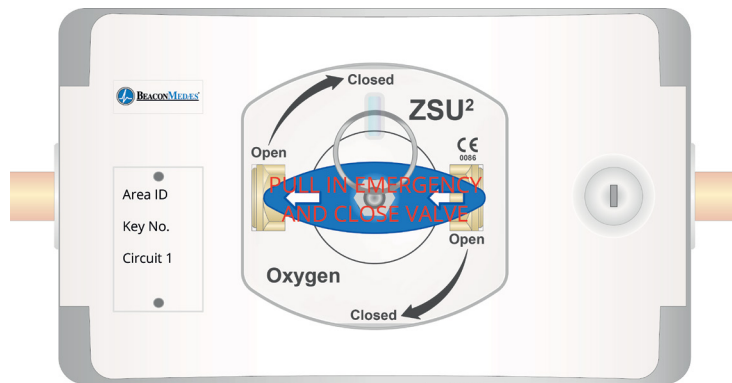


Installation Instructions



Area Valve Service Unit ZSU2 2nd Fix Assembly

Part number 4233500268

Revision 03

Installation Instructions

Area Valve Service Unit - ZSU2 2nd Fix Assembly

This unit is purchased from:

Date purchased:

Model number:

Serial number:

Option(s) included:

Any information, service or spare parts requests should include the serial number and be directed to:

BeaconMedæs
Greaves Close Markham Vale
Chesterfield S44 5FB UK

Telephone: +44 (0) 1246 474242
Email: gbn.info@beaconmedaes.com
Website Contacts: www.beaconmedaes.com

BeaconMedæs reserves the right to make changes and improvements to update products sold previously without notice or obligation.



BeaconMedæs Greaves Close Markham Vale
Chesterfield S44 5FB UK



Personnel must make themselves familiar with the contents of this manual and the function of the unit before installing, operating or maintaining.

Abbreviations			
Abbreviation	Full Description	Abbreviation	Full Description
HTM	Health Technical Memorandum	%	Percentage
BS	British Standard	Kg	Kilograms
BSP	British Standard Pipe	kPa	Kilo pascals
ISO	International Organisation for Standardization	PSI	Pounds per square inch
EN	European Standards	NRV	Non-return valve
ID	Identification	1st	First
Med	Medical	2nd	Second
°C	Degree Celsius	O2	Oxygen
∅	Diameter	N2O	Nitrous oxide
OD	Outside Diameter	N2O/O2	O2/N2O 50%/50% V/V
m	Meter	MA	Medical Air
mm	Millimetres	SA	Surgical Air
"	Inch	VAC	Medical Vacuum
Max	Maximum	CO2	Carbon Dioxide
Min	Minimum	N2	Medical Nitrogen

Area Valve Service Unit - ZSU2 2nd Fix Assembly

Issue Record

Document No	Revision No.	Details of Changes	Date
4233500268	03	IAR 10799: Audit findings update	04-Dec-2025

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Area Valve Service Unit - ZSU2 2nd Fix Assembly

1. Safety, Storage and Handling

1.1 Warning

1. Read through these entire instructions before using or showing others how to use this equipment. As with all medical equipment, attempting to use this device without a thorough understanding of its operation may result in patient or user injury.
2. Do not attempt to modify this device in any way not strictly described within this manual.
3. Obtain a work permit before commencing any work on a medical gas installation.
4. No attempt should be made to use this product with a gas service or at a pressure other than as identified.
5. Do not use this product if it appears damaged in any way.
6. Do not use this product if there is evidence of contamination internally or on any of gas wetted connections (e.g. debris, particles, oil, lubricants or grease).
7. This equipment should only be installed, commissioned, operated and maintained by technicians who are suitably trained with medical gas systems, such as Competent or Authorised Persons as defined in UK Department of Health Technical Memorandum No. 02-01 (HTM 02-01).
8. Keep all components dry and clean during installation. BeaconMedaes AVSU can be safely handled and stored under normal working and environmental conditions. Adverse environmental conditions, harsh abrasives or chemicals may damage to the unit.
9. Incompatible oil and greases can auto ignite in pressurised oxygen. Do not lubricate this product with oil or grease. Safe and compatible lubricants can be obtained from BeaconMedaes if necessary.
10. The device can weigh in excess of 40 kg. Use proper lifting equipment and techniques where necessary. Failure to do so can result in personal injury or equipment damage.
11. In an emergency, break the pull-out window marked **"PULL IN EMERGENCY AND CLOSE VALVE"** to access and shut off the valve while the door remains locked.

1.2 Cautions

1. Check that the correct gas type union sub-assembly is fitted to the correct gas pipeline. Gas identity is stamped on the union and printed on the NIST label
2. Use of sub-standard or inappropriate parts and materials may damage the product and invalidate the warranty. Only use genuine BeaconMedaes spare parts.
3. Pressurised gas from the medical gas pipeline system may cause personnel injury or property damage if the unit is incorrectly operated or maintained.

4. Leak detection fluids contain surface active agents (surfactants) that can damage plastic components under stress. Only use leak detection fluids that are compatible with the materials being tested.
5. Always wash leak detection fluids off with clean water immediately after use.
6. Improper selection or use of the first fix mounting screws and fixings may cause the device structure to fall. Consult the suppliers advice for correct selection and installation.

Notes

1. All information, specifications and illustrations within this manual are those in effect at the time of printing.
2. The manufacturer reserves the right to change or make improvements without notice and without incurring any obligation to make changes or add improvements to products previously provided.

1.3 Identification of symbols

The following symbols apply to this product and are used in these instructions and on the product in question. The meanings of these symbols are as specified below: -

Symbols	Title
	Manufacturer
	Date of manufacture
	Authorized representative in the European Union
	Batch code
	Catalogue Number
	Serial number
	Protect from heat and radioactive sources
	Keep dry
	Temperature limit

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	Humidity limitation
	Atmospheric pressure limitation
	Caution
	Unique Device Identifier
	Do not use if package is damaged and consult instructions for use
	Keep away from sunlight
	Lower limit of temperature
	Upper limit of temperature
	Biological risks
	Consult instructions for use or consult electronic instructions for use
	Medical device
	Do not dispose of in general waste

Environmental Transport and Storage Conditions

All products are separately packaged and stored in controlled conditions.

Minimum storage temperature: 0 °C

Maximum storage temperature: +40 °C

Environmental Operating Conditions

Adverse environmental conditions and harsh abrasives or chemicals may cause damage to the unit.

Minimum working temperature: -15 °C

Maximum working temperature: +60 °C

Cleaning

Care should be taken when cleaning terminal units to ensure that alcohol based cleaning fluids do not enter the terminal unit.

2. General Information

Device Description

The device shall operate in a manner that complies to both HTM 02-01 and ISO 7396-1 requirements.

This device is defined within ISO 7396-1 as providing isolation to sections of the pipeline distribution system for maintenance, repair, planned future extensions and to facilitate periodic testing.

Intended Use of the device

The device is intended to work in conjunction with other devices within the medical gas pipeline system (MGPS) to assist with maintaining continuity of the medical gas and vacuum supply throughout the hospital to local connection points for eventual introduction or removal of gas and fluids to or from the human body.

The device assists with the continuity of supply by allowing for sections of the MGPS to be isolated while the rest of the system maintains its supply. Gas specific connections are provided to allow for the connection of alternative gas supply in the event of source equipment failure.

Intended patient population

The device is intended to be used in conjunction with other medical gas and vacuum pipeline equipment in hospitals and have no direct contact with patients. MGPS supply to medical equipment which can be used across any populations & all age groups.

Intended user profile

AVSU are intended for use by appropriately qualified and trained personnel only who have undergone relevant 'HTM 02-01 Authorised Person' (AP) training regarding the safe use of medical gas supply systems.

The device should only be installed, commissioned, operated, and maintained by technicians who are suitably trained with medical gas systems, such as Competent or Authorised Persons as defined in UK Department of Health Technical Memorandum No. 02-01 (HTM 02-01 Part B: Operational Management). The device is intended for use by appropriately qualified technical personnel only. This condition is emphasised in the IFUs.

Reference: HTM 02-01 Medical gas pipeline systems – Part B: Operational Management

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Authorised Person (MGPS)

4.21 The Authorised Person (MGPS) is defined as that person designated by the Executive Manager to be responsible for the day-to-day management of the MGPS at a particular site or sites. This includes the issue of permits in accordance with the permit-to-work procedure. The principal responsibilities of the Authorised Person (MGPS) in respect of the permit-to-work procedure are set out in paragraph 6.91. The Authorised Person (MGPS) also has specific duties with regard to VIE installations (see Appendix E).

Competent Person (MGPS)

4.40 The Competent Person (MGPS) is the person who carries out the installation and/or maintenance work on the MGPS. A list of his/her responsibilities and duties is set out in paragraph 6.92. The Competent Person (MGPS) should have received appropriate training and should be on a list of Competent Persons (MGPS). In the case of directly employed labour, this list should be held by the Authorised Person (MGPS); in the case of contracted labour, it should be held by the contractor's Authorised Person (MGPS) or project manager.

Indications

AVSU are used as part of MGPS where an uninterrupted supply of medical gas and vacuum is required. The medical device works in conjunction with other medical devices for the immediate and reliable delivery of medical gas and vacuum to terminal units used for introduction or removal of gas and body liquids in healthcare facilities. In all cases there are medical devices installed between this device and the patient that controls the pressure and flow of gas and vacuum to safe levels to and from the patient. This device therefore only delivers medical gas and vacuum within specification to the MGPS, not directly to the patient.

Contraindications

If the device sustains any damage or malfunctioning, the assembly or faulty part should be replaced completely. This ensures all damaged components are replaced. Contraindications for use, warnings and precautions related to the safe use of the devices are detailed in the IFU supplied with the devices. These sections shall be read by the intended user before installing the device and starting to use it.

2.1 Dvice Limitation

The AVSU and AVSU modules are designed for fixed indoor installation in medical gas pipeline systems compliant with HTM 02-01 and ISO 7396-1, providing continuity of supply by allowing sections of the medical gas pipeline system to be isolated while maintaining supply to the remainder of the system. They include gas-specific connections for alternative gas supplies in the event of primary source failure. Installation, operation, and maintenance must be performed only by trained personnel in accordance with manufacturer instructions and applicable standards. Use with non-approved gases, unauthorized modifications, or outside regulated healthcare environments is prohibited.

2.2 Anticipated lifetime

The anticipated lifetime of shut-off valve is 15 years from the date of installation, assuming proper maintenance, service and environmental conditions are met. This estimate is based on product design, historical performance, and internal technical assessments.

2.3 Safe Disposal and Environmental Considerations

At the end of its service life, the Area valve service modules must be decommissioned and disposed of in accordance with local regulations for electronic and hazardous waste.

While the final responsibility for disposal lies with the healthcare facility or authorized service provider, the following guidance is provided by the manufacturer to support safe and environmentally responsible disposal:

- Ensure all gas supplies connected to the AVSU are safely shut off and isolated at the main supply source.
- Mechanical Parts (Brass or stainless-steel valves, copper pipe stubs, and fittings) can usually be recycled through appropriate waste channels.
- Packaging should be separated and recycled in accordance with local waste segregation policies (e.g., cardboard, plastic, protective foam).

If specific assistance is required for safe disposal, users may contact the manufacturer's technical support team.

3. Description and Operation

The Zone Service Unit is an advanced development of the basic valve box, designed to provide a reliable zone isolation system with additional facilities to enable connection of an emergency supply, purge gas and sampling equipment.

ZSU2s should be fitted to all medical gas and vacuum services in a prominent and accessible position. One valve per gas should be placed at the entry to a Department and one valve per gas at the entry to each suite; that is the Operating, Anaesthetic, Intensive Therapy and Recovery rooms, and entry to Wards.

The ZSU2 consists of a quarter-turn ball valve enclosed in a valve box with a lockable hinged cover that incorporates an emergency access panel.

Operation of the valve isolates the downstream zone and a physical barrier may be fitted if required to provide additional safety.

Unions fitted on both sides of the valve incorporate a gas specific NIST connector, complete with self-sealing check valve (except on vacuum) and blanking nut, for connection of emergency supplies, purge gas and sampling equipment via a length of hose and connectors to BSEN739.

4. Installation

The second fix has been designed to be easy to install, and is supplied as a complete unit, ready to install.

The second fix is roughly placed on the first fix, and the four M4 bolts supplied in the kit are pushed through the mounting holes in the bezel. The M4 screws may require turning with a screwdriver to fully tighten.

The lock and window and ring pull are already fitted and should require no further adjustment.

The area ID label space, in the lower left corner of the door can be fitted with a handwritten or printed paper label, or an Avery L7060 heavy duty label. Paper labels should be sized 64 by 39mm. A plastic cover is provided to protect the label.

Check that the blanking spade and 'O' ring seal are correctly stowed in the bottom of the box. Secure the ZSU2 and carry out the commissioning procedure in accordance with the installation contract.

5. Reporting Serious Incidents

In accordance with Regulation (EU) 2017/745 (MDR), a notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

A serious incident is defined as any incident that directly or indirectly led, might have led, or might lead to:

- The death of a patient, user, or other person
- The temporary or permanent serious deterioration of a patient's, users, or other person's state of health
- A serious public health threat.

These events may occur during device use, due to device failure, malfunction, labeling error, or IFU omission.

User Responsibilities

The user or healthcare professional should report any suspected serious incident without delay (Immediately, but no later than 2 calendar days after the manufacturer becomes aware of the threat.)

If a serious incident is suspected, users must:

- Immediately discontinue use of the device, if safe to do so
- Retain the device (if possible) for investigation
- Notify the manufacturer without delay using the contact information below
- Report the event to the local competent authority of their country as required

Contact Information for Reporting Serious Incidents

- Manufacturer: www.beaconmedaes.com
- Support Email: BMCS@beaconmedaes.com
- Phone: 01246 474242
- Authorized Representative (EU): Atlas Copco Airpower n.v. Boomsesteenweg 957 2610 Wilrijk-Belgium
- Competent Authority: https://health.ec.europa.eu/md_authorities

6. Online access

IFUs are available in digital format on the BeaconMedaes official website HTM/ISO products (beaconmedaes.com), where the latest versions can be accessed and downloaded. For previous versions, end users may contact us via the "Request Information" section on the website.



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