KSA

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&

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Non-Condensable Gas Test

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"A continuous supply of saturated steam is required for steam sterilization. Excess moisture carried in suspension can cause damp loads, while too little can not prevent the steam from becoming superheated during expansion into the sterilizer chamber. The accurate measurement of the percentage of moisture content in the steam is difficult and the traditional methods where constant steam flow is required are not suitable for sterilizers. The test method described should be regarded not as measuring the true content of moisture in the steam, but as a method by which the provision of acceptable steam quality can be demonstrated" - EN 285:2006 (E) 22.2.1.

The non-condensable gas test is carried out using simply by condensing steam and collecting any gases that may be present in a burette. By comparing the volume of gases collected with the amount of condensate we collect, we are able to calculate how much gas is present in the steam.

This entire tutorial should be read before commencing testing. A number of tips/discussion items are present and these not need be in the exact order in which testing will be carried out. The manual with the SQ1 provides extracts from EN 285:2006, which is the definitive, but concise approach with no background or guidance. This tutorial is intended to supplement and not replace the manual. Any guidance provided relates to the use of the SQ1 Steam Quality Test Kit and may/will not apply to any other equipment.

Health & Safety

- **Read the Installation Guide first**
- **Steam is hot!**
- **Steam pipes and fittings are hot!**
- **Steam leaks may not be visible to the naked eye!**
- **Isolate steam supply and check that <u>no</u> residual pressure remains before fitting test points.**
- **Pipe insulation can be an irritant.**

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Health and Safety

Care should always be taken when working on or near steam pipes due to the very high temperatures involved. It is recommended that thermal gloves, overalls that cover arms and eye protection are used.

Steam contains @ 5 times the energy of boiling water at the same temperature which makes it a dangerous medium to work with. The steam issuing from pitot tubes for the dryness and superheat test can be invisible to the naked eye and poses a particular risk.

Do not dismantle steam pipework with any pressure within it!

Special care must be taken when fitting test points or testing steam.

The insulation surrounding steam pipes may be made from a variety of materials which can cause irritation to the skin, in some instances. It is therefore recommended that gloves or a good quality barrier cream be applied as a precaution before handling the material.

We reference EN 285

- **Less rigid on test equipment requirements:**
- **Impact on Non-Condensable Gas Test**
  - Allows the use of more robust/safer equipment
  - Allows the use of alternative (better) methods
  - Requires comparison with standard methods

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HTM 2010 is a UK NHS (National Health Service) document to provide guidance to operate sterilizers in a compliant fashion. The underlying standard is EN 285:2006 which defines the European Standard, which therefore takes precedence. To provide uniformity within a large organisation, HTM 2010 is more specific in a number of ways than EN 285:2006.

The test equipment described in HTM 2010 is more specifically described which effectively prevents the use of alternative and more robust equipment or the use of better and more accurate methods. By contrast EN 285:2006 does not precisely specify the equipment and allows alternative methods provided that they are shown to be comparable.

The equipment provided by KS & A is made to be robust and to provide repeatable results. Specifically the differences for the non-condensable gas test are that we use a condenser which prevents the steam coming into contact with the cooling medium. This results in more reliable results because:

1. Any gases given off by the cooling medium will not affect the result and there is no need to pre-boil/cool the cooling medium
2. The flow of steam can be closely controlled to avoid localised boiling and provide a consistent and repeatable test
3. The test can be carried out multiple times or for an extended period without needing to dismantle the equipment

Comparison Data

- **Side by side trials**
- **EN 285/HTM 2010 average = 1.007915%**
- **KS & A average = 1.010359%**
- **Difference in methods = + 0.002444%**
- **Difference is not significant**

*Five simultaneous tests were performed using the same steam supply at the same time.

One set of tests used the equipment described in EN 285/HTM 2010 and the other, the SQ1 system. The former results indicated a non-condensable gas level between 0.396 and 1.600%, giving an average non-condensable gas level of 0.1.007915%.

The non-condensable gas tests performed using the SQ1 steam quality test kit produced results that varied between 0.400 and 1.569 with an average of 1.010359.

It can be seen that the test equipment used supplied with the KS & A steam quality test kit produced results that were higher by an average 0.002444%. We only would normally report results to two decimal places and the difference in the two methods is not considered significant.

* The tests were conducted on 28th September 1999.

Frequency/No. of Tests

- **The only reference to test frequency is to be found in HTM 2010 and is:**
  - On initial validation/commissioning of sterilizers
  - Annually as part of the validation of each sterilizer
- **It is generally accepted that annual Point of Use testing is sufficient.**
- **The number of non-condensable gas tests needed is <u>three</u> (HTM 2010/EN 285).**

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The only documented test frequency is detailed within HTM 2010 and this details the need to test the steam quality as part of the original validation/commissioning of a sterilizer and annually thereafter, as part of the re-validation programme.

Generally, annual testing is deemed adequate for <u>sterilizer</u> point of use testing.

When qualifying new steam generators, some regulators may require more frequent testing, under different flow regimes. Subsequently, annual testing would normally be deemed appropriate.

Qualifying Steam Generators & Distribution Systems

- **Reference in HTM 2031**
- **Usual to test at generator at min/max flow rates**
- **May need to exhaust steam to atmosphere to generate max flow**
- **Test distribution system under min/max flow rates at extreme points**

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Ensure that the operating pressure of the generator does not exceed the rating of the SQ1 test kit. If this is the case, please notify us.

Dryness Test – 6 BarG (165° C)

Superheat Test - 6 BarG (165° C)

Non-Condensable Gas Test - 5 BarG (160° C)

Test Conditions: HTM 2010/EN 285

- **EN 285:2006 requires that the test should be carried out following a warm up run and with a small test pack (linen).**
- **HTM 2010 requires that the test should be carried out with a chamber that is empty other than the normal chamber furniture – no warm up run.**
- **Consistent approach is indicated**

Our experience is that the most important factor is consistency of approach.

If carrying out multiple runs, a warm up before each test may not be appropriate.

Our approach would be to use an empty chamber as linen test packs are sometimes not available, particularly in the pharma industry.

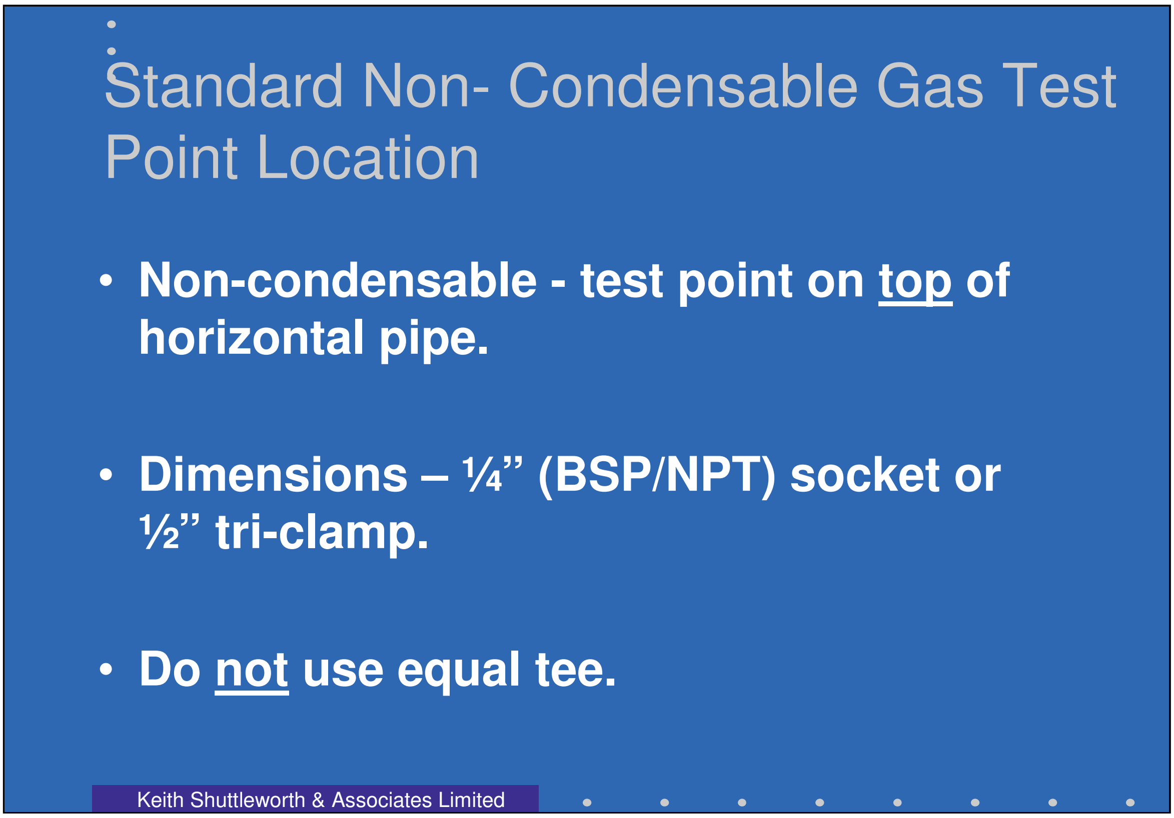
The worst case condition would be with a load having the greatest heat capacity (mass x specific heat). Given that this is not deemed necessary, our normal approach would be to use an empty chamber without a warm up run, followed by two repeat tests, where deemed necessary. Our experience has been that no discernible difference is evident where the steam quality is consistent.

Non-condensable Gas Testing Essentials

- **Do not improve on the test method!**
- **Attention to detail**
- **Repeatable technique**

Do not attempt to improve on the methods described without validating the impact of any change. Most of the errors we find in obtaining satisfactory results are due to poor sample point location, closely followed by “improvements” to the standard method. Small changes may not be deemed important, but on balance will be seen to impact on results.

We suggest that an identical approach is adopted to every test. It is therefore essential that you use an identical approach in order that you may determine if steam quality is improving or deteriorating.



Objectives:

To establish the configurations that define the non-condensable gas test point as being “standard”.

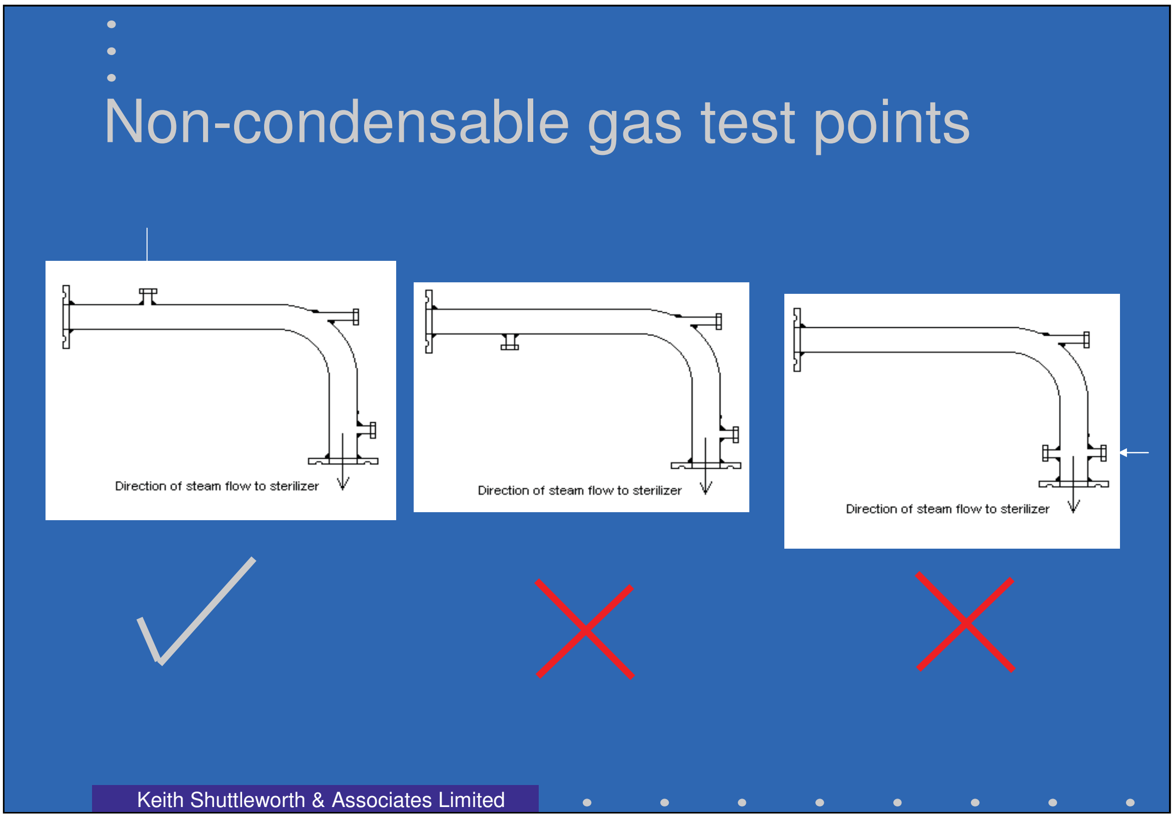
Notes:

The pipe size should be the same as the pipe supplying the sterilizer with steam.

The non-condensable gas test point should be on the top of the steam supply pipe. If at the bottom it will be subject to the effects of condensate which will be present in greater quantities at the bottom of the pipe. This could result in a pass condition, where a fail should be recorded.

Experience has shown that if located on the side of the pipe, variable results will be obtained which tend to be worse than the standard location.

The sample port should be constructed of a ¼” socket else ½” tri-clamp connection irrespective of the pipe size. Unless the steam supply pipework is ½” tri-clamp, a tee should not be used. The test assumes that a film of air will be present on the wall of the pipe. The larger the sample point, the greater the volume of gases that will be present and the more likely that condensation will occur in the sample point, which will liberate yet more gases. For this reason, the sample point should be kept as short as practicable. If a ½” tee is utilised, the branch should be shortened. The impact of a large diameter or long sample point is that the non-condensable gas test is more likely to fail.



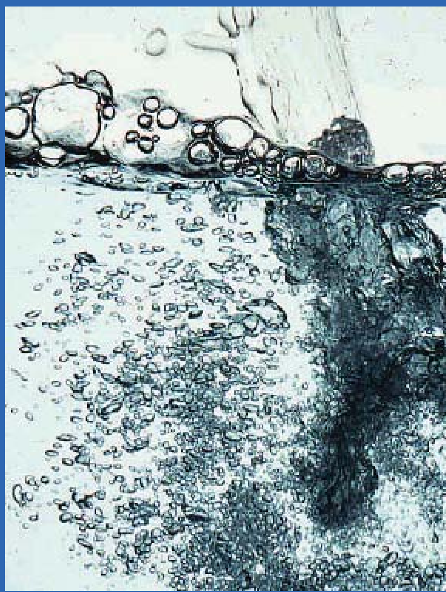
Non-condensable gas test points

Should be on the top of the steam pipe facing vertically upwards.

Should not be on the bottom of the steam pipe facing downwards.

Should not be in a horizontal plane on the side of steam pipes.

Theory



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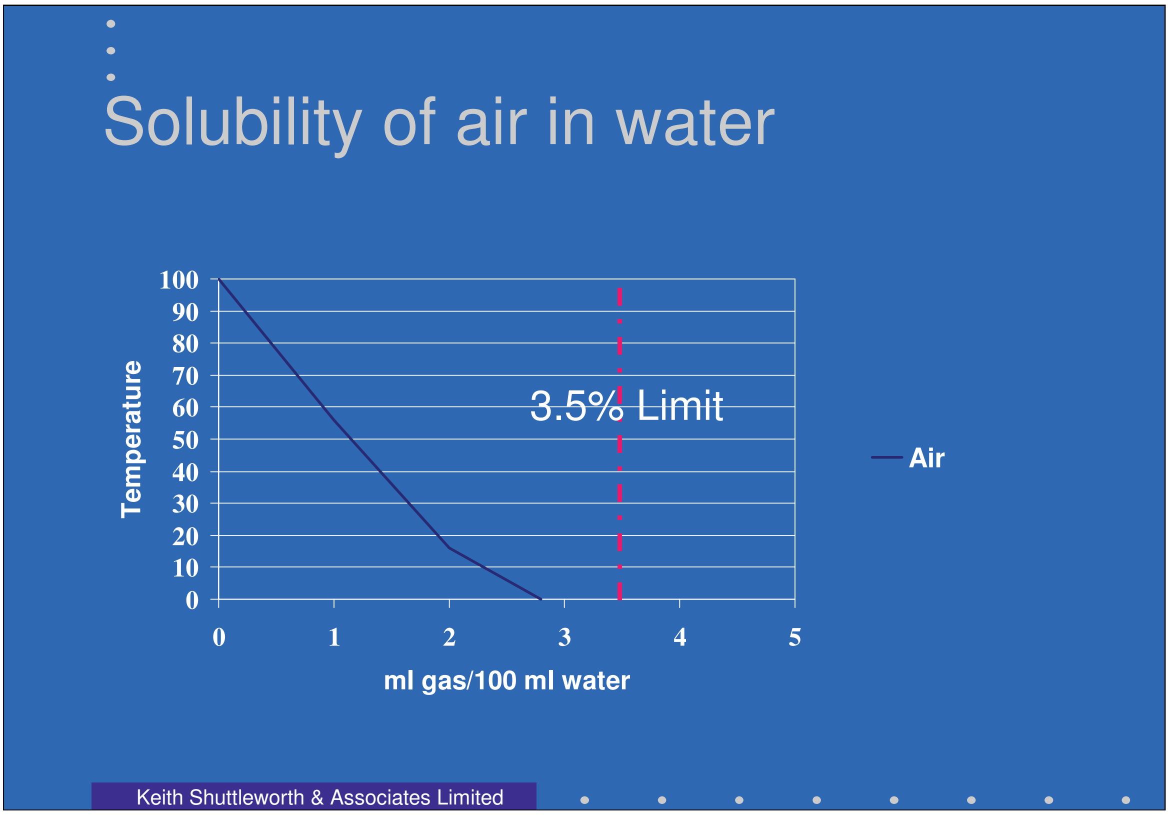
When we heat water we can see small bubbles on the heating surfaces well before the water starts to boil. These bubbles are gases that become less soluble with increasing temperature. If we put cold water into a steam generator these gases will end up in the steam distribution system.

Levels of non-condensable gases are not often consistent and tend to change, usually upwards, when water is put into the steam generator.

The gas bubbles that we observe are usually air, but depending on the water quality and the water treatment regime, carbon dioxide may be present. This can be present in very large quantities water can contain @ 30 times more CO_2 than air.

In the pharma industry we often aerate the water as a result of continuous circulation, passing through spray balls etc. which means that the theoretical solubility limits are often exceeded.

The simplest method of eliminating/reducing high levels of non-condensable gases is to heat the water before it enters the steam generator to liberate the gases. Most steam generators have pre-heaters as part of their design to reduce energy consumption. However, the heating that is applied in in a closed system and while the gases may leave the water, there is often no means of them leaving the system.



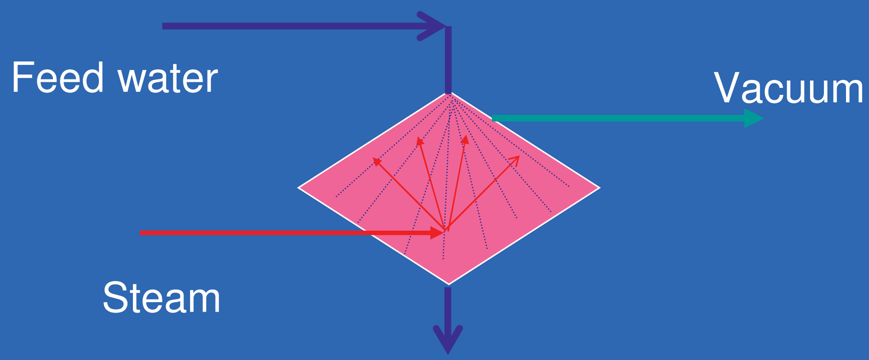
It will be seen that the solubility of air in water is always less than 3 ml of gas/100 ml of water. The limit for our non-condensable gas test is 3.5 ml of gas/100 ml of water.

This means (theoretically) that it is not possible to fail the test even if we put water close to freezing point into our steam generator.

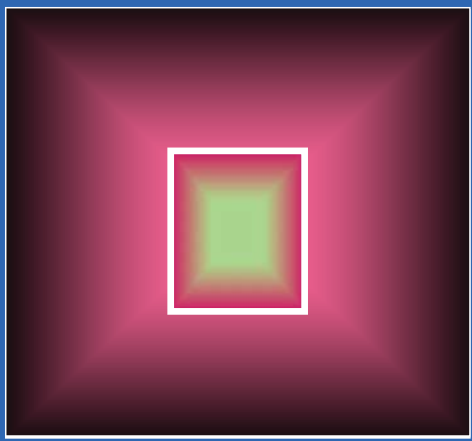
The previous slide relating to water aeration explains why/how large volumes of gas can result.

At room temperature water can hold @ 90 ml of CO_2/100 ml. This indicates that where CO_2 is present, the 3.5% limit can be easily exceeded.

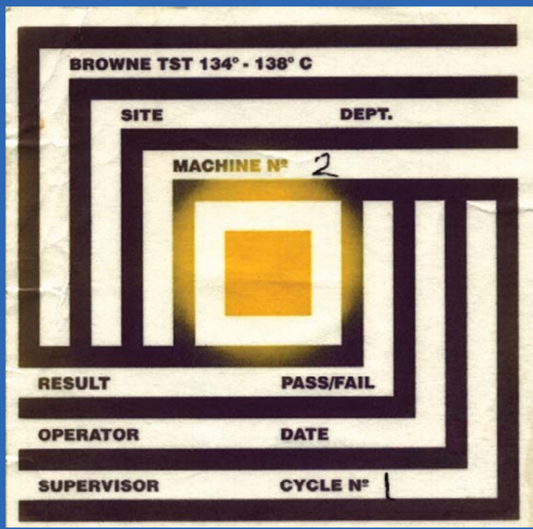
De-Aerator



The effect of a load



Bowie Dick Test



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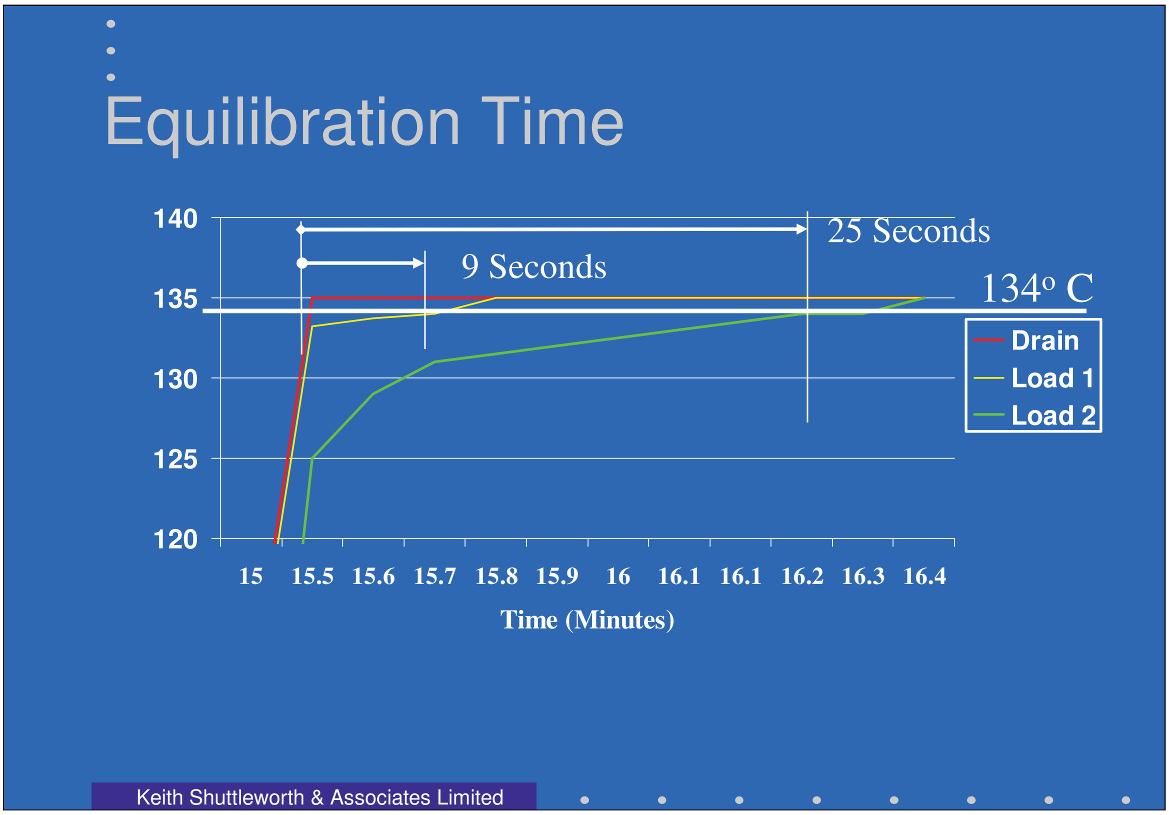
The effects of excessive levels of non-condensable gases can be seen in the failed Bowie Dick Test result above.

Instead of the indicator being penetrated by steam to provide a uniform colour change, the non-condensable gases have accumulated in the centre of the test pack and formed an insulating mass. This has prevented the steam reaching all parts of the indicator and the absence of moisture has prevented the chemical indicator changing colour.

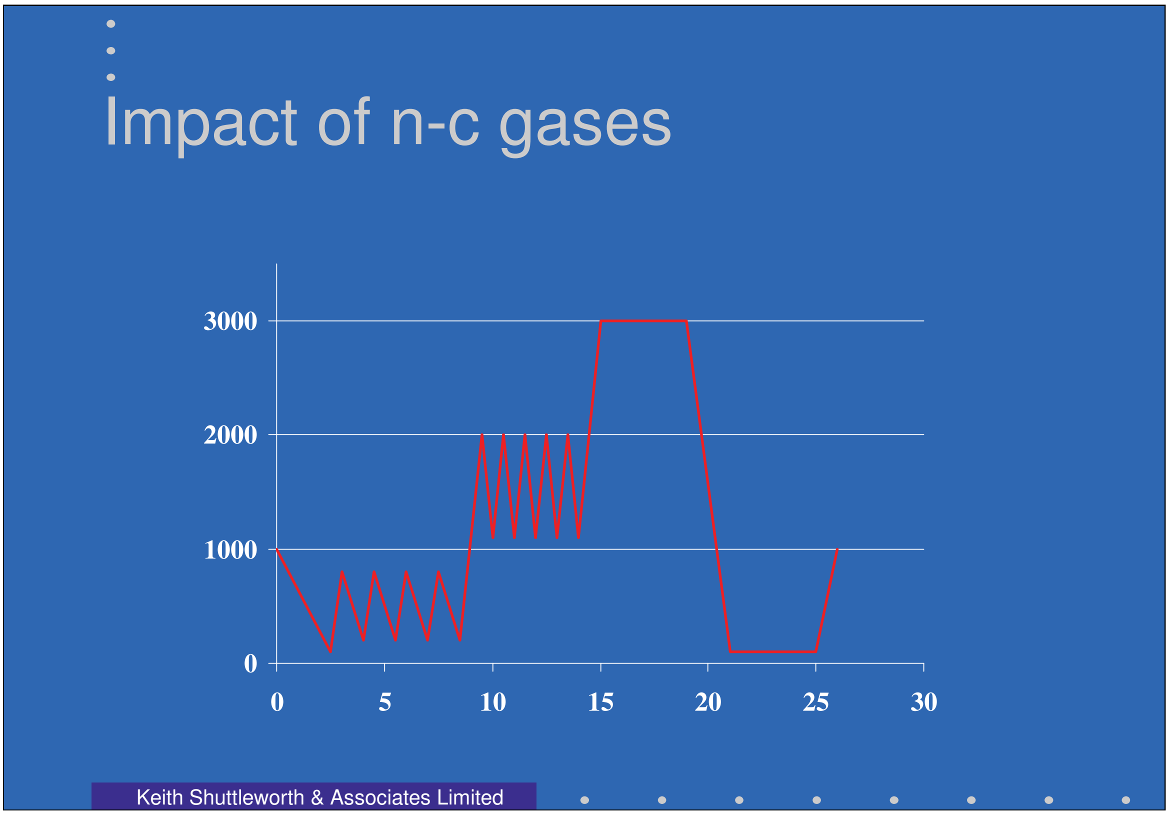
This result was obtained from a sterilizer which had @ 6.5% of non-condensable gases present.

The presence of non condensable gases will have the same impact as a leaking chamber or inadequate air removal stage.

The extent of the problem will be dependent on the effectiveness of the sterilizer air removal system and the amount of gases present.

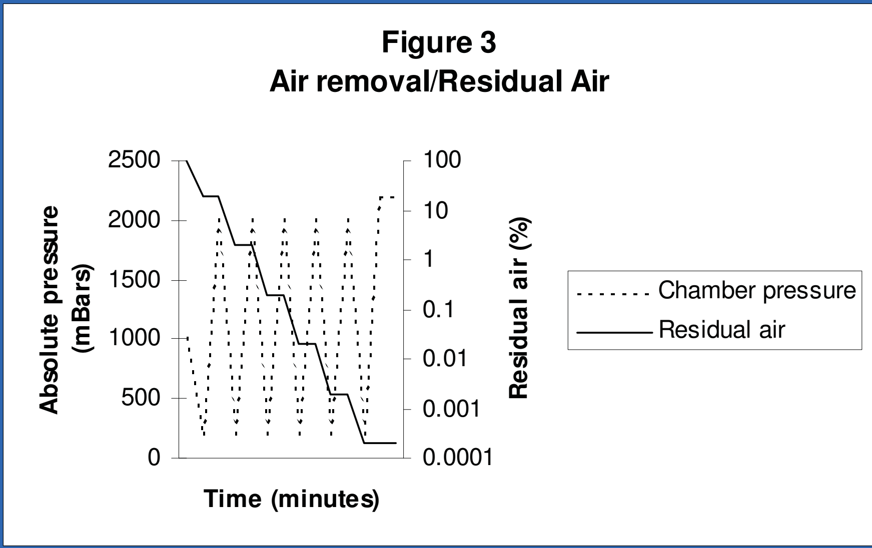


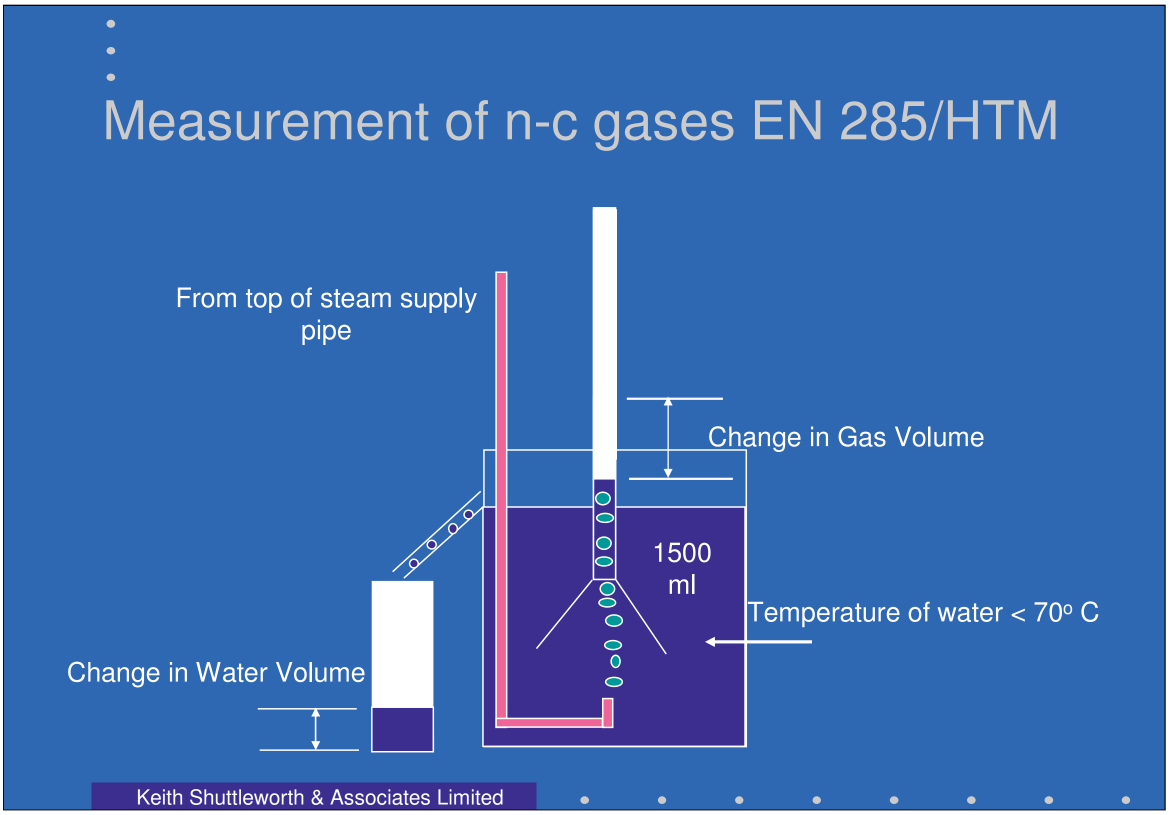
Non-condensable gases can also have an adverse impact on equilibration times. Gases will surround a thermocouple insulating it from steam. Because the air will only heat slowly, its presence will show as an extended heat up time, when compared with the sterilizer drain.



The impact of non-condensable gases can be such that in large quantities they can eliminate the benefits of one or more of the air removal pulses.

Residual air





To measure the amount of non-condensable gases we simply condense steam into water and any gases present rise into the burette displacing water. The steam that has condensed overflows into a measuring cylinder. The test has to complete before the temperature of the water exceeds 70º C. The purpose of this is to prevent gases being liberated from the water used to condense the steam.

We measure the amount of gases (ml) and the amount of condensate (ml) and the calculation is:

% of N-C Gas = (Change in volume of gas in burette/Change of volume of water in measuring cylinder) X 100/1

Therefore if 3.7 ml of gas are collected and 125 ml of condensate the result will be:

= (3.7/125) X 100/1 = 2,96%

This is less than the limit of 3.5% and the test is deemed to have passed.

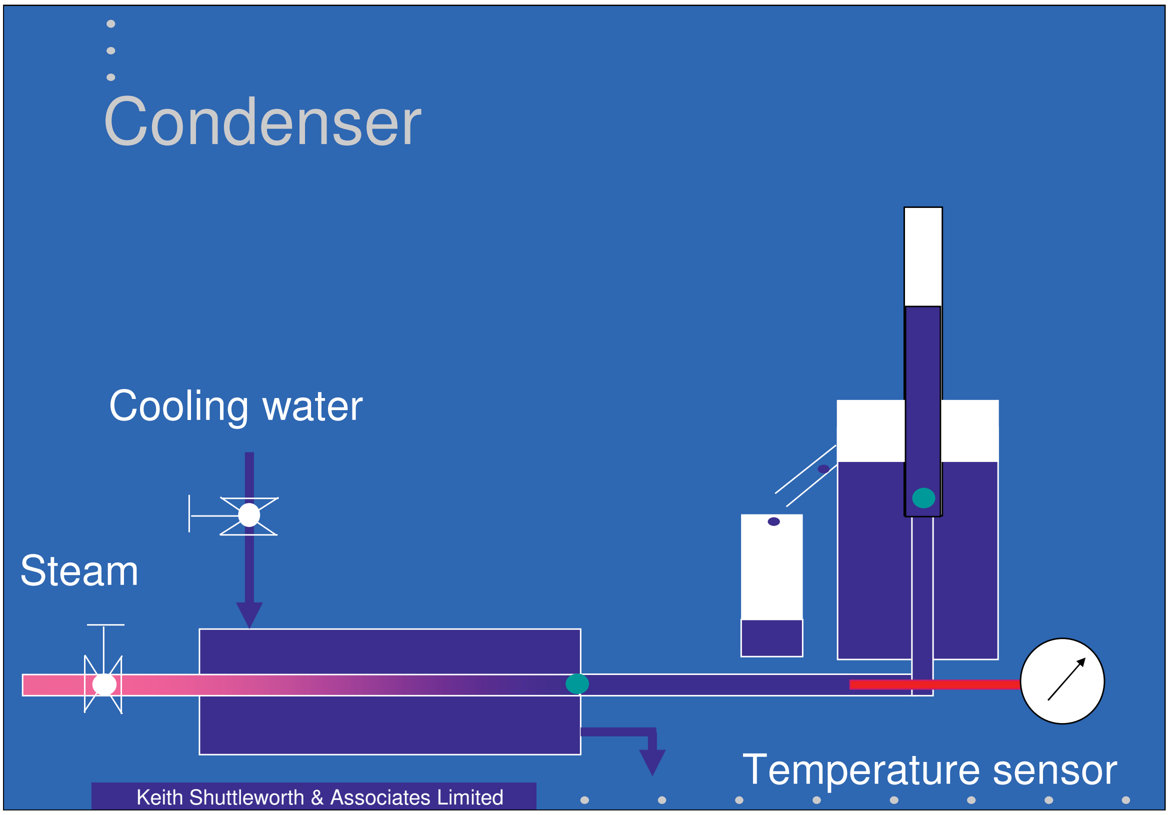
Problems associated with the standard test are:

The distance between the steam entering the flask and the funnel is not specified. If too high the water in the funnel and/or burette can boil well in advance of the water as a whole heating to > 70º C. This will cause a false failure.

If the flow of steam is to high, this will also cause localised boiling in the flask/funnel/burette and give a false high (fail result.

If the water in the flask has not been previously boiled and stored in the absence of air, air can be liberated from the water and give a false high result.

The equipment has to be carefully dismantled after the water has heated to 70º C and the flask emptied and refilled before another test can start.



The method used in the SQ1 non-condensable gas test is to ensure that the steam and cooling medium do not come into contact with one another. This prevents all of the issues with localised boiling and aerated cooling water.

Steam is condensed in a heat exchanger and gas bubbles pass into the burette, while the condensate overflows into a measuring cylinder. The calculation and acceptance criteria is identical to the previous slide.

Provided an adequate supply of cooling water is available, it is possible to run the test for an extended time.

When testing at a point of use we are not usually aware of when water enters the steam generator which usually results in a peak in results. By running the test for an extended period, we are able to satisfy ourselves that we have a satisfactory condition at any time.

The temperature meter

Measures the condensate outlet temperature

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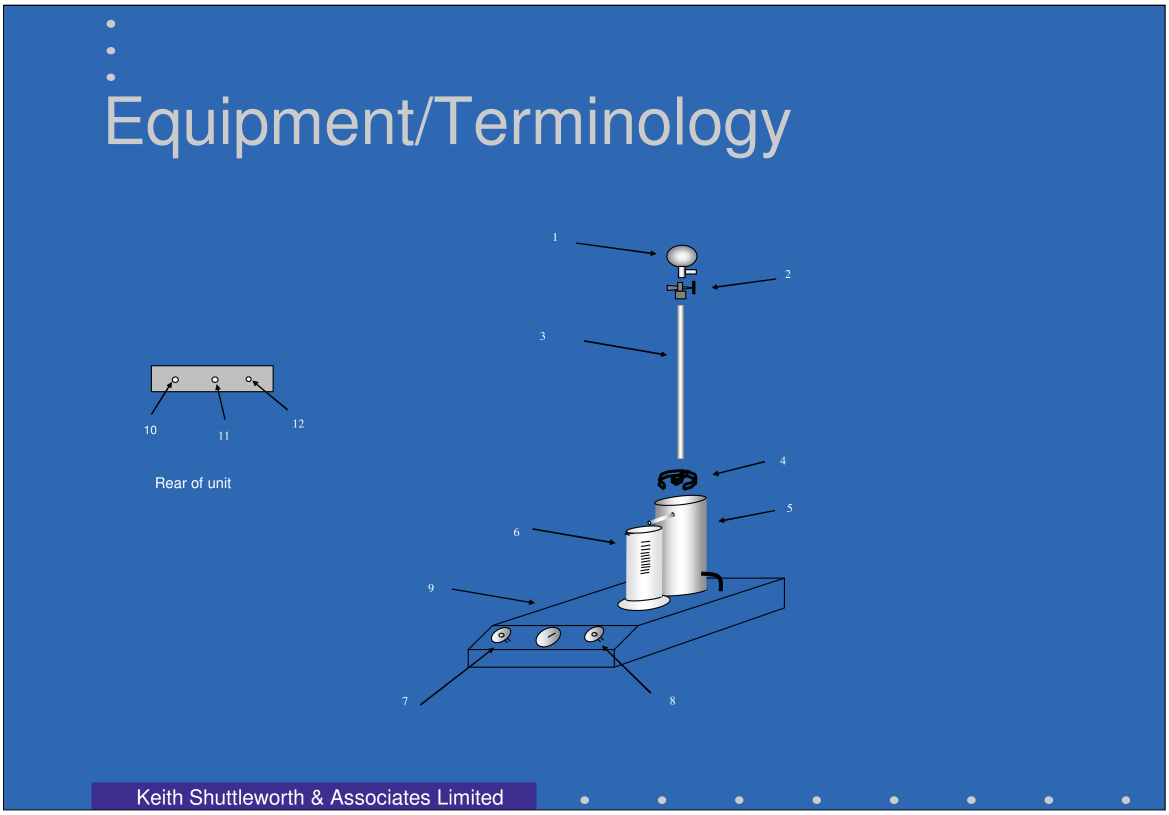
When the SQ1 was developed we were concerned that any gases that are liberated may be reabsorbed into the condensate if it were too cold. We provided the temperature meter to allow us to assess the impact of this effect. We felt that it was necessary to have a high condenser outlet temperature to avoid this risk and the gauge was a simple way of achieving this.

Subsequently, we have carried out a number of trials to determine if the condensate temperature has any impact on the results. Our findings were twofold:

Under normal conditions, the temperature does not have any effect and the test may be run at as cold a temperature as desired as the time available for reabsorbtion appears insufficient. This makes controlling the temperature easier and quicker to achieve.

<u>However</u>, we did discover that on the rare occasions that CO_2 were present, it could easily be reabsorbed if the test is run at a low temperature. Given that the HTM 2010/EN 285 method operates below 70º C, a low temperature test regime is clearly compliant, but may not detect problems that could exist with high levels of CO_2. We therefore suggest that at least one test is carried out at any elevated temperature (> 70º C) to confirm the presence or otherwise of CO_2. This aspect will be covered later in the document.

The gauge is a simple contact type device that cannot be easily calibrated and we do not recommend that it is attempted. If an accurate assessment of temperature is required we suggest that you place a calibrated temperature probe into the condense collection cylinder.



1. Burette Bulb
2. Burette Cock
3. Burette
4. Burette Guide
5. Condense collection cylinder
6. 250 ml Measuring Cylinder
7. Steam Valve
8. Cooling Water Valve
9. Steam condensing unit
10. Cooling Water Inlet
11. Cooling Water Outlet
12. Steam inlet

Cooling water for the condenser

- **Choice of methods**
- **From mains water supply**
- **From sterilizer water tank – if fitted**
- **From bucket – recirculating**
- **From bucket – to drain**

A number of alternatives exist to supply cooling water to the condenser. We can:

Supply water via mains water supply and run to waste via a drain. The pressure in the condenser must not exceed X Bar (YPSIG).

We can supply water to the condenser using a bucket and the submersible pump provided. Water can be pumped from a bucket, through the condenser and back into the bucket. 10 litres of water will normally be sufficient for three standard non-condensable gas tests. Because the water is recirculated the water temperature will increase and care should be taken to ensure that it does not get so hot that it may present a hazard when disposing of it.

Alternatively we can use a bucket and discharge the water straight into a drain. While this avoids any hazards associated with buckets of hot water, there is a risk that the pump may run dry and care needs to be taken that this does not happen as the pump may be damaged.

Cooling water pump

Used to provide cooling water to the condenser

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To condense the steam in the non-condensable gas-testing unit a supply of cold water is needed. Due to the difficulty that is often found in finding a accessible supply of water in a sterilizer plant room, a coolant transfer unit has been included in this kit.

The pump unit is may either by mains electrically powered or a low voltage version that needs to be submerged totally in water. If a mains powered unit is used it should be connected via a residual current circuit breaker.

There are two methods of utilising this pump unit.

The unit may be dropped into the make up tank of the sterilizer or other convenient water reservoir.

Alternatively, place the pump unit in a bucket of water. There should be enough water in a standard bucket to enable testing to continue for approximately 15 -20 minutes before a top up is required.

✍ **Do not place the pump in a make up tank that re-circulates its water, as the fluctuating temperatures could make obtaining a consistent condensate temperature difficult and damage to the pump may occur**.

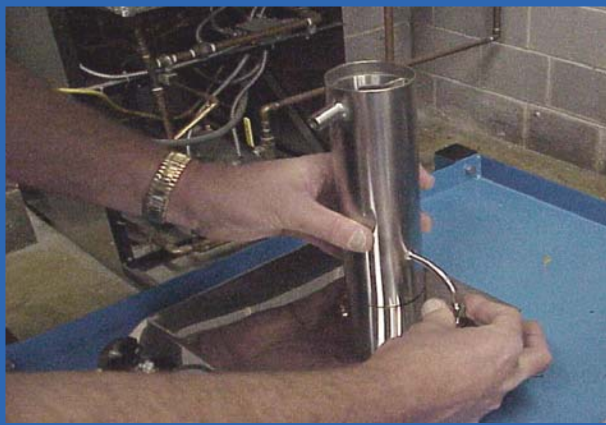
In a tank that has silt or other debris it is recommended that the filter be fitted.

Note Do not let the pump unit run dry as damaged to the pump may occur.

N-C gas test kit assembly

STEP 1
Remove the metal condense collection cylinder and attach it to the steam condensing unit.

Note:
Prepare a bucket of tap water (@ 10 litres) and a pouring cup



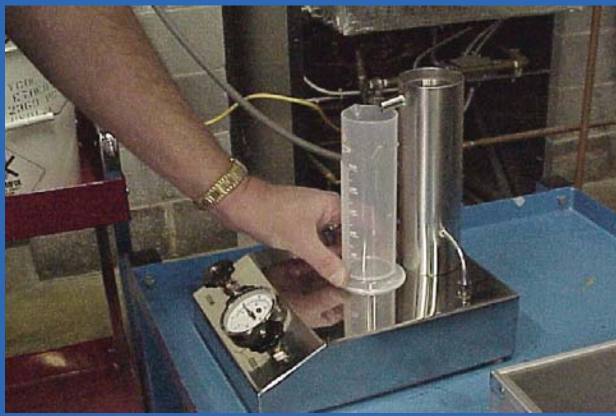
The entry pipe to the condense collection cylinder is fitted with one or more o-rings to provide a seal. We have tried using stainless steel olives in the past but our experience has been that with extensive use that they leak. By contrast, the o-rings are easily replaced. NB. Do not overtighten the connection as these o-rings may be damaged.

On the steam condense unit, ensure that the cooling water valve is fully open and the steam valve is fully closed.

Turning the valves clockwise closes them and anticlockwise opens them.

N-C gas test kit assembly

STEP 2
Remove the 250 ml measuring cylinder and locate it directly in front of the metal condense collection cylinder.



N-C gas test kit assembly

STEP 3

Remove the 1/8” copper steam supply tubing and attach an end to the back of the Steam condensing unit labelled “STEAM IN”.

The dimensions of the copper pipe may vary from country to country. Either 1/8” or 4 mm pipe may be used.

Tighten, but do not overtighten.

N-C gas test kit assembly

STEP 4
Isolate the steam supply and connect the other end of the 1/8" copper steam supply tubing to the top of the pipe that provides steam to the sterilizer.

Ensure that the steam supply is turned off and that no steam pressure is present.

The connection will be either into a ¼" BSP (or NPT – US) socket on the test elbow or pipe or into a ¼" socket – ½" tri-clamp adaptor if the sanitary version is being used.

The picture shows this being carried out with the steam pipe cold. If it is hot or there is even a risk of it being hot, personal protective equipment, such as gloves, face mask should be worn and overalls to cover exposed skin.

N-C gas test kit assembly

Step 5
Remove the two pieces of the green, submersible Water pump and attach together.

N-C gas test kit assembly

Step 6
Remove the white power supply and be sure the 18/24v switch is set at 24v.

This relates to the low voltage system used in the US and your version may be different!

N-C gas test kit assembly

Connect the green submersible Water pump's black cord to the white power supply's black connection.

N-C gas test kit assembly

Step 7
Remove the white Water feed supply tubing from the case.

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Current equipment is supplied with two coloured hoses:

Blue – To represent “cold” and is used to connect between the pump outlet and the Steam condensing unit.

Red – To represent “hot” and is used to connect between the Steam condensing unit and either a return to the bucket or to drain.

N-C gas test kit assembly

Attach an end of the Water feed supply tubing to the Water pump and secure.

Use the **Blue** tube.

N-C gas test kit assembly

Step 10
Locate the Water pump into a bucket of tap water.

N-C gas test kit assembly

Attach the other end of the water supply tubing to Steam condensing unit labelled "COOLING IN" and secure.

Blue tube from pump

N-C gas test kit assembly

Step 8
Attach a 2nd plastic water supply tubing to the Steam condensing unit labeled "COOLING OUT" and secure.

Cooling out tube is Red **and can either be run to drain or back to the bucket with the pump in.**

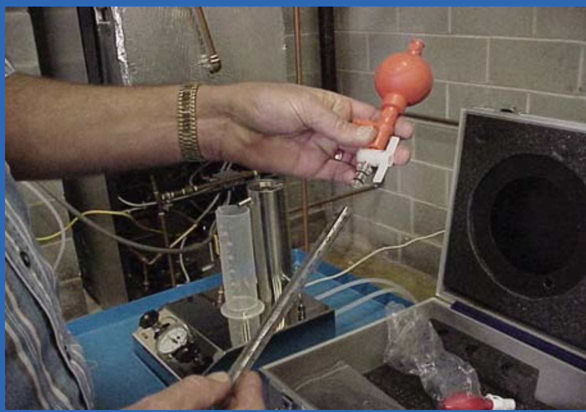
N-C gas test kit assembly

Locate the other end of this plastic tubing from the "COOLING OUT" into a drain or back into the bucket.

The other end of the **Red** tube

N-C gas test kit assembly

Step 9
Remove the plastic Burette, burette valve and burette bulb from the case and attach.



N-C gas test kit assembly

Place the plastic burette upright into the metal Condense collection cylinder.

N-C gas test instructions

Step 1
Fill the metal Condensing collection cylinder with tap water.

N-C gas test instructions

Step 2
Using the bulb, open the burette cock to fill the burette with water and then close.

Next

- **Put power onto the cooling water pump by plugging it in.**
- **Make sure that there is water flowing**
- **Turn on the steam supply - slowly**
- **Check for water and steam leaks**

N-C gas test instructions

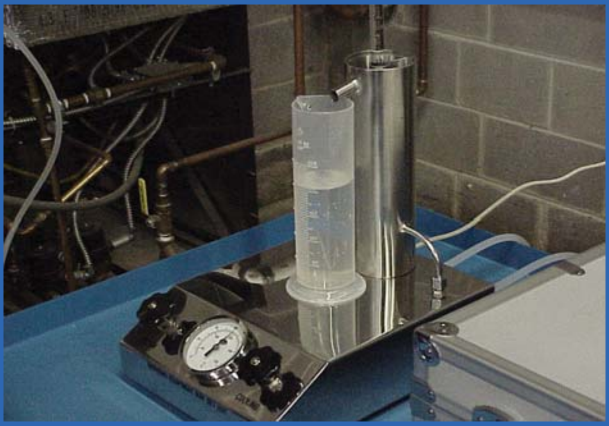
Step 3
Fractionally open the Steam valve (on the left) and allow the temperature to raise to between 50C - 95C.

N-C gas test instructions

Using the Steam and Cooling values, be sure to maintain the temperature between 50C-95C.

N-C gas test instructions

Pour out any water that has collected in the 250ml Measuring cylinder.



N-C gas test instructions

Step 5
Confirm that the flow rate is between 10 – 30 ml per minute by use of a stop watch.

Note:
Take readings with temperature between 55C-95C.

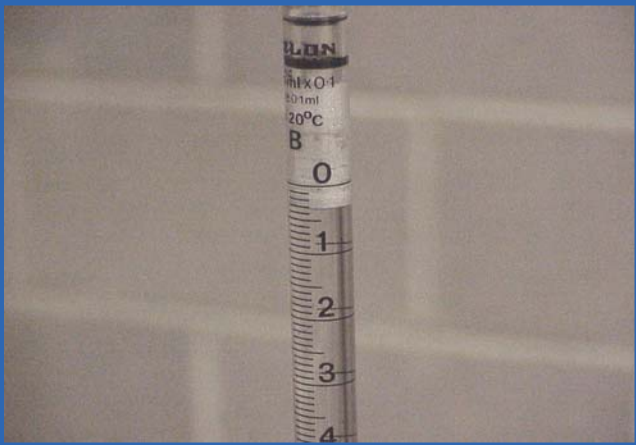
N-C gas test instructions

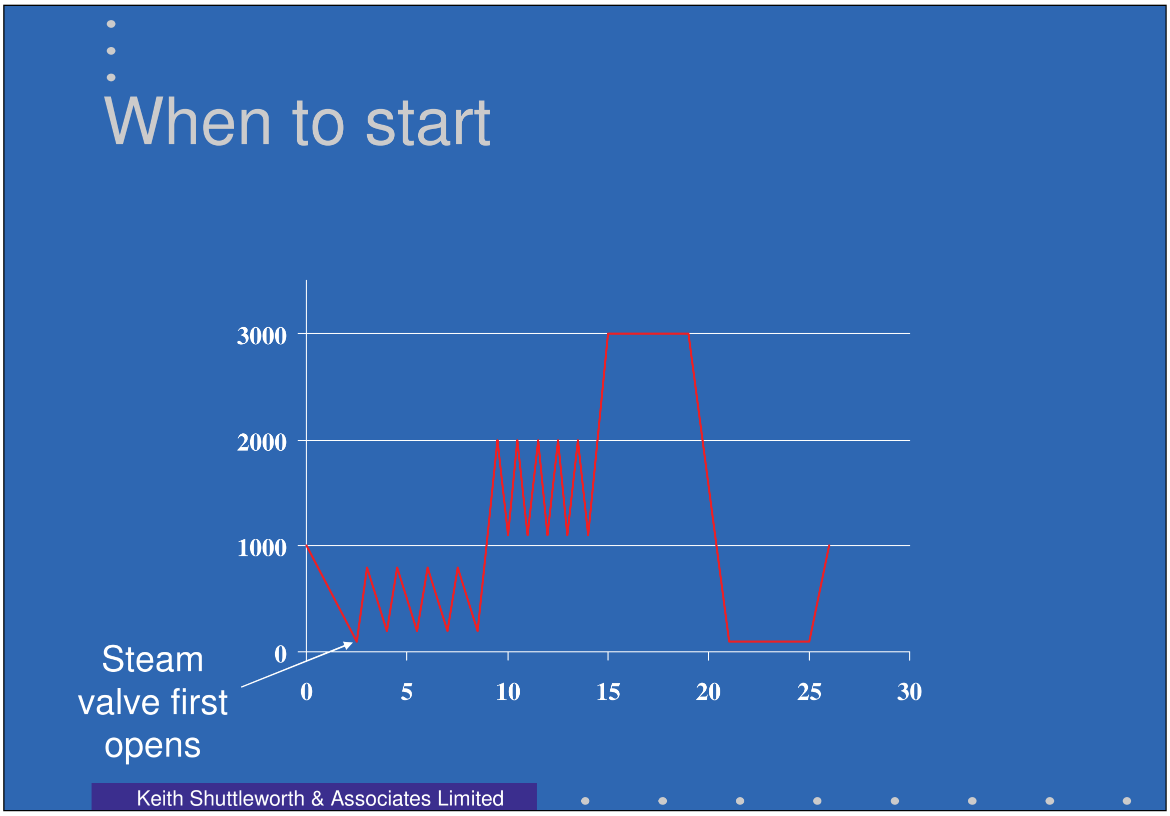
Step 6
Select a porous load Steam cycle and start the sterilizer.

Note:
Do not include a load, but include any racking that is normally used.

N-C gas test instructions

At the start of the sterilizer cycle, note the water level in the burette and in the Measuring cylinder.





The test should commence when the steam to chamber valve first opens. This may be an on/off valve, a control valve or both.

This is often (wrongly) confused with the start of the heat up. The test should start when steam enters the sterilizer chamber for the first time in the process.

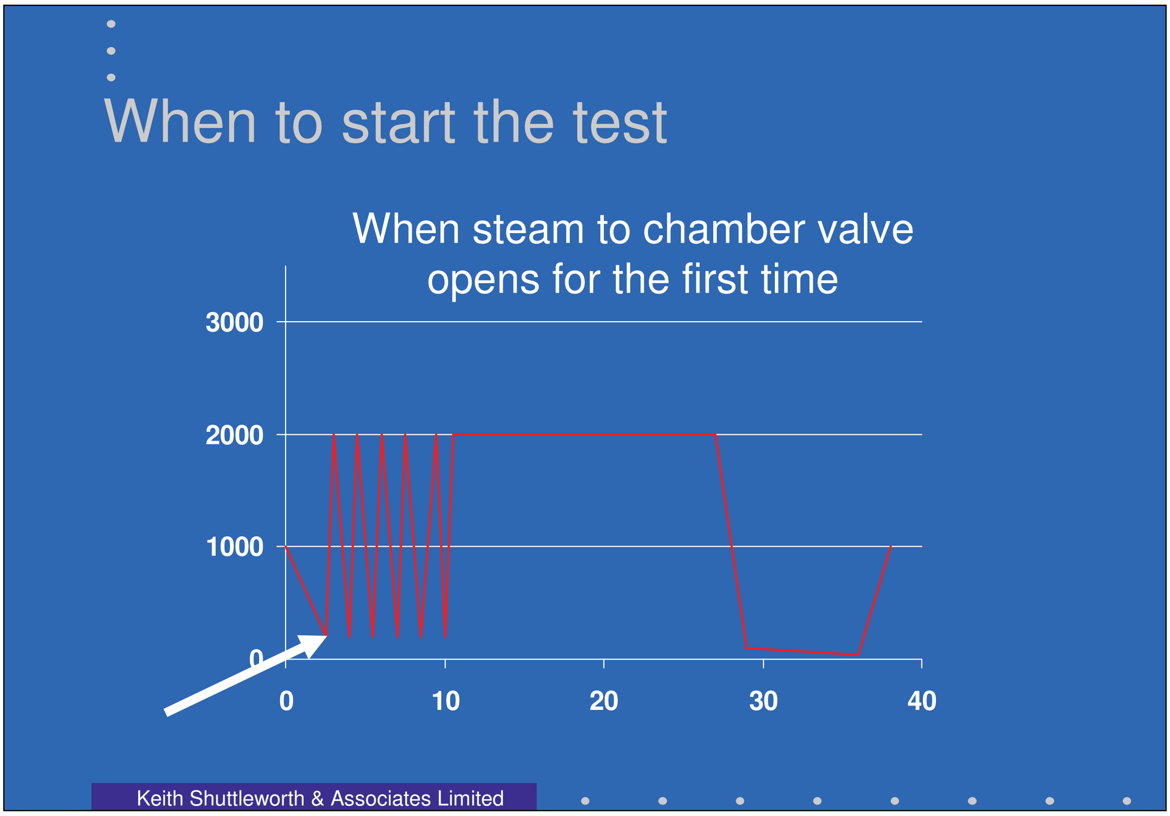
This usually reflects the following conditions:

The vacuum is often the deepest

The vessel and pipework are at their coolest

This would normally result in the greatest steam demand. While this aspect need not be critical a consistent approach is highly recommended.

It will be seen that the conditions sampled will vary on machines having different cycles and/or being of different sizes. That is to the sample taken on a small machine with a fast process could be most of the vacuum/pulsing stage, whereas on a large machine the sample could be taken of a single pulse.



The test should commence when the steam to chamber valve first opens. This may be an on/off valve, a control valve or both.

This is often (wrongly) confused with the start of the heat up. The test should start when steam enters the sterilizer chamber for the first time in the process.

This usually reflects the following conditions:

The vacuum is often the deepest

The vessel and pipework are at their coolest

This would normally result in the greatest steam demand. While this aspect need not be critical a consistent approach is highly recommended.

It will be seen that the conditions sampled will vary on machines having different cycles and/or being of different sizes. That is to the sample taken on a small machine with a fast process could be most of the vacuum/pulsing stage, whereas on a large machine the sample could be taken of a single pulse.

N-C gas test instructions

When the water level in the Measuring cylinder increases by 100 ml (Vc), record the volume of gas that has been collected in the burette (Vb).

N-C gas test instructions

Repeat the test 3 times, making sure the temperature is maintained between 55C-95C for each test.

N-C gas test results

Calculate the fraction
of non-condensable
gases as a %…
NCG = 100 x (Vb/Vc)

The test is satisfactory
if the level of NCG
does not exceed 3.5%

Dalton’s Law

Total Pressure in Chamber (Bar)	Chamber Content (litres) Steam : Air	Dalton’s Law Steam + Air Pressure Pressure (Bar) (Bar)	Chamber Temperature (^{o}C)
2·10	1000 : 0	2·10 + 0	121·8
2·10	900 : 100	1·89 + ·21	118·5
2·10	990 : 10	2·079 + ·021	121·47
2·10	999 : 1	2·0979 + ·0021	121·77

Some causes of n-c gases

- **Intermittent generator operation**
- **Cold/aerated feedwater**
- **Leaking feedwater glands**
- **Poor venting**
- **Design of distribution system**

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Potential problems in pure steam systems are significantly fewer than in plant steam systems, where demand and feedwater quality can vary seasonally and chemical dosing may cause different effects.

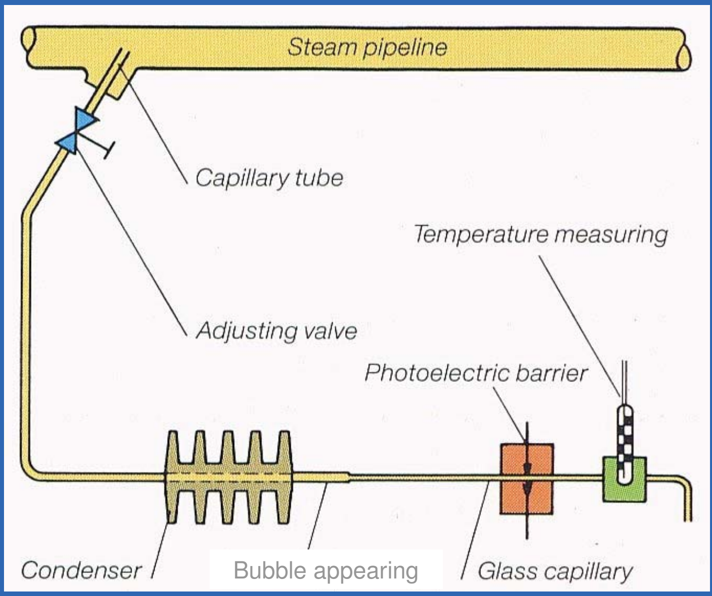
It is self evident that if steam plant is kept running 24 hours per day air cannot enter the system. If steam raising plant is shut down every night, the plant will start up with a distribution system full of air that must be vented, else find its way out of the system by means of the connected processes.

Both cold or aerated feedwater sources will cause problems with excess non-condensable gases. Gross failures are often caused by leaking glands on feedwater pumps.

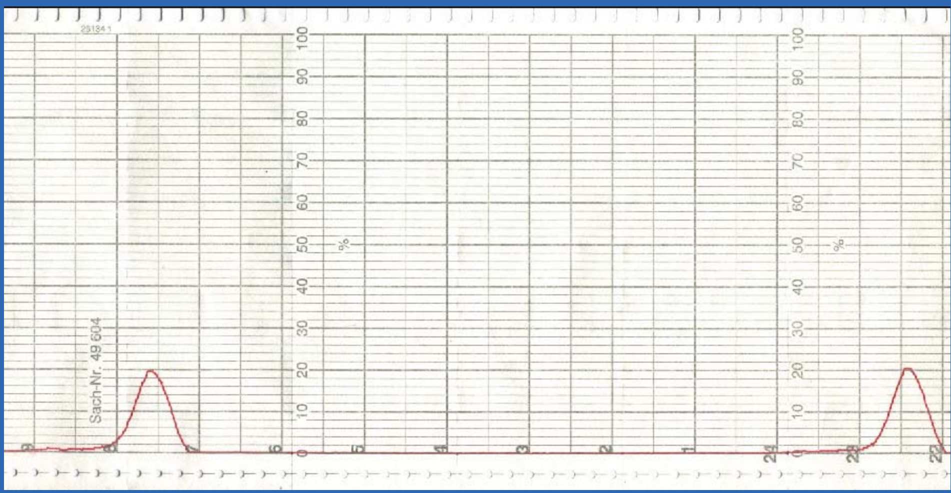
The application of air vents is often over emphasised. Non-condensable gases are liberated at the point of condensation, which can be anywhere in the distribution system, being of similar density to the steam they will be carried in the direction of flow. Typical pipeline velocities are 25 - 35 m/s (56 - 78 mph) and it is difficult to conceive how air vents can improve the steam quality. At best, they will eliminate excessive levels under low or no flow conditions, provided time is available for them to accumulate and cool.

Large and/or unlagged distribution systems will result in large volumes of gases being liberated which can accumulate/concentrate to excessive levels. While generally solved at source, in extreme cases, localised plant may be the only solution.

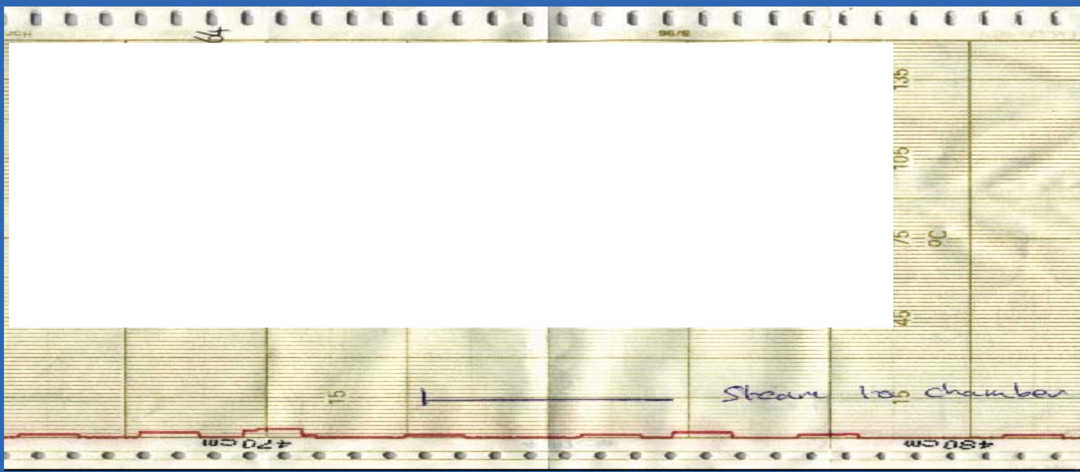
Methods - Non-condensable gases



Impact of feedwater



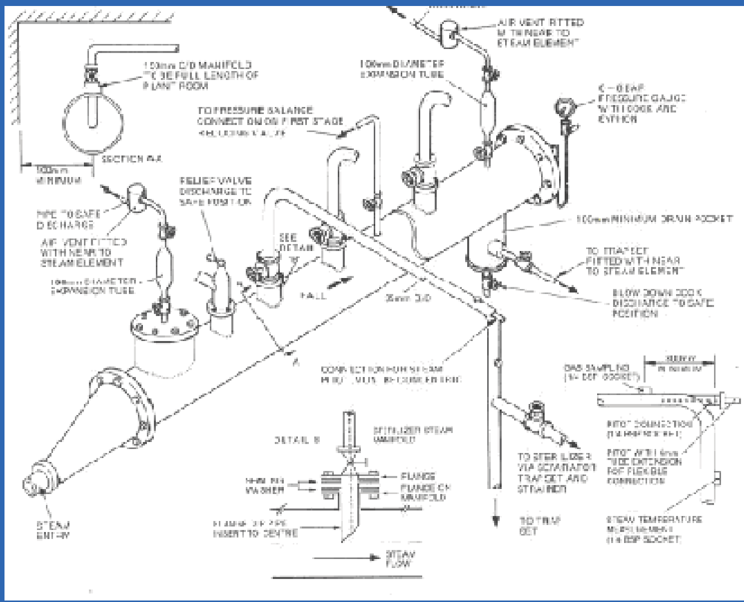
Post hysterisis adjustment



Summary

- **Cycle effectiveness**
- **Equilibration time**
- **Cold & aerated feedwater**
- **Bowie Dick test**

Steam header



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This slide shows a typical steam header. Features of the header are:

The header operates at a pressure no more than two times greater than the sterilizer.

Following the pressure reducing stage the steam is allowed to expand into the header which is of significantly larger diameter than the reducing valve.

A distinct fall is provided to allow proper condensate removal.

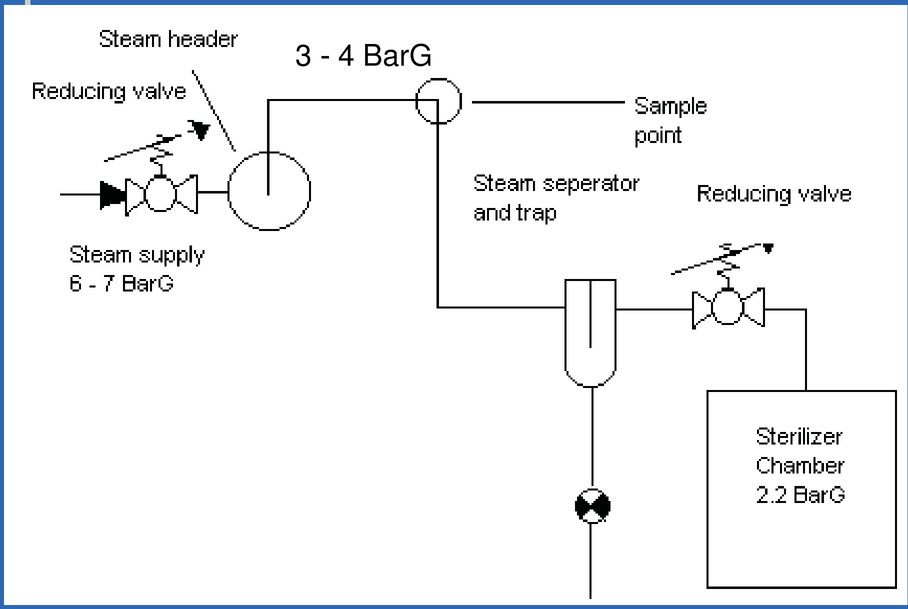
Air vents are fitted at both ends of the sterilizer.

Steam for the sterilizer is taken from the centre of the header to prevent both condensate and non-condensable gases entering the supply.

A steam separator will be fitted between the header and the sterilizer.

Note that a further steam trap is fitted between the header and the separator.

Implied installation



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Please do not hesitate to contact us if you have questions

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