

Field Safety Notice

C-10 Probetester
FSCA No. 6.6.2-2019-38496

Datum: 2019-05-27

Attention: All customers and distributors

Details on affected devices:

C-10 Probetester (Model nr. T80002) with serialnr. from 0710003 - 1705001 manufactured by Optima Scandinavia AB and serialnr. from 1708001 - 1801014 manufactured by ES-Medical AB.

Description of the problem:

A manufacturer´s Field Safety Corrective Action Report (FSCA) has been set up after that the Hospital in Varberg (Sweden) had elevated microbiological values in the final rinse water. The device had been stagnant with water inside which could favor the growth of microorganisms.

Our conclusion is that the problem of the growth in the rinse water is not caused by product defects, the user has not followed the recommendations that we as a manufacturer prescribe in the manual and during product training.

There are no hazards or risks for patients, provided the instructions of the manual are followed.

As a **corrective action**, we have sent out to all end customers and distributors a clarification of the handling/ routine around C-10 Probetester to avoid the causes of increased microbiological values in the final rinse water (see Appendix 1). If micro-organisms occur in the final rinse water, the rinse water part of the equipment must be disinfected.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred

Appendix 1; Extract from the manual for cleaning and maintenance

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Cleaning and maintenance of the C-10 Probetester

Extract from the manual

To avoid microorganism in the final rinse water following care is recommended by the **user**:

- Run the self-disinfection program after **two days of break** in use
- **If needed**, run the self-disinfection program and then use a different disinfectant than that normally used in the C-10. This is to counteract that resistant bacteria grow internally in the device.
- **After the last run of the day**, remove the water pipe and run it in a washer disinfector.
- Clean the process tube **at the end of each week**. The glass tube can be run in a washer disinfector.
- Replace the water filter **every 3 months**.
- **If the device is not in use for five days**, all parts in the C-10 that is in contact with water must be disinfected and new filters installed.

Before every process is it very important that the edges of the upper part of the process tube and the spout is disinfected manually after the probe is connected to the C-10. It is also important that the probe is cleaned according to the probe manufacturers recommendation before the probe is placed in the C-10 Probetester.

In our user manual we refer to ISO 15883 where the last rinse water should be free of *Pseudomonas aeruginosa* and mycobacteria and less than 10 cfu / 100 ml. The standard recommends that the last rinse water be tested for *Pseudomonas aeruginosa* and mycobacteria once a year. At least 250 ml is taken from the spout. The final rinse water should also be tested to be less than 10 cfu / 100 ml. weekly at the beginning and at longer intervals thereafter. At least 250 ml is taken from the spout and from the process tube.

If the results are not ok, the rinse water part of the equipment must be disinfected.