HI-PRO® 2

User Guide

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Part No. 7-50-09800-EN

CE 0459

otometrics
a division of natus

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2019-11-26 (215442)

Technical support
Please contact your supplier.

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1 Introduction to HI-PRO 2

The HI-PRO 2 Hearing Instrument Programming Unit together with fitting software and programming cables constitute the complete HI-PRO 2 system. The HI-PRO 2 hardware serves as a standardized interface between a PC and programmable hearing instruments.

Connection to the PC is by means of the supplied USB (Universal Serial Bus) cable. The USB connection both establishes the electrical power and the data communication between the PC and the HI-PRO 2.

On the cabinet front two 6-pole mini-DIN connectors for the cables to the programmable hearing instruments facilitate programming of both a left and a right hearing instrument.

The PC software for programming the hearing instrument (Fitting Software) and the cables for connecting hearing instruments to HI-PRO 2 are supplied by the hearing instrument manufacturer.

1.1 Intended use

HI-PRO 2 is intended for audiologists, hearing instrument dispensers, and other health care professionals.

The intended use is to make the necessary adjustments to programmable hearing instruments connected to the HI-PRO 2 unit.

1.2 Intended population

The intended patient population is all patient groups from pediatric through adulthood.

1.3 Intended user profile

Audiologists, hearing instrument dispensers, and other health care professionals

1.4 About this manual

This manual is your guide to installing and using HI-PRO 2. We strongly recommend that you read this manual carefully before using HI-PRO 2 for the first time.

The manual contains a description of the main functions of HI-PRO 2. Otometrics recommends that you make yourself familiar with the following issues in particular:

- When you receive HI-PRO 2 ► 5

- Installation ▶ 7
- Safety ▶ 19

1.4.1 Safety

This manual contains information which must be followed to ensure the safe performance of HI-PRO 2. Local government rules and regulations, if applicable, should also be followed at all times. Safety information is stated where it is relevant, and general safety aspects are described in Safety ▶ 19.

1.4.2 Typographical conventions

The use of Warning, Caution and Note

To draw your attention to information regarding safe and appropriate use of the device or software, the manual uses precautionary statements as follows:

Warning • *Indicates that there is a risk of death or serious injury to the user or patient.*

Caution • *Indicates that there is a risk of injury to the user or patient or risk of damage to data or the device.*

Note • *Indicates that you should take special notice.*

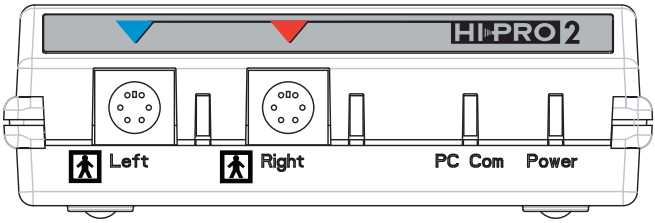
2 When you receive HI-PRO 2

2.1 Unpacking and inspection

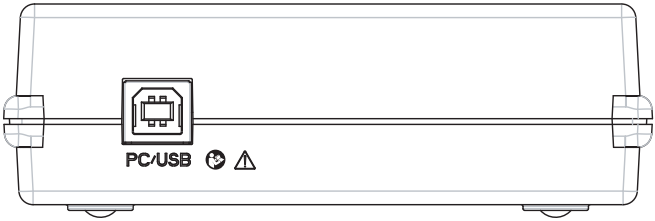
1. Unpack your HI-PRO 2 carefully.
   When you unpack HI-PRO 2, it is a good idea to keep the packing material in which it was delivered. If you need to send the HI-PRO 2 in for service, the original packing material will protect against damage during transport, etc.
2. Visually inspect the equipment for damage. If damage has occurred, do not put the HI-PRO 2 into operation. Contact your supplier for assistance.

3. Check that the package includes the items listed below:
   - HI-PRO 2 unit
   - USB interface cable
   - Software Installation CD
4. If your package is incomplete, contact your supplier.

2.2 HI-PRO 2 front and rear view



HI-PRO 2 front view



HI-PRO 2 rear view

2.3 Storage and shipment

If you need to store HI-PRO 2 before you put it into operation, follow the guidelines below:

- Store HI-PRO 2 and accessories in the box provided to protect the equipment from damage.
- Store HI-PRO 2 as stated in Technical Specifications

3 Installation

- Site the HI-PRO 2 unit in a well-ventilated location away from all liquids and sources of heat.
- An installation CD is provided with HI-PRO 2. Before you connect HI-PRO 2 to the PC, this software must be installed.

3.1 Installing the HI-PRO 2 software

> ***Note*** • *You are required to log on with Administrator rights to install this software.*

- Place the installation CD in the CD drive.
- If the **Autorun** feature is enabled on your computer, the installation will start automatically when the CD is inserted, otherwise
- Open **My Computer** by double-clicking the icon on the desktop, double-click on the CD drive icon, then double-click on the **Setup** application icon to start the installation.
- Follow the instructions on the screen.

3.2 Connecting the HI-PRO 2 to the PC

> ***Note*** • *An installation CD is provided with HI-PRO 2. Before you connect HI-PRO 2 to the PC, this software must be installed.*

- Connect the USB connector on the rear of HI-PRO 2 to a USB port of a personal computer (PC) by means of the supplied USB cable. See Fig. 1.

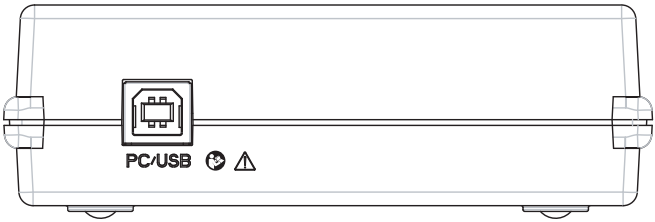


Fig. 1

> ***Note*** *• If the HI-PRO 2 unit is connected to the PC via a USB hub, the hub must be self-powered (have a separate power supply). This is to ensure that the USB hub can deliver enough current for proper operation of the HI-PRO 2 unit.*

3.3 Starting up HI-PRO 2

> ***Note*** *• Before using the HI-PRO 2, make sure that the operating system on your PC has been updated with the latest official Windows security patches.*

When the HI-PRO 2 Installation CD is installed, HI-PRO 2 powers on as soon as the unit is connected to the PC and the PC is powered ON.

During power-up, the LEDs next to the connectors on the front panel will flash once indicating that a brief self-test is in progress.

When the self-test is completed, only the power LED will light. If only the left LED flashes, the self-test has failed and you should try powering on again. Should the unit fail again, contact your local distributor.

The HI-PRO 2 connector LEDs will also light up when a hearing instrument is being programmed, indicating which side is active.

The LED above the text 'PC Com' lights up to indicate communication with the PC.

> ***Caution*** *• Do not attempt to connect or disconnect a hearing instrument while the connector LED is active! The LED indicates that the connector is active, and this might damage the hearing instrument.*

Caution • *Even though the hearing instrument connectors on the front of the HI-PRO 2 are galvanically insulated from the PC and mains earth, it is still possible to release an electrostatic discharge (ESD) to a connected hearing instrument, and through the HI-PRO 2 to earth. An electrostatic discharge can be very uncomfortable for the client because it feels like a minor "electric shock", and can even produce loud pulses of noise. Cases of electrical damage to hearing instruments have been reported. It is recommended to install the unit in an environment that minimizes the amount of static electricity. For example, anti-static carpeting is recommended.*

3.4 Disconnecting HI-PRO 2 from the PC

HI-PRO 2 automatically powers off together with the PC, but if you wish to power off the HI-PRO 2 without powering off the PC, you can disconnect the USB cable from the HI-PRO 2 or from the PC.

Caution • *Do not attempt to disconnect the USB cable while a hearing instrument is being fitted. Doing so might damage the hearing instrument or set it in an undefined state.*

4 Service and Maintenance

4.1 Equipment failure, service, and repair

Warning • *Do not use a defective device.*
If you suspect that the correct function or operation safety of the HI-PRO 2 may be faulty in any way, disconnect HI-PRO 2 from the PC, and make sure that it cannot be used by others until it has been serviced.

Warning • *Do not disassemble the HI-PRO 2 as there is a risk of electric shock. There are no user-serviceable parts inside the HI-PRO 2 device cabinet. For the*

sake of safety and in order not to void the warranty, service and repair of electro-medical equipment should be carried out only by the equipment manufacturer or by service personnel at authorized workshops. In case of any defects, make a detailed description of the defect(s) and contact your supplier. Do not use a defective device.
Following repair, the equipment should be tested by suitably qualified personnel.

4.2 Maintenance

HI-PRO 2 requires no preventive maintenance. However, it is recommended that you observe the guidelines below.

- Use a soft, slightly damp cloth with a small amount of detergent to clean the unit.

4.3 Troubleshooting

Troubleshooting Checklist

Make sure that:

- the USB cable between the PC and the HI-PRO 2 is connected,
- the PC is powered on,
- the HI-PRO 2 software provided on the installation CD is installed,
- the correct programming cable is used,
- the programming cable is firmly connected to the front connector on HI-PRO 2 and to the hearing instrument programming connector.

5 Technical Specifications

Type identification

HI-PRO 2 is type 1072 from Natus Medical Denmark ApS.

PC Interface

The serial USB (Universal Serial Bus) port is used for communication between a PC and the HI-PRO 2 unit.

Communication	USB 2.0 full Speed (USB 1.1 compatible)
USB Connector Type	"Type B" connector (on the HI-PRO 2 unit)

Power Supply

The HI-PRO 2 unit is powered from the PC USB port.

Rated Voltage	4.50V - 5.25V
Maximum Current Consumption (active)	< 500 mA (2.5 W)
Power Consumption during USB Suspend	< 500 µA (2.5 mW)

Operating system

Windws XP Pro SP3, Windows 7b (32 and 64 bit), Windows 8 (32 and 64 bit), Windows 10

Product Lifetime

The estimated lifetime of the HI-PRO 2 unit is 5 years.

Essential performance

HI-PRO 2 has no essential performance.

Standards

Safety	IEC 60601-1:2005+AMD1:2012
	EN 60601-1:2006+A1:2013
	ANSI/AAMI ES60601-1:2005 + A1:2012
	CAN/CSA-C22.2 NO. 60601-1:14
EMC	IEC 60601-1-2:2007 EN 60601-1-2:2007
	IEC 60601-1-2:2014 EN 60601-1-2:2015

Systems	IEC 60601-1:2005+AMD1:2012
	EN 60601-1:2006+A1:2013
Hearing Instrument Interface	IEC 60118-14:1998 EN 60118-14:1998

To comply with the above standards, the programming cable and the connector to the hearing instrument must meet the following requirements:

- No conductive parts may be accessible when the programming cable is connected to HI-PRO 2 unit.
- The programming cable and the connector must provide double isolation and be able to withstand a dielectric strength test potential of 500 V.

Output ratings

The following output ratings are valid for Left and Right hearing instrument connectors.

Fixed Battery supply (pin1), common for Left and Right side	1.35V, 10/50 mA (current rating is controlled by fitting software)
Programmable battery supply (pin5), common for Left and Right side	-3.50 V to +3.50 V, 30 mA (voltage is controlled by fitting software)

Operating environment

Temperature	+5°C to +40°C (41°F to +104°F)
Rel. humidity	30 to 90%, non-condensing
Warm-up time	< 20 seconds.
Air pressure	600 hPa to 1060 hPa

Operation at temperatures below -20°C or above +60°C may cause permanent damage.

Storage and handling

Temperature	-20°C to +60°C (-4°F to +140°F)
Rel. humidity	< 90 %, non-condensing
Air pressure	500 hPa to 1060 hPa

Dimensions and Weight

Size (L x W x H)	137 mm x 114 mm x 37 mm (5.39 inch x 4.49 inch x 1.46 inch)
Net weight	230g (0.43 lb)

5.1 Accessories

Item	Part number
1072 HI-PRO 2, Installation CD	8-49-91200
USB Cable, 3 meters	8-71-79100
USB Cable, 2 meters	8-71-79200
USB Cable, 1 meter	8-71-86500
HI-PRO 2 User Guide	7-50-09800-XX

5.2 Notes on EMC (Electromagnetic Compatibility)

- HI-PRO 2 is part of a medical electrical system and is thus subject to special safety precautions. For this reason, the installation and operating instructions provided in this document should be followed closely.
- Portable and mobile high-frequency communication devices, such as mobile phones, may interfere with the functioning of HI-PRO 2.

IEC 60601-1-2:2014 and EN 60601-1-2:2015

Guidance and manufacturer's declaration - electromagnetic emissions for all equipment and systems		
HI-PRO 2 is intended for use in the electromagnetic environment specified below. The user of HI-PRO 2 should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR11	Group 1	HI-PRO 2 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Guidance and manufacturer's declaration - electromagnetic emissions for all equipment and systems		
RF emissions CISPR11	Class B	HI-PRO 2 is suitable for use in all environments, including domestic environments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and manufacturer's declaration - electromagnetic immunity for all equipment and systems			
HI-PRO 2 is intended for use in the electromagnetic environment specified below. The user of HI-PRO 2 should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	+/- 1 kV for input/output lines	No relevant ports that could be affected	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	No relevant ports that could be affected	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration - electromagnetic immunity - for equipment and systems within Professional Healthcare use environment			
HI-PRO 2 is intended for use in the electromagnetic environment specified below. The user of HI-PRO 2 should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**

Guidance and manufacturer's declaration - electromagnetic immunity - for equipment and systems within Professional Healthcare use environment			
Conducted RF **IEC 61000-4-6**	3 V rms 150 kHz to 80 MHz 6 V rms ISM Bands andAmateur	3 V rms 150 kHz to 80 MHz 6 V rms ISM Bands andAmateur	
Radiated RF **IEC 61000-4-3**	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	
Proximity fields from RF wireless communications **IEC 61000-4-3**	27 V/m 386 MHz 28 v/m 450 MHz, 9 v/m 710 MHz, 745 MHz, 780 MHz 28 v/m 810 MHz, 870 MHz, 930 MHz, 28 v/m 1720 MHz, 1845 MHz, 1970 MHz 28 v/m 2450 MHz, 9 v/m 5240 MHz, 5500 MHz, 5785 MHz	27 V/m 386 MHz 28 v/m 450 MHz, 9 v/m 710 MHz, 745 MHz, 780 MHz 28 v/m 810 MHz, 870 MHz, 930 MHz, 28 v/m 1720 MHz, 1845 MHz, 1970 MHz 28 v/m 2450 MHz, 9 v/m 5240 MHz, 5500 MHz, 5785 MHz	Separation distance between any electronic parts of HI-PRO 2 and any RF wireless communication equipment must be more than 30 cm (11.8 inches). **Note**: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

IEC 60601-1-2:2007 and EN 60601-1-2:2007

Guidance and manufacturer's declaration - electromagnetic emissions for all equipment and systems		
HI-PRO 2 is intended for use in the electromagnetic environment specified below. The user of HI-PRO 2 should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**

Guidance and manufacturer's declaration - electromagnetic emissions for all equipment and systems		
RF emissions CISPR11	Group 1	HI-PRO 2 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	HI-PRO 2 is suitable for use in all environments, including domestic environments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and manufacturer's declaration - electromagnetic immunity for all equipment and systems			
HI-PRO 2 is intended for use in the electromagnetic environment specified below. The user of HI-PRO 2 should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	+/- 1 kV for input/output lines	No relevant ports that could be affected	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration - electromagnetic immunity - for equipment and systems that are NOT life-supporting			
HI-PRO 2 is intended for use in the electromagnetic environment specified below. The user of HI-PRO 2 should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**

Guidance and manufacturer's declaration - electromagnetic immunity - for equipment and systems that are NOT life-supporting			
Conducted RF **IEC 61000-4-6**	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of HI-PRO 2, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ for 80 MHz to 2.5 GHz,
Radiated RF **IEC 61000-4-3**	3 V/m 80 MHz to 2.5 GHz	3 V/m	where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with this symbol: ((•))
Note 1: At 80 MHz and 800 MHz the separation distance for the higher frequency range applies. **Note 2**: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Guidance and manufacturer's declaration - electromagnetic immunity - for equipment and systems that are NOT life-supporting

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which HI-PRO 2 is used exceeds the applicable RF compliance level above, the HI-PRO 2 should be observed to verify normal operation. If abnormal performance is observed, additional measures might be necessary, such as reorienting or relocating HI-PRO 2.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and HI-PRO 2

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

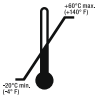
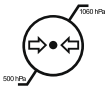
6 Safety

This manual contains information and warnings, which must be followed to ensure the safe performance of HI-PRO 2. Local government rules and regulations, if applicable, should also be followed at all times.

6.1 HI-PRO 2 symbols

 IEC 60601-1:2005+AMD1:2012 EN 60601-1:2006+A1:2013	Applied part type BF Complies with Type BF requirements of IEC 60601-1:2005+AMD1:2012 and EN 60601-1:2006+A1:2013.
 IEC 60601-1 Table D.2 #10	Follow instructions for use
 ISO 15223-1 Symbol 5.4.3 and IEC 60601-1 Table D.1 #11	Consult instructions for use Indicates the need for the user to consult the instructions for use.
 ISO 15223-1 Symbol 5.4.4 and IEC 60601-1 Table D.1 #10	Caution Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
 93/42/EEC	CE marking of conformity Complies with Medical Devices Directive 93/42/EEC and RoHS Directive (2011/65/EU).

CE 93/42/EEC	CE marking of conformity Complies with Medical Devices Directive 93/42/EEC and RoHS Directive (2011/65/EU). (For accessories only)
 ISO 15223-1 Symbol 5.1.1	Manufacturer Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
MD	Medical device Indicates that the item is a medical device.
SN ISO 15223-1 Symbol 5.1.7	Serial number Indicates the manufacturer's serial number so that a specific medical device can be identified.
REF ISO 15223-1 Symbol 5.1.6	Catalog/product number Indicates the manufacturer's catalogue number so that the medical device can be identified.
EC REP ISO 15223-1 Symbol 5.1.2	Authorized representative in the European Community (If applicable for accessories only). Indicates the authorized representative in the European Community.
℞ ONLY 21 CFR Part 801. §801.109(b)(1)	Device is cleared for the US market as requiring a pre-scription USA Code of Federal Regulations. 21 CFR Part 801. § 801.109(b)(1)
c UL us	UL recognized component for Canada and the United States

 ISO 15223-1 Symbol 5.3.7	Temperature limit Indicates the temperature limits to which the medical device can be safely exposed.
 ISO 15223-1 Symbol 5.3.8	Humidity limitation Indicates the range of humidity to which the medical device can be safely exposed.
 ISO 15223-1 Symbol 5.3.9	Atmospheric pressure limitation Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
Made in China	Made in China Indicates that the device is manufactured in China.
 EN 50419	Electronic equipment covered by the Directive 2012/19/EU on waste electrical and electronic equipment (WEEE). All electrical and electronic products, batteries, and accumulators must be taken to separate collection at the end of their working life. This requirement applies in the European Union. Do not dispose of these products as unsorted municipal waste. You can return your device and accessories to Natus Medical Denmark ApS, or to any Natus Medical Denmark ApS supplier. You can also contact your local authorities for advice on disposal. See the full Natus WEEE Statement ▶ 22

Referenced standards

- ISO 15223-1:2016: Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
- BS EN 50419:2006: Marking of electrical and electronic equipment in accordance with article 11(2) of Directive 2002/96/EC (WEEE)

- CRUUS: https://marks.ul.com/about/ul-listing-and-classification-marks/appearance-and-significance/marks-for-north-america/
- USA Code of Federal Regulations. 21 CFR Part 801. § 801.109(b)(1)

6.2 WEEE Statement

Natus is committed to meeting the requirements of the European Union WEEE (Waste Electrical and Electronic Equipment) Regulations 2014. These regulations state that electrical and electronic waste must be separately collected for the proper treatment and recovery to ensure that WEEE is reused or recycled safely. In line with that commitment Natus may pass along the obligation for take back and recycling to the end user, unless other arrangements have been made. Please contact us for details on the collection and recovery systems available to you in your region at www.natus.com

Electrical and electronic equipment (EEE) contains materials, components and substances that may be hazardous and present a risk to human health and the environment when WEEE is not handled correctly. Therefore, end users also have a role to play in ensuring that WEEE is reused and recycled safely. Users of electrical and electronic equipment must not discard WEEE together with other wastes. Users must use the municipal collection schemes or the producer/importers take-back obligation or licensed waste carriers to reduce adverse environmental impacts in connection with disposal of waste electrical and electronic equipment and to increase opportunities for reuse, recycling and recovery of waste electrical and electronic equipment.

Equipment marked with the crossed-out wheeled bin is electrical and electronic equipment. The crossed-out wheeled bin symbol indicates that waste electrical and electronic equipment should not be discarded together with unseparated waste but must be collected separately.

6.3 HI-PRO 2 Warning notes

	When connecting equipment to the USB connector, the following must be considered: • Equipment must be certified to relevant EN/IEC safety standards, e.g. EN/IEC 60950. • Use of connected equipment in a patient environment, see Note 1. Ensure that the electro-medical system complies with the requirements of IEC 60601-1:2005+AMD1:2012 and EN 60601-1:2006+A1:2013.

1. The HI-PRO 2 is a part of an electromedical system. When assembling an electromedical system, the person carrying out the assembly must take into account that connecting other equipment that does not comply with the same safety requirements as the HI-PRO 2 may lead to a reduction in the overall safety level of the system.

   The HI-PRO 2 is designed to ensure compliance with requirements in IEC 60601-1:2005+AMD1:2012 and EN 60601-1:2006+A1:2013 when the PC, printer, etc. are placed out of reach of the patient, i.e. not closer than approx. 1.5 meters/5 ft.
2. Keep the HI-PRO 2 away from liquids. Do not allow moisture inside the instrument.
3. Do not use the instrument in the presence of flammable anesthetics (gases).
4. If the HI-PRO 2 unit is exposed to a strong radio field, it may interfere with the process of fitting a hearing instrument. Many types of electrical devices, e.g. mobile telephones, may generate radio fields. We recommend that the use of such devices in the vicinity of the HI-PRO 2 is restricted as much as possible.
5. The HI-PRO 2's RF emissions are very low and are not likely to cause any interference in nearby electronic equipment, but negative effect or loss of functionality of other local devices may occur if they are placed in close vicinity of HI-PRO 2.
6. No parts may be eaten, burnt, or in any way used for purposes other than the fitting of hearing aids or similar devices.

7. For safety reasons and due to effects on EMC, accessories connected to the equipment's outlet fittings must be identical to the type supplied with the system.
8. No conductive parts may be accessible when the programming cable is connected to HI-PRO 2 unit.
9. The programming cable and the connector must provide double isolation and be able to withstand a dielectric strength test potential of 500 V.
10. Verify the hearing instrument functionality after programming. See the Instructions for Use of the programming application.
11. Do not store or operate the device at temperatures and humidity exceeding those stated in the Technical Specifications. See Technical Specifications
12. We recommend that the device should not be stacked with other equipment or placed in a poorly ventilated space as this may affect the performance of the device. If it is stacked or placed adjacent to other equipment, make sure that the operation of the device is not affected.
13. Accidental damage and incorrect handling can have a negative effect on the functionality of the device. Contact your supplier for advice.
14. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and to the competent authority of the country or the EU Member State in which the user and/or patient is established.
15. HI-PRO 2 can be disposed of as normal electronic waste, according to WEEE and local regulations.

7 Manufacturer

Natus Medical Denmark ApS
Hoerskaetten 9, 2630 Taastrup
Denmark
+45 45 75 55 55
www.natus.com

7.1 Responsibility of the manufacturer

The manufacturer is to be considered responsible for effects on safety, reliability, and performance of the equipment only if:

- All assembly operations, extensions, re-adjustments, modifications or repairs are carried out by the equipment manufacturer or personnel authorized by the manufacturer.
- The electrical installation to which the equipment is connected complies with EN/IEC requirements.
- The equipment is used in accordance with the instructions for use.

The manufacturer reserves the right to disclaim all responsibility for the operating safety, reliability and performance of equipment serviced or repaired by other parties.