

WORLD CONGRESS OF STERILIZATION COMBINED MEETING WFHSS / AIOS



**Small Steam Sterilizers
BS EN 1360:2004**

L Kingston. Registered Authorised Person {Sterilizers} Member of :-

- ***BSI - CH198 – Sterilization***
- ***CEN - TC 102 wg 2/3 – Steam Sterilizers***
- ***ISO - TC 198 wg 3 – Moist Heat
Sterilization.***
- ***EPL/66 Safety of Measuring, Control and
Laboratory Equipment.***
- ***BSI LBI 35- 1***

SCOPE OF THE PRESENTATION FOR THE CHANGES WITHIN BS EN 1360

- ***To provide a brief introduction to the update requirements and changes.***
- ***To introduce the current standard focusing on what is the requirement of small steam sterilizer:***
- ***Definition Small steam sterilizer:-Size one which is unable to accommodate sterilization module and has a chamber volume less than 60 litres***

Note One Sterilization module =300mmx 300mm x600mm

SCOPE OF THE PRESENTATION FOR THE CHANGES WITHIN BS EN 1360

- **Sterilization cycle type:- classification of the process based on performance**
- **Solid:- product not made from porous materials no recesses which present a greater or equal challenge than a hollow load (B)**
- **Hollow load A :-single ended open space ratio of length to diameter of cavity greater than 1 less or equal 750 ($1 \leq L/D \leq 750$) or ($L \leq 1\,500\text{mm}$) or ($2 \leq L/D \leq 1\,500$) ($L \leq 3000\text{mm}$) which is not a hollow load (B)**

REVIEW OF THE CHANGES WITHIN BS EN 1360

- **Hollow load B :- single ended open space ratio of length to diameter of cavity greater than 1 less or equal to 5 ($1 \leq L/D \leq 5$) Where diameter greater than or equal to 5mm ($D \geq 5\text{mm}$) or double ended where ratio length / diameter greater than equal to 2 less than 10 ($2 \leq L/D \leq 10$) or ($D \geq 5\text{mm}$)**
- **Temperature measurement reference position:- identified by manufacture condition in useable space of chamber**

BS EN 1360– Structure

SMALL STEAM STERILIZER TYPE REQUIREMENTS

B

Type
All wrapped or
non wrapped
products

Type
B
All wrapped or non
wrapped products

N

Type
All non
wrapped
Solid products

Type
N
All non wrapped
Solid products

S

Type
All wrapped or
non wrapped
products

Type
S
All wrapped or non
wrapped products

BS EN 1360– Structure

**SMALL STEAM STERILIZER
TYPES WITHIN **S**
LOADS IN TYPE TESTS**

S1

Type
All wrapped or
non wrapped
products

Type
S1
Hollow Load A&B
Dryness Solid Load

S2

Type
All non
wrapped
Solid products

Type
S2
Dryness, Porous Load
& Solid products

S3

Type
All wrapped or
non wrapped
products

Type
S3
Specific Medical Devices

Operational Services

Points to be aware of :

- ***Water Supply Steam Generation.***
- ***Designed to function with water free of contaminants***
- ***Cause no harm to sterilizer or the sterilizer load***

Operational Services

Points to be aware of :

- ***Water Used other than for Steam Generation.***
- ***Potable quality***
- ***Range specified manufacturer, including 15°C***
- ***Cooling Purposes***
- ***Vacuum systems***
- ***Total hardness value 0,7mmol/l 2,0mmol/l***

Operational Services

Points to be aware of :

- ***Water reservoir if fitted***
- ***Pipe work shall be fitted with valve or other device / automatic to allow draining by operator reservoir and pipework***
- ***Manufacturers design shall facilitate cleaning filling and inspection***
- ***Indicate sufficient water for operating cycle or shall not be capable of starting cycle***
- ***Designed to prevent back siphoning to chamber***

BS EN 1360 PROCESS PERFORMANCE DATA

Values Type testing

<i>1 of 2 Sheets Type Tests</i>	<i>Sterilization Process Cycle Types</i>					
	<i>B</i>	<i>N</i>	<i>S1</i>	<i>S2</i>	<i>S3</i>	
<i>Dynamic chamber pressure</i>	YES	YES	YES	YES	YES	
<i>Air leakage</i>	YES		YES	YES	YES	
<i>Empty chamber</i>	YES	YES	YES	YES	YES	
<i>Solid load</i>	YES	YES	YES	YES	YES	
<i>Small Porous items</i>	YES					
<i>Small porous loads</i>	YES					
<i>Full porous load</i>	YES					



BS EN 1360 PROCESS PERFORMANCE DATA


Values Type testing



<i>2 of 2 Sheets Type Tests</i>	<i>Sterilization Process Cycle Types</i>					
	<i>B</i>	<i>N</i>	<i>S1</i>	<i>S2</i>	<i>S3</i>	
<i>Hollow load B</i>	YES		YES	YES	YES	
<i>Hollow load A</i>	YES		YES	YES	YES	
<i>Multiple wrapping</i>	YES			YES	YES	
<i>Dryness solid load</i>	YES	YES	YES	YES	YES	
<i>Dryness porous load</i>	YES			YES		
<i>Residual air</i>		YES				
<i>Specific medical devices</i>					YES	

BS EN 1360 PROCESS DATA

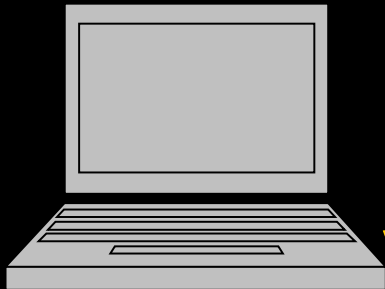
limiting values to be recorded

Start	Time for vacuum pulse	Time for pressure pulse	Sterilization start time	Holding time	Sterilization end time	Drying start time	Drying end time
YES	YES	YES	YES	YES	YES	YES	YES
	0kPa to 400kPa			50°C to 150°C			
	Sample each channel At least every 2.5sec			Sample each channel At least every 2.5sec			
	Accuracy Better than ±5kPa			Accuracy Better than ± 1%			
Sterilizers which have no vacuum phase Pressure Scale 100kPa to 400kPa							

BS 1360 Sterilizers Process Evaluation System

If fitted

- 1. Compare with validated cycle any change pressure or temperature time period that change occurs***
- 1. Change beyond programme limits***



***Shall cause an
indicate***

Fault



BS 1360 Sterilizers Process Evaluation System

If fitted

- 1. Compare two independent temperature sensors sterilizer temperature instrument chamber and recorder ; or***
- 1. Capable comparing theoretical steam temperature with chamber during the holding period***



Shall cause an indicate

Fault



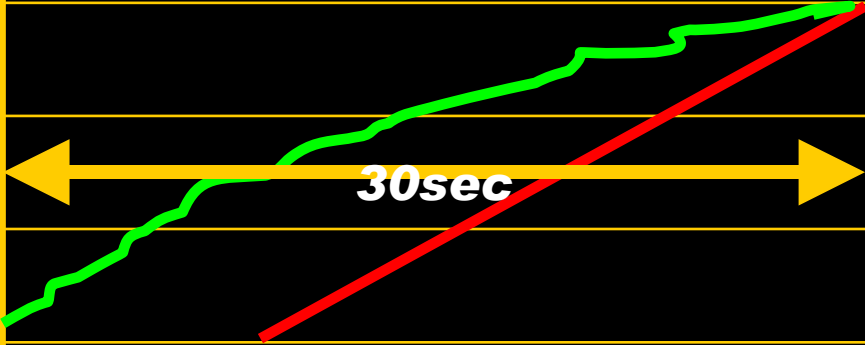
BS 1360 Sterilizers Process System

Time – Temperature relationships:- **STERILIZATION**

Sterilization Temperature °C	Minimum Holding Time Minutes
121°C	15_{Min}
126°C	10_{Min}
134°C	3_{Min}
143°C	1_{Min}

BS 1360 Sterilizers Process System

Time – Temperature relationships:- *Equilibration*

Temperature °C	Equilibration Time Seconds
121° 126° 134° 143°	15 seconds
	Not exceeding 30 seconds is acceptable
>1K/min < 8K/min	If ?

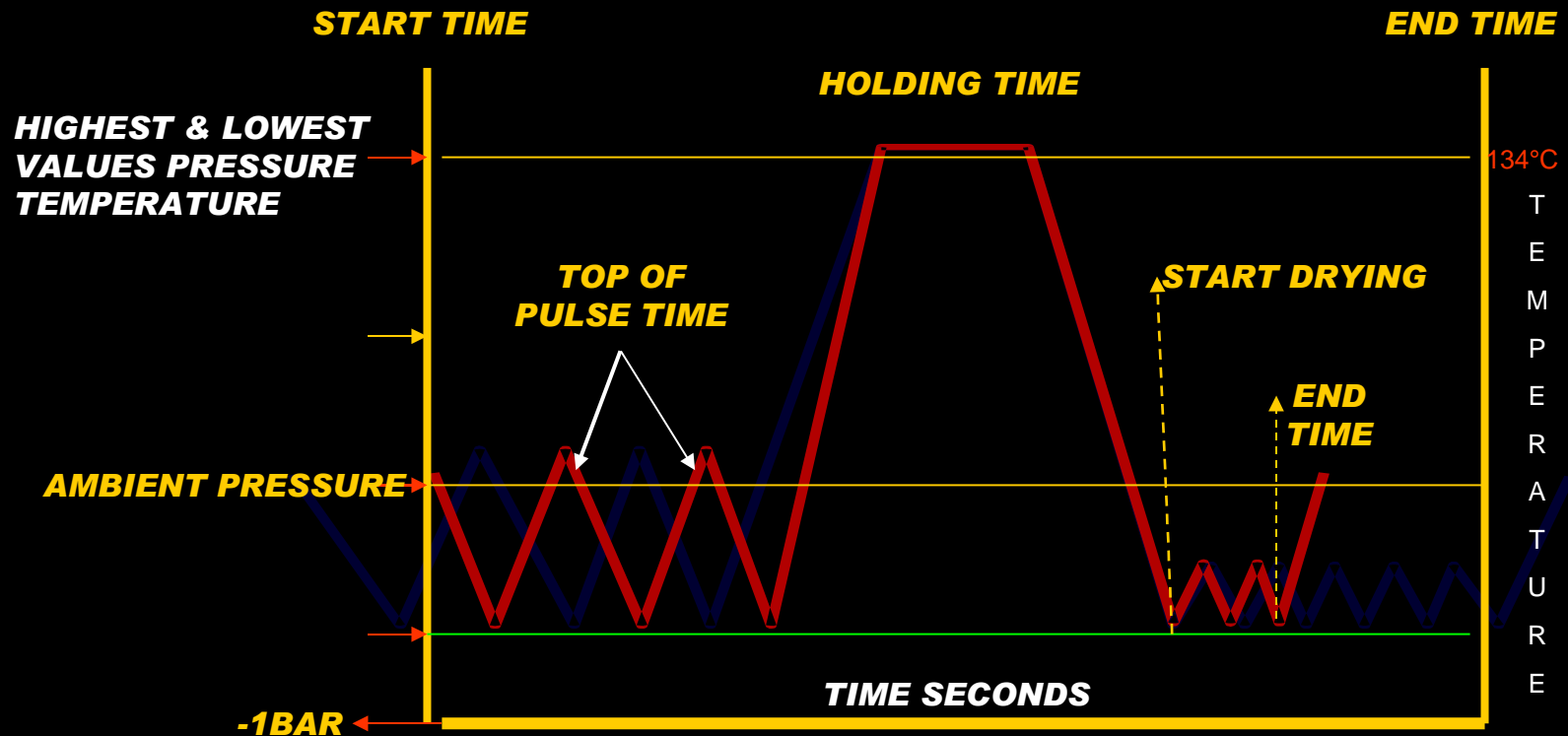
BS 1360 Sterilizers Process System

Time – Temperature relationships:- Equilibration

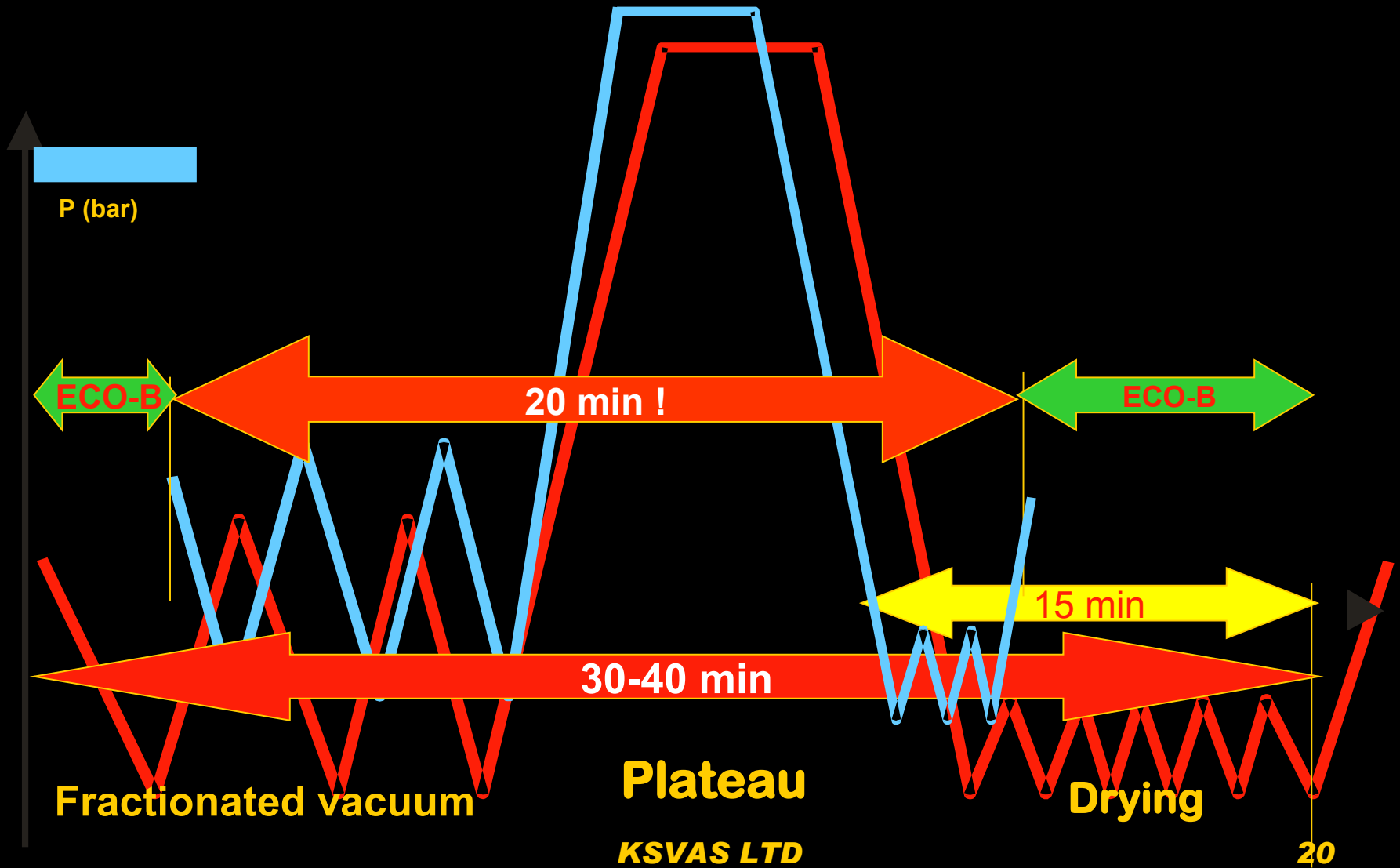
Temperature °C	Equilibration Time Seconds
121° 126° 134° 143°	30 seconds
Theoretical steam Temperature 10K heating stage Less than 8K/min But greater than 1K/min	During last 10K of heating stage chamber and load do not differ by more than 2K

BS 1360 Sterilizers Process Cycle

DATA AND LIMITING VALUES TO BE RECORDED



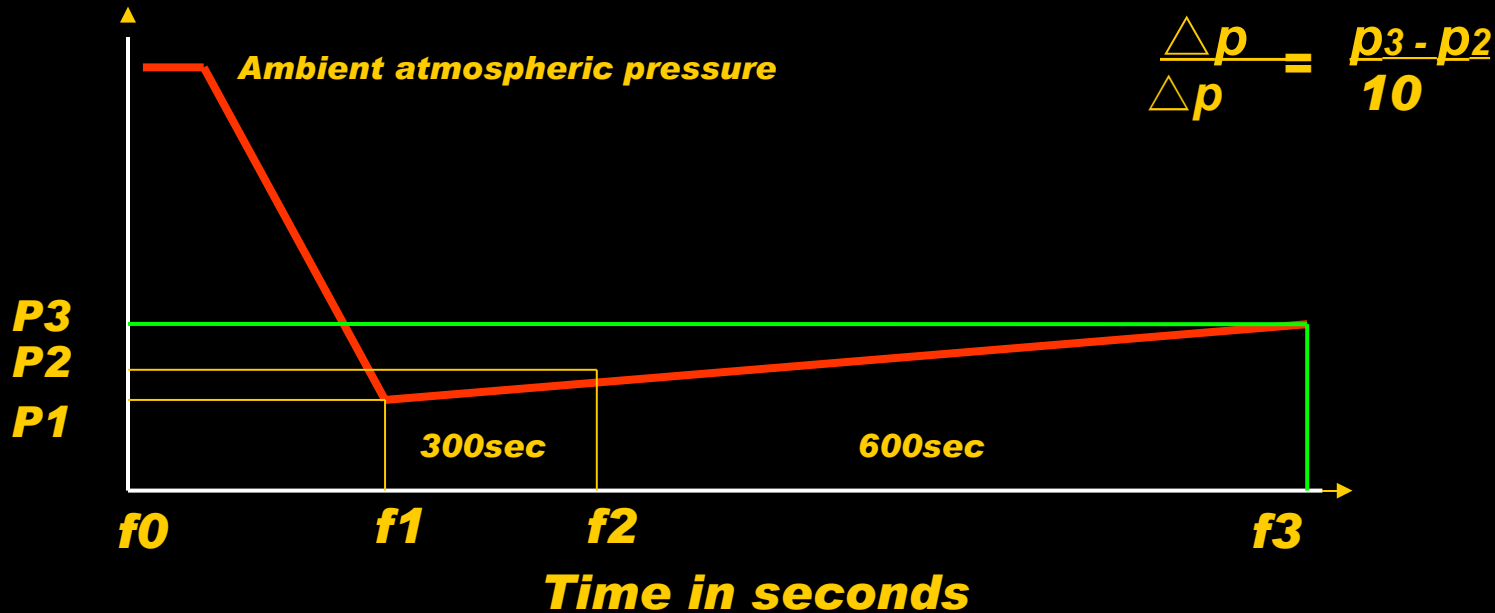
TYPE B cycle



BS 1360 Sterilizers Testing System

Air Leakage Test

Requirement Shall not cause rate pressure rise to exceed **0.13kPa/min{1.3mbar/min}** when tested



BS 13060 STERILIZER

Leak Test Reports

W&H Sterilization Lisa 517 08-0066 00.12.02.00.12

Horsham WSCPDS

Cycle: VACUUM TEST

Number: 00196

Date: 03/04/08 14:50:13

Phase	Time	part.	T °C	P bar
Start	00:00	00:00	42,98	0,026
P1	02:02	02:02	44,48	-0,870
P2	07:02	05:00	45,57	-0,855

A390 VACUUM TEST P3

Number: 00196

Date: 03/04/08 15:06:30

P Chamber	-0,842 bar
T Chamber int.	45,16 °C
T Chamber ext.	58,58 °C
T Steam gen.	48,36 °C

Date: 03/04/08 15:07:42

Test
failed

Trk. C2138C200196

FAIL

W&H Sterilization Lisa 517 08-0066 00.12.02.00.12

Horsham WSCPDS

Cycle: VACUUM TEST

Number: 00197

Date: 03/04/08 15:11:22

Phase	Time	part.	T °C	P bar
Start	00:00	00:00	38,73	0,026
P1	01:58	01:58	39,66	-0,870
P2	06:58	05:00	41,06	-0,864
P3	16:58	10:00	39,93	-0,861
END	18:15	01:17	44,84	0,023

Date: 03/04/08 15:29:37

Test
passed

Trk. C2138C200197

PASS

BS 1360 Sterilizers Performance

ATTAINMENT STERILIZATION CONDITIONS

***All temperatures measured in useable
space and load***

***are not lower than the sterilizer selected
temperature***

Requirement:-

***Are not more than 4K above sterilization
temperature selected***

***Do not differ from each other by more
than 2K***

BS 1360 Sterilizers Performance

TYPE TEST PROCEDURE

Test equipment requirements



Thermometric measurement
Eight sensors shall be used



One external pressure sensor



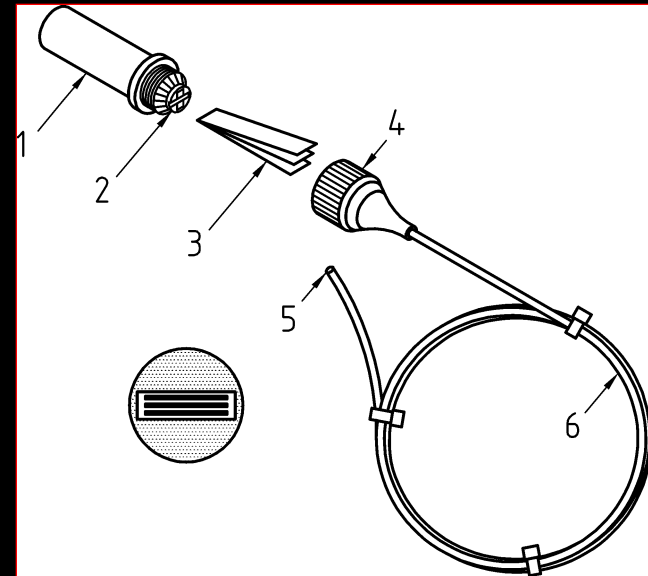
Sensors connect to chamber
Type tests shall be repeated
Twice (three tests in all)

BS 1360 Sterilizers Testing Process Cycle

Process Challenge Device & Chemical Indicator system for Hollow Load A

Key

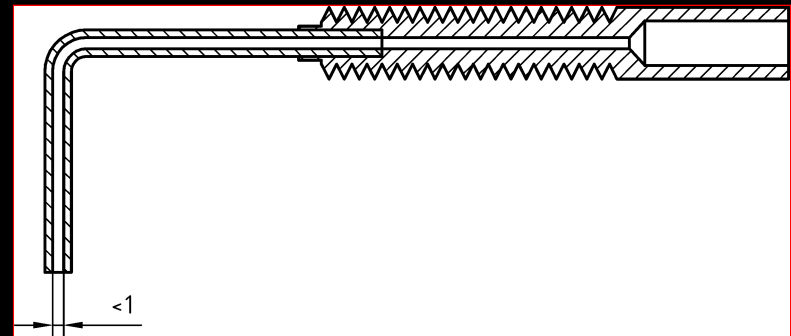
- 1 Capsule**
- 2 Sealing**
- 3 Indicator system**
- 4 Connector**
- 5 Open end**
- 6 Tube**



BS 1360 Sterilizers Steam Testing

- ***Steam pressure kPa (bar) Bore mm $\pm 0,02$ up to 400 (3) $0,8$ up to 500 (4) $0,6$ up to 800 (7) $0,4$***

Bulkhead fitting

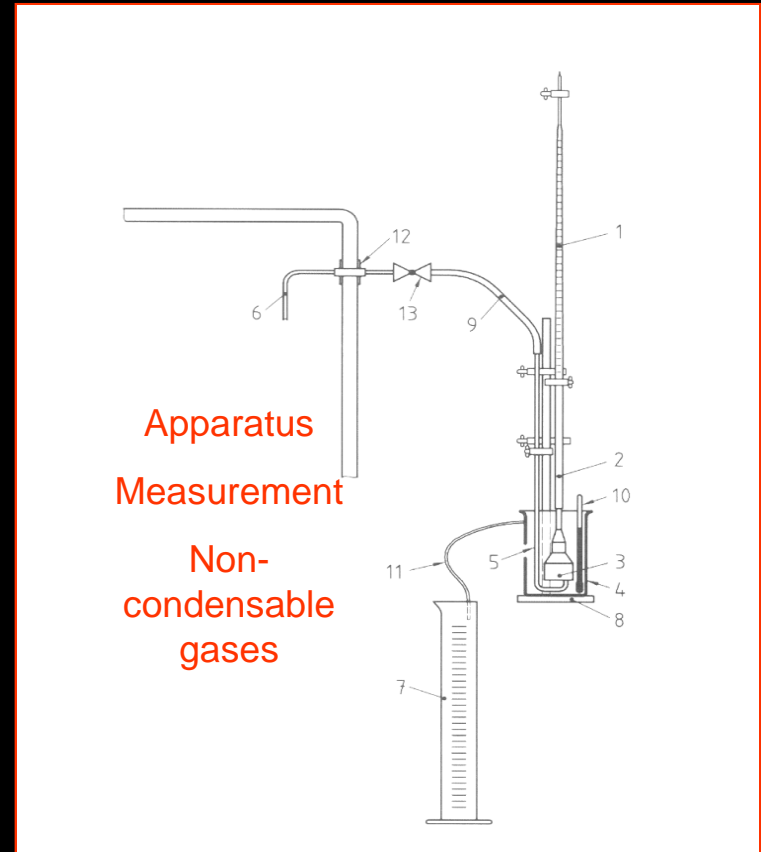


Dimensions in millimetres

BS EN 1360 Porous load Non- Condensable Gases

Exact position of the capillary tube inlet to sample from the sterilizer chamber has been found to vary in position for collection of sample

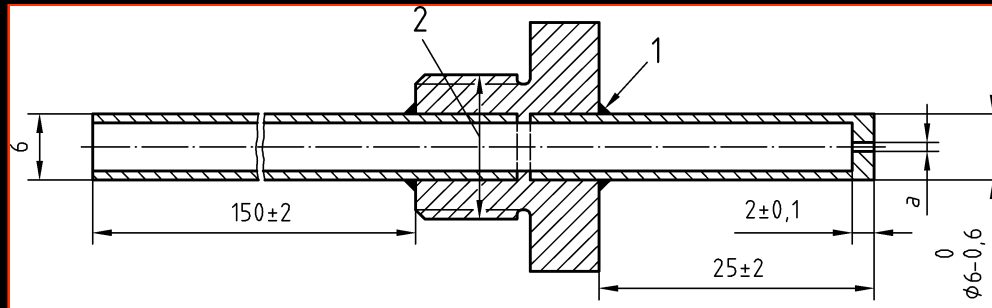
For measurement of non – condensable gases



BS 1360 Sterilizers Steam Testing

Steam Service supply main steam

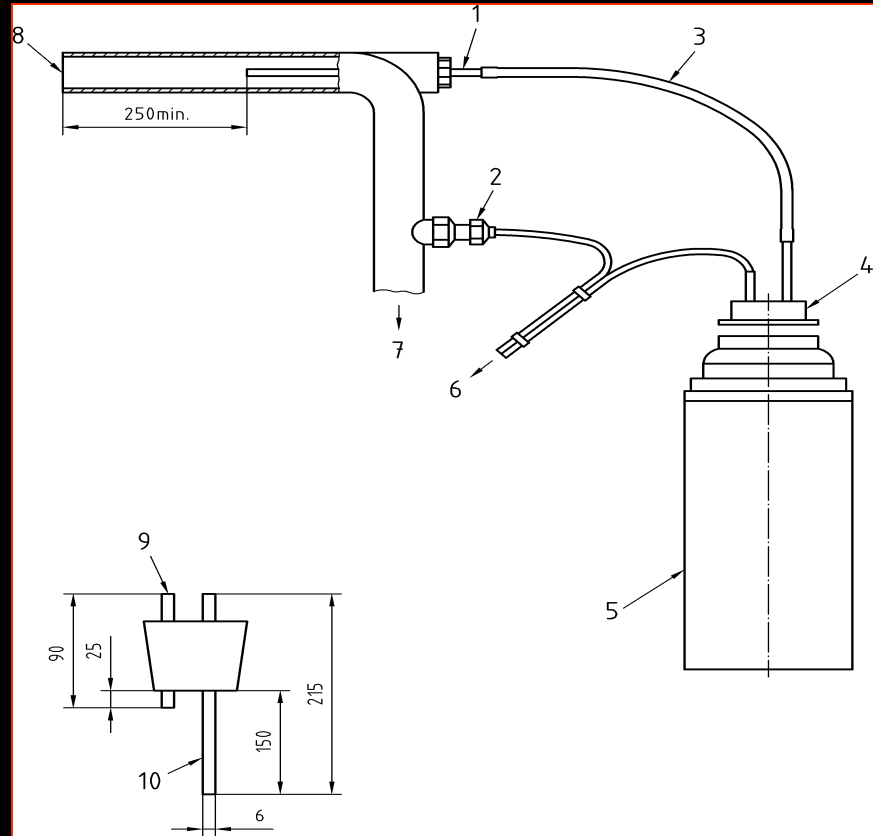
- **Steam pressure kPa (bar) Bore mm \pm 0,02 up to 400 (3) 0,8 up to 500 (4) 0,6 up to 800 (7) 0,4**



BS 1360 Sterilizers Steam Testing

Steam Service supply main steam

- **Apparatus**
- **for sampling**
- **Steam**
- **Condensate**
- **for chemical**
- **analysis**



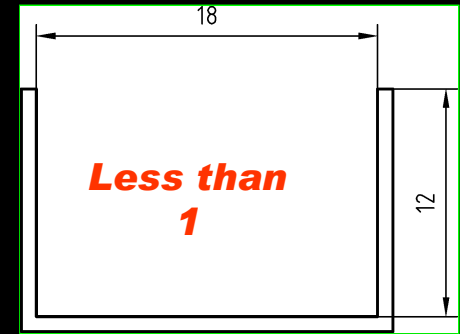
BS 1360 Sterilizers

Definition hollow space A

Not hollow

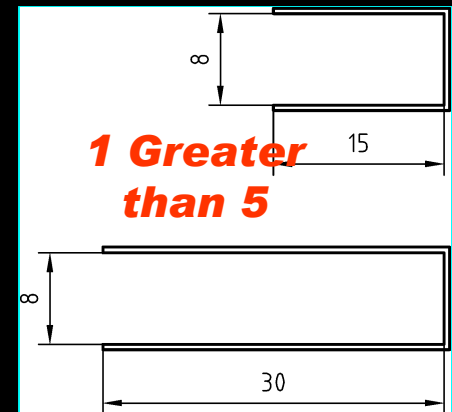
Objects which are not hollow

**Within standard cavity to diameter
less than 1**



Hollow A objects

**Cavity with length to diameter greater
than 1 and greater than 5 for all objects**

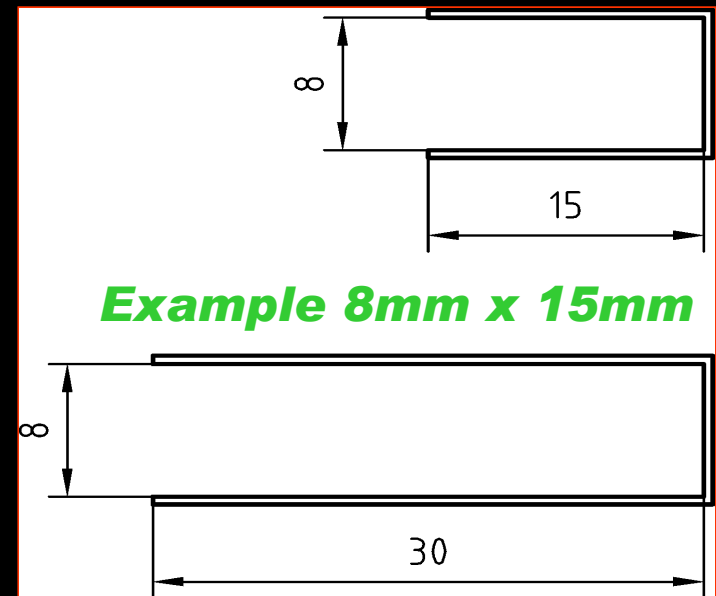


BS 1360 Sterilizers

Definition hollow space **B**

Hollow B objects

Ratio of the length of cavity to diameter greater than 1 and less than 5 for both objects



BS EN 1360 Porous load

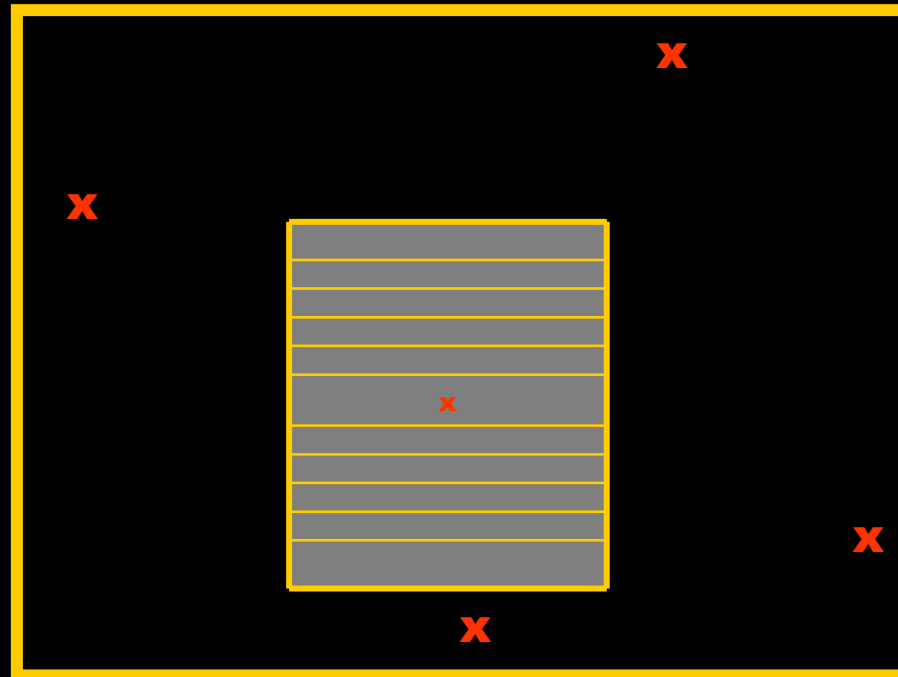
WORKS / INSTALLATION TEST

Small load textiles cotton sheets
450mm x 300mm

**Reduced test
pack**

**Small porous
load test single
wrapped**

**Thermal
Sensors X
positions**



**Volume of
more than
54 litres**

**Diameter
of at least
35 cm**

BS EN 1360 Porous load

TYPE TEST

***Small load textiles cotton sheets
450mm x 300mm***

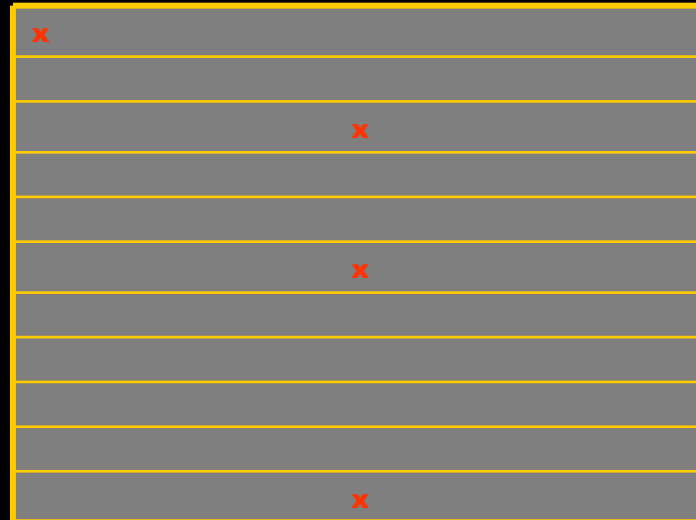
***Reduced test
pack***

***Small porous load test
single wrapped***

***Volume of
more than
54 litres***


***Diameter
of at least
35 cm***

***Thermal
Sensors **x**
positions***



SMALL STERILIZERS

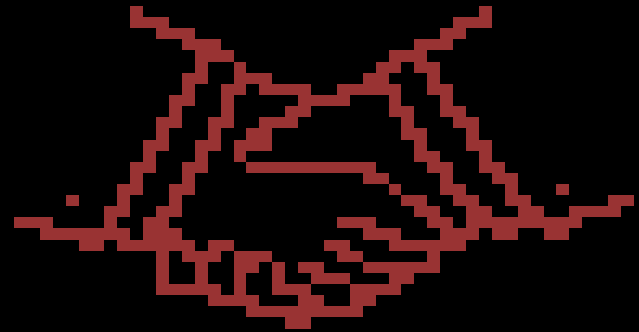
Moist Heat Sterilization

 ***The future may be a combined standard applicable to all moist heat sterilizers***

➤ ***EN 13060***

➤ ***EN 285***

➤ ***In accordance with the Vienna agreement***



The Vienna Agreement

➤ An agreement made between CEN and ISO to ensure harmonisation of standards published by the two organisations.





Thank you

Question

JUNE 2008

Time