User Manual

Medical Network Isolation

Type NwI Giga V4.4

Galvanic Network Isolation for
medical electrical devices and systems according to
EN 60601-1:2006/AC:2010/A1:2013,
EN 60601-1-2:2015

WARNING
Prior to commission / operation of the NwI,
the user has to make himself familiar with the functionality
of the NwI by careful reading of this instruction manual!

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1 General Safety Instructions

The NwI must be used solely for the purpose specified in Chapter 2 Purpose of Determination The NwI must be installed and put into operation only by persons who qualify for Operating Personnel MPBetreibV § 5. The case of the NwI may not be opened! There are no user-serviceable parts inside the NwI. Do not perform any repairs or modifications to the NwI yourself! Otherwise, the correct functioning of the NwI and the security may be jeopardized. Opening or modifying the NwI voids the warranty.
The DeMeTec GmbH reserves the right to modify the device without prior notice.
Before using the NwI Giga, contact the manufacturer of your medical device / system, and make sure that it is allowed – while sufficient galvanic Isolation is given – to link your medical device / system with local area networks (LAN) or other PCs!

1.1 Application area

Note that the NwI is not protected against the effects of greater mechanical force and the penetration of liquids. The NwI is not intended for operation in combustible atmospheres!

1.2 Functional safety

When the electrical consumers are connected to the NwI, make sure that the following points are met:

- only network components according to IEEE 803.2 (10/100/1000-Base T, Twisted-Pair) are connected to the NwI Giga. Do not connect any telecommunication-devices, power supplies or similar things! The NwI Giga could be damaged, or even persons could be harmed!
- only tested CAT 5e or better network cables with according marks of conformity are used.
- the maximum length of network cables is reduced to 95m when using 100MBit network (100BaseT).
- the maximum length of network cables is reduced to 80m when using 1000MBit network (1000BaseT).

1.3 Maintenance

Warning
The NwI must be periodical inspected and maintained by by persons who qualify for MPBetreibV, § 5, will be subjected. Repair of the NwI must be carried out only by persons referred to above, to ensure a hazard-free operation.
See also 5 Safety Technical Inspection/Control STC. If in doubt please contact your supplier or the manufacturer, DeMeTec GmbH.

1.4 Environmental Protection / disposal

The DeMeTec GmbH is aware of its responsibility towards the environment. The NwI may not be disposed of into household waste!
According to the WEEE, DeMeTec GmbH has been involved since 2005-08-13 takes back all equipment, which put into circulation by DeMeTec GmbH, for the purpose of proper disposal.
Please contact us in this regard if required and inform your customers when reselling.

1.5 Instructions to suppliers / manufacturers of *Medical Electrical Devices and -Systems*

Networking: The NwI is an *electrical device* that was designed specifically for use in medical technology, developed for various *ME-Devices / -Systems. The* existing isolation distances in the NwI meet the requirements of the standard:

EN 60601-1 Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance.

The isolation chart is available upon request from the manufacturer of the NwI.
The supplier / manufacturer of the *ME-Devices / -Systems* is recommended to consider the use of additional active safety measures, such as an additional ground wire, into account.
Basically, to be considered by the supplier / manufacturer of the *ME-Devices / -Systems,* device combinations with the requirements of the Medical Devices Act and the following standards:

- *EN 60601-1 (IEC 60601-1)*
  Medical electrical Equipment -
  Part 1: General requirements for basic safety and essential performance
- *EN 60601-1-2 (IEC 60601-1-2)*
  Medical electrical equipment -
  Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

1.6 Declaration of Symbols

	Follow this user manual!
	Network connection PC over patch-cable or cross link-cable when linking PC to PC
	Network connection LAN (Hub, Switch) or LAN-cable when linking PC to PC
	Must not be disposed of with household waste!

2 Purpose of Determination

The device „Medical Network Isolation" (NwI Giga) is especially designed for usage in the medical technology.

Its purpose is to connect a medical device or system, which is equipped with a standard-network-interface, to a local area network, while relevant standards for electrical safety are met. Linking two PCs with a cross

link-network-cable is possible, too. Other examples are:

- Linking the PC of a long-term-EEG system to the practice or clinical network.
- Linking a EMG measuring system to a PC for analysis in the doctor's or consulting room.

Please refer chapter 1 General Safety Instructions!

3 Connection and Commissioning

The NwI Giga may only be installed and put into operation by qualified personnel. Please contact your medical-technical section or a system / network administrator.

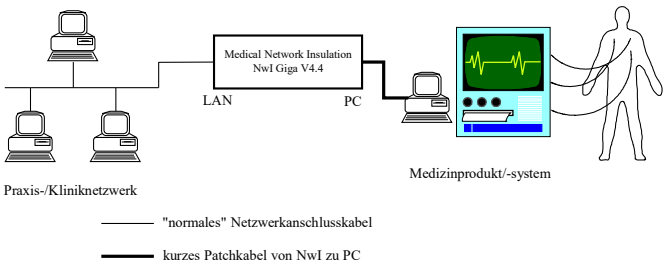
For the installation of the NwI Giga, two pluggable connectors (RJ45) are used. Put the network-cables into the sockets of the NwI Giga until you hear the locks making a clicking sound.

The NwI Giga should be installed near to the medical device / system (PC).

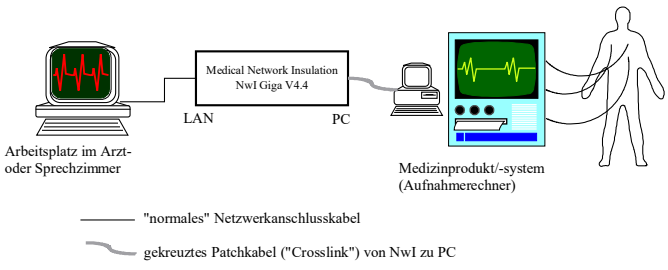
Take account of the safety instructions of chapter 1.2 Functional safety!

According to the operation purpose, one of the following installations is advised:

1. Linking a medical device or system (PC) to a local practice or clinical network:



2. Direct link of a medical device or system (PC) to a work-place in the doctor's or consulting room:



4 Cleaning and Disinfection

Attention

Switch off before cleaning the *ME-Device / -System*! Disconnect the NwI before cleaning!

To clean the device you should use a cloth moisturised with a mild cleaning agent!

You can also use clinical cleaning- and disinfection agents (Vol. Alcohol <70%). Scouring agents or aggressive cleaning agents are not suitable.

You should also take care that no liquids get into the NwI!

5 Safety Technical Inspection/Control STC

We recommend that you regularly perform a STC by persons who qualify for Operating Personnel § 5. This includes the following steps:

- Visual inspection
  Visual inspection for external damage (housing, power cables / connectors, readable labels, dirt, etc.), Availability and completeness of documentation

- Measurement of Isolation resistance
  All pins of one RJ45 have to be connected together and with the shield of the cable. The Isolation resistance between signal input- and signal output part has to be higher than 50M Ohm.

6 EU Declaration of Conformity

DeMeTec GmbH

Lützelwiesen 5, D-35428 Langgöns (Germany)

We hereby declare in sole responsibility that the product

Medical Network Isolation – NwI Giga V4.4

(item no. FG-245)

with the serial numbers 72245nnnnn

complies with the relevant regulations of the Low Voltage Directive **2014/35/EU (LVD),** the Electromagnetic Compatibility **(EMC) Directive 2014/30/EU** as well as those of Directive **2011/65/EU (RoHS-II)** on the restriction of the use of certain hazardous substances in electrical and electronic equipment. Applicable changes at the time of the declaration are included.

CE

Meeting the following standards: **EN 60601-1:2006/AC:2010/A1:2013**
EN 60601-1-2:2015

Langgöns, 2022-02-01

Manager,
Head of Development Department

Quality Management Officer,
Regulatory Affairs

7 Contact, Manufacturer

If you have any questions or problems, please contact your local dealer or the manufacturer:

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8 Technical Description

8.1 Classification

manufacturer		DeMeTec GmbH, Lützelwiesen 5 35428 Langgöns (Germany)
product designation		Medical Network Isolation – NwI Giga
mains voltage		not applicable
mains frequency		not applicable
power consumption		not applicable
classification	protection class	not applicable
	protection against penetration of liquids or solids	IP20
	protection class of the applied part against electric shock	not applicable
	protection class against discharge of defibrillators	not applicable
	protection in presence of explosive gases or aerosols, e.g. nitrous oxide or anaesthetics (according to EN 60601-1:2006 annex G cause G2)	no protection
operation mode		continuous operation
operating conditions	temperature	+32°F to +158°F / 0°C to +70°C
	relative humidity	10% to 90% (non-condensing)
storage conditions	temperature	-13°F to +185°F / -25°C to +85°C
	relative humidity	10% to 95% (non-condensing)
dimensions (L×W×H)		(90×50×25)mm³
weight		64g

8.2 Technical Data

network-specification		IEEE 803.2 10/100-Base T, Twisted-Pair, auto-conf (completely transparent in the network)
voltage endurance between the network connectors		4kV (for 230V AC, 2×MOPP)
connectors		2 × RJ45
attenuation	10MBit (10-Base T)	< 0,5dB (Network cable length maximal 100m)
	100MBit (100-Base T)	< 0,7dB (max. Network cable length: min. 95m)
	1000MBit (1000-Base T)	< 2,3dB (max. Network cable length: min. 80m)

8.3 Accessory

The following accessory can be obtained for the NwI:

- Patch-cable 0,5m, grey, CAT5e (item no. WR-083)