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INSTRUCTIONS FOR USE

for

Electric Suction Device

Type: VICTORIA

Models:

Portable

Versa

Thorax

Lipos

Economy

CE 2265

Manufacturer of Electric Suction Device VICTORIA

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Electric Suction Device VICTORIA

Models: Portable, Versa, Thorax, Lipos, Economy

Document: Victoria – Instructions for use
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Table of Contents

1. INTRODUCTION

These instructions for use apply to the medical device titled **Electric Suction Device Victoria** and manufactured as **Portable, Versa, Thorax, Lipos and Economy models** (the “device”).
These instructions for use form an integral part of the device.

1.1 Symbols

The device and the instructions for use provide warning and informative notices important for proper and safe operation of the device.

1.1.1 Safety Information Priorities

The safety information is intended to inform the user about potential hazards and to prevent any improper use of the device and to prevent the occurrence of any dangerous situations.

Warning

Warns against potentially dangerous situations which could result in serious injuries or death of persons.

Caution

Alerts to potentially dangerous situations which could result in light or medium injuries of persons.

The user and/or patient should report the serious adverse event that occurred in connection with the device to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

2. BASIC INFORMATION ON PRODUCT

2.1 Expected lifetime

The expected lifetime of the device set by the manufacturer is 10 years, provided that the device is used for its intended purpose, the instructions in this user manual are followed, metrological continuity is ensured and regular safety and technical inspections are carried out, the frequency of which has been determined by the manufacturer at an interval of 1x in 2 years by a person authorized by the manufacturer. The user can influence the expected life of the device by the way they use and service the device. The list of persons authorized by the manufacturer to carry out this activity is available on request from the manufacturer at servisni.objednavky@cheiron.eu

2.2 Intended Purpose

The medical device is intended for suction by creating a negative pressure in accordance with the stated purpose of use of the connected medical device that comes into contact with the patient.

2.2.1 Indication

The device does not come into contact with the patient, it only serves as a source of negative pressure for the connected medical device (suction catheter), which is then used to perform the medical procedure (suction). For this reason, the determined medical indication for the use of the device depends on the determined medical indication of the used connected medical device and on the decision of the attending physician.

2.2.2 Contraindication

The device does not come into contact with the patient, it only serves as a source of negative pressure for the connected medical device (suction catheter), which is then used to perform the medical procedure (suction). For this reason, the determined medical contraindication for the use of the device depends on the determined medical contraindication of the connected medical device used and on the decision of the attending physician. The device should not be used in patients in whom the use of vacuum devices or devices/means connected to a suction device is contraindicated.

2.2.3 Clinical benefit

The device has an indirect clinical benefit. The clinical benefit lies in the method that the medical device implements by creating negative pressure. The benefit of the suction method lies in the desired removal of fluids, liquids and solid particles from the designated area of the human body. The suction method has multidisciplinary uses, therefore the clinical benefit depends on the specific use for a given area of the human body and for a given medical procedure, as well as on the devices that are attached to the Victoria medical device and on the intended goals of the doctor who uses the device.

2.2.4 Undesirable side-effects

As such, the device has no known undesirable side effects. Any unknown undersirable side effects are detected through subsequent post-marketing clinical surveillance.

2.3 Classification

Classification to Regulation (EU) 2017/745 of the European Parliament and of the Council

The device is classified as a non-invasive active medical device of risk class IIa (non-sterile, with a measuring function) according to Annex VIII of Regulation (EU) 2017/745 of the European Parliament and of the Council (the “MDR”), *Rule 12.*

Classification to the criteria for electrical equipment

According to the criteria for electrical equipment, the device is a protection class I electrical instrument installed to a fixed point, with patient connection of Type B applied part, intended for permanent operation. The device is not intended for environment with explosion hazard.

2.4 Basic UDI-DI

The manufacturer assigned the following basic UDI-DI to the device: 8592722VIC1A3

2.5 Labels and Marking on the Product

The nameplate is located on the rear part of the device, showing the identification data of the manufacturer, technical data and user symbols.

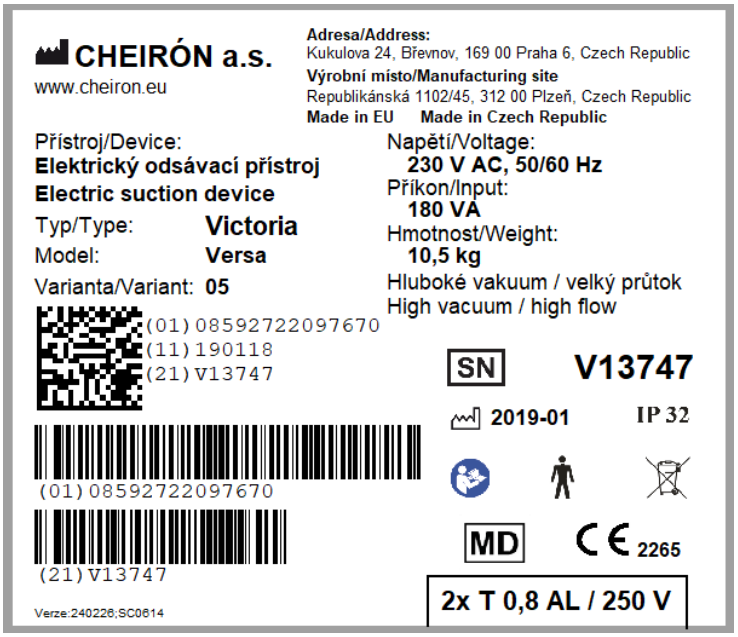


Fig. 1: Device nameplate specimen

Tab. 1: Values and symbols shown on the device labels

	Warning		Earthing connector
	Caution		Electrical waste
	Type B applied part	CE 2265	Compliance symbol providing the number of the notified body
	Alternating current	SN	Serial number
	Do not reuse		Date of manufacture
	Manufacturer		Temperature limitation
	Does not contain latex	LOT	Batch code
REF	Catalogue number	**IP 32**	IP code
	Use by	**AC**	Alternating current
F1-F2	Fuse		Reference to the instruction for use
MD	Medical device symbol		

3. TECHNICAL INFORMATION

3.1 Ambient Conditions

Electric suction device Victoria is intended for use in interiors without explosion hazards, such as hospital wards, ICU, medical examination rooms.

3.1.1 Operation Conditions

Ambient temperature: (0 to +40) °C
Relative humidity: (15 to 90) %
Atmospheric pressure: 620 to 1060 hPa

3.1.2 Transport and Storage Conditions

The device must be transported by covered means of transport without major shocks and must be protected by adequate packaging during transport.
Ambient temperature: −40 °C to +70 °C
Relative humidity: 15 % to 90 %
Atmospheric pressure: 620 to 1060 hPa

3.2 Basic Information – Description

The vacuum source of the device is an oilless membrane vacuum pump, which provides the required suction power and requires no maintenance by the user. The vacuum regulator regulates vacuum ranging from −7 kPa to −92 kPa. The vacuum value is measured with a vacuum gauge located on the front of the device.

The device itself (all 5 models) consists of a suction device and accessories (mobile stand with/without euro rail), a collection jar holder for the euro rail, a catheter container holder, a catheter container, a suction circuit holder, a storage basket, a collection jar changeover switch, and a foot switch).

A pneumatic foot switch is available as a special accessory part to facilitate handling and control during suction (*).
(*) Note:
Requirement to install this accessory must be specified when ordering the device. This accessory can only be installed additionally by the manufacturer.

The device is supplied non-sterile. During regular operation, the surface of the device does not exceed 48 °C.

3.3 Technical Parameters

Tab. 2: Technical data for Victoria 230 V models

TECHNICAL DATA	MODEL				
	VERSA 230 VAC	LIPOS 230 VAC	PORTABLE 230 VAC	THORAX 230 VAC	ECONOMY 230 VAC
Device weight – suction device	10.5 kg	10.5 kg	10.5 kg	10.5 kg	10.5 kg
Maximum weight including accessories	36 kg	36 kg	Portable only	36 kg	36 kg
Mobile stand	Yes	Yes	No	Yes	Yes
Device dimensions (W x H x L) suction device	440 x 300 x 310	440 x 300 x 310	440 x 300 x 310	440 x 300 x 310	440 x 300 x 310
Permanent operation	Yes	Yes	Yes	Yes	Yes
Acoustic pressure level	57.2 ± 1.4 dB	57.2 ± 1.4 dB	57.2 ± 1.4 dB	57.2 ± 1.4 dB	57.2 ± 1.4 dB
Device operation signalled with light	Yes	Yes	Yes	Yes	Yes
Double oversuction protection	Yes	Yes	Yes	Yes	Yes
Max. vacuum level (deep vacuum)	(−92 ± 5) kPa	(−93 ± 5) kPa	(−92 ± 5) kPa	(−92 ± 5) kPa	(−92 ± 5) kPa
Free air flow velocity (large flow-rate)	(40 ± 5) l/min	(50 ± 5) l/min	(40 ± 5) l/min	(40 ± 5) l/min	(40 ± 5) l/min
Use of limiting water valve in thoracic drainage	N/A	N/A	N/A	Yes	N/A
Range of vacuum in thoracic drainage	N/A	N/A	N/A	0–40 cmH_2O	N/A
Voltage	230 VAC	230 VAC	230 VAC	230 VAC	230 VAC
Frequency	50/60 Hz	50/60 Hz	50/60 Hz	50/60 Hz	50/60 Hz
Rated power input	180 VA	180 VA	180 VA	180 VA	180 VA
Rated fuse value	2x T 0.8AL/250 V	2x T 0.8AL/250 V	2x T 0.8AL/250 V	2x T 0.8AL/250 V	2x T 0.8AL/250 V
IP code	32	32	32	32	32
Vacuum gauge accuracy class	1.6 %	1.6 %	1.6 %	1.6 %	1.6 %

Tab. 3: Technical data for Victoria 120 V models

TECHNICAL DATA	MODEL				
	VERSA 120 VAC	LIPOS 120 VAC	PORTABLE 120 VAC	THORAX 120 VAC	
Device weight – suction device	10.5 kg	10.5 kg	10.5 kg	10.5 kg	
Maximum weight including accessories	36 kg	36 kg	Portable only	36 kg	
Mobile stand	Yes	Yes	No	Yes	
Device dimensions (W x H x L) suction device	440 x 300 x 310	440 x 300 x 310	440 x 300 x 310	440 x 300 x 310	
Permanent operation	Yes	Yes	Yes	Yes	
Acoustic pressure level	57.2 ± 1.4 dB	57.2 ± 1.4 dB	57.2 ± 1.4 dB	57.2 ± 1.4 dB	
Device operation signalled with light	Yes	Yes	Yes	Yes	
Double oversuction protection	Yes	Yes	Yes	Yes	
Max. vacuum level (deep vacuum) (*)	(−92 ± 5) kPa	(−93 ± 5) kPa	(−92 ± 5) kPa	(−92 ± 5) kPa	
Free air flow velocity (large flow-rate)	(40 ± 5) l/min	(50 ± 5) l/min	(40 ± 5) l/min	(40 ± 5) l/min	
Use of limiting water valve in thoracic drainage	N/A	N/A	N/A	Yes	
Range of vacuum in thoracic drainage	N/A	N/A	N/A	0–40 cmH2O	
Voltage	120 VAC	120 VAC	120 VAC	120 VAC	
Frequency	60 Hz	60 Hz	60 Hz	60 Hz	
Rated power input	180 VA	180 VA	180 VA	180 VA	
Rated fuse value	2x T 2AL/250 V	2x T 2AL/250 V	2x T 2AL/250 V	2x T 2AL/250 V	
IP code	32	32	32	32	
Vacuum gauge accuracy class	1.6 %	1.6 %	1.6 %	1.6 %	

(*) Note:

The maximum vacuum level (−92 ± 5) kPa is related to the sea level atmospheric pressure of 101.325 kPa. Deviations may occur depending on the local conditions, such as the atmospheric pressure, altitude, and temperature. Tab. 4 can be used for reference as it contains several factors to multiply the max. vacuum level according to the local measurement conditions.

Tab. 4: Vacuum level factor

Altitude / max. vacuum	Seal level	1 000 m	2 000 m
Factor	1.00	0.88	0.78

3.4 Basic Parts

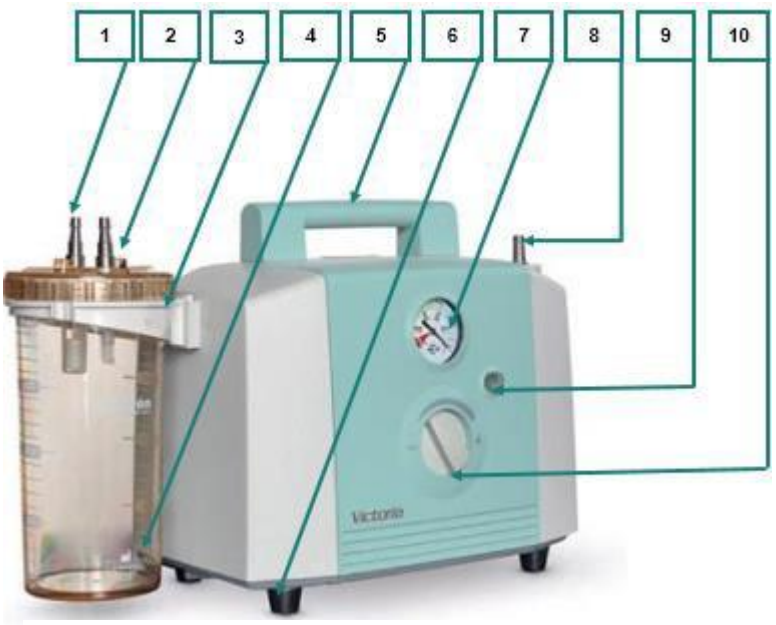


Fig. 2: Electric suction device Victoria – front part (the holder and the collection jar are not an integral part of the device)

***Not included in the basic delivery**

1) VACUUM inlet on the collection jar*
2) PATIENT inlet on the collection jar*
3) Collection jar holder
4) Collection jar
5) Device grip (*)
6) Rubber foot – 4x
7) Vacuum gauge
8) Port of bottle against oversuction
9) Mains switch
10) Vacuum regulation knob (**)

(*) Note:

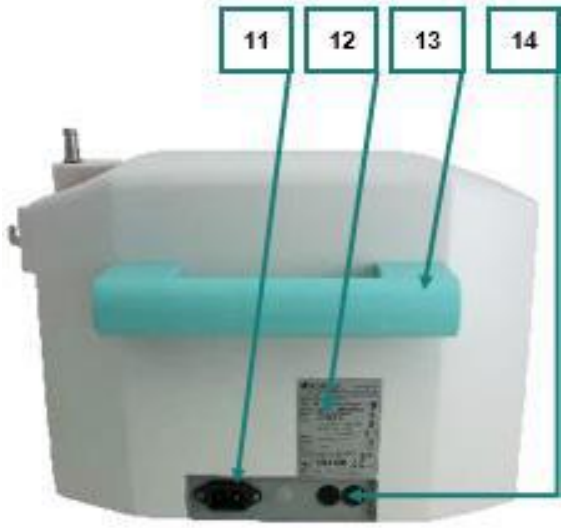
In the Thorax, Versa, Lipos models, the grip is located on the rear part of the device housing.

In the Portable model, the grip is located on the top of the device housing.

The Economy model is not equipped with any grip on the device housing.

(**) Note:

The regulation direction is shown above the vacuum regulation knob. It does not provide any scale of values to be set. The resulting vacuum level is shown on the vacuum gauge.



11) IEC socket to connect the power cord
12) Device nameplate
13) Device grip (*)
14) Fuse box 2x

Fig. 3: Electric suction device Victoria – rear part

15) Bottle against oversuction (*)
16) Filter replacement self-adhesive sticker
17) VD holder with a hook

Fig. 4: Electric suction device – side

Fig. 5: Electric suction device Victoria Thorax

*Not included in the basic delivery

18)	Housing of suction device Victoria II	23)	Connection tube (interconnection of 2 collection jars) *
19)	Double limiting water valve with safety non-return valve*	24)	1.5 m PVC suction tube (silicone)*
20)	Euro rail of Victoria II stand	25)	Storage basket II
21)	MSF suction filter	26)	Victoria II mobile stand
22)	Connection tube (interconnection of the device and the collection jar)*	27)	Stop valve (optional)*

*Not included in the basic delivery

3.5 Contents of Victoria Basic Delivery

- Suction device Victoria (Portable, Versa, Thorax, Lipos, Economy models)
- Bottle against oversuction (*)
- Complete outer suction circuit, PVC (silicone)
- Removable mains supply cable
- VD holder plug (**)

(*) Note

The Thorax model is equipped with a different bottle against oversuction containing an element for connection of a limiting water valve.

(**) Note

The Economy model is not equipped with the VD holder for collection jars and with the VD holder plugs. The collection jar holders are located on the front side of the Economy mobile stand.

3.6 Models

Tab. 5: Overview of Victoria models

Model	Voltage	REF	Voltage	REF
Portable	230 VAC	11-1112	120 VAC	11-1113
Versa	230 VAC	11-1122	120 VAC	11-1123
Thorax	230 VAC	11-1132	120 VAC	11-1133
Lipos	230 VAC	11-1142	120 VAC	11-1143
Economy	230 VAC	11-1152		

3.6.1 Recommended Sets of Individual Models

Victoria Portable

Device specification:

A powerful device intended predominantly for medical facilities and hospital inpatient wards. It is suitable for short- and long-term extraction and for building in endoscopic towers. For convenience in transport, the device is equipped with a grip on the top.

An assembly example of this model consists of the following parts:

- Victoria Portable – suction device
- Collection jar (1 l, 2 l) holder
- Collection jar (1 l, 2 l), insertable lid
- Complete outer suction circuit, PVC (silicone)

Fig. 6: Portable Model

Victoria Versa

Device specification:

Most frequently used model with a wide application range in hospital inpatient wards, anaesthesiology and resuscitation departments, ICU, operating theatres, internal medicine, ORL, surgery, gynaecology, orthopaedics, endoscopy, etc.

An assembly example of this model consists of the following parts:

- Victoria Versa – suction device
- 2 l collection jar holder for the euro rail
- 2 l collection jar, insertable lid
- Complete outer suction circuit, PVC (silicone)
- Victoria II mobile stand (with optional additional equipment to customer's request)

Fig. 7: Versa Model

Victoria Thorax

Device specification:

The device is intended both for regular extraction and for drainage performed during intensive care, thoracic and abdominal surgery.

The device has a simple and unique solution for extraction at full power even during drainage.

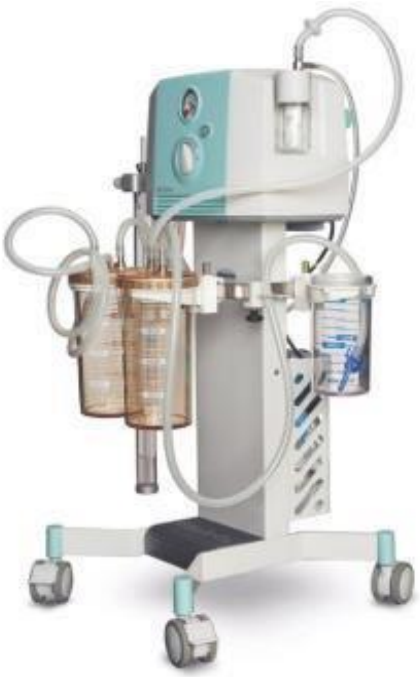


Fig. 8: Model Thorax

An assembly example of this model consists of the following parts:

- Victoria Thorax – suction device
- 2 l collection jar holder for the euro rail, 2 pcs
- 2 l collection jar, threaded lid, 2 pcs
- Complete outer suction circuit, PVC (silicone)
- Victoria II mobile stand (with optional additional equipment to customer's request)
- Double limiting water valve
- Interconnection tube between the bottle against oversuction and the limiting water valve

Victoria Lipos

Device specification:

High suction power. The device is intended predominantly for liposuction and use in operating theatres.

Fig. 9: Model Lipos

An assembly example of this model consists of the following parts:

- Victoria Lipos – suction device
- 2 l collection jar holder for the euro rail
- 2 l collection jar, insertable lid
- Complete outer suction circuit, PVC (silicone)
- Victoria II mobile stand (with optional additional equipment to customer's request)

Victoria Economy

Device specification:

The device is intended for regular extraction. It has a reduced range of accessories with a mobile stand that has no euro rail.

An assembly example of this model consists of the following parts:

- Victoria Economy – suction device
- 1 l, 2 l collection jar holder
- 2 l collection jar, insertable closure
- Complete outer suction circuit, PVC (silicone)
- Economy mobile stand (with no euro rail, 2 collection jar holders located on the front side) with optional additional equipment to customer's request

Fig. 10: Model Economy

The choice of accessories allows the customer to achieve variability according to the intended application.

4. SAFETY INSTRUCTIONS

4.1 Warnings

1. Improper use of the device may harm the patient, operator or property.
2. The device is not intended for use in an explosive atmosphere.
3. Do not use flammable substances to clean the device.
4. Do not immerse the device in water or wash under running water.
5. Do not use the device in an environment in conjunction with enriched oxygen - there is a risk of explosion.
6. The device is not approved for outdoor use or use during transport.
7. Do not use the device in the immediate vicinity of an MRI unit.
8. Do not service the device or any of its parts while in patient use.
9. Do not route cables and suction tubes that are part of the device in a way that could create a risk of strangulation or suffocation.
10. For patients in whom a malfunction of the device could cause a critical situation, a spare device must be available at all times.
11. No modifications to the device are permitted. Never disassemble the device.
12. It is forbidden to dismantle the handles of the collection jar holders that are attached to the device housing. Disassembly may only be carried out by trained personnel in accordance with the instructions issued by the manufacturer.
13. Before performing any cleaning or other handling tasks not related to clinical operation, disconnect the device from the external power source.
14. Never install the device in such a way that it is difficult to disconnect the power cord from the power supply.
15. Always leave the mobile versions of the device with all the wheels locked so that the mains plug cannot be disconnected inadvertently from the mains socket. In the portable version of the device, prevent the device from moving spontaneously on the surface where it is placed.
16. To avoid the risk of electric shock, the device must be connected to the power supply with a protective conductor.
17. The vacuum pump of the device is equipped with a thermal cut-out to turn off the device if overheated. In such a case, turn off the device with the mains switch, disconnect the power cord from the mains and wait at least 30 minutes. Before using the device again, check the suction and connection tubes for continuity.
18. In case of continuous extraction when the operator of the device is not present, the patient being extracted must be connected to another medical device to monitor the current status of the patient.
19. Always keep the power cord away from hot surfaces.
20. There is no risk with patient or operator exposure to the device between 1-59 seconds. If the operator needs a longer period of contact with the device or parts of the device, he or she must turn the device off.
21. Use the manufacturer's recommended accessories and medical devices.
22. Use the accessories and medical devices for the device exactly according to the operating instructions to ensure patient's safety.
23. To prevent the spread of infection from the collection jars, the manufacturer specifies the use of a microbiological suction filter (MSF).

24. The filter must be changed regularly (no more than 24 hours after it has been installed in the outer suction circuit). The simplest, safest and most comprehensive solution is to use FLOVAC disposable secretion bags that already contain a microbiological filter.
25. Take extra care when handling the collection jars to avoid contamination of the surrounding environment.
26. The device operator must monitor the filling process of the collection jar during extraction. The collection jars to be filled during extraction are transparent and the amount of liquid and foam being extracted can be monitored easily. Undesirable foaming of the liquid in the collection jar may cause dysfunction of the mechanism against oversuction.
27. Use only a collection jar with a threaded cap for thoracic drainage.
28. For thoracic drainage, the collection jar and the limiting water valve must always be positioned lower than the patient.
29. When using the limiting water valve, the opening of the inner tube at the top of the limiting water valve (intended for vacuum adjustment) must be open - free to pass through - at all times during operation. This opening must never be closed. Closing the opening can lead to serious patient injury.
30. Never pour disinfectants (persteril, chlorinated lime, etc.) into collection jars to decontaminate infectious fluid during extraction. Exposure to disinfectant vapours may damage the materials of which the device is made. There is a risk of damaging the other parts of the device.

4.2 Cautions

1. Check the correct connection of the individual parts of the suction system to ensure that the vacuum value does not drop.
2. The device is not intended for contact with the patient.
3. Never disconnect the electrical plug from the socket by pulling the power cord.
4. Never leave the device unattended when turned on.
5. Contact the manufacturer or its representative for assistance in using the device.
6. The device does not distinguish between use for adults and children. The method of use with regard to the condition of paediatric patients is entirely at the discretion of the operator.
7. If a liquid or solid particles have entered the device, contact the authorized service provider or CHEIRÓN a.s. immediately for timely service to prevent the occurrence of more serious losses.
8. If no suction circuit is connected to the device, ensure that no other objects or dirt enter the device through the suction circuit connection port.
9. The device includes a suction tube, which must never come into contact with the area to be extracted. A sterile extraction catheter must always be used to prevent infection.
10. The device is intended for use up to a maximum altitude of 2000 m.
11. In case of contamination with biological material, especially blood, disinfect the device with a virucidal product.
12. The use of additional attachments to the extraction circuit may reduce the suction performance.
13. The Economy model has limited ability to attach accessories to the mobile stand.

14. When mounting the device on the mobile stand (Versa, Thorax, Lipos, Economy models), only use the connecting parts designed and supplied by the manufacturer.
15. When using two collection jars simultaneously, i.e., when having two collection jars interconnected, remove the mechanism preventing overfilling from the other (the one to which the suction tube is connected).

4.3 General Instructions

1. Do not use the device if you have not read the instructions for use or if you do not understand its contents and instructions.
2. Always keep other operating instructions together with this manual for reference.
3. The operator of the device must not be a patient at the same time. One person operates the device, while the other is the patient.
4. Do not operate the device if you are aware of any damage to it.
5. Do not use the device unless you have first satisfied yourself that it is complete and that all its functions are correct.
6. Do not use the device if it is damaged or cannot be adjusted. In such a case, have the device inspected or repaired immediately.
7. Do not replace the fuses of the device yourselves as this must only be done by an appropriately qualified person.
8. Always keep the device in such a way that nothing prevents it from being disconnected from the power supply.
9. The direction of suction power control is marked above the regulation knob. This does not serve as a scale of adjustable values. The result of increasing or decreasing the suction power is only visible on the vacuum gauge of the device.
10. If any serious adverse event occurs in connection with the device, report it to the manufacturer and to the competent authority in the locality where the user and/or patient is established.

4.4 Intended User’s Profile

The user is a doctor or trained medical staff. The user must read and follow the instructions provided in the manual before putting the medical device into operation. The operator must not be colour blind. The device may only be used by a user authorized to perform the medical procedure in question in accordance with the attached accessories. A trained user is a person who is familiar or has familiarized himself or herself with the instructions for use, either by self-study or by a person authorized by the manufacturer.

Caution

The doctor is responsible for assessing the compatibility of the patient's condition with the surgical procedures and treatments being performed. The doctor must always use his or her knowledge and experience to evaluate and select the most appropriate treatment procedure.

4.5 Intended Population of Patients

The device does not come into contact with the patient; it only serves as a source of vacuum for the connected medical device (suction catheter), which is then used to perform the medical procedure (extraction). For this reason, the intended population of patients is dependent on the intended population of patients of the connected medical device and on the decision of the attending doctor.

- Age: no limitation
- Weight: no limitation
- Health: not important
- Patient's status: the patient is not the user

5. STORAGE

The ambient conditions for storage are specified in Art. 3.1.2 of these instructions for use.

6. WARRANTY

The warranty period of the vacuum pump of the electric suction device Portable, Versa, Thorax and Lipos models, is 6 years. The other parts' warranty period is 1 year. The warranty and post-warranty service is provided by CHEIRÓN a.s. or its authorized service organizations.

Caution

If a liquid or solid particles have entered the device, contact the authorized service provider or CHEIRÓN a.s. immediately for timely service to prevent the occurrence of more serious losses.

Note:

Defective material will be replaced free of charge during the warranty period, provided that the defect was not caused by misuse or incorrect operation.

7. INSTRUCTIONS FOR USE

Electric suction device Victoria may only be used in the way described in these instructions for use. Please familiarize yourselves with and follow the warnings and safety instructions before putting the device into operation. These instructions for use must be available at all times by the device for reference.

Caution

These instructions for use contain the general instructions concerning device operation.

7.1 Electrical Part

The device consists of an electrical oilless membrane vacuum pump with a thermal cut-out, a cooling system, and an electric circuit. The device is connected to the mains by means of a power cord plugged to the three-pole socket in the device and to a three-pole mains socket.

Warning

The device may only be plugged into a mains socket with a grounding element. The category of protection against electric shock is class I (protection by a grounding conductor).

7.1.1 Fuses

- Fuses used in the device; 230 VAC models:

Fuse T – slow 5 x 20 mm; 0.800 A / 250 V; L – with low cut-out ability

Cut-out ability:	35 A
Fuse size:	5 x 20 mm
Response speed:	T – slow
Rated current:	0.8 A
Rated voltage:	250 V

- Fuses used in the device; 120 VAC models:

Fuse T – slow 5 x 20 mm; 2 A / 250 V; L – with low cut-out ability

Cut-out ability:	35 A
Fuse size:	5 x 20 mm
Response speed:	T – slow
Rated current:	2 A
Rated voltage:	250 V

Warning

The vacuum pump of the device is equipped with a thermal cut-out to turn off the device if overheated. In such a case, turn off the device with the mains switch, disconnect the power cord from the mains and wait at least 30 minutes. Before using the device again, check the suction and connection tubes for continuity.

7.2 Pneumatic Part

The pneumatic part of the device consists of an outer suction circuit that is accessible to the operator and an inner suction circuit that is inside the device and inaccessible to the operator.
A mechanical vacuum regulator is located on the control panel of the device to control the vacuum level, which is simultaneously monitored by means of a built-in vacuum gauge. The device includes a detachable bottle against oversuction.

7.2.1 Vacuum Setting

Set the required vacuum level by turning the vacuum regulation knob (Fig. 2, Pos. 10). Clockwise rotation increases the vacuum level, while counterclockwise rotation decreases the vacuum level.
When turning the vacuum regulation knob, follow the vacuum gauge of the device (Fig. 2, Pos. 7). The measured vacuum value indicator rotates continuously. If the movement of the gauge is jerky or the gauge does not move, inform the competent service provider.

Note:

Verification of the measuring function of the vacuum gauge is carried out by an authorized service provider during the specified professional maintenance.
The set vacuum value is only indicated on the vacuum gauge if the outer suction circuit is closed, that is if, for example, the connection tube is kinked or squeezed between fingers.

7.3 Handling the Device

Electric suction device Victoria are **movable,** intended to be transported from one place to another. The Portable model is **portable** (without the option of a mobile version), with the device being equipped with a wide grip on the top for being transported by a single person.
The Versa, Thorax, Lipos and Economy models are **mobile** after being mounted on the mobile stand Victoria (see the chapter titled Optional Accessories for Victoria Device). Pull the device mounted on the stand by the grip. One person is enough to move the device.

Caution

The collection jars must always be emptied when the device is transported.

Always lock all the castors of the mobile stand versions of the device after transport. Hold the Versa, Thorax and Lipos models by the grip on the rear side of the device during transport and tow the stand in the direction of the grip.
Hold the Portable model by the grip on the top of the device during transport and move it by hand (one person is enough) to the intended place.
Hold the Economy model in both hands during transport and move it (one person is enough) to the intended place.

PERFORM A FUNCTION TEST BEFORE PUTTING THE DEVICE INTO FULL OPERATION.

7.4 Instructions before Putting the Device into Operation

- Check the supplied product for completeness and general condition.
- Before using the device, first check the power cord for not being damaged or the device itself for safety defects.
- Before using the device, check that the parts of the outer suction circuit are not damaged.

Caution

- *Before putting the device into full operation, the user must read and follow the instructions provided in the instructions for use.*
- *Regular safety and technical inspections of the device with the issuing of inspection reports are set by the manufacturer to be carried out every 2 years.*
- *The manufacturer specifies that the vacuum gauge should be calibrated every 2 years. The vacuum gauge was tested by the manufacturer during the output control.*

7.5 Turning the Device ON and OFF

7.5.1 Turning the Device ON

To turn on the device, connect the detachable power cord to the power inlet on the back of the device (Fig. 3, Pos. 11) and plug the other end of the power cord with the mains plug into a fixed mains socket. This secures the power supply. To operate the device, turn the mains switch on the front side of the device to the ON position (Fig. 2, Pos. 9).

7.5.2 Turning the Device OFF

To stop the device, press the mains switch to the OFF position. The mains switch does not serve as the main element for disconnecting the device. To completely disconnect the device from the power source, grasp the plug and disconnect the power cord from the fixed mains socket. Never pull on the power cord. Always have the device positioned in such a way that nothing prevents it from being disconnected from the mains.

7.6 Function Test

Assemble the device according to Art. 3.6.1.

Secure a suitable power source and start the device by means of the mains switch (Fig. 2, Pos. 9).

User control of the measurement accuracy of the device's vacuum gauge

Disconnect the external suction circuit from the anti-overflow bottle. Seal the opening of the vial connector bottle against oversuction. Set the minimum vacuum by turning the vacuum control knob to minimum (to the left). The displayed value on the vacuum gauge is -7 ±5 kPa. Set the maximum vacuum by turning the vacuum control wheel to maximum (to the right). The displayed value on the vacuum gauge is -90 ±5 kPa.

Set the required vacuum level:

Seal the control hole of the stop valve with a finger (Fig. 2, Pos. 2). This creates a vacuum, the level of which is increased or decreased by the vacuum regulation knob (Fig. 2, Pos. 10). Turn clockwise (increase) or counterclockwise (decrease) to the desired value, which is currently displayed on the vacuum gauge of the device (Fig. 2, Pos. 7).

Note:

If the device does not reach the required vacuum level, the fault can be in poor leak-tightness of the outer or inner suction circuit. In such a case, perform the leak test described in Art. 7.8.1 and 7.8.2.

7.7 Assembling the Outer Suction Circuit

Insert the bottle against oversuction (Fig. 4, Pos. 15) into the dedicated port on the side of the device. Use the short connection tube to connect the suction filter MSF (Fig. 5, Pos. 21) to the port on the bottle against oversuction (Fig. 2, Pos. 8). Put the connection tube (Fig. 5, Pos. 22) onto the other side of the suction filter. Attach the connection tube to the VACUUM inlet on the connection jar lid (Fig. 2, Pos. 2).

Note:

If the disposable FLOVAC or MONOKIT bag is used, the MSF suction filter need not be attached to the outer suction circuit.

7.8 Interconnection of Two Collection Jars

Connect the suction tube (Fig. 5, Pos. 24) to the PATIENT inlet on the collection jar lid (Fig. 2, Pos. 2). If you are using two collection jars, interconnect them one after the other according to the procedure in Fig. 11. Connect the connection tube (Fig. 5, Pos. 23) from the device to the VACUUM inlet on the lid (Fig. 2, Pos. 1) of the first collection jar, connect the PATIENT inlet on the first collection jar lid to the VACUUM inlet on the second collection jar lid with a short connection tube (supplied by the manufacturer as a standard when ordered). Connect the suction tube to the PATIENT inlet on the lid of the second collection jar (Fig. 5, Pos. 24).

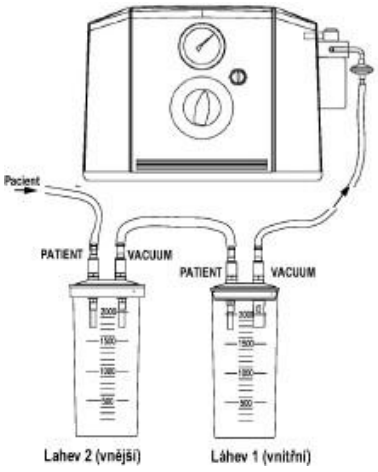


Fig. 11: Interconnection of two collection jars

7.8.1 Leak Test – INNER SUCTION CIRCUIT

Disconnect the outer suction circuit, i.e., the connection tube (Fig. 5, Pos. 23) including the connected MSF suction filter (Fig., Pos. 21) from the port of the bottle against oversuction (Fig. 2, Pos. 8). Seal the released port of the bottle against oversuction with a finger. Turn the vacuum regulation knob (Fig. 2, Pos. 10) clockwise to increase the vacuum level to maximum.

If the device responds by increasing the suction power and if the vacuum gauge (Fig. 2, Pos. 7) shows vacuum increase to the maximum level of (−92 ± 5) kPa, the inner suction circuit of the device is in order and the defect (leakage) should be sought in the outer suction circuit of the device (outside the device). In such a case, perform a leak test of the outer suction circuit (see below).

7.8.2 Leak Test – OUTER SUCTION CIRCUIT

Assemble the device according to the instructions provided in Art. 7.7 Assembling the Outer Suction Circuit. Seal the end of the suction tube (Fig. 5, Pos. 24), use the vacuum regulation knob (Fig. 2, Pos. 10) to set the vacuum power of the device to maximum and monitor the smooth increase of vacuum on the vacuum gauge of the device (Fig. 2, Pos. 7).

7.8.3 Leak Test Conclusion

If the device fails according to Art. 7.8.1 Leak Test – INNER SUCTION CIRCUIT, the leakage occurs in the inner part of the suction circuit.

If the device passes according to Art. 7.8.1 Leak Test – INNER SUCTION CIRCUIT but fails the leak test according to Art. 7.8.2 Leak Test – OUTER SUCTION CIRCUIT, the leakage occurs in the external parts.

Caution

Always check the correct connection of the individual parts of the suction circuit to prevent vacuum level drops.

8. Optional Accessories for Victoria Device

Tab. 6: Optional accessories

Description	Ordering number	Manufacturer
8 x 14 mm silicone hose (25 m in package)	232-008-014	DICOINSA, S.L.
MSF suction filter	271-022-001	CHEIRÓN a.s.
Complete suction circuit, Victoria Lipos, Versa – PVC	11-5133	CHEIRÓN a.s.
Complete suction circuit, Victoria Lipos, Versa – silicone	11-5134	CHEIRÓN a.s.
Complete suction circuit, Victoria Portable – PVC	11-5135	CHEIRÓN a.s.
Complete suction circuit, Victoria Portable – silicone	11-5136	CHEIRÓN a.s.
Complete suction circuit, Victoria Thorax – silicone	11-5137	CHEIRÓN a.s.
Suction circuit, Victoria – Economy	11-5146	CHEIRÓN a.s.
1.5 m PVC suction circuit with a stop valve	305-999-002	CHEIRÓN a.s.
1.5 m silicone suction circuit with a stop valve	305-999-001	CHEIRÓN a.s.
Victoria mobile stand	11-5104	Metal&Wood Art s.r.o.
1 l bottle holder – plastic, flexible	11-5142	CHEIRÓN a.s.
FLOVAC bottle holder– plastic, flexible	11-5144	CHEIRÓN a.s.
4 l bottle holder for euro rail II	11-5109	CHEIRÓN a.s.
4 l bottle holder, double II	11-5114	CHEIRÓN a.s.
Catheter container, 1000 ml	0-80-0030	CHEIRÓN a.s.
1000 ml catheter magazine holder	11-5126	CHEIRÓN a.s.
Victoria suction circuit holder	11-5110	CHEIRÓN a.s.
Foot switch*	114-047-000	CHEIRÓN a.s.
Foot switch for suction device with a cradle switch*	114-047-000/1	CHEIRÓN a.s.
Bottle filling changeover switch – basic	11-5131	CHEIRÓN a.s.
Storage basket II	11-5105	CHEIRÓN a.s.
Storage plate Victoria	11-5116	CHEIRÓN a.s.

(*) To be specified when ordering. Will only be installed additionally by the manufacturer.

Tab. 1: Accessories applicable to individual Victoria models

Victoria accessories by models						
Description	**Ordering number**	**Lipos**	**Portable**	**Thorax**	**Versa**	**Economy**
8 x 14 mm silicone hose (25 m in package)	232-008-014	•	•	•	•	•
MSF suction filter	271-022-001	•	•	•	•	•
Complete suction circuit, Victoria Lipos, Versa – PVC	11-5133	•			•	
Complete suction circuit, Victoria Lipos, Versa – silicone	11-5134	•			•	
Complete suction circuit, Victoria Portable – PVC	11-5135		•			
Complete suction circuit, Victoria Portable – silicone	11-5136		•			
Complete suction circuit, Victoria Thorax – silicone	11-5137			•		
Suction circuit, Victoria – Economy	11-5146					•
1.5 m PVC suction circuit with a stop valve	305-999-002	•	•	•	•	•
1.5 m silicone suction circuit with a stop valve	305-999-001	•	•	•	•	•
Victoria mobile stand	11-5104	•		•	•	•
1 l bottle holder – plastic, flexible	11-5142	•	•	•	•	•
FLOVAC bottle holder– plastic, flexible	11-5144	•	•	•	•	•
4 l bottle holder for euro rail II	11-5109	•		•	•	
4 l bottle holder, double II	11-5114	•		•	•	
Catheter container, 1000 ml	0-80-0030	•		•	•	
1000 ml catheter magazine holder	11-5126	•		•	•	
Victoria suction circuit holder	11-5110	•		•	•	
Foot switch*	114-047-000	•	•		•	
Foot switch for suction device with a cradle switch*	114-047-000/1	•	•		•	
Bottle filling changeover switch – basic	11-5131	•		•	•	
Storage basket II	11-5105	•		•	•	
Storage plate Victoria	11-5116	•		•	•	

9. Optional Medical Devices for Victoria

Tab. 8: Optional medical devices

Description	Ordering number	Manufacturer
1 l bottle with a threaded lid	000-110-000	Flow-Meter S.p.A.
1 l bottle with a threaded lid, polysulphone	000-110-050	Flow-Meter S.p.A.
2 l bottle with a threaded lid	000-030-000	Flow-Meter S.p.A.
2 l polysulphone bottle with a threaded lid	000-030-050	Flow-Meter S.p.A.
2 l bottle with an insertable lid with the CH logo	000-030-130	Flow-Meter S.p.A.
4 l bottle with an insertable lid	000-100-000	Flow-Meter S.p.A.
4 l polysulphone bottle with an insertable lid	000-100-010	Flow-Meter S.p.A.
2 l reusable FLOVAC bottle	970-010-212	Flow-Meter S.p.A.
2 l disposable FLOVAC bottle	000-036-001	Flow-Meter S.p.A.
2 l FLOVAC bottle with a 1.8 m hose	000-036-021	Flow-Meter S.p.A.
2 l FLOVAC bottle with a 1.8 m hose and a stop valve	000-036-041	Flow-Meter S.p.A.
Monokit 2 l	000-035-020	Flow-Meter S.p.A.
FLOVAC 2 l	000-036-011	Flow-Meter S.p.A.
FLOVAC 2 l with a 1.8 m hose	000-036-031	Flow-Meter S.p.A.
FLOVAC 2 l with a 1.8 m hose and a stop valve	000-036-051	Flow-Meter S.p.A.
Double limiting water valve II	11-5106	Flow-Meter S.p.A.
600 ml catheter container	000-210-000	Flow-Meter S.p.A.
Stop valve	200467	Flow-Meter S.p.A.
8 x 12 mm PVC suction hose (20 m in package)	524-000-0094	Pacific Hospital Supply. Co.Ltd
1 l bottle holder – plastic	920-200-421	Flow-Meter S.p.A.
2 l bottle holder – plastic	920-200-422	Flow-Meter S.p.A.
FLOVAC bottle holder – plastic, 25x5	970-010-210	Flow-Meter S.p.A.
Holder clamp – plastic	000-230-500	Flow-Meter S.p.A.

Note:
A complete list of accessories, medical devices and spare parts for the device can also be found on the website of the manufacturer CHEIRÓN a.s.

Note:
For other additional information regarding the accessories, medical devices and spare parts for the device, please contact the manufacturer CHEIRÓN a.s. or its distributors.

Note: *The medical devices listed in Tab. 7 are produced by other manufacturers and supplied by CHEIRÓN a.s. Interconnection of such medical devices is always within the competences of the user.*

Tab. 9: Medical devices applicable to individual Victoria models

Medical devices applicable to Victoria by models						
Description	**Ordering number**	**Lipos**	**Portable**	**Thorax**	**Versa**	**Economy**
1 l bottle with a threaded lid	000-110-000	•	•	•	•	•
1 l bottle with a threaded lid, polysulphone	000-110-050	•	•	•	•	•
2 l bottle with a threaded lid	000-030-000	•	•	•	•	•
2 l polysulphone bottle with a threaded lid	000-030-050	•	•	•	•	•
2 l bottle with an insertable lid with the CH logo	000-030-130	•	•	•	•	•
4 l bottle with an insertable lid	000-100-000	•		•	•	
4 l polysulphone bottle with an insertable lid	000-100-010	•		•	•	
2 l reusable FLOVAC bottle	970-010-212	•	•	•	•	•
2 l disposable FLOVAC bottle	000-036-001	•	•	•	•	•
2 l FLOVAC bottle with a 1.8 m hose	000-036-021	•	•	•	•	•
2 l FLOVAC bottle with a 1.8 m hose and a stop valve	000-036-041	•	•	•	•	•
Monokit 2 l	000-035-020	•	•	•	•	•
FLOVAC 2 l	000-036-011	•	•	•	•	•
FLOVAC 2 l with a 1.8 m hose	000-036-031	•	•	•	•	•
FLOVAC 2 l with a 1.8 m hose and a stop valve	000-036-051	•	•	•	•	•
Double limiting water valve II	11-5106			•		
600 ml catheter container	000-210-000	•		•	•	
Stop valve	200467	•	•	•	•	•
8 x 12 mm PVC suction hose (20 m in package)	524-000-0094	•	•	•	•	•
1 l bottle holder – plastic	920-200-421	•	•	•	•	•
2 l bottle holder – plastic	920-200-422	•	•	•	•	•
FLOVAC bottle holder – plastic, 25x5	970-010-210	•	•	•	•	•
Holder clamp – plastic	000-230-500	•		•	•	•

Information on the Use of Some Products Listed in Tab. 6 and 7

9.1 Double Limiting Water Valve with Safety Non-return Valve

Use of the limiting water valve

The double limiting water valve is used in the Thorax model only to secure safe thoracic extraction.
The Thorax model design allows to extract with full device power with simultaneous thoracic drainage.

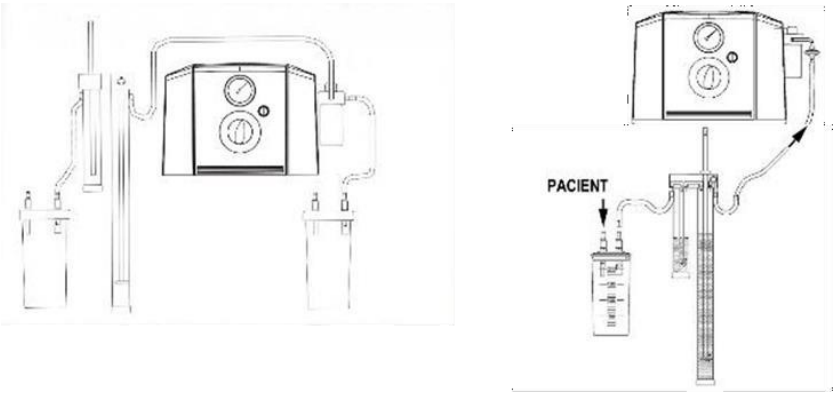


Fig. 12: Limiting water valve – connection

Warning

- Use the limiting water valve precisely to the instructions for use to ensure patient's safety.
- The limiting water valve is added to the suction circuit between the collection jar and the bottle against oversuction.

Description of the double limiting water valve

1) Safety non-return valve
2) Outer tube of the limiting water valve
3) Outlet for connection to the collection jar
4) Inner tube for vacuum level adjustment
5) Outlet for connection to the vacuum source
6) Lock nut
7) Flow valve

Fig. 13: Limiting water valve

Pour water into the outer tube of the limiting water valve (2) to approx. 2/3 of the maximum volume (according to the desired vacuum level) using the following procedure. Pull out the inner vacuum adjustment tube (4) and secure it with the lock nut (6). Then unscrew the outer tube counterclockwise, fill it with water, carefully screw it back in and tighten appropriately (be sure not to damage the thread). Loosen the lock nut and insert the inner tube back into the outer tube, adjust the depth of immersion of the inner tube to the desired vacuum in cmH_2O (see the equation in "Vacuum adjustment on limiting water valve").

Secure the final position of the inner tube with the lock nut to prevent leakage and inadvertent movement of the inner tube. Pour water into the safety non-return valve tube (1) so that after screwing (same procedure as in the previous case) the inner tube is 3 to 5 cm below the water level.

Note:

The safety non-return valve of the limiting water valve (1) puts resistance to the suction flow according to the depth of immersion of the tube (cmH2O). Thus, it reduces the vacuum level set by the inner tube (4) in the outer tube of the limiting water valve (2); therefore, you have to compensate for this loss of vacuum (immerse the inner vacuum adjustment tube deeper) to get the vacuum level desired for the patient.

Vacuum adjustment on limiting water valve

Set the desired vacuum by submerging the inner tube (4) below the water level in the outer tube (2). The depth of submersion adjusts the desired vacuum (see the equation below). Secure the final position of the inner tube with the nut (6) to prevent leakage and spontaneous movement of the inner tube.

Vacuum calculation equation: **P = X − Y**

P – resulting vacuum (cmH_2O)

X – depth of immersion of the inner tube (4) for vacuum adjustment (cm)

Y – depth of immersion of the inner tube of the safety non-return valve (cm)

Example:

If a vacuum level of **20 cmH_2O** is required for a patient and if the tube is immersed **5 cm** below the water level in the safety non-return valve (1), the system power is reduced by this value. Therefore, immerse the inner tube (4) to **25 cmH_2O**.

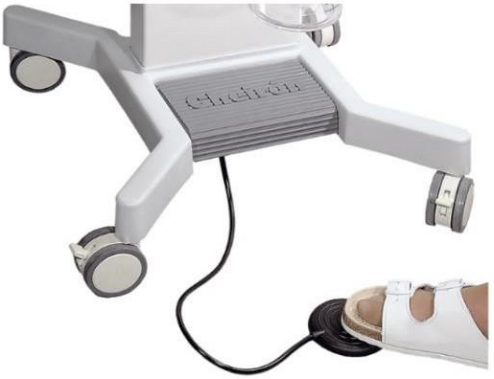
Leak test of the limiting water valve

Connect the connection tube to the connector of the bottle against oversuction and connect the other end of the connection tube to the vacuum source connection outlet (5) on the limiting water valve. Turn on the device and set the vacuum regulator to MAX. Close the flow valve of the limiting water valve (7) in a clockwise direction. Seal the end of the suction tube with your finger. Now slowly turn the flow valve counterclockwise. If the entire extraction system is leak tight, the limiting water valve will begin to “bubble” by drawing in atmospheric air through the inner tube (4). This way, the limiting water valve is tested and ready for use. There can be no more vacuum increase in the suction circuit than the calculated vacuum value according to the equation (Article 10.1.3) for calculating the resulting vacuum. Use the flow valve to reduce the “bubbling” intensity so that the bubbling rate is approximately **3 bubbles per second.**

The patient can be connected after performing all the activities above.

9.2 Foot Switch

The pneumatic foot switch is used to turn the device off and on during extraction. It can be used when the operator's workstation is located at a distance of approx. 2 m from the device. The device must be turned on with the mains switch before using the foot switch.



Caution

After finishing operation, while the vacuum pump is still running, turn off the device with the mains switch. If you turn off the device with the foot switch and then disconnect the foot switch, the vacuum pump in the device will not start suction when you turn on the device again with the mains switch, even though the mains switch indicator is lit green.

Fig. 14: Foot switch

Note

Requirement to install this accessory must be specified when ordering the device. This accessory can only be installed additionally by the manufacturer.

9.3 Collection Jar Holder

The holder is supplied for the 0.5 l, 1 l and 2 l sizes of the collection jar. The holder is fixed on the side of the device by inserting into the chosen VD holder. The required collection jar is then placed in the collection jar holder.

Fig. 15: Flexible collection jar holder

9.4 Collection Jar Filling Changeover Switch

The collection jar filling changeover switch is used when using two collection jars during extraction. The switch allows you to select which of the two collection jars the system will discharge the extracted liquid into. Compared to the standard serial connection of the collection jars without this switch, each collection jar can be changed and cleaned separately in the system with the changeover switch.

Fig. 16: Collection jar filling changeover switch

9.5 Catheter Storage Container

600 ml and 1000 ml polycarbonate cylinders are used to store extraction catheters. The container is mounted to the euro rail by means of a holder.

Fig. 17: Catheter storage container

9.6 Storage Basket II

The storage basket II can be removed easily from the rear side of the mobile stand. It is intended to hold not contaminated consumption materials. The storage basket can be installed additionally onto the mobile stand without any further modifications.

Fig. 18: Storage basket II

9.7 4 l Collection Jar Holder for Euro Rail, Single/Double

The 4 l collection jar holder is designed to hold one or two 4 l collection jars. Mount the holder onto the euro rail and place the collection jar in it.

Fig. 19: 4 l collection jar holder

9.8 Victoria Suction Circuit Holder

The suction circuit holder is intended for convenient attachment of the suction circuit. Mount the holder onto the euro rail and place the suction circuit in it.

Fig. 20: Victoria suction circuit holder

9.9 Catheter Storage Container Holder

The catheter storage container is intended for convenient attachment of the catheter container. Mount the holder onto the euro rail and place the catheter container in it.

9.10 Holder Clamp – Plastic

Mount the clamp onto the euro rail of the mobile stand and place the collection jar holder in it.

Note:

The FLOVAC collection jar holder comprises a collection jar holder and a plastic FLOVAC holder clamp. Quote both items when ordering.

Fig. 21: Holder clamp – plastic

9.11 Victoria Mobile Stand

The Versa, Thorax, Lipos and Economy models are ready for mounting on the mobile stand, which improves device mobility to facilitate its operation. The mobile stand can be ordered additionally at any time and the device mounted onto it easily. All the Victoria series devices support additional mounting onto the mobile stand (*). The storage basket II can be installed onto the rear side of the mobile stand.

(*) Note:

The Economy model has a reduced choice of accessories to be mounted onto the mobile stand.

Fig. 22: Victoria mobile stand

10. CLEANING AND MAINTENANCE

10.1 General

- When working with disinfectants, follow the instructions for use of the disinfectant and the hygiene regulations.
- When working with disinfectants, observe the health and safety principles at work and use personal protective equipment to protect your skin and eyes.
- Dispose of drained fluids and contaminated disposable components of the device in accordance with the applicable regulations.
- After reassembling the collection jar, always check that the lid is correctly fitted and the tubes are firmly connected.

Warning

Always unplug the device first before cleaning. Clean and disinfect the accessories and medical devices for the device exactly according to the instructions for use.

10.2 Replacement of Collection Jars

The spare collection jar with cap must always be ready in advance for quick replacement.

Replace the collection jar when it is filled to the mark of its maximum capacity (e.g. 2 l, 4 l). Disconnect the tubes from the collection jar lid. Carefully remove the filled collection jar from the holder and dispose of the extracted contents according to the applicable hygiene regulations.

The collection jar is equipped with an overfill prevention mechanism. The level of fluid drawn into the collection jar raises the float of the valve, closes the corresponding lid port and interrupts the extraction process. The MONOKIT or FLOVAC disposable bag for 2 l collection jars is a suitable accessory for quick change and hygiene. The lid of the disposable bag contains a hydrophobic bacterial filter which also acts as an overfill prevention mechanism. Close the bag after it has been filled so that the infectious contents cannot be spilled. The use of disposable bags usually eliminates the need to sterilize the collection jars.

Note:

Before using a collection jar with an overfill prevention mechanism, always check that the float in the float cage (on the inside of the collection jar lid) is positioned with the sealing ring towards the lid.

If the MONOKIT or FLOVAC disposable bag is used, do not connect the MSF suction filter to the suction circuit.

10.3 Cleaning Electric Suction Device Victoria

Disconnect the device from power supply. Disinfect your hands and put on disposable gloves and suitable protective equipment. For manual cleaning of the device, use a cloth soaked in lukewarm water less than 40 °C. The cloth must not be soaked excessively to prevent the solution from getting into the internal parts of the device. When finished, dry the surface with a dry cloth or a paper towel.

Warning

Never immerse the device in water or other liquid.

When cleaning the device, do not use abrasive substances, alcohol and solvents, which could damage the plastic parts or remove the self-adhesive stickers.

10.4 Disinfecting Electric Suction Device Victoria

Disinfect your hands and put on disposable gloves and suitable protective equipment. Proceed according to the instructions of the disinfectant's manufacturer.

The products listed below are proven by the manufacturer to be mild disinfectants. The use of the specified products does not cause degradation of materials.

Bacillol® 30 Sensitive Tissues and Bacillol® 30 Sensitive Foam

The disinfectant manufacturer specifies the following microbiological effects:

- Bactericidal
- Anti-yeast
- Tuberculocidal
- Mycobactericidal
- Virucidal against enveloped viruses (incl. HBV, HIV, HCV)
- Limited spectrum of virucidal activity
- Polyomavirus

11. SERVICE

These instruction for use provide sufficient user information about the device for safe use by the user. Detailed technical information is given in the service manual. The service manual is intended for use by persons approved by the manufacturer to perform service and is available upon request from the manufacturer CHEIRÓN a.s. Diagrams, parts lists, descriptions, calibration instructions, and other information intended to provide service support for repair of those parts of the device identified by the manufacturer as repairable are available upon request from the manufacturer of the device.

The term "service" means execution of technical safety inspections and repairs of the device in compliance with the manufacturer's instructions and the applicable legal regulations.

Requirements for the service staff

The person performing service must:

- be the manufacturer or a person provably authorized by the manufacturer;
- be authorized by a competent organization to perform the activity;
- be familiarized with the instruction for use of the device;
- be aware of the consequences resulting from incorrectly performed service and able to prevent such circumstances.

11.1 Technical Safety Inspection

In accordance with legal requirements, the manufacturer stipulates that technical safety inspections are to be carried out once in 2 years during the entire period of use of the device.

Failure to perform the inspection increases the risk of malfunction and limitation of the intended purpose of the device and compromises the patient and user safety.

12. DISPOSAL OF THE DEVICE

If the device is not contaminated with hazardous substances and there is a requirement to dispose of the device, it is the responsibility of the manufacturer to take the electrical equipment back from the user. The manufacturer is doing so in accordance with Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE). For the reasons stated above, please contact the manufacturer or its authorized service provider when disposing of the device.

12.1 Disposal of the Device

A responsible organization must assess whether the device has been contaminated with hazardous substances as a result of its use and proceed with its disposal with regard to potential contamination.
If the device:

a) **is not** contaminated with hazardous substances, the manufacturer will take the device back upon request. In the Czech Republic, the manufacturer CHEIRÓN a.s. is involved in the collective electrical equipment recycling system. If you dispose of the device in the Czech Republic, please use the option of disposing of the device by handing it over to the electrical waste collection points. In other countries, dispose of the device in accordance with the applicable regulations governing the disposal of electrical waste.
b) **is** contaminated with hazardous substances, it must be disposed of as hazardous waste.

Do not dispose of the device together with the mixed municipal waste. If the device is not contaminated with hazardous substances, its parts can be offered for reuse. By recycling old instruments, you contribute considerably to environmental protection.

12.2 Environmental Protection

The manufacturer is aware of the importance of protecting the environment and the role it plays for future generations. The device is manufactured in accordance with Directive 2011/65/EU restricting the use of certain hazardous substances. The packaging materials used are manufactured in compliance with the relevant directives and MDR.
Follow the locally applicable regulations for disposal.
Hand over waste only to a person authorized to handle the given type of waste.
The main parts of the device are made of the following recyclable materials: metals and plastics.
Make sure that packaging materials are disposed of in accordance with their labels.

13. SPECIFICATIONS

Tab. 10: General specifications

Product lifetime	10 years

Tab. 11: Loading capacities – mechanical specifications

Euro rail	15 kg
Storage basket II	3 kg
Bottle holder	By type
Mobile stand loading capacity	36 kg

ATTENTION: The sum of the partial loads on the parts of the device must not exceed its total maximum loading capacity!

Tab. 12: Electrotechnical specifications

Electrical instrument protection class	Class I
Operation mode	Permanent
IP code	IP 32
Electrical installations power supply	AC 230 V / 120 V
Frequency	50 Hz / 60 Hz

Tab. 13: Emission limits by environment

Phenomenon	Environment of professional medical facilities (a)
Conducted and radiated RF emissions	CISPR 11
Harmonic distortion	see IEC 61000-3-2 (b)
Voltage fluctuation and flicker	see IEC 61000-3-3 (b)

a) For information concerning the environment of INTENDED USE see Chap. 2.2

b) This test is unusable in this environment if the applied ME INSTRUMENTS and ME SYSTEMS are connected to the PUBLIC SUPPLY NETWORKS and power supply is otherwise within the applicability of the basic EMC standard.

Tab. 14: Inlet/outlet through device housing

Phenomenon	Basic EMC standard or testing method	Environment of professional medical facilities
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	±8 kV for contact discharge ±2 kV, ±4 kV, ± 15kV for discharge through air
Radiated RF EM fields (a)	IEC 61000-4-3	3 V/m (f) 80 MHz-2,7 GHz (b) 80 % AM at 1 kHz (c)
Near fields form RF wireless communication devices	IEC 61000-4-3	See 8.10.
Magnetic fields of DETERMINED network frequencies (d), (e)	IEC 61000-4-8	30 A/m (f) 50 Hz or 60 Hz

a) If an interface is used between the PATIENT's physiological signal simulation and the ME DEVICE or ME SYSTEM, it must be located within 0.1 m from the vertical plane of the homogeneous field region in one orientation of the ME DEVICE or ME SYSTEM.

b) The ME DEVICES or ME SYSTEMS that intentionally receive RF electromagnetic energy for the purpose of their operation must be tested at the receiving frequency. Testing may be performed on other modulations specified in the RISK MANAGEMENT PROCESS. This test assesses the BASIC SAFETY and the ESSENTIAL FUNCTIONALITY of the intended receiver when the ambient signal is in the passband. It is understood that the receiver might not achieve normal reception during the test.

c) Testing may be performed on other modulation frequencies determined in the RISK MANAGEMENT PROCESS.

d) Only applies to ME DEVICES or ME SYSTEMS with magnetically sensitive parts or circuits.

e) During the test, the ME DEVICE or ME SYSTEM may be supplied with any RATED input voltage, but at the same frequency as the test signal.

f) This test level assumes a minimum distance of at least 15 cm between the ME DEVICE or ME SYSTEM and the magnetic field sources of the mains frequency. IF THE RISK ANALYSIS indicates that the ME DEVICE or ME SYSTEM will be used closer than 15 cm to the mains frequency magnetic field sources, the TEST LEVEL OF RESISTANCE must be set as appropriate for the minimum expected distance.

Tab. 15: AC power supply inlet/outlet

Phenomenon	Basic EMC standard	Environment of professional medical facilities
Electrical fast transients / bursts (a) (l)	IEC 61000-4-4	±2 kV Repetitive frequency 100 kHz
Surges (a) (b) (j) (o)	IEC 61000-4-5	±0,5 kV, ±1 kV
Surges (a) (b) (j) (k) (o) between phase and earth	IEC 61000-4-5	±0,5 kV, ±1 kV, ±2 kV
Immunity to conducted disturbances, induced by radio-frequency fields (c) (d) (o)	IEC 61000-4-6	3V (m) 0,15 MHz-80MHz 6V (m) in the ISM bands between 0.15 MHz and 80 MHz (n) 80 % AM at 1 kHz
Short voltage dips (f) (p) (r)	IEC 61000-4-11	0 % U t-0.5 cycle (g) at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°(q)
		0 % U t-1 cycle 70% U t-25/30 cycles (h) Single phase: at 0°

Interrupted voltage (f) (i) (o) (r)	IEC 61000-4-11	0 % U t – 260/300 cycles (h)

a) The test may be performed at any supply voltage within the range of the ME DEVICE or ME SYSTEM SET voltages. If the ME DEVICE or ME SYSTEM is tested at one input supply voltage, it is not necessary to retest it at other voltages.

b) All ME DEVICE or ME SYSTEM cables are connected during the test.

c) The calibration of the injected current by pliers must be carried out in a 150 Ω system.

d) If the ISM or amateur band, if used, is skipped in frequency stepping, the additional test frequency in the ISM or amateur band must be used. This applies to each ISM and amateur radio band within the specified frequency range.

e) Testing may be performed on other modulation frequencies determined in the RISK MANAGEMENT PROCESS.

f) ME DEVICES and ME SYSTEMS with DC power supplies intended for use with AC/DC converters must be tested using a converter that meets the ME DEVICE or ME SYSTEM MANUFACTURER's specifications. TEST RESISTANCE LEVELS are used for AC powered converters.

g) Only applies to ME DEVICES or ME SYSTEMS connected to a single-phase AC power network.

h) For instance, 10/12 means 10 periods at 50 Hz or 12 periods at 60Hz.

i) ME DEVICES or ME SYSTEMS with a SET input current greater than 16 A/phase must break once every 260/300 cycles at any angle and all phases simultaneously (if possible). ME SYSTEMS and ME DEVICES with battery backup must resume operation on mains power after the test. For ME DEVICES and ME SYSTEMS with a SET input current not exceeding 16 A, all phases must be interrupted simultaneously.

j) ME DEVICES and ME SYSTEMS which do not have a surge protective device in the mains supply circuit may only be tested to ±2 kV between phase(s) and earth and to ±1 kV between phases.

k) Does not apply to ME DEVICES and ME SYSTEMS of PROTECTION CLASS II.

l) Direct link must be used.

m) Effective values before using modulation.

n) ISM (industrial, scientific, medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6. 795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; 40.66 MHz to 40.70 MHz Radio amateur bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz;18.07 MHz to 18.17 MHz; 21.0 MHz to 21.4 MHZ; 24.89 MHz to 24.99 MHz; 28.0 MHz to 29.7 MHz; 50.0 MHz to 54.0 MHz

o) Only applies to ME DEVICES and ME SYSTEMS with a SET input current less than or equal to 16 A/phase and ME DEVICES and ME SYSTEMS with a SET input current greater than 16 A/phase.

p) Only applies to ME DEVICES or ME SYSTEMS with a SET input current less than or equal to 16 A/phase

q) At some phase angles used by this test for ME DEVICES with transformers, the mains supply could cause activation of overcurrent protection. This may occur due to saturation of the magnetic flux of the transformer core after a short voltage drop.

If this happens, the ME DEVICE or ME SYSTEM must provide BASIC SAFETY during and after the test.

r) For ME DEVICES and ME SYSTEMS that have multiple voltage settings or automatic voltage selection capability, the test must be performed at the minimum and maximum SET input voltage. ME DEVICES or ME SYSTEMS with a range of RATED input voltages less than 25 per cent of the highest SET input voltage must be tested at one SET input voltage within the range.

Tab. 16: Specification of RESISTANCE test against INPUT/OUTPUT through DEVICE HOUSING from RF wireless communication devices

Test frequency (MHz)	Band[a)] (MHz)	Service[a)]	Modulation[b)]	Maximum output (W)	Distance (m)	Test resistance level (Vm)
385	380 to 390	TETRA 400	Pulse modulation[b)] 18 Hz	1.8	0.3	27
450	430 to 470	GMRS 460, FRS 460	FM[c)] ± deviation 5 kHz 1 kHz Sine curve	2	0.3	28
710	704 to 787	LTE band 13, 17	Pulse modulation[b)] 217 Hz	0.2	0.3	9
745						
780						
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE band 5	Pulse modulation[b)] 18 Hz	2	0.3	28
870						
930						
1720	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE band 1, 3, 4, 25; UMTS	Pulse modulation[b)] 217 Hz	2	0.3	28
1845						
1970						
2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE band 7	Pulse modulation[b)] 217 Hz	2	0.3	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation[b)] 217 Hz	0.2	0.3	9
5500						
5785						

NOTE: If necessary to achieve the test level, the distance between the transmitting antenna and the ME device or ME system may be shortened to 1 m. According to IEC 61000-4-3, a test distance of 1 m is allowed.
a) For some services only uplink frequencies are included b) The carrier wave must be modulated using a rectangular signal fill factor of 50 %. c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used, as although this does not represent true modulation, it would be a worst case.

14. POSSIBLE DEFECTS AND THEIR REMOVAL

14.1 The device cannot be put into operation

- Check that the device is turned on.
- Check that the mains voltage is correct.
- Check that the plug is connected correctly to an external power source.
- A thermal cut-out may have tripped the vacuum pump of the device. Press the mains switch to the off position and wait 30 minutes. Then turn the device on again with the mains switch.

➡ If the defect persists, contact the manufacturer or an authorized service provider.

14.2 Insufficient vacuum

- Check that the vacuum regulation knob is in the correct position.
- Check the tightness of the outer and inner suction circuits as described in Article 7.8.3 Leak Test Conclusion.
- Check for defects in the parts of the outer suction circuit. Replace if necessary.

➡ If the defect persists, contact the manufacturer or an authorized service provider.