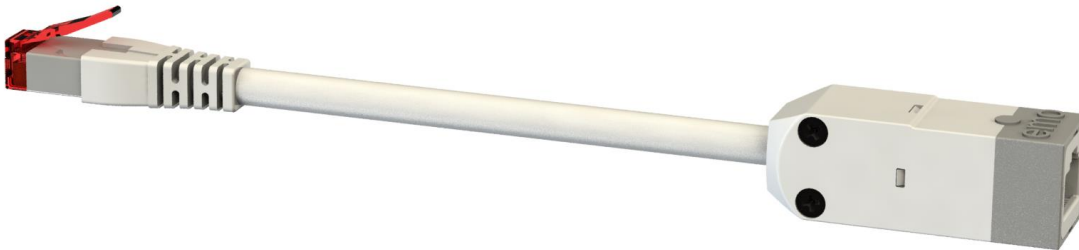


EMOSAFE EN-85e

Product Datasheet

Network Isolator with Overtension Auto-Release



1 FEATURES AND ADVANTAGES

1.1 OVERVIEW

- High Performance Gigabit Ethernet
- 4.6 kV AC dielectric strength
- 8.5 kV DC dielectric strength
- Overtension Auto-Release (OTAR)
- Designed and tested to meet IEC 60601-1
- UL Recognized Component
- ISO 11801 Class D Ethernet Performance attainable
- Extremely low insertion losses; thereby total cable lengths of 100 metres are achievable
- Suitable for devices with supply voltages up to 400 V AC
- RoHS compliant
- 100% inspection by our Quality Control

1.2 OVERTENSION AUTO-RELEASE (OTAR)



Figure 1. Overtension Auto-Release (OTAR) system automatically decouples the Ethernet cable under excessive loading.

The overtension auto-release (OTAR) system incorporated into the EN-85e offers, in addition to the electrical protection provided by EMOSAFE Network Isolators, a mechanical protection to the Ethernet interface. A common cause of failure for potentially expensive equipment arises from mechanical damage to Ethernet sockets resulting from excessive tensile or lateral forces. These forces act upon RJ45 sockets and

their supporting circuit boards, potentially damaging them beyond repair.

Such forces can arise, for example, when movable Ethernet devices are moved further than their connecting Ethernet cable naturally allows, or when people accidentally trip over attached patch cables. When the EN-85e is plugged into an Ethernet socket of a device to be electrically protected, the socket is simultaneously protected against such hazards. The OTAR socket of the connected Network Isolator simply releases the Ethernet cable automatically when applied tensile forces exceed a defined limit.

2 GENERAL DESCRIPTION

The EMOSAFE EN-85e Network Isolator disconnects every electrically conducting connection (specifically the data and shield conductors) between devices connected together via a copper-based Ethernet network. The Network Isolator prevents current flow resulting from differences in electrical potentials, and also protects connected devices and their users from stray external voltages and power surges which may be directly or inductively coupled onto the network lines by causes such as installation errors, lightning, switching operations, and electrostatic discharge.

Connected to a medical electrical (ME) product, the EMOSAFE EN-85e Network Isolator facilitates the safe Ethernet connection of this ME product within the patient environment. The EN-85e satisfies all construction requirements of IEC 60601-1 in the formation of two means of patient protection (MOPP) within the network interface, thereby practically eliminating the risk of electrical shocks arising from such stray external voltages at the network connection. With its UL approval, the EN-85e is also suitable for devices destined for export to the North American markets.

Low-frequency signal components are strongly attenuated, protecting connected devices from ground loops.

EMOSAFE Network Isolators transmits high-frequency signals through the principle of electromagnetic induction. The Network Isolator therefore does not require any external power supply. There are no software drivers to be installed.

3 APPLICATIONS

3.1 PATIENT PROTECTION

Electrical separation of Ethernet interfaces of medical electrical (ME) devices and systems, where patients must be protected from dangerous leakage currents, in conformity with applicable standards.

3.2 EQUIPMENT PROTECTION

Applications, in which valuable or critical devices or devices requiring special protection need to be protected against ripple, mains hum, and surge voltages from the network periphery.

Through its OTAR functionality, the EN-85e protects against damage to the RJ45 interface in the attached end device. Refer to section [1.2 OVERTENSION AUTO-RELEASE \(OTAR\)](#).

3.3 MEASUREMENT TECHNOLOGY

Electrical measuring and monitoring equipment, which needs to be protected against external and interference voltages arising from the Ethernet periphery.

3.4 POTENTIAL DIFFERENCES (TECHNICAL BUILDING SYSTEMS)

Computer systems, which are electrically connected with each other over significant distances via Ethernet cabling, where current flows caused by potential differences must be prevented.

3.5 AUDIO

Audio applications, in which the transmission of low frequency alternating current voltages (mains hum) over the network connection is to be reduced to an imperceptible level.

4 TECHNICAL DRAWINGS

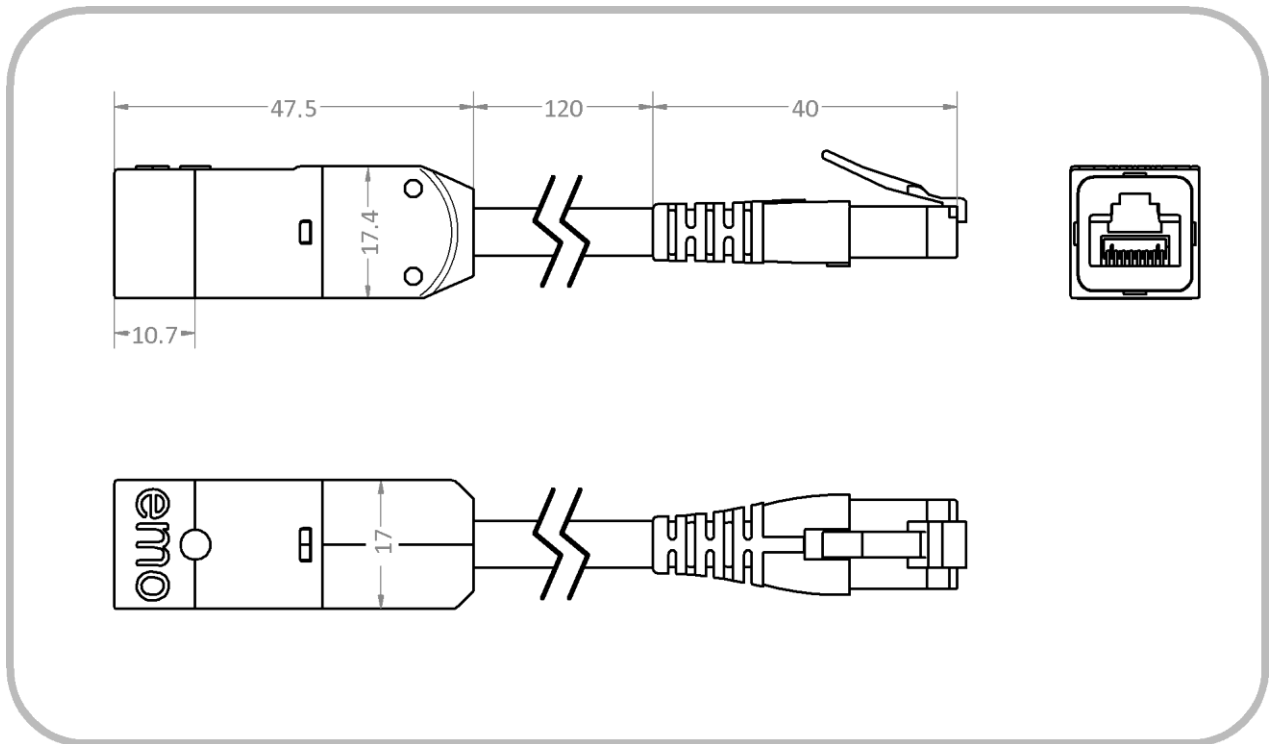


Figure 2. Technical drawing for EN-85e. All dimensions are in millimetres.

5 ACCESSORIES

5.1 R&M ACCESSORY RANGE

The Network Isolator EN-85e is constructed from high-quality cables and connectors from the Swiss company Reichle & De-Massari AG (R&M). Their entire accessory range for colour-coding and security fixtures is therefore compatible with the EN-85e, and available from R&M distributors.

6 INSTALLATION INFORMATION

6.1 GENERAL

EN-85e Network Isolators are designed to be retrofitted to the Ethernet interfaces of end devices. It is important to ensure that the conductive parts of the incoming patch cable are kept distanced from all conductive parts of the end device, as indicated in Figure 3 on page 4. If necessary, the incoming patch cable must be fixed in place to avoid accidental contact.

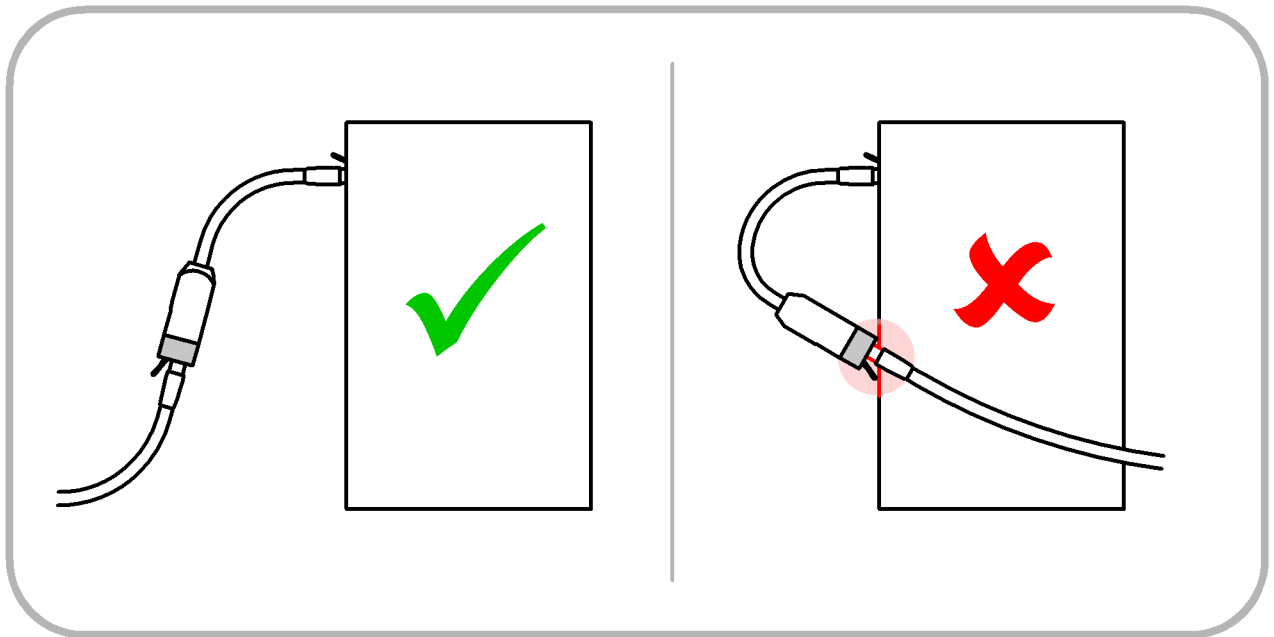


Figure 3. Positioning of EN-85e when connecting to PCs or other Ethernet-capable devices with metallic surfaces.

6.2 DEVICE INSTALLATION

When fitting the EN-85e, it is essential that the installer pays careful attention to the creepage and clearance distances between the exposed metallic surfaces on the plug of the incoming Ethernet cable (plugged into the EN-85e) and all conductive surfaces of the end device (which the EN-85e is plugged into). These distances must meet or exceed those required by the appropriate standards and regulations, or these conductive surfaces must be satisfactorily connected to a protective earth.

6.3 ELECTRICALLY ISOLATED WALL OUTLETS

EMOSAFE EN-85e Network Isolators can also be used to provide permanently installed Ethernet cabling with electrical isolation at the outlet termination. For an Ethernet cabling installation, including its termination of an EN-85e Network Isolator, to completely meet the requirements of Permanent Links according to ISO 11801 Class D or TIA/EIA 568 Cat.5e for Gigabit Ethernet, the cabling itself (without the Network Isolator) must provide a performance reserve. The following performance reserves to the Class D or Cat.5e limiting curves must be met without a Network Isolator:

NEXT:	4.0 dB
Return Loss:	4.0 dB
Insertion Loss:	1.5 dB

If a cabling installation which satisfies this requirement is terminated with an EN-85e Network Isolator, the installation as a whole will meet the requirements stated above. As required, this can then be verified using a cable certification device. See also [8.1 FUNCTION AND COMPLIANCE TESTING](#).

7 SAFETY NOTICE

7.1 ASSEMBLY

During design and assembly into medical electrical systems, attention should be paid to clearance and creepage distances, to ensure that the distances required by IEC 60601-1 are met. The isolating effect of

the Network Isolator must not be compromised by neighbouring conductive components. If, for example, the installation of the Network Isolator is to be within a metal plate, this plate must be connected to the ground potential (protective earth).

As a matter of principle, Network Isolators should be mounted as close as possible to the equipment requiring protection.

7.2 ENCLOSURE AND CONNECTION AREAS

The Network Isolator provides excellent protection between input and output, however the plastic enclosure provides only basic isolation. Furthermore, the connected plugs and the areas around the receptacles may have metal surfaces accessible to human contact, and therefore provide no protection. If the risk management process of the responsible organisation (i.e. manufacturer or operator, as defined in IEC 60601-1) reveals unacceptable risks that operators or patients can touch the housing or exposed conducting parts while the Ethernet cabling is connected to a potentially dangerous voltage, the Network Isolator and the exposed conducting surfaces must be surrounded with an appropriate enclosure to ensure the required means of protection for the application.

7.3 DAMAGE AND CONTAMINATION

Damaged Network Isolators, and Network Isolators which are contaminated by dust or liquids, are to be replaced.

8 SAFETY AND FUNCTION TESTING

8.1 FUNCTION AND COMPLIANCE TESTING

The transmission properties of permanent network installations fitted with EN-85e Network Isolators can be checked with cable certification devices which are suitable for testing electrically isolated cable sections. To be able to conduct such an inspection, the test equipment must be configured in an AC wire-map mode. The entire cable route, including the Network Isolator, can be tested to EIA/TIA-568 Cat.5e or ISO 11801 Class D. Testing of the cable shielding and the conductor resistance is not possible in this mode.

8.2 SAFETY INSPECTIONS

Regular safety inspections and post-repair inspections are not prescribed for network isolators in medical use, as network isolators themselves are not classified as medical electrical (ME) devices. However, together with a connected medical device, network isolators form an ME system, which altogether may be subject to inspection. The test interval, as well as the requirements to be met for both regular safety inspections and post-repair inspections will be specified by the responsible organisation (i.e. manufacturer or operator, as defined in IEC 60601-1), and based upon the applicable standards for the entire ME system.

To simplify implementation, the system components (in this case, the network isolator) can be individually tested. The responsible organisation provides the test parameters, specifies the test interval, and specifies the actions to take when a component fails the test. Such an assessment may, depending upon requirements, include the following checks:

8.2.1 VISUAL INSPECTION

Check for evidence of external damage and ingress of substances; dust or liquids for example.

8.2.2 LEAKAGE CURRENT TEST

The leakage current is to be measured, to ensure that it falls within the prescribed limits. For this purpose, test equipment which can perform equipment leakage current measurements in accordance with IEC 62353 may be used. To perform a leakage current test, all conductors on the input side must be short-circuited together, and all the conductors on the output side must also be short-circuited together. The AC test voltage specified by the responsible organisation is then applied across these two connections. Input and output sides are interchangeable. The expected current flow can be found in section *9 SPECIFICATIONS*.

8.2.3 HIPOT TEST

To ensure that the device under test is not damaged, it is recommended that a DC voltage source is used in place of the AC voltage source, and that the DC voltage is 1½ times that of the required AC voltage. The test setup is essentially the same as that of the Leakage Current Test above. The expected dielectric strength can be found in section *9 SPECIFICATIONS*.

8.2.4 FUNCTIONAL TEST

After conducting the tests above, and reconnecting the Network Isolator into the network, an examination is recommended to ensure that the signal transmission is performing correctly. Such a functional test can be performed, for example, with a suitable Ethernet cable certification device. Refer to section *8.1 FUNCTION AND COMPLIANCE TESTING*.

9 SPECIFICATIONS

9.1 GENERAL

Category	Standards or Test Criteria	Property
Designation		EMOSAFE EN-85e
Housing Colour		White / Grey
Housing Material		Plastic
Construction		Standalone
Cable Length	Flexible cable segment between plug and housing	120 mm
Minimum Bending Radius		25 mm
Maximum Short-term Loading upon Cable		70 N for up to 10 s
Mounting Arrangement		Free-hanging
Input Interface		RJ45 Jack, straight
Output Interface		RJ45 Plug, cable
Weight		approximately 24 g
Protection Rating	EN 60529	IP40
Mating Cycles:	Correct: RJ45 plug in RJ45 socket	> 1000 cycles
	Mismatched: with RJ11 / RJ12 / RJ25	maximum of 100 cycles
Mean Time To Failure (MTTF)	SN 29500 Standard Temperature: 25°C Duty cycle: 100% (24 hours, 7 days)	4,590 years
	SN 29500 Standard Temperature: 40°C Duty cycle: 100% (24 hours, 7 days)	4,260 years

9.2 ETHERNET PERFORMANCE

Category	Standards or Test Criteria	Property
Transmission Speeds and Supported Network Protocols	10 Mbit/s, 10Base-T (IEEE802.3 Cl.14)	✓
	100 Mbit/s, 100Base-Tx (IEEE802.3 Cl.25)	✓
	1000 Mbit/s, 1000Base-T (IEEE802.3 Cl.40)	✓
Performance Category	ISO 11801, Permanent Link (PL)	Class D
Insertion Loss (absolute)	Typical:	0.4 dB @ 100 MHz
	Maximum:	0.8 dB @ 100 MHz
Return Loss (absolute)	Typical:	17.0 dB @ 100 MHz
	Minimum:	14.0 dB @ 100 MHz

9.3 ELECTRICAL

Category	Standards or Test Criteria	Property	
AC Dielectric Strength	at 50 Hz, for 60 seconds	4.6 kV	
DC Dielectric Strength	for 60 seconds	8.5 kV	
Reinforced Isolation	IEC 60601-1	✓	
Coupling Capacitance per Channel		37.5 pF ±25%	
Total Coupling Capacitance		150 pF ±25%	
Total Leakage Current	275 V AC at 50 Hz	Typical:	12.0 µA
		Maximum:	16.0 µA

9.4 OPERATING CONDITIONS AND AREA OF APPLICATION

Category	Standards or Test Criteria		Property
Pollution Degree	IEC 61010		2 *
Overvoltage Category	IEC 60664-1		III
Maximum Working Voltage †	Maximum mains voltage of the connected devices, in accordance with IEC 60601-1		400 V AC 450 V DC
Temperature		Minimum:	-10°C
		Maximum:	+60°C
Air Humidity	Non-condensing	Minimum:	10%
		Maximum:	90%
Air Pressure		Minimum:	700 hPa
		Maximum:	1,060 hPa
Altitude		Maximum:	3,200 m

9.5 ENVIRONMENTAL CONDITIONS: STORAGE AND TRANSPORTATION

Category	Standards or Test Criteria		Property
Temperature		Minimum:	-40°C
		Maximum:	+70°C
Air Humidity	Non-condensing	Minimum:	10%
		Maximum:	90%
Air Pressure		Minimum:	500 hPa
		Maximum:	1,060 hPa

* Normally only nonconductive pollution occurs. Temporary conductivity caused by condensation is to be expected.

† The Network Isolator can be permanently exposed to this voltage level.

9.6 CERTIFICATES

Category	Property
UL Recognized Component	✓
UL File No.	E249126 E362969
IEC 60601-1	✓
IEC 60601-1-2	✓
ANSI/AAMI ES 60601-1	✓
CAN/CSA-C22.2 No. 60601-1	✓
Low Voltage Directive	✓
EMC Directive	✓
RoHS Directive	✓
Lead-free	✓

The versions of the cited standards and directives to which our products comply with can be found in our Declaration of Conformity and our UL certificate on our website under "[Standard Conformity and Certificates](#)".

9.7 ISOLATION DIAGRAM

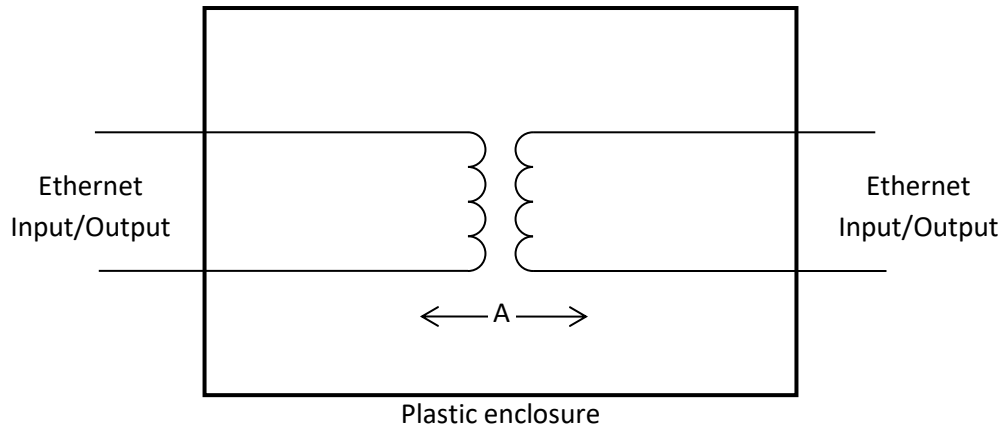


Figure 4. Isolation diagram for EN-85e.

Area	Number and type of Means of Protection	Material Group (from CTI)	Maximum Operating Voltage		Required creepage distance (mm)	Required clearance distance (mm)	Measured creepage distance (mm)	Measured clearance distance (mm)
			V AC	V _{peak}				
A	2 MOPP *	IIIb †	400	565	12.0	7.0	12.0	9.0

* MOPP = Means of Patient Protection

† Materials in the Material Group IIIb have a Comparative Tracking Index (CTI) value between 100 and 175.

9.8 FREQUENCY RESPONSE

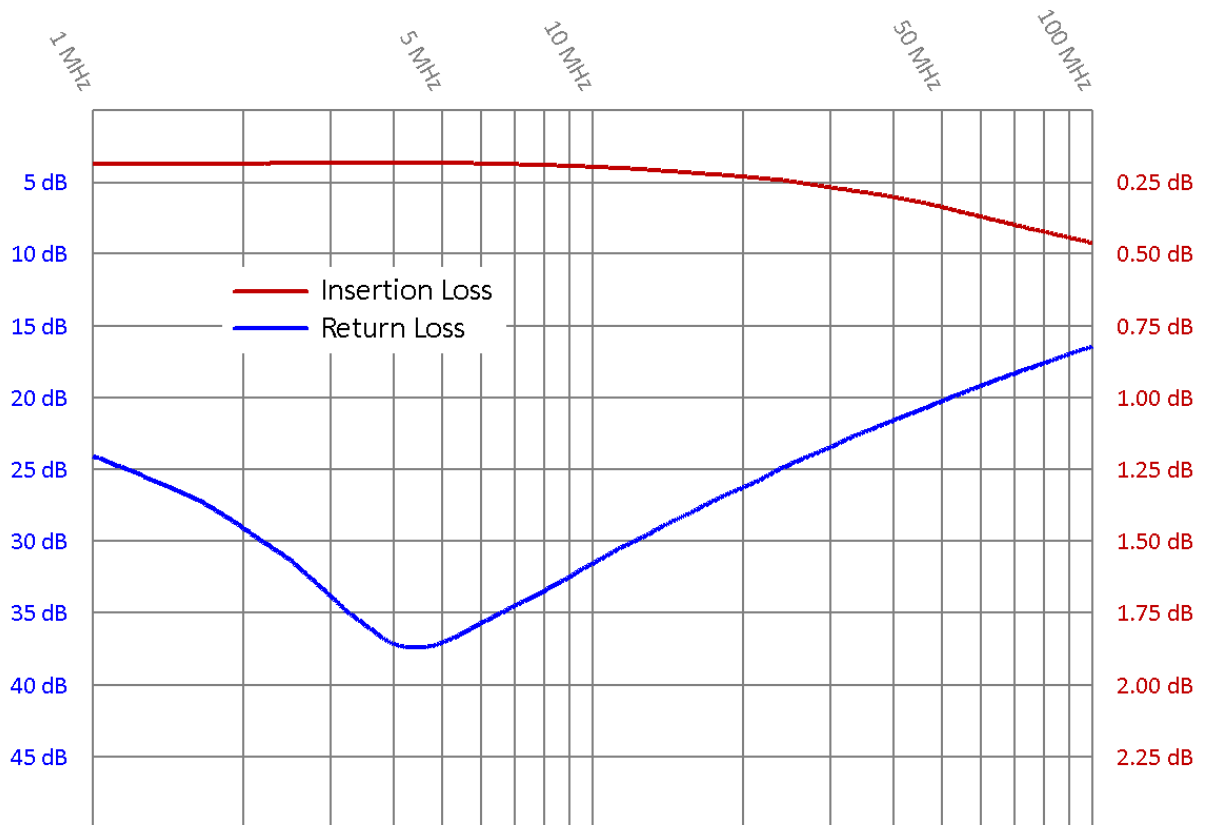


Figure 5. Typical frequency response for EN-85e.

10 SCHEMATIC DIAGRAM

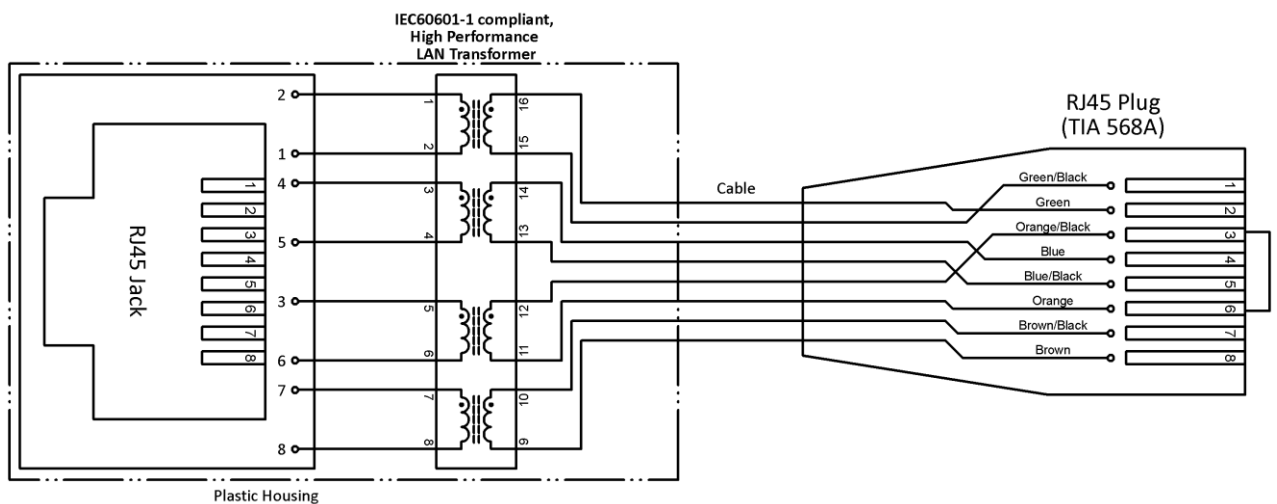


Figure 6. Schematic diagram of the EN-85e.

11 PACKAGING






Contents:

- EN-85e
- Installation Guide

A packaging label provides the following information:

- Article Description
- Quantity
- Date of Manufacture
- Part Number (PN)
- Serial Number (SN)
- The Serial Number is printed as both a linear (Code 128) and a 2-D Barcode (Data Matrix)

12 PRODUCT MARKINGS

	Through this mark, the conformity of the product with all applicable EU Directives is confirmed.
	Designates the product as a UL "Recognised Component"; File numbers E249126 and E362969.
	The product may not be disposed of in domestic rubbish.
	This product contains no substances containing lead and is manufactured using lead-free solder.
	This product meets the requirements of EU Directive concerning the limitation of the use of certain hazardous substances in electric and electronic equipment.

13 SCHEDULED MAINTENANCE

When used as directed, EMOSAFE Network Isolators are maintenance-free.

14 ENVIRONMENTAL PROTECTION INFORMATION

This device contains electronic components. At the end of its service life it is to be returned to the manufacturer for disposal.

15 QUALITY

EMO Systems operates a certified quality management system for development and production in accordance with ISO 9001 and ISO 13485. Prior to delivery, each Network Isolator is subjected to a comprehensive quality inspection. This inspection ensures, among other factors, that the attained values for leakage

currents, dielectric withstand strengths, insertion losses, return losses, and near end crosstalk values all meet the specified requirements.

16 CONTACT AND SUPPORT

Please find our up-to-date contact details on our website: <http://www.emosystems.de/en/contact>

Or send us an e-mail at the following address: support@emosystems.de

17 LEGAL NOTIFICATION

The information provided above in this datasheet has been compiled with all due care, and is believed to be accurate and reliable. However, we cannot guarantee that the information contained is completely free from error.

The end user is responsible and liable for the proper use of this product; EMO Systems GmbH. assumes no liability. We reserve the right to make changes to this datasheet without notice.

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