

FlowStar Double Hood Scavenging Circuit

Instructions for Use



Notice

Please read the Instructions for Use carefully and completely before initial use to protect yourself and your patients from operating errors! This manual also contains instructions on control checks that must be performed regularly by the user. Keep this manual for future reference. The company Baldus Sedation GmbH & Co. KG does not guarantee that the information is up-to-date, correct and complete. We reserve the right to make changes. If any problems or leaks occur with the Scavenging Circuit, immediately contact Baldus Sedation GmbH & Co. KG. Do not carry out any repair attempts on your own. Disregard will result in loss of warranty.

R_xonly: Federal law restricts this device to sale by or on the order of a physician.

Contact with the manufacturer:



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Manufactured for/ distributed by:



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1. General information

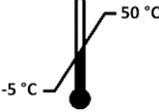
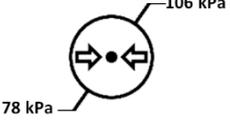
1.1. Warnings and Cautions

Table 1: Warnings and Cautions

 WARNING	<ol style="list-style-type: none">1. Please comply with the recommended ambient air contamination limit of your country [(USA: The recommended exposure limit is 25 ppm TWA (time weighted average 8 hours))]2. The suction capacity must be at least 45 l/min.3. Allergies must be discussed with the patient prior to treatment. If there is an allergy to fragrances, please contact Baldus Sedation GmbH & Co. KG for more detailed information.
 CAUTION	<ol style="list-style-type: none">1. For reasons of service life, functional efficiency and traceability, the combination of different batches is prohibited.2. Hot air sterilizers must not be used.3. The Scavenging Circuit may only be used in combination with an oxygen-nitrous oxide mixer.4. Chemical disinfectants must not be used.5. The Vacuum Control Block must not be cleaned or sterilized by machine.

1.2. Symbols and technical data

Table 2: Overview symbols and their meaning

Symbols	Meaning
	Manufacturer country and date
	Manufacturer
	Unique Device Identification
	Reference number
	Batch designation
	Do not reuse
	Non-sterile
	Temperature limits
	Humidity limits
	Observe Instructions for Use
	Air pressure limits

	Distributor
R _x Only	Federal law restricts this device to sale by or on the order of a physician
	Usable until
	Medical device

Table 3: Overview technical data

Technical data	
Storage temperature	-5 – 50 °C (23 – 122°F)
Operating temperature	-10 – 35 °C (14 – 95°F)
Humidity	0 – 90 %
Air pressure	78 – 106 kPa
Shelf life	3 years
Disposal	Observe the usual disposal methods
Double Tube	L 700,00 x OD 14,00 x OD 10,90 x ID 10,40 x ID 6,90
Vacuum Tube	L 2500,00 x OD 15,00 x ID 9,60 mm
Fresh Gas Spiral Tube	L 900,00 x OD 31,18 x ID 20,50 mm
Vacuum Control Block (H x W x D)	117,55 x 35,50 x 20,15 mm
Connection for Inner Vacuum Tube Diameter	5,95 mm
Connection for Vacuum Tube	5,95 mm
Minimum suction power	45,00 l/min
Outer Hood Single Use, Adult (H x W x D)	50,08 x 129,24 x 55,89 mm
Inner Hood Single Use, Adult (H x W x D)	41,31 x 95,97 x 46,05 mm
Weight Double Hood, Adult (Single Use)	35,00 g
Weight Double Hood, Adult (autoclavable)	41,00 g
Outer Hood Single Use, Pediatric (H x W x D)	44,31 x 108,83 x 50,00 mm
Inner Hood Single Use, Pediatric (H x W x D)	35,31 x 82,98 x 38,28mm
Weight Double Hood, Pediatric (Single Use)	25,00 g
Weight Double Hood, Pediatric (autoclavable)	32,00 g
Material Double Hood (autoclavable)	Silicon
Material Double Hood (Single Use)*	Thermoplastic elastomer (TPE)
Material Scavenging Circuit	Silicone
Material Connectors	Polycarbonat
Latex free	yes

* For more information about the ingredients of Single Use Double Hood, contact the manufacturer.

1.3. Indications for Use

The Scavenging Circuit is connected to an O₂-N₂O mixer and is used to deliver a gas mixture of O₂ and N₂O to the patient's nose for inhalation sedation. At the same time, the gas mixture exhaled by the patient is exhausted through the Scavenging Circuit and the suction connected to the system. The Vacuum Control Block is used to monitor and adjust the suction power.

1.4. Description of application

Delivered mixed gas, nitrous oxide and oxygen, through the tubing and Inner Hood.
To remove the exhaled gases from the patient, through the Exhalation Membrane, Outer Hood, Vacuum Tube, Vacuum Control Block, into the Vacuum System, and exhausted to the outside of the building. The Vacuum Control Block is a safety feature and is used to monitor and precisely adjust the vacuum/suction levels. Correct settings will keep the scavenging level of 45 lpm. While incorrect scavenging adjustments can result in exhaled gases escaping into the ambient air of the office.

2. Description of the components and handling

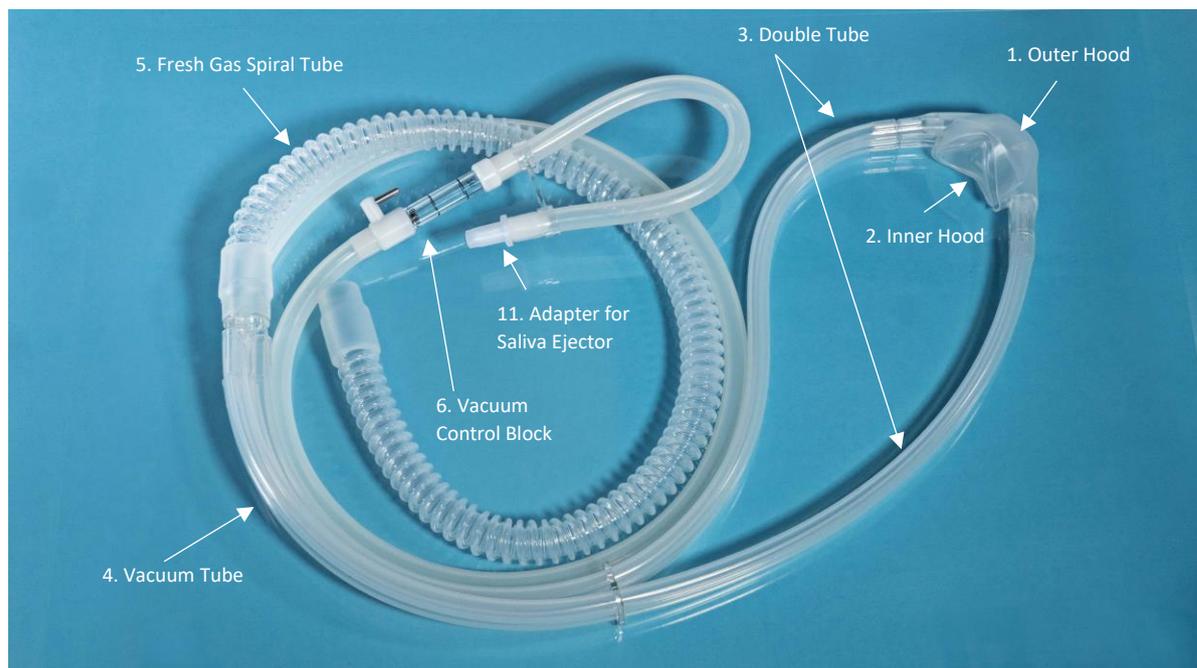


Figure 1: Components of the Scavenging Circuit



Figure 2: Components from left to right: 7. Y-Connector, 8. Slider, 9. Hanger und 10. Connector

Table 4: Description of the components of the Scavenging Circuit

Components	Description
1. Outer Hood	The Outer Hood encloses the Inner Hood. Via the Outer Hood, the exhaled gas of the patient is conducted to the outside via the small lumen of the Vacuum Tube and the suction. A Connector can be connected to each of the outer sides, which connects the Outer Hood to the Double Tube.
2. Inner Hood	The Inner Hood is attached to the Outer Hood by means of small round barbs on both sides. For better orientation, both Hoods are marked "L" (left) and "R" (right). The patient exhales the oxygen-nitrous oxide mixture and an oval membrane made of silicone opens. The gas mixture is thus directed into the Outer Hood.
3. Double Tube	The large lumen is for the fresh gas and the small lumen for the extracted gas. The Vacuum Tube is attached to the Double Tube using the small Y-Connector and the Fresh Gas Spiral Tube is attached using the large Y-Connector.
4. Vacuum Tube	The Vacuum Tube is supplied in a length of 2.50 m. From this, the user must cut two individually long pieces. A shorter piece that is connected to the suction by means of an Adapter. This should be long enough to form a loop with the Hanger. Also, no longer piece of the Vacuum Tube to connect the Double Tube and thus the Double Hood. The Vacuum Control Block is positioned between the two parts of the Vacuum Tube.
5. Fresh Gas Spiral Tube	The Fresh Gas Spiral Tube is connected to the Double Tube via the large Y-Connector. The other side of the Fresh Gas Spiral Tube is connected to the left 22 mm connection of the Bag Tees (see Figure).
6. Vacuum Control Block	The oxygen-nitrous oxide mixture inhaled through the Hood is extracted by means of a Vacuum Tube. The Vacuum Control Block (see Figure) must be located between the two pieces of the Vacuum Tube, which are cut individually by the user. The "VAC" connection is connected to the short piece, which in turn is plugged into the dental vacuum (HVE). The longer Vacuum Tube is plugged onto the second connection "HOOD" and points towards the Double Hood. The flow ball in the flow tube indicates whether the suction is too strong or too weak when the block is positioned vertically. There is a marked area in the center of the flow regulator, the suction flow is approx. 45 l/min. The Vacuum Control Block has a rotary knob with which the suction flow can be adjusted. If the knob is turned clockwise, the suction capacity will increase, but if it is turned counterclockwise, it will decrease. It is possible to turn the knob between 9 o'clock and 12 o'clock. The suction is stopped when it is in the 9 o'clock position. The strongest suction power is at 12 o'clock. However, the Vacuum Control Block is not intended to shut off the vacuum flow for the long term. The Scavenging Circuit must be disconnected from the vacuum source after treatment.
7. Y-Connectors	The large Y-Connector on the Double Tube serves as a connection with the Vacuum Tube. The smaller Y-Connector on the Double Tube serves as a connection piece with the Fresh Gas Spiral Tube.
8. Slider	With the help of the Slider, the Double Tube inside is pulled closer to the patient's head so that the Hood fits perfectly to the face.
9. Hanger	With the help of the Hanger, you can form a loop with the short piece of the Vacuum Tube in order to hang up the Vacuum Control Block and thus be able to read it vertically.

10. Connectors	The Connectors are used to connect the Outer Hood to the Double Tube. Important feature: Confusion-proof Connector.
11. Adapter for Saliva Ejector	Adapter for HVE/Saliva Ejector, multiple-use: The adapter is used to connect the Vacuum Tube to the HVE (high volume evacuator)/saliva ejector on the dental unit

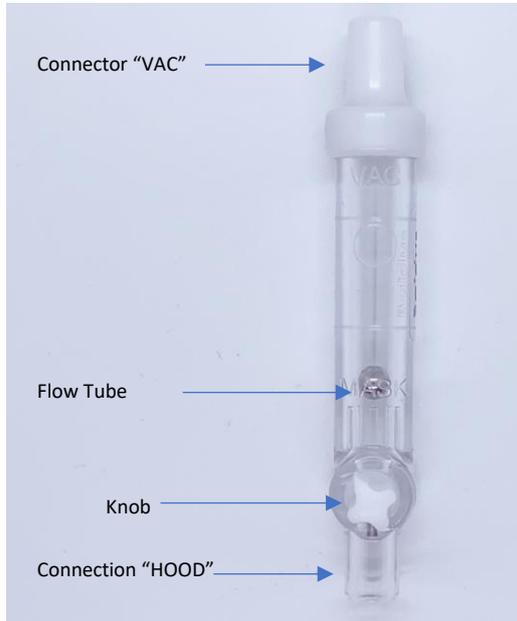


Figure 3: Vacuum Control Block



Figure 4: Bag Tee with two 22 mm connections. Left as connection for Fresh Gas Spiral Tube. On the right as connection for the Breathing Bag

Assembly instruction

The Fresh Gas Spiral Tube is plugged into the left 22 mm connection of the oxygen-nitrous oxide mixer and the Breathing Bag is plugged into the right connection (see Figure). The other end of the Fresh Gas Spiral Tube is connected to the large lumen of the Double Tube using a connector (large Y-Connector). The thin Vacuum Tube is connected to the small lumen of the Double Tube using the small Y-Connector (see Figure 3 right). With the help of the Connectors, the Outer Hood is attached to the Double Tube (Figure 3 left). To ensure that the Inner Hood is correctly placed inside the Outer Hood, both have been marked with the letters „L“ and „R“ (left & right) see Figure 4. When using the dental chair suction system, insert the other end of the Vacuum Tube with the adapter to connect it to the HVE. **Please note: The adapter for HVE cannot be autoclaved.** The Vacuum Control Block is mounted between the two parts of the Vacuum Tube. The „VAC“ connection must be positioned in the direction of the suction, the „HOOD“ connection points in the direction of the Scavenging Circuit. The Vacuum Control Block is used to monitor the suction power and to set the suction strength.



Figure 3: Left: Connection Outer Hood with Double Tube; Right: Connection Fresh Gas Spiral Tube, Vacuum Tube and Double Tube



Figure 4: Marking of the Outer Hood with "L" and "R"

3. Product variants



Figure 5: Available scents of the Double Hood

Table 5: Overview of the product variants

Product variants	Article number	Description
1	NSP0010	Vacuum Control Block Incl. Adapter and Hanger Weight: 30 g
2-7	NHA12HA	12x Double Hood (Single Use) Happy Apple, Adult
	NHA12BD	12x Double Hood (Single Use) Blueberry Dance, Adult
	NHA12PG	12x Double Hood (Single Use) Pure Ghost, Adult
	NHA12BB	12x Double Hood (Single Use) Bouncy Bubble, Adult
	NHA12CV	12x Double Hood (Single Use) Chilla Vanilla, Adult
	NHA12SD	12x Double Hood (Single Use) Strawberry Delight, Adult
8-13	NHP12HA	12x Double Hood (Single Use) Happy Apple, Pediatric
	NHP12BD	12x Double Hood (Single Use) Blueberry Dance, Pediatric
	NHP12PG	12x Double Hood (Single Use) Pure Ghost, Pediatric
	NHP12BB	12x Double Hood (Single Use) Bouncy Bubble, Pediatric
	NHP12CV	12x Double Hood (Single Use) Chilla Vanilla, Pediatric
	NHP12SD	12x Double Hood (Single Use) Strawberry Delight, Pediatric
14	NHAA101	Double Hood Adult, autoclavable
15	NHAP101	Double Hood Pediatric, autoclavable
16	NSP0030	Scavenging Circuit, autoclavable Double Tube with 2 Connectors, Slider, Y-Connectors („small“ and „large“), Fresh Gas Spiral Tube and Vacuum Tube
17	NSC-001	Double Hood Scavenging Circuit Incl. 3x Double Hood „Blueberry Dance“, Adult (Single Use), 3x Double Hood Pediatric „Strawberry Delight“ (Single Use) Weight: 967 g
18	NSC-VCB	Double Hood Scavenging Circuit Incl. Vacuum Control Block, Adapter, Hanger, 3x Double Hood Adult „Blueberry Dance“ (Single Use) and 3x Double Hood Pediatric „Strawberry Delight“ (Single Use) Weight: 997 g
19	NH-KIT	Sample Package Double Hoods (Single Use) 1x Double Hood „Blueberry Dance“, Adult 1x Double Hood „Strawberry Delight“, Pediatric

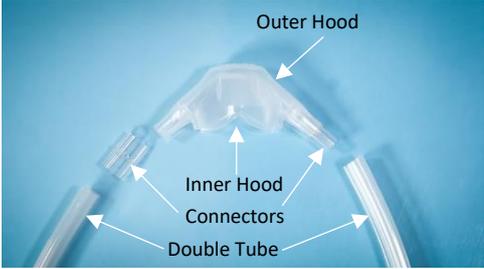
4. Safety and regular checks

Table 6: Checks to be carried out regularly

Before each treatment:	
Check of the membrane	Before each treatment, check that the membrane is correctly positioned on the Inner Hood. If this is not the case, it must be ensured that the membrane is correctly seated before the treatment starts. If it is missing, a new one must be inserted, otherwise no sedation can be performed.

Weekly:	
Check of the Vacuum Control Block	As soon as damage is visible or the flow ball can no longer be regulated in the marked area by the suction power or the flow ball shows no movement at all, the Vacuum Control Block must be replaced.

Monthly:	
Leakage verification	All components of the Double Hood Scavenging Circuit must be checked for holes or damage to prevent leakage.

<p>Rapid test to check the Breathing Bag and the Scavenging Circuit for leaks</p>	<ol style="list-style-type: none"> 1. The Double Hood and one of the two Connectors must be removed (see Figure 6) 2. The two ends of the Double Tube are connected to each other using the Connector so that a closed system is formed. 3. Turn the O2 flow to 5 LPM, the Breathing Bag should start to fill and balloon out. Once the bag becomes full and ballooning out, turn off the O2 Flow. 4. The Breathing Bag should be observed for one minute. 5. If the Breathing Bag remains filled after the time has elapsed, the test was successful and there are no leaks. If the Breathing Bag did not remain filled, the Y-Connectors, Connectors, Tubes or the Breathing Bag have leaks and must be replaced. <p>Afterwards, the Scavenging Circuit must be reinstalled again.</p>  <p><i>Figure 6: For the test, the Double Hoods and a Connector must be removed.</i></p>
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5. Hygiene

Table 7: Instructions and information

Instructions and information	
<p>Warning</p>	<p>The Double Hood Scavenging Circuit is not sterile when it is delivered, please clean and autoclave all components which can be autoclaved before used in line with instructions for use listed below in steps 1-3.</p> <p>Please note that you also follow the cleaning instructions for Breathing Bag, which is supplied separately.</p>
<p>Restrictions on reprocessing</p>	<p>Frequent reprocessing has an impact on the Double Hood Scavenging Circuit. The end of the product life is normally determined by wear and damage from use. If severe discoloration is acceptable. Please not the expiration date.</p>  <p><i>Abbildung 2: Discolored Double Hood that should be replaced</i></p>
<p>Point of Use Treatment</p>	<p>Immediately after use remove contamination with a disposable cloth/ paper towel.</p>
<p>Storage and transport</p>	<p>No special requirements. Storage temperatures see section 1.2.</p> <p>We recommend the reprocessing of the Double Hood Scavenging Circuit as soon as possible after use</p>

Inspection	For all cleaned, disinfected and sterilized components, check after each step: Perform a visual inspection for damage, wear and residual contamination. Should there be any visible residual contamination, please repeat cleaning, disinfection or sterilization processes.
Packaging: Outer Maks, Inner Hood, Double Tube, Vacuum Tube, Fresh Gas Spiral Tube, Connectors, Slider, Y-Connectors and Hanger	A standardized packaging material according to ISO 11607 can be used. The sterile packaging must be large enough for the component to be sterilized so that the seal is not in tension.
Assembly before the next treatment	Please connect the Inner Hood to the Outer Hood. Pull the Slider over the Double Tube. Insert the two connectors into the Outer Hood and the Double Tube. Now connect the Y-Connectors to the Double Tube, Vacuum Tube and Fresh Gas Spiral Tube. Then connect the Vacuum Control Block and the Hanger to the Vacuum Tube.
Validation	The above instructions have been approved by the medical device manufacturer. The person carrying out the preparation is responsible for ensuring that the preparation actually carried out achieves the desired results with the equipment, materials and staff in the preparation facility. Validation and routine monitoring of the procedure are normally required for this. Any deviation from the instructions provided should be carefully evaluated by the person carrying out the preparation for possible negative consequences.

Table 8: Preparations and disinfection

1. Step: Preparations and disinfection (For reusable Double Hoods, DO NOT REUSE SINGLE-USE DOUBLE HOODS)	
Preparation/dismantling of the Scavenging Circuit before cleaning	<ul style="list-style-type: none"> • Separate the Inner Hood from the Outer Hood • Remove the Connectors from the Outer Hood and the Double Tube • Remove the Y-Connectors from the Double Tube, Vacuum Tube and Fresh Gas Spiral Tube • Remove the Slider from the Double Tube • Finally remove the Vacuum Control Block, Adapter and the Hanger from the Vacuum Tube
Disinfection: Vacuum Control Block, Adapter for Saliva Ejector	Do not clean or sterilize the Vacuum Control Block by machine! Before first use – and whenever required from a clinical hygiene point of view – please disinfect with a EPA-registered disinfectant which does not attack the materials used (PC, POM, stainless steel and NBR). We recommend to use Monarch Surface Disinfectant Spray for disinfection. Clean gloves must be used during disinfection. The environment should be clean and as dust-free as possible.

Table 9: Mechanical cleaning

2. Step: Mechanical cleaning in the thermal disinfecter	
<p>Mechanical cleaning of the following autoclavable components</p> <p>Outer Hood (autoclavable) Inner Hood (autoclavable) Double Tube Vacuum Tube Fresh Gas Spiral Tube Connectors and Slider Y-Connectors and Hanger</p>	<p>Mechanical cleaning in the thermal disinfecter and disinfection in a cleaning disinfection device in accordance with ISO 15883.</p> <p>Tubes: One end of each Tube must be put on the injector nozzle/ Tube nozzle. Depending on the length, the rest of the length of the Tube will be put in a respective cleaning basket. Take care to ensure that the windings do not overlap or do not come into contact, they must lie flat to guarantee a cleaning of all parts.</p> <p>Hoods: Must be put separately into cleaning baskets.</p> <p>Connectors, Y-Connectors etc.: Must be put on nozzles.</p> <p>Adapters: The Adapters for Double Tubes are available from the manufacturers: Miele (Device No. PG8591, PG8581) Melag (Adapter-No. 80200)</p> <p>Please contact the manufacturer of your thermo washer disinfecter/washer disinfecter if you have any questions.</p> <p><u>Procedure of mechanical cleaning:</u></p> <ul style="list-style-type: none"> • 2 min pre-cleaning with cold tap water • Empty • 5 min cleaning with 55°C warm tap water and 0.5 % cleaning solution of Neodisher MediClean by Dr. Weigert, Hamburg (used in the preparation validation) • Empty • 3 min rinse with cold demineralized water • Empty • 2 min rinse with cold demineralized water • Empty • Thermal disinfection taking into account the national requirements in terms of the A0 value (e.g. A0 value of 3000 at 93°C und 3 min hold time) <p>All components must be completely dry before the next step (Sterilization). If necessary, contact the manufacturer for adapters/ additional nozzles.</p> <p>Do not use any chemical disinfectants!</p>

Table 10: Sterilization

3. Step: Sterilization	
<p>Sterilization of the following autoclavable components</p> <p>Outer Hood (autoclavable) Inner Hood (autoclavable) Double Tube Vacuum Tube Fresh Gas Spiral Tube Connectors and Slider Y-Connectors and Hanger</p>	<p><u>Steam-autoclave:</u></p> <ul style="list-style-type: none"> • 3-pre-vacuum phases • Sterilization temperature: 132°C • Duration: 4 min • Drying time: 20 min <p>Exceeding the sterilization time of 20 min decreases the service life. Do not use hot air sterilizers!</p> <p>Storage: After sterilization, please store the components in a dry and dust-free location.</p>



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