The Celerity™ 20 STEAM Process Challenge Device is used for qualification, routine microbial monitoring, and load monitoring of steam sterilizers. The validated steam sterilization cycles include:

- Gravity 250°F (121°C) 30 minutes
- Gravity 270°F (132°C) 15 minutes

Performance of the Celerity 20 STEAM BI was tested per methods described in American National Standards Institute, Association for the Advancement of Medical Instrumentation, and the International Organization of Standards (ANSI/AAMI/ISO) 11138-1:2017 and 11138-3:2017; and the process indicator on the BI vial cap meets the Type 1 chemical indicator requirements of ANSI/AAMI/ISO 11140-1:2014.

**FEATURES**

- 20-minute incubation time for fast results and quick device turn-around
- Compact size requiring minimal shelf space in sterilizer chamber
- Visibility of integrating indicator through PCD, provides immediate knowledge of sterilization failures without opening PCD
- Barcode on process indicator label makes electronic documentation of lot numbers and expiration dates easy
- Equivalent performance to ANSI/AAMI 16-towel biological indicator test pack; same resistance as AAMI gold standard
- BI has a Twist & Flick activation, reducing the potential of contamination from "over activated" vials and eliminating need of a second activator
- Glass-free BI design reduces potential for injury from broken glass

**APPLICATION**

The Celerity™ 20 STEAM Process Challenge Device is used for qualification, routine microbial monitoring, and load monitoring of steam sterilizers. The validated steam sterilization cycles include:

- Gravity 250°F (121°C) 30 minutes
- Gravity 270°F (132°C) 15 minutes

**DESCRIPTION**

The Celerity 20 STEAM Process Challenge Device (PCD) for Gravity cycles is a pre-assembled pack consisting of a clear plastic housing sealed with a laminate foil. The PCD design includes a small channel for air removal and steam penetration. Each PCD contains a Celerity 20 STEAM Biological Indicator (BI) and an integrating indicator.

Each BI consists of a plastic vial inoculated with Geobacillus stearothermophilus spores and media sealed within the cap. The BI cap includes a wraparound label that identifies the lot number and expiration date and is printed with a process indicator for steam. A barcode printed on the label can be scanned to electronically document the lot number and expiration date of the BI.

The Celerity 20 STEAM BI employs an enzyme detection system. Following the sterilization process, enzyme associated with any remaining viable spores begins a chemical reaction with defined media. Media contains a substrate, 4-methylumbelliferyl-α-D-glucopyranoside (MUD), which reacts with the enzyme α-Glucosidase to generate a fluorescent signal. An increase in fluorescent signal is detected by the Incubator and results in a positive growth response.

The final incubation time for the Celerity 20 STEAM BI when used in conjunction with the Celerity STEAM Incubator is 20 minutes. The incubation time has been validated using the FDA guidance for validating reduced incubation times of biological indicators.

**Ordering Information**

- LCB050 - Celerity 20 STEAM Process Challenge Device for Gravity Cycles; Quantity: 25 Test Packs plus 25 Controls
- LCB051 - Celerity STEAM Incubator; Quantity: 1

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1 Tech Data 10852856 provides details concerning the Celerity 20 STEAM BI
STANDARDS

ANSI/AAMI/ISO 11138-1:2017 Sterilization of health care products- Biological indicators- Part 1: General requirements. Association for the Advancement of Medical Instrumentation; 2017


ANSI/AAMI/ST79:2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities. Association for the Advancement of Medical Instrumentation; 2017

DIRECTIONS FOR USE

IMPORTANT:
This section enables the Customer to have a good understanding of directions for use. It is never to be used in place of actual instructions or in place of information provided on product packaging or labeling. Always refer to the directions that come with the product and adhere to all applicable warnings and cautions.

Qualification Testing
For Qualification Testing, all tests are performed in an empty steam sterilization chamber. Three consecutive test cycles are run for each preprogrammed cycle on the sterilizer.

Routine Monitoring or Load Monitoring
For routine or load monitoring, PCD is placed in a loaded steam sterilization chamber on lowest rack over drain.

For each test cycle:
1. Place the Celerity 20 STEAM PCD in most challenging location, typically on bottom rack directly over drain.
2. Run sterilization cycle.
3. After sterilization cycle, remove PCD and allow to cool.
4. Check integrating indicator strip for passing results (see Figure 1). If passing, open PCD and remove BI.
5. Evaluate process indicator for a passing result. Process indicator starts pink and turns brown after exposure to steam.
6. Seal and activate BI by twisting cap clockwise.
7. Media releases with one quick shake of sealed BI.
8. Incubate BI for 20 minutes using Celerity STEAM Incubator.

The incubator is a fully automated system. At completion of the incubation process (or as soon as a positive biological indicator is identified) the incubator indicates the conclusion of the test. A permanent record of the test results may be printed using an optional printer.

Figure 1. Interpretation Guide For Integrating Indicator Strip

TECHNICAL PROPERTIES

Components:
- Foil cover
- Clear polypropylene housing
- Celerity 20 STEAM BI
- Chemical Integrator

Dimensions: 3 x 3 ¼ x ¾” (76.2 x 82.6 x 19 mm)

Bacterial species: Geobacillus stearothermophilus NRRL B-1172

Mean population recovery: 1.0 x 10^6 to 4.0 x 10^6 cfu/biological indicator of Geobacillus stearothermophilus

Detection system: Reaction of α-Glucosidase with 4-methylumbelliferyl α-D-glucopyranoside

Fluorogenic substrate: 4-methylumbelliferyl-α-D-glucopyranoside (MUD)

Medium: Defined medium

D-value for saturated steam at 250°F (121°C): ≥ 1.5 minutes

Note: The D-value is reproducible only when the biological indicator is exposed and cultured under the same conditions which were used by STERIS Corporation to determine the D-value.

Incubation time: 20 minutes

PCD Shelf life: Shelf life is established at the time of manufacture, as indicated by the expiration date on the lot label.
**STORAGE CONDITIONS**

Prior to use, PCDs should be stored at 60-75°F/16-24°C with a relative humidity of 30-60% (RH). Avoid contact with sterilant or chemicals. Store away from sterilizers as conditions in that environment may affect performance.

**DISPOSAL**

Before discarding, treat unexposed biological indicators and positive biological indicators as appropriate for standard biological waste, nonpathogenic species. All other components and negative biological indicators may be disposed of as regular waste.

**SERVICE**

**Technical**

STERIS is pleased to provide a completely staffed and well equipped technical service laboratory capable of performing needed tests and providing both telephone and on-site assistance when needed. More details on how this service can benefit a facility’s particular situation can be provided upon request.

**Education**

STERIS University prepares both today’s and tomorrow’s leaders. With a wide range of learning opportunities, curriculum and expertise; STERIS University provides a tailored accredited education program that fits anyone’s busy schedule. Visit [http://university.steris.com/sterisu](http://university.steris.com/sterisu) to learn more.

**TECHNICAL DATA**

The performance of the Celerity 20 STEAM PCD is equivalent to the 16-towel biological indicator test pack as defined in ANSI/AAMI ST79. **Table 1** compares performance of the Celerity 20 STEAM PCD for Gravity Cycles against that of the ANSI/AAMI ST79 16-towel biological indicator test pack.

Performance of the Celerity 20 STEAM BI was tested per the methods for biological indicators for steam sterilization processes as defined in ASNI/AAMI/ISO 11138-1 and 11138-3. The PCD indicator strip is an integrating indicator and meets performance specifications as defined by FDA guidance for chemical integrators.

<table>
<thead>
<tr>
<th>Exposure Conditions</th>
<th>16-Towel Test Pack #Positive/#Tested</th>
<th>Process Challenge Device* #Positive/#Tested</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Integrator</td>
<td>BI Fluorescence</td>
</tr>
<tr>
<td><strong>Aborted Cycle</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>250°F (121°C) Gravity 30 Minutes</td>
<td>6/6</td>
<td>18/18</td>
</tr>
<tr>
<td>250°F (121°C) Gravity 15 Minutes</td>
<td>6/6</td>
<td>18/18</td>
</tr>
<tr>
<td><strong>Full Cycle</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>250°F (121°C) Gravity 30 Minutes</td>
<td>0/6</td>
<td>0/18</td>
</tr>
<tr>
<td>250°F (121°C) Gravity 15 Minutes</td>
<td>0/6</td>
<td>0/18</td>
</tr>
</tbody>
</table>

*Results for PCDs are combined for three lots of test articles
CUSTOMER IS RESPONSIBLE FOR COMPLIANCE WITH APPLICABLE LOCAL AND NATIONAL CODES AND REGULATIONS.

For further information, contact:

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060-1834 • USA
440-354-2600 • 800-548-4873
www.steris.com

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