
Urgent Field Safety Notice
Relax wall mounted shower seat**Field Correction****2015-07-03**

Dear valued customer,

With this Field Safety Notice, Etac provides information on important issues in relation to a Field Correction of Relax. The Field Safety Notice is intended to ensure that all users and health facilities with influence of Relax users will receive important information on the background and execution of this Field Correction.

Affected medical devices:

Relax wall mounted shower seat

For article and serial numbers: see page two of this document.

Background:

Etac has received information from a few users of malfunctions with the Relax wall mounted shower seat. It is reported that the seat in some cases gets cracks and in one case has broken. Etac is unaware that cracked seats would have resulted in any harm or serious injuries. There is however a potential risk for harm and injury if the wall mounted shower seat would break while used.

Field correction:

To prevent a potential situation of wall mounted shower seat crack or break, Etac is voluntarily issuing this Field Correction of all potentially affected wall mounted shower seats.

All Relax in the table on page two are within the scope of this field correction. The Relax wall mounted shower seat needs to be completely replaced to ensure a continuous long term safe use.

If you have a Relax within the affected serial number range, please contact your Etac representative to arrange for the replacement.

The activities will be carried out as soon as possible and is planned to be finished by latest December 31 2015.

There are no reasons for an immediate stop of using Relax, however as an intermediate precautionary action awaiting the replacement, you are requested to be observant and inspect the Relax wall mounted shower seat to see if there are visible signs of a crack.

Etac apologizes for any inconvenience, and asks user facilities that this notice is passed on to all those who need to be aware within your organization, or to any organization where the potentially affected devices have been transferred.

Should you have any concerns or questions in relation to this notice do not hesitate to contact your local Etac sales company or Etac distributor.

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

Anderstorp 2015-07-03

Sincerely,


Quality Manager [@etac.com](mailto: [redacted]@etac.com)Telephone: +46 371 Etac Supply Center AB
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Affected devices serial no:s and distribution dates

Art no	Device name	Affected S:no	Date of delivery from Anderstorp
81703010	Shower seat Relax white	1 - 441	November 2013 - November 2014
81703020	Shower seat Relax white with arm support	1 - 451	November 2013 - April 2014
81703030	Shower seat Relax white with supporting legs	All	November 2013 – March 2015
81703040	Shower seat Relax white with arm support supporting legs	1 - 205	November 2013 - August 2014
81703050	Shower seat Relax white with arm support supporting legs and back support	1 - 205	January 2014 – November 2014
81703060	Shower seat Relax white with arm support and back support	1 - 451	March 2014 – February 2015
81703070	Shower seat Relax green	All	February 2014 – February 2015
81703080	Shower seat Relax green with arm supports	All	November 2013 – February 2015
81703090	Shower seat Relax green with supporting legs	All	March 2014 – August 2014
81704000	Shower seat Relax green with arm support and supporting legs	All	November 2013 – October 2014
81704010	Shower seat Relax green with arm support and supporting legs and back support	All	June 2014
81704020	Shower seat Relax green with arm support and back support	All	January 2015