SAN-O-SUB ITALIA

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SAN-O-SUB	**USER INSTRUCTION** VIPRS PRESSURE REGULATOR WITH INTEGRATED VALVE	Rev. :10 01/01/2020 SERIE RO.165

RESIDUAL - CLICK ADJUSTMENT - FIXED CALIBRATION model RO.165.12294 - 12295
CE0123, ; 93/42 CEE, 2007/47/CE π 1370, 2010/35/UE

ATTENTION: READ THESE INSTRUCTIONS CAREFULLY BEFORE USING THE DEVICE; NON-COMPLIANCE CAN ORIGINATE EXPLOSIONS AND SERIOUS DAMAGES. DO NOT HAVE THE INSTRUMENT USED BY NON-SPECIALIZED OR APPROPRIATELY TRAINED PERSONNEL.
The instructions must always be available to all those involved in its purchase and use such as:
- - Owner of the medical device
- - Medical device installer
- - Responsible for filling the cylinder with the medical device mounted
- - Maintenance workers for medical devices or the cylinder with medical device assembly
- - Users of the medical device mounted on the cylinder
SAN-O-SUB guarantees the compliance of the valve with the above directives, it remains the responsibility of the indicated persons to verify compliance with the reference legislation in the country in which the device will be used.

Strictly follow the instructions provided in this manual, failure to comply with them will result in the forfeiture of the warranty of the device supplied and the consequent exclusion from any liability for any damage that may occur.
In the case of assembly of the device supplied on another product, it will be the responsibility of the person who carries it out to prepare and provide a new instruction manual for use and maintenance

SAN-O-SUB ITALIA SRL reserves the right to modify this use and maintenance manual without notice in compliance with directive 93/42

SAN-O-SUB ITALIA SRL cannot be held liable to anyone for any failure or damage resulting from use that does not comply with the following instructions and recommendations

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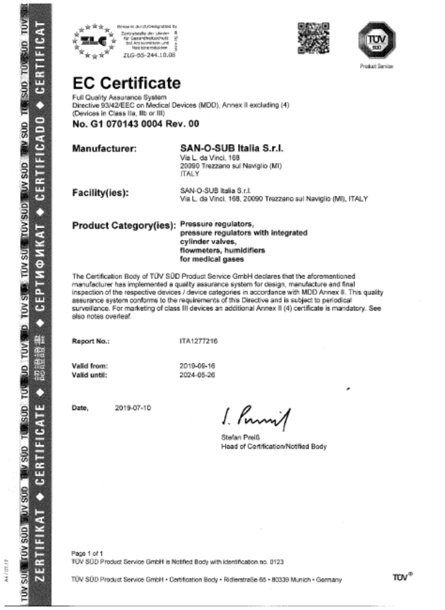
The approval process for the SAN-O-SUB devices involves a phase of analysis of the project by a Certification Body, the carrying out of type tests, as required by applicable rules, and finally, verification activities such as:

- Verification of manufacturing processes
- Evaluation of project documentation
- Check calculations and drawings
- Approval of quality systems
- Verifying compliance with the essential requirements of the RID, ADR Directives
- Approval of the Internal Inspection Service
- Qualification and approval of staff and permanent junction procedures
- Periodic auditing and on-site inspections
- Test collection
- Data plate verification
- Reliability assessment of taps and accessories with direct safety function
- Periodic/intermediate/extraordinary checks
- Material Control Certification
- Obtaining European-recognized Certificates, Reports and Technical Documentation

1 INDEX

25 CERTIFICATIONS


EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)

No. G1 070143 0004 Rev. 00

Manufacturer: SAN-O-SUB Italia S.r.l.

Product Category(ies): Pressure regulators, pressure regulators with integrated cylinder valves, flowmeters, humidifiers for medical gases


CERTIFICATO

SAN-O-SUB ITALIA S.r.l.

VIA L. DA VINCI 168

I - 20090 TREZZANO SUL NAVIGLIO (MI)

UNI CEI EN ISO 13485:2016


CERTIFICATO DI APPROVAZIONE DEL TIPO ADR/RID/ADN

ai sensi della Direttiva 2010/35/UE (TPED)

N° ADR/RID/ADN-T-SOS 006-12-ITA


N° ADR/RID/ADN-T-SOS 006-12-ITA

ALLEGATO AL CERTIFICATO DI APPROVAZIONE DEL TIPO

ANNEX TO THE TYPE APPROVAL CERTIFICATE

DISASSEMBLY AND SHIPMENT OF INTEGRATED VALVES FOR REPAIR
Before disassembling the valve, make sure that the cylinder is completely empty.
Thoroughly clean the reducing valve as described in chapter 19.

- Make sure you have the bags and boxes available for packing and shipping
- Remove the device only when it can be immediately stored in the packaging and thus ensure its cleaning
- Blow the threaded stem for fixing on the cylinder (1) with compressed air and remove the Teflon and / or dirt residues
- If the original packaging is no longer available, use alternatives which still guarantee the transport.

23 DISPOSAL

At the end of the life cycle provided by the manufacturer, the device must be disposed of differently from other waste and in compliance with the applicable national regulations in force. The person who starts the disposal of the reducing valve must evaluate its correct separate collection and subsequent sending to disposal / recycling thus avoiding any possible damage to the environment and health and favoring the reuse of the materials with which it was made.

24 WARRENTY

SAN-O-SUB ITALIA guarantees each product and component for 1 years from the manufacturing date indicated on the lot. The guarantee is intended for SAN-O-SUB ITALIA domicile and is not due for careless or improper use.
It covers any manufacturing defects in materials or construction of the device. SAN-O-SUB declines all responsibility for damages related to production failure, loss of profit, damages and indirect losses.
Any returns must be agreed in advance with SAN-O-SUB.
Responsibility for the device irrevocably passes to the owner or user of the same, if the device is maintained, modified or repaired by personnel not employed by SAN-O-SUB or not authorized by the same.
SAN-O-SUB declines all responsibility in case of improper use due to non-compliance with this manual.

2 SYMBOLOGY

Standard EN ISO 15223-1 Medical Device – Symbology used to labelling the medical device


Consult instructions for use


Attention to consult documents


Date of manufacture


Upper temperature limit


Re-use not allowed


Do not lubricate


Manufacturer

Lot of manufacture


One-way valve

3 INTRODUCTION

This use and maintenance manual contains and provides the essential information for the use of the Integrated Oxygen Reducing Valve device produced in SAN-O-SUB ITALIA S.R.L. The devices are produced and CE / marc marked in accordance with European Directives 93/42 EEC and 2007/47 / EC (concerning medical devices), Directive 2010/35 / EU (relating to transportable pressure equipment).As for the use of the cylinders on which the device is mounted and the various accessories connected to the device, please refer to the instructions for use and warnings for the individual products.

4 DEVICE DESCRIPTION

Integrated pressure reducer unit is made of CW 617N UNI EN 12165 brass. It is machined, externally chromed and carefully assembled and calibrated. In all its configurations the safety valve is assembled which is pre-calibrated during assembly and must not be tampered with. The field of use is represented by the distribution of medical gases. The device is suitable for mounting on medical gas cylinders in accordance with existing ADR regulations.
The connection for recharging, in the Italian model, is of the UNI 11144/2 type. In case you want to make a vacuum inside the cylinder, the charging connection must be equipped with the special connection with a pin that keeps the check valve open. The valve-metering unit is delivered clean in accordance with EN ISO 15001 and must be maintained as such with all the devices in which it comes into contact both during installation and during use.
Most malfunctions are caused by contamination of the product. It is the responsibility of the gas distributor company to make the end user aware of all the contents of these instructions.

5 GENERAL SAFETY REQUIREMNTS

- Anyone who uses this device must have complete knowledge of the instructions given in the this manual and other instructions and manuals applicable to the product.
- All parties involved in the use of the device must adhere to and comply with the laws and specific national or local regulations in force.
- Any other non-use is not permitted without written authorization from SAN-O-SUB covered in these instructions.
- Failure to observe the warning instructions provided in this manual can cause damage to people and things.
- The valves must be handled with caution and must not be subjected to shocks or falls, if the valve is damaged should not be used.
- Keep the device out of the reach of children.
- Do not immerse in any liquid and do not expose to high temperature.
- Do not use the flow from the device to supply other devices.
- The customer is responsible for all damages to people and things, direct and indirect, that may occur derive from improper use or inadequate maintenance.
- Correctly use the flow selector inside the trigger positions corresponding to desired flow.
- Before commissioning the device at the patient, in case of connection to others medical devices or accessories, check their compatibility with the technical characteristics and operating characteristics in the manual in the "technical characteristics" section. In particular, the maximum allowable pressure to the accessory / device coupled to the valve reducer must be twice the pre-calibrated outlet pressure.
- The non-compatibility of the accessory / device coupled to the reducing valve can cause excessive or insufficient gas supply.

6 PRECAUTIONS IN THE USE OF OXYGEN

Oxygen can be extremely dangerous for its combustion gas characteristic, not burns directly, but significantly speeds up combustion. For this reason it is important that if a spark, flame, external heat source or an increase of pressure of oxygen in contact with other materials, the device must be clean and manipulated with attention to this aspect.

- Before using the integrated valve for the first time, check the general state of cleanliness, in particular that of fillets and fittings.
- Most of the drawbacks derive from the intrusion of dust particles or other materials.
- Do not grease or lubricate the valve
- Do not expose the reducing valve to contact with electrical devices or possible sparks.
- Do not smoke near the reduction valve mounted on a filled oxygen cylinder.

USER		
DEFECT	**CAUSE**	**REMEDY**
Insufficient or nonexistent oxygen flow supply.	open on/off main vave (3) probably were not completly open	Open on/off main valve (3) and check the pressure on the pressure gauge (12)
	The integrated valve does not work	Return the cylinder to the gas supply company
	Presence of particles in the cylinder / valve assembly	Return the cylinder to the gas supply company. DO NOT USE THE CYLINDER
	Inhalation device stopped or defective	Disconnect the inhalation equipment, if flow is restored, clean or replace the inhalation equipment.
Opening of the valve (3) is not possible.	The on/off main valve (3) is defective.	Return the cylinder to the gas supply company
	The on/off main valve was tightened too much during the last closing	Return the cylinder to the gas supply company. DO NOT ATTEMPT TO FORCE THE INTERCEPTION VALVE OPENING

22 REPAIR OF THE INTEGRATED VALVE DEVICE

Integrated valve devices that must be sent to SAN-0-SUB for repairs must be cleaned, packaged, and labeled with the identification of the defect found, such as:

- Broken or defective pressure gauge
- Shut-off valve not working
- Malfunction or loss from the filler connection
- Filter / dip in the threaded stem broken, defective or missing
- Loss of gas from the rubber holder
- Hospital attack broken or not working
- Broken rubber holder
- Leakage from the safety valve
- Loss from the regulator fixed setting

Other defects not included in the list will be reported on the label that accompanies the device in order to make the repair intervention more detailed and quick.

The reducing valves sent for checks and repairs must be sent to SAN-O-SUB ITALIA SRL - Via Pier della Francesca, 17 - 20090 Trezzano sul Naviglio (MI) and must be accompanied by shipping documents and reference persons for the contacts.

21 DEFECTS – CAUSES - REMEDIAL

SUPPLIER COMPANY		
Defect	**Cause**	**Remedy**
The indicator of the gauge (12) indicates "0".	The cylinder is empty	Replace the cylinder
No fow from nipple	➢ Flow selection knob (11) at position "0"	➢ Set the flow selection knob (11) correctly
	➢ Main on/off valve (3) not opened correctly	➢ Open main on/off valve (3)
Gas leak from: valve connection(1)/tank	Incorrect assembly of the integrated valve on the cylinder	Take the cylinder in ventilate place and call the service of your gas supplier.
Gas leak from: refilling port (5)	Incorrect assembly or OR/SEAL damaging on refilling connection (5) .	Call your vendor's support service.
Gas leak from: gauge (12)	Gauge (12) damaged or incorrect mounting	Close the integrated valve (3), bring the cylinder to ventilate place and call the assistance service of your gas provider.
Gas leak from: interception valve (3)	on/off main valve (3) damaged or incorrect mounting	
no return device (13)	Damaged no return device (13) or incorrect assembly	
low-pressure safety valve (8)		Close the on/off main valve (3), bring the cylinder to ventilate place and call the assistance service of your gas provider.
	Fixed calibrated overpressure valve(7)	
Increased exit or intervention pressure	Fixed calibrated over pressure valve damage (7)	
Difficulty rotating the on/off main valve (3)	Damage to the reducting valve	Call your vendor's support service.

- The company that takes care of filling the cylinder with our reducing valve installed he must ensure that the container is kept clean and that there are no containers on its surface traces of dust particles, plastic, metal, grease or lubricants (EN ISO 15001).
- When connecting the integrated valve to another device or accessory, make sure that the latter is compatible with a supply pressure at least double that of pre-calibration of the reducing valve.
- When checking for leaks or gas leaks, use only products compatible with the use oxygen. It is not allowed to use ammonia-based leak detection products as they do not compatible with the brass that constitutes the integrated valve.
- When used, the shut-off valve of the reducing valve must be very open slowly opening quickly could result in high output speed and temperature such as to cause a fire or explosion hazard.
- Position yourself laterally at the opening of the valve.

7 Precautions for the final supplier of the cylinder with valve

This device has been designed for use on high pressure gas cylinders. The end supplier (reducer valve and cylinder) is responsible for making the instructions and warnings suitable and sufficient to ensure compliant and safe use available to the end user. All instructions and warnings in the use and maintenance manual must be made available to the end user.

- Use only devices in perfect condition, compatible with the type of gas used and at specified operating pressures and at the required flow rates.
- Do not modify or alter the marking of the reducing valve.
- Respect the tightening torque indicated during the assembly phase on the cylinder.
- The pressure gauge mounted on the reducing valve cannot be used as a reference for determine the filling of the cylinder.
- This device is supplied with a CE marking and therefore complies with these technical indications, the customer must ascertain its traceability after assembly, the customer is required to inform SAN-O-SUB of all possible anomalies and return the defective valves to analysis checks.
- The reducing valve that integrates the check device must be filled using only specifically designed and manufactured SAN-O-SUB specific filling adapters.

8 Precautions for the end user

- This use and maintenance manual must be available to every person who needs to operate on the integrated valve installed on the cylinder.
- Absolutely avoid working on the integrated valve or trying to remove it from the cylinder.
- Do not attempt in any way to fill the cylinder.
- This device must be used in compliance with the regulations under which it was carried out and to the instructions given by the competent medical staff

9 Technical characteristics of the reducing valve

Materials – Connections - Dimension

Materiali componenti valvola	
Body	In Chromed brass (ottone CW 617N UNI EN 12165)
Shut-off valve	Polyamide
Flow regulator	Polyamide
Pressure Gauge	Stainless steel
Handwheel	Poliammide 6.6 (Nylon 6.6) con 30% fibra di vetro
Cappellotto di protezione	(ABS)
Internal component	brass
Valve shutter and pressure regulator	Polyamide 6.6 (Nylon 6.6)
Filling valve plug	Polymer Peek
O-ring	EPDM (monomero etilene-propilene diene)
Connections	Cylinder Connection: 17E EN ISO 11361-1
	Cylinder Connection: 25 E EN ISO 11361-1
Filling Connection	W 21.7x1/14 UNI 11144/2
Outlet Connection	Rubber holder attachment Ø 6 mm
Pressure Gauge	Scale 0 ÷ 315 bar, class 2.5, Ø 40 rear, connectionG1/8"
Inlet protection filter	Syntered type
Dimensions	Total depth 100 mm
	Total height 125 mm
	Total width 80 mm
Weight	1 kg.
Compliance with	EN ISO 10524-3; 93/42 CEE, 2007/47/CE; 2010/35/UE
Markings	Name or chemical symbol of the gas in use
	Year – month of manufacture and batch numer
	Valve – Cylinder connection
	Manufacturer's initial
	Maximunm inlet pressure
	Symbol CE e π numer of Notified Bodies
Protective Cap	Protection of the valve is necessary: the cylinder must be. Always supplied with protection in accordance with ISO 11117

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Life cycle
If properly maintained and periodically checked and used in accordance with the instructions for use, the manufacturer has established a valve life of 10 years from the date of manufacture.
Traceability of the integrated valve
The integrated valve device can be traced through the manufacturing lot marked on the body and present on the packaging.

18 REPAIRS THAT CAN BE CARRIED OUT BY THE USER

19 CLEANING

The cleaning of the device, its periodic maintenance and the protection of the connections and fittings with appropriate covers are the responsibility of the owner of the reducing valve.
For a general cleaning (always and only external) of the device use a cloth wet with soap and water, rinse carefully with clean water.
If using cleaning solutions, check that they are not abrasive and compatible with the brass that makes up the valve body, the plastic components, the labels and the gas used.

Never use solutions containing ammonia or flammable liquids.
Do not immerse the reducing valve in water or other liquids
Do not expose the device to high temperatures
Prevent the entry of the cleaning solution into the fittings and openings of the device

20 STORAGE

- The integrated valves or the valve / cylinder assembly must be stored in clean and dry environments, preferably in the packaging in which they are delivered.
- The integrated valves or the valve / cylinder assembly must be stored away from open flames or heat sources and must be protected from prolonged exposure to direct sunlight.
- The integrated valves or the valve / cylinder assembly must not be stored in very cold places. The limit temperatures are shown in the chapter TECHNICAL FEATURES OF THE INTEGRATED VALVE

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⚠ In the event that the flow selection knob (11) is inadvertently positioned in a position between two values, the flow delivery may not correspond to any of the values between which it is positioned

DELIVERY OF GAS THROUGH HOSPITAL CONNECTION (10) (optional)
Check the compatibility of the fittings and auxiliary devices to be connected with the characteristics of the reducing valve. Connect the hospital connection (10) checking its correct positioning. Slowly open by turning the shut-off valve (3) counterclockwise. The flow selection knob (11) must be positioned on "0".
Coupling type AFNOR (NF S90-116):
- proceed with the connection by inserting the coupling in the relative lost until the end of the stroke,
- turn the coupling clockwise to hook it to the socket
Coupling type UNI (UNI 9507):
- proceed with the connection by inserting the coupling in the relative lost until the end of the stroke, if you must hear a click.
Attention: when connecting do not pull the ring nut
- Make sure that the coupling is hooked to the socket.
CLOSING OF GAS DELIVERY
Close the shut-off valve (3) by turning it clockwise. Do not apply an excessive tightening torque, 3 Nm is the limit value.
Coupling type AFNOR (NF S90-116):
- disconnect the coupling by pushing it towards the reducing valve until the end of the stroke
- rotate the clutch anticlockwise
- remove the graft
Coupling type UNI (UNI 9507):
- disconnect the clutch by holding it with one hand while with the other hand push the ring nut of the socket towards the valve until the clutch is released.
- remove the graft

⚠ ATTENTION: during the use of the hospital connection (10) the flow value is not adjustable

⚠ Pay attention to the connection phase to the hospital attack (10) since an incorrect connection can cause leaks and / or cause the expulsion of the same, causing an injury.

⚠ Make sure that the flow rate is compatible with the equipment or devices connected to the integrated valve.

⚠ The too rapid opening of the shut-off valve (3) can increase the risk of fire or explosion due to the high pressure and speed of the outgoing gas. An incomplete opening can limit the supply of gas.

⚠ The pressure gauge (12) indicates the pressure value of the gas contained in the cylinder with the valve open

17 PERIODIC CHECKS

At each filling of the cylinder it is necessary to check:
- The integrity of the cylinder - The integrity of the rubber holder (9)
- The functioning of the pressure gauge (12) and its integrity - The integrity of the protective cap
- The regularity of rotation of the flow selection knob
- The presence of the sealing o-ring on the filler connector cap (6)
- The state of cleanliness, any oxidation or residues of dirt, dust or other substances on the device

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Application limits		
Parameters	**Storage**	**Exercise**
Temperature:	from -20 to + 50 °C(1)	from -20 to + 50 °C
Relative humidity:	from 10 to 100% HR(2)	from 10 to 100% HR
Ambient Pressure:	from 600 to 1.200 mbar	from 600 to 1.200 mbar

(1) When storing at temperatures below -20 ° C, wait until the valve has reached at least this temperature.
(2) Temporary storage at 100% relative humidity (HR) values deriving from environmental or climatic conditions details requires a subsequent check of the integrity of the packaging and the device.

Expected operation	
Gas:	Medical Oxygen / Oxygen / Air based mixtures
Inlet Pressure (P1)	maximum 230 bar (also indicated on the valve body)
Pre-set outlet pressure (P2)	3,5 bar / 5 bar
Available flow rate	Model 0-6 lit/min(3) Model 0-15 lit/min(3)
Available doser mod. 0-6 lit/min	0.5 - 1 - 1.5 - 2 - 2.5 - 3 - 4 - 5 - 6 lit/min
Available doser mod. 0-15 lit/min	1 – 1.5 - 2 - 3 - 4 - 6 - 9 - 12 - 15 lit/min
Safaty valve	Trip over 5,5 bar (calibrated during assembly)
Residual device	from 3 to 5 bar (according to ISO 10524-3)

(3) Delivery accuracy as required by ISO 10524-3: 2005 (E) in point 5.4.18.1. The actual flow rate must be within ± 20% of each set value with a flow rate greater than 1.5 lit / min or ± 30% of each value indicated for the flow rates of 1.5 lit / min or less, while the supply pressure decreases from the maximum cylinder filling pressure up to 10 bar (15°C and 101,3 KPa)

Accessory devices
Protective cover (Chalice, Universal). ISO 1117: 2008 drop test compliant
Stretcher hook
Filling adapters (not necessary if no check valve is not installed).
Low pressure connection UNI ns. model 12067, G1 / 4 "
Low pressure connection AFNOR ns. model 12064, G1 / 4 "

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10 HAZARDS

During use, always observe the cleaning and safety rules provided in these instructions for the proper use of the oxygen and medical gases used.

The valve must be kept away from heat sources (fire, cigarettes, open flames, etc.) and easily flammable materials. The flow of oxygen, or of oxygen mixtures, at the output MUST NEVER and FOR NO REASON be exposed to sources of heat, sparks or flames. Oxygen and its mixtures can be very dangerous. Although not flammable, oxygen promotes combustion. The material which is not flammable in air, can burn in the presence of pure oxygen at high pressure. An increase in the oxygen concentration in the environment from the normal level of 21% to 25% is sufficient for the ignition of a flame, in the presence of a spark, flame or heat source, of all the materials present

Do not lubricate any part of the reducing valve with oils and / or greases, nor touch it with fingers, hands or utensils soiled with grease and / or oil. Combustion hazard.

The cylinder must be protected from sudden blows. Integrated valve device must be protected for the entire period of its use from dust, water and other unfavorable environmental conditions, which could adversely affect its quality, reliability and safety

The device must be used only if in good condition. In the event that the user checks that the valve is defective or only suspects it, he must immediately discontinue its use and return it to the manufacturer.

Any home or hospital treatment with medical gas must be subject to medical prescription except in cases of urgency and emergency in which operators in the medical health sector intervene (e.g. ambulance operators).

To ensure patient safety, check the compatibility of the reducing valves with the medical devices and accessories connected to them

MEDICAL SUPERVISION - data recording for the traceability system.Pursuant to 93/42 EEC directives; 2007/47 / CE every accident or near accident with possible consequences on the health and safety of people must be communicated to local authorities in accordance with the national surveillance system. The surveillance system requires the manufacturer of the medical device to be informed immediately. In order to guarantee a possible recall SAN-O-SUB ITALIA SRL recommends that the owner and users keep the registration of the data necessary to guarantee traceability updated

Stand sideways and open the shut-off valve slowly, too rapid openings can cause the valve to self-ignite. Observe all the precautions provided for the use of oxygen contained in the product safety sheet.

Make sure that the shrink valve, cylinder and all used accessories are cleaned as indicated in these instructions.

When filling, be careful not to reach too high temperatures. Be careful not to exceed 50°C.

If the reducer valve device highlights anomalies or malfunctions, it should not be attempted to repair it, it must be sent to SAN-O-SUB or subject by the latter format and enabled for repair and maintenance. Test leaks with each fill.

16 USE

Remove all the protections adopted to ensure the cleaning of the device and used during transport and storage before putting the cylinder into use with the integrated valve. Make sure that the rubber holder (9) and / or the hospital connection (10) are clean and the surfaces with no oil or grease.

Pay attention to the connection of the tube on the rubber holder (9) since an incorrect connection can cause leakage or expulsion of the tube with consequent possible injuries.

It is forbidden to use any type of lubricant.

DELIVERY OF GAS THROUGH RUBBER HOLDER (9)

The gas can be delivered through the rubber holder (9) for connection to the mask tube or through the hospital connection (10).
The supply of gas using the rubber holder can only take place when compatibility with the fitting, tube, mask, etc. has been verified. the characteristics of the integrated valve. Only after checking, connect the mask tube or other device and check correct positioning.
Position yourself laterally and open slowly, by turning the shut-off valve (3) anticlockwise.
Select the required gas flow by setting it on the flow selection knob (11).
Be careful not to position the flow selector in the intermediate area between two values as the output would be

Do not force the rotation of the flow selection knob (11) beyond the "0" or beyond the maximum value

CLOSING OF GAS DELIVERY
To stop the gas supply from the device, turn the flow selection knob (11) clockwise to the "0" position.

Do not force the rotation of the flow selection knob (11) beyond the "0" or beyond the maximum value.

Close the shut-off valve (3) by turning it clockwise. Do not apply an excessive tightening torque, 2.5 Nm is the limit value.

14 FILLING

⚠ Scrupulously follow the prescriptions present in the medical gas filling centers in compliance with the procedures, legal provisions and standards issued by specific sector bodies.

➢ Unscrew the cap for the filling connector (6) taking care not to lose the sealing gasket housed in it. Check that it is intact, clean and in good condition, replace it otherwise to ensure correct sealing.
➢ To carry out the vacuum and filling operations if the non-return valve is present, it is necessary to have the specific adapter supplied by SAN-O-SUB which allows you to exclude the non-return device (13) once connected to the filling (5).
➢ Connect the adapter only if the filling fitting is clean and intact.
➢ During assembly, do not apply excessive tightening torque.
➢ The flow selection knob (11) must be positioned on "0".
➢ The shut-off valve (3) must be completely open by operating it anticlockwise.
➢ Once the filling operation is complete, the shut-off valve (3) must be closed by turning it clockwise applying a tightening torque not exceeding Nmt. 2,5
➢ At this point it is possible to remove the filling adapter and refit the cap (6) by applying a force of 40-50

In the event that, detecting the residual pressure from the pressure gauge (12), is greater than 20 bar, the cylinder must be emptied before applying the adapter by opening the shut-off valve (3) and selecting the maximum flow valves on the knob flow selection (11). This procedure will ensure the integrity of the connection for filling and the adapter.

⚠ The cylinders on which this device is installed must only be filled with medical gas.

⚠ When filling cylinders that have already been used, check that there is residual pressure inside by connecting the adapter to the filling connection and checking for gas leakage .If there is no residual pressure, the integrated valve must be disassembled and sent to SAN-O-SUB for checking.

15 CHECKS AFTER FILLING

⚠ Once the filling operation is complete, check for any gas leaks in the vicinity
At the valve sealing points.
Check the operation of the pressure gauge
For verification use specific oxygen leak detector. Do not use ammonia-based leak finders that could damage the valve body and other materials.
Check the accuracy and stability of the flow according to the standard 10524-3: 2013 Paragraph 5.4.18.1 when the device is put into operation and at least once a year.
In the filling cycles following commissioning, check the presence of gas at the outlet from any low pressure intake and in all positions of the flow meter, check the seal in the zero position.
At the end of the tests, apply the white seal on the hose connector

In the event of detection of leaks on the device, proceed as follows:
- Immediately remove the cylinder from the distribution circuit
- Take it to a suitable place and empty it
- Disassemble the reducing valve, replace it and have it sent to SAN-O-SUB for checks and checks. Avoid working on the reducing valve and attempting repairs.
- Place the cylinder with the valve replaced in the "CHECKS BEFORE FILLING" phase.

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11 Integrated Valve

Integrated valve device has been designed and manufactured for easy and safe use in order to facilitate the multiple needs of the patient and the gas supplier.
In particular, the reducing valve is easy to use, also thanks to the simplicity and ergonomics with which it was designed.
Respect the characteristics of administration that have been prescribed to the patient by the medical staff.
Facilitates the filling, control and maintenance activities that are carried out by the gas supplier.
All these qualities have been achieved by following and respecting the safety requirements imposed by the various regulations in force.
The SAN-O-SUB integrated valve device has been designed and manufactured for the only permitted use, which is that of its permanent mounting on the cylinder. The reducing valve constitutes a single system with the cylinder and therefore its maintenance is borne by the owner of the cylinder.

The valve is composed of the following elements:
1) Threaded stem for fixing on the cylinder.
2) Filter / Pescante
3) Shut-off valve
4) Residual pressure device
5) Connection for filling
6) Cap for the filling connector
7) Fixed setting pressure reducer
8) Low pressure safety valve
9) Rubber holder for connecting the use tube
10) Exit for hospital attack
11) Flow selection knob
12) Pressure gauge
13) Non-return device if present

The device, in emergencies and only by duly trained or medical personnel, can be used to power other equipment for therapeutic use.

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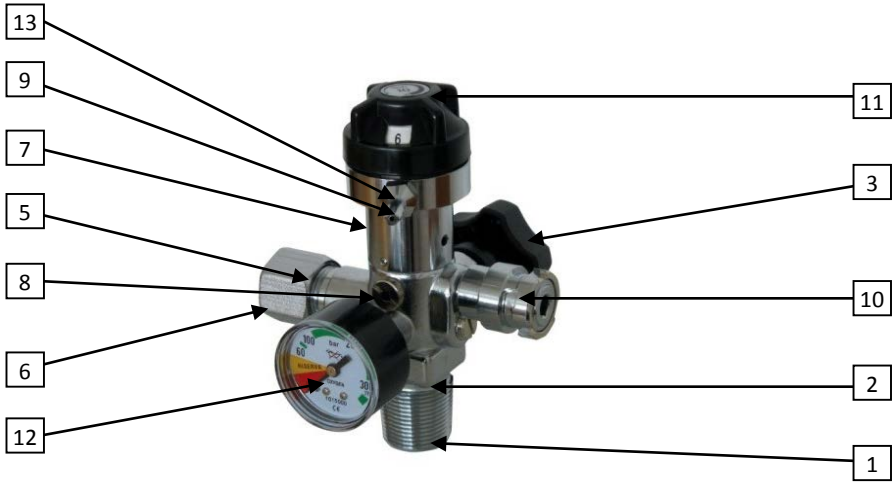

12 ASSEMBLY OF THE INTEGRATED VALVE DEVICE

- Respect the cleaning and safety rules provided in these instructions for the correct use of gases.
- Check the inside of the cylinder making sure that it is free of contaminants (e.g. water, insects, dust, dirt in general).
- Check the cleanliness of the keys and tools used for assembly.
- Check that the threads of the cylinder and the reducing valve are compatible and not damaged.
- Make sure that the reducing valve and the cylinder are made for the same type of gas, otherwise do not install the device on the cylinder.

The integrated valve must only be used with the gas marked on the body of the same by the manufacturer. It must never be used with any other type of gas

The valve must be mounted on the cylinder according to the values indicated in the table below.
Attention: too high tightening torques, excessive amount of Teflon, non-homogeneous distribution of Teflon and lubricating substances on the thread can lead to damage to the thread with the consequent impossibility of using the reducing valve

To screw the integrated valve onto the cylinder, position the key in the appropriate housings on its body above the threaded stem (1). Do not force on other components such as the pressure gauge (12) or the shut-off valve to avoid damaging them
Do not disassemble parts of the integrated valve for mounting on the cylinder.

Where required by applicable standards, always protect the integrated valve with a suitable protection cap.
The integrated valve mounted on cylinders with a capacity greater than 5 liters must be protected by a suitable cap according to EN ISO 11117.

Benchmark for valve tightening pairs according to Standard EN ISO 13341

Thread conical	Valve fillet	Weldless steel cylinders		Welded steel cylinders		Aluminium alloy cylinders			
						Unreinforced cylinder neck		Reinforced cylinder neck	
		MIN Torque Nm	MIAX Torque Nm	MIN Torque Nm	MAX Torque Nm	MIN Torque Nm	MAX Torque Nm	MIN Torque Nm	MAX Torque Nm
	17 E	120 (80*)	150 (100*)	90	150 (120*)	75	95	75	140
	25E	200 (130*)	300 (200*)	110	300 (200*)	95	110	95	180

13 CHECKS BEFORE FILLING

Check that the device is not damaged (body, flow selection knob (11), pressure gauge (12), shut-off valve (4), etc.). In the event that the device or the protective cap shows signs of external damage, do not use the cylinder and adequately signal to the owner that the device cannot be used. As for repairs and maintenance, carefully read the dedicated parts of this manual (see the chapter "repairs that can be carried out by the user"). Check that the integrated valve and the cylinder on which it is assembled are clean, if this is not the case, carry out cleaning according to the instructions given in the "cleaning" chapter.

Verify that the maximum usage period for the device has not been exceeded. On the same there is the marking showing its date of manufacture. When testing the cylinder (after 10 years), the replacement of the valve is prescribed.
Mark interpretation:
LOT. 18-02/200 N.001
YEAR-MONTH LOT / LOT NO.
SERIES LOT IN 2018 / FEBRUARY MONTH / LOT 200 / N.SERE 001

It is not allowed to reuse the device beyond the 10-year term inferable from the marking on the body of the same

Check the integrity and cleanliness of the connection for filling.

Before the filling phase, it is necessary to remove the filling connector cap (6), check the presence and condition of the seal inside the filling connector cap. If damaged, replace it.
Check the presence or absence of the non-return valve inside the refill connection. If this is present, use the original SANOSUB filling fitting to avoid damaging it
Do not use seals that have fallen on the floor, dirty with grease or oils, and have been damaged.