DIN EN ISO 9001
DIN EN ISO 13485

User Manual

Medical Network Isolation

Type NwI Giga V4.4

Galvanic Isolation for
medical electrical devices and systems
according to DIN EN 60601-1

DEMETEC
development of measurement
and medical technologies

1 Common Safety Instructions

1) Please read the following instructions carefully before using the NwI Giga!
2) This device may only be installed and put into operation by qualified personnel.
3) The enclosure of the NwI Giga must no be opened! The are no parts inside, which have to be maintained by the user.
4) 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 Positioning the NwI Giga

The NwI Giga is not protected against penetration of liquids. It is not intended to be used in presence of explosive gases or aerosols.

1.2 Connecting the NwI Giga

When the NwI is connected, make sure that:

- only network components according to IEEE 803.2 (10/100/1000-BaseT, 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 / Safety Check

In order so ensure safe operation, it is advised to perform a safety check once in a year. This safety check may only be performed by qualified personnel. For more information, see chapter 4 Maintenance.
If in doubt, contact your local dealer or the manufacturer.

1.4 Environmental Protection

There may be some regulations under public law concerning the disposal of this device. Please contact your local dealer or the manufacturer before taking the NwI Giga out of operation.

1.5 Symbols


Refer to documentation

Network connection PC over patch-cable or crosslink-cable when linking PC to PC

Network connection LAN (Hub, Switch) or LAN-cable when linking PC to PC

2 Normal Use

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 (DIN EN 60601-1 und DIN EN 60601-1-1) are met. Linking two PCs with a crosslink-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 to the fourth point of chapter 1 Common Safety Instructions!

3 Installation

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.

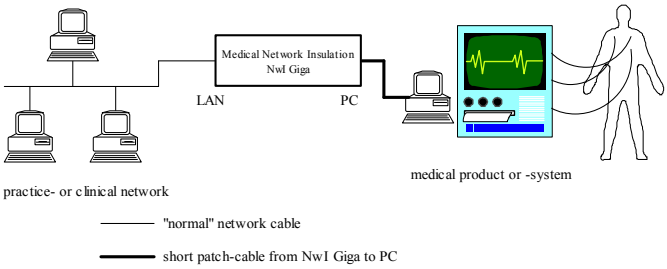
For the installation of the NwI Giga, two pluggable connectors (RJ45) are used. Put the network-cables into the sockets of the NwI Giga until you hear the locks making a clicking sound.

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

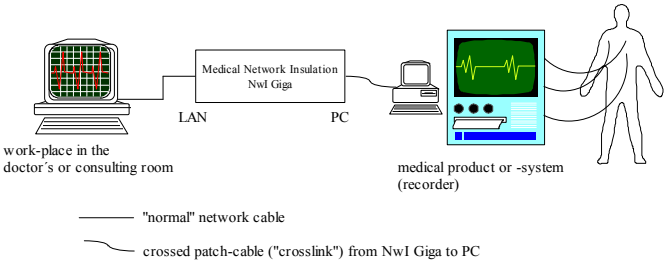
Take account of the safety instructions of chapter 1.2 Connecting the NwI Giga!

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 Maintenance

A safety check according to DIN VDE 0751-1 has to be performed once in a year, including the following points:

- Visual check of housing, network connectors, labels (damaging)
- 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.

5 Declaration of Conformity

EC Declaration of Conformity for medical devices

(as defined by medical device directive 93/42/EEC Annex VII from 1993-06-14)

DeMeTec GmbH
Lützelwiesen 5, 35428 Langgöns (Germany)

We hereby declare, that the product

Medical Network Isolation Gigabit – NwI Giga V4.4

was manufactured in harmony with the technical documentation as defined by Annex VII, section 3 of the medical device directive and that it corresponds to the requirements of the following directive:

Medical Device Directive 93/42/EEC from 1993-06-14

meeting the following harmonized standards: EN 60601-1:1990 + A1:1993 + A2:1995 + A13:1996
EN 60601-1-1:2001
EN 60601-1-2:2001

CE

Langgöns, 2010-03-23

Head of Development Department

Quality Officer

6 Contact, Manufactor

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

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35428 Langgöns (Germany)
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Fax: +49-6403-7874-30

Email: email@DeMeTec.de
Internet: http://www.DeMeTec.de

7 Technical Description

7.1 Classification

manufacturer		DeMeTec GmbH, Lützelwiesen 5 35428 Langgöns (Germany)
product designation		Medical Network Isolation – Nwl Giga
mains voltage		not applicable
mains frequency		not applicable
power consumption		not applicable
classification	protection class	not applicable
	protection against penetration of liquids	no protection
	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 +160°F / 0°C to +70°C
	relative humidity	10% to 90% (non-condensing)
	air pressure	860hPa to 1060hPa
storage conditions	temperature	-15°F to +185°F / -25°C to +85°C
	relative humidity	10% to 95% (non-condensing)
	air pressure	500hPa to 1060hPa
dimensions (L×W×H)		(90×50×25)mm³
weight		64g
classification as defined by Annex IX, MDD		class I

7.2 Technical Data

network-specification		IEEE 803.2 10/100-BaseT, Twisted-Pair, auto-conf (completely transparent in the network)
voltage endurance between the network connectors		4kV
connectors		2 × RJ45
attenuation	10MBit (10-BaseT)	< 0,5dB (network cable maximum length 100m)
	100MBit (100-BaseT)	<0,7 dB (network cable maximum length min. 95m)
	1000Mbit (1000-BaseT)	< 2,3dB (network cable maximum length min. 80m)

7.3 Accessory

The following accessory can be obtained for the Nwl:

- patchcable 0,5m, grey, CAT5e (item no. WR-083)
- patchcable 3m, grey, CAT5e (item no. WR-084)