autochair	*FIELD SAFETY NOTICE*	FSN Doc No.	FSN-0001
		Issue Date	27/10/17

Affected Product	**SmartBase**
Product Code	**9934100**
Manufacture Dates	February 2012 to August 2017
Serial Numbers	All
MHRA Reference	**2017/008/015/601/007**
Autochair Reference	AC-FSN-001-MHRA
Type of Action	**Retrofit of Fail-safe Device**

Who is this intended for?

This FSN is intended for distributors, agents, dealers and end users.

Details on the affected device:

The SmartBase manufactured by Autochair Ltd is used in conjunction with the Milford Person Lift to provide a Person Lift solution. It is used to transfer users between a seat and a wheelchair and is for home use only. When not in use the device can be folded.

This FSN applies to all SmartBase units manufactured by Autochair Ltd.

SmartBase - 9934100	In Use	Folded

Background:

The combination of a weak spring and incorrect alignment of the locking pin for latching the leg positions in the intended operating positions has led to the legs closing fully when a side load is applied to the legs. This has caused the legs to close fully to the stowed position, causing the device to become unstable and the patient to fall.

Although there have been no other related incidents reported for any of the devices already in use (632 units), Autochair has identified that this could also occur if the pin becomes worn, and it therefore represents a potential risk to all users of the device.

Health Hazard Analysis:

The collapse of the unit will lead to a user fall. The product is of metal construction and, by nature of the shape of the device, has a number of edges and sections which may press or scrape against the user during the fall. This in most cases, may only cause cuts, scrapes or bruising to the user or the operator. This will however depend on the surroundings at the location of the fall which may cause further injury.

Advice on action to be taken by the user:

- Check the operation of the locking mechanism and, if there is any concern over the use of the device, remove it from service.
- Autochair Ltd will provide a Retrofit Fail-safe Kit which can easily be installed on all the SmartBase units.
- Upon receipt of the Retrofit Fail-safe Kit, follow the instructions provided to complete the install on the SmartBase.
- Check the Kit is fitted and operating correctly by following the checking procedure detailed in the instructions.
- If it is not possible to fit the kit, it cannot be made to operate correctly, or there are any further concerns over the correct operation of the device, refer to the contact section for the number to call.
- Complete and return the Customer Response Form which will have been provided with the Kit and Instructions.
- **Even if you do not have a SmartBase, please complete the Customer Response Form indicating such and return to Autochair Ltd, 1 Olympic Way, Wembley, Middlesex, HA9 0NP using the prepaid envelope provided.**

Transmission of this Field Safety Notice:

For distributors, agents and dealers, this notice needs to be passed on to all end users that have been provided with the SmartBase device, along with the Retrofit Fail-safe Kit and the fitting instructions and Customer Response Form.

Each Smartbase end user will be provided with:

1. This Field Safety Notice
2. An instruction manual, detailing;
   - How to install the Retrofit Failsafe Kit
   - How to check the Retrofit Failsafe Kit is installed correctly
   - How to operate the Smartbase when fitted with the Retrofit Failsafe Kit
3. The Retrofit Failsafe Kit
4. An Allen Key for tightening the clamp
5. A Customer Response Form
6. A prepaid envelope for the return of the completed Customer Response Form.

autochair	*Customer Response Form*	CRF Doc No.	CRF-0001
		Issue Date	6/11/2017

Affected Product	**Smartbase**
Product Code	**9934100**
Manufacture Dates	February 2012 to August 2017
Serial Numbers	All
MHRA Reference	**2017/008/015/601/007**

Please review and check [✓] all statements that apply;

1.	I do not have any Smartbase units manufactured by Autochair Ltd	[ ]
2.	I have a Smartbase unit and it is in regular use	[ ]
3.	I have a Smartbase unit but it is not used	[ ]
4.	I have checked the Smartbase and believe it is functioning correctly	[ ]
5.	I have a Smartbase unit but I am unable to fit the Retrofit Failsafe kit provided	[ ]
6.	I have installed the Retrofit Failsafe Kit but cannot get it to function as intended	[ ]
7.	I have installed the Retrofit Failsafe Kit and it functions as intended	[ ]

If you have checked item 5 or 6 above please contact Autochair Ltd, 1 Olympic Way, Wembley, Middlesex, HA9 0NP, or call 03301595270 for more information.

For end users only;

Customer Name	
Post Code	
Country	
Serial Number (if known)	
Date	
Signature	

Please complete this form within 14 days of receipt and return in the prepaid envelope provided.

Thank you for your time and cooperation.