3M™ Electronic Test System

The integrated solution to revolutionize sterilization monitoring

3M Health Care
Developed in close consultation with health care professionals, the 3M Electronic Test System (ETS) is a world’s first and a vital step forward for sterilization assurance programmes.

3M ETS is a unique, stand-alone test device for the measurement of the physical parameters of a steam sterilization cycle providing:
- an accurate temperature, pressure and time measurement
- a unique air detection system
- a totally computerised engineering tool for precise analysis

3M ETS is highly innovative and easy to use. Thus, as well as providing an alternative to the traditional Bowie and Dick Test Pack, this unique test device performs a number of other important functions.

Reproducible results/Precise data acquisition
Results are reproducible and equivalent in performance to a standard Bowie and Dick Test Pack (as described in EN 285 and ISO DIS 11140-3). Tested to methods described in prEN 867-4, ISO DIS 11140-4 and BS 7720, the 3M ETS satisfies the daily steam penetration test requirement prescribed in EN 554.

Clear ‘Pass’/‘Fail’
Unlike any other test system, the 3M ETS Sensing Unit 4008, boasts a unique device which functions as a stand-alone measurement system which not only gives clear ‘Pass’ or ‘Fail’ results, but also ‘Early Warning’ indication and Sterilization Parameter Indication (SPI) measurements.

Diagnostic features
In addition to the Bowie and Dick test results, the ETS also provides a number of diagnostic features, for example Sterilization Parameter Indication (SPI), Leak Rate Test (LRT), Early Warning, Superheated Steam Detection, F₀ Integration, Engineering Tests and Help Files which are important in assuring the safe operation of sterilizers.

Electronic graphic analysis and print outs
The system can be further enhanced by using the 3M ETS DataConverter (4009), and 3M ETS Software (4010), for connection to a standard printer or PC. Thus 3M ETS will computerise all the results, producing graphs of time, pressure and temperature as well as the ‘Pass’ or ‘Fail’ results.
The software will also provide measurements for the Leak Rate Test (EN 285), F₀ Integration and Sterilization Parameter Indication.
Its diagnostic functions will also suggest potential causes of failure and recommendations for possible remedial action.

Precise data acquisition/Digital archives
To maintain precise record keeping and eliminate all possible transcription errors, the 3M ETS Sensing Unit (4008) will create an electronic archive using dedicated PC software. The data logging mode allows for the individual interpretation of the sampled data for steam sterilization cycles operating at temperatures other than 134°C for 3 minutes.

The 3M Sterilization Assurance Programme
The 3M Sterilization Assurance Programme is a comprehensive and prudent approach to sterilization monitoring procedures and methods that you can count on to reduce the risk of unnoticed sterilization failure. The Programme consists of five separate, but interrelated processes, illustrated above, which monitor every aspect of the sterilization cycle and help you establish, manage and maintain a consistent protocol for sterilization in your facility.
What we’ve taken out

- Subjective interpretation of results
- Inconclusive tests results
- Hand written record keeping
- Monthly purchase orders
- Wasted valuable storage space
- Unplanned downtime
- Unnecessary upgrading costs

and what we’ve put in

- Unambiguous ‘Pass’ or ‘Fail’ indication
- Reusable 400 times
- Electronic archiving and filing
- One purchase order raised every eighteen months*
- Device taking up minimum space
- Diagnostic functions allowing planned maintenance
- Precise, accurate and independent measurement of sterilizer performance

*Statistic assuming a once a day use, six times a week

is simply revolutionary
Driven by the future

- **Bowie Dick Test (BDT)**
  Receive a clear ‘Pass’/’Fail’ answer, requiring no interpretation for your daily air removal and steam penetration test (as required in EN 554 and EN 285).

- **Early Warning**
  Detect an early indication of potential sterilizer malfunction: ETS gives the indication of air entrained in the chamber insufficient to cause a BDT failure. Corrective maintenance can eliminate production down time.

- **The Leak Rate Test (LRT)**
  Conduct a meaningful LRT to determine chamber seal integrity even for equipment with low resolution pressure gauges or no pressure gauge.

- **Sterilization Parameter Indication (SPI)**
  Plan corrective maintenance to avoid production downtime: ETS measures the parameters indicating inadequate processing due to temperature or time.

- **Diagnostics**
  Accelerate fault identification with the ETS Software featuring simple help screens to illustrate failure types, causes and possible remedial actions.

- **Superheated Steam Determination**
  Decide on remedial action before processing load items. The ETS compares theoretical and measured temperature giving an indication of the presence of superheated steam in the sterilization chamber.

- **Calibration Check**
  Save downtime and servicing costs with the ETS procedure for checking the calibration of sterilizer instruments. Calibration checks can now be carried out on-site during normal equipment control procedures (eg. BDT).
Dilution Factor Calculation
Plan corrective maintenance, avoiding equipment breakdown: ETS monitors changes or deterioration by the calculation of the dilution factor for air removal using the standard method described in DIN 58946-2.

Data Logging
Monitor and record precise temperature, time and pressure (T/t/P) data in electronic (Intelligent Archiving) or hard copy formats, by using the ETS Sensing Unit in data logging mode.

Engineering Tests
Eliminate variables when carrying out tests in which sterilizer performance is determined using a thermometric textile test pack (as defined in EN 285 and HTM 2010):
- The thermometric small load test
- The thermometric full load test
- The air detector function test

Versatile Data Handling and Archiving
Share files and records with the easy to use ETS Software features allowing:
- On screen data analysis
- Intelligent data archiving
- Summary report writing

Electronic Lethality Calculation ($F_0$)
Monitor cycle-to-cycle variability as a single function because ETS calculates the total energy input of the process and expresses it as a function of microbial lethality – $F_0$, an application for industrial and hospital environments.
Ordering Information for the 3M™ Electronic Test System (ETS)

<table>
<thead>
<tr>
<th>Cat No</th>
<th>Product name</th>
<th>Items/Box</th>
<th>Boxes/Case</th>
</tr>
</thead>
<tbody>
<tr>
<td>4008</td>
<td>ETS Sensing Unit</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>4009</td>
<td>ETS DataConverter</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>4010</td>
<td>ETS Software Version SW1.1</td>
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Understanding the role of each component of 3M ETS

<table>
<thead>
<tr>
<th>Test Descriptions</th>
<th>ETS Sensing Unit</th>
<th>ETS Sensing Unit +DataConverter</th>
<th>ETS Sensing Unit +DataConverter +Software</th>
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</thead>
<tbody>
<tr>
<td><strong>EQUIPMENT CONTROL</strong></td>
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<tr>
<td>Bowie and Dick Test: according to EN 285, BS 7720, prEN 867-1</td>
<td>✔✔✔</td>
<td>✔✔✔</td>
<td>✔✔✔</td>
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<tr>
<td>Sterilization Parameter Indicator (SPI)</td>
<td>✔</td>
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<tr>
<td>Early Warning of pending Bowie and Dick test failure</td>
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<td><strong>ELECTRONIC RECORD KEEPING</strong></td>
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<tr>
<td>Store Bowie and Dick test data in writing or electronically</td>
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<td>✔</td>
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<tr>
<td>Electronic File Management (intelligent archiving)</td>
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<td>Generate written reports for management overviews and quality systems</td>
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<tr>
<td><strong>SPECIAL FUNCTIONS</strong></td>
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<tr>
<td>Help files: Embedded ‘tips’ to help analyse/diagnose potential failures (Diagnostic Poster)</td>
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<tr>
<td>Calibration check (as per EN 285)</td>
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<tr>
<td>Leak Rate Test (LRT) as per EN 285 (1.3mB/min)</td>
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<tr>
<td>Detection of presence of superheated steam</td>
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<tr>
<td>Dilution Factor Calculation</td>
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<tr>
<td>Engineering Tests</td>
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<td>Data Logging</td>
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<tr>
<td><strong>F₀ INTEGRATION</strong></td>
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<td>Measures total energy delivered to kill micro organisms</td>
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3M Health Care not only provides quality products but also appropriate supporting services which enable correct product use and optimised outcomes. 3M strives to contribute to one of the ultimate goals of all health care organisations: infection-free patients and health care professionals, throughout the continuum of care.

3M Sterilization Assurance products are one part of a full line of products 3M has developed for hospital and home use. Contact your local 3M representative for further information on: • skin health products • surgical masks • respirators for personal protection • surgical draping and gowns • clippers for pre-operative hair removal.

3M

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