

Field Safety Notice

Concerned products: Ceiling Lift Altair, Roomer S and HeliQ

FSCA 30th of June 2016

Safety Alert

Date: 30th of June 2016

Attention: Users of the concerned products

Details on affected devices:

Ceiling Lift Altair with model number 55200-EU, 55200-GB, 55210-EU, 55210-GB, 55220-EU, 55220-GB, Roomer S with model number 55300-EU, 55300-GB

and HeliQ with model numbers 55100-EU, 55100-GB, 55110-EU, 55110-GB, 55120-EU, 55120-GB, 55130-EU, 55130-GB, 55140-EU, 55140-GB, 55150-EU, 55150-GB

That has been manufactured before 2016-06-20 with serial number starting with a number lower than 327162XXXXX are affected by this FSCA.

Description of the problem:

It has come to our attention that some customers use the emergency lowering button in order to lower the lift/hanger bar instead of using the down button on the hand control. As stated in the user manual, the emergency lowering button shall only be used in emergency situations and not under normal conditions.

For safety reasons the emergency lowering function disables other safety functions such as end stop breakers, and belt tension guard switch. When using the emergency lowering button the lift gets down faster which can give unnecessary discomfort to the patient. There is also a risk for the belt roll in the lift to turn in the opposite direction, which can damage the product.

There have been reported incidents where the emergency lowering function been broken after extended misuse and caused a constant motion of the belt resulting in a fully retracted belt with a permanent damaged to the hoist. If this would occur with a patient attached to the lift the emergency break should always be used.

In order to prolong the lifetime of the product and also to increase comfort for the patient, the emergency lowering button should never be used, except in a true emergency situation.



Action to be taken by the distributor and the user:

- Secure that staff have proper education and understand how to use the hand control.
- Secure that the staff understand the consequences that could happen when systematically using the emergency lowering function in daily operation.
- Confirm back to Human Care by signing this document that this message has been received and understood.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices are in use.

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

Manufacturer Contact:

Christian Andersson
Human Care HC AB
Årstaängsvägen 21 C
117 43 Stockholm
christian.andersson@humancaregroup.com

The undersign confirms that this notice has been notified the appropriate Regulatory Agency.

Director of Quality and Operations



Fredrik Skantz

The undersign confirms that this notice has been received and understood.

Signature and date