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