inSITE Integrity Testing System

Confidence at the point of use

As the value of processes increases with each downstream bioprocessing step, the value of sterility and leak detection becomes even more critical. The confidence of a final integrity test prior to use, at the point of use, is what the Thermo Scientific™ inSITE™ Integrity Testing System provides to customers. The technology of the inSITE Integrity Testing system protects single-use consumables from potential flaws by testing Thermo Scientific™ BioProcess Containers (BPCs) for damage that can occur in their facility.

- Detects gross or fine leaks that can occur between the end user’s warehouse and the cleanroom floor
- Helps safeguard end users from injury associated with improper handling and loading procedures

Loading and filling with ease

BPC loading and placement is another valuable step prior to filling, which must be taken with care. The inSITE system will inflate to a specified pressure, so that placement of the BPC in the tank is accurate and errors that can result from pinching and creasing are limited.

Once the BPC is ready to be filled, the liquid filling cycle moderates the internal pressure within the BPC while fluid is being introduced. The cycle is configured to regulate the open/close position of the coaxial valve mounted on the inSITE unit.

Advantages

- Gross and fine leak detection
- Guided validation setup
- Tests single-use BPCs up to 5,000 L in any tank
- Inflation procedure improves loading and placement in tanks
- Liquid filling cycle regulates internal pressure while fluid is being introduced
- Permanent and disposable pressure sensors provide comparative pressure data
- Improved product consistency
Features and benefits

- **Inflation procedure for BPC tank loading** — the inflation cycle assists the operator in the loading of BPCs with minimal interaction and reduces the risk of damage from handling.

- **Pressure decay integrity test** — the inSITE system uses the pressure decay method to test its sensitivity and practicality at the point of use.

- **Gross leak detection** — this detection test quickly finds small leaks (100–1,000 μm) and confirms the connection and setup of the BPC system.

- **Fine leak detection** — a unique, validated detection test for each tank and BPC assembly, which is dependent on time allotment and environment.

- **Point of use** — the inSITE system is designed to test at the process location.

- **Liquid filling cycle** — moderates internal pressure within the BPC while the fluid is introduced.

- **Pressure sensors** — permanent and disposable pressure sensors provide comparative pressure data.

- **BPC sizes** — the point-of-use feature of the inSITE system will apply to BPCs in any tank size (the maximum size of a BPC to be used in conjunction with the inSITE system is 5,000 L).

- **Tank sizes** — any tank can be used; the fine leak detection process requires a specific validation for each container.

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### inSITE Integrity Testing System specifications

<table>
<thead>
<tr>
<th><strong>Maximum operating pressure</strong></th>
<th>Up to 125 mbar</th>
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</thead>
</table>
| **Measuring ranges** | - Test pressure: Up to 40 mbar  
- Maximum measurable volume: 5,000 L  
- Gross leak flaw sizes: 100–1,000 μm |
| **Operating conditions** | - Room temperature: 18–24°C (65–75°F)  
- Relative humidity: 5–95%, noncondensing |
| **Compliance** | CE and ETL |
| **Wireless PC** | A wireless PC operating system allows the user to save, store, and email testing results |
| **Label printer** | Create product report labels |
| **Onboard barcode scanner** | Scan product report labels |
| **USB port** | Download testing results |
| **Scanner selection** | - Both single-channel and multichannel inSITE systems are compatible with PendoTECH™ and Thermo Scientific™ TruTorr™ sensors  
- End user will have to use correct sensor cord to attach appropriate sensors  
- Both sensor cords will be sold as a standard item with each model |

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Air output valve locations:  
Single-channel: 1  
Multi-channel: 3
### Ordering information

<table>
<thead>
<tr>
<th>Description</th>
<th>Overall dimensions (W x D x H)</th>
<th>Weight</th>
<th>Power requirements</th>
<th>Cat. No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single-channel</td>
<td>66 x 74 x 147 cm (26 x 29 x 58 in.)</td>
<td>175 kg (386 lb)</td>
<td>110–220 VAC, 50–60 Hz</td>
<td>IN1009</td>
</tr>
<tr>
<td>Multi-channel</td>
<td>66 x 74 x 147 cm (26 x 29 x 58 in.)</td>
<td>200 kg (440 lb)</td>
<td>110–220 VAC, 50–60 Hz</td>
<td>IN1010</td>
</tr>
</tbody>
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*Please contact your Thermo Fisher Scientific sales representative for more information.*