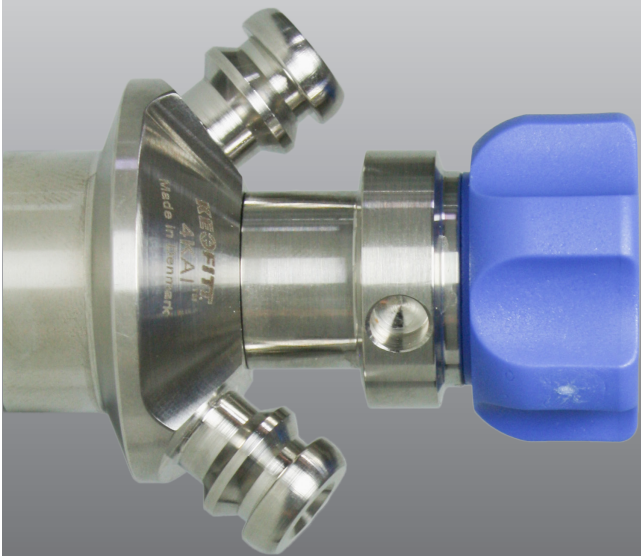


4KAI™ SAMPLING VALVE

User Manual



DOCUMENT VERSION LOG

The table below lists previous versions of this User Manual and states the major changes between versions.

This version list is introduced in March 2020.

Version #	Version date	Major changes from previous versions
1	March 2020	Latest version without log

INTRODUCTION:

MANUFACTURER:	Keofitt A/S Kullinggade 31 B+E 5700 Svendborg, Denmark
TYPE:	4KAI™ SAMPLING VALVE
YEAR OF INTRODUCTION:	2020
YEAR OF REVISED DESIGN:	2020
MANUAL LAST UPDATED:	March 2020

The English version of this Manual is the governing version and it is the only authorized version. Consequently, KEOFITT cannot be held liable for other versions including translations of this Manual.

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1. PRESENTATION

This manual describes the Keofitt 4KAI™ sampling valve in all its variants and configurations.

The Keofitt 4KAI™ sampling valve can be readily cleaned and disinfected/sterilized as it meets both hygienic and process design requirements. Effective cleaning and disinfection/sterilization of the sampling valve can be carried out between random samples independently of the course of the production process without compromising the same. The coaxial design ensures cleanability and sterilizability.

Keofitt works since many years with several associations promoting good hygienic standards such as 3-A. The American 3-A Sanitary Standard is normative for the component's ease of cleaning and sterilization and ensures optimum conditions for food products, which is in contact with the component in question. Various test reports and certificates are to be found on the Keofitt website www.keofitt.dk.

Keofitt valves are used in a wide range of processing industries, such as breweries, dairies, juice/soft drinks and the biotechnological and pharmaceutical industries, which all have different requirements and demands.

1.1 Definition of terms

In order to ease the reading of this manual and to avoid any misunderstanding, please refer to the definition of terms in the table below:

TERM	DEFINITION
3-A Sanitary Standard, Inc.	3-A SSI is an independent, not-for-profit US corporation dedicated to advancing hygienic equipment design for the food, beverage and pharmaceutical industries.
Acids	An acid is a chemical substance whose aqueous solutions are characterized by a sour taste and the ability to react with bases and certain metals (like calcium) to form salts. Aqueous solutions of acids have a pH of less than 7. A lower pH means a higher acidity, and thus a higher concentration of positive hydrogen ions in the solution. Removes limestone and most mineral deposits.
Alkali	Alkalis are all bases, which form hydroxide ions (OH-) when dissolved in water. The terms “base” and “alkali” are often used interchangeably. Alkalis have a pH value above 7. Alkalis dissolves fat and oil, destroys protein and attacks light metal.
Aseptic sampling	The process of withdrawing a sample from the production equipment through a closed circuit, which has been sterilized and kept sterile with no exposure to the surroundings during the sampling process.
Bioload	See Microbial load.
Bioburden	See Microbial load.
Chemical Sterilant	A few disinfectants will kill spores with prolonged exposure times (3–12 hours); these are called chemical sterilants.
Chlorine	Chlorine is a chemical element with symbol Cl and atomic number 17. It belongs to the halogen group together with for instance iodine. It is a strong oxidizing agent and reacts with many substances. These properties make chlorine compounds efficient disinfectants.
CIP	Abbreviation of Clean-In-Place. The process of cleaning a process component (like a sampling valve) without removing it from the production line.

Cleaning	Removal, usually with detergent and water or enzyme cleaner and water, of adherent visible soil on a surface.
Complexing agent	A substance capable of forming a complex compound with another material in solution. Improves the cleaning properties of a detergent.
Contact time	The time span during which the item is in contact with the detergent or the disinfectant.
Enzymes	Molecules, which are added to cleaning agents to ease the removal of specific organic material. Assures same cleaning effect at a lower temperature.
Disinfectant	Usually a chemical agent that destroys harmful microorganisms but might not kill bacterial spores.
Disinfection	Thermal or chemical destruction of microorganisms. Disinfection is less lethal than sterilization, because it destroys most recognized microorganisms but not necessarily all microbial forms (e.g. bacterial spores).
Detergent	A cleaning agent that has no antimicrobial effect, but in diluted solutions good cleaning properties.
EHEDG	Abbreviation for the European Hygiene Engineering and Design Group. EHEDG is a consortium of equipment manufacturers, food industries, research institutes as well as public health authorities promoting safe food by improving hygienic engineering and design in all aspects of food manufacture.
Electro polishing	Electro polishing is an electrochemical process by which the high points within the microscopic surface texture are removed and the corners rounded. This results in Reduced Product Adhesion, Ease of Cleaning and Improved Corrosion Resistance.
Exposure time	Period in a sterilization/disinfection process during which the item is exposed to the sterilant/disinfectant at the specific sterilization/disinfection parameters.
Flow path	The path the sample flows from the tank or process equipment to the sample recipient.
Germicidal	The property of an agent to destroy microorganisms.
Microbial load	The number and types of viable microorganisms with which an item is contaminated; also called bioload or bioburden.
Microorganisms	Animals or plants of microscopic size. As used in food and pharmaceutical industries, generally refers to bacteria, fungi, viruses and bacterial spores.
Peracetic acid	A commonly used disinfectant, which is efficient at low temperature and short contact time. Relatively harmless as it decomposes into carbon dioxide (CO ₂) and water (H ₂ O).
Process media	The product in the process equipment and the product from which a sample is taken.
Representative sample	A sample which when it reaches the laboratory is still identical to the process media. A sample which is in no way contaminated or altered during neither the sampling process nor the transport to the laboratory.
Sanitization	The application of a chemical agent that reduces the number of bacterial contaminants to a safe level as judged by the public health authorities. The official sanitizer protocol indicates that 99.999% of the specific test bacteria be killed in 30 seconds under the conditions of the test.

SIP	Abbreviation for Sterilize-In-Place. The process of rendering a process component (like a sampling valve) sterile without removing it from the production line.
Spores	Relatively water-poor resting cells surrounded by an impervious cell wall, which makes them relatively resistant to disinfectants and sterilants. They are dangerous as they can survive in adverse conditions and re-emerge as live bacteria at a later stage.
Sporicidal	The property of an agent that kills spores.
Steaming	The process of using saturated steam under pressure as the sterilizing agent.
Sterile	State of being free from all living microorganisms. In practice, usually described as a probability function, e.g., as the probability of any microorganism surviving sterilization being one in one million.
Sterilant	A few disinfectants will kill spores with prolonged exposure times (3–12 hours); these are called chemical sterilants.
Sterilisation	Validated process used to render an item free of all forms of viable microorganisms. In a sterilization process, the presence of microorganisms is expressed in terms of probability. Although this probability can be reduced to a very low number, it can never be reduced to zero.
Sterility Assurance Level	The probability of a viable microorganism being present on an item after sterilization. Usually expressed as 10 ⁻ⁿ ; a SAL of 10 ⁻⁶ means <1/1,000,000 chance that a single viable microorganism is present on a sterilized item.
Tensides	A tenside is a surfactant that reduces the surface tension of water and assures a faster and better contact between the detergent and the soil.

1.2 Quick start

The table below gives you an overview of the relevant chapters to read depending on the operations you want to perform to obtain the required hygienic level.

Required hygienic level	4.1 Batch change cleaning	4.2 Chemical cleaning (CIP)	4.3 Chemical disinfection	4.4 Steaming	5.1 Chemical CIP	5.2 Chemical disinfection	5.3 Steam sterilization	5.4 Sampling
Cleaning	✓	✓			✓			✓
Disinfection	✓		✓			✓		✓
Sterilisation	✓			✓			✓	✓

2. CLEANING – DISINFECTION – STERILIZATION

This chapter gives introduction to the concepts of cleaning, disinfecting and sterilizing process equipment in general, but with focus on sampling valves.

2.1 Clean-In-Place (CIP)

Thorough cleaning of the valve is a prerequisite for proper disinfection or sterilization. Cleaning of the valve is the removal of any visible residual product; it be organic or inorganic. It may be done using either steam (continuous steam will eventually lead to sterility; SIP = Sterilize-In-Place) or a suitable liquid detergent.

Cleaning is the removal of adhering soil from the environment and from the previous sample (to the extent it has not been removed by the recommended post-sample cleaning). Cleaning is usually performed by flushing with water followed by a thorough washing with an appropriate detergent and finished off with a thorough rinsing with water.

Depending on the actual process media the proper detergent must be determined in cooperation with your usual supplier of detergents. The company Novadan ApS, Kolding, Denmark - www.novadan.dk, has supplied the generic table below for your convenience.

What to clean for	Generic cleaning agents	Comments
Fat	Alkali and Tensides	Heat will facilitate the cleaning process as the fat melts
Protein	Alkali, Acids, Tensides and Chlorine	Coagulation and burning when heated, which makes the product hard to remove.
Sugar, Salt	Water is usually sufficient as the product is water soluble	Sugar caramelizes when heated, turning into a hard sticky substance, which is difficult to remove
Minerals	Acids, Complexing agent	Often seen as lime scale
Biofilm	Alkali and Chlorine, Peracetic acid, possibly Enzymes	Biofilm is an accumulated mass of microorganisms that is tightly adhered to a surface and cannot be easily removed.
Starch	Alkali and Chlorine	

2.2 Disinfection

Although CIP removes all visible residues of the process media the valve surfaces will still be contaminated on a microscopic level. Depending on your actual process media it will be necessary to carry out a disinfection operation in order to a) reduce the microbial load to an acceptable level (also referred to as Sanitization) or b) destroy critical microorganisms, but not necessarily all microbial forms (e.g. bacterial spores).

The disinfection process may be carried out in one of two ways and to different levels of disinfection depending on a) the initial microbial load distribution, b) the required hygienic level and c) the type, exposure time and concentration of the chemicals used (if using a chemical disinfectant)

- By steaming (in a continued process after steam cleaning).
- By applying one or more suitable liquid chemical disinfectants.

There are several chemical disinfectants. It is important to choose the right one, the right concentration and contact time and the right method for your current application. Your usual supplier of chemical disinfectants can support you in choosing the right disinfectant for your process media and the specific group of microorganisms you are aiming at.

The company Novadan ApS, Kolding, Denmark has supplied the table below, as a preliminary indication of which type of disinfectant to use:

Disinfectant	Halogens (Chlorine)	Peroxides (Hydrogen peroxide & Peracetic acid)	Alcohol (70%)
Microbes to inactivate			
Gram-neg bacteria Salmonella Campylobacter E. Coli and others...			
Gram-pos bacteria Listeria Bacillus cereus Clostridium and others...			
Bacteria spores Bacillus cereus and others...			
Bacteriophage			
Yeast			
Fungi			
Virus			

Legend:

Efficient	Limited effect	Little/No effect
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NOTE! The final choice of detergent, disinfectant and method lies with the user, supported by the supplier of the CIP fluids and disinfectants, as it is very much dependent on individual concerns and circumstances.

2.3 Sterilization

Sterilization is a high-level disinfection designed to render the valve free of all forms of viable microorganisms (incl. bacterial spores) to a high level of certainty; the so-called Sterility Assurance Level or SAL. A SAL value of 10⁻⁶ means that the probability (or risk) of a single viable microorganism being present on the valve interior afterwards is only 1 in 1,000,000 which is a generally accepted level for calling an item sterile. Although the probability can be reduced to a very low number, it can never be reduced to zero.

Sterility may in practice only be obtained by steaming. Disinfectants exist that in high concentrations and for a prolonged exposure time will be able to inactivate all forms of microorganisms and render the valve interior sterile with a high probability; these disinfectants are called chemical sterilants. However, the application of chemical sterilants is most often problematic due to a) a required high concentration, which causes an operator hazard and b) the several hours of exposure time.

NOTE! Furthermore, sterilization with a chemical sterilant may not convey the same sterility assurance as sterilization with steam, because the germicidal and sporicidal kinetics are much less investigated and documented for chemical sterilants compared to steam.

3. VALVE DESIGN AND FUNCTIONING

The Keofitt sampling valve is conceived to extract representative samples from a production process at regular intervals during a batch without compromising the ongoing process. The valve is therefore designed such that effective cleaning, disinfection/sterilization and sampling can be carried out regularly without disturbing the production process.

3.1 Valve body configurations

4KAI BODIES:

Valve bodies may be welded to the process equipment or connected by means of one of the standard connector systems.

Welding configurations encompass the following options:

- Tank welding, Ø28 mm
- Pipe welding, DIN EN ISO 1127 25x1.25

Connector configurations encompass the following options:

- Clamp ½” Mini-Clamp or Mini Tri-Clamp (always use a gasket; not included in valve body delivery)
- Clamp 1”; NA-connect, DIN (always use a gasket; not included in valve body delivery)

The inlet and outlet ports are available in the following configuration:

- Hose Piece (Keofitt Quick Coupling)

All valve bodies machined in one piece of steel, thus avoiding all crevices and fissures from screwed or welded parts.

For further information please consult www.keofitt.dk

3.2 Valve head configurations

4KAI HEADS:

Valve heads come in the following configurations:

- Turn knob (type H)
- Pneumatic (type N)

All configurations may be delivered with M4™-membranes EPDM, Silicone or PTFE.

For further information please consult www.keofitt.dk

3.3 Rubber caps and steel plugs

The hose piece version of the valve bodies all come with a set of rubber caps (EPDM) connected to the body by a double chain.

The purpose of the caps is to protect the valve chamber from the environment between sampling. Furthermore, a cap on the top port forces product to only flow out through the lower port during sampling; in case of high flow/pressure.

Steel plugs (part no. 800061) may be used instead of rubber caps and will provide a stronger mechanical fixation to the hose piece and thus be operational under higher pressure and temperature. Furthermore, the steel plugs may be autoclaved.

For further information please consult www.keofitt.dk

3.4 Sampling coil

When sampling beer, the pressure from inside the tank (CO₂ pressure in 2-3 bar) to outside will drop rapidly, causing excessive foam formation, even when opening the valve very slowly and very little. This phenomenon may be alleviated connecting a sampling coil (either part no. 800058 or 800059)

between the sampling valve and the sample recipient. A sampling coil provides a slower pressure drop as the sample flows through the full length of the coil.

For further information please consult www.keofitt.dk

3.5 Membranes

All valve heads may be delivered with any of the 3 materials: Silicone, EPDM, and PTFE.

They all have different properties and different resistance to various chemical substances, as seen in the table below.

Resistance to -	EPDM	Silicone	PTFE
- weather and Ozone	✓✓✓	✓✓✓	✓✓✓
- hydrolysis (water and steam)	✓✓✓	✓✓	✓✓✓
- to acids and bases	✓✓	✓	✓✓✓
- mineral oil and gas	X	✓	✓✓✓

X=Not suitable ✓=Less suitable ✓=Suitable ✓✓=Very Good ✓✓✓=Excellent

Put in words the properties can also be described like this:

- The Silicone membrane has the advantage that it in general can withstand high temperatures, but it cannot tolerate moisture condensation resulting from steam sterilization.
- The EPDM membrane is better able to cope with the condensation in the steam and at the same time it can be used with most CIP fluids and disinfectants in normal concentrations.
- The PTFE membrane resists all CIP fluids and disinfectants except highly oxidizing acids in high concentrations.

Membranes in rubber materials like EPDM and Silicone are fully interchangeable. This means that you may change from for instance Silicone to EPDM, if required.

However, valve heads with PTFE membranes are designed differently from the others. As PTFE is a stiff material with no elastic properties, it cannot be stretched. Therefore, it is made with a bellow to allow for the valve movement.

If you want to upgrade from Silicone/EPDM to PTFE, it is necessary to contact your local Keofitt dealer or Keofitt directly.

NOTE! The membrane functions as a dynamic seal in the valve seat as well as a hygienic static sealing against the valve head.

3.6 Parts and Accessories

Keofitt provide a large number of spare parts and accessories to the entire range of sampling valves. These include spare parts like:

- Membranes
- O-rings and gaskets
- Chains and bushings
- Handles and Tommy Bars
- Set screws

and other accessories like:

- Barbed fittings and tube welding fittings for tubes and hoses
- Adaptors between Tri-clamp, Mini Tri-clamp and Hose Piece (Quick Coupling)
- Fitted PTFE tubing for Quick Coupling and Tri-clamp

- Any length of PTFE tube
- Clamps for Tri-clamp connections
- Hypodermic needles
- Click-on steamer
- Circulator
- Sampling Bags
- Sampling bottle systems

3.7 Pressure and vacuum

Pressure ratings:

All valves feature a spring to provide the closing force against the valve seat. The spring is dimensioned such that all valves must pass a pressure test up to 6 bar. At some tank pressure above 6 bar the spring will give way and the valve will leak.

A nominal max. constant pressure of 6 bar allow enough tolerance to cater for the most common pressure peaks in a process line.

Vacuum ratings:

On installations where vacuum may occur temporarily, rubber membranes (EPDM, Silicone) are at risk of being sucked hard into the valve seat, whereby the valve might not open properly. However, the additional (closing) force from the vacuum (corresponding to max. -1 bar(g) or 0 bar(abs)) is rather small (10%) compared the force exerted by the spring (corresponding to at least 6 bar(g)), so there is no risk of damaging the membrane as long as the vacuum is only present when the valve is closed.

Besides, attempting to open a sampling valve under vacuum makes no sense, since nothing will flow out, so the incident is rather improbable.

Rubber membranes will seal perfectly well against vacuum, when the valve is kept closed.



WARNING! When opening the valve while the process side is under vacuum there is a risk that the membrane may be sucked past the valve seat and into the valve opening, which could cause the membrane to be damaged.

On installations where vacuum will occur, PTFE membranes don't have the risk of being sucked into the valve seat, but as it is a harder and less flexible material a complete tightness against the ambient air may not be secured.

3.8 Valve cleaning / disinfection / sterilization

The table below describes the two fundamentally different ways of preparing the valve for sampling, 1) Chemical cleaning/disinfection and 2) Steaming:

	Method	Description	Pros & Cons
Chemical	Chemical cleaning	Liquid detergents are used to clean the valve. CIP = Clean-In-Place	This process is adopted where steam is not available or where the product cannot withstand the exposure to heat. Involves several stages with flushing, cleaning and rinsing between batches.
	Chemical disinfection	A disinfection process using an appropriate chemical liquid disinfectant usually follows the cleaning process. The valve interior is wetted, soaked or flushed with an appropriate disinfectant.	It adds 2 more stages to the CIP: application of disinfectant and final rinse. Involves handling of potentially hazardous chemicals.
Thermal	Sterilisation	Steam is supplied for 1 minute just before and immediately after sampling.	Steaming does flushing, cleaning, rinsing and sterilisation in one operation. Steaming may be less suitable with very heat sensitive products. Steaming entails the risk of burns.

Flushing with water followed by the supply of a chemical detergent through the upper of the valve's two hose pieces results in cleaning the valve (CIP). It is the perfect, hygienic design and surface finish of the inner part of the valve, which enables easy, efficient and reliable cleaning in a closed state of the valve. Supplying steam through the upper of the valve's two hose pieces results in cleaning and sterilization. It is the perfect, hygienic design and surface finish of the inner part of the valve, which enables sterilization in a closed state. Steaming is therefore a SIP process (Sterilize-In-Place). Following CIP or SIP, but prior to sampling, a sterile cap of rubber or plug of stainless steel is fitted to the top hose piece. When the valve is opened the process product will run out of the lower hose piece.



WARNING!

- During sterilization with steam the valve will become hot and care should thus be taken when operating the valve.
- The valve is designed for use in working conditions of up to 6 bar(g) pressure and temperatures of up to 121 °C. It is therefore important to be aware that the rubber cap (designed for max. 3 bar(g)) or the steel plug (designed for max. 12 bar(g)) may be forced out at high speed, if not seated properly.
- When steaming always use dry saturated steam without condensation at max. 1 bar(g). At higher pressure the membrane may be damaged/split.
- Always remember to use safety goggles when steaming, cleaning, taking samples and all other operations of the sampling valve.
- For valve heads allowed under ATEX



- II 2 G Ex h IIB T4 Gb
- II 2 D Ex h IIIC T135°C Db

both handle and top of valve heads N must be cleaned before use.



IMPORTANT!

- CIP fluids are hazardous.

4. EVERYDAY USE OF THE VALVE

This chapter introduces how the sampling valve works in different operating conditions, such as the cleaning of the entire production line before starting a new batch (chapter 4.1) and the cleaning of the valve between each sample during the batch production (chapters 4.2-4.4).

The illustration in this chapter shows a valve head with a turn knob (type H), but the instructions also apply to a valve heads with a pneumatic actuator (type N).

Please see chapter 3.1 for a description of the different valve configurations.

For specific operator instructions please refer to the chapter 5. “VALVE OPERATIONS”.

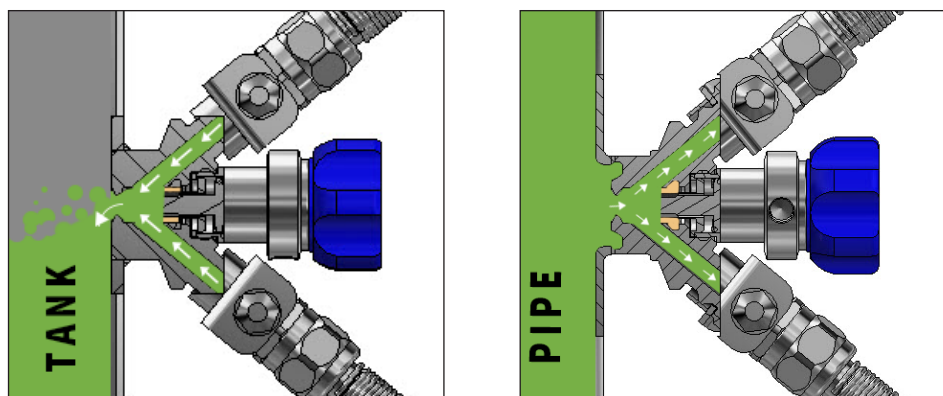
4.1 Batch change cleaning

Before every new production batch, the sampling valve is cleaned and disinfected/sterilized together with the tank or vessel or the entire production line.

Make sure the valve is in its OPEN position during the initial line CIP to allow cleaning of the valve seat and the membrane contact surface.

Also allow CIP fluid, disinfectant or steam to flow through the inlet and outlet hose pieces. If the valve is fitted to a tank, which is spray cleaned there will be insufficient flow of CIP liquid through the valve. Therefore, connect CIP hoses to the two ports for CIP fluids to flow through the valve into the tank (see illustration below).

If the valve is fitted to a pipe there will usually be enough pressure and flow during the CIP process for the CIP fluid to flow through the valve.



Remember to close the valve after the final rinse and prior to starting up the next production batch.

4.2 Chemical cleaning (CIP)

During production and prior to sampling, cleaning takes place with the valve closed and involves the following stages:

1. Pre-rinse

Flushing with water to mechanically remove product residues.

2. Clean

Applying a detergent to remove remaining visible product residues.

3. Final rinse

Rinse with clean water to remove all traces of detergents.

Usually this procedure is followed by disinfection (see below), but for some application CIP might be enough. It depends on your (microbiological) requirements, the detergents applied and the process media to clean for. Consult your supplier of CIP fluids.

In some cases where the process media is for instance water, CIP might not even be necessary, and you may go directly to disinfection.

4.3 Chemical disinfection

Disinfection takes place with the valve closed and involves the following stages of which the first 3 are identical to CIP:

1. Pre-rinse

Flushing with water to mechanically remove product residues.

2. Clean

Applying a detergent to remove remaining visible product residues.

3. Intermediate rinse

Rinse with clean water to remove all traces of detergents.

4. Disinfection

Apply an appropriate disinfectant targeting one or more or all microorganisms.

5. Final rinse

Rinse with cleaned water to remove all traces of the disinfectant.

4.4 Steam sterilization

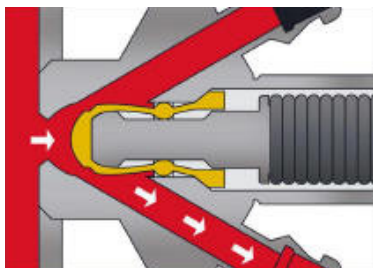
Steaming has the advantage that it does flushing, cleaning and sterilization in one operation. However, the heat from the steam will cause sugary substances to caramelize and substances containing protein to coagulate and burn; see chapter 2.1. In this case flushing with an appropriate fluid must precede post-sampling steaming.

If steaming is the preferred procedure, but no steam is installed near the sampling point, an option is to use a portable steam generator. Keofitt supplies an adapter for a Kärcher steam generator as well as other mobile steam supply systems. The steaming process with a Keofitt sampling valve has been validated to obtain sterility after 1 minute of steaming at 121°C (1 bar(g)). Documentation is available at the Keofitt Online Service Center on www.keofitt.dk

4.5 Sampling

Once the cleaning/disinfecting/sterilizing is accomplished taking a sample is done by opening the valve and closing it again once the required sample volume is obtained.

For detailed operator instructions see chapter 5.4.



5. VALVE OPERATIONS

This chapter provides clear instructions on how to operate the sampling valve in different situations. Before sampling the valve must be cleaned followed by disinfection or sterilization, depending on your requirements.

NOTE! For the initial cleaning before a new batch please refer to chapter 4.1 “Batch change cleaning” and integrate the valve cleaning in your standard CIP procedure.

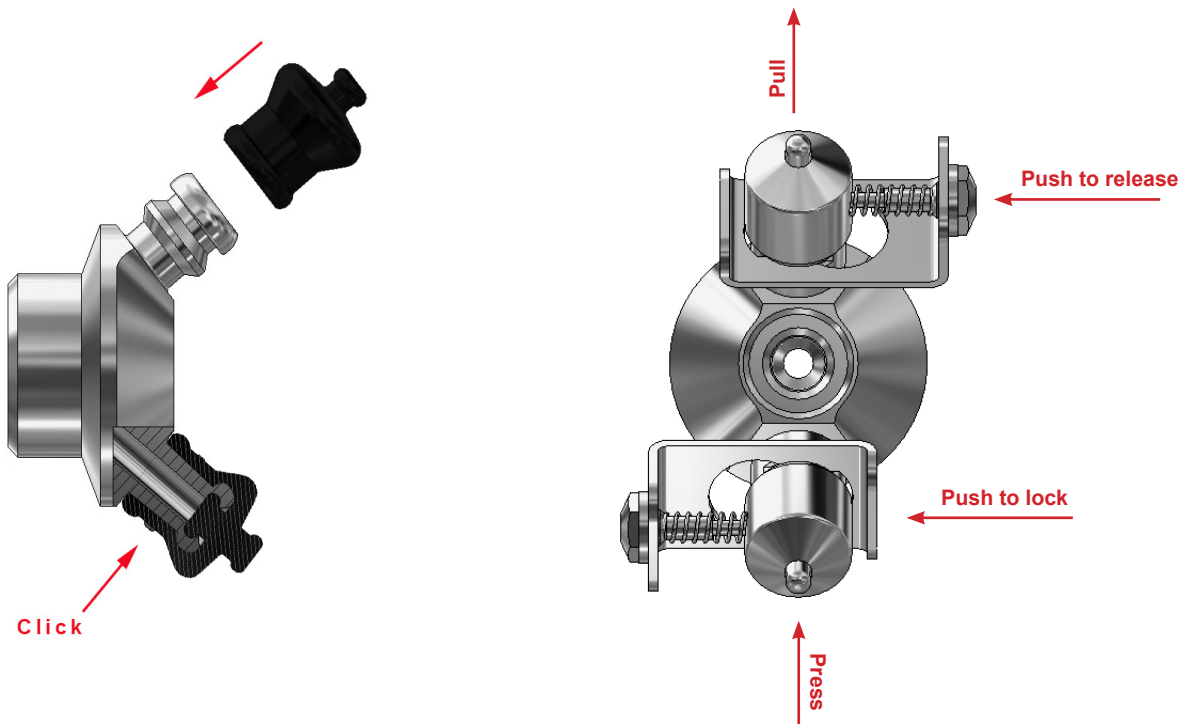
Valve bodies with hose piece connectors (Quick Couplings) are supplied with rubber caps (part no. 600062) to protect the inlet/outlet ports and the valve chamber from being contaminated by the environment between samples.

A rubber cap placed at the inlet port (top port) during sampling also protects the sample and prevents it from flowing through the top port in case of high pressure/flow.

To place a rubber cap simply press it axially against the hose piece until it “clicks in”. Remove it by pulling it outwards axially.

Plugs in stainless steel are available as accessories (part no. 800061). They are mechanically more robust, withstand higher pressure and may be autoclaved.

To fit the steel plug, compress the spring-loaded lock pin, place the plug over the hose piece and release the lock pin. Make sure the lock pin has moved fully back to its initial position for a secure locking.

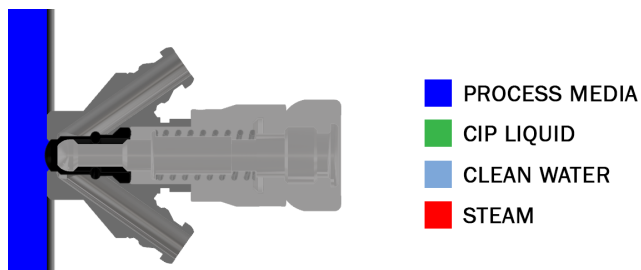


IMPORTANT!

- All illustrations show a sampling valve with Keofitt hose piece connection.
- All illustrations in the following sub-chapters show a valve head with a turn knob (type H), but the instructions also apply to a pneumatic actuator (type N). Please see chapter 3.2 for a description of the different valve head configurations.

5.1 Chemical CIP

The CIP takes place with the valve remaining in its closed position. Perform the following steps:



1. Remove the caps/plugs.	
2. Connect a water hose to the upper hose piece.	
3. Connect a hose to the lower hose piece and let the hose go to a drain.	
4. Flush with clean water.	
5. Remove the water hose and let the CIP liquid flow through the upper hose piece. If the CIP liquid must not go to drain, circulate it or collect it in a suitable container and dispose of correctly.	
6. Reconnect the water hose to the upper hose piece and rinse with clean water.	

If disinfection is not needed the valve is now ready for taking a sample. If disinfection is required proceed with the steps mentioned in the section “Chemical disinfection” below.

Flush with clean water after sampling. If the process media is sticky, viscous or aggressive or for any other appropriate reason, do repeat the full CIP cycle after sampling.



WARNING!

- Carefully follow the guidelines given for the chemicals involved.
- Always remember to use safety goggles when steaming, cleaning, taking samples and all other operations of the sampling valve.

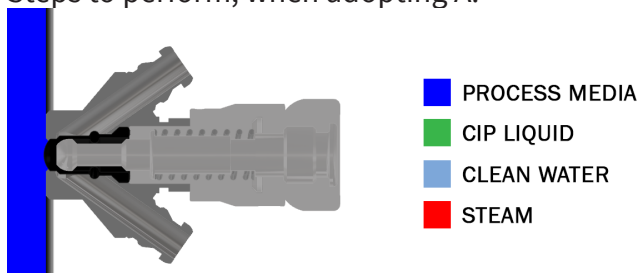
5.2 Chemical disinfection

Immediately following the CIP, perform the disinfection, if required. The disinfection takes place with the valve remaining in its closed position.

There are 2 recommended ways to carry out the disinfection:

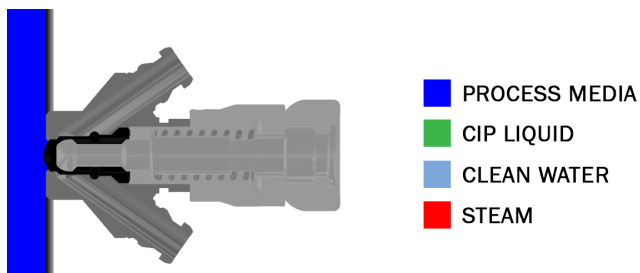
- A) by letting the disinfectant flow through the valve chamber.
- B) by filling the valve chamber with the disinfectant (advantage: smaller volume of disinfectant needed and quicker and more reliable disinfection).

Steps to perform, when adopting A:



1.	Connect a hose with an empty bottle to the lower hose piece. This bottle or similar recipient is to collect the disinfectant (step 3) and the rinsing water (step 6).	
2.	Fill a flexible bottle with the defined amount of disinfectant.	
3.	Connect the flexible bottle via a hose to the upper hose piece and press the disinfectant slowly through the valve to wet the interior of the valve.	
4.	Allow the disinfectant to act for the prescribed time.	
5.	Disconnect the hose from the upper hose piece and connect a flexible bottle with cleaned water to the upper hose piece.	
6.	Rinse through the upper hose piece by squeezing the bottle, thus pressing the water through the valve chamber.	
7.	Leave the squeezed bottle connected to the hose piece and clamp the hose to avoid contamination from air being sucked in through the valve.	

Steps to perform, when adopting B:



<p>1. Plug the lower hose piece with a rubber cap (or a steel plugs). In case of a valve with mini clamp connections the closing of the outlet may be obtained by using a tri clamp blind cap (always use a gasket) or by squeezing an attached piece of tubing or by any other appropriate means.</p>	
<p>2. Fill the valve chamber with the disinfectant through the upper hose piece.</p>	
<p>3. Leave to act for the prescribed time.</p>	
<p>4. Empty the valve chamber by unplugging the lower hose piece while holding a recipient under the valve allowing the disinfectant to flow out.</p>	
<p>5. Connect a flexible bottle with cleaned water to the upper hose piece and rinse through the upper hose piece.</p>	
<p>6. Leave the squeezed bottle connected to the upper hose piece and clamp the hose to avoid contamination from air being sucked in through the valve.</p>	

The valve is now ready to take a sample. The sampling must be performed immediately after disinfection to avoid any contamination of the sample.

Flush with water after sampling. If the process media is sticky, viscous or aggressive or for any other appropriate reason, do repeat the full CIP cycle after sampling.



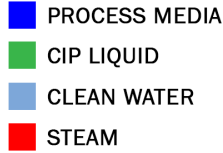
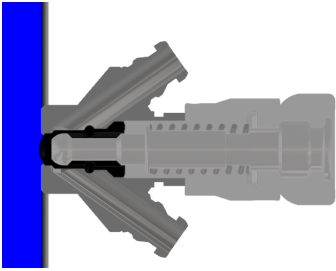
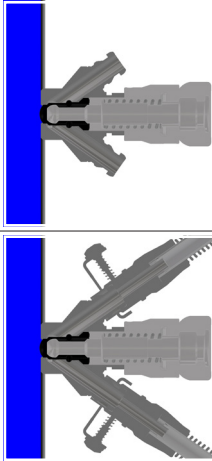
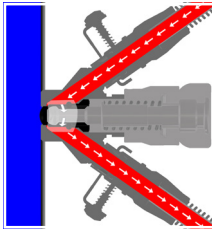
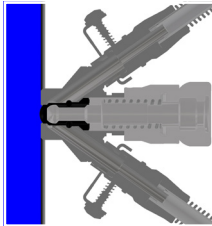
WARNING!

- Carefully follow the guidelines given for the chemicals involved.
- Always remember to use safety goggles when steaming, cleaning, taking samples and all other operations of the sampling valve.

5.3 Steam sterilization

Chemical CIP and chemical disinfection are usually not needed when using steam, as steam does it all. An exception from this is with sugary substances, which caramelize and with substances containing protein, which coagulate and burn; see chapter 2.1. In this case flushing with an appropriate fluid must precede post-sampling steaming.

Steam sterilization takes place with the valve remaining in its closed position. Perform the following steps:

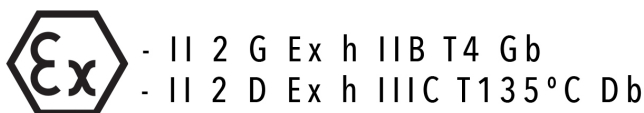
		
1.	Remove the caps/plugs from the hose pieces.	
2.	Connect the steam hose to the valve's upper hose piece.	
3.	Connect a hose to the lower hose piece and let it go to drain.	
4.	Open the steam supply and let it flow through the valve for sterilisation. Allow 1 minute at 121° C (1 bar(g)).	
5.	Close the steam supply, but leave the hose in place to prevent contamination to the surroundings during sampling. If removal of steam hose is required, fit a sterile rubber or stainless steel plug onto the upper hose piece.	



WARNING!

- During sterilization with steam the valve will become hot and care should thus be taken when operating the valve.
- The valve is designed for use in working conditions of up to 6 bar(g) pressure (depending on choice of valve head). It is therefore important to be aware that the rubber cap (designed for max. 3 bar(g)) or the steel plug (designed for 12 bar(g)) may be forced out at high speed, if not seated properly.

- For valve heads allowed under ATEX



both handle and top of valve heads N must be cleaned before use.

- Always remember to wear safety goggles when steaming, cleaning, taking samples or any other operations of the sampling valve.



IMPORTANT!

- Don't attach a steam trap to the hose from the valve steam outlet (lower hose piece) as it will impede the flow of steam and hence the flushing effect, and make the sterilization dependent on temperature only, demanding a much longer sterilization time.
- If the steam capacity is low and/or the outlet hose from the valve is short and/or with a large diameter, the temperature will drop, and condensation may occur in the valve chamber. In this case a counter pressure must be established using a pressure relief valve or a needle valve at the outlet.
- Leave the steam hose in place to prevent contamination from the surroundings during sampling. If removal of steam hose is required, fit a sterile rubber cap or stainless-steel plug onto the upper hose piece.

5.4 Sampling

Prepare a recipient for your sample.

For aseptic sampling use steam and a Keofitt Sampling Bag (available in different sizes; please see data-sheet on www.keofitt.dk). Leave the steam hose in place to prevent contamination from the surroundings during sampling.

For all other sampling use a Keofitt Sampling Bag, which provides a closed flow path for your sample protected against the surroundings. Alternatives are bottles with a screw cap, jars or any other available container. If removal of steam/CIP hose is required, fit a sterile rubber cap or stainless-steel plug onto the upper hose piece.

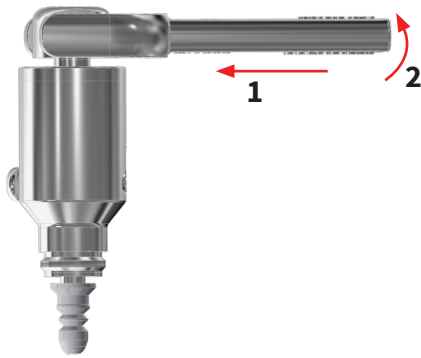
There are 2 means of opening the sampling valve depending on valve head type:

1. Turn knob
2. Pneumatic activation

They are all explained in the following:

Valve head	Illustration	Instructions
Turn knob Type H	<p>CLOSE OPEN</p>	<p>To fully open the sampling valve, turn the knob clockwise nearly a full turn; see arrow marking on the center base plate at the turn knob.</p> <p>To close the valve, turn the knob counterclockwise. When closed the turn knob sits loose on the spindle, since a spring provides the closing force on the valve.</p> <p>NOTE: The valve opens in the opposite direction compared to a normal water tap. This is a safety precaution to avoid unscrewing the valve head from the valve body instead of opening the valve.</p>

Pneumatic
Type N



This valve head is usually operated pneumatically.

It may however also be operated manually using a lever handle:

Enter the lever handle into the groove of the valve head. Move the tip of the handle slowly away from the valve head and into a position co-axial with the valve head; the valve is now fully open.

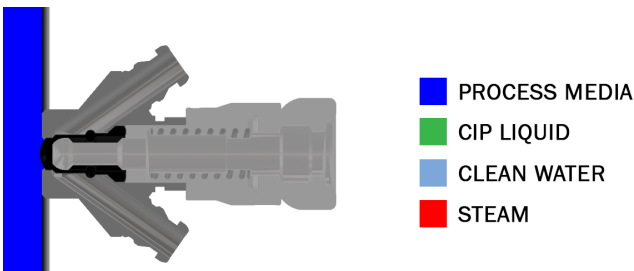
For closing, there are 2 options:

1. Continue the movement of the handle another 90 degrees; the valve is now closed, and the lever handle locked in position.

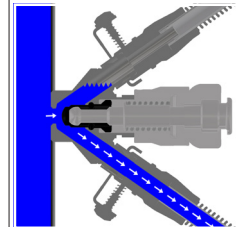
2. Reverse the initial movement of the handle. The valve is now closed, and you may remove the lever handle to avoid it falling out.

Removing the lever handle after sampling impedes unintentional opening of the valve.

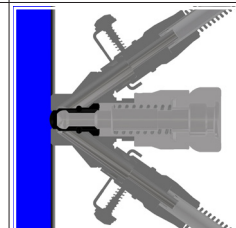
Take the sample immediately after cleaning/disinfection/sterilization performing the following steps:



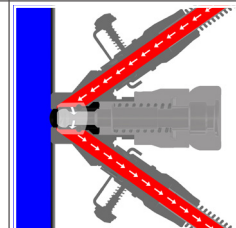
1. Open the valve slowly and take the sample.
NB! In order to flush the valve seat before sampling you may choose to let the first few seconds of flow go to drain.



2. Close the valve after the sample has been taken.



3. Clean the valve by flushing with steam, water or hot water.



If the process media is sticky, viscous or aggressive or for any other appropriate reason, do repeat a full CIP cycle after sampling in case steam is not available and flushing with water prove insufficient.



WARNING!

- When sampling at a high pressure and/or with a low viscosity process media it may flow rapidly into the sample recipient. Therefore, open the valve slowly. Special care must be taken with pneumatically operated valves, as they open abruptly. If problematic, consider adjustable actuators.
- Always remember to wear safety goggles when steaming, cleaning, taking samples or any other operations of the sampling valve.

6. TECHNICAL DATA

6.1 Material

Valve body:	AISI 316L (1.4404)
Valve head:	AISI 304 (1.4307)
Membrane:	Silicone (grey) EPDM (black) PTFE (white)

6.2 Certificate

3-A:	Conforming to 3-A Sanitary Standards for 55-02 (Boot Seal-Type Valves)
Valve body:	3.1*

*A 6-digit code is marked on the valve body. This code refers to a 3.1 certificate which accompanies every consignment of valve bodies. The 3.1 certificate is available at the Keofitt Online Service Center on www.keofitt.dk. Click Certificates and then 3.1.

Membrane:	Silicone acc. to FDA, 3A, EC1935, USP88 Class VI, BfR XV, EC2023 EPDM acc. to FDA, 3A, EC1935, USP88 Class VI, EC2023 PTFE acc. to FDA, EU10, EC1935, USP88 Class VI, EC2023
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6.3 Pressure (max.)

Working pressure:	6 bar(g) / 87 psi(g)
Rubber cap:	3 bar(g) / 44 psi(g)
Steel plug:	12 bar(g) / 218 psi(g)

6.4 Temperature

Steam:	Sterilization using dry, saturated steam at 121 °C / 250 °F and 1 bar(g). Dry, saturated steam at temperatures up to 134 °C / 272 °F and 2 bar(g) is possible but might reduce the service life of the membrane.
Process medium:	The acceptable operating temperature range for the process medium depends on the choice of membrane as follows: Silicone: 0 °C to 130 °C (32-265°F) EPDM: 0 °C to 130°C (32-265°F) PTFE: 0 °C to 150°C (32-300°F)

Sub-zero Centigrade operation is possible with all membranes. Please consult your local distributor and KEOFITT if occasion arises.

Ambient:	The range of acceptable ambient temperatures is limited by the polymer handle and the pneumatic cylinder from -40 °C to 80 °C.
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6.5 Surface finish

Internal:	Not electropolished Ra ≤ 0.8 µm / 31 µinch
External:	Not electropolished Ra ≤ 1.2 µm / 47 µinch

6.6 Viscosity

Viscosity range: 0-100 cP, with particles up to Ø1.5 mm in diameter.
Higher viscosity liquids may be sampled, only will the sampling take longer.

6.7 Flow

The graphs below illustrate (for water at 20°C/68°F) the following:

- Pressure drop across valve*) as a function of the flow for different positions of the turn knob.
- Pressure drop for flow between the inlet and outlet ports (CIP ports).

*) From tank/pipe side to lower port (outlet) with upper port blocked.

Based on the tank pressure and the requested sample flow the graphs may be used to get an indication of to which degree the valve must be opened.

Graph coming soon

The generally accepted sampling time is around 10 sec. for small samples and around 30 sec. for larger samples. As usual sample sizes are between 100 ml and 1000 ml the needed flow lies from 600 to 2000 ml/min.

As the pressure on the sample side usually is 0 bar(g) the pressure drop across the valve equals the process pressure (tank pressure or line pressure).

The volume flow through a valve is given by: $k_v = Q \sqrt{\frac{\rho}{1000 \times \Delta p}}$

Symbol	Unit	Description
k_v	m ³ /h	Flow in m ³ /h through a valve at a pressure drop of 1 bar as defined in VDE/VDI norm 2173.
Q	m ³ /h	Volume flow through the valve
ρ	kg/dm ³	Density of the fluid. For Water it is 1.
Δp	bar	Pressure drop across valve. As the gauge pressure at the valve outlet usually is 0 bar(g) the pressure drop is often equal to the gauge pressure at the input (the process side)

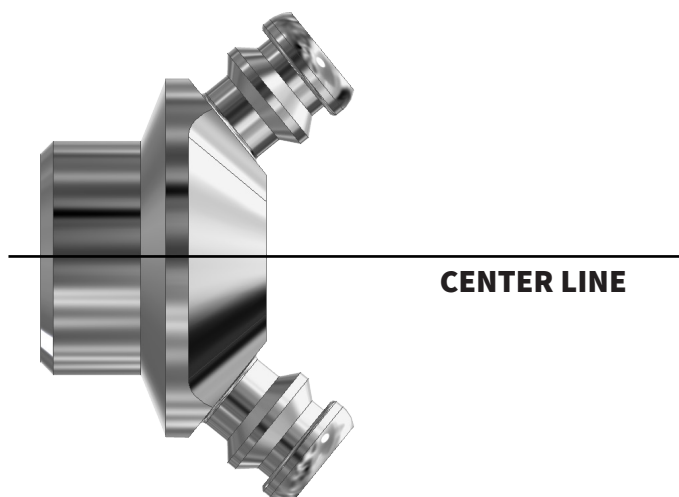
7. MOUNTING INSTRUCTIONS

7.1 Location

The valve should always be located with its center line in a horizontal position and with the hose piece in a vertical position pointing downwards as shown on the figure. Only with this orientation the valve will be self-draining.

IMPORTANT!

- The tank-side of the valve body must be positioned flush with the inside of the tank or the pipe in order to avoid any dead space.



7.2 Before welding

Remember to disassemble the valve body and head. The valve body and head must be separated during welding. Rubber caps, chain and membrane must be removed from the valve body, as otherwise heat from the welding process will damage them.

8. WELDING INSTRUCTIONS

Valves for welding are available in two types: T (tank) and P (pipe).

1. For type T (tank) it is necessary to drill a hole $\text{\O}28$ mm into the tank wall, and then fit the valve into this hole flush with the inside of the tank. Welding should be carried out as a penetration welding. Material thickness less than 4 mm: Weld from inside. Material thickness greater than 4 mm: Weld from both outside and inside.

Since type T has a solid end piece, the valve will not be damaged by penetration welding. However, the use of purge gas in the form of either Argon or Formier gas is recommended in order to give the best result.

2. For type P (pipe) penetration welding must be carried out from outside. The valve is machined with a recess-like shoulder on the outside of the end piece which gives approximately the same material thickness (1.5 mm material thickness) as in the pipe wall.

This machined shoulder can be modified according to the customer's wishes.



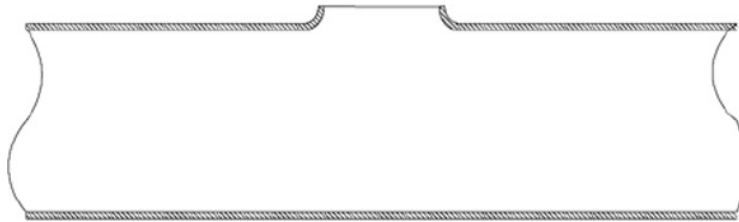
IMPORTANT!

When grinding/polishing the internal weld, the valve seat must not be touched.

8.1 Welding method

The welding result will be best if the following method is used:

A collar is made on the pipe section so that the valve has a flat contact face. This flaring must look like a T-piece, as shown in the example below.



- The pipe section and the valve's hose pieces are sealed with sponge rubber or similar.
- Purge gas such as Argon or Formier gas is fed through the valve body into the pipe section and the system is now filled with 6 times the estimated volume of the pipe section. All O_2 is thus expelled from the system and welding can commence.
- Welding must take place only with the purge gas continually flowing in the system.
- The gas remains in the system until the item is lukewarm, after which the set-up can be dismantled.

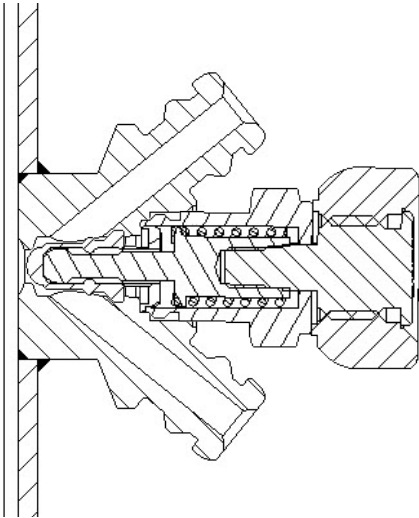
8.2 Guideline welding values

4KAI™ sampling valve welded onto a 2 mm 3" dairy pipe: 50-60 Amp.

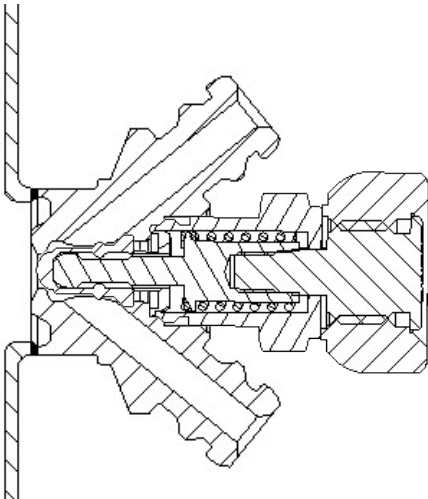
9. BLOCK DIAGRAMS

This chapter only illustrates different ways to attach a 4KAITM valve to the process line.

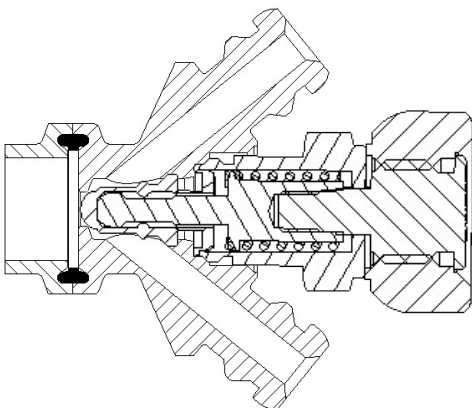
9.1 Keofitt valve type T (tank)



9.2 Keofitt valve type P (pipe)



9.3 Keofitt valve type C (clamp connection)



10. MAINTENANCE

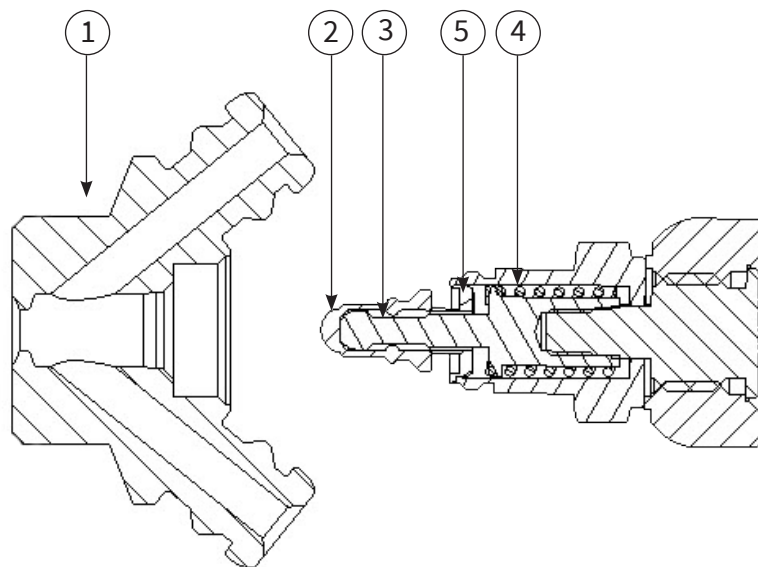
10.1 Maintenance

All membranes must be inspected between batches.

The EPDM and Silicone membranes should be replaced at every batch change or at least every 2-3 months. PTFE membranes should be replaced every 12 months. In the event of intensive cleaning it may be necessary to replace it more frequently. The appropriate replacement frequency should be determined by the user by starting with short intervals and continuously extend the time in use until one reaches the limit of the membrane's durability. Based on the desired safety margin the user then decides on the replacement interval to adapt.

See chapter 3.5 Membranes for more information.

The rubber cap must be replaced at least once every six months. In each individual case a standard operating procedure including maintained intervals should be endorsed based on experience. For disassembly of valve body and valve head, see instructions in chapter 10.3.

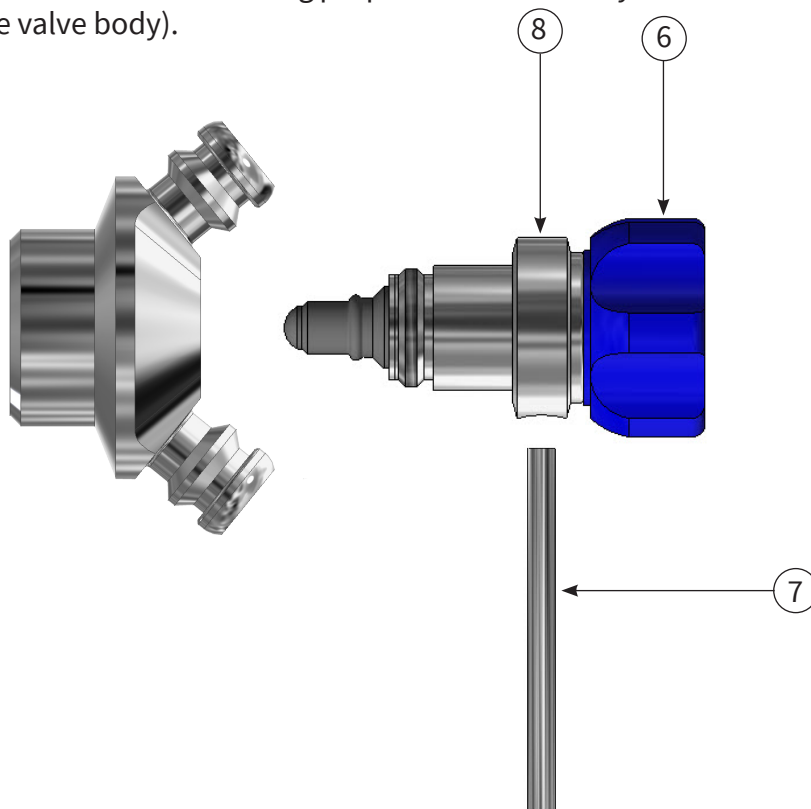


10.2 Spare parts list

1. Valve body
2. Membrane Silicone (grey), Membrane EPDM (black) and Membranes PTFE (white)
3. Lower stem (slightly different shape for PTFE membrane)
4. Spring
5. Steel bushing

10.3 Disassembly and assembly of valve body and head

For inspection of the membrane or for cleaning purposes it is necessary to disassemble the valve (separate the valve head from the valve body).



In order to disassemble and assemble the valve body and valve head please perform the following operations:

1. Set the valve head at the OPEN position. For types H this is done by turning pos. 6 clockwise.
2. Remove the valve head pos. 8. DON'T use a wrench. A Tommy bar pos. 7 should be used for disassembly and assembly. This is carried out by unscrewing pos. 7 until loose and then pulling the valve head off.
3. Refit the valve head (in the OPEN position) once the necessary parts have been replaced. Care should be taken not to damage the threads. Use suitable lubricant.
4. Tighten with Tommy bar.

NOTE!

The Tommy bar has been provided to avoid the risk of tightening the nut too much, if using a big wrench.

When using the Tommy bar, you may use your full forces by hand.



WARNING!

- When replacing the membrane, set the valve head in the OPEN position before it is unscrewed and pulled out of the valve body. Omitting to do so may result in twisting and cutting of the membrane.
- Don't use a big wrench to tighten the valve head to the valve body.
- Don't clean the valve head in an ultrasonic bath or by immersing it in a degreasing liquid, as it will impede the proper functioning of the screw action. When in doubt, contact your local Keofitt dealer.
- When reassembling the valve head and body grease the thread slightly with a lubricant compatible with your production.

10.4 Replacing a rubber membrane

The membrane must be replaced a regular interval determined by the operating conditions of the sampling valve.

As each application is different the customers must establish their own replacement scheme. Start with very short replacement intervals, keep the used membranes for reference and extend the intervals until the condition of the used membrane is such that it cannot safely be used anymore. Establish then a slightly shorter replacement interval to allow some safety margin.

Replacing the membrane is done as follows:

1. Unscrew the valve head as explained in chapter 10.3.
2. Turn the valve head to its CLOSED position.
3. Hold on to the base of the membrane and pull it off the stem.
4. Fit a new membrane by pressing it onto the stem.
5. Screw the valve head on to the valve body as explained in chapter 10.3

10.5 Replacing a PTFE membrane

The description and illustrations below show a type N with lever handle, but the instructions also apply to other valve head types.

To remove an old membrane from the valve head:

1. OPEN the valve (lever position as in illustration A).
2. Unscrew the valve head from the valve body as described in chapter 10.3.
3. CLOSE valve head (illustration A).
4. Push the membrane and bushing apart (illustration B) until the tool for membrane fits under it.
5. Insert tool for membrane, between the membrane and the bushing (illustration B).
6. OPEN valve head (illustration C).
7. Now the membrane is loosened from the valve head and can be replaced.

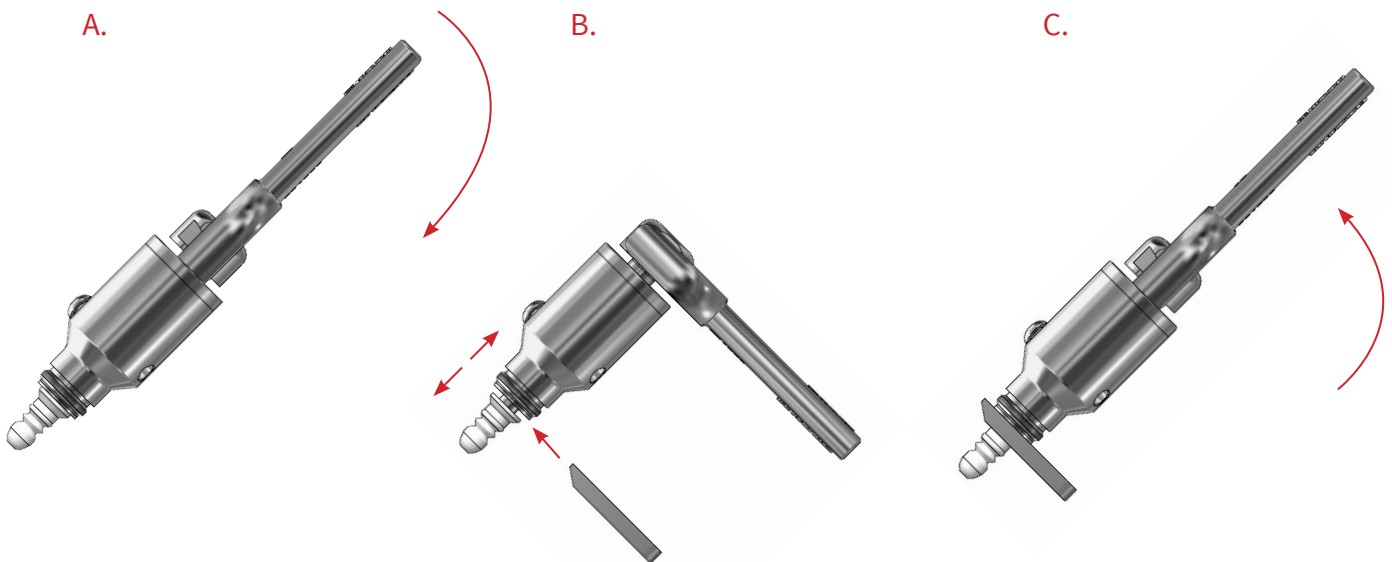
To attach a new membrane to the valve head:

8. Set the valve head to CLOSED position (lever position as in illustration B).
9. Place the new membrane on valve head.
10. Mount the membrane bushing with the new PTFE membrane by pressing the tip of the membrane with your hand until it clicks.
11. Set the valve head in OPEN position (lever position as in illustration A).
12. Insert the valve head into the valve body as described in chapter 10.3.
13. CLOSE valve head.



IMPORTANT!

- Once the membrane has been removed from the valve head the click system in the membrane might be damaged. Therefore, the membrane might be unsafe for further use and it is recommended not to use the membrane again.
- Do not use hammer or other tool that might scratch the surface of the membrane.



10.6 Regrease the head spindle

Over time the turn knob may become harder to turn, which may be remedied by regreasing the threaded part of the turn knob. Perform the following steps to take the valve head apart after having separated it from the valve body as explained in chapter 10.3:

- Set the valve head in CLOSED position.
- Pull off the membrane.
- Remove the bushing.
- Fix the lower stem in a vice using soft jaws.
- Unscrew the valve head top using the Tommy bar (hold it back when it gets loose, as the spring will push it out).
- Pull by the knob to separate it from the union nut.
- Unscrew the upper stem from the turn knob.
- Lubricate the upper stem's threaded part in contact with the turn knob.

Assembly is the same in reverse order, but please note:

- Discard the membrane and replace with a new one.
- Push the membrane and the bushing together so that the membrane is situated against the shoulder of the bushing.

11. FAILURE MODES

If the membrane is not replaced with a new one at regular intervals (depending on the application), it may eventually break, usually around the tip and more seldom along the side.

11.1 Broken membrane tip

This failure usually causes product to leak from the process side and more or less product will flow out through the lower port, also when the valve is in closed position. As such the valve port acts as a leakage hole (weep hole).

11.2 Broken membrane side

A longitudinal slit in the membrane is a rare incident and will only occur if the membrane has been kept in operation far beyond its expected service life.

Should it happen, product will during sampling enter the cavity between the internal surface of the membrane and the rod operating the membrane. As there is no significant pressure in the valve chamber during sampling product will only flow slowly through the slit and will eventually leak between the head union nut (Chapter 10.3 pos. 7) and the turn knob (Chapter 10.3 pos. 6). However, this is likely to take many rounds of samplings due to the short sampling time and the very low pressure on the external side of the membrane.

The valve is not foreseen with a leakage hole in the valve head as the risk of building-up of dirt inside the valve head from such a hole does not outweigh the manageable consequences of a broken membrane side.

The effect of such a failure will be an accumulation of a small quantity of product, which cannot be removed during the ordinary post-sampling cleaning or steaming. The consequence of this is a risk of contaminating samples taken after the failure occurred. However, the risk of contaminating the process side is considered to be negligible.

11.3 Cleaning the valve after a failure

In case of any of the above failures the valve needs to be completely taken apart and cleaned properly using a non-abrasive cleaning agent by performing the following sequence of operations (the choice of cleaning agent is for the user to decide as it depends on the product in the process line):

1. Unscrew the valve head from the valve body as explained in chapter 10.3
2. Disassemble the valve head as explained in chapter 10.6
3. Clean all individual components from the disassembled valve head
4. Clean the valve body
5. Assemble the valve head as explained in chapter 10.6 and fit a new membrane
6. Fit the valve head to the valve body as explained in chapter 10.3

12. CHANGE FROM SILICONE/EPDM TO PTFE MEMBRANE

All rubber membranes (Silicone/EPDM) are interchangeable.

To change from a rubber membrane to a PTFE membrane please contact your local Keofitt dealer or Keofitt directly.