

IMPORTANT INFORMATION

EN ISO 15883-4:2018 and Cleaning process temperature change

Dear Customer,

EN ISO 15883-4 is the harmonized standard providing presumption of conformity of Soluscope Serie 4 PA Automatic Endoscope Reprocessor (AER).

A new version of EN ISO 15883-4 has been released in 2018 and supersedes previous EN ISO 15883-4 from 2009. EN ISO 15883-4:2018 is in force since October 2021 and the Soluscope Serie 4 PA you have received complies with this standard version.

New requirement in the standard has led to specification changes on Soluscope Serie 4 PA. In particular, one change concerns the cleaning process of cycle 1 with Soluscope CLN detergent; it is performed at 40°C instead of 35°C previously used to claim EN ISO15883-4:2009 compliance.

Due to stock management you may still have Soluscope CLN in your warehouse or coming orders to be delivered with labels indication to operate at 35°C.

Despite the label indication you can operate Soluscope CLN on Soluscope Serie 4 PA working at 40°C for the cleaning process without any risk of mis-use:

- The temperature setting is defined automatically by the Soluscope Serie 4 PA with no intervention of the user,
- Soluscope CLN has been validated at both 35°C and 40°C temperature and can operate on all Soluscope Serie 4 PA whatever the cleaning temperature set by the machine.

We are currently updating the label of Soluscope CLN to remove temperature indication and harmonize instruction for use to comply with both Soluscope Serie 4 PA population standard version.

Please note that all Soluscope Serie 4 PA placed in the market before October 2021 and compliant with EN ISO15883-4:2009 can still be operated with no changes.

It is not required to update these AER according to the new EN ISO15883-4:2018. They will still operate Soluscope CLN at 35°C.

This document has been provided along with the User Manual of the Soluscope Serie 4 PA and must remain available for consultation by the User.

Do not hesitate to contact your Soluscope representative if you have any questions.

Best regards,

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