



URGENT – FIELD SAFETY NOTICE

Arjo Quick Connect Scale used with Maxi Sky 2

Date:	dd-mmm-2018				
Product Issue:	Quick connect scale used with Maxi Sky 2 ceiling lifts – Disconnection hazard				
Affected Product:	Quick connect scale manufactured between June 2016 and November 2017. Quick connect scale serial numbers range: <table> <tr> <td><u>Part number 700-19490:</u></td><td><u>Part number 700-19485:</u></td></tr> <tr> <td>From serial number 300142013 up to serial number 300219867</td><td>From serial number 300146551 up to serial number 300220716</td></tr> </table>	<u>Part number 700-19490:</u>	<u>Part number 700-19485:</u>	From serial number 300142013 up to serial number 300219867	From serial number 300146551 up to serial number 300220716
<u>Part number 700-19490:</u>	<u>Part number 700-19485:</u>				
From serial number 300142013 up to serial number 300219867	From serial number 300146551 up to serial number 300220716				
Resolution:	Upgrade the devices with a retrofit solution in order to ensure the device is operating safely				
Affected Serial No.:	Attachment A				
Field Safety Notice:	FSN-MAG-2018-01				
Pages:	3 + Attachment A				

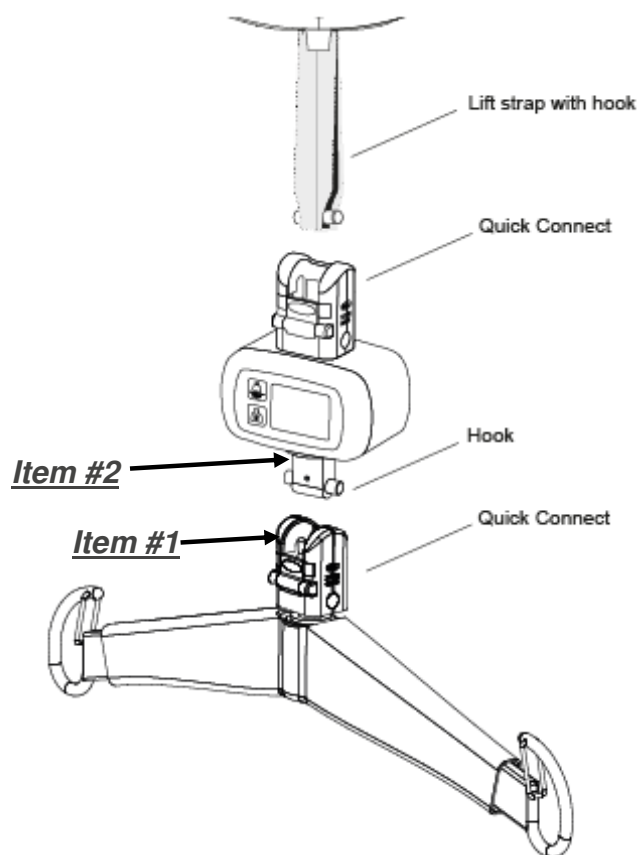
Dear Customer,

Our records indicate that you may have one or more Arjo quick connect scale(s) within your facility(ies). This type of scale is intended to be used with Maxi Sky 2 ceiling lift to measure the weight of a patient who cannot stand on a scale.

This letter is to inform you of a corrective action that will be performed on the affected device(s).

Arjo has received a limited number of complaints where it was mentioned there was a disconnection occurrence of the spreader bar (item #1 of image on next page) from the quick connect scale (item #2).

Arjo has investigated the failure mode and has concluded that this hazard could be replicated under a specific sequence of events and may lead to a potential risk of injury to patients.



Although the likelihood of this occurring is remote, Arjo takes this matter seriously and is advising you to take the following steps:

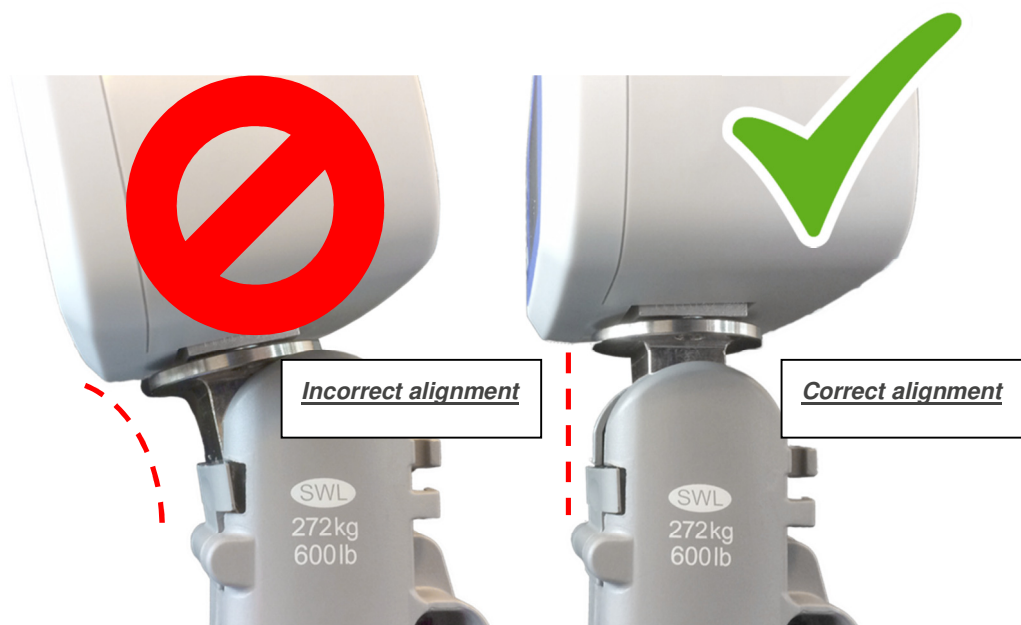
Next Steps

1. Ensure that all caregivers and users of the Arjo quick connect scale are made aware of this Field Safety Notice (FSN) and all listed devices at your facility are available to be upgraded free of charge during the service technician visit.
2. Complete and sign the enclosed Customer Response Form and return this form to your local Arjo office and we will contact you to schedule the service call.

The device may stay in use until the upgrade will be performed, on the condition that the following instructions are carefully followed:

- Before initiating the patient transfer, once the patient is installed in the sling and the weight is gradually taken up, always check that the scale quick connect lower attachment is aligned with the spreader bar quick connect (Look at the images below).
- If not, do not proceed with the patient transfer, lower the patient, remove completely the patient weight on the scale and then reinstall adequately the spreader bar attachment.

Note: If the quick connect scale is correctly aligned with the spreader bar quick connect, there is no disconnection hazard.



Distribution of this Field Safety Notice

This Field Safety Notice must be distributed to those individuals who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

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

We regret any inconvenience that this Field Safety Notice may cause, however we greatly appreciate your understanding as we take actions to ensure the safety of your patients.

The undersigned confirms that the notice has been submitted to the Regulatory Agency *[insert name]*.

Additional Comment

If you have any further questions or require assistance completing the Customer Response Form, please contact Arjo at *[insert local phone number]* or via email at *[insert email]*.

Attachment A

[illegible]