

Manufacturer's recommendation for renewed performance qualification after replacing components

**Steam sterilizers, washer-disinfectors,
combination steam sterilizers, sealing
devices**

EN

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1 Renewed performance qualification

According to §8 section 1 MPBetreibV, an operator of medical devices is required to “use validated procedures to perform the low-germ or sterile reprocessing of medical devices used in application [...] taking into account the manufacturer’s specifications and in such a way as to ensure the demonstrable success of this procedure to ensure that the health and safety of patients, users or third parties is not threatened.” The validation (IQ, OQ, PQ) is an essential and specified procedure. Responsibility for ensuring a valid reprocessing is always held by the operator.

The validation / renewed performance qualification is usually performed:

- When the device is setup
- Upon alterations of process steps or accessories and process agents etc.
- During the introduction of new instruments to be reprocessed
- Due to legally-required and regulatory repeating periods
- After repairs, the replacement of components or e.g. software update

MELAG is often asked within the scope of repairs, service work and component replacement about the necessity of performing an unscheduled and renewed performance qualification on specific grounds. In response, we have compiled an overview of the replacement parts often requested and their requisite testing measures. From the manufacturer’s viewpoint, the replacement of the components specified in the chapter [Process-relevant components](#) [▶ page 4], does not necessarily require a complete performance qualification on technical grounds given a positive outcome of the testing measures.

The minimum requirements for this are:

- The work is performed by a MELAG-authorized technician.
- Only original MELAG spare parts are used.
- The work is performed in accordance with manufacturer's specifications (repair instructions). These can be downloaded from the service portal (www.melagservice.com) after registration.
- The installation location of the device within the operating premises remains unchanged.
- A complete test run in a validated program is performed successfully at the installation location. Malfunction messages from the process monitoring system are not displayed, and comparison of the process parameters from the test run and validation report do not indicate any significant deviations.

PLEASE NOTE

In the ophthalmic sector and in deviation from the specifications of the chapter [Process-relevant components](#) [▶ page 4] the test runs must be performed in the Ophthalmic-Program (washer-disinfectors) or - if used in the practice - the Prion-Program (steam sterilizers).

Software updates

MELAG-trained service technicians will be provided with information about software alterations via a TechInfo, as to the necessity (as considered by the manufacturer) of updating the device software and performing renewed and complete performance qualification. MELAG recommends performing the software updates which we have generated and provided. This should be performed within the scope of maintenance at the latest or directly within the scope of the periodically recurring renewed performance qualification.

The practice operator is responsible for the final assessment of the necessity of a renewed performance qualification.

PLEASE NOTE

Consult the responsible authority given any inclarities.

2 Process-relevant components

2.1 Steam sterilizers

Replaced component	Testing measures required	Background information
Steam generator or tubular heating element	Perform a vacuum test (if available) and check that the threshold value of the leakage rate is maintained (see maintenance instructions). Perform a test run in Quick-Program B (Vacuklav) or the Universal-Program. Check for malfunction messages and other deviations. Check the device rear panel for moisture.	The manufacturer checks the steam generator or tubular heating element individually for their heating performance, high voltage resistance and for leaks. Only steam generators or tubular heating elements that comply with the specification are delivered. The spare parts are taken from current production. The process monitoring system integrated in the software discovers anomalies in the test run such as poor performance or over-long steam intake times during the test run and triggers malfunction messages.
Pressure sensor	Perform a vacuum test (if available) and check that the threshold value of the leakage rate is maintained. Perform a test run in Quick-Program B (Vacuklav) or the Universal-Program. If a vacuum test is not available, compare the process parameters of the test run with the values in the saturated steam table. Check for malfunction messages and other deviations.	The sensors are delivered in a tested and calibrated state. The process monitoring system integrated in the software discovers anomalies in the test run and triggers malfunction messages.
Cooler	Perform an extended vacuum test with Vacuklav with a membrane pump and check the leakage rate for maintenance of the threshold (see maintenance instructions). Perform a test run in the Quick-Program B or the Universal-Program. Check for malfunction messages and other deviations.	The manufacturer checks each individual cooler for leaks. Only coolers that comply with the specification are delivered. The replacement coolers are taken from current production. The process monitoring system integrated in the software discovers anomalies such as poor performance or pressure release times and evacuation times during a test run and triggers malfunction messages.
Solenoid valves	Perform a vacuum test (if available) and check that the threshold value of the leakage rate is maintained (see maintenance instructions). Perform a test run in Quick-Program B (Vacuklav) or the Universal-Program. Check for malfunction messages and other deviations.	The manufacturer checks the solenoid valves individually for their function, throughflow and for leaks. Only valves that comply with the specification are delivered. The replacement valves are taken from current production. The process monitoring system integrated in the software discovers anomalies such as poor performance or over-long steam intake times, pressure release times and evacuation times during the test run and triggers malfunction messages.

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Replaced component	Testing measures required	Background information
Feed pump	Perform a vacuum test (if available) and check that the threshold value of the leakage rate is maintained (see maintenance instructions). Perform a test run in Quick-Program B (Vacuklav) or the Universal-Program. Check for malfunction messages and other deviations.	The manufacturer checks the feed pumps individually for their function, performance and for leaks. Only pumps that comply with the specification are delivered. The replacement pumps are taken from current production. The process monitoring system integrated in the software discovers anomalies such as poor performance or under-supply of the steam generator with feed water during a test run and triggers malfunction messages.
Control electronics	Perform a test run in Quick-Program B (Vacuklav) or the Universal-Program. Check for malfunction messages and other deviations.	The electronics are checked and approved at the manufacturer's. The analogue inputs of the sensors are calibrated. The process monitoring system integrated in the software discovers anomalies in the test run and triggers malfunction messages.
Temperature sensor	Perform a vacuum test (if available) and check the leakage rate in comparison to the manufacturer's inspection report or the last validation report. Perform a test run in Quick-Program B (Vacuklav) or the Universal-Program. Check for malfunction messages and other deviations.	The sensors are delivered in a tested and calibrated state. The process monitoring system integrated in the software discovers anomalies in the test run and triggers malfunction messages.
Drying pump	Perform a trial run in Universal-Program or Quick-Program (Euroklav, MELAtronic 15 EN+, MELAquick 12+ p). Do not abort the drying. Check the load for sufficient drying.	The manufacturer tests each individual pump on a special test stand. Only pumps that comply with the specification are delivered. The replacement pumps are taken from current production. The process monitoring system integrated in the software discovers anomalies in the test run such as poor performance or too slow pressure build-up in the drying process during the test run and triggers malfunction messages.
Door parts incl. door seal and pressure-retaining parts	Perform a vacuum test (if available) and check that the threshold value of the leakage rate is maintained (see maintenance instructions). Perform a test run in Quick-Program B (Vacuklav) or the Universal-Program. Check for malfunction messages and other deviations.	If the door is properly installed according to the manufacturer's instructions and the tightness is verified by a vacuum test and a test run, replacing the identical door including the locking assemblies has no effect on the process flow in the sterilization chamber.
Vacuum pump	Perform an extended vacuum test with Vacuklav with a membrane pump or a simple vacuum test with devices with a water ring pump and Euroklav. Check the prescribed evacuation time. Check the leakage rate for maintenance of the threshold (see maintenance instructions). Perform a test run in Quick-Program B (Vacuklav) or the Universal-Program. Check for malfunction messages and other deviations.	The manufacturer tests each individual pump on a special test stand. Only pumps that comply with the specification are delivered. The replacement pumps are taken from current production. The process monitoring system integrated in the software discovers anomalies such as poor performance or over-long evacuation times during the test run and triggers malfunction messages.

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Replaced component	Testing measures required	Background information
Heat exchanger	Perform an extended vacuum test. Check the leakage rate for maintenance of the threshold (see maintenance instructions). Perform a test run in the Quick-Program B or the Universal-Program. Check for malfunction messages and other deviations.	The heat exchangers are delivered in a assembled and tested state. The process monitoring system integrated in the software discovers anomalies such as leakage, poor performance or pressure release times and evacuation times during a test run and triggers malfunction messages.

2.2 Washer-disinfectors (WD)

Unless otherwise specified, the information regarding the replaced components applies to MELAtherm 10 and MELAtherm 10 Evolution as well as MELAtherm 20.

Device type	*) Perform a test run in ...
MELAtherm 10, MELAtherm 10 Evolution (MT10)	Quick-Program or Universal-Program
MELAtherm 20 (MT20)	Universal+ or Universal program

Replaced component	Testing measures required	Background information
Drain pump Pressure increase pump (MT20)	Perform a test run*). Check for malfunction messages and other deviations.	The level pressure monitoring within the programs checks the function of the drain pump / pressure increase pump.
Metering electronics	Determine the feed rates of the pumps and calibrate the pump values. Perform a test run*) to determine the actual metered quantities. Check for malfunction messages and other deviations.	The process monitoring system integrated in the software discovers anomalies in the test run and triggers malfunction messages. Determining the actual metered quantities restores the same level as the time of the original validation.
Metering pump or measuring turbine for metering	Determine the feed rates of the pumps and calibrate the pump values. Perform a test run*) to determine the actual metered quantities. Check for malfunction messages and other deviations.	The process monitoring system integrated in the software discovers anomalies in the test run and triggers malfunction messages. Determining the actual metered quantities restores the same level as the time of the original validation.
Metering pump hoses	Determine the feed rates of the pumps and calibrate the pump values. Perform a test run*) to determine the actual metered quantities. Check for malfunction messages and other deviations.	The process monitoring system integrated in the software discovers anomalies in the test run and triggers malfunction messages. Determining the actual metered quantities restores the same level as the time of the original validation.
Pressure sensor	Perform a test run*). Check for malfunction messages and other deviations. Check the graphic logs before and after the conversion or compare against the manufacturer's inspection report or last validation report for comparable rinse pressure. A deviation of $\pm 5\%$ is permissible.	The process monitoring system integrated in the software discovers anomalies in the test run and triggers malfunction messages. The rinse pressure is used for fault detection, which is additionally performed by determining the rinsing arm speeds.
Flow heater	Perform a test run*). Check for malfunction messages and other deviations.	The process monitoring system integrated in the software discovers anomalies in the test run and triggers malfunction messages. The water temperature is monitored by two independent temperature sensors.

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Replaced component	Testing measures required	Background information
Water softening unit	Perform a test run ^{*)} . Check for malfunction messages and other deviations.	The process monitoring system integrated in the software discovers anomalies in the test run and triggers malfunction messages.
Condensate/collection tank pump set (MT10)	Perform a test run ^{*)} . Check for malfunction messages and other deviations.	The process monitoring system integrated in the software discovers anomalies in the test run and triggers malfunction messages.
Solenoid valves	Perform test run ^{*)} , additionally run Regenerate once. Check for malfunction messages and other deviations.	The process monitoring system integrated in the software discovers anomalies in the test run and triggers malfunction messages.
Water inflow measuring turbine (MT10) Vortex sensor water inlet (MT20)	Perform a test run ^{*)} . Check for malfunction messages and other deviations.	The process monitoring system integrated in the software discovers anomalies in the test run and triggers malfunction messages.
Salt container	Perform test run ^{*)} , additionally run Regeneration once. Check for malfunction messages and other deviations.	The process monitoring system integrated in the software discovers anomalies in the test run and triggers malfunction messages.
Switches (door switch, float switch, flow monitor)	Perform a test run ^{*)} . Check for malfunction messages and other deviations.	The process monitoring system integrated in the software discovers anomalies in the test run and triggers malfunction messages.
Control electronics	Perform a test run ^{*)} . Check for malfunction messages and other deviations.	The process monitoring system integrated in the software discovers anomalies in the test run and triggers malfunction messages.
Temperature sensor	Perform a test run ^{*)} . Check for malfunction messages and other deviations. If both temperature sensors have to be exchanged, an additional temperature measurement using an external data logger is necessary.	The sensors are delivered in a tested and calibrated state. The use of two sensors in connection with the process monitoring system integrated in the software means that anomalies in the test run are discovered and trigger malfunction messages.
Door and door gasket	Perform a test run ^{*)} . Check for malfunction messages and other deviations, especially leakages in the door area.	If the door or door gasket is properly installed according to the manufacturer's instructions and the tightness is verified by a test run, the replacement of the identical door or door gasket has no effect on the process flow in the washing chamber.
Circulation pump	Perform a test run ^{*)} . Check for malfunction messages and other deviations. Check the graphic logs before and after the conversion or compare against the manufacturer's inspection report or last validation report for comparable rinse pressure. A deviation of $\pm 5\%$ is permissible.	The process monitoring system integrated in the software discovers anomalies in the test run and triggers malfunction messages. The rinse pressure is additionally monitored by the rinsing arm speed.

2.3 Combination steam sterilizers

In addition to the components listed here, the same testing measures apply to combination steam sterilizers as to the components of a steam sterilizer and a washer-disinfector (WD), see [Steam sterilizers](#) [▶ page 4] and [Washer-disinfectors \(WD\)](#) [▶ page 6].

Replaced component	Testing measures required	Background information
Carebox	Perform "Carebox test" service program. Check whether all filling levels are at or above the minimum level. Refer to the user manual of the device for more information on how to perform the test.	Each Carebox is individually tested at MELAG in a test stand. In doing so, all relevant parameters are checked and documented. The test results are clearly assigned to the Carebox on the basis of the serial number. The results of the Carebox function test are verified on site in the device.
Metering distributor block	Perform a vacuum test with the program variant "Dosing chamber" and check that the threshold value of the leakage rate is maintained (see maintenance instructions). Perform the "Oil dosing vent" service program and then the Care-S program. Check for malfunction messages and other deviations.	The process monitoring system integrated in the software discovers anomalies in the test run and triggers malfunction messages.
Pressure regulator	Perform the Care-S program. Check for malfunction messages and other deviations.	The manufacturer checks the pressure regulator individually for its function, performance and for leaks. The process monitoring system integrated in the software detects anomalies such as insufficient pressure or under-supply of compressed air and leads to malfunction messages.
Instrument adapter	Perform "Carebox test" service program. Check whether all filling levels are at or above the minimum level. Refer to the user manual of the device for more information on how to perform the test.	Perform the test when replacing or reinstalling an instrument adapter and when replacing the seal on the instrument adapter, e.g. during maintenance.
Oil can socket	MELAG recommends checking the function of the oil can insert with the "Oil dosing vent" service program. Check for malfunction messages and other deviations.	Oil maintenance of instruments has no medical purpose. Therefore, a renewed performance qualification of the oil maintenance according to §8 para. 1 MPBetreibV (Medical Devices Operating Directive) is not mandatory.
Pump chuck care	MELAG recommends checking the performance of the pump with the function "Chuck care venting".	The maintenance of the collet chuck of an instrument has no medical purpose. Therefore, a renewed performance qualification of the oil maintenance according to §8 para. 1 MPBetreibV (Medical Devices Operating Directive) is not mandatory.

2.4 Sealing devices

Replaced component	Testing measures required	Background information
Pressure rail	Check the seal seams in accordance with the "Manufacturer's Recommendation for Routine Operation for sealing devices".	The work on components involved in the production of the seal seam can be performed incorrectly despite a correct calibration. Checking the seal seam will reveal faulty settings and calibrations.
Force sensor	Check the seal seams in accordance with the "Manufacturer's Recommendation for Routine Operation for sealing devices".	The work on components involved in the production of the seal seam can be performed incorrectly despite a correct calibration. Checking the seal seam will reveal faulty settings and calibrations.
Sealing rail	Check the seal seams in accordance with the "Manufacturer's Recommendation for Routine Operation for sealing devices".	The work on components involved in the production of the seal seam can be performed incorrectly despite a correct calibration. Checking the seal seam will reveal faulty settings and calibrations.
Software	Check the seal seams in accordance with the "Manufacturer's Recommendation for Routine Operation for sealing devices".	The electronics are calibrated after installation using the sensors. The process monitoring system integrated in the software discovers anomalies in the test run and triggers malfunction messages. Checking the seal seam will reveal faulty settings and calibrations.
Control electronics	Check the seal seams in accordance with the "Manufacturer's Recommendation for Routine Operation for sealing devices".	The electronics are calibrated after installation using the sensors. The process monitoring system integrated in the software discovers anomalies in the test run and triggers malfunction messages. Checking the seal seam will reveal faulty settings and calibrations.
Teflon strips (MELAseal Pro, MELAseal 200, MELAseal 100+)	Check the seal seams in accordance with the "Manufacturer's Recommendation for Routine Operation for sealing devices".	The electronics are calibrated after installation using the sensors. The process monitoring system integrated in the software discovers anomalies in the test run and triggers malfunction messages. Checking the seal seam will reveal faulty settings and calibrations.
Temperature sensor	Check the seal seams in accordance with the "Manufacturer's Recommendation for Routine Operation for sealing devices".	The electronics are calibrated after installation using the sensors. The process monitoring system integrated in the software discovers anomalies in the test run and triggers malfunction messages. Checking the seal seam will reveal faulty settings and calibrations.
Motor	Check the seal seams in accordance with the "Manufacturer's Recommendation for Routine Operation for sealing devices".	The electronics are calibrated after installation using the sensors. The process monitoring system integrated in the software discovers anomalies in the test run and triggers malfunction messages. Checking the seal seam will reveal faulty settings and calibrations.