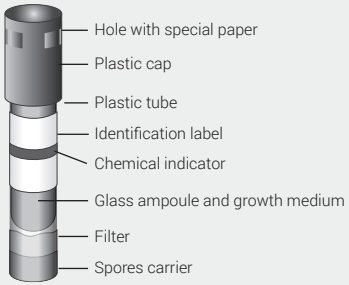
Ultra Rapid Readout
Biological indicators

Rev. 0 / 10.2019

20´ Fluorescence System

WTL198-0072

Tuttnauer
Innovation · Legacy · Partnership



Quality certification

STEAM

Steam sterilization
Geobacillus stearothermophilus ATCC 7953

LOT

Heat Shock Population _____ CFU / vial

D - value (121 °C) _____ min.

Survival time _____ min.
Survival time = (log_{10} labeled population - 2) x labeled D-value

Kill time _____ min.
Kill time = (log_{10} labeled population + 4) x labeled D-value

D - value (132 °C) _____ sec.

Survival time _____ min.
Survival time = (log_{10} labeled population - 2) x labeled D-value

Kill time _____ min.
Kill time = (log_{10} labeled population + 4) x labeled D-value

D - value (135 °C) _____ sec.

Survival time _____ sec.
Survival time = (log_{10} labeled population - 2) x labeled D-value

Kill time _____ min.
Kill time = (log_{10} labeled population + 4) x labeled D-value

Z-value _____ °C

System Sensitivity:
The sensitivity of the system is determined as the difference between the number of positive indicators after 7-day incubation and false negative indicators (negative by fluorescence readout and visually positive) in relation to the number of 7-day positive indicators.

Sensitivity = $\frac{\text{(Nº Positives at 7 days) - (Nº False negatives) X 100}}{\text{(Nº Positives at 7 days)}} \geq 97\%$

Parameters determined at time of manufacture according to ISO 11138-1: 2017, ISO 11138-3: 2017 and IRAM 37102: 1999 (Parts 1 and 3) standards. The values shown in this certificate are reproducible only under the conditions in which they were established.

ISO and USP Compliant
ATCC is a registered trademark of American Type Culture Collection.

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Technical Director

Biological Indicators

For Steam sterilization

Indications for Use

United States
WTL198-0072 SCBI is a self-contained biological indicator inoculated with viable 10^6 *Geobacillus stearothermophilus* bacterial spores and is intended for monitoring the efficacy of steam sterilization processes. On each WTL198-0072 SCBI is a chemical process indicator that changes color from pink to brown when exposed to Steam. See Intended Use Table for reference.

Outside the United States
WTL198-0072 Fluorescence Ultra Rapid Readout Biological Indicators have been designed for quick and easy monitoring of vacuum assisted and gravity displacement steam sterilization cycles at 132-135ºC.

Device Description
WTL198-0072 Ultra Rapid Readout Biological Indicators are single-use Self-Contained Biological Indicators (SCBIs) that consist of a polypropylene tube, a spore carrier and a glass ampoule with a culture medium, enclosed with a colored cap. Each tube contains a population of *Geobacillus stearothermophilus* ATCC 7953 spores inoculated on a spore carrier, a plastic cap with holes and a barrier permeable to Steam. Each WTL198-0072 has a Process Indicator on label that changes from pink to brown when exposed to Steam.

Precautions
WARNING: Do not use WTL198-0072 SCBIs to control Hydrogen Peroxide, EO, Dry Heat, Formaldehyde or other sterilization processes. Do not reuse SCBIs.
WARNING: Place one or more SCBIs in sterilizing hard-to-reach areas to ensure all areas of the chamber are sterilized. Please evaluate all load configurations to ensure All hard-to-reach areas have been identified, and place a SCBI in each of those locations.
WARNING: Do not reuse the sterilizer until the SCBI test result is negative.

Instructions for Use
1. Identify the WTL198-0072 SCBI by writing the sterilizer number (in case of having more than one), load number and processing date on the label.
2. Pack the SCBI along with materials to be sterilized in an appropriate package according to recommended sterilization practices. Place the package in those areas which are considered most inaccessible for the sterilizing agent (e.g., the center of the load and areas near the door).
3. Sterilize as usual.
4. After the sterilization process has finished, open the sterilizer door, wait five minutes and remove the SCBI from the package. **CAUTION:** Wear safety glasses and gloves when removing the WTL198-0072 SCBI from the sterilized package. **WARNING:** Do not crush or handle the SCBI excessively, since this might cause the glass ampoule to burst. Let the SCBI cool down until it reaches room temperature.
5. Check the Process Indicator on SCBI label. A color change to brown indicates that the SCBI has been exposed to Steam. **IMPORTANT:** this color change does not evidence the process effectiveness to achieve sterility. If the Process Indicator color has not changed, check the sterilization process.
6. Press the lid to seal the tube. Crush the ampoule contained in the SCBI with an individual ampoule crusher or with the ampoule crusher placed within the incubator´s incubation area.
Then shake the tube down vigorously, with movements similar to those performed to lower the temperature in a mercury thermometer, until the medium reaches the base of the tube and soaks the spore carrier entirely. Finally, place the SCBI in the incubator.
IMPORTANT: Use a non-sterilized SCBI as a positive control in order to ensure that correct incubation conditions were met; capability of medium to promote rapid growth; viability of spores has not been altered due to improper storage temperature, humidity or proximity to chemicals and proper functioning of Auto-Reader Incubators. Both, the positive control indicator and the processed indicator, should belong to the same batch.
7. Incubate the processed indicator and the positive control indicator in Auto-Reader Incubators for a maximum of 20 minutes at (60 ± 2) °C for ultra rapid readout. **NOTE:** Holding time between sterilization and incubation should not exceed a 7-day period. Fluorescence detection by the reader (excitation 340-380 nm / emission 455-465 nm) means a failure in the sterilization process. If no fluorescence is detected at 20-minute incubation, the result is negative. The positive control must give positive fluorescence readout. It is good practice to incubate a positive control for a visual color change.
Record the positive results and discard the SCBIs immediately, as it is indicated below.

Ultra Rapid readout: 20 minutes
The Ultra Rapid Readout must be carried out in the Auto-Reader Incubators. Fluorescence is emitted after the reader stimulates the spore carrier with UV light. Final readout of negative results is readily available after 20 minutes of incubation. Fluorescence readout is an indirect measure of the germination and growth of *Geobacillus stearothermophilus* spores, which have survived the sterilization process (positive result). Furthermore, a failure in the sterilization process can also become evident by culture medium color change. Due to the high sensitivity of the fluorescence results at 20 minutes, conventional incubation for color change of WTL198-0072 is not an advantage.

Visual confirmation: 48 hours
Optionally, you can perform a visual color-change confirmation after a 48-hour incubation. If the sterilization process has not been successful,

culture medium will turn yellow during incubation at 60 ºC, indicating the presence of living spores. If sterilization was successful, culture medium will remain purple after incubation. The positive control must show a color change from purple to yellow for results to be valid.

Readout time: 7 days
A 7-day readout is optional and may be routinely performed. This is an initial validation of the 20-minute readout. Fluorescence results are compared to the 7-day visual readouts. **NOTE:** If 7-day readout is performed, a humidified environment will be required to prevent medium from drying out.

Monitoring frequency
Follow facility Policies and Procedures which should specify a biological indicator monitoring frequency compliant with professional association recommended practices and/or national guidelines and standards. As the best practice and to provide optimal patient safety, Tuttnauer recommends that every sterilization load be monitored with an appropriate biological indicator.

Storage
Store in a dark place at temperature between 10-30 ºC and 30-80 % Relative Humidity. Do not freeze. Do not store biological indicators near sterilizing agents or other chemical products.

Shelf life
Biological Indicators have an expiration date of 2 years from the date of manufacture when stored at recommended conditions. Do not use indicators after their expiration date. Chemical Process Indicator on SCBI label have an expiration date of 2 years when used as part of SCBI.
End Point Stability Reaction: Chemical Process Indicator endpoint shall remain unchanged for a period of 6 months when stored at previously indicated conditions.

Disposal
Discard biological indicators after use according to your country's healthcare and safety regulations. The positive biological indicators can be autoclaved in a gravity air displacement steam sterilizer at 121 ºC for 30 minutes, 132 ºC for 15 minutes or 134 ºC for 10 minutes; or in a dynamic air removal steam sterilizer at 132 °C for 4 minutes or 135 °C for 3 minutes.

Intended Use Table

Autoclave/Steam Cycles		
Model	Gravity Displacement	
WTL198-0072	132 ºC	135 ºC
	10 minutes 15 minutes 25 minutes	10 minutes
	Dynamic Air Removal (Vacuum Assist)	
	132 °C	135 °C
	4 minutes	3 minutes
	Fluorescence Read Time	pH Color Change
	20 minutes	48 hours

Explanation of Symbols

STEAM	Product designed for use in Steam sterilization processes
LOT	Batch number
	Manufacture date
	Expiration date