English

Description:
Natus reusable ancillary cables for EMG, EEG, PSG and IOM are optional devices used to connect sensors and amplifiers.

Intended Use:
The cables are intended to be used with EEG and/or EMG monitoring supplies and devices. The patient cable is used to connect at appropriate sites to a monitoring device for general monitoring and/or diagnostic evaluation by health care professionals.

Intended User and Target Patient Group:
The product is for use only under the direction of trained medical professionals in acquiring electrophysiologic signals. Patient selection is at the clinician's discretion. These cables do not directly interface with patients.

Clinical Benefits:
Facilitates obtaining an EMG recording to detect any irregularities indicative of muscle disorders.

Contraindications and Side Effects:
There are no known contraindications or side effects for procedures performed with Natus Ancillary Cables. See Warnings or Precautions below.

Operating Instructions:
Connector types vary by cable.
- Plug an electrode or sensor into the sensor end of the cable.
- Connect the amplifier end of the cable to an amplifier.
- Extension cables are used between cables leading from a sensor and the amplifier to extend the sensor cable length or to change the type of connector on the amplifier end.
- Check that the cables attach tightly and do not easily separate.
- Check that clear, strong signals are being transmitted following connection.

Cleaning Instructions:
- Clean with a commercial wipe such as CaviWipes™ or Sani-Cloth® to remove visible soil.
- Wipe the article using a lint-free cloth and air dry.

Understanding Cautions Statements:

⚠ 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.

Warnings and Precautions:

⚠ CAUTION
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.
Improper connection leads to loss of data transmission. • Assure proper connections and check signal quality before using.
Modifications to the device can affect function and performance. • Do not modify this equipment without authorization of the manufacturer.

Environmental Specifications:
Operating Conditions:
- Temperature: +10°C (+50°F) to +30°C (+86°F)
- Relative Humidity: 20% to 80% (non-condensing)
- Atmospheric Pressure: 70 kPa to 106 kPa

Storage Conditions:
- Temperature: 0°C (+32°F) to +30°C (+86°F)
- Relative Humidity: 20% to 80% (non-condensing)
- Atmospheric Pressure: 50 kPa to 106 kPa

Transportation Conditions:
- Temperature: -25°C (-13°F) to +55°C (+131°F)
- Relative Humidity: 20% to 80% (non-condensing)
- Atmospheric Pressure: 50kPa to 106kPa

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.

Disclaimer:
Natus Medical Incorporated is not responsible for injury, infection or other damage resulting from the use of this product.
Any serious incident that has occurred in relation to the device should be reported to Natus Medical Incorporated and the competent authority of the Member State in which the user and/or patient is established.
Refer to the Natus website for an electronic copy of this document.

Glossary of Symbols:

Symbol	Standards Reference	Standard Title of Symbol	Symbol Title as per Reference Standard	Explanation
Medical Device	-	-	An indication of Medical device	This product is a medical device.
Rx only	21 CFR Part 801.109(b)(1)	Labeling-Prescription devices.	Prescription only	Indicates the product is authorized for sale by or on the order of a licensed healthcare practitioner.
	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 5.1.6	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.
	ISO 15223-1 Symbol 5.1.5	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Batch or Lot code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	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.

Symbol	Standards Reference	Standard Title of Symbol	Symbol Title as per Reference Standard	Explanation
	ISO 15223-1 Symbol 5.4.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	ISO 60601-1 Table D.1 #11	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	Operating instructions	
	ISO 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: Read all warnings and precautions in instructions for use	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.
	ISO 60601-1 Table D.1 #10	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.		
	ISO 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.
	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.
	ISO 15223-1 Symbol 5.2.8	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	ISO 15223-1 Symbol 5.4.5 (Reference Annex B for the general prohibition symbol)	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Not made with Natural Rubber Latex	Indicates a medical device that is not made with natural rubber latex.
	-	-	Quantity	Number of parts in a package.
	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.

Product Part Numbers	Product Description
019-401100	Male to female, 2.0m (79"), (1.5mm DIN), 6 colors, 6/pkg
019-420100	Male to female (x2) adapter, 10.2cm (4"), (1.5mm DIN), 3/pkg
019-431500	Male to female, 1.0m (39"), (1.5mm DIN), 6 colors, 6/pkg
019-408400	Male to female, 1.0m (39"), (1.5mm DIN), red and black, 1 pair/pkg
019-432200	Male to female, 2.0m (79"), (1.5mm DIN), red and black, 1 pair/pkg
117-401900	1.25m (49"), (1.5mm DIN), 3 colors, 3/pkg
019-417000	1.25m (49"), (1.5mm DIN), red and black, 1 pair/pkg
019-417200	1.25m (49"), (1.5mm DIN), 1/pkg
019-433000	Male and female, 51cm (20"), (1.5mm DIN), 6 colors, 6/pkg
085-417401	5-pin DIN to two 1.5mm DINs and 1 stackable jumper/linker, 15.2cm (6"), 1/pkg
2002-TP	3 touchproof sockets to 5-pin DIN, 61cm (24"), 1/pkg
CB0102	3 colors, 61cm (24"), (1.5mm DIN), 3/pkg

Supplementary sheet for EEG/EMG cables

1. Product name: EEG/EMG cables
2. Model number: See Table 1

Table 1 EEG/EMG cables Models, Specifications

Item	Type	Product Description	Connector	Package	Picture
1.	117-401900	– Cables with alligator clip (3 cables in red/green/black, 1.25m, shielded) – Reuse – Used with EEG/EMG/intraoperative neural electrical signals monitoring devices.	– 1.5mm DIN 42802 connector (device side) – alligator clip (electrode side)	3 pieces/ pkg	
2.	019-417000	– Cables with alligator clip (2 cables in red/black, 1.25m, shielded) – Reuse – Used with EEG/EMG/intraoperative neural electrical signals monitoring devices.	– 1.5mm DIN 42802 connector (device side) – alligator clip (electrode side)	1 pair/pkg	
3.	019-417200	Cables with alligator clip (1 cables in green, 1.25m, shielded) – Reuse – Used with EEG/EMG/intraoperative neural electrical signals monitoring devices.	– 1.5mm DIN 42802 connector (device side) – alligator clip (electrode side)	1 piece/ pkg	
4.	085-417401	5-hole cables (3 cables in red/black/green, 15.2cm, shielded) – Reuse – Used with EEG/EMG/intraoperative neural electrical signals monitoring devices.	– One 5-hole DIN female connector – Two 1-hole 1.5mm female connectors – One stackable connector (male/female)	1 piece/ pkg	
5.	019-431500	Electrode extension cables (6 cables in green/blue/yellow/red/purple/grey, 1m) – Reuse – Used with EEG/EMG/intraoperative neural electrical signals monitoring devices.	– 1.5mm DIN 42802 connector – Male/female ends	6 pieces/ pkg	
6.	019-401100	Electrode extension cables (6 cables in green/blue/yellow/red/purple/grey, 2m) – Reuse – Used with EEG/EMG/intraoperative neural electrical signals monitoring devices.	– 1.5mm DIN 42802 connector – Male/female ends	6 pieces/ pkg	
7.	019-408400	Electrode cables (2 cables in red/black, 1m) – Reuse – Used with EEG/EMG/intraoperative neural electrical signals monitoring devices.	– 1.5mm DIN 42802 connector – Male/female ends	1 pair/pkg	
8.	019-432200	Electrode cables (2 cables in red/black, 2m) – Reuse – Used with EEG/EMG/intraoperative neural electrical signals monitoring devices.	– 1.5mm DIN 42802 connector – Male/female ends	1 pair/pkg	
9.	019-433000	Stackable cables (6 cables in pink/grey/purple/blue/green/yellow) – Reuse – Used with EEG/EMG/intraoperative neural electrical signals monitoring devices.	– Male/female ends	6 pieces/ pkg	
10.	019-419000	Snap cables (5 cables in blue/grey/purple/green/yellow, 1m) – Reuse – Used with EEG/EMG/intraoperative neural electrical signals monitoring devices.	– 1.5mm DIN 42802 connector (device side) – Snap (electrode side)	5 pieces/ pkg	
11.	019-419100	Snap cables (5 cables in blue/grey/purple/green/yellow, 1.5m) – Reuse – Used with EEG/EMG/intraoperative neural electrical signals monitoring devices.	– 1.5mm DIN 42802 connector (device side) – Snap (electrode side)	5 pieces/ pkg	
12.	019-419200	Snap cables (5 cables in blue/grey/purple, 2m) – Reuse – Used with EEG/EMG/intraoperative neural electrical signals monitoring devices.	– 1.5mm DIN42802 connector (device side) – Snap (electrode side)	5 pieces/ pkg	
13.	019-419300	Snap cables (5 cables in blue/grey/purple/green/yellow, 3m) – Reuse – Used with EEG/EMG/intraoperative neural electrical signals monitoring devices.	– 1.5mm DIN42802 connector (device side) – Snap (electrode side)	5 pieces/ pkg	
14.	2002-TP	EMG cable (shield, 61cm) -Reuse -Used with EEG/EMG/intraoperative neural electrical signals monitoring devices.	-3pin touchproof connector(Electrode End) -5pin(Device End)	1 piece/ pkg	

3. Operating, cleaning, warning, handling, symbol explanation, operating and storage conditions: See Instruction Manual

4. Production date: See English label; Service life: 26 weeks.

5. Registrant Information
   Registrant/Manufacturer name: Natus Neurology Incorporated
   Registrant/manufacturer location: 3150 Pleasant View Road Middleton, Wisconsin 53562 USA
   Manufacturer address: 3150 Pleasant View Road Middleton, Wisconsin 53562 USA;
   IDA Business Park Gort Co.Galway Ireland
   Registrant/Manufacturer contact: +1 800-356-0007

6. Agency Information
   Agency: Natus Medical Equipment (Beijing) Co., Ltd.
   Domicile of agency: Room 55,3/F, Tower D, Vantone Centre NO.6 Chao yang menwai Avenue, Chaoyang District, Beijing
   Agency contact: 010-59070036

7. After-sales service
   After-sales service agency: Guangzhou Nicolet Scientific Instrument Co., Ltd.
   After-sales service address: Room 404, No. 88 Taoyu Road, Tianhe District, Guangzhou
   Phone: 020-38872388

8. Medical device record certificate No. / Product technical requirements No.: G.X.Bei. 20210518

9. Application: Used to transmit electrophysiological signals acquired from the body surface. For use with EMG device, EMG analyzer, Monitors etc., connected between the instrument and electrodes.

10. Product components: It consists of metal cable, copper jacket and insulation sheath.

11. Specifications preparation date: July 12, 2023

12. Electrical safety features of the product:
    1) Classified by electric shock protection type: Not applicable, depends on host;
    2) Classified by electric shock protection level: Not applicable;
    3) Classified by IP level: IPX0;
    4) Classified by safety level when used with mixed gases of flammable anesthetic gas and air or mixed gases of flammable anesthetic gas and oxygen or nitric oxide: The product is not AP and APG tequipment;
    5) Classified by pperation mode: continuous operation;
    6) Rated voltage and frequency of the equipment: Not applicable;
    7) Input power of the device: Not applicable;
    8) Does the device have an applied part that is protected against defibrillation discharge effects: Not applicable;
    9) Does the device have signal output or input: Not applicable;
    10) Permanently or non-permanently installed device: Non-permanently installed device;

13. EMC Declaration of Conformity: (Cables is the abbreviation of “EEG/EMG cables”)
    1) This section contains specific information for electromagnetic compatibility. Cables should be installed and used according to EMC information in this chapter.
    2) Cables comply with EMC requirements of Standard YY9706.102-2021.
    3) Portable and mobile RF communications equipment may affect the operation of the cables, and it is recommended that portable and mobile RF communications equipment be kept away from the cables or turned off during use of the cables.
    4) Cables are not used in a residential environment and cannot provide adequate protection for radio reception.
    5) Use the cables supplied by us, see Table 1.
    6) Caution: The use of accessories other than those provided by us may result in increased emissions or decreased immunity of the cables. See Table 2.
    7) When the cables are used, it should not be stacked or placed adjacent to other equipment of the same operating frequency. If it needs to be stacked or placed adjacent to other equipment, make sure that the operation of the cables is not affected. See Table 3.

Table 2

Guidance and manufacturer's declaration – electromagnetic emissions		
The cables is intended for use in the electromagnetic environment specified below, the purchaser or user should ensure that it is used in such an environment:		
Radiation testing	Compliance	Electromagnetic environment – guidance
RF emissions GB 4824	Group 1	Cables uses RF energy only for its internal functions. So it's RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions GB 4824	Class A	The cables is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings
Harmonic radiation GB 17625.1	Not applicable	
Voltage fluctuation/flicker radiation GB/T 17625.2	Not applicable	

Table 3

Guidance and manufacturer's declaration – electromagnetic immunity			
The cables is intended for use in the electromagnetic environment specified below; the purchaser or user should ensure that it is used in such an environment.			
Electromagnetic immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge GB/T 17626.2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst GB/T 17626.4	±2 kV for power line ±1 kV for input/output lines	——	Mains power quality should be that of a typical commercial or hospital environment.
Surge GB/T 17626.5	±1 kV differential mode voltage ±2 kV common mode voltage	——	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines GB/T 17626.11	<5% U_T for 0.5 cycle (>95% dip in U_T) 40% U_T for 5 cycles (>60% dip in U_T) 70% U_T for 25 cycles (30% dip in U_T) <5% U_T for 5 s (>95% dip in U_T)	——	Mains power quality should be that of a typical commercial or hospital environment. If the user of the cables requires continued operation during power mains interruptions, it is recommended that the cables be powered from an uninterruptible power supply or a battery.
Power frequency magnetic fields (50Hz) GB/T 17626.8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the AC power voltage prior to application of the test level.			

Table 4

<table>
<tr><td colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</td></tr>
<tr><td colspan="4">The cables is intended for use in the electromagnetic environment specified below; the purchaser or user should ensure that it is used in such an environment:</td></tr>
<tr><td>Immunity test</td><td>IEC 60601 test level</td><td>Compliance level</td><td>Electromagnetic environment – guidance</td></tr>
<tr><td rowspan="2">RF Conduction GB/T 17625.6</td><td rowspan="2">3 Vrms
150 kHz to 80 MHz</td><td>3 Vrms</td><td rowspan="3">Portable and mobile RF communications equipment should be used no closer to any part of the cables, including cables, than the recommended separation distance. This distance should be calculated using the formula that corresponds to the transmitter frequency.
Recommended separation distance:
d = 1.2√P
d = 1.2√P 80 MHz to 800 MHz (3 V/m)
d= 0.35√P 80 MHz to 800 MHz (10 V/m)
d = 2.3√P 800 MHz to 2.5 GHz (3 V/m)
d = 0.7√P 800 MHz to 2.5 GHz (10 V/m)
Where:
P - the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
D - the recommended separation distance in meters (M).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with this symbol:
  </td></tr>
<tr><td>3 V/m</td></tr>
<tr><td>RF radiation GB/T 17626.3</td><td>3 V/m</td><td></td></tr>
<tr><td>GB/T 17626.3</td><td>80 MHz to 2.5 GHz</td><td></td></tr>
<tr><td colspan="4">Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects and people.</td></tr>
<tr><td colspan="4">a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones, land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be accurately predicted theoretically. 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 cables is used exceeds the applicable RF compliance level above, the cables should be observed to verify normal operation If abnormal performance is observed, additional measures might be necessary, such as reorienting or relocating the cables.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

Table 5

<table>
<tr><td colspan="6">Recommended separation distances between portable and mobile RF communications equipment and the cables</td></tr>
<tr><td colspan="6">The cables is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The purchaser or user of the cables can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the cables as recommended below, according to the maximum rated power.</td></tr>
<tr><td rowspan="2">Rated maximum output power of transmitter W</td><td colspan="5">Separation distance according to transmitter frequency / m</td></tr>
<tr><td>150 kHz to 80 MHz
d = 1.2√P</td><td>80 MHz to 800 MHz
d = 1.2√P
(3V/m)</td><td>800 MHz to 2.5 GHz
d =2.3√P
(3V/m)</td><td>80 MHz to 800 MHz
d = 0.35√P
(10V/m)</td><td>800 MHz to 2.5 GHz
d =0.7√P
(10V/m)</td></tr>
<tr><td>0.01</td><td>0.12</td><td>0.12</td><td>0.23</td><td>0.035</td><td>0.07</td></tr>
<tr><td>0.1</td><td>0.38</td><td>0.38</td><td>0.73</td><td>0.11</td><td>0.22</td></tr>
<tr><td>1</td><td>1.2</td><td>1.2</td><td>2.3</td><td>0.35</td><td>0.7</td></tr>
<tr><td>10</td><td>3.8</td><td>3.8</td><td>7.3</td><td>1.11</td><td>2.21</td></tr>
<tr><td>100</td><td>12</td><td>12</td><td>23</td><td>3.5</td><td>7</td></tr>
<tr><td colspan="6">For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects and people.</td></tr>
</table>

14. Complies with China Measures for the Control of Pollution from Electronic Information Products and SJ/T 11364–2014 Restriction of the Use of Hazardous Substances in Electrical and Electronic Products:
15. Cleaning

The product is non-contacted to patient, therefore cleaning times within the service life (26 weeks) does not affect the product's essential performance.