak check.
- Calibration: in-the-ear calibration with ear-canal volume adjustment
- Frequency ratio f_2/f_1: 1.22
- Minimum DPOAE level criterion: off, 0 dB, -5 dB, -10 dB, -15 dB
- Sample rate: 48 kHz (stimulus, response)
- Measurement interval: 4096 samples
- Stimulus modes:
    - Frequency-modulated DPOAE (f_m = 1.4-1.6 Hz, modulation depth = 50 Hz at 1 kHz, 100 Hz at 4 kHz)
    - Multi-channel DPOAE (simultaneous measurement of DPOAEs at up to two f_2 frequencies in one ear)
- Frequencies f_2: 1, 1.5, 2, 3, 4, 5, 6, 8 kHz
- Stimulus level L_2: 50, 55, 60 , 65 dB SPL
- L_2/L_1 relation: automatic (scissors paradigm: $L_1 = 0.4\ L_2 + 39$ dB SPL, Kummer et al. 1998)
- Overall stop criterion: x out of y (with y = number of selected frequencies, x = number of frequencies with single frequency pass result, e.g. 3/4, 4/4, 3/5, 4/5, 5/5, 4/6) with “Auto Stop” option, i.e. stop as soon as overall criterion is fulfilled or cannot be fulfilled anymore

9.5.3 ABR

- Artifact rejection: weighted averaging, notch filter (50/60 Hz, self-tuning)
- Residual noise calculation: collecting noise energy from each frame, calculating residual noise level (absolute RMS value in nV)
- Response detection: auto peak-marker setting via template matching
- Display and storage of waveform, impedance, residual noise, averages
- Electrode impedance check:
    - Continuous monitoring of electrode impedance
    - Auto start after impedance OK: $Z \leq 4$ kΩ, $\Delta Z \leq 2$ kΩ
    - Allow testing: $Z \leq 12$ kΩ, $\Delta Z \leq 4$ kΩ;
- Sample rate: 48 kHz (stimulus), 16 kHz (response)
- Simultaneous measurement on left/right ear
- ABR low-pass filter for trace smoothing
- Stimulus type: Chirp (broadband, 1 to 8 kHz)
- Stimulus polarity: alternating
- Stimulus rate: 85 Hz ± 10Hz, jittered

- Stimulus level: 30, 35, 40, 45, 50 dB nHL
- Spread spectrum

10 Electromagnetic Compatibility Information

Electromagnetic compatibility (EMC) as stated by standard DIN EN 60601-1-2 (Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests) and 60601-2-40 (Medical electrical equipment - Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment) was certified by an accredited laboratory. Information on the full report is available from PATH MEDICAL upon request.

The user must take care that the device is used in an environment with electromagnetic radiation as specified in *Table 5* and *Table* 6.

Emitted interference measurement	**Compliance**	**Electromagnetic environment**
High-frequency emission according to CISPR11	Group 1	The medical electric device uses high-frequency (HF) energy only for internal operation. Hence, its HF emissions are very low and it is unlikely that adjacent electronic devices are disturbed.
	Class B	The medical electric device may be used in all establishments, including those in residential environments and those that are directly connected to a public power network that also supplies buildings used for residential purposes.
Emission of harmonic components according to IEC 61000-3-2	Class A	---
Emission of voltage fluctuation / flicker according to IEC 61000-3-3	Compliant	---

Table 5: Compliance with electromagnetic emission guidelines and resulting requirements for electromagnetic environment

Tests for immunity to interference	**IEC 60601 test level**	**Concurrent level**	**Electromagnetic environment**
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 2, 4, 8 kV contact discharge ± 2, 4, 8, 15 kV air discharge	± 2, 4, 8 kV contact discharge ± 2, 4, 8, 15 kV air discharge	To reduce ESD effects, the ground floor shall consist of wood, concrete or ceramic tiles.
Fast transient electric disturbance; bursts according to IEC 61000-4-4	± 2 kV for power lines ± 1 kV for input and output lines	± 2 kV for power lines ± 1 kV for input and output lines	The quality of supply voltage shall correspond to typical hospital or commercial environment.
Impulse voltage, surges according to IEC 61000-4-5	± 1 kV voltage outer conductor – outer conductor	± 1 kV voltage outer conductor – outer conductor	The quality of supply voltage shall correspond to typical

Tests for immunity to interference	IEC 60601 test level	Concurrent level	Electromagnetic environment
	±2 kV voltage outer conductor – earth		hospital or commercial environment.
Voltage drop, short interruption and fluctuation of supply voltage according to IEC 61000-4-11	0 % U_T (>95 % U_T drop) for ½ and 1 period 0 % U_T for 250/300 periods 70 % U_T (30 % U_T drop) for 25/30 periods	0 % U_T (>95 % U_T drop) for ½ and 1 period 0 % U_T for 250/300 periods 70 % U_T (30 % U_T drop) for 25/30 periods	The quality of supply voltage shall correspond to typical hospital or commercial environment. If the user of the medical electric device also demands continued proper functioning of the device during an interruption of energy supply, the connection of the device to an uninterrupted power supply (UPS) or battery is recommended.
Magnetic field at mains frequency (50/60 Hz) according to IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields at the mains frequency shall correspond to typical hospital or commercial environment.
Note: U_T is the mains AC voltage before applying the test level.			

Table 6: Compliance with immunity to interference tests and resulting requirements for electromagnetic environment

The user must take care, that the device is used in an environment with minimum distances to potential radiators as described in *Table 7*.

Tests for immunity to interference	IEC 60601 test level	Concurrent level	Electromagnetic environment
Conducted high-frequency disturbance according to IEC 61000-4-6	3 V (150 kHz – 80 MHz) 6 V (ISM and amateur radio frequencies)	3 V 6 V	Portable and mobile radio units shall not be used closer than 30 cm (12‘‘) to the device and its components (i.e. connected cables).
Radiated high-frequency disturbance according to IEC 61000-4-3	10 V/m (80 MHz – 6 GHz) 9-28 V/m* (wireless RF communication)	10 V/m 9-28 V/m*	Portable and mobile radio units shall not be used closer than 30 cm (12‘‘) to the device and its components (i.e. connected cables).
* Wireless RF communication frequencies and levels: 28 V/m: 450 MHz, ±5 kHz FM, 1 kHz sine; 810 MHz, 50% PM at 18 Hz; 870 MHz, 50% PM at 18 Hz; 930 MHz, 50% PM at 18 Hz; 1720 MHz, 50% PM at 217 Hz; 1845 MHz, 50% PM at 217 Hz; 1970 MHz, 50% PM at 217 Hz; 2450 MHz, 50% PM at 217 Hz; 27 V/m: 385 MHz, 50% PM at 18 Hz; 9 V/m: 710 MHz, 50% PM at 217 Hz; 745 MHz, 50% PM at 217 Hz; 780 MHz, 50% PM at 217 Hz; 5240 MHz, 50% PM at 217 Hz; 5500 MHz, 50% PM at 217 Hz; 5785 MHz, 50% PM at 217 Hz;			

Table 7: Minimum distance to potential radiators

11 Radio Communication Regulatory Approval

This section outlines the regulatory information for the QSCREEN and docking station radio communication.

11.1 Radio interface specifications

The QSCREEN device and its docking station use radio transmission with the following parameters:

- Frequency band/band width: 2.402-2.480 GHz (Bluetooth), 110-205 kHz (wireless charging)
- Modulation characteristics: GFSK, π/4-DQPSK and 8DPSK (Bluetooth), ASK (wireless charging)
- Maximum transmitting power: 2.5 mW (Class 2) (Bluetooth), 5 W (wireless charging)

11.2 United States

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.

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.

The QSCREEN device contains Transmitter Module FCC ID: A8TBM78ABCDEFGH

The Docking Station contains Transmitter Module FCC ID: 2ABCB-RPI4B

11.3 Canada

This device complies with Industry Canada's license-exempt RSS standard(s). Operation is subject to the following two conditions:
(1) This device may not cause interference; and
(2) This device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes:
(1) l'appareil ne doit pas produire de brouillage;
(2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

The QSCREEN device contains Transmitter Module IC: 12246A-BM78SPPS5M2.

The Docking Station contains Transmitter Module IC: 20953-RPI4B.

11.4 European Union

Hereby, PATH MEDICAL GmbH declares that the radio equipment type QSCREEN and the docking station is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: https://www.pathme.de/certificates

11.5 Taiwan

注意 ！
依據 低功率電波輻射性電機管理辦法
第十二條 經型式認證合格之低功率射頻電機,
非經許可,
公司、商號或使用者均不得擅自變更頻率、加大
功率或變更原設計
之特性及功能。
第十四條 低功率射頻電機之使用不得影響飛航安
全及干擾合法通信；
經發現有干擾現象時，應立即停用，並改善至無
干擾時方得繼續使用。
前項合法通信，指依電信規定作業之無線電信。
低功率射頻電機須忍受合法通信或工業、科學及
醫療用電波輻射性
電機設備之干擾。

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