Nox SAS Head Cable – Instructions for Use

The Nox SAS Head Cable is available in one size, adult, and has a total length of 95 cm (37 in). The Nox SAS Head Cable is clean and ready for use.

Available packages:

Nox SAS Head Cable (ESNAP10SASLMPAC1US)	#56 22 18

Intended Use

The Nox SAS Head Cable is intended to enable the recording of EEG/EMG signals during sleep studies. The Nox SAS Head Cable is used with the Nox A1s recorder, the Nox SAS Body Cables and industry standard double snap electrodes. The Nox SAS Head Cable is indicated for use in adult patients. The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments, including the patient´s home.

Patient Population

The intended patient population are patients that are having symptoms of, or suspected to suffer from sleep disorders, especially those that may suffer from Sleep Disordered Breathing (SDB) and are determined by a physician to require a diagnostic sleep test.

Intended Users

The users are healthcare professionals who have received training in the areas of hospital/clinical procedures, physiological monitoring of human subjects, or sleep disorder investigation. When conducting a simple sleep study in the home environment, the patient may perform a self-hook-up, with or without assistance from a family member, after being instructed by a qualified healthcare professional.

Information for Safety

The Nox SAS Head Cable does not provide protection against the effect of the discharge of a cardiac defibrillator (is NOT defibrillator-proof) nor against high frequency burns. The cable should not be used in areas where a patient might be defibrillated.

The Nox SAS Head Cable is multi-patient use and shall be cleaned/disinfected between patient uses.

The Nox SAS Head Cable is not made to be sterilized.

WARNINGS:

- Electrodes should only be used by or in consultation with a healthcare provider familiar with their proper placement and use. Not using and placing the electrodes correctly may affect recording of data, and therefore interpretation and diagnostics.
- Electrodes should be applied only to intact, clean skin (e.g. not over open wounds, lesions, infected or inflamed areas) to prevent infections.
- Do not use damaged equipment. Use of damaged equipment may result in patient harm, such as burn or electrical shock or lead to incorrect patient diagnosis.
- Carefully route cables and connections to reduce the possibility of entanglement or strangulation.
- Not cleaning the Nox SAS Head Cable between patient uses poses a risk of cross-contamination.
- Do not use the Nox SAS Head Cable in an MRI (Magnetic Resonance Imaging) environment. The energy absorption in conductive materials might lead to excessive heating and cause burns.
- Remove the Nox SAS Head Cable from a patient before defibrillation. Not doing so may alter the intended flow of the current, affecting the defibrillation efficiency and causing injuries or death of the patient.
- Do not use the Nox SAS Head Cable during radiography/X-ray studies. The energy absorption in the equipment might lead to excessive heating and cause burns.
- Only connect the Nox SAS Head Cable to Medical Electrical Equipment/Systems complying with the patient safety standard IEC 60601-1, 3rd edition or newer. Non-compliant electrical systems may result in serious patient harm, such as electrical shock or burn. Any person that connects the Nox SAS Head Cable to an electrical device[1] has formed a new electrical system and is responsible for the patient safety of the system. If in doubt, contact a qualified medical technician or your local representative.
- Make sure the conductive parts of electrodes and associated connectors, including the neutral electrode, do not contact other conductive parts including earth to prevent potential serious harm to the operator/patient.
- Avoid accidental contact between connected but unused patient applied parts and other conductive parts including those connected to protective earth to prevent potential serious harm to the operator/patient.
- The Nox SAS Head Cable are not intended to be used with high frequency (HF) equipment. Using the equipment with high frequency (HF) equipment could cause potential serious harm to the patient.
- No modification of this equipment is allowed. Unauthorized modifications may result in patient harm, such as burn or electrical shock or lead to incorrect patient diagnosis.
- **Caution:** U.S. federal law restricts this device to sale by or on the order of a physician.

[1]Another device than intended per this instruction.

Potential Adverse Event

If, during the use of this device or as a result of its use, an adverse event has occurred, please report it to the manufacturer and to your national authority.

Directions for Use

Before the electrodes are placed it is important to inspect the skin location and make sure the electrode is placed in a dry and clean location that has no small abrasions and wounds. To prepare the skin, it is recommended to clean the skin with alcohol wipes.

1. Place double snap electrodes:
- Middle of the forehead
- Right and left temple at eye level
- Between the temple and the middle of the forehead

2. Connect the electrode snap receptacles to the double snap electrodes that have been applied to the skin (on the temples and forehead), starting with the cable on your right and move to the left side. Make sure that each snap is securely fastened.

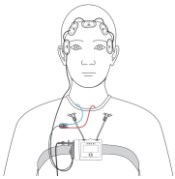
3. Connect the Nox SAS Body Cables to the corresponding color-coded USB-Micro connector on the Nox SAS Head Cable.

4. Connect the cables' device end to the proxy end of the Nox A1s recorder.

Note: Hookup instructions are available on the Nox Medical Support Site which explain the hook up for the lay user.[2]

[2] An electronic copy of the hookup instructions can be found here: https://noxmedical.com/ifu

1.



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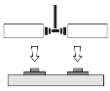

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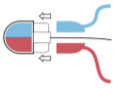

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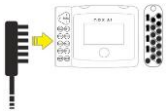

Compatible devices

Nox A1s Recorder	#56 11 21
Nox SAS Body Cable – Right	#56 22 16
Nox SAS Body Cable - Left	#56 22 17

Suitable for use

The following electrodes have been tested with the Nox SAS Head Cable: DyMedix Dual EMG Electrodes.

Cleaning materials/equipment

- Endozime® AW Plus or equivalent validated hospital cleaner
- Lint-free cloths
- Gloves
- Soft bristle nylon brush (i.e. electrode brush, toothbrush, or nail brush)
- PDI Sani-Cloth Plus Germicidal Disposable Cloth or equivalent validated disinfectant*

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Cleaning/Disinfecting procedure:

1. Prepare a solution with the Endozime® AW Plus hospital grade cleaner
   - Follow the instructions accompanying the hospital grade cleaner
2. Dampen a lint-free cloth with the solution
   - Do not immerse the component in liquid
   - Avoid contact of the cleaning solution to component connectors
3. Wipe all surface areas thoroughly to remove all visible soil and contaminants. Wipe the component for at least 2 minutes. Use a soft bristle nylon brush if necessary.
4. Visually inspect the cleaned components to ensure no soil remains. Pay good attention to all junctions and details. Repeat steps 2 and 3 if necessary.
5. Allow components to air dry completely before disinfection (minimum of 3 minutes)
6. For disinfection, take a new wipe of PDI Sani-Cloth Plus Germicidal Disposable Cloth or equivalent validated disinfectant*
7. Wipe all surface areas of the component with the disinfectant for at least three minutes.
   - If other disinfection materials are used than PDI Sani-Cloth Plus Germicidal Disposable Cloth make sure:
     - they are safe to use on metals and plastics
     - to read the instructions from the manufacturer regarding required contact time of the solution to provide sufficient disinfection
8. Allow components to air dry completely before next use (minimum 1 minute)
9. Visually inspect the components under adequate lighting conditions (and magnification if needed) to confirm that the cleaning/disinfection process has not damaged components. Inspect for surface wear, discoloration, corrosion, or cracking. **

* PDI Sani-Cloth Plus Germicidal Disposable Cloth (#55 90 12) is Environmental Protection Agency (EPA) registered product for disinfection of medical devices in the United States of America.

** If any component damage occurs during the cleaning process, contact Nox Medical immediately at support@noxmedical.com. Do not attempt to use the Nox SAS Head Cable until the device has been inspected and repaired by authorized Nox Medical personnel.

Notes:

- All reusable components should be cleaned immediately after use by a health care provider, to prevent accumulation of residual soil and minimize soil transfer between patients.
- Soiled towelettes/cloths should be disposed of as biohazard material in accordance with federal, state, and local regulations.

Maintenance

- Handle the product with care and store it in a clean, dry place.
- Product service life is 6 months, or 100 studies. No regular testing is necessary.

Environmental Conditions

Temperature	Operation: +5°C to +40°C (+41°F to +104°F) Transport/Storage: (-25°C to +70°C (-13°F to +158°F)
Rel. Humidity	Operation: 15-90% (non-condensing) Transport/Storage: 10-95% (non-condensing)
Pressure	Withstands atmospheric pressure from 700 hPa to 1060 hPa

Material Information

- Wire Jacket: Polyvinyl Chloride (PVC)
- Wire: Tinned Copper
- Snap: Nickel plated brass sockets with stainless steel spring wire
- Snap Overmold: TPE (Riteflex®)
- Double USB-Micro Connector Overmold: TPE (Riteflex®)
- Connector Pins in Proxy Connector: Gold-plated contacts
- Proxy Connector Overmold: TPE (Riteflex®)
- Shrink tube: Ethylene Vinyl Acetate (EVA)
- Lanyard: Polyester band with nickel-plated crimp

Disposal

Follow local governing ordinances and recycling instructions regarding disposal or recycling of this product. Please contact your distributor regarding take-back or recycling of the components.

Description of Symbols

	Operating instructions / Consult instructions for use		Temperature limitation
	Manufacturer Information		Humidity limitation
	Country of manufacture and date of manufacture		Atmospheric pressure limitation
	Medical device		Unsafe for MR (Magnetic Resonance) environment
	Batch code / Lot number		Catalogue number / Reference number
	Unique device identifier	**Rx only**	US federal law restricts this device to sale by or on the order of a physician.
	2d barcode carrier for UDI information		

(01)15694311111XXXX
(11)YYMMDD
(10)ZZZZZZ

Unique Device Identifier (UDI); Application Identifier (01) represents the device identifier (DI) (“15694311111XXXX”), the Application Identifier (11) the production date/date of manufacture (“YYMMDD”, with “YY” the last two digits of the production year, “MM” the production month and “DD” the production day), and the Application Identifier (10) the lot number of the device (“ZZZZZZ”) if applicable.

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NOX-ESNAP10SASLEAUS-0100-REV01, 2025-05

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