



Urgent Field Safety Notice

ROHO® HIGH PROFILE® Single Compartment Cushion with Sensor Ready™ Technology
ROHO® MID PROFILE™ Single Compartment Cushion with Sensor Ready™ Technology
FSCA-identifier : MDD17.062

Date: March 14, 2017

Attention:

Details on affected devices:

ROHO® HIGH PROFILE® Single Compartment Cushion with Sensor Ready™ Technology (Sensor Ready Cushion) and ROHO® MID PROFILE™ Single Compartment Cushion with Sensor Ready™ Technology (Sensor Ready Cushion) with production dates from **January 8, 2016 to February 28, 2017**. Only cushions with one of the attached model numbers and a serial number falling between **A2920163 and A3185287** are affected (see Annex A for model numbers).

NO OTHER ROHO PRODUCTS ARE AFFECTED BY THIS NOTICE.

Description of the problem:

A problem was discovered internally with a supplied component for the affected products listed above. When a Smart Check® by ROHO® (Smart Check), model number SMARTCHECK-01, is used to perform a Smart Setup with one of the affected cushions, the nonconforming part may adversely affect the setup process resulting in an improper cushion setup. Sitting on an over inflated or under inflated Sensor Ready Cushion may reduce or eliminate the benefits provided by the cushion, increasing the risk to skin or to other soft tissue. It is a highly unlikely scenario where this would happen, however, in an abundance of caution, ROHO, Inc. is notifying the market.

This risk is not present when the Sensor Ready Cushion is used without the Smart Check.

This risk is not present when the Sensor Ready Cushion is used with the Smart Check and the setup is performed using the Optional Setup mode.

Shipping Address: 1501 S. 74th Street, Belleville, IL 62223 USA
Corporate Address: 100 N. Florida Avenue, Belleville, IL 62221 USA
ROHO.com

Phone: (618) 277-9173
Toll Free: (800) 851-3449



Advice on action to be taken by the user:

If you are using the Sensor Ready Cushion without a Smart Check, no action is needed.

If you are using the Sensor Ready Cushion with a Smart Check:

1. Perform a new setup on your Sensor Ready Cushion, using either:
 - a) an Optional Setup per the original instructions for use

OR

- b) a Smart Setup per the original instructions in the operation manual, followed by a hand check to confirm proper setup. Hand Check instructions are listed below.
2. Follow the original warnings and cautions on the product labelling and in the instructions for use. Information for safety that is applicable to this Field Safety Notice is listed in Annex B.
3. If you would like a copy of your instructions for use, contact your supplier, dealer or distributor.

Contact your supplier / dealer / distributor to either:

1. Notify them you would like to keep your current cushion and will follow the instructions in this Field Safety Notice when performing a Smart Setup using a Smart Check.

OR

2. Notify them you would like a replacement cushion sent, free of charge, that does not require use of the instructions in this Field Safety Notice for the Smart Setup process. Be sure to reference this Field Safety Notice as part of your request.

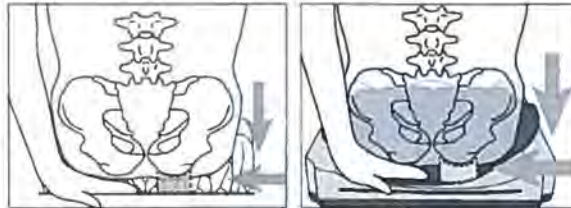


Hand Check Instructions

A hand check is required after performing Smart Setup with a Sensor Ready Cushion that has been identified in this notice.



Before you perform a hand check, refer to important safety information and read the warning about using an under-inflated cushion or an over-inflated cushion.



Make sure that there is at least a 1/2 in. (1.5 cm) of air supporting the individual's bony prominences.

1. Place your hand between yourself and the cushion. Feel for the lowest bony prominence. You should be able to slightly move your fingertips.
2. If it feels like the cushion has too much air or not enough air, perform a HARD RESET and perform a new setup using the Optional Setup instructions.

Transmission of this Field Safety Notice: (if appropriate)

This notice needs to be passed on all those who need to be aware within your organization or to any organization or customer where the potentially affected devices have been transferred. (If appropriate)

Please transfer this notice to other organizations and customers on which this action has an impact. (If appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. (if appropriate)

Complete the attached Acknowledgement Form and return it to ROHO to show that you have received this notice and all applicable transmissions are complete. See Annex C.

Contact reference person:

Robin Gergen / ROHO, Inc., 100 North Florida Avenue, Belleville, IL 62220.
Email: robin.gergen@permobil.com

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The undersigned confirms that this notice has been sent to the appropriate Regulatory Agency.

There have been no reported injuries related to the quality issue on the supplied component. ROHO, Inc. takes the safety of its customers seriously and strives to provide only the highest quality of products.

Sincerely,



Robin Gergen
Director of Quality and Regulatory Compliance

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Annex A

Model Numbers			
1R1010H-CA-SC	1R109M-CA-SR	1R1211H-CH-SR	1R88H-CA-SR
1R1010H-CA-SCDM	1R109M-CF-SR	1R1212H-CA-SR	1R88H-CF-SR
1R1010H-CA-SR	1R109M-CH-SR	1R1212H-CH-SR	1R88H-CH-SR
1R1010H-CF-SCDM	1R1110H-CA-SC	1R129H-CA-SR	1R88M-CA-SR
1R1010H-CF-SR	1R1110H-CA-SR	1R1310H-CA-SR	1R88M-CF-SR
1R1010H-CH-SR	1R1110H-CF-SR	1R1310H-CF-SR	1R89H-CA-SR
1R1010M-CA-SC	1R1110H-CH-SC	1R1311H-CA-SR	1R89H-CF-SR
1R1010M-CA-SCDM	1R1110H-CH-SR	1R1311H-CH-SR	1R89M-CA-SR
1R1010M-CA-SR	1R1110M-CA-SR	1R1411H-CA-SR	1R89M-CF-SR
1R1010M-CF-SCDM	1R1110M-CF-SR	1R1411H-CF-SR	1R910H-CA-SR
1R1010M-CF-SR	1R1110M-CH-SC	1R1511H-CA-SR	1R910H-CF-SR
1R1010M-CH-SR	1R1110M-CH-SR	1R66H-CA-SR	1R910H-CH-SC
1R1011H-CA-SC	1R1111H-CA-SC	1R66H-CF-SR	1R910H-CH-SR
1R1011H-CA-SR	1R1111H-CA-SR	1R67H-CF-SR	1R910M-CA-SR
1R1011H-CF-SR	1R1111H-CF-SR	1R77H-CA-SR	1R910M-CF-SR
1R1011H-CH-SC	1R1111H-CH-SC	1R77H-CF-SR	1R911H-CA-SC
1R1011H-CH-SR	1R1111H-CH-SR	1R77M-CA-SR	1R911H-CA-SR
1R1011M-CA-SC	1R1111M-CA-SR	1R77M-CF-SR	1R911H-CF-SR
1R1011M-CA-SR	1R1111M-CF-SR	1R78H-CA-SR	1R911H-CH-SR
1R1011M-CF-SR	1R1111M-CH-SR	1R78H-CF-SR	1R98H-CA-SR
1R1012H-CA-SR	1R1112H-CA-SR	1R78M-CA-SR	1R98H-CF-SR
1R1012H-CF-SR	1R1112H-CF-SR	1R78M-CF-SR	1R99H-CA-SC
1R1012H-CH-SR	1R1112H-CH-SR	1R79H-CA-SR	1R99H-CA-SCDM
1R108H-CA-SR	1R119H-CA-SC	1R79H-CF-SR	1R99H-CA-SR
1R108H-CF-SR	1R119H-CA-SR	1R810H-CA-SR	1R99H-CF-SCDM
1R109H-CA-SCDM	1R119H-CF-SR	1R810H-CF-SR	1R99H-CF-SR
1R109H-CA-SR	1R1210H-CA-SC	1R810M-CA-SR	1R99H-CH-SR
1R109H-CF-SCDM	1R1210H-CA-SR	1R87H-CA-SC	1R99M-CA-SR
1R109H-CF-SR	1R1210H-CF-SR	1R87H-CA-SR	1R99M-CF-SR
1R109H-CH-SC	1R1210H-CH-SR	1R87H-CF-SR	1R99M-CH-SR
1R109H-CH-SR	1R1211H-CA-SR		

Annex B



General Cushion Safety Information

- Skin/soft tissue breakdown can occur due to a number of factors, which vary by individual. Check skin frequently, at least once a day. Redness, bruising, or darker areas (when compared to normal skin) may indicate the beginning of soft tissue breakdown and may need to be addressed. If there is any discoloration to skin/soft tissue, **STOP USE** immediately. If the discoloration does not disappear within 30 minutes after disuse, immediately consult a healthcare professional.
- **DO NOT** use an under-inflated cushion or an over-inflated cushion because the product benefits will be reduced or eliminated, resulting in an increased risk to skin and other soft tissue. If the cushion does not appear to be holding air, or if you are not able to inflate or deflate the cushion, see **TROUBLESHOOTING**. Immediately contact your clinical caregiver, distributor, or ROHO, Inc. if the problem persists.
- Check inflation frequently, at least once a day!
- ROHO medical products are intended to be part of an overall care regimen. ROHO, Inc. recommends that a clinician make product recommendations based upon an evaluation of the individual's medical and therapeutic needs and overall condition (for example, potential allergic reactions). Use of this device does not eliminate routine inspection of the product and all normal activities associated with skin and soft tissue protection (weight shifts, skin inspection, overall skin care, etc.)

Proper Cushion Inflation Setting: A) sink down into the cushion and B) "float" above the cushion base.



= 1/2" - 1" (1.5 cm - 2.5 cm)

recommended distance between the individual and the seating surface.



Annex C

ACKNOWLEDGEMENT FORM

PLEASE FILL OUT AND RETURN to:

Robin Gergen / ROHO, Inc., 100 North Florida Avenue, Belleville, IL 62220.
Email: robin.gergen@permobil.com

Product Name:

ROHO® HIGH PROFILE® Single Compartment Cushion *with Sensor Ready™ Technology*
ROHO® MID PROFILE™ Single Compartment Cushion *with Sensor Ready™ Technology*

Model Numbers: See Annex A of Field Safety Notification

Serial Numbers: A2920163 and A3185287

Verification/Effectiveness Check (Select 1):

- ☐ We have forwarded this notice to all affected organizations and customers.
- ☐ We have not forwarded this notice because we have not distributed affected product.

SIGNATURE: _____

NAME: _____ TITLE: _____

COMPANY NAME: _____

ADDRESS: _____

CITY: _____ STATE: _____ ZIP CODE: _____

COUNTRY: _____

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