

INSTRUCTIONS FOR USE CLARAVUE® PATIENT MONITORING

- EC ACCORDING TO EU MDR 2017/745**
- MEDICAL DEVICE**
- UNIQUE DEVICE IDENTIFICATION**
- QUANTITY**
- PHT FREE**
- BPA FREE**
- ROHS COMPLIANT**
- SEPARATE COLLECTION AS WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT**
- CAUTION: U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN**
- X-RAY TRANSLUCENT**
- READ INSTRUCTIONS FOR USE**
- MANUFACTURER**
- DATE OF MANUFACTURER**
- REFERENCE**
- LOT CODE**
- EXPIRY**
- TEMPERATURE LIMITS**
- KEEP AWAY FROM DIRECT SUNLIGHT**
- PROTECT FROM MOISTURE**
- DO NOT USE IF PACKAGING IS DAMAGED**
- MR UNSAFE**
- NOT DEFIBRILLATION PROOF**

CLARAVUE® PATIENT MONITORING

I. DESCRIPTION AND SPECIFICATION
CLARAVUE® PM are prewired electrodes intended for use in electrocardiographic procedures as passive sensors for the derivation of electrical signals from the heart in a hospital setting by qualified medical personnel. The prewired electrodes are pre-gelled, single patient use, non-sterile, and are to be applied on clean intact skin. Intended patient groups are adults, children, and infants.

IDENTIFICATION

Part number	Description	Population	X-ray Compatibility	Combination
50401-US 32028776	CLARAVUE NEONAT/PEDI-ATRIC 3 RT	Children/Infants	Yes	-
50600-US 32028777	CLARAVUE 3 RT	Adult	Yes	50600-US + 50603-US
50601-US 32028778	CLARAVUE 5 RT	Adult	Yes	50601-US + 50604-US
50602-US 32028779	CLARAVUE 12 RT	Adult	Yes	-
50603-US 32028780	CLARAVUE 6 RT	Adult	Yes	50600-US + 50603-US
50604-US 32028781	CLARAVUE 5C RT	Adult	Yes	50601-US + 50604-US

CLARAVUE® PM product family meets the requirements of the standard, ECG TRUNK CABLES and PATIENT LEADWIRES (ANSI/AAMI EC53). CLARAVUE® PM is intended for SINGLE-PATIENT USE.

Performance Characteristics

Gel type	Adhesive hydrogel
Sensor	Ag/AgCl
Adapter/Connector	Integrated leadwire
Compatibility	IP Cable & Leadwire product range
Wear time	Up to 24 hours
Shelf-life	24 months

II- GENERAL WARNING AND SAFETY PRECAUTIONS

Contraindications for Use

There are no specific contraindications known for using the product.

Warnings and safety precautions



- **CLARAVUE® PM** is for single-patient-use only and must not be used on multiple patients. Use on other patients can cause patient infection or cross-infection.
- **CLARAVUE® PM** must be used on intact (non-injured) skin only.
- MR Unsafe – These **CLARAVUE® PM** should not be operated in magnetic resonance imaging environments.
- These **CLARAVUE® PM** are not Defibrillation Proof.
- This product can only be used by trained personnel familiar with the proper placement and use of the electrodes.
- Make sure to carefully read this instruction for use, as well as the ones of the other medical devices that may be used along.
- Make sure to check the integrity of the packaging before use. Look for tears on the pouch or the sealing. Discard the product if there are any marks of damage.
- Do not use a product found in packaging which expiry date has passed.
- Do not modify the product.
- Do not soak, rinse, or sterilize this device as it may cause malfunction of the device.
- U.S. federal law restricts this device to sale by or on the order of a physician.
- Report any serious incident that occurred in relation to the device to the manufacturer at **FRquality@nisshamedical.com** and to the competent authority of the Member State where the hospital is established.

III- INSTALLATION / USE / CLEANING / MAINTENANCE / DISPOSAL

SELF HANDLING AND PREPARATION:

- Remove excess hair from the electrode sites to ensure maximal contact
- Clean the electrode sites with mild soap and water or a non-alcoholic wipe
- Make sure that the skin is completely dry before the application of the electrodes.
- If necessary, perform a light exfoliation of the skin gently to improve the adherence of the product.

APPLICATION/ USE:



- Check the product for physical damage before use.
- The product should be replaced if the electrodes no longer stick firmly to the skin.

1. Open the single **CLARAVUE® PM** patient kit only immediately before use. Remove inner bag. Unwind sets from the holder card.
2. Check if the electrodes are undamaged. In case of any damage, discard the product.
3. Gently remove electrode sets from the release liner by peeling away from the thumb tab.
4. Place the electrodes on the patient.
5. Connect the set of leadwires to the appropriate trunk cable from **IP Cable & Leadwire** product range.
6. When applicable, close the bag carefully so that the remaining electrodes do not dry out.
7. Start ECG recording. If the ECG trace is not acceptable, check that the electrodes are positioned correctly and well attached to the skin. If the trace is still not acceptable, discard the product and place a new one.

REMOVAL:



- Uncareful removal of electrodes can cause skin irritation.

1. Unplug the set of leadwires from the trunk cable.
2. Carefully remove the electrodes from the patient's skin. Keep the electrode close to the skin surface as you pull it back and support the skin with a finger immediately adjacent to the adhesive being removed.
3. If the electrodes are difficult to remove, use water to dissolve the adhesive.
4. Gel residue can be removed using paper towels or water.
5. To minimize the risk of skin irritation, find a new area of skin on which to place the electrodes when repositioning the product.
6. Throw away the product after use (see "Disposal").

PACKAGING / STORAGE:

• The **CLARAVUE® PM** should be stored in the original packaging, in temperature ranging from 15 to 35° C, protected from the sunlight, dampening, and dirt. After the packaging is opened, unused electrodes should be left in the original packaging and secured by folding an edge of the packaging. When opened, the product must be used immediately.

MANUAL CLEANING / DISINFECTING:

• The **CLARAVUE® PM** must not be reprocessed. Please discard after use.

MAINTENANCE:

• The **CLARAVUE® PM** must not be repaired. Please discard any defective product.

DISPOSAL:

• Discard the product after duration of use on one patient, or immediately discard if any damage or deterioration is observed.
• The **CLARAVUE® PM** should be disposed of according to hospital waste policies and procedures.