

Changenotification_AB@sartorius.com

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Sartorius Stedim Switzerland AG Ringstrasse 24a
8317 Tagelswangen, Switzerlandt: +41 52 354 36 36
www.sartorius.com

Sartorius Stedim Switzerland AG, 8317 Tagelswangen, Switzerland

Change Notification Letter**ECR 27697:** Firmware update for the Biowelder® TC with serial number BWTC2000 upward

Dear valued customer,

This letter is to inform you of a firmware update for the Biowelder® TC and implementation of an additional FPGA.

Change Description

At the current global situation, it is hard to get FPGA (Field Programmable Gate Array). The current suppliers cannot hold current lead times defined by Sartorius. Therefore, a different FPGA was selected on top of previously used FPGAs. In future previous and new FPGAs will be used to manufacture Biowelder® TC and both can be run with the same updated firmware.

The new firmware can handle all existing motherboards on the market from serial number BWTC2000 upward. A downgrade from the new software version 02.003.001 is not possible.

Welding parameters and welding parameter files are not impacted by this update and remain unchanged. This firmware update has no impact on the welding process.

All customers can continue to use the existing devices with the initial delivered software version. **An update is not required.** A software update will be necessary only in case of a repair of the main board. The update as well as the software will be provided free of charge. Only the repair and subsequent re-qualification will be charged.

Recommendation for qualified (IQ/OQ) devices

After exchanging the motherboard and updating the software, we recommend a partial re-qualification of the device by performing the following tests from the IQ/OQ test protocol:

- BQT-302-BWTC Piping, instrumentation and design check
- BQT-319-BWTC Welding parameter check
- BQT-317- BWTC Temperature validation
- BQT-327-Process interruption check

Impacted Products

The following product lines are affected by this change:

Sartorius part number	Product description
16389	BioWelder® TC second generation serial number from BWTC2000 upward (from 2018 onward)

Change Implementation

This change is controlled internally in accordance with Sartorius change management procedures.

Any Biowelder® TC with the serial number BWTC7102 and upwards will have the new software already installed from April 2022 onward.

For devices with serial numbers between BWTC2000 and BWTC7102, the software update is not mandatory. Exception would be above-described repairs.

We continuously strive to implement solutions to our products and services to enable you to get your treatments to patients faster. We thank you for your trust and continued use of Sartorius products, and we look forward to assisting you in managing this change.

Yours sincerely,

Garland Grant
Head of Product Management FMT
Sartorius Stedim North America, Inc.

Martin Gerber
Head of Quality System Efficiency BPS
Quality Management & Regulatory Affairs
Sartorius Stedim Biotech GmbH