

User Manual

Medical Network Isolation

Type Nwl Giga V4.4

Galvanic Isolation for

medical electrical devices and systems according to

IEC 60601-1:2005 (DIN EN 60601-1:2006) & IEC 60601-1-2:2007 (DIN EN 60601-1-2:2007)



WARNING

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



1 General Safety Instructions

The Nwl must be used solely for the purpose specified in Chapter 2 Purpose of Determination. The Nwl must be installed and put into operation only by persons who qualify for Operating Personnel MPBetreibV § 2 Abs 2. The case of the Nwl may not be opened! There are no user-serviceable parts inside the Nwl. Do not perform any repairs or modifications to the Nwl yourself! Otherwise, the correct functioning of the Nwl and the security may be jeopardized. Opening or modifying the Nwl voids the warranty. The DeMeTec GmbH reserves the right to modify the device without prior notice.

Before using the Nwl 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 Nwl is not protected against the effects of greater mechanical force and the penetration of liquids. The Nwl is not intended for operation in combustible atmospheres!

1.2 Functional safety

When the electrical consumers are connected to the Nwl, 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 Nwl Giga. Do not connect any telecommunication-devices, power supplies or similar things! The Nwl 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 Nwl must be periodically inspected and maintained by persons who qualify for MPBetreibV, § 6, Abs 4, will be subjected. Repair of the Nwl 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 Nwl 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 Device and - Systems*

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

IEC 60601-1:2005 Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance, German Version EN 60601-1:2006 (3rd Edition)

The insulation chart is available upon request from the manufacturer of the Nwl. 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:

- *IEC 60601-1:2005 (EN 60601-1:2006) Medical electrical equipment Part 1: General requirements for basic safety and essential performance*
- *IEC 60601-1-2:2007 (EN 60601-1-2:2007) 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



Refer to documentation



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“ (Nwl 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 to the fourth point of chapter 1 General Safety Instructions!

3 Connection and Commissioning

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

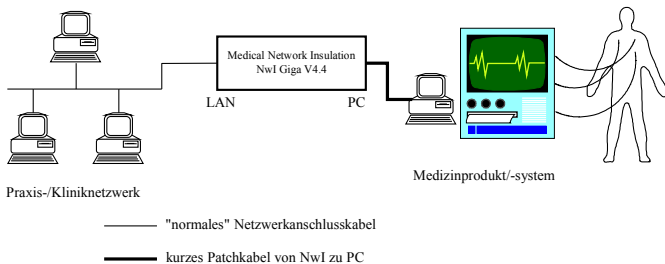
For the installation of the Nwl Giga, two pluggable connectors (RJ45) are used. Put the network-cables into the sockets of the Nwl Giga until you hear the locks making a clicking sound.

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

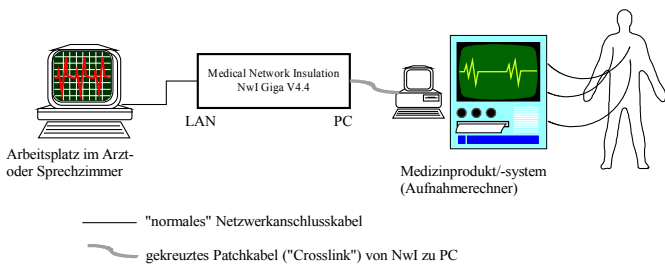
Take account of the safety instructions of chapter 1.2 Functional safety!

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 Nwl 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 Nwl!

5 Safety Technical Inspection/Control STC

We recommend that you regularly perform a STC by persons who qualify for Operating Personnel § 6 Abs 4. 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 EC Declaration of Conformity for medical devices

(as defined by directive for medical devices 93/42/EEC, MDD 2007, Annex VII)



DeMeTec GmbH
Lützelwiesen 5, 35428 Langgöns (Germany)

We hereby declare, that the product

Medical Network-Isolation Gigabit – Nwl Giga Version 4.4

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

Meeting the following standards: IEC 60601-1:2005 (DIN EN 60601-1:2006)
IEC 60601-1-2:2007 (DIN EN 60601-1-2:2007)

As well the following guideline will be followed:

Directive 2002/95/EC (RoHS)

In compliance with the national law: Electrical and Electronic Equipment (WEEE)



Langgöns, 2012-05-31

Harald Hellmann
Manager
Head of Development Department

Najet Nahali
Quality Management Officer
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7 Contact, Manufacturer

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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<http://www.DeMeTec.de>

8 Technical Description

8.1 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)
storage conditions	temperature	-15°F to +185°F / -25°C to +85°C
	relative humidity	10% to 95% (non-condensing)
dimensions (L×W×H)		(90×50×25)mm ³
weight		64g
classification as defined by Annex IX, MDD		class I

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
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 Nwl:

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