PATH MEDICAL

User Manual

Senti & Sentiero

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Manual Information

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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.

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1 Overview

1.1 Introduction

Thank you for purchasing a Senti or Sentiero. This manual is your guide for safely operating and maintaining your device.

Please read this manual carefully before using Senti or Sentiero 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.

Senti and Sentiero are reliable, easy-to-use, and mobile medical devices. All devices provide easy navigation via touch-screen and are 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 include more modules.

1.2 Device Versions

There are multiple versions available within the Senti and Sentiero device families.

HANDHELD DEVICES:

Senti

(Model: SIH100097)

Sentiero

Including:
Sentiero
(Model: SOH100098)
Sentiero Advanced
(Model: SOH100360)

Senti and Sentiero with PCB revision ≥ 67 differ from Senti and Sentiero with PCB revision <67 in extended internal memory (e.g. for speech tests). Sentiero Advanced differs from Sentiero in socket layout and offers the additional ability to conduct acoustically evoked potential (AEP) tests. Sentiero and Sentiero Advanced with PCB revision ≥ 70 offer the ability to conduct tympanometry and acoustic reflex measurements when used together with the tympanometry add-on TY-MA.

DESKTOP DEVICES:

Senti Desktop

Including:
Senti D. (Model: SID100419)
Senti D. Flex (Model: SID100433)

Sentiero Desktop

(Model: SOD100497)

Senti Desktop and Senti Desktop Flex differ in sockets. Senti Desktop offers jack plugs and is calibrated to a specific headphone and/or bone conductor. Senti Desktop Flex offers the ability to exchange different calibrated transducers. Sentiero Desktop offers the same modules as Sentiero together with the ability to conduct tympanometry and acoustic reflex measurements.

1.3 Intended Use

Devices of the Senti and Sentiero device families offer different test methods which can be configured to fit the professional's needs for hearing screening or diagnostics. Devices of the Senti device family provide multiple psycho-acoustic test procedures including conventional and image-based pure-tone audiometry (e.g. Audio, MAGIC) and speech tests (e.g. SUN, MATCH). Devices of the Sentiero device family additionally provide physiological test procedures including transitory evoked otoacoustic emissions (TEOAE), distortion product otoacoustic emissions (DPOAE), auditory brainstem responses (ABR; Sentiero Advanced only), auditory steady state responses (ASSR; Sentiero Advanced only), and auditory impedance and acoustic reflex measurements (Sentiero Desktop, Sentiero and Sentiero Advanced with tympanometry add-on).

Available psycho-acoustical methods on Senti and Sentiero are especially indicated for use with cooperative patients starting at the age of two years or adequate development age, which enables them to do play/interactive audiometry. All other physiological modules are suitable to be used for all ages elder than infants from 34 weeks (gestational age) that are ready for discharge from the hospital.

All physiological test methods are especially indicated for use in defining the type and configuration of hearing loss particularly for individuals whose behavioral audiometric results are deemed unreliable or to assist in the diagnosis of otologic disorders. Estimation of cochlear hearing thresholds (DPOAE Threshold) is possible at various frequencies without the need of cooperative interaction with the patient. Acoustic reflex and tympanometry are featured to evaluate the functional condition of the middle and outer ear. For each method, several protocols can be configured. The results can be used to make further recommendations regarding appropriate intervention strategies.

Devices of the Sentiero device family are intended for the following purposes:

- Diagnostics, monitoring and follow-up after newborn hearing screening
- Pre-school, school, and adult hearing screening
- ENT diagnostics based on measurement of
    a) Otoacoustic emissions
    b) Tympanometry and acoustic reflex (Sentiero Desktop, Sentiero and Sentiero Advanced with tympanometry add-on)

c) Auditory Brainstem Responses (Sentiero Advanced only)
d) Auditory Steady State Responses (Sentiero Advanced only)

Senti and Sentiero are intended for use by audiologists, ear-nose-throat (ENT) doctors, and other hearing health care professionals and audiologically trained technicians in a medical environment. Please consider local regulations regarding the qualification requirements for performing measurements with a specific test module.

Senti and Sentiero are 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.

Senti and Sentiero are 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*. Senti and Sentiero are not intended for use in oxygen-rich environments.

CONTRAINDICATIONS:

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

SIDE EFFECTS:

There are no known undesirable side effects for devices of the Senti and Sentiero device families.

See also section *8: Notes on Safety*.

1.4 Performance Characteristics

All Senti and Sentiero devices are capable of producing acoustic signals which are transmitted to the patient via an air or bone conduction transducer. All Sentiero devices are capable of recording acoustic signals from the patient via an ear probe. Sentiero Advanced is capable of recording bio-potential signals from the patient via an electrode. Sentiero and Sentiero Advanced with tympanometry add-on TY-MA and Sentiero Desktop are capable of producing static air pressure. 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*).

Senti and Sentiero devices have no essential performance as related to DIN EN 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 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

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 Operational Concept

After switching on the device, the device can be operated via a touch-sensitive display. In the following the most important device functions and screen elements are explained.

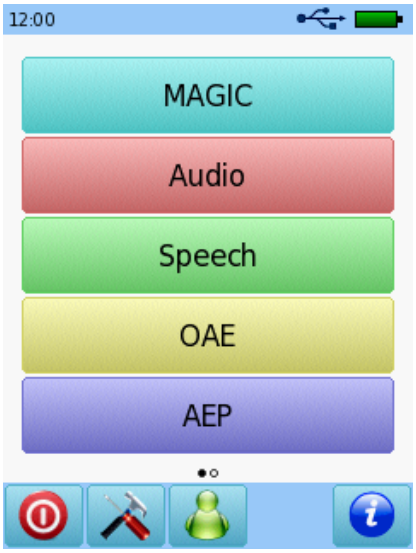
Further information and details about the various test modules, potential clinical applications and recommendations for combining several test procedures are explained in the guide for practical application (***How-To-Manual***). You can download this document from www.pathme.de/downloads.

Further technical details as e.g. maximum levels for the various test modules and for all available transducers and specifications regarding test module parameters are described in a separate ***Technical Specification*** document. You can download this document from www.pathme.de/downloads.

Please note that screen shots or references to test modules in this manual may not reflect the actual test configuration of your device.

3.1 Screen Layout

The device screen is in general split up in three sections (see *Figure 1*):



① Header

② Main screen

③ Footer

Figure 1: Device screen layout

① **Header**, including the following elements:

- Device time (e.g. 12:00)
- Screen-related information (e.g. selected patient name, selected test module/preset name)
- USB connection (is shown if USB cable is connected to a PC)
- Battery status (fully charged charging status indicator from empty to full)

② **Main screen**, including screen-related elements (e.g. test module list, patient list, test data result view)

③ **Footer**, including control elements (e.g. for browsing to different screens) and online help (see section *3.2: Online Help*)

For explanation of symbols please refer to the device online help (see section *3.2: Online Help*).

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 blue information icon, which is displayed in the footer. The help screens explain the currently available symbols and their functions.

At some screens, there is an additional information icon, which will provide further information for the user (e.g. recommendations for measuring DPOAEs in a noisy environment, explanation of free-field calibration).

3.3 Test Result Status Icons

In the test history list, test results are shown with an overall test result status icon. The icons correspond to the following definitions:

	**Test result OK** Screening test: pass result Diagnostic test: result within expected range of normal hearing
	**Test result incomplete, in-between OK and not OK, further test interpretation needed** Test with hearing threshold result (e.g. Audio, MAGIC Audio, and DPOAE Threshold): result within expected range of mild hearing loss
	**Test result not OK** Screening test: refer result Diagnostic test: result within expected range of moderate to severe hearing loss

The test result status icon is meant as a rough hearing status estimator. It is not to be interpreted as a binding result. A green status icon is not necessarily an indication that the full auditory system is normal. A full audiologic evaluation should be administered if concerns about hearing sensitivity persist. A yellow or 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 audiologic 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 On/Off Switch

The on/off switch is located at the right side of the device housing for handheld devices and at the rear panel of the device housing for desktop devices (see *Figure 2*). The on/off switch can be used to switch on or off the device. For switching on the device, press the switch briefly. The welcome screen appears. For switching off the device, press the switch for about 10 seconds.

Alternatively the device can be switched off via the off switch icon in the footer of the device display.

In addition, the on/off switch can be used in some test modules (e.g. MAGIC, SUN) to show the footer, which may be hidden in these modules during the test.

Figure 2: On/off switch for handheld (left) and desktop device (right, marked with blue circle)

3.4.2 Device Reset

If the device is stalled (i.e., no reaction when pressing the touch screen), the device can be reset. After reset, the device can be started again with the on/off switch. The reset button does not reset any device or test module settings or any other data on the device.

In order to reset the device, for handheld devices, press the reset button on the back side of the device below the rubber casing (see *Figure 3*). For desktop devices, press the on/off switch for several seconds.

Figure 3: Device reset button for handheld device

3.4.3 Device Sockets

Multiple accessories can be connected to the device. This includes e.g. transducers (e.g. headphones, ear probe), electrode cable, patient response button, label printer, communication cable (RS232, USB), and power supply unit. For further information see section *6: Accessories*.

Desktop devices: When printing via label printer, please make sure that both the **device and the label printer** are connected to the power supply unit; otherwise no printout will be possible.

For handheld devices (see *Figure 4* and *Figure 5*) the sockets can be used as described in *Table 1*.

Socket	Connectable accessory
 Blue	Headphones, insert earphones, free-field loudspeaker Sentiero, Sentiero Advanced: 2nd ear probe, tympanometry add-on (PCB revision ≥ 70 only) Sentiero Advanced: ear coupler cable
 Red	Sentiero, Sentiero Advanced: Ear probe, microphone Sentiero Advanced: Bone conductor, trigger cable
 Grey	Senti, Sentiero: Patient response button, label printer, power supply, bone conductor Senti: RS232 cable (for connection to computer)
 White	Sentiero Advanced: Electrode cable, patient response button, label printer, power supply, modem
USB socket	USB cable with type mini B connector (for connection to computer)

Table 1: Device socket overview for handheld devices

Figure 4: Socket panel of handheld devices (from left to right: Senti, Sentiero, Sentiero Advanced)

Figure 5: USB socket of handheld device

For desktop devices (see *Figure 6*) the sockets can be used as described in *Table 2*.

Socket	Connectable accessory
 Blue	Senti Desktop Flex, Sentiero Desktop: Headphones, insert earphones, free-field loudspeaker Sentiero Desktop: 2nd ear probe, trigger cable
 Red	Senti Desktop Flex, Sentiero Desktop: Bone conductor Sentiero Desktop: Ear probe, microphone
 ①	Senti Desktop: Headphones Please note that only a headphone specifically calibrated to the device can be used.
 ②	Senti Desktop: Bone conductor Please note that only a bone conductor specifically calibrated to the device can be used.
 ③	Patient response button
 ④	Label printer, modem
 ⑤	USB cable with type B connector (for connection to computer)
 ⑥	Power supply

Table 2: Device socket overview for desktop devices

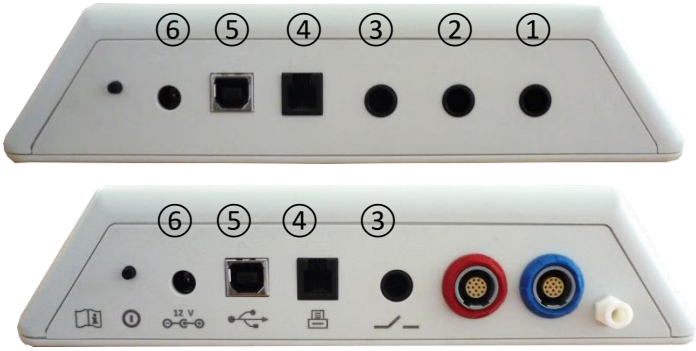


Figure 6: Socket panel of desktop devices (top: Senti Desktop, bottom: Sentiero Desktop)

Please note that Senti Desktop Flex in comparison to Sentiero Desktop does not contain an additional pressure outlet socket nearby the blue connector socket in *Figure 6* bottom.

3.4.4 Charging the Device

Connect the power supply unit to the device (see section *3.4.3: Device Sockets*). For charging the device, connect the power plug to a power mains socket with appropriate output voltage and frequency. For more information about power supply units please see section *9: Technical Specifications* and information provided on the power supply unit. The charging process starts

automatically and is finished within about 2 hours (handheld) or 8 hours (desktop), respectively. The battery status can be derived from the battery status icon symbol:  fully charged;  charging;  status indicator from empty to full.

3.5 Device Functions

3.5.1 User Management

With the Mira PC software you can activate or de-activate the user management on your device (see Mira online help for more information). If the user management is activated, after switching on the device, you will be asked to select a user and to enter the user password. Please follow the explanations on the device. If you would like to change a user you need to logoff from the device and 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 Senti/Sentiero devices, the device does not provide any inherent access protection (i.e. no login with password).

3.5.2 Patient Management

After switching on the device (and if applicable after login) a patient can be added, selected from the list of patients or the test module selection can be called in “Anonymous” mode, i.e. without adding a patient. It is also possible to delete a single patient or all patients (Device Settings → Data Management).

In “Anonymous” mode tests can be conducted and saved to a session. The session can later be renamed with the appropriate patient data. This may be helpful e.g. for quickly testing a sleeping child if there is no time to enter the patient data in advance. When conducting data in “Anonymous” mode, always make sure that you are able to assign the test data later to the correct patient.

For further information about patient management please see device online help (see section *3.2: Online Help*) on the “Select Patient” screen.

3.5.3 Device Settings

There are multiple options to configure the device to your needs.

The device settings can be reached with the tools button  from the main patient or test module selection screen. The following device settings are available:

- Date and time, date and time format
- Language, sound (key click, result sound), display brightness, energy options, start menu, keyboard preferences

- Test preferences (e.g. BC symbol representation, speech calibration)

For further information about device settings please see device online help (see section *3.2: Online Help*) on the "Settings" screen and its submenus.

3.5.4 Hardware Tests

The main device functions can be tested with the "Functional Checks" option.

The **device self-test** examines several device properties as internal power supply, codec function, and memory integrity. If a device property is correctly working, a green checkmark icon ✓ is shown. Otherwise a red "x" icon ✗ is shown. If not all device properties are tested successfully (i.e., not only green checkmarks), please contact your distributor.

The **probe test** examines ear probe functionality. Please use either the red test cavity for testing the large probe tip (PT-A) or the blue test cavity or blue probe/electrode cable check kit for testing the small probe tip (PT-S, PT-LT). Do not use other combinations. The probe test either results in a pass (probe OK) or in one of the error messages shown in *Table 3*. Please follow the recommended actions for troubleshooting mentioned in *Table 3*.

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. * For EP-TE ear probes only one channel is available and hence only one curve is shown

Table 3: Probe test error messages and recommended actions

If the recommended actions in *Table 3* or in the online FAQ (www.pathme.de/faq) do not help in solving the problem, please contact your distributor.

The **electrode cable test** examines electrode cable functionality. To perform an electrode cable test it is necessary to connect the electrode cable clips to the electrode testing device (metal bolt) or the metal part of the probe / electrode cable check kit to short circuit all electrodes. Please follow the instructions on the device. The electrode cable test detects broken cables and ineffective cable shielding. If an electrode cable property is correct, a green checkmark icon ✓ is shown. Otherwise a red "x" icon ✗ is shown. If not all electrode cable properties are tested successfully (i.e., not only green checkmarks), please contact your distributor.

The **pump unit test** examines the functionality of the pneumatic system of Sentiero Desktop or of the tympanometry add-on connected to Sentiero or Sentiero Advanced. If the pump unit test fails (red icon), please contact your distributor.

The **volume calibration** of the device ("tymp calibration") shall be checked regularly with the probe fitted to the calibration cavities. The functionality of the device shall also be checked on an ear known to produce a normal, peaked tympanogram (e.g. to ensure the pump is operational and its tube is not blocked).

3.5.5 License Management

If you would like to add modules to your device please contact your distributor. You can also use the demo mode to evaluate the need for additional modules (see section *3.5.6: Demo Mode*).

When upgrading your license, you will receive a new license key that needs to be entered on your device. Before entering a new license key on the device, 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 (Device Settings → About Device). The existing license key and all currently licensed modules are displayed. When correctly entering and confirming the new license key, the additional modules will be available on the device.

If you order a speech license, you will additionally receive a speech license file, which needs to be installed on the device via Mira. Please follow the speech file installation instructions that you receive together with the speech license file.

3.5.6 Demo Mode

You can activate the demo mode a limited number of times. In demo mode, you are able to use all modules that are available for your device until the end of the day. Please note, that after activating the demo mode, you cannot change your device date and time until the end of the day. If you are interested in upgrading your device permanently with a specific module, please contact your distributor.

3.5.7 System Information

On the system information screen, general information about the device and firmware version is displayed. 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) please have these details available to pass onto your distributor.

3.5.8 Test Module Information

Multiple test modules are available for each device. This includes standard pure-tone audiometry (Audio), image-based pure-tone audiometry (MAGIC), speech tests (e.g. SUN, MATCH), other subjective tests (e.g. MAUS, BASD), otoacoustic emissions (OAE) (e.g. transient otoacoustic emissions (TEOAE), distortion product otoacoustic emissions (DPOAE)), evoked potentials (e.g. auditory brainstem responses (ABR), auditory steady-state responses (ASSR)), tympanometry, and acoustic reflex measurements. This list may be subject to change. Please contact your distributor or check the PATH MEDICAL homepage for an up-to-date list of available modules and features.

When conducting a measurement, please consider the following aspects:

If necessary for appropriate test performance (e.g. Audio, OAE), the device must be used in a quiet environment (e.g. soundproof cabin, room with low ambient noise). For measurements with ear probes (e.g. OAE) also a sound insulation headphone can be used. For AEP measurements (e.g. ABR, ASSR) acoustical noise is less influential on test performance than muscle artefacts (e.g. patient movement). For AEP 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 AEP test performance. It is recommended to perform AEP 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). A wrong 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 while it is placed inside the ear during OAE testing. This may introduce noise into the measurement. Common sources of noise relate to room noise, patient movement (e.g. breathing, moving, talking, chewing, etc.), or ear probe movement.

For further information and details about the various test modules, potential clinical applications and recommendations for combining different test procedures please refer to the ***How-To-Manual***, which can be downloaded from www.pathme.de/downloads.

3.5.9 Error Handling

If an error occurs with your device please check the below list and proceed as recommended in *Table 4*. Further information about error handling can be found in section *3.5.4: Hardware 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.
No feedback, black display, device stalled	If the device does not respond to user action you might need to restart the device by pressing the reset switch (see section *3.4.2: Device Reset*). Charge the battery if necessary.
Error message: "Battery is too low for testing."	Connect the device to the power supply unit 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.	Connect the device to the power supply unit 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: "Remove cable"	Remove the connector cable (e.g. label printer cable, RS-232 cable, modem cable).
Error message: "Touch screen error"	The error message appears if there is a permanent pressure on the touch screen during startup of the device. Check if there is a particle between the display and the surrounding display frame. Remove the particle with a small and soft tool (e.g. paper strip).
Error message: "Calibration interval expired"	The error message appears if a transducer calibration interval 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 *Table 4* or in the online FAQ do not help in solving the problem, please contact your distributor.

3.6 Mira PC Software

The latest Mira PC software is available via download from the PATH MEDICAL homepage (see www.pathme.de/downloads). Mira includes the latest firmware and speech files for updating the device. Mira comes with an online help for further information about correct handling.

Mira 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, printing test data to a standard PC printer, and exporting test data in various formats (e.g. GDT, Excel).

Some of the functionality only works with a communication license installed on the device (e.g. data download from device). You do not need a communication license installed for the following activities with Mira:

- updating your device to a new firmware
- updating a speech license or speech files

- updating user management on the device
- uploading patients to the device
- pdf export of test data (Direct Print)

Information about Mira 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 Mira is running, the computer(s) on which the Mira 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 (this is likewise applicable to similar PC software as e.g. NOAH Connector).

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

3.7 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. Additional hardware (e.g. CaliPro device, loopback cable) and training from PATH MEDICAL is required. For further information see separate PATH Service Tool manual or contact PATH MEDICAL (service@pathme.de).

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

PATH MEDICAL defines device service and transducer calibration intervals in order to ensure safe operation and valid measurements. The recommended device service interval is set to one year (maximum two years) and the transducer calibration interval is set to one year. Both intervals may be lower if required by local regulations, if there is any doubt that the system is functioning correctly, or if the device or transducer could have been influenced e.g. due to physical impact (e.g. drop of device/transducer). Information on the device service and transducer calibration status is shown on the device (see section *3.5.7: System Information*). For device service or transducer calibration, please return the device or accessory to your distributor or service partner.

Free-field loudspeakers need to be calibrated regularly by the user according to device instructions. Hence, free-field loudspeakers are exempt from the above mentioned annual calibration procedure.

Please note that for all Senti and Sentiero devices (except Senti Desktop), it is easy to exchange transducers individually and recalibrate them separately. This will help you to increase uptime and availability of your device.

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 ISO 8253-1 for audiometers and by DIN EN 60645-6 and DIN EN 60645-7 for OAE and AEP test equipment, respectively.

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. Before using the middle ear analyzer module each day, use the calibration volume cavities provided with your device to check the calibration of the ml/mmho meter. 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 (e.g. power supply unit).

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 (e.g. headphone cushions) are subject to standard disinfecting procedures between patients. This includes physical cleaning and use of recognized disinfectants. The use of hygiene protective covers is recommended for headphones (if available for the used headphone model).

For further information about cleaning instructions for accessories (e.g. ear probe) please refer to the respective manual or data sheet of the accessory.

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.

6 Accessories

Available accessories for Senti and Sentiero devices include:

Type	Model examples	Applied part	Max. cable length*
Headphone	HP-*[xx]*: HDA-280, HDA-300, DD-45, DD-65 (v2), DD450, PD-81	yes	3.0 m (118'')
Insert earphone	IP-*[xx]*: PIEP, IP-30	yes	2.0 m (79'')
Ear coupler cable	PECC-*[xx]*	yes	2.0 m (79'')
Related accessories: ear coupler			
Bone conductor	BC-*[xx]*: B-71, B-81	yes	2.8 m (110'')
Free-field loudspeaker	JBL Control 2P	no	---
Free-field loudspeaker cable	FFC	no	2.5 m (98'')
Ear probe	EP-TE, EP-DP, EP-VIP, EP-TY, EP-LT	yes	1.8 m (71'')
Tympanometry add-on	TY-MA	yes	1.8+0.9 m (71+35'')
Related accessories: - probe tips (adult and baby size) - ear tips (multiple sizes and types) - test cavity (corresponding to adult and baby size probe tip), probe/electrode cable check kit - calibration volume cavity for tympanometer (0.5, 2, 5 ml) - inspection/cleaning tool - fixation clip			
Microphone (for live speech)	Mic-*[xx]*	no	0.95 m (37'')
Electrode cable	Electrode cable	yes	1.8 m (71'')
Electrode trunk cable	EC-03 (connected to electrode lead cable)	no	1.4 m (55'')
Electrode lead cable	Multiple configurations (connected to electrode trunk cable)	yes	0.5 m (20'')
Related accessories: - electrode testing device, probe/electrode cable check kit - electrodes			
Label printer	Seiko SLP 650 SE, Able AP1300	no	---
Label printer cable	LP-*[xx]*	no	1.6 m (63'')
Related accessories: printout paper rolls			
Patient response button	PB-*[xx]*	yes	1.95 m (77'')
Sound insulation headphone	Peltor Optime III	no	---
Communication cable	USB	no	2.0 m (79'')
Communication cable	RS-232	no	1.5 m (59'')
Related accessories: RS232-to-USB converter			
Trigger cable	TIC	no	2.4 m (94'')
Modem (for pathTrack)	Cinterion EHS6T, Cinterion PLS62T-W	no	---
Modem cable	MC-*[xx]*	no	1.5 m (59'')
Transportation bag / case	---	no	---
PC software	Mira, NOAH Connector	no	---
Power supply unit	Sinpro MPU12C-104/MPU12A-104, Sinpro MPU16C-104, Friwo FW7662M/12, Friwo FW8002.1M/12, Adapter Tech. ATM012T-W090V	no	3.2 m (126'')

* 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.

Please note that the same accessory may be available with different connectors and therefore different article numbers for different devices (see section *3.4.3: Device Sockets*). When asking your distributor about accessories please always refer to your device (Senti, Sentiero, Sentiero Advanced, Senti Desktop, Senti Desktop Flex, and Sentiero Desktop).

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.

Please note that the warranty between the end user and the distributor cannot be managed by PATH MEDICAL as it is not under PATH MEDICAL's responsibility. Nevertheless, PATH MEDICAL encourages all regional distributors to provide at least the warranty stated by law or stated by the following rules.

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.

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 Senti and Sentiero (handheld and desktop) 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 operate the device if its power supply is connected to the device and shows a damaged cord or plug. Likewise, this is true for any accessory with a separate power supply (e.g. label printer).

The device is capable of producing high stimulus levels for diagnostic purposes. Always make sure to use only stimulus levels, which will be acceptable for the patient. Do not present high stimulus levels to a patient if it could cause a hearing damage.

Do not change a transducer during a test. This may result in wrong stimulus output and potential wrong test results.

The patient is an intended operator for the following tests: pure-tone audiometry, MAGIC, MATCH, SUN, and BASD. For pure-tone audiometry the patient is allowed to press the patient response button, for MAGIC, MATCH, SUN, and BASD the patient is allowed to operate the device touch screen (i.e. press the user interface elements on the main test screen) during the test according to instructions from qualified personnel. Supervision by qualified personnel is required for all subjects at all times.

Senti Desktop: The transducers supplied with the device are calibrated to a specific device. In order to ensure proper stimulus calibration and output, always check that the connected transducer matches the transducer specified in the system information screen on the device. Failure to do so may result in a mismatch of the stimulus level displayed on the device compared to the actual stimulus level delivered to the patient. This may result in over or under-estimation of hearing. It can also result in higher than expected stimulus levels being delivered to the patient which may damage hearing. This does not apply to the flexibly exchangeable transducers for all other Senti and Sentiero devices.

The enclosure of the tympanometry add-on TY-MA (not the ear probe) may reach surface temperatures above 41°C (and below 48°C) during prolonged operation at high ambient temperatures. Direct skin contact should therefore be avoided.

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. See also section *3.5.8: Test Module Information*.

For AEP measurements the device needs to be operated in an environment with low electromagnetic disturbance. It is recommended to perform AEP 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. There are no device parts, which can be serviced by the patient when the patient is an intended operator. See also section *4: Service and Maintenance*.

The device can be separated from the power network by unplugging the power supply unit from the mains socket or by unplugging the power cable from the device. Do not set up the device in such a way that it is difficult to separate the device from the power network (e.g. do not position the device close to a wall or immovable equipment).

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. Do not immerse the device in fluids as e.g. cleaning agents.

Dust particles may corrupt the touch pad. Please make sure to keep the touch pad clear of dust particles.

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

The power supply is specified as a part of the device. Do not use any power supply 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 device. Likewise, using the Senti/Sentiero power supply on other types of devices may cause damage to those devices.

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.

Accessible conductive parts (e.g. power supply unit plug) must not be touched by the operator especially while touching the patient.

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.

When using the power supply unit Sinpro MPU16C-104 (protection class I), in order to avoid risk of electrical shock, the power supply unit must only be connected to a supply mains with protective earth.

Do not connect the label printer, RS232, or modem cable to the device during testing.

If a connection is established from the device to a computer, special precautions must be taken in order to maintain electrical safety. This can be achieved by using 1) a medically approved computer (compliant to DIN EN 60601-1), 2) a standard battery powered computer (not connected to any charger or other mains powered equipment like printers), or 3) a standard computer which is located outside the patient environment (i.e. at least 1.5 m away from the patient). A standard computer refers to a typical computer which is suitable for office use and compliant to EN 60950.

8.4 Electromagnetic Compatibility

The use of Senti/Sentiero 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 (Senti/Sentiero: 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, Senti/Sentiero 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 Senti/Sentiero 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 Senti/Sentiero 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 Senti/Sentiero 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 Senti/Sentiero (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 between patients (or ears of the same patient) 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 *3.5.4: Hardware Tests*).

The 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 Sockets*.

Do not try to insert any plug into a device socket with excessive force. A plug fits only into a device socket if the mechanical coding of the plug is corresponding to the device socket. Color-codes help finding the correct device socket. For desktop devices, please also check the icons on the back panel of the device for correct insertion. See section *3.4.3: Device 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 NiMH (handheld) or Li-Ion (desktop) rechargeable 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, patient response button, label printer, communication 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.

Before disposal of the device, make sure to take care of proper archiving of patient and test data (considering applicable data retention periods) and make then sure to delete all personal data from the device.

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

9 Technical Specifications

This section provides a summary of the most important technical specifications. Further technical details are described in a separate ***Technical Specification*** document, which can be downloaded from www.pathme.de/downloads.

9.1 General Device Information

Dev. classification (93/42/EEC, 2017/745) (MDR Canada)	Class II a Class II
Applied part classification (DIN EN 60601-1) Applied parts	Type BF (body floating) Headphones, insert earphones, ear probe, tympanometry add-on, ear coupler cable, bone conductor, electrode cable, patient response button
Device safety class (DIN EN 60601-1)	Class II
Ingress protection rating (IP code)	IP20
Mode of operation (DIN EN 60601-1)	Continuous
Applied standards	DIN EN ISO 389-1, DIN EN ISO 389-2, DIN EN ISO 389-3, DIN EN ISO 389-4, DIN EN ISO 389-5, DIN EN ISO 389-8 (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 60645-1 (pure-tone audiometry), DIN EN 60645-5 (tympanometry), DIN EN 60645-6 (OAE), DIN EN 60645-7 (ABR), DIN EN 62304 (software lifecycle)

9.2 Device Characteristics

Device dimension	Handheld: ca. 209 x 98 x 52 mm (8.22 x 3.86 x 2.05'') Desktop: ca. 150 x 210 x 45 mm (5.91 x 8.27 x 1.77'')
Device weight (including battery pack)	Handheld: ca. 500 g Desktop: ca. 475 g
Display properties	240 x 320 pixel, graphic LCD Handheld: 3.5'', Desktop: 5.0''
Maximum power consumption from battery	Handheld: ca. 5 V, 0.4 A = 2 W Desktop: ca. 4 V, 0.5 A = 2 W
Typical power consumption from power supply unit during charging	Handheld: ca. 9 V, 1.0 A = 9 W Desktop: ca. 12 V, 0.17 A = 2 W

9.3 Power Supply

For medical applications the following power supply units are exclusively allowed when used with Senti and Sentiero devices:

- Sinpro MPU12C-104, MPU12A-104
- Sinpro MPU16C-104
- Adapter Tech. ATM012T-W090V
- Friwo FW7662M/12 – for desktop devices only
- Friwo FW8002.1M/12 – for desktop devices only

For Senti and Sentiero do not use any power supply unit other than the ones mentioned above. Failure to do so may reduce electrical safety and may damage the device.

When using the power supply unit Sinpro MPU16C-104 (protection class I), in order to avoid risk of electrical shock, the power supply unit must only be connected to a supply mains with protective earth.

Input rating of power supply units	Sinpro MPU12C-104: 100-240 V, AC, 47-63 Hz, 0.16-0.29 A Sinpro MPU12A-104: 100-240 V, AC, 47-63 Hz, 0.16-0.29 A Sinpro MPU16C-104: 100-240 V, AC, 47-63 Hz, 0.18-0.33 A Adapter Tech. ATM012T-W090V: 100-240 V, AC, 50-60 Hz, 0.19-0.32 A Friwo FW7662M/12: 100-240 V, AC, 50-60 Hz, 0.11-0.25 A Friwo FW8002.1M/12: 100-240 V, AC, 50-60 Hz, 0.08-0.16 A
Output rating of power supply units	Handheld: 9 V, ≥1.2 A Desktop: 9-12 V, ≥0.4 A
Rechargeable battery pack	Handheld: 4.8 V (NiMH) Desktop: 3.7 V (Li-Ion)
Maximum operating time with fully charged batteries	ca. 6-8 hours (dependent on usage)
Maximum charging cycles	500-1000 (life time > 2 years for normal usage)
Maximum charging time:	Handheld: ca. 2 hours Desktop: ca. 8 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.

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. Requirements from DIN EN 60601-1-2:2016-05 (see tables below, see also section *8.4: Electromagnetic Compatibility*) are applicable to all devices delivered from 01/2019 (Handheld: PCB Rev. ≥ 70 with connector board, Desktop: PCB Rev. ≥ 333; for previous PCB versions please refer to the previous manual version or contact PATH MEDICAL). 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 in *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	± 8 kV contact discharge ± 2, 4, 8, 15 kV air discharge	± 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 ±2 kV voltage outer	± 1 kV voltage outer conductor – outer conductor ±2 kV voltage outer	The quality of supply voltage shall correspond to typical hospital or commercial environment.

Tests for immunity to interference	IEC 60601 test level	Concurrent level	Electromagnetic environment
	conductor – earth	conductor – earth (for Sinpro MPU16C)	
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 300 periods 70 % U_T (30 % U_T drop) for 30 periods	0 % U_T (>95 % U_T drop) for ½ and 1 period 0 % U_T for 300 periods 70 % U_T (30 % U_T drop) for 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 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	3 V/m (80 MHz – 2.7 GHz) 9-28 V/m* (wireless RF communication)	3 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

The device is intended for use in an environment in which high-frequency disturbances are controlled.

Contact information from distributor/service partner:

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