


URGENT FIELD SAFETY NOTICE

Configura Advance Chair

Date:	21 June 2021	
Product Issue:	Risk of backrest becoming detached from chair	
Affected Product:	All Configura Advance Chair models	
Affected Serial No.	See table in the Affected Product section below	
Resolution:	Product modification	
Field Safety Notice:	FSN-2021-FA003	

For the Attention of: End Users, Distributors, Dealers

Affected Product:

The following devices are affected by this Field Safety Corrective Action:

Model Number	Description	Serial Number / Batch	Qty (in field)
CHAIR-0-SC1-030	Advance Chair, 100mm Castors, Std Backrest, Manual	10001-SC1-20 to 10483-SC1-20 10001-SC1-21 to 10224-SC1-21 10231-SC1-21 to 10456-SC1-21 10481-SC1-21 to 10570-SC1-21	UK: 544 IE: 24
CHAIR-0-SC2-030	Advance Chair, 100mm (4in) Castors, Std Backrest, Electric	10001-SC2-20 to 10135-SC2-20 10001-SC2-21 to 10240-SC2-21	UK: 154 IE: 3
CHAIR-0-SC3-050	Advance Chair, 125/150mm (5in/6in) Castors, Standard Backrest, Manual	10116-SC3-20 to 10145-SC3-20 10236-SC3-20 to 10295-SC3-20 10001-SC3-21 to 10090-SC3-21 10271-SC3-21 to 10360-SC3-21	AUS: 270
		10001-SC3-20 to 10115-SC3-20 10146-SC3-20 to 10235-SC3-20	USA: 122
CHAIR-0-SC4-050	Advance Chair, 125/150mm (5in/6in) Castors, Standard Backrest, Electric	10001-SC4-20 to 10030-SC4-20	AUS: 30

Description of the problem:

As part of our ongoing post market surveillance, Accora has identified a potential problem with the attachment of the backrest to the chair. We have received one notification where the backrest has become detached from the chair. Accora have received no reports of any injuries associated with this issue.

As a precaution, we have decided to carry out a voluntary modification to all chairs. The corrective action will be to fit a modification kit to eliminate this fault condition and ensure the backrest cannot detach from the chair. All new production chairs will have this kit fitted as standard.

Actions required by End Users, Distributors, Dealers:

1. Please make sure that all caregivers and users of the Configura Advance Chair devices specified in the affected products section of this notice are made aware of this Field Safety Notice (FSN).
2. Check against the list above for relevant products sold or supplied by your organisation to end users or dealers.
3. If you have supplied any of the above products or put the device into use then please supply a list of device locations to Accora so that installation of the corrective action kit can be arranged. Any existing stock is not to be supplied until a corrective action kit has been installed.
4. Contact Accora to arrange a Field Safety Corrective Action kit to be installed on each product. This will be fitted free of charge.
5. Acknowledge the receipt of this Field Safety Notice within 2 days by completing the form below and sending it to info@accora.care.
6. For Distributors, the rework must be completed within 10 working days of receiving this Field Safety Notice. Please work with your Accora representative if you need support completing the modification.
7. For distributors using Accora to complete the rework, address details for each device must be supplied within 3 days of receiving this Field Safety Notice.

We regret any inconvenience that this Field Safety Notice may cause, however, we ask that you treat this as a safety related issue. We appreciate your understanding as we take actions to ensure the safety of our end users.

This Field Safety Corrective Action has been notified to all appropriate regulatory agencies.

If you have any further questions or require any assistance, please contact Accora:

Accora Limited, Charter House, Barrington Road, Orwell, Cambridge SG8 5QP
 T: +44 (0)1223 206100 E: info@accora.care

Field Safety Notice Acknowledgement

I / we acknowledge the receipt of this Field Safety Notice (FSN-2021-FA003) and fully understand the actions required (listed above).	
Print Name:	
Position:	
Organisation:	
Signed:	
Date:	