Wall and Ceiling Mount Accessories

Instructions for Use

Publisher's Notice

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Wall and Ceiling Mount Accessories Instructions for Use

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Associated Product Part Numbers:

022664, 022639, 022638

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Warnings and Precautions

WARNING

Refers to a hazardous situation that could result in death or serious injury if not avoided.

- Information on how the hazardous situation is avoided.

CAUTION

Refers to a hazardous situation that could result in minor or moderate injury or material damage if not avoided.

- Information on how the hazardous situation is avoided.

WARNING

System components immersed in or in contact with liquids may cause electrical shock.

- Do not immerse, drip, or spray liquids onto the device

CAUTION

Unauthorized modification could lead to loss of device function and performance.

- Do not modify device.

Device dropped or damaged in transit/use could lead to loss of function or delayed diagnosis.

- Inspect the device prior to each use and do not use if damaged.

Introduction

The Wall and Ceiling Mount Accessories allow for the installation of a video camera within a patient environment to optimize the view or perspective of a video recording of a patient. Installation of the wall and ceiling mount accessories is performed by a Natus Field Service Specialist or Natus trained professional. Video recorded with an EEG or PSG study provides more information regarding a patient's well-being and may be helpful with respect to patient care. The Wall and Ceiling Mount Accessories can support a camera plus any associated power sources, cabling, or hardware to facilitate an EEG or PSG recording with audio and video. The Wall and Ceiling Mount Accessories help to protect the equipment and facilitate a more obstruction-free environment for clinicians or patients who move about in a typical room.

The Wall and Ceiling Mount Accessories include the following major components:

- Video camera with High Definition (HD) or Full High Definition (FHD) options, plus pan, tilt, and zoom capabilities
- Infrared (IR) light source
- Power supply
- Microphone
- Ceiling tile or Wall enclosure

The Wall or Ceiling mount accessories may be included as part of a larger assembly or system that is designed for a patient room or a technician room. A system designed for a patient or technician room setup may include an acquisition computer, keyboard, periphery tray, cable management, and an isolation transformer. A wall track assembly may also be included to support the storage of these devices within a patient or technician room. Consult the manufacturer of each of these devices if you require further information or to ensure proper setup and operation.

It is recommended that you read the Warnings and Cautions section of this manual prior to using the Wall or Ceiling Mounts.

Intended Use

The Wall and Ceiling Mount Accessories are intended to be used in combination with Natus EEG (electroencephalography) or PSG (polysomnography) software, which allows a qualified medical practitioner trained in electroencephalography or polysomnography to acquire, display, archive, review, and analyze physiological signals along with audio and video.

Intended Users and Patient Target Group

The intended users of the Wall and Ceiling Mount Accessories used in conjunction with a Natus EEG or PSG system are trained medical professionals or someone instructed by a trained medical professional. At minimum, it is expected that the user has a basic understanding of clinical EEG and PSG, conducting an EEG or PSG study, and proficiency with computers and modern operating conventions. The Wall and Ceiling Mount Accessories can be used with patients of all ages.

Clinical Benefits

The Wall and Ceiling Mount Accessories used in combination with a Natus EEG/PSG system may help clinicians to diagnose and consider treatment options for patients of all ages.

Contraindications and Side Effects

There are no known contraindications or side effects when using the Wall and Ceiling Mount Accessories in combination with Natus EEG (electroencephalography) or PSG (polysomnography) software.

Installation

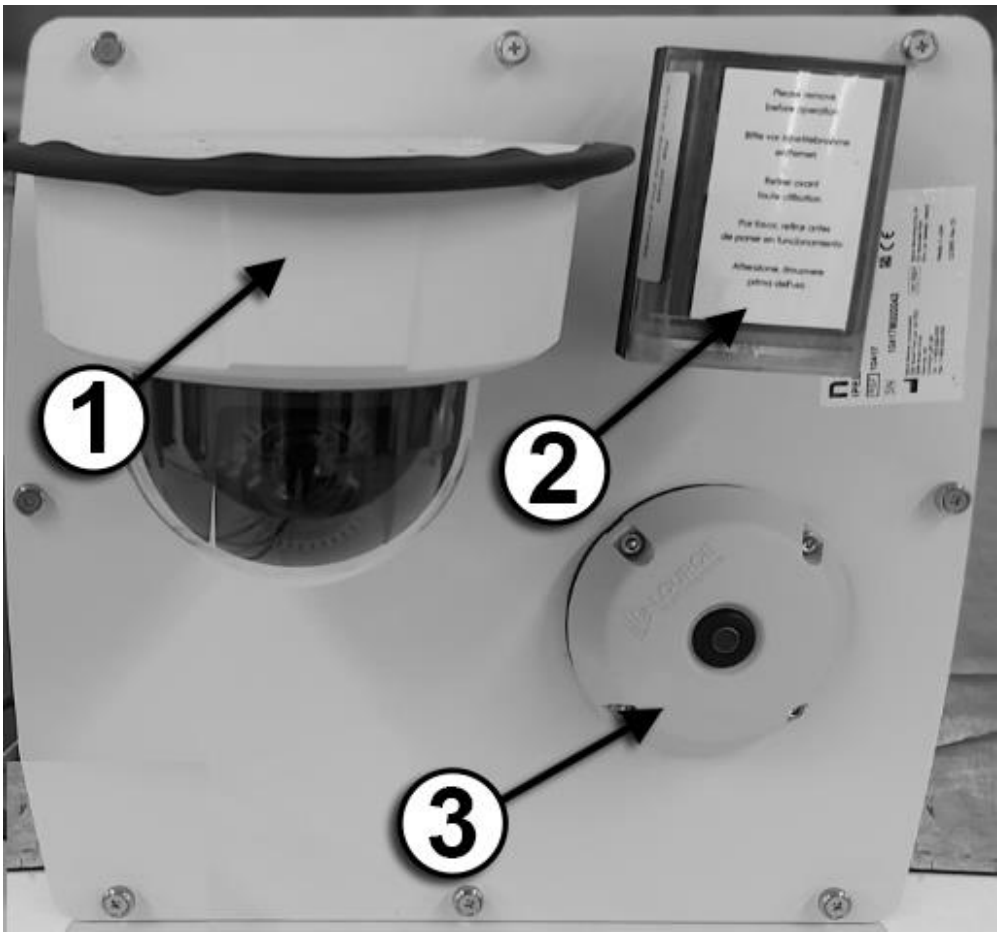
The Wall and Ceiling Mount Accessories are intended to be installed by a Natus Field Service Specialist or a qualified technician using instructions provided with the accessory.

Wall Mount Accessory

The Wall Mount Accessory (P/N: 022664/022639) is designed to be mounted onto a wall. The box assembly consists of these components:

- Enclosure/Box
- Support Bracket (for enclosure/box)
- Wall Mount Hole Pattern
- Cover/Lid (for enclosure/box)
- Video Camera
- IR Light
- Microphone
- 2 x Power over Ethernet (PoE) Injectors (1 for camera + 1 for IR light)

The camera, IR light, and microphone are installed on the exterior cover of the enclosure facing the room.

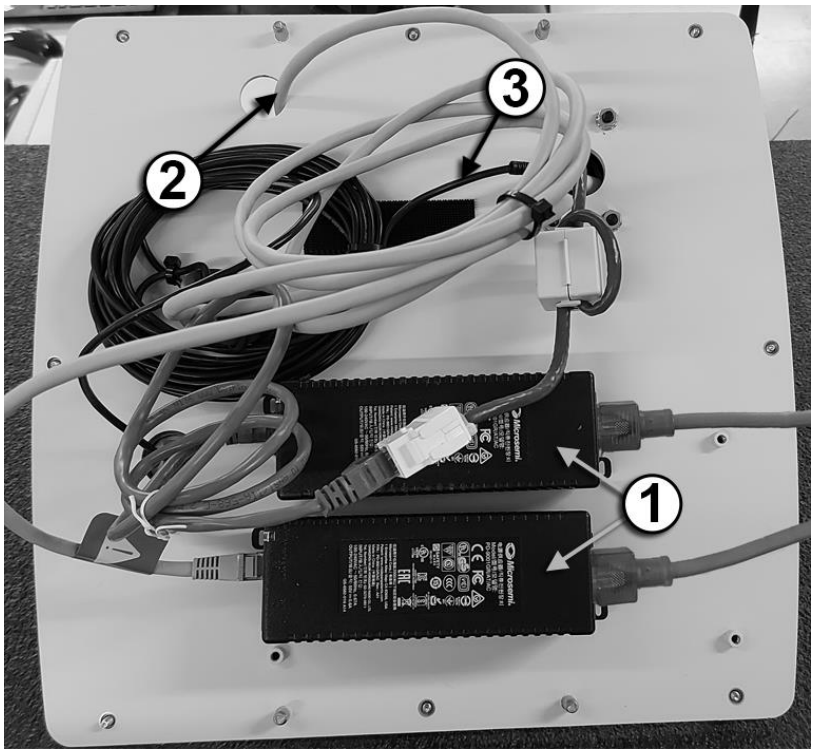


1 Camera

2 IR Light

3 Microphone

Inside the wall enclosure there are two PoE injectors – one to supply power to the IR and one to supply power and facilitate data to the camera. The underside of the camera is partially accessible on this side of the enclosure where cable connections are made, which includes an adapter to connect a microphone cable. The microphone is installed on the wall mount exterior. Major components inside the enclosure are shown in the image below.



1 PoE Injector (x2)

2 IR Cable

3 Microphone Cable

Using the Wall Mount Accessory

The camera is controlled and operated using Natus software, such as NeuroWorks or SleepWorks. Instructions for controlling your camera's pan, tilt, zoom, and any other recording options can be found in the Natus software instructions for use. During normal use, there is no physical interaction required with the accessory to perform its function.

Note where your camera, IR light, and microphone are installed relative to your recording subject or patient. They should be situated in a location that offers you the best audio recording and viewing perspective of your subject or patient without any obstruction or noise interference. You can verify the quality of your audio and video recording in daylight and dark conditions by following the Natus software instructions for use on recording and reviewing a patient study.

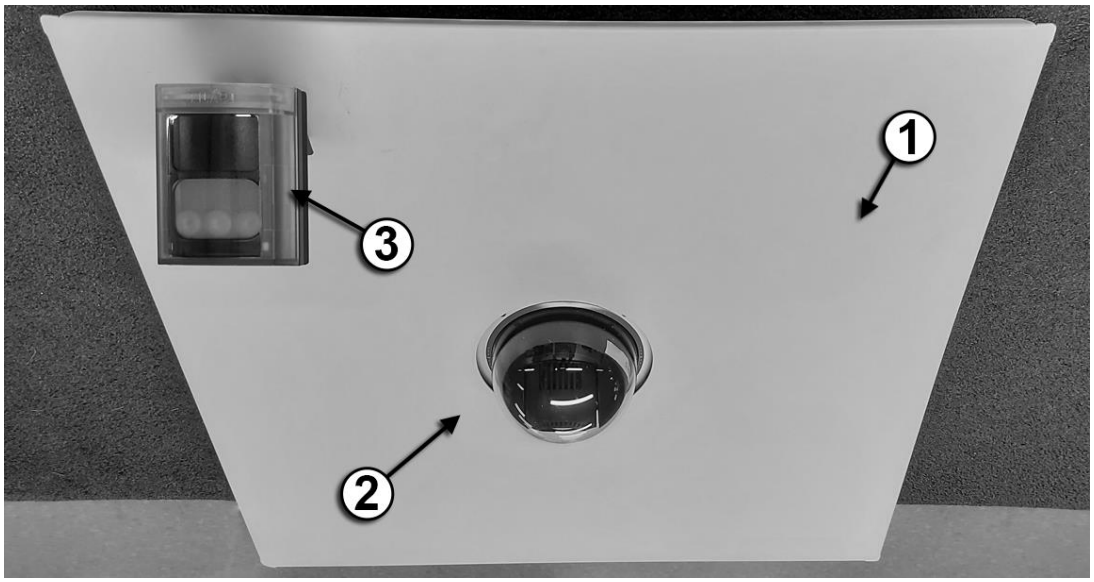
Ceiling Mount Accessory*

(*Ceiling Mount Accessory may not be available in all markets.)

The Ceiling Mount Accessory (P/N: 022638) is designed to be installed in an existing ceiling structure that consists of acoustic tiles. The Ceiling Mount Accessory consists of these components:

- Ceiling Tile (approximately 2 feet x 2 feet)
- Video Camera (attached to ceiling tile)
- IR Light (attached to ceiling tile)
- Power over Ethernet (PoE) injectors for camera and IR (attached to ceiling tile)
- Microphone (to be installed separately on another ceiling tile)
- Microphone/Mic Mounting Hole Template

The camera and IR light are installed on the side of the ceiling tile facing the room. The microphone is installed separately on another existing ceiling tile.

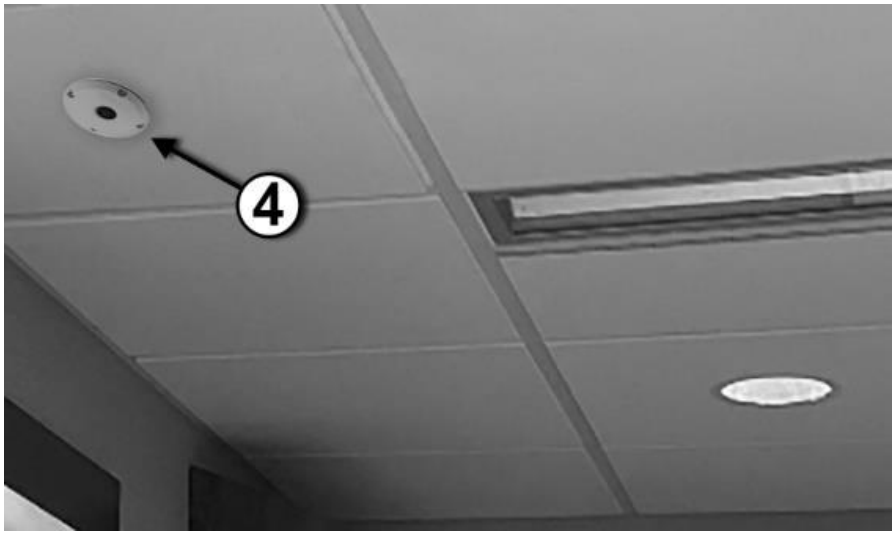


1 Ceiling Tile

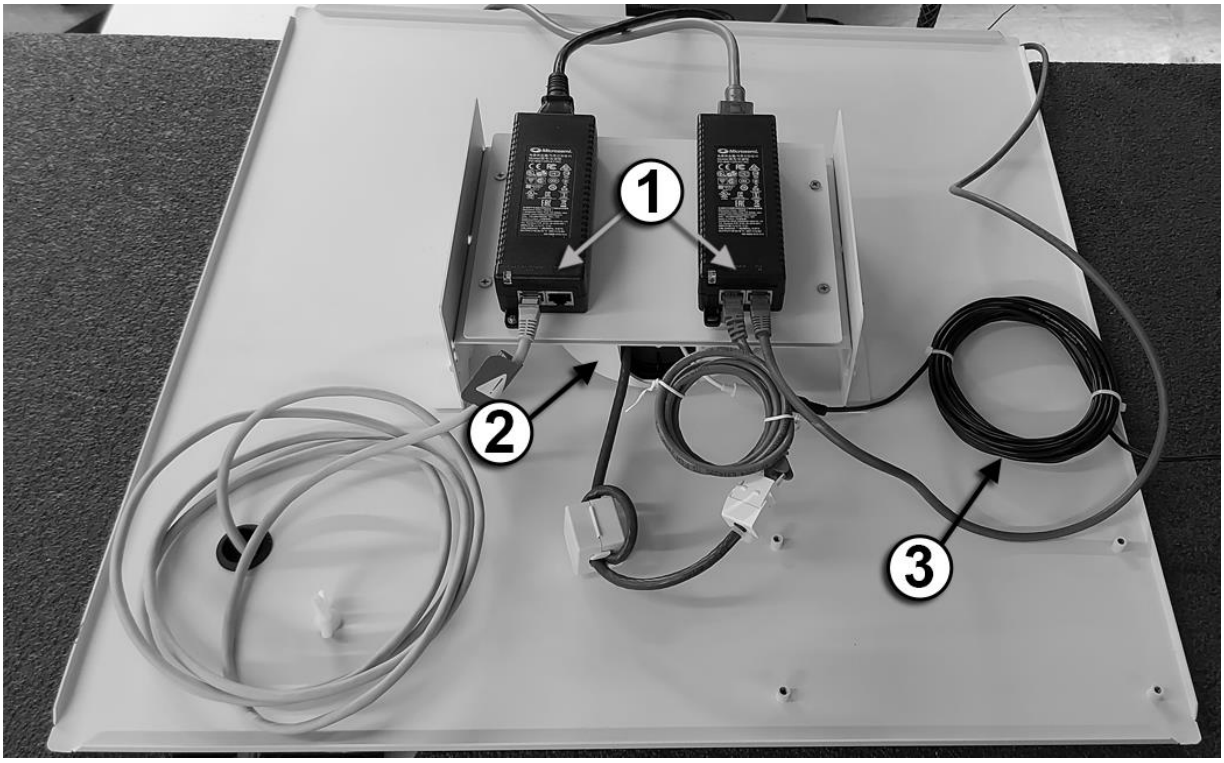
2 Camera

3 IR Light

4 Microphone



The other side of the tile, which is the side that faces the ceiling, holds two PoE injectors – one to supply power to the IR and one to supply power and facilitate data to the camera. The underside of the camera is exposed on this side of the tile where cable connections are made, which includes an adapter to connect a microphone cable. The microphone is typically installed separate from the ceiling tile. Major components are shown in the image below.



1 PoE Injector (x2)

2 Camera

3 Microphone Cable

Using the Ceiling Mount Accessory

The camera is controlled and operated using Natus software such as NeuroWorks or SleepWorks. Instructions for controlling your camera's pan, tilt, zoom and any other recording options can be found in the Natus software instructions for use manuals. During normal use, there is no physical interaction required with the accessory to perform its function.

Note where your camera, IR light, and microphone are installed relative to your recording subject or patient. The patient should be situated in a location that offers you the best viewing perspective of your subject and as close as possible to the microphone to produce a quality sound recording. You can verify the quality of your audio and video recording in daylight and dark conditions by following the Natus software instructions for use on recording and reviewing a patient study.

Maintenance and Cleaning Instructions

Your wall and ceiling mount accessory requires relatively low maintenance during normal use and operation. You should regularly inspect the visible components and the wall mount and ceiling tile for any damage prior to use. If any damage is suspected, do not use the system until you can verify with your facility manager or Natus representative that your system has not been compromised.

Your wall and ceiling mount accessory should be cleaned twice a year or as needed if visible dust or soil is observed. Prior to any cleaning, disconnect power to your wall or ceiling mount accessory first.

- Clean with a commercial wipe such as CaviWipes™ or Sani-Cloth® to remove visible soil or use a lint-free cloth dampened with distilled water to wipe the surface area of the ceiling tile or wall mount enclosure including the camera dome, IR light, and microphone casing.

- Dry using a lint-free cloth and air dry.

Recommendations:

- Take care not to allow any fluid to seep into the internal electronic components of the system.

Environmental Specifications

Operating Conditions:

- Temperature: +10°C to 30°C (+50°F to +86°F)
- Relative Humidity: 30% to 75% Non-Condensing
- Atmospheric Pressure: 700 hPa to 1060 hPa

Storage Conditions:

- Temperature: -25°C to +60°C (-13°F to 140°F)
- Relative Humidity: 10% to 95%
- Atmospheric Pressure: 500 hPa to 1060 hPa

Compliance Standards

ISO 10993-1: 2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
EN ETSI 300 019-2-1	Environmental Engineering (EE); Environmental conditions and environmental tests for telecommunications equipment; Part 2-1: Specification of environmental tests; Storage
EN ETSI 300 019-2-2	Environmental Engineering (EE); Environmental conditions and environmental tests for telecommunications equipment; Part 2-2: Specification of environmental tests; Transportation
EN 55035:2017	Electromagnetic compatibility of multimedia equipment Immunity requirements
EN 55032:2012 /AC:2013	Electromagnetic compatibility of multimedia equipment – Emission requirements
CISPR 32:2015/AMD1:2019	Electromagnetic compatibility of multimedia equipment – Emission requirements
AS/NZS CISPR 32:2015	Electromagnetic compatibility of multimedia equipment – Emission requirements
EN 61000-3-2:2014	Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)
EN 61000-3-3:2013	Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection
EN 62368-1: 2014+A11:2017	Audio/video information and communication technology equipment - Part 1: Safety requirements
EN 62368-3:2020	Audio/video information and communication technology equipment - Part 3: Safety aspects for DC power transfer through communication cables and ports

Table 1 - Electromagnetic Emissions

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The **Wall and Ceiling Mount Accessories** are intended for use in the electromagnetic environment specified below. The customer of the **Wall and Ceiling Mount Accessories** should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
Radiate emissions CISPR 11	N/A	N/A
Radiated emissions CISPR 32	Class A	The **Wall and Ceiling Mount Accessories** are suitable for use in all establishments **other than** domestic establishments and those directly connected to public low voltage power supply network that supplies buildings used for domestic purposes.
Radiated emissions EN 55032	Class A	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2 - Electromagnetic Immunity

Guidance and Manufacturer's Declaration – Electromagnetic Immunity
The **Wall and Ceiling Mount Accessories** are intended for use in the electromagnetic environment specified below. The customer or the user of the **Wall and Ceiling Mount Accessories** should assure that it is used in such an environment.

Immunity Test	**EN 55035 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic Discharge (ESD) EN 61000-4-2	±4 kV contact ±8 kV air	Complies	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrostatic fast transient/burst EN 61000-4-4	±0.5, 1 kV, 5Khz for AC input of camera controller ±0.5, 1 kV, 5Khz for AC input of PoE ±0.5 kV, 5Khz for Data port of PoE	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	AC input of camera controller ±1 kV differential mode ±2 kV common mode AC input of PoE ±1 kV differential mode ±2 kV common mode	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field EN 61000-4-8	1 A/m	N/A	N/A
Voltage dips, short interruptions, and voltage variations on power supply input lines EN 61000-4-11	(Dip) Residual voltage: <5%, Number of cycles 0.5 (dip). (Dip) Residual voltage: 70%, Number of cycles: 25 (50Hz) (Interrupt) Residual voltage: < 5% Number of cycles: 250 (50Hz)	Complies	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **Wall and Ceiling Mount Accessories** requires continued operation during power mains interruption, it is recommended that the **Wall and Ceiling Mount Accessories** to be powered from a suitable uninterruptible power supply or a battery.
NOTE: *UT* is the AC supply voltage prior to application of the test level.			

Table 3 - Electromagnetic Immunity – for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The **Wall and Ceiling Mount Accessories** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Wall and Ceiling Mount Accessories** should assure that it is used in such an environment.			
Immunity test	**Test Level EN 55035**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 0.15MHz to 10MHz 3 Vrms to 1 Vrms[3] 10 MHz to 30 MHz 1 Vrms 30 MHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the **Wall and Ceiling Mount Accessories**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d=1.2 \times \sqrt{P}$ 150kHz to 80MHz $d=1.2 \times \sqrt{P}$ 80MHz to 800MHz $d=2.3 \times \sqrt{P}$ 800MHz to 2.5GHz 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 meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic Site survey[1], should be less than the compliance level in each frequency range[2]. Interference may occur in the vicinity of equipment marked with the following symbol:  .
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 1 GHz and 1800 MHz, 2600 MHz, 3500 MHz, 5000 MHz	3 V/m	
Note 1: At 80 MHz and 800 MHz, 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. Note 3: The test levels decrease linearly with the logarithm of the frequency in the range 10 MHz to 30 MHz.			

[1] 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 the **Wall and Ceiling Mount Accessories** are used exceeds the applicable RF compliance level above the **Wall and Ceiling Mount Accessories** should be observed to verify normal operation. If abnormal operation is observed, additional measures may be necessary, such as re-orienting or relocating the **Wall and Ceiling Mount Accessories**.

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

Declaration of Compliance for FCC

Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his/her own expense.

Warning: Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

Disposal Instructions

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 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 below 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.

Notice

Any serious incident that has occurred in relation to the device should be reported to Natus Medical Incorporated DBA Excel-Tech Ltd. (Xltek) and the competent authority of the Member State in which the user and/or patient is established.

Instructions to Access the Electronic Instructions for Use (IFU)

A copy of the Instructions for Use in PDF format is in the associated product area:

- Neurology: https://neuro.natus.com/neuro-support

Scroll down to EEG Product IFUs, find “Wall and Ceiling Mount Accessories Instructions for Use” (refer to the Product Part Numbers), and choose the version for your local language for the instructions to use.

The files can be printed, saved, or searched using Adobe Reader. A copy of Adobe Reader can be downloaded directly from Adobe Systems (www.adobe.com).

Glossary of Symbols

Symbol	Standard Reference	Standard Title	Symbol Title	Explanation
	ISO 15223-1 Symbol 5.7.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	An indication of Medical Device	This product is a medical device.
	2012/19/EU	Waste Electrical and Electronic Equipment (WEEE)	Disposal at end of operating life instructions	Indicates that electrical and electronic equipment waste should not be discarded together with unseparated waste but must be collected separately.
	ISO 15223-1 Symbol 5.1.1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Manufacturer	Indicates the medical device manufacturer.
	ISO 15223-1 Symbol 5.1.2	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Authorized representative in the European Community	Indicates the Authorized representative in the European Community.
	ISO 15223-1 Symbol 5.1.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Date of manufacture	Indicates the date when the medical device was manufactured.
	ISO 15223-1 Symbol 5.1.6	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Catalogue number	Indicates the manufacturer’s catalogue number so that the medical device can be identified.

Symbol	Standard Reference	Standard Title	Symbol Title	Explanation
	ISO 15223-1 Symbol 5.1.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	ISO 15223-1 Symbol 5.4.3 Annex A #A.15	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Consult instructions for use	Indicates an instruction to consult an electronic instructions for use (eIFU).
	IEC 60601-1 Table D.2 #10	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance	Follow instructions for use	Refer to instruction manual/ Booklet. NOTE on ME EQUIPMENT "Follow instructions for use"
	ISO 15223-1 Symbol 5.4.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	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.
	IEC 60601-1 Table D.1 #10	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance		
	IEC 60601-1 Table D.2 #2	Medical electrical equipment — Part 1: General requirements for basic safety and Essential performance	General warning sign	Indicates a hazard of potential personal injury to patient or operator.
	MDR 2017/745	EU Medical Device Regulation	CE marking	Signifies European technical conformity.
	ISO 15223-1 Symbol 5.3.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Temperature limit	Indicates the (storage) temperature limits to which the medical device can be safely exposed.
	ISO 15223-1 Symbol 5.3.8	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Humidity limitation	Indicates the range of (storage) humidity to which the medical device can be safely exposed.

Symbol	Standard Reference	Standard Title	Symbol Title	Explanation
	ISO 15223-1 Symbol 5.3.9	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Atmospheric pressure limitation	Indicates the acceptable upper and lower limits of atmospheric pressure for transport and storage.
	ISO 15223-1 Symbol 5.3.1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Fragile; handle with care	Indicates that the contents of the transport package shall be handled with care.

Product Part Number	Product Description
022664, 022639, 022638	Input: 100-240VAC, 50/60Hz Communication: Ethernet

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A Total Service Solution

Natus Systems are backed by a comprehensive & extendable warranty.

Our support team is available around-the-clock. Our technical staff provides phone and remote PC support, while our nationwide network of service engineers can be dispatched quickly when required.

Natus Medical Incorporated

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