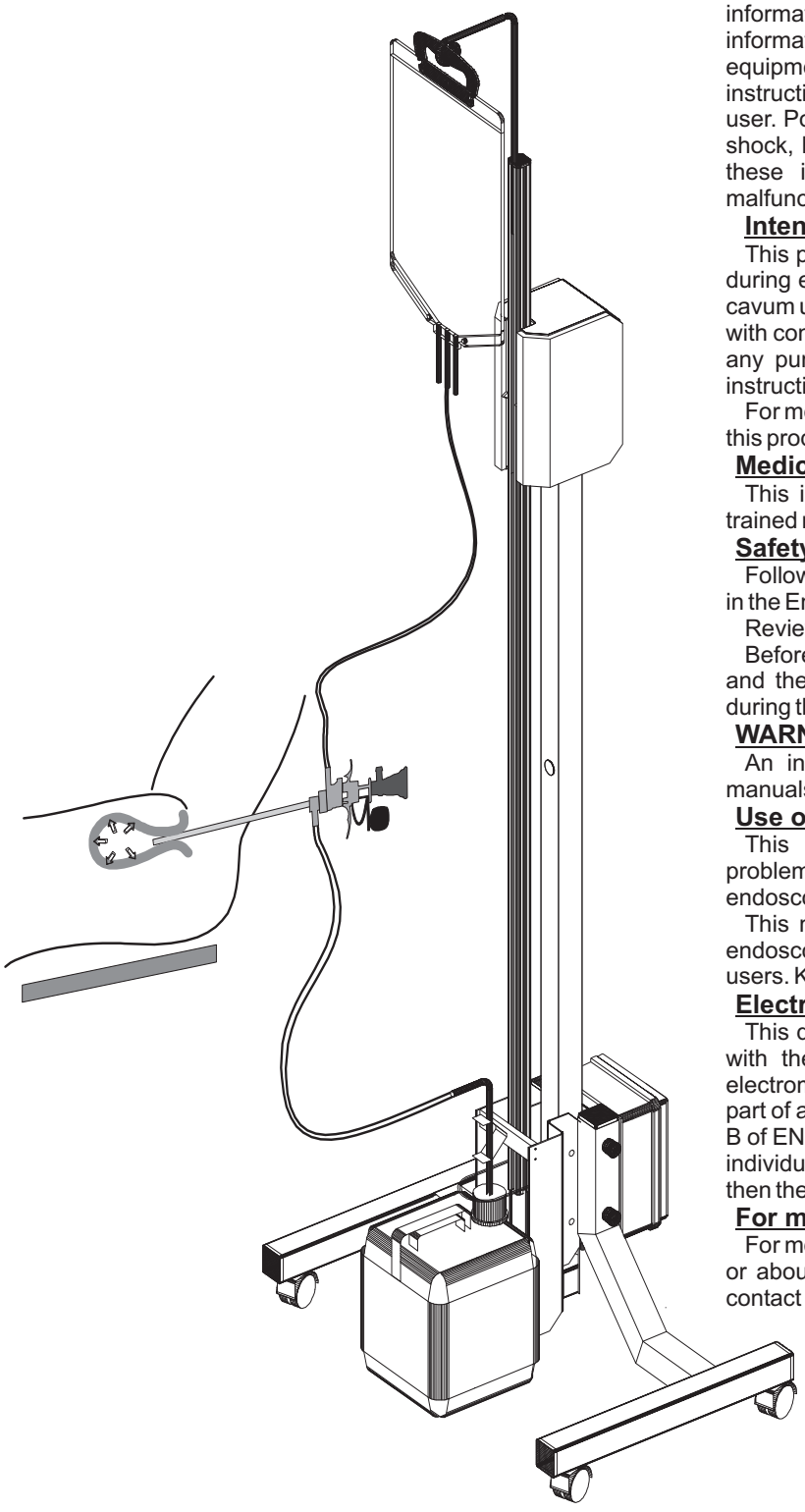
VARIO FLOW

VA 3000 D

Technical description



Only physicians and medical staff who are thoroughly trained in performing the procedure described in this manual should use the instruments in this set. Before performing the procedure, it is essential to read and thoroughly understand all of the information contained in this manual as well as all of the information contained in the manuals accompanying additional equipment used in the procedure. Failure to follow these instructions may result in injuries to both the patient and the user. Potential injuries include perforation, electrical burns and shock, hemorrhage, infection, explosion, etc. Failure to follow these instructions may also result in damage to and/or malfunction of the instrument.

Intended use

This product was designed for the infusion of irrigating liquid during endoscopic procedures. It is mainly used to distend the cavum uteri by means of liquids of low viscosity for hysteroscopy with continuous flow hysteroscopes. Do not use this product for any purpose other than for the procedure described in this instruction manual.

For more information regarding the application and safe use of this product,refer to the Endoscopy System Guide.

Medical use

This instrument is to be used only in a medical facility by trained medical personnel.

Safety advisory.

Follow all warnings and cautions contained in this manual and in the Endoscopy System Guide.

Review all instruction manuals thoroughly.

Before use, review this manual, the Endoscopy System guide, and the manuals for all other equipment which will be used during the procedure.

WARNING!

An insufficient understanding of the information in these manuals can result in serious injury or equipment damage.

Use of this manual.

This manual contains valuable specification, care, and problem solving information which will help you use the endoscope safely and effectively.

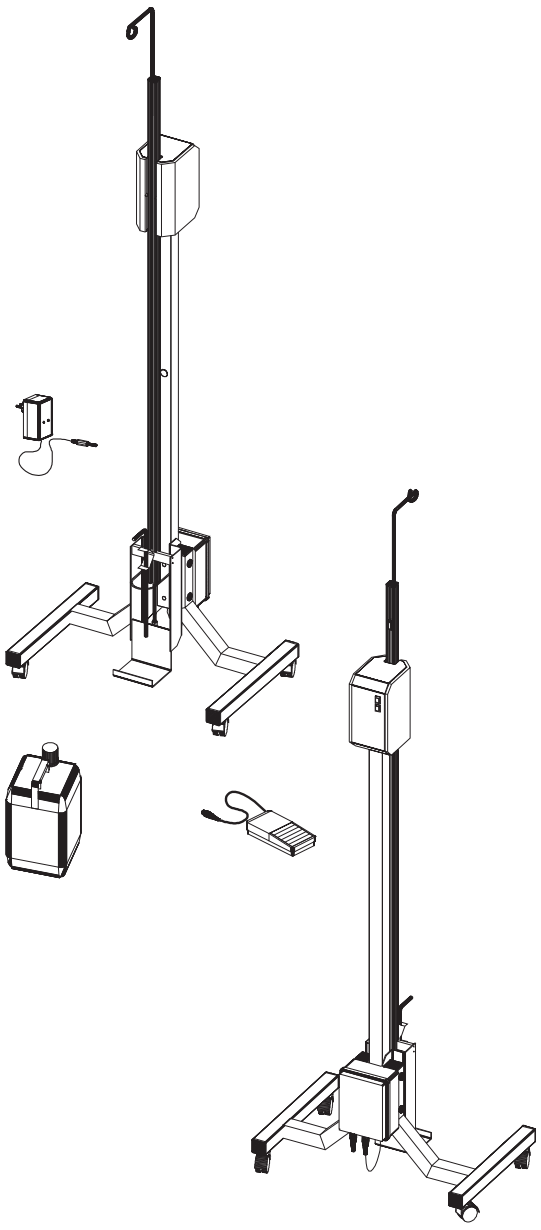
This manual can be a useful training aid for new users of endoscopic equipment and is a good reference for experienced users. Keep it in a safe, accessible location.

Electromagnetic Compatibility

This device and its compatible ancillary equipment complies with the requirements of Directive 89/336/EEC concerning electromagnetic compatibility. When this device is used as a part of an endoscopic system, the system will comply with class B of EN 55011 if all electrical devices within this system comply individually with class B. If one device complies with class A only, then the system will comply with class A.

For more information.

For more information about materials described in this manual or about operating or safely using the equipment in this set, contact your nearest representative.



Technical data

Dimensions

height	min. 1850 mm max. 3000 mm
width	600 mm
depth	350 mm
Weight	20 kg
Carrying capacity	5 kg
Base diameter	600 mm
for Water bag max.	5000 ml
Battery	12 V - 7.2 Ah
Max. load	5000 g
Fuse	T5A

Safety

Protection class	IP 25
EMC test	EN-60601-2

Operating conditions

temperature	10 - 40oC
relative humidity	30 - 75%

Storage and transport conditions

temperature	-40 - +70oC
relative humidity	10 - 100%

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Functional design

Course of Irrigating Liquid

A water bag containing an irrigating liquid of low viscosity is hanged on the bag holder. A tube connects the water bag and the endoscope's supply stopcock. The endoscope's discharge tube leads to a receptacle tube which other end is placed to the bottom of the receptacle.

Continuous Flow System

The automatic continuous flow system "VARIO-FLOW" produces a continuous irrigation flow from the water bag through the endoscope into the operating field and out again through the endoscope into a receptacle. In this way both a continuous distention of the operating field and clear visibility by constant irrigation is attained.

Warning

The system is designed for use of flexible water bags or glass containers with sufficient air inlet.

Pressure Control

The position of the container holding the distention liquid on the Vario Flow rod above the examination area, determines the weight component of the mechanical energy of the liquid flow. Physiological or operative parameters require linear fine tuning, which is achieved by regulating the difference between the height of the container and the operative area.

Physiological needs require different pressures which depends from the operative area

Operating field	mm Hg	mm H2O
Elbow joint	80 - 150	1088 - 2040
Knee joint	35 - 90	476 - 1224
Shoulder joint	80 - 150	1088 - 2040
Wrist joint	30 - 80	408 - 1088
Uterus	75 - 110	1020 - 1496

1mm Hg = 13.6 mm H2O

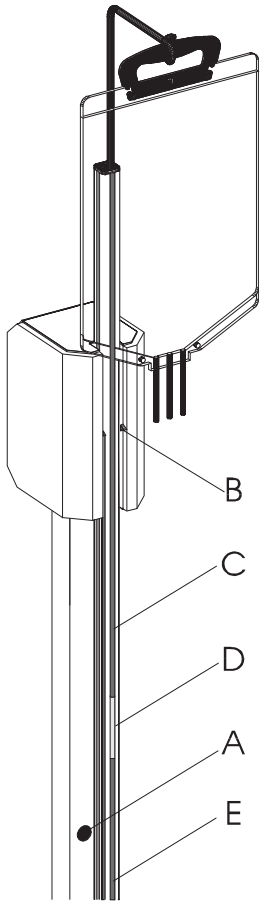
The energy of the liquid flow in the operative area differs from the theoretical value caused by the height above the operative area by diminuing his value caused by resistance of the tubing and type of the endoscope (8mm and 6mm).

Marks

A - Operative area mark -On the support rod there is a mark for adjusting the height of the operating area. To reach good conditions for achieving the continuous flow through the endoscope it is necessary to lift or lower the operating area to the level of the mark.

B - Working area mark - Marks on the front side of the motor casing determine the position of the lifting rod and simultaneously the energy of the distention liquid in the system.

According to the different operating areas it is necessary to adjust the marks for the physiological, limit and dangerous areas on the lifting rod. Adjustment



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is achieved by placing the appropriate measurement belt on the lifting rod designed for the specific operating field. The measurement belt is divided into three fields:

C - Physiological field (green) - determines the values of pressure for diagnostic and operative work where the distention pressures does not exceed the recommended values for the specific operating area.

D - Limit field (yellow) - determines the upper limit values of distention pressure for the specific operating area

E - Dangerous field - determines the values over the upper limits of the distension pressure for timely limited work

Training.

Only thoroughly trained extensively experienced, highly skilled endoscopic surgeons familiar with the endoscopic procedure described in this manual can safely perform the procedure. Inadequately trained, inexperienced, or unskilled surgeons unfamiliar with endoscopy or surgeons who use incorrect instruments risk perforating, electrically burning and shocking, hemorrhaging, infecting, or causing explosions within the patient.

Explosion Hazard.

Install and operate this instrument apart from the anaesthetic gas zone of risk.

Water Intoxication

During prolonged procedures, the combination of open blood vessels and certain pressure conditions can cause water to infiltrate the circulation system (creating a water intoxication condition called TUR- or fluid overload-syndrome). Water intoxication presents a lethal hazard to the patient.

Anaphylactic Shock.

When a dextran solution is used as dilation medium for a patient who is hypersensitive to dextran, there is a dangerous risk of the patient lapsing into anaphylactic shock. Before beginning the procedure, prepare for potential emergencies.

Decontamination

Properly reprocess all equipment before firs and each subsequent use following the instructions in this manual and in the Endoscopy System Guide. Improper reprocessing can cause patient infection.

Use

Before use

Make sure that the instrument has been properly reprocessed, inspected, and tested.

Functional inspection

Water bag

Suspend a water bag containing a sterile irrigating liquid (not included) on the water bag hook

Warning

Maximum load for the instrument is 5 kg or 5 l distention liquid

Tube set - inlet

Assemble the tube set (not included) an insert the cannulas into the water bag's connectors. Connect the Luer-lock-adapter to the supply stopcock of the continuous flow endoscope.

Tube set - outlet

Assemble the outlet tube set. Connect the Luer-lock-adapter to the discharge stopcock of the continuous flow endoscope. Connect the free tube end section on the receptacle tube and place the receptacle tube through the tube holder to the bottom of the receptacle.

Caution

Do not use any connectors that shrink or minimize the free space of the tubing

Deaerate Tube System

Open all tube clamps and the endoscope's supply stopcock. Now the gravity pressure forces the irrigating liquid out of the bag and through the tube to the endoscope. The irrigating liquid must issue in a constant jet from the distal end of the endoscope's inner sheath.

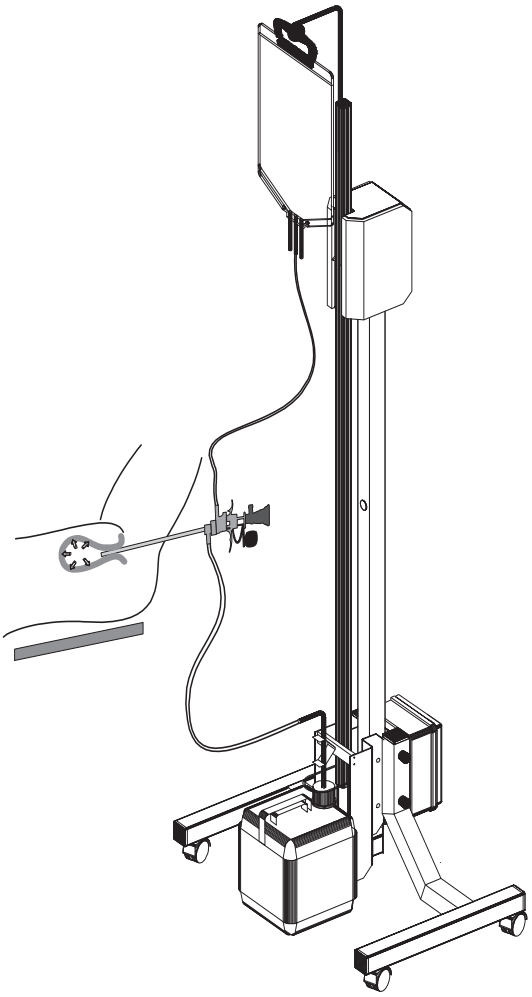
Let the irrigating liquid flow until all air bubbles have disappeared from the tube system.

Finishing Functional inspection

Close the endoscopes supply stopcock

Warning

For the appropriate function of the system follow the marks on the instrument



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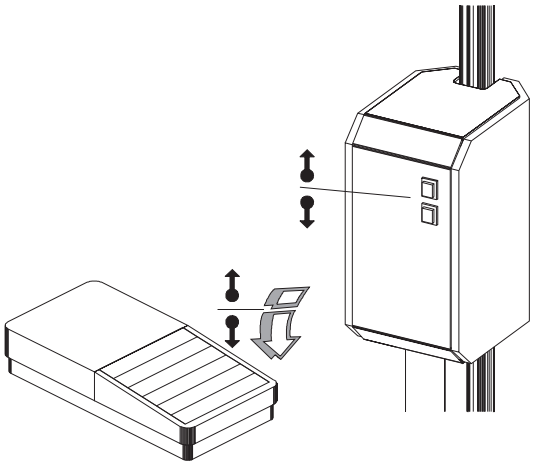
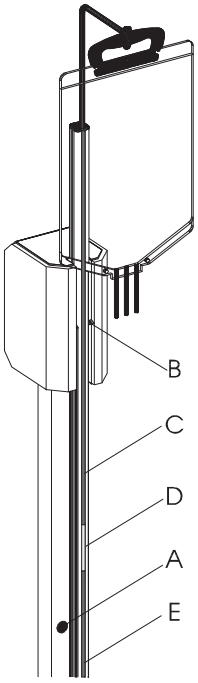




The device

Pressure control

By means of the keys on the motor casing or foot switch lift the water bag to the 4/5 of the green field on the lifting rod.

By pressing the upper key (red) the lifting rod is rising, by pressing the lower key (black) the lifting rod is descending. The lifting rod rises and descends until the key is pressed and the end-switches are released.

Parallel to the keys on the motor-casing operates the foot-switch what allows his alternative use. The foot-switch works in two steps. By pressing the pedal with a minor force to the first knick the lifting rod rises, pressing the pedal with a major force to the second knick the lifting rod descends.

Ascending and descending of the lifting rod is protected by two limit-switches which stop the mechanism when the lifting rod reaches one of the end positions.

Warning

Check that the appropriate measurement belt designed for the specific operating field is placed on the lifting rod.

Procedure

Setting the operating field level

For succesful functioning of the instrument it is necessary to adjust the height of the operating field to the level of the mark (A) on the stand of the lifting mechanism. This adjustment simultaneously adjusts also the marks on the lifting rod and gives enough height difference for the outlet part of the continuous flow system.

Setting the distension liquid flow

Lift the bag with distension liquit to the 4/5 height of the green field on the lifting rod.

Introduce endoscope

Open the stopcocks of the endoscope.

Introduce the endoscope into the operating field.

Refer to instructions of the endoscope.

Adjust the pressure

By pressing the keys on the motor casing or footswitch the pressure can be adjusted during the procedure

Replace the water bag

Close the tubing clamps. Lower the lifting rod and replace the empty water bag with a new one. Lift the lifting rod to the prior position. Open the tubing clamps.

Replace receptacle

Close the tubing clamps. Lift the receptacle tube out from the receptacle. Release the receptacle holder. Replace the full receptacle with an empty one. Fasten the receptacle and lower the receptacle tube to the bottom of the receptacle.

After use

End the procedure

Remove the endoscope. Close all stopcocks.

Lower the water bag

Lower the lifting rod with the water bag by pressing tke lower key on the motor casing or firmly press the foot-switch.

Tubing set

Immediately after use remove the tubing from the instruments. Dispose the tubings. Do not reuse!

Reprocess the receptacle tube.

Reprocessing

Bring the equipment to the reprocessing area.

Reprocess all equipment following the instructions in this manual and in the Endoscopy System Guide.

Warning

Properly reprocess all equipment before first and each subsequent use following the instructions in this manual and in the Endoscopy System Guide. Improper reprocessing can cause patient infection.

Observe the following instrument specific instructions.

Cleaning

Using a soft cloth, remove all dust and soilings.

Use a damp cloth to remove hard to-clean soilings.

Caution

Never immerse unit in liquids.

Wipe disinfection

Wipe the unit with a cloth that has been dampened with 70% ethanol solution.

Sterilization

The unit is not sterilizable.

Maintenance

The materials for the instrument are carefully selected for reducing the maintenance to the minimum.

Refilling the battery

Battery

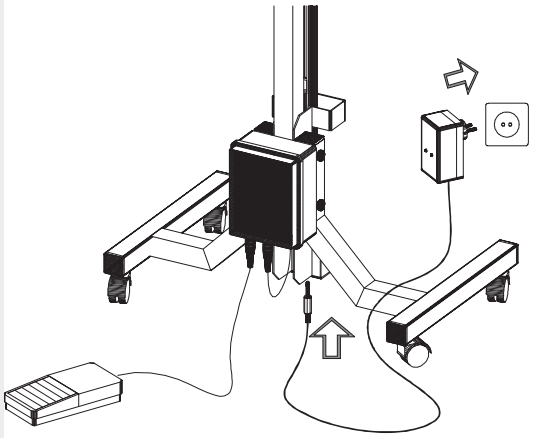
The instrument is equipped with a sealed lead battery 12 V/ 6.5(7.2) Ah. A full capacity of the battery is sufficent for an 1.5 hour continuous work. A total discharge of the battery can cause a not recoverable damage of the battery. Charging of the battery once a week is recommended depending on the frequency of the procedures. A damaged battery must be replaced with a new one (VA 3503).

Battery charger

The battery can be recharged without surveillance with an electronical regulated battery charger. (VA 3504).

Place the battery charger into the 220 V/ 50 Hz mains supply.

Connect the two pin connector into the socket on the bottom of the energy box. The green LED lights on the battery charger casing. When the battery is refilled the green LED turns off. In case of damaged or warned out



battery after a longer period of charging the LED does not turn off but lights less.

Pull out the two pin connector. Remove the battery charger from the mains supply.

The battery charger is designet for use in dry and airy place.

Caution

Charging the battery disconnects for safety reasons the power source from the instrument. The functions of the instrument are in the period of charging the battery not available. Functions are restored by removing the two pin connector from the socket on the energy box.

Inspection

Visual and functional inspection

After each use, visually inspect and functionally test the device. In the case of defects or irregularities, contact the nearest Service center.

Quarterly inspection

A hospital technician must inspect this device every 3 months.

The following tests are part of this inspection:

- Lifting mechanism test

Test record

The results of the quarterly inspection have to be recorded. For this purpose, make a copy of the sample from the appendix A. Collect the trest records in a separate file and keep them together with this instruction manual close to the unit.

Repair

Contact your representative or an authorized service for repair and warranty information.