

URGENT FIELD SAFETY NOTICE

HCM FSN 002

HCM Ref.: **QA6861_6862**

Date: February 27, 2018

For the Attention of: Users of WheelDrive™

Applicability:

This FSN applies to WheelDrive™ A Manual Wheelchair powered assist system manufactured and sold by Sunrise Medical HCM (formerly known as Handicare B.V.) and manufactured prior to March 2017 and within the following serial number range:

Model: WheelDrive	Serial Numbers:
Article Nos 9007928, 9007929, 1018154, 1018155	From 1506SN00123 to 1704RW01761

Action required

Our records show that you have received WheelDrives within the serial number range shown above.

The product can be identified by the name Handicare or Quickie WheelDrive on the battery lever and the printed serial number on the serial label, affixed under the battery pack.

Reason for Action

UPGRADE/REPLACEMENT OF Handrim & Software

Via the Post Market Surveillance process, Sunrise Medical has identified an area of concern, where the WheelDrive product can sometimes operate unintentionally. There have been no reported incidents; however we have enough defective returns to analyze this as a potential safety issue. There are two potential issues:

1. A batch of User Interface foils (for the potentiometer wiper) could mislead drive signals
 Correction: User Interface software update that corrects the misleading signals by constantly monitoring the status and will put the WheelDrive in fault mode if the misleading signals are present

HCM FSN 002 continued

2. All mounting plates on the drive hand-rim are susceptible to having the lip for the operation spring break off. This can lead to a unit that could continue to operate when you let go of the drive hand rim
 - a. Correction 1: The lip is now produced with an extra weld to reinforce the bend to prevent breakageCorrection 2: Software update for the Motor Controller now provides a means to override any drive signal to the drive hand-rim by any movement of the large hand-rim (known as the assist rim)

Sunrise has performed a risk analysis of the situation, and determined that the occurrence and risk of injury is low however action is required and even though we determine the risk of injury is very low, we have decided a Field Safety Corrective Action is necessary to reduce the risk further.

Sunrise Medical also wishes to state that based upon the risk analysis it has performed the affected WheelDrive's can continue to be used as intended until they have been rectified.

Please be aware of the following:

That we will be carrying out one or more of the following corrective actions:

- Units which have the user foils that can mislead the drive signal we shall be updating the software. This software will constantly monitor the signal and will put the WheelDrive in fault mode if the misleading signals are present.
- To correct the second reason will shall be adding a second weld to reinforce the bend to prevent breakages
- We shall also update the software for the Motor Control this shall provide a means to override any drive signal to the drive handrim by any movement of the large handrim

We shall therefore be contacting you as you have purchased a unit through our distributors in the UK & Eire to arrange a visit to carry out the corrective action required.

Please check your service history records for each WheelDrive serial number and respond to the questions asked in the FSN response form.

Please also use the FSN Receipt/Response Form below to inform us of your understanding of this notification and any changes in ownership or end of life for the WheelDrive

Transmission of this Field Safety Notice:

Please ensure that the information in this notice is made available to all relevant personnel within your organisation and / or customer base, and that awareness is maintained for an appropriate period.

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



FSN Receipt / Response Form

FIELD SAFETY NOTICE: HCM/FSN002

Date:

To ensure receipt of the important safety information contained in the above FSN to all persons necessary, Sunrise Medical requires positive feedback as confirmation.

I, _____, acknowledge I am in receipt of the above FSN.

The WheelDrive serial Number/s are:

(please indicate which option applies)

Still in service Y/N

No longer in service Y/N

Ownership changed Y/N if yes are details of new owner known Y/N

Date completed: __/__/__

Completed by: _____

Signature: _____

Please return this completed form to

Please return this completed form to Sunrise Medical

By faxing to 01384 6056689 or emailing to: jeremy.fletcher@sunmed.co.uk