108TPDA04034-B

Steam Quality Testing - Hints and Tips

General

What is steam quality (EN 285 and HTM)

Who needs to test steam quality

When to test (Frequency)

Where to test steam quality

How to test steam quality

Example of one commercial Steam Quality Test Kit

Accuracy

Non-condensable Gas Test

- Presence of non-condensable gases

  Acceptance Criteria
  Pressure/Temperature Comparison

Superheat Test

- Steam at a temperature above its boiling point

  Acceptance Criteria
  Methodology Problems

Dryness Value Test

- Acceptable amount of moisture

  Acceptance Criteria
  Causes of Wet Steam - Pure/Clean Steam

The difference between EN 285 and HTM 2010

- HTM 2010, UK National Health Service guidance document
- Produced in anticipation of EN 285 and seeks to provide guidance to hospitals to allow their compliance with EN 285 (EU standard)
- EN 285 is a European standard for Sterilization – Steam Sterilizers– Large Sterilizers, which describes the steam quality tests and is the definitive reference.

Who needs to test steam quality?

- Manufacturers and processors of sterile products and medical devices within Europe and those who supply Europe.
- The requirement is restricted to the porous loads/dry goods/ equipment processes, which impact on the **sterility of finished products**.

108TPDA04034-B

When & Testing frequency

The only references to the frequency of steam quality testing are to be found in HTM 2010, where it is indicated that steam quality should be tested as part of the annual re-validation exercise for each sterilizer.

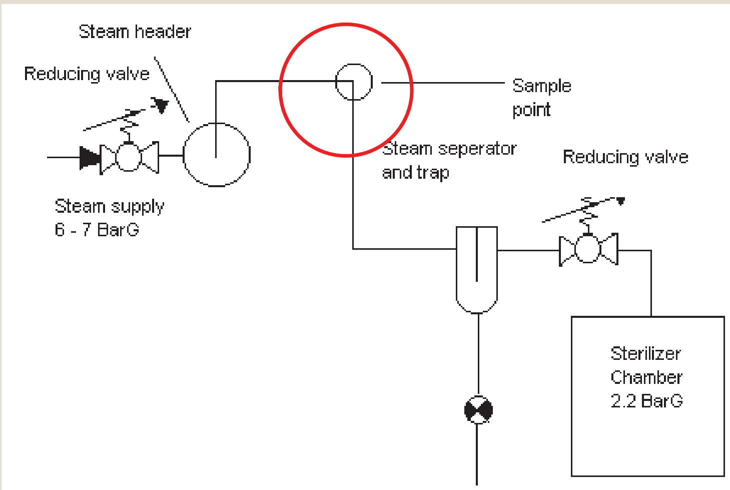
Where steam systems are either routinely or irregularly shut down, large quantities of air will be present in the distribution system on restarting.

It is recommended that in such circumstances a comprehensive and validated venting procedure should be applied and testing for non-condensable gases may be appropriate.

Where - Steam Quality Test Points

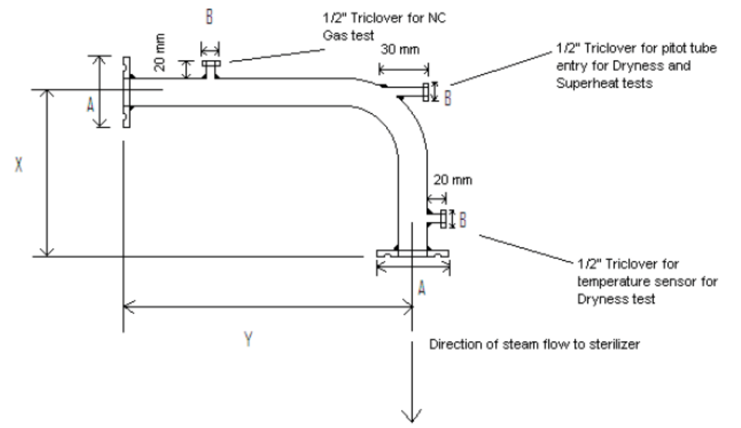
- In order to test the steam quality, specific test points on the steam line are required.
- The location of the three test points on the steam supply pipe just prior to the sterilizer.
- This test point is usually installed between the steam main supply isolating valve and the sterilizer.

Steam Quality Test Points (lay-out)



While not stated in either HTM 2010 or EN 285, there is an assumption that the steam sample point will be located as shown in above. This indicates that the sample pressure will be 3 – 4 Bar Gauge and that after the sample point there will be a steam separator and reduction stage prior to the sterilizer, which will be operating at 2.2 Bar Gauge (134 degrees Celsius).

Steam Quality Test Points (lay-out, cont.')



Test Elbow Dimensions

Nominal size	Pipe outside diameter (inches/mm)	Pipe wall thickness (mm)	X (mm)	Y (mm)	A - Both ends (mm)	B - All sample points (mm)
*½" & ¾"	¾"/19.05	1.65	90	400	24.9	24.9
1"	1"/25.4	1.65	90	400	50.3	24.9
1 ½"	1 ½"/38.1	1.65	110	400	50.3	24.9
2"	2"/50.8	1.65	160	400	64	24.9
2 ½"	2 ½"/63.5	1.65	225	400	77.5	24.9
3"	3"/76.2	1.65	225	400	90.9	24.9
4"	4"/101.6	2.11	253	253	119	24.9

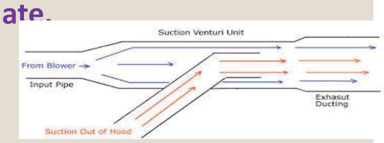
Other test conditions

- The standard test procedures require the steam quality to be sampled when steam is first admitted to the sterilizer chamber after a cycle is started.
- While this provides a reference condition, it may be inadequate to fully characterizing the steam system which may perform differently under different flow conditions.
- It is suggested that the steam supplies should be tested under both low and full flow conditions and particularly for the non-condensable gas test, include conditions where the feed water pump switches on and off (where applicable).
- Where aerated water is present, the worst case condition is invariably when water enters the steam generator.

Non-Condensable Gas Test

The presence of these gases causes problems

1. **Air is an insulator having resistance to heat transfer some 12,000 times greater than copper. Either a layer or pocket of air can result in the heating process being adversely affected.**
2. **Either a layer or pocket of air may cause a physical barrier to steam/moisture reaching all parts of the load. The presence of moisture being essential to the sterilization process by allowing the walls of cells to coagulate.**



Other causes of non-condensable gases

1. **Leaking glands on steam generator feed water pumps allowing air to be pumped into the steam generator each time the feed water pump operates.**
2. **Leaking glands on steam valves where a Ventura effect can cause air to be drawn into steam distribution systems.**
3. **Where steam systems are either routinely or irregularly shut down, large quantities of air will be present in the distribution system on restarting. It is recommended that in such circumstances a comprehensive venting procedure should be applied and testing for non-condensable gases may be appropriate.**

Non-Condensable Gases Test

Purpose of the test:
To demonstrate that the attainment of sterilization conditions in all parts of a sterilizer load (particularly for porous load items) is not impaired by the presence of non-condensable gases.

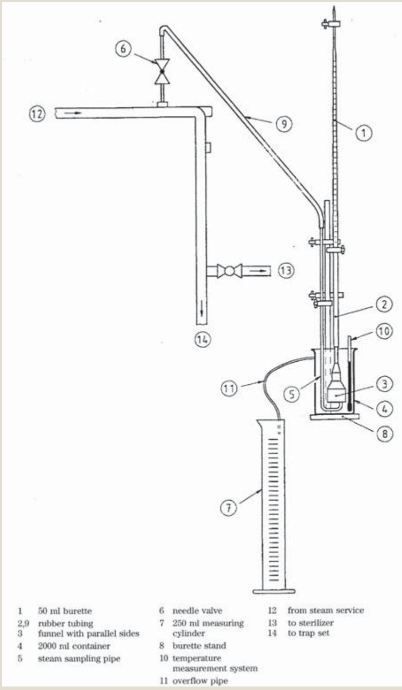
Method employed:
The measurement of non-condensable gases is made by cooling a steam sample with a condenser, using water siphoned from a tank at 200ml per minute. The minimum requirements are: a one meter head of water and its temperature below 28°C. A pumped or pressurized water supply is not required.

When the sampled steam is condensed any non-condensable gases present are released and separated from the cooled condensate into two sight glass columns. The gas and steam condensate volumes are measured by 'zero-adjustable' calibrated scales mounted behind the sight glasses. The temperature of the condensate is maintained above 80°C by controlling the steam flow through the inlet needle valve while measuring the condensate temperature from a thermocouple probe on the outlet of the condenser.

To carry out repeated tests a return to the 'zero scales' position is made by opening the condensate drain and gas bleed valves. The valves are then closed when a new sample is required. Volumes up to 14ml gas and 140ml condensate are possible for each sample.

The non-condensable gas test is considered to be acceptable for sterilization purposes on clinical sterilizers if the percentage of gas to condensate is less than 3.5%.

EN285 24.1.2.1
Non-condensable Gas



The Non-Condensable Gas Test method obstacle

- **In HTM 2010/EN 285 described method requires considerable skill to obtain repeatable test results.**
- **The water used for the tests should be degassed by boiling and allowing to cool in a closed container.**
- **If this is not done, gases will be released from the water in addition to that coming from the steam supply. This may result in high values being encountered.**

The Non-Condensable Gas Test method obstacle

- This is exacerbated by the speed at which the test is carried out, the rate determining whether high or low results are obtained.
- Generally, the faster the test is conducted, the higher the test result. In many respects the test method is subjective.
- The test has to be completed when the cooling water temperature reaches 70 degrees Celsius.
- It will be seen that to properly test the steam, it may be necessary to test under different flow conditions.
- The time involved in draining and replacing the cooling water may cause vital information to be lost and an incomplete picture formed.

The Non-Condensable Gas Test method obstacle

- These problems are avoided when using a condenser.
- This setup prevents the steam coming into contact with the cooling water and avoids problems due to its aeration.
- The only source of gases can be from the steam. Also, the tests can be carried out for an indefinite time, allowing the steam supply to be tested under a range of flow conditions, in addition to the reference conditions described in the test methodology.

Superheat Value Test

Purpose of the test:

To demonstrate that the amount of moisture in the steam supply is sufficient to prevent the steam from being superheated as it enters the expanded space of a sterilizer chamber.

Method employed:

The temperature is measured by a thermo-couple placed at the center of an expansion tube placed over the pitot tube as steam passes through its orifice.

The temperature is considered to be **acceptable if it is less than 25º C** above that of the local temperature of boiling water

Superheat Value Test

Background

- Superheated steam is steam at a temperature above its boiling point for its pressure.
- Superheated steam is a clear colorless gas that will not condense until its temperature drops to its boiling point.
- Until this occurs the moisture necessary for sterilization cannot be produced and therefore presents a risk to the process.
- Superheated steam acts as hot air and requires sustained high temperatures and long hold times before sterilization can occur.

Superheat Value Test

Reason of occurrence

- While superheated steam is not usually intentionally generated in the healthcare or pharmaceutical industries it can be produced as the result of excessive pressure drops.
- If we reduce steam from a high to a low pressure its energy level will remain the same.
- This high energy level will initially result in any moisture present in the steam to be evaporated.
- Any additional energy will then result in a temperature increase in the steam and the superheat phenomena will become evident.

Superheat Value Test

Effects

- Because the superheat will reduce as heat is transferred to the load, this is generally a temporary phenomena at the start of the sterilizing period.
- Superheated steam has the greatest adverse impact where high temperature / short time sterilizing cycles are used.
- Despite, the impact being duration dependent, good practice indicates that superheated steam should not be tolerated.
- EN 285 indicates that pressure drops should not exceed a ratio of 2:1. If the pressure drops occur sufficiently far away from the sterilizer it will be found that any superheat generated will diminish as it loses energy to the pipe walls and any moisture present.

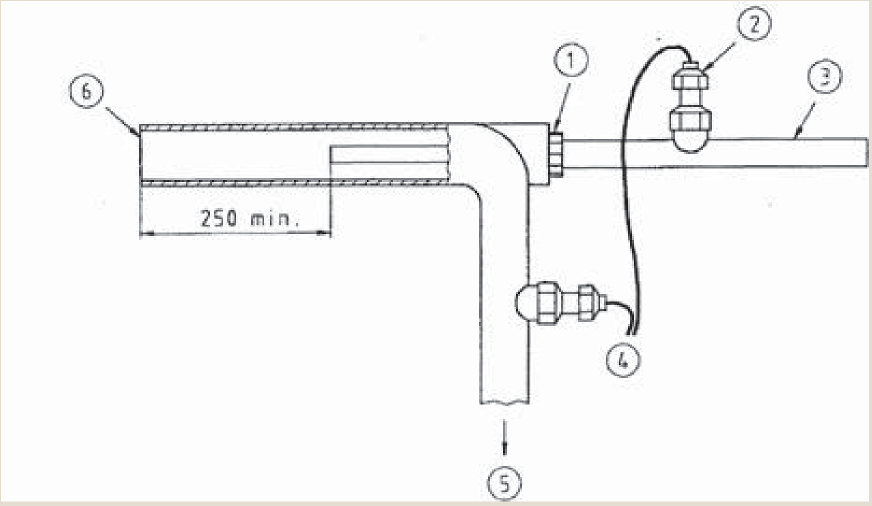
Acceptance Criteria

- When steam is reduced from line pressure to atmospheric using the pitot and expansion tube shown, the temperature measured should not exceed 25°C above boiling temperature for the atmospheric pressure at the test point (typically the measured value should not exceed 125° C).
- It is stressed that the limit describes the maximum temperature and that no minimum value applies to this test.
- The assumption made by the standards, but not specified, is that if this limit is not reached, when the steam expands into the chamber its condition will be satisfactory.
- In this respect, the test is predictive and its worth is dependent upon the specific configuration of the sterilizer with respect to the pressure drops involved after the test point and any further conditioning that may occur from steam separators etc.

Methodology Problems

- The temperature sensor should be sufficiently small to not represent a large heat sink which will dissipate any superheat.
- A bare thermocouple is best in this respect.
- The thermocouple should be moved across the steam jet issuing from the pitot tube until the highest temperature is reached.
- The value achieved will depend on the dryness of the steam and the size of the pressure drop involved.

EN285 24.2.2.2
Superheat



Dryness Value Test

Purpose of the Steam Dryness Value Test:

- To ensure that an **acceptable amount** of moisture is present in the steam supply.
- Too little moisture were present, superheating of the steam may occur.
- Too much moisture, the load may not be able to be dried by completion of the cycle.

Method employed:

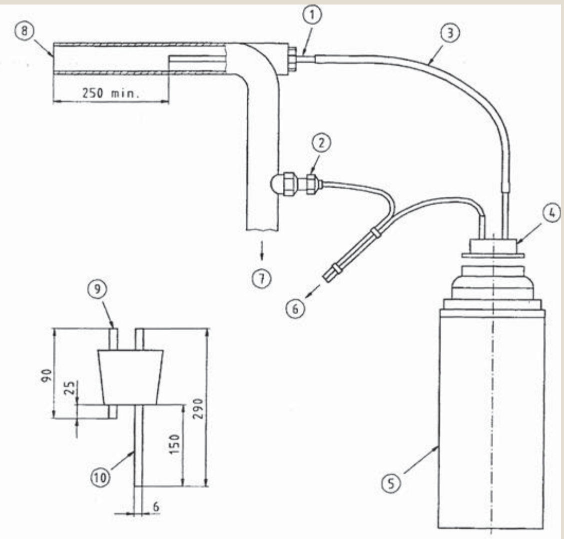
Heat balance using a stainless steel vacuum flask.

- The principal is that the flask is primed with a known mass of water at a known temperature. Steam is condensed in the flask thus raising the water temperature.
- The final mass and temperature of the water are then measured and placed into a calculation.
- If the final water temperature was lower or the final mass was greater, the steam would be 'wetter' (having a lower value).

Accept criteria

- Whilst the method is not regarded as a truly accurate measurement of moisture in the steam, it can be used to demonstrate acceptable dryness for sterilization purposes.
- A dryness value of 1.0 is equivalent to Dry Saturated Steam.
- For sterilization purposes, **a 0.95 is considered to be acceptable**.

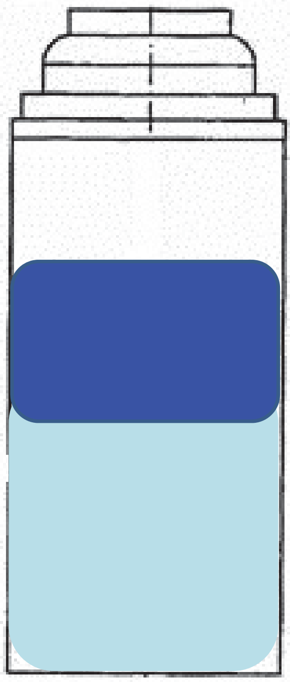
EN285 24.3.1.2
Dryness Value



Dimensions in millimetres

1 pitot tube
2 temperature sensor entry gland
3 rubber tubing
4 rubber bung assembly
5 one-litre Dewar flask
6 to temperature measuring instrument
7 to sterilizer
8 from steam service
9 pipe for thermocouple and vent
10 sample pipe

Figure 9. Diagrammatic representation of the apparatus for the measurement of steam dryness value



***Me*: kg、 initial mass (flask)**

***Ms*: kg、 initial mass (flask + water)**

***Ts* : ºC、 initial water temperature (water)**

***Mf*: kg、 final mass (flask + water + condensate)**

***Tf* : ºC、 final water temperature (flask)**

***Ta* : ºC、 average steam temperature (to sterilizer)**

L* : Ta ($KJkg^{-1}$) latent heat of dry saturated steam at temperature *Ta

The energy is required to change phases of a substance.

Ts : ºC， initial water temperature (flask)

Tf : ºC， final water temperature (flask)

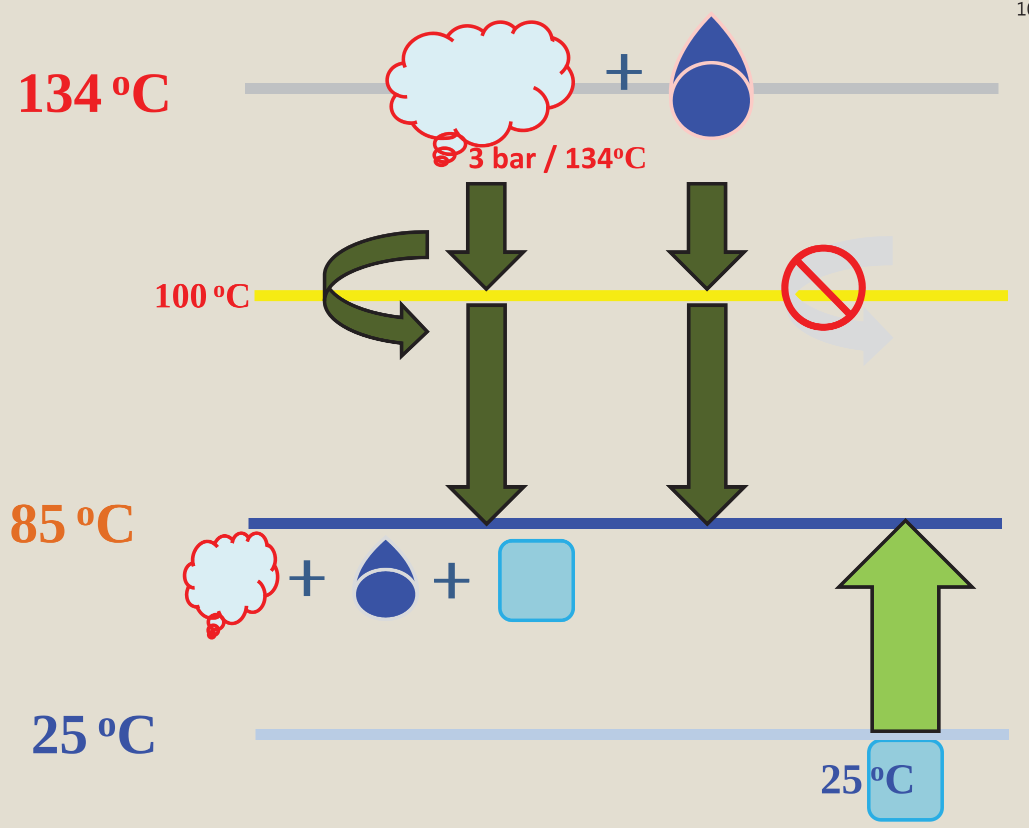
Ta : ºC， average steam temperature (to sterilizer)

Me: kg， initial mass (flask)

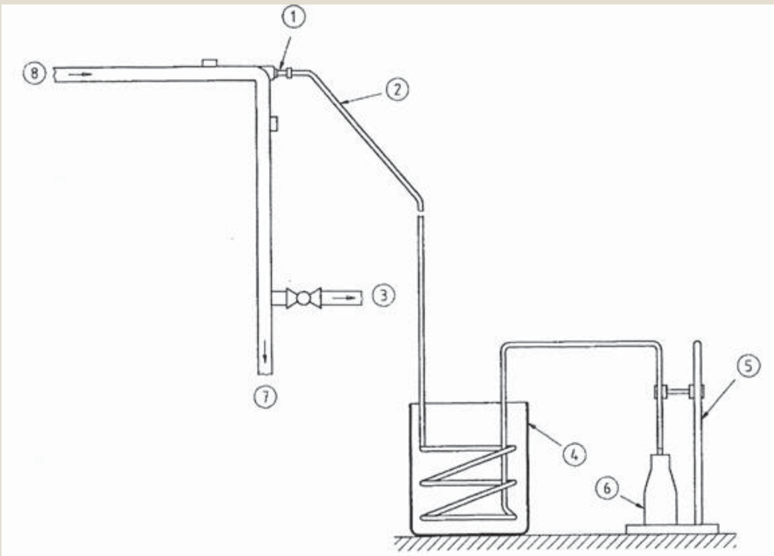
Ms: kg， initial mass (flask + water)

Mf: kg， final mass (flask + water + condensate)

L : Ta ($KJkg^{-1}$) latent heat of dry saturated steam at temperature Ta



EN285 24.4.1
Steam Sampling

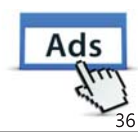


Example of Steam Quality Records

Organisation performing tests: The ValiSteri Company				
Site: South West Pharma Farmer Co. Ltd	Department: Validation	Date(s) of tests: 7-Dec-11		
Sterilizer Manufacturer: MtSterX	Model: ASTFB321	This file reference: ABD		
Serial number: apotdng12ktf	Plant ref. number: 1			
		Unit	Validation	Yearly
Non-condensable Gases tests	Test number		1	1
	Cycle number		321	678
	Cycle start time (real)	hr:min:s	11:01:04	09:06:04
	Vb (gas volume)	ml	4.3	2.2
	Vc (water volume)	ml	120.0	100.0
	Fraction of gases	%	3.6	2.2
	Test number		2	2
	Cycle number		322	679
	Cycle start time (real)	hr:min:s	11:30:00	09:32:04
	Vb (gas volume)	ml	6.5	2.0
	Vc (water volume)	ml	110.0	100.0
	Fraction of gases	%	5.9	2.0
	Test number		3	3
	Cycle number		322	680
	Cycle start time (real)	hr:min:s	11:58:00	10:12:05
	Vb (gas volume)	ml	6.0	3.4
	Vc (water volume)	ml	100.0	100.0
	Fraction of gases	%	6.0	3.4
Superheat test	Test number		4	4
	Cycle number		323	681
	Cycle start time (real)	hr:min:s	12:17:08	10:47:08
	Steam service supply temp.	°C	145.0	161.3
	Te (expansion tube temp.)	°C	127.0	106.0
	LAP (local atmos. Pressure)	mbar	987	1020
	To (water boiling point at LAP)	°C	99.3	100.2
	Superheat level	°C	27.7	5.8
Dryness value test	Test number		5	5
	Cycle number		324	682
	Cycle start time (real)	hr:min:s	13:05:08	11:25:45
	M_s (empty flask assembly mass)	g	541	592
	M_e (filled flask assembly mass)	g	1230.1	1234.2
	T_S (initial flask contents temperature)	°C	17.3	18.2
	T_A (average steam supply temperature)	°C	156.2	162.4
	T_F (final flask contents temperature)	°C	81.4	79.4
	M_f (final flask assembly mass)	g	1321.0	1309.5
	D (dryness value)		0.901	0.978
Maximum supply temperature difference between superheat test and dryness value test		°C	11.2	1.1

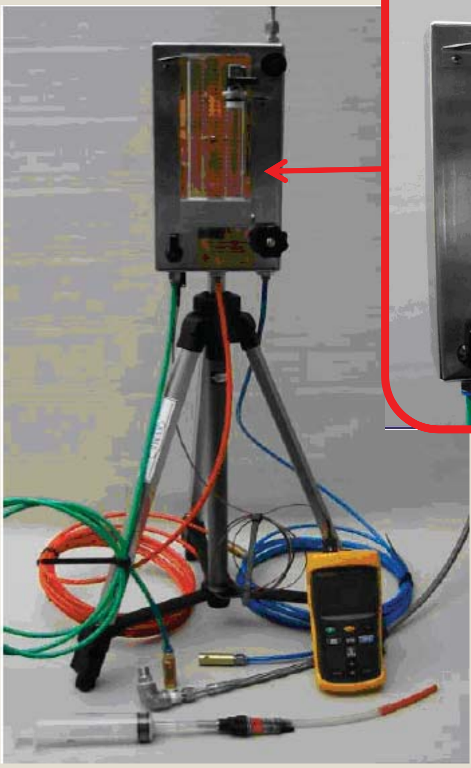
Test Person signature .... print name .... date................................

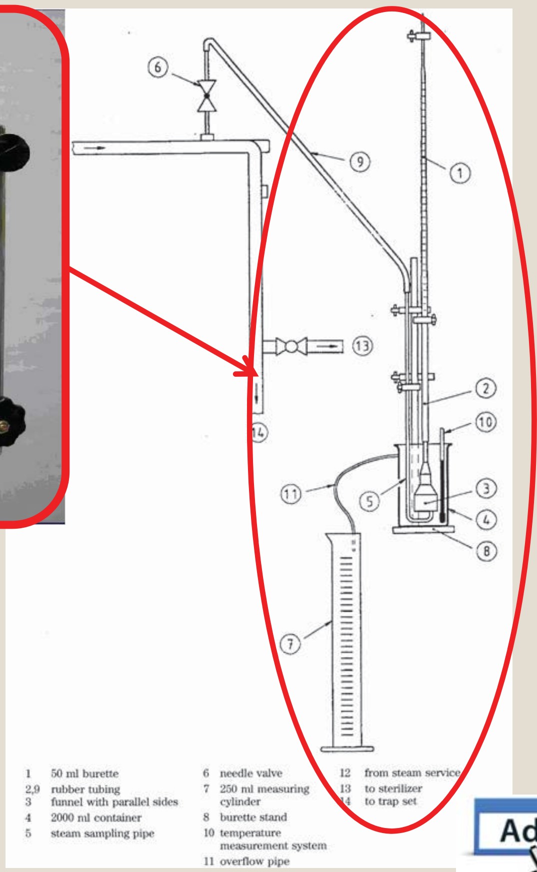
Evaporated



Bowie Dick test pack

Non-condensable Gas (commercial)





Ads

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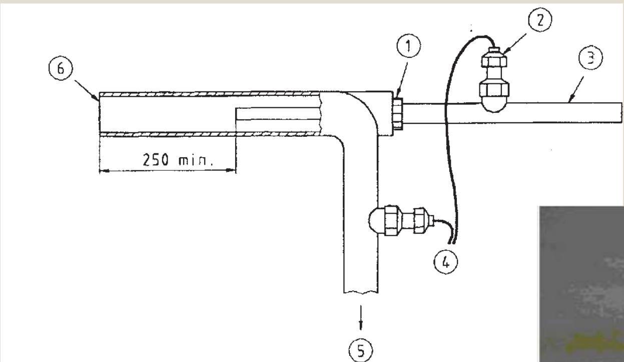
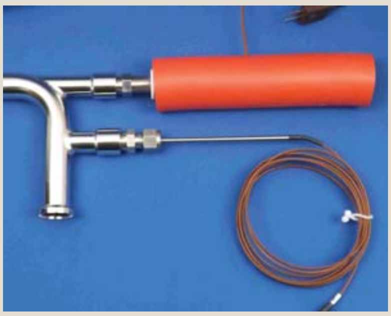
Superheat (commercial)





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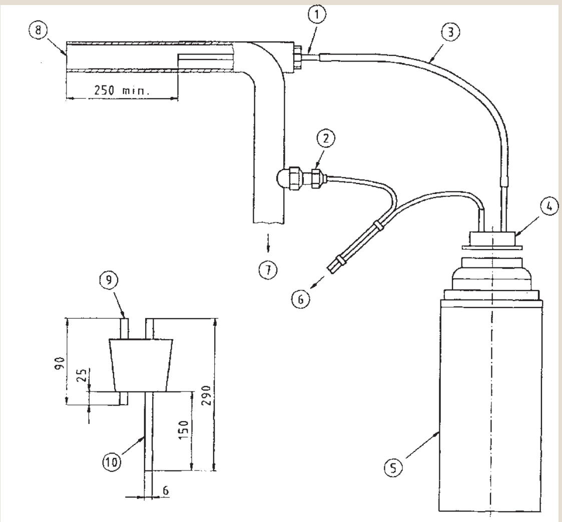
Dryness Value (commercial)



Dimensions in millimetres

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4 rubber bung assembly
5 one-litre Dewar flask
6 to temperature measuring instrument
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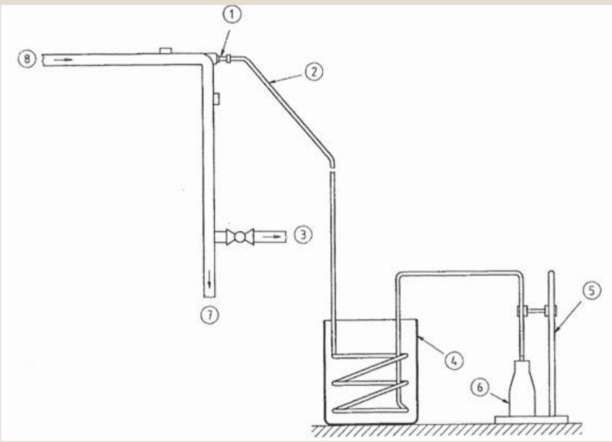
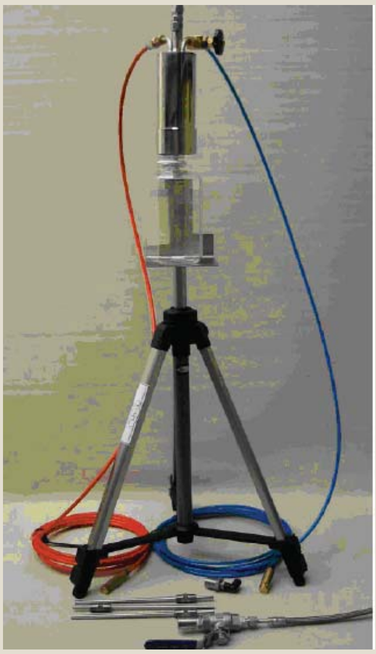
8 from steam service
9 pipe for thermocouple and vent
10 sample pipe

Figure 9. Diagrammatic representation of the apparatus for the measurement of steam dryness value

Steam Sampling (commercial)





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Really FINISHED !

謝謝聆聽

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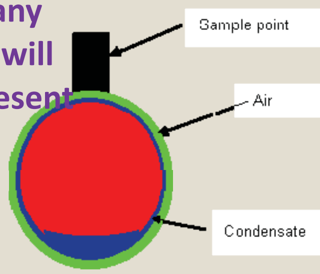
Pressure/Temperature Comparison

It is often believed that a simple pressure/temperature comparison using steam tables will allow the presence of non-condensable gases to be discovered. If 1% of air by volume were to be present in the steam supply, a value many times in excess of the 3.5 % limit (0.00206% by volume), using Daltons Law, it will be seen from the table below that the resulting temperature depression will only be 0.33 degrees Celsius. Given the differences in response times and calibration errors between pressure and temperature instruments, it will be seen that such a comparison will only detect very large and wholly unacceptable levels of gases (between 1 and 10%).

The theory of steam flowing through a pipe indicates that any gases present will be adjacent to the pipe wall. Within this will be a layer of condensate and further condensate will be present on the bottom of the pipe.



Dryness Value Test

Wet steam is undesirable as it has less energy than dry steam and more importantly can cause wet loads. The packaging used for sterile products prevents reinfection when dry, but its bacterial retentive properties will be adversely affected by the presence of moisture. Wet loads can be considered to be unsterile.

The amount of moisture present in steam is measured by the dryness fraction, which is directly proportional to the amount of latent heat present. The dryness fraction describes how dry steam is with a value of 1 representing steam that is 100 dry and therefore free of entrained moisture. Steam with a dryness fraction of 0.99 consists of 99% steam and 1% water. Similarly, steam with a dryness fraction of 0.95 consists of 95% steam and 5% water.

If we measure the latent heat present in steam that has a dryness fraction of 0.99 we will find that it possesses 99% of the full quotient of latent heat. By establishing the amount of latent heat present in steam we can determine its dryness fraction.

Calorimetry

We measure the latent heat in steam by condensing a sample in a known volume of water having a known starting temperature. The increase in mass of the water represents the amount of steam utilized to heat the water to its new, higher temperature. From this simple exercise we can calculate the amount of energy in the steam.

If we also measure the temperature of the steam supply we can determine from steam tables the latent heat that would be present if the steam was 100% dry. By comparing the two values we establish the dryness fraction of the steam sample. Because the steam is sampled only from the center of the pipe and does not take into account moisture on the pipe wall or condensate at the bottom of the pipe, the test is deemed to be an approximation rather than an absolute value. For this reason, instead of using the term dryness fraction, the test method uses the term **Dryness Value**, and this term is always used when describing test results for steam for sterilization.

The calculation provided by HTM 2010 takes account of the heat loss from the test kit by the use of a constant that is dependent on the test equipment used. When using the SQ1 Portable Steam Quality Test Kit this constant has been modified to take account of the stainless steel vacuum flask and dip tube construction. This variation is detailed in the calculation in the manual and in the Excel calculation provided on floppy disk. EN285 does not specify the construction of the test equipment that should be used or provide any information on how the constant is calculated.

Acceptance Criteria

The dryness value of the steam should be equal to or greater than 0.9 for porous loads or 0.95 where metal loads are processed. Invariably this means the latter limit is applicable. In any event, in plant steam terms, steam containing 5% of moisture would be seen to be of poor quality and a dryness value of 0.99 would be more commonly seen to be acceptable.

Methodology Problems

Out of specification results are often caused by the test method not being strictly followed. Where the test point is not as indicated problems can easily result. Similarly, modifications to the test points by the installation of valves and/or additional pipe fittings etc. can result in additional heat losses being encountered which are not taken into account by the calculation.

The start and end temperatures within the flask should be established by agitating the flask and water until a constant value is reached. The test should be completed when the water temperature reaches 80o C. If the temperature is hotter or localized boiling occurs, energy will be lost in the form of steam venting from the flask and misleading results obtained. To avoid this the flask should be constantly, but gently agitated during the course of the test, and preferably the test completed before rather than after the 80o C limit is reached. It will be found that the effects of agitation following the test will tend to result in an increased temperature rather than a lowering. The use of a sheathed temperature sensing probe results in a relatively slow response time for small changes in temperature and time must be allowed for the sensor to stabilize.

If the test is carried out too slowly, the heat losses tend to increase and have a greater impact as time progresses. The purpose of the pitot tube is simply to provide a controlled flow of steam into the vacuum flak. It is our experience that the use of a pitot tube one size larger than that specified by the standard test method will provide a suitably fast test to avoid such problems. Provided that the water in the flask is not allowed to boil and heat to be lost from the system as steam/vapour, the size of the pitot tube is immaterial. When we conduct the test, we aim to complete it within 10 minutes.

Great care should be taken with mass measurements and weighing equipment must discriminate to 0.1g. Water droplets on surfaces of the flask that is not subject to the heating effects of the steam can affect the results if present in sufficient quantities. In between tests it is recommended that the flask is dried internally and externally and that fresh water is added in such a fashion that it is not splashed on the outer surface of the flask. When agitating the flask, care should be taken to prevent any loss of water which will affect the outcome of the test.

The temperature of the steam supply should be logged in order that its average temperature may be calculated for the duration of the test. While the pressure of the steam supply would not be expected to fluctuate by more than 10% (EN 285) any fluctuations not recorded will cause misleading results to be generated.

Causes of Wet Steam - Plant Steam

Wet steam may be caused by excessive pressure drops on the boiler due to high demands. As the pressure drops, the size of steam bubbles increase in turn increasing the volume of water in the boiler and causing it to be closer to the steam outlet. The increased size of the steam bubbles results in a more aggressive boiling action, which causes more/larger droplets of water to leave the water surface and enter the steam space and thus be carried over into the steam. Steam at a low pressure occupies more space than steam at a high pressure and a further affect of a pressure reduction is to increase the velocity of the steam leaving the boiler. This can reach such a velocity that it will take some of the boiler water with the steam. Certain contaminants in the boiler water can cause a froth to form on the water surface, again allowing moisture to enter the steam supply.

Once in the distribution system, the quality of steam is likely to deteriorate as the result of heat losses causing further condensation. To minimize such deterioration, the steam distribution system should be well insulated and be provided with a well designed and installed condensate removal system (steam traps and separators). Pipework should always have a fall towards steam traps. A common problem that causes wet steam is where pipework is sagging. This allows pockets of water to accumulate until they are sufficiently large to occlude the steam pipe, causing the increased steam velocity to carry them to the points of use in discrete slugs.

Causes of Wet Steam - Pure/Clean Steam

Pyrogen free steam produced by a clean/pure steam generator should be dry saturated (dryness value of 1). That is to say it should be dry and at its saturation temperature (boiling point for its given pressure). Pure steam generators are normally fitted with a pressure sustain valve which prevents excessive pressure drops and therefore the potential to carry over water with the steam. This valve will prevent pressure drops at the generator by maintaining the generators internal pressure at the expense of the distribution system. As with plant steam its quality can only deteriorate within the steam distribution system as described above, where the same design requirements apply to insulation and condensate removal.

非凝結氣體檢測

1. 將蒸汽供應管路與系統獨立分離出來，並確認管路壓力與大氣壓力相同。



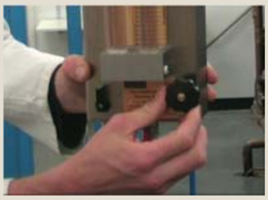
2..將蒸汽供應管路閥鬆開，準備與非凝結氣體檢測之軟管連接。

3. 調整腳架到需要的高度。

4. 將非凝結氣體檢測儀安裝於腳架上。

5. 將藍色塑膠管兩端分別接在檢測儀之進水入口及供水源。確保冷卻水維持28ºC 以下常溫，以及1公尺以上的位差，以維持每分鐘 200~500ml 的流速。接下來連接紅色冷卻水排放管，以及凝結水排放管。


6. 順時針關閉冷卻水調節閥。

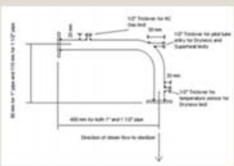


7. 連接紅色冷卻水排放管兩端於檢測儀及適當的排放桶。

8. 連接綠色凝結水排放管兩端於檢測儀及適當的排放桶。

9. 關閉檢測儀上之蒸汽調節閥

10. 將L型不鏽鋼彎管連兩端接於管路系統與滅菌斧。



11. 連接蒸汽軟管兩端連接檢測儀上蒸汽分離口及L型彎管蒸汽出口。

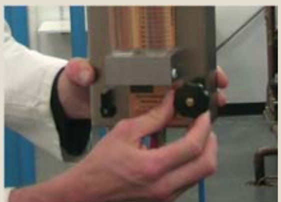

12. 打開檢測儀上凝結水排放閥以及氣體排放閥。


13. 預先注水至檢測儀的冷卻水槽，觀察視窗水位到”0”刻度時停止進水，並略為調整刻度表”0”與液面齊平。

14. 將溫度計及不鏽鋼架安裝於檢測儀側邊。


15. 將溫度探針A (兩端皆為插頭形式) 分別插入檢測儀左側插孔及溫度計T1輸入孔。

16. 以重力供給冷卻水時，將進水閥完全打開，以針筒幫浦進行冷卻水槽注水。將針筒上紅色短管接於 管側，手動至注射管內水流入為止，將冷卻排水導入排水桶，並維持200~500ml/min之流速。



17. 打開管路之蒸汽供應閥，為避免水鎚效應，慢慢打開蒸汽閥。

18. 同時慢慢打開檢測儀上蒸汽限制閥，排除檢測儀內之空氣。

19. 當凝結水從凝結排放管流出時，調整觀測窗水位高度歸零(移動刻度板)。

20. 調整蒸汽流量限制閥，以維持凝結水分離排放口溫度介於$80^{o}C$ to $90^{o}C$。

21. 必要時重新歸零觀測窗水位。
22. 確認滅菌斧艙內淨空後，啟動一滅菌週期，以確認蒸汽開始進入滅菌斧。

23. 當蒸汽開始進入滅菌斧艙內時，請 關閉凝結水排放閥和氣體排放閥。

24. 在視窗水位達到最高水位前，建議收集100ml凝結水，做為計算標準。

25. 利用提供的表格來計算非凝結氣體的比例。

26. 若要重複樣本收集：
- 打開凝結水排放閥將水位排放到刻度為零
- 打開氣體排放閥
- 重複步驟 19 到 25

27. 完成所有的樣本收集及檢測過程，分離蒸汽與冷卻水供應源，並確認管路與大氣壓力無壓差。



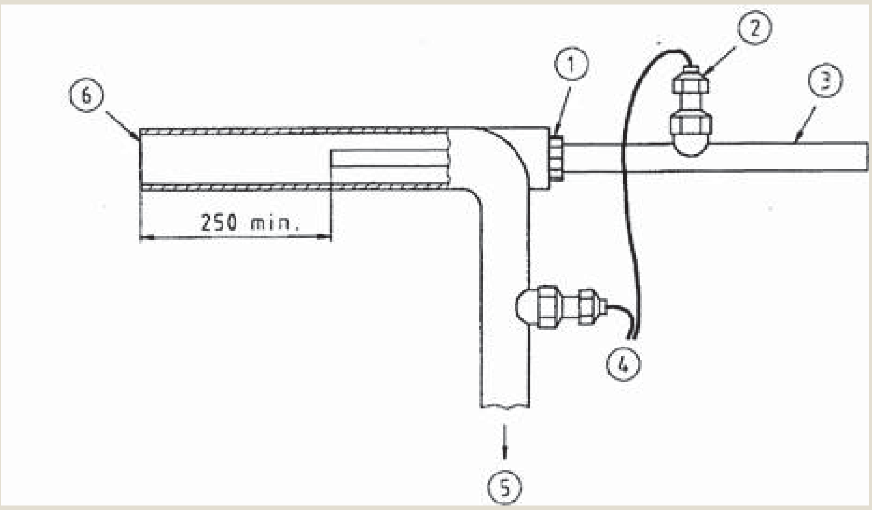
28.待檢測儀冷卻後，分離冷卻水源，並拆卸管線、街頭、溫度探針線與溫度計。.

29. 所有設備配件必須排放完全、乾燥後裝入封口塑膠袋中，再裝入設備箱內。(確認檢測儀冷卻水槽內完全排放)

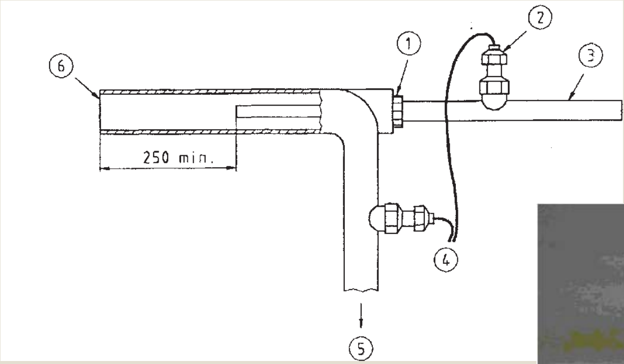
30. 計算及格標準為非凝結氣體比例不超過3.5%。

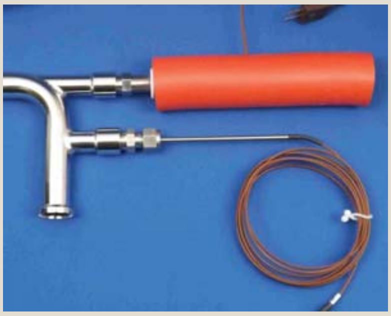
31. 將現場恢復原狀。

EN285 24.2.2.2
Superheat



Superheat (commercial)





蒸汽過熱檢測

1. 將蒸汽供應管路與系統獨立分離出來，並確認管路壓力與大氣壓力相同。

2. 將L型不鏽鋼管之皮托管位置及溫度計位置封口移除。

3. 選擇適當管徑的皮托管，與現場管路水平安裝於L行不鏽鋼管彎角處。

蒸汽壓力	to 3 bar	3 ~ 4 bar	4 ~ 7 bar	7~8 bar	8~10 bar
管徑	0.8mm	0.6mm	0.4mm	0.3mm	0.25mm

(EN 285:2006 + A2:2009 standard :1.0mm.)

4. 將溫度感應探針平行安裝於蒸汽管路。

5. 將3mm直徑之溫度探針B 插入溫度探針位置，調整探針使末端位於蒸汽管路中央 ，固定並確認無洩漏等情況。.

6. 將溫度探針C插入擴大管中央位置，末端位於擴大管中央 (如下圖)。

7. 將擴大管插入皮托管尾端。

8. 連接溫度探針B插入溫度計上 T2位置，表示供應蒸汽溫度。
9. 連接溫度探針C插入溫度計上 T1位置，表示擴充管溫度。

10. 恢復蒸汽供給。

11. 啟動溫度計T1數值顯示於螢幕上方，T2位於下方。

12. 確認溫度計量測T型探針。

13.確認滅菌斧艙內淨空後，啟動一滅菌週期，確認蒸汽開始進入滅菌斧。

14.當蒸汽開始進入滅菌斧艙內時， 紀錄蒸汽供給與擴充管的兩處溫度讀數，按下溫度計上HOLD鍵。

15. 將溫度輸入Excel計算檔案，以計算過熱溫度。

16. 檢測之過熱溫度以不超過25ºC為合格之檢測。

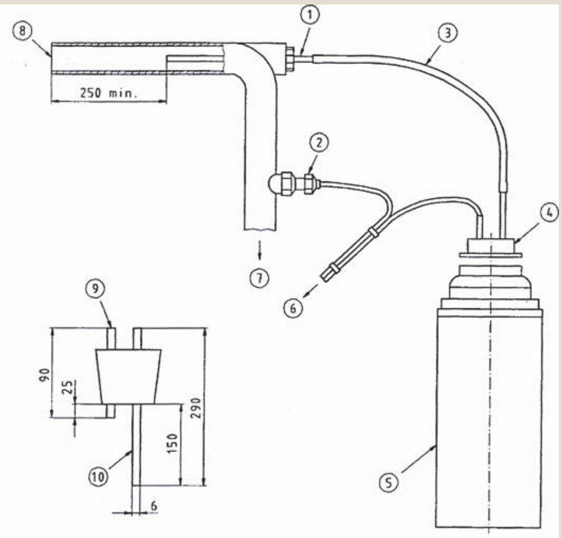
17. 在樣本收集與檢測週期完成，將蒸汽供給源切斷，確認供應端與大氣間無壓力差異。

18. 從皮托管處移除擴充管及溫度探針，注意高溫時的個人防護。

19. 移除蒸汽管路上肢溫度探針、皮托管，注意高溫之人身防護。

20. 將管路系統恢復原狀。

EN285 24.3.1.2
Dryness Value



Dimensions in millimetres

1 pitot tube
2 temperature sensor entry gland
3 rubber tubing
4 rubber bung assembly
5 one-litre Dewar flask
6 to temperature measuring instrument
7 to sterilizer
8 from steam service
9 pipe for thermocouple and vent
10 sample pipe

Figure 9. Diagrammatic representation of the apparatus for the measurement of steam dryness value

Dryness Value (commercial)

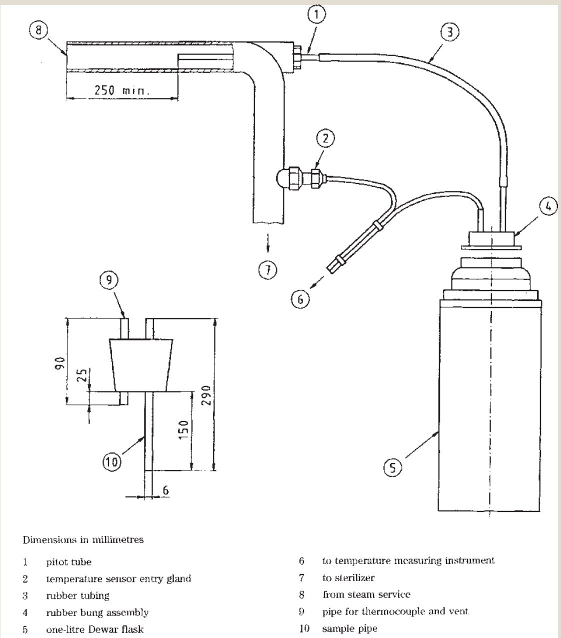


Figure 9. Diagrammatic representation of the apparatus for the measurement of steam dryness value

Ads

乾燥值檢測

1. 將蒸汽供應管路與系統獨立分離出來，並確認管路壓力與大氣壓力相同。


2. 將L型不鏽鋼管之皮托管位置及溫度計位置封口移除。



3. 選擇適當管徑的皮托管，與現場管路水平安裝於L行不鏽鋼管彎角處。

蒸汽壓力	to 3 bar	3 ~ 4 bar	4 ~ 7 bar	7~8 bar	8~10 bar
管徑	0.8mm	0.6mm	0.4mm	0.3mm	0.25mm

(EN 285 2006+A1:2009 up to 2, 3 and 6 Bar respectively)

4. 將溫度探針安裝於蒸汽系統管路。

5. 將3mm溫度探針B安裝於管路上，調整探針長度以確保探針於蒸汽管正中位置。

6. 連接溫度探針D於溫度計T1位置，量測不銹鋼瓶內溫度；溫度探針B於溫度計T2位置，量測場內蒸汽溫度。

7. 天平安置於乾燥硬質表面，調整確認水平後，開啟電源。測量重量時，先確認螢幕穩定顯示”0”。

8. 確定橡皮管已連接於不鏽鋼瓶較高的細管。

9. 將橡皮塞與橡皮管至於不鏽鋼瓶上。

10. 量測並記錄不鏽鋼瓶及管重量(Me)。

11. 測量完成後移開鋼瓶。

12. 打開瓶蓋，並加入650ml +/- 50ml 乾淨之冷水，水溫約27ºC以下。以量杯可約略得到該容量之水。

13. 蓋上橡皮蓋並確認瓶體外部之乾燥。

14. 重新稱包括鋼瓶、瓶蓋、水之總重 ，並記錄其重量 (Ms)。

15. 在橡皮管長度連接皮托管範圍內，將鋼杯外掛於管路上，將鋼瓶安置於鋼杯內。

16. 將溫度探針D連接於溫度計之T1位置，另一端經由鋼瓶之排氣管深入瓶內約240mm，輕微搖晃並確認瓶身附加物之穩固。

17. 啟動溫度計電源，檢視T1與T2分別顯示於螢幕上。

18. 同時確認溫度探針種類為type 'T'。

19.確認滅菌斧艙內淨空後，啟動一滅菌週期，確認蒸汽開始進入滅菌斧。

20. 在檢測過程確認無乾燥或熱源影響。

21. 當蒸汽進入滅菌斧艙內，紀錄啟始不銹鋼瓶溫度 Ts(溫度計上T1數值)；並立即將連接鋼瓶之橡皮管另一端與皮托管連接。由於蒸汽溫度極高，請注意自身安全並使用隔熱手套。

22. 在溫度計上，連續按三次Mx/Mn按鍵，以便開始記錄平均供應蒸汽溫度 Ta (溫度計上T2數值)，不需要考慮T1平均值。

23. 當鋼瓶溫度達到80ºC時，輕晃鋼瓶但避免任何液體濺出，紀錄最終鋼瓶溫度 Tf (溫度計上T1數值)。操作時注意自身安全。

24. 輕按Mx/Mn按鍵一 次，紀錄供應蒸汽之平均溫度Ta(此刻溫度計上T2平均數值)。25. 將不鏽鋼瓶取下，確認無任何瓶內液體流失。

26. 將鋼瓶組及內部如溶液置於天平上並記錄最終重量 Mf。

27. 計算出乾燥之相關值。

28. 若需重複讀取，關閉溫度計後再重新啟動，倒空瓶內水並確認內部完全乾燥，等待鋼瓶組冷卻到室溫。

29. 合格的乾燥值讀數條件：
   a) 非金屬待滅菌物之乾燥讀數不小於0.9；金屬物不小於0.95。
   b) 在過熱檢測時供應蒸汽的溫度變化在3ºC範圍內。

30. 當樣本收集與檢測週期完成後，將蒸汽供給源切斷，確認供應端與大氣間無壓力差異。


31. 使用隔熱手套將溫度探針、皮托管從蒸汽供應管路系統中移除，請注意操作人員自身安全防護。

32. 將現場管路恢復並仔細檢查確認。

33. 將鋼瓶淨空，確實乾燥後裝箱。