

Reprocessed by



Sustainability Solutions

Instructions for Use








Reprocessed Stanley® Bed Alarm Sensormat® Pad Exposed to Vaporized Hydrogen Peroxide (VHP)

Reprocessed Device for Single Patient Use

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

- NON-STERILE
- Not made with natural rubber latex

Explanation of Symbols

Symbol	Rules/ Standard Reference	ISO 7000 Registration Number	Symbol Title	Description
Rx Only	21CFR801	N/A	Prescription only	Indicates Federal (USA) law restricting device to sale by or on order of a physician
	ISO 15223-1 Clause 5.1.1	3082	Manufacturer	Indicates the medical device manufacturer
	ISO 15223-1 Clause 5.2.7	2609	Non-Sterile	Indicates a medical device that has not been subjected to a sterilization process.
	ISO 15223-1 Clause 5.1.3	2497	Manufacturing Date (Reprocessing Date)	Indicates the date which the medical device is manufactured
	ISO 15223-1 Clause 5.1.6	2493	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1 Clause 5.1.5	2492	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1 Clause 5.4.3	1641	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	ISO 15223-1 Clause 5.4.2	1051	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

Reprocessed Stanley® Bed Alarm Sensormat® Pad Description

The Reprocessed STANLEY® Bed Alarm Sensormat® Pads are sensor pads designed for use with STANLEY® Fall Alarms to detect when a patient has taken weight off the sensor to help notify nurses and caregivers that the patient has gotten up from a sitting or resting position.

Indications for Use

The Stryker Sustainability Solutions Reprocessed STANLEY® Bed Alarm Sensormat® Pads are designed to sense body-weight distributed over an area to detect when the patient lifts off the bed.

Warnings and Precautions

- Read all instructions carefully prior to use. Failure to do so could result in injury of a person in your care.
- Always test the system before each use.
- Model 74010FA Sensormat® pads are not recommended for persons weighing less than 80 lbs.
- Model 74030 and 92010 Sensormat® pads are not recommended for persons weighing less than 70 lbs.
- Sensormat® pads can be defeated by a cognitively aware person, a person with only a few moments of lucidity or an uncooperative person. Properly assess each individual before a Sensormat® pad is used.
- The device should not be considered a substitute for routine staff visual monitoring consistent with your facility protocols or other regulations.
- Keep the Sensormat® pad flat at all times. Do not bend, fold, roll, submerge in liquid, or tamper with Sensormat® pad. If the Sensormat® pad is folded, it may not function properly.
- Sterilization by heat, gas or radiation voids all warranties.
- For model 74030, use only with STANLEY® Healthcare M200, Bed-Check®, UMP® or Micro-Tech® brand fall monitors.
- For model 74010FA, use only with STANLEY® Healthcare M200 or Bed-Check® brand fall monitors.
- For model 92010, use only with Bed-Check®, UMP® or Micro-Tech® brand fall monitors.
- For single patient use only.
- Only incontinence pads and mattress covers should be placed between pad and patient.
- For model 74010FA, using enclosed elastic bands and clips, secure the pad to bedsprings, bed frame, or mattress piping.
- Route the cable to the monitor so that it does not cross the pad surface, is not a trip hazard, and cannot be damaged by bed or gurney mechanisms.
- Follow the Monitor User Guide procedures to connect the pad's cable, and to test system functions.
- Before each use and then daily thereafter, test system functions and check the pad's expiration date. If any test fails or the pad has expired, discard the pad and DO NOT place it into service.
- Sensormat® pads may not be effective with air type bed mattresses or air type chair cushion pads; test before using.
- Operators of this equipment must be familiar with the functions and usage described in the Monitor User Guide, and must be properly trained in the resident care policies and procedures of the facility.

Directions for Use

1. Read all Sensormat® pad and alarm instructions prior to use.
2. Check that Sensormat® pad, cord, and plug are clean and undamaged. Discard entire sensor if there is any damage.
3. When putting sensor pad into use, record the first use date and calculate expiration date from initial use.
4. Place the Sensormat® pad across the width of the bed, on top of the mattress with the labeled side up.
5. The preferred pad location is directly under the patient/resident's buttocks 8 to 13 cm (three to five inches) below the bend in the mattress when the head of the bed is elevated (refer to Figure 1).
 - a. Effective operation of the Sensormat® pad in the alternative location, behind the patient/resident's back, is dependent upon their weight and the articulation angle of the bed (refer to Figure 1).
6. For model 74010FA, secure the Sensormat® pad to the bedsprings, bed frame, or mattress piping with attached clips.
7. Plug the Sensormat® pad into the fall monitor and test before using (refer to Directions for Testing Sensormat® Pad).

Directions for Testing Sensormat® Pad

1. Plug the Sensormat® pad into the alarm monitor.
2. Apply FULL and FIRM palm pressure with your hand to the Sensormat® pad, and then remove pressure to make sure local audible alarm is functioning properly.
3. Repeat this pressure/release test in several different areas along the entire length of the sensor pad to ensure entire sensor pad functions properly.
4. If nurse call is used, make sure connections are properly made and functioning correctly.

Storage and Handling

- This device is designed for use in normal indoor environments.
- This device may be stored in ambient warehouse temperatures at normal humidity levels. Avoid excess moisture or high humidity that may damage product materials.

Compatibility

- For model 74030, use only with STANLEY® Healthcare M200, Bed-Check®, UMP® or Micro-Tech® brand fall monitors.
- For model 74010FA, use only with STANLEY® Healthcare M200 or Bed-Check® brand fall monitors.
- For model 92010, use only with Bed-Check®, UMP® or Micro-Tech® brand fall monitors.

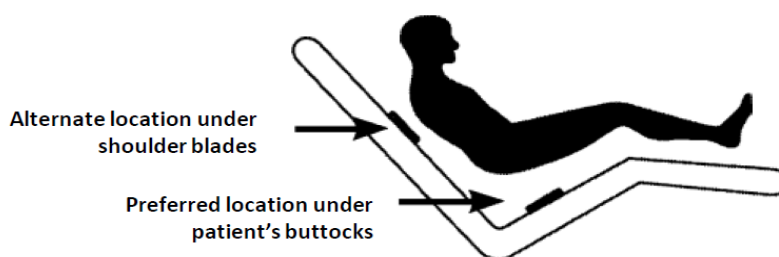


Figure 1 – STANLEY® Bed Alarm Sensormat® Pad Positioning

Warranty

74030 - This product is warrantied for up to 14 days from recorded "in-use date," in accordance with Stryker's standard limited warranty.

74010FA - This product is warrantied for up to 30 days from recorded "in-use date," in accordance with Stryker's standard limited warranty.

92010 - This product is warrantied for up to 45 days from recorded "in-use date," in accordance with Stryker's standard limited warranty.

Reprocessed Products

Unless agreed otherwise in writing, 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 LAIBLE 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; (5) products that have been repaired with any unauthorized or non-Stryker components; or (6) failure to follow the instructions for use.

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.

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.

Warning: This product can expose you to chemicals including Nickel, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

Sensormat®, STANLEY®, Bed-Check®, UMP®, and Micro-Tech® are registered trademarks of STANLEY® Security Solutions, Inc.

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