Reprocessed by

Sustainability Solutions

Instructions for Use
Reprocessed ECG 3-Lead Set and 5-Lead Set

Reprocessed Device for Single Use

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

- **NON-STERILE (Exposed to EO gas)**
- **Not made with natural rubber latex**

Explanation of Symbols


Date of Reprocessing

Batch Code

Catalog Number


Do Not Reuse


Consult Instructions for use

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Reprocessed ECG 3-Lead Set and 5-Lead Set

Reprocessed ECG Lead Set Description

(Philips: 989803173121, 989803173131, 989803173141, 989803173151, 989803192141)

- Reprocessed ECG lead sets for bedside monitoring are available in 3-lead and 5-lead set configurations. The 5-lead limb and 5-lead chest lead sets can be used simultaneously to measure limb and chest ECG.
- Reprocessed telemetry leads include a shower shield and are available in 3-lead and 5-lead versions.
- Reprocessed leads terminate with a color-coded and labeled grabber, and have a peel-apart ribbon-style cable.

Indications for Use

The Reprocessed ECG Lead Sets are intended for use only by trained healthcare professionals for measurement of a patient's ECG for both diagnostic and monitoring purposes. Use is limited by the indications for use of the connected monitoring or diagnostic equipment. These Reprocessed Lead Sets are intended for short-term use only (an average patient stay of 5 days).

Contraindications for Use

Reprocessed ECG Lead Sets are contraindicated for:

- None

Warnings

- Refer to the IFU for the monitor/defibrillator for additional warning and cautions.
- Refer to the IFU for the monitor/defibrillator for information regarding proper lead/electrode placement that complies with standard AAMI or IEC practices.
- For Single-patient use only. Do not use on multiple patients. Multi-patient use may result in patient infection or cross-infection.
- Ensure that the patient is properly grounded during electro-surgical (ESU) or defibrillation procedures.
- Reprocessed leads can be used in the operating room only if used with the OR trunk cable.
- Do not use ECG leads and cables in magnetic resonance imaging (MRI) environments or during MRI procedures.
- Ensure that lead sets are carefully positioned to avoid entanglement, choking, and strangulation.
- For telemetry applications, be sure to use telemetry lead set that has the included protective shield over the trunk connector.

Precautions

- Inspect lead sets prior to use. Do not use if visual inspection reveals damage from liquid, lint or other contaminants.
- Ensure that lead set is fully and properly inserted into trunk cable or instrument.
- Do NOT use lead set in excessively wet environments or under massive influence of fluids (e.g. rain).

Adverse Reactions

- None

Compatibility

These Reprocessed ECG leads are compatible with the Philips M8105A (IntelliVue MP5) monitor plus many validated Philips monitors or defibrillators (such as IntelliVue MP monitors, IntelliVue MX monitors, ECG and MMS Modules, VM monitors, HeartStart defibrillators) when used with an IntelliVue trunk cable. IntelliVue ECG lead sets and trunk cables can be used with an ECG monitor or defibrillator for which they are listed as accessories in that product's IFU. Telemetry leads can be used with Philips patient-worn devices with an IntelliVue-style connection. Other leads and monitor combinations are not recommended.

Reprocessed ECG 3-Lead Set and 5-Lead Set

Warranty

Reprocessed Products

Stryker warrants all reprocessed products, subject to the exceptions provided herein, to be free from defects in reprocessing and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for one use in accordance with the instructions for use of such product.

STRYKER SHALL NOT BE LIABLE FOR ANY DAMAGES TO THE EXTENT CAUSED BY ANY DEFECT IN MATERIAL, WORKMANSHIP OR DESIGN BY THE ORIGINAL MANUFACTURER OF THE PRODUCT OR ANY ACT OR OMISSION OF THE ORIGINAL MANUFACTURER OF THE PRODUCT.

Products for which Stryker is the Original Manufacturer

Stryker warrants all products for which it is the original manufacturer, subject to the exceptions provided herein, to be free from defects in design, materials and workmanship and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for a period of one year from the date of purchase.

General Warranty Terms Applicable to All Products

TO THE FULLEST EXTENT PERMITTED BY LAW, THE EXPRESS WARRANTY SET FORTH HEREIN IS THE ONLY WARRANTY APPLICABLE TO THE PRODUCTS AND IS EXPRESSLY IN LIEU OF ANY OTHER WARRANTY BY STRYKER, EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL STRYKER'S LIABILITY ARISING IN CONNECTION WITH THE SALE OF THE PRODUCT (WHETHER UNDER THE THEORIES OF BREACH OF CONTRACT, TORT, MISREPRESENTATION, FRAUD, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR ANY OTHER THEORY OF LAW) EXCEED THE PURCHASE PRICE, CURRENT MARKET VALUE OR RESIDUAL VALUE OF THE PRODUCTS, WHICHEVER IS LESS. STRYKER SHALL NOT BE LIABLE FOR INDIRECT, SPECIAL, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES RESULTING FROM ANY BREACH OF WARRANTY OR UNDER ANY OTHER LEGAL THEORY.

This warranty shall apply only to the original end-user purchaser of products directly from Stryker or a Stryker authorized distributor. This warranty may not be transferred or assigned without the express written consent of Stryker.

This warranty does not apply to: (1) products that have been misused, neglected, modified, altered, adjusted, tampered with, improperly installed or refurbished; (2) products that have been repaired by any person other than Stryker personnel without the prior written consent of Stryker; (3) products that have been subjected to unusual stress or have not been maintained in accordance with the instructions in the user manual or as demonstrated by a Stryker representative; (4) products on which any original serial numbers or other identification marks have been removed or destroyed; or (5) products that have been repaired with any unauthorized or non-Stryker components.

If a valid warranty claim is received within thirty (30) days of the expiration of the applicable warranty period, Stryker will, in its sole discretion: (1) replace the product at no charge with a product that is at least functionally equivalent to the original product or (2) refund the purchase price of the product. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property. In any event, Stryker's liability for breach of warranty shall be limited to the replacement value of the defective or non-conforming part or component.

If Stryker determines in its reasonable discretion that the claimed defect or non-conformance in the product is excluded from warranty coverage as described hereunder, it will notify the customer of such determination and will provide an estimate of the cost of repair of the product. In such an event, any repair would be performed at Stryker's standard rates.

Products and product components repaired or replaced under this warranty continue to be warranted as described herein during the initial applicable warranty period or, if the initial warranty period has expired by the time the product is repaired or replaced, for thirty (30) days after delivery of the repaired or replaced product. When a product or component is replaced, the item provided in replacement will be the customer's property and the replaced item will be Stryker's property. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property.

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The OEM information listed on the label is provided as device ID prior to reprocessing and may contain the trademarks of unrelated third parties that do not sponsor this device.

This product and its packaging have been exposed to ethylene oxide gas (EtO). Even though the product then is processed in compliance with all applicable laws and regulations relating to EtO exposure, Proposition 65, a State of California voter initiative, requires the following notice:

Warning: This product and its packaging have been exposed to ethylene oxide. The packaging may expose you to ethylene oxide, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.

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