Operating Manual Ref. Nr.: BAHRT-EN-1201 Version: ECO15-2188/2015-12-01

UniTip High Resolution Catheter

For application in the field of

Gastroenterology

Kxxxx-xx-xxxx
Maximum Period of Application:
24 hours

UNISENSOR

Unisensor AG
Bahnstrasse 12a
8544 Attikon
Switzerland

Tel. +41 52 337 37 01
Fax +41 52 337 37 51
Email: info@unisensor.ch
Web: www.unisensor.ch

CE
0344

This Operating Manual is delivered with UniTip HR Catheter.

This catheter is supplied in a non sterile condition! See Preparation / Reprocessing instructions for recommended cleaning, disinfection and sterilization procedures.

Contents

1 Introduction

UniTip HR Catheters are delicate and precise devices. To ensure a long life the catheter must be handled carefully. The catheter may not be used for purposes other than the one it was designed for. The user must read the operating manual carefully before initial use. Only careful attention to the following instructions assures safe and reliable function.

The operating manual contains important advice on how to use the UniTip HR Catheters safely and properly. The operating manual helps to avoid user mistakes and reduces the risk for the patient. Therefore, this operating manual should always be stored at a place, where it is available for the user.

It is the user's responsibility to read the contents of this operating manual thoroughly and, in cases of doubt, to contact the supplier or Unisensor.

The following symbols are used:

 **Order Number**	 **Manufacturer**	 **Attention**
 **Forbidden**	 **Immediately**	 **Pressure**
 **Temperature Range**	 **Max. Temperature**	 **Keep Dry**
 **Keep from Sunlight**	 **Time Indication**	 **Ethylene Oxide Sterilization**
 **Wipe Dry with Soft Tissue**	 **Clean with Soft Tissue**	 **Use Gloves**
 **Syringe**	 **Tap Water**	 **Distilled / Distilled Sterile Water**

Model Variations:

UniTip HR Catheters are manufactured in many model variations. These variations include different combinations of sensors, features and distances. Therefore, some parts of this operating manual may not apply to your specific device.

2 General Safety Precautions

For proper function of UniTip HR Catheters, they must be connected, operated, maintained, and repaired as described in this operating manual. Repairs should only be performed by Unisensor or by a company that is comissioned and authorized by Unisensor.

Please contact your sales partner or Unisensor, if there are any repairs necessary or if there are any questions relating to the UniTip HR Catheter. The manufacturer does not assume any liability or warranty for damages due to improper repair or changes of the UniTip HR Catheter caused by unauthorized persons.

2.1 Safety Instructions

In case of any doubts concerning the effectiveness of the disinfection / sterilization with regard to infectious diseases (e.g. Creutzfeldt-Jakob, HIV or their like) the catheter must be destroyed after use.

Only persons having recognized qualifications, authorizing them to perform the examination, may use the device.

UniTip HR Catheters are supplied non-sterile, therefore, a proper cleaning / disinfection / sterilization is required prior to use.

The USER is responsible for proper cleaning / disinfection / sterilization of the UniTip HR Catheter. Additionally, please pay attention to the laws / regulations / guidelines of your country as well as to the hygienic instructions of your hospital.

UniTip HR Catheters may only be connected to medical devices with sufficient electrical isolation (type CF and BF equipment complying with EN IEC 60601-1).

The catheter must be cleaned immediately after the application!

UniTip HR Catheters are thermosensitive devices that can only be exposed to low temperature procedures (max. Temperature 70℃ / 160℉).

To avoid the ingress of liquids, the catheter must be checked for signs of damage prior to use.

Do not squeeze the sensors.

Do not clean the catheter with tools like stiff bristled brushes, needles or wires.

Do not cut, crease, knot, fold, kink, stretch or crush the catheter (with forceps). Never bend the catheter to less than 5 cm / 2 Inch in diameter.

Do not expose to alcohol, wound benzene, cresols, phenols, acetone, hydrogen peroxide (H_2O_2) at higher concentrations than 15%, mercury compounds, chlorides, sodium hypochlorites (Bleach), xylene, trichloroethylene, Freon, Bomix or any other liquid that leads to softening, swelling, or embrittling of rubber, silicone or other plastics.

Do not use ultrasonic cleaners.

Do not use autoclaves or gamma irradiation.

Do not use the measuring signals for diagnosis during the operation of HF-devices and similar devices.

Do not perform MRI examinations on patients with inserted UniTip HR Catheters.

Do not use electrocautery and defibrillation equipment on patients with inserted UniTip HR Catheters.

Never use a catheter where pieces have separated, with cuts, cracks, deformations or other damages of the surface.

Label must not be removed from catheters!

2.2 Conditions of Warranty

Only persons having recognized qualifications, authorizing them to perform the examination, may use the device.

All catheters are subject to a stringent quality assurance procedure. The warranty covers damage on material and deviations from the specifications, providing this is not attributable to improper handling, poor or incorrect cleaning. In particular, the guarantee excludes any damage that may result from mechanical influence on the sensor, catheter or the connector due to negligence on the part of the user.
The manufacturer does not assume any liability or warranty for damages due to improper repair or changes of the UniTip HR Catheter caused by unauthorized persons.

Warranty period: 2 years from the date of shipment or 200 uses (whichever comes first) with the exception of prolonged manometry measurements **up to 24h** for which the warranty period is reduced to 2 years from the date of shipment or 20 uses (whichever comes first).

2.3 Disposal

DO NOT dispose with normal trash. Consult your local waste management authority for proper disposal procedures or return the catheter (cleaned / disinfected / sterilized) to your distributor or directly to Unisensor.

3 Initial Commissioning without Patient

We suggest that you check the whole measuring system a few days prior to the first scheduled examination.

All parts (UniTip HR Catheter, connection cable, and the recorder / measurement device) must be checked together, in order to ensure the correct function of the whole measurement chain.

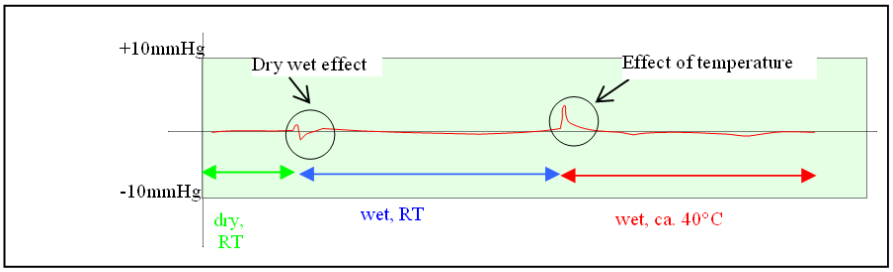
3.1 Pressure Sensors

3.1.1 Zero-Point Adjustment

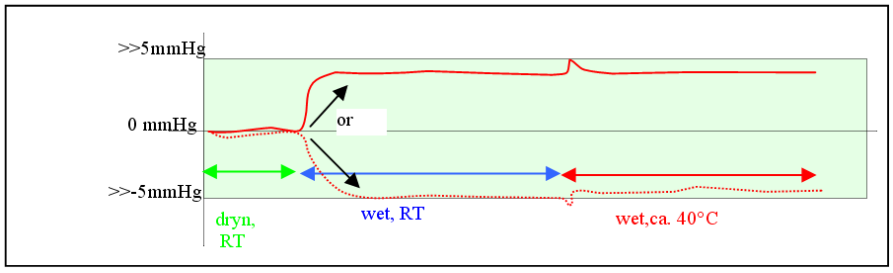
For the zero-point adjustment the pressure sensors should be immersed in distilled water for at least 2 minutes (max. depth of the water is 1cm = 1mbar = 0.75mmHg = 0.1kPa).
The most frequent reason for incorrect measurements is a wrong zero-point adjustment of the sensors.

3.1.2 'Dry/Wet-Effect' and Influence of Temperature

The zero point of properly cleaned pressure sensors does not change significantly, if a change of the medium air-water takes place.



Typical curve of a clean sensor [Dry 20 ℃ / 68 ℉ → Wet 20 ℃ / 68 ℉ → Wet 40 ℃ / 104 ℉]



Typical curve of an unclean and crusted sensor

Explanation:
Even if the catheter seems to be clean, a coating of protein compounds that is only visible with a microscope can be on it. This coating can disturb the measurement. While it is relatively hard under dry conditions, it relaxes over the pressure-sensitive zone ('measurement window') under wet conditions and this relaxation leads to a zero-point drift in any direction. This coating can only be removed with a special process.

Send your cleaned and disinfected / sterilized UniTip HR Catheter to your sales partner or Unisensor. Unisensor provides a thorough cleaning of the catheter and control of the specifications under favourable conditions.

Protein residues are fixed by disinfection solutions that use an aldehyde basis. Therefore always: **CLEAN before DISINFECTION!**

3.1.3 Sensitivity Test

1. Connect the UniTip HR Catheter to the measuring device.
2. As soon as the sensor is located approximately 1cm under the surface of the water, the zero-point can be set on the monitor.
3. Immerse the sensor 20cm deep in a flask with water (column of water, mark accordingly).
4. The pressure indicated on the monitor should now increase to 20mbar = 15mmHg = 2kPa.

In case of deviations greater than ±5% = ±1cmWC = ±0.75mmHg = ±0.1kPa you will have to adjust the sensitivity of the related channel on the monitor. Please follow the instructions of the operating manual from the manufacturer of the monitor.

The pressure sensors are adjusted to an accuracy of the sensitivity of ±2% at 100mmHg.

Dry soiling covering the sensor can lead to a lower sensitivity.

Are the results of the measurement not plausible?
If you have any doubts about the performance characteristics, please send the UniTip HR Catheter with a description of the failure to your sales partner or to Unisensor for a technical check.

3.2 Electrodes for Impedance Measurement

Test of the Electrodes:

Please follow the instructions of the manufacturer of your measurement device.

4 Preparations / Reprocessing

UniTip HR Catheters must be prepared / reprocessed prior to every application. Effective cleaning and disinfection is an indispensable requirement for effective sterilization of UniTip HR Catheters.

Important note: The USER is responsible for cleaning / disinfection / sterilization of the UniTip HR Catheter. Take care that only proven procedures and solutions are used for cleaning / disinfection / sterilization, and that the required parameters are met in every cycle. Additionally, please pay attention to the laws / regulations / guidelines of your country as well as the hygienic instructions of your hospital.

The catheter must be cleaned immediately after the application!

UniTip HR Catheters are thermosensitive products that may only be exposed to low temperature procedures (max. Temperature 70°C / 160°F).

For cleaning and disinfection solutions choose whenever possible a higher concentration according to the manufacturer's instruction for use to shorten the immersion time.
Choose the minimum temperature according to the manufacturer's instruction for use.

With every reprocessing of UniTip HR Catheters the storage box has to be reprocessed adequately too.

Under the condition that the connector's cap is completely closed (no gap between cap and connector) and the o-ring is in a good state/shape (needs to be regularly checked), the UniTip HR Catheters that are labelled IPx5 / IPx7 can be immersed into water for up to 45 minutes.
However, we recommend that the connector shall not be immersed into solutions during manual reprocessing as it is not necessary and it increases the risk of possible defects due to not completely closed connector's cap, bad/old o-ring, etc.

For easy to use instructions please download the UniTip wall-chart for the manual cleaning and disinfection procedures.
This document is not part of the device's labelling. The latest version of this document is available on our website (www.unisensor.ch/en/cleaning). Please check it with the appropriate frequency to be kept informed on the latest updates.

4.1 Validated Procedures

4.1.1 High Level Disinfection (except FDA)

Cleaning:
Aniosyme DD1, Laboratoire ANIOS (concentration: 0.5% | immersion time: 5min)

Disinfection:
Anioxyde 1000, Laboratoire ANIOS (undiluted | immersion time: 30min)

4.1.2 High Level Disinfection

Cleaning:
Revital-Ox 2X Concentrate Enzymatic Detergent, STERIS Corporation (concentration: 0.4% | immersion time: 5min)

Disinfection:
Revital-Ox Resert XL HLD, STERIS Corporation (undiluted | immersion time: 8min)

4.1.3 EO/ETO Sterilization

Cleaning:
Deconex 36 Intensiv®, Borer Chemie (immersion time: 30min)

Disinfection:
Cidex®, Johnson&Johnson (immersion time: 45min)

Sterilization:
EO/ETO (45°C cold-cycle)

Further information regarding material compatibility for cleaning and disinfection agents can be found on Unisensor's website.
Unisensor does not guarantee the effectiveness of these procedures. This document is not part of the device's labelling. The latest version of this document is available on our website (www.unisensor.ch/en/cleaning). Please check it with the appropriate frequency to be kept informed on the latest updates.

4.2 Prohibited Cleaning and Disinfection Agents

The following solutions and liquids are prohibited (lead to defects, damage the materials):

All solutions and liquids that lead to softening, swelling, or embrittling of rubber, silicone or other plastics are strictly forbidden.

Do not expose to alcohol, wound benzene, cresols, phenols, acetone, hydrogen peroxide (H_2O_2) at higher concentrations than 15%, mercury compounds, chlorides, sodium hypochlorite (Bleach), xylenes, trichloroethylenes, Freon, or Bomix.

Do not use a combined cleaning / disinfection solution that fixates protein residues on the catheter.

Do not use ultrasonic cleaners.

Do not clean with tools like stiff bristled brushes, needles or wires.

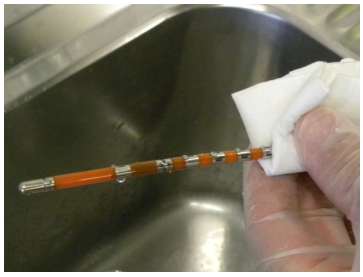
4.3 Cleaning (Manual Procedure)

Clean only the outer part of the connectors with a tissue moistened with cleaning solution.

The UniTip HR Catheter should be immersed into the cleaning solution for the minimal time period that is recommended by the manufacturer, but not longer than 45 minutes. The lumen must be rinsed thoroughly using a 10-ml syringe at least three times at the

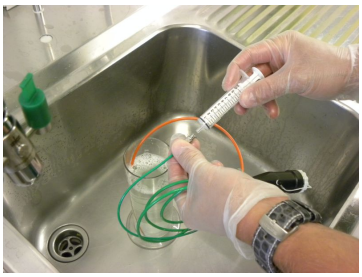
beginning and the end.

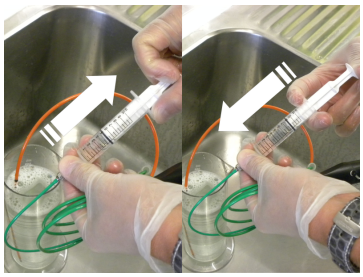
Step 1



The catheter must be cleaned immediately after the application! Rinse the catheter with warm tap water for at least 1 minute. The lumen must also be rinsed with warm tap water using a 10-ml syringe at least three times.
Wipe the catheter carefully with a soft gauze or tissue.

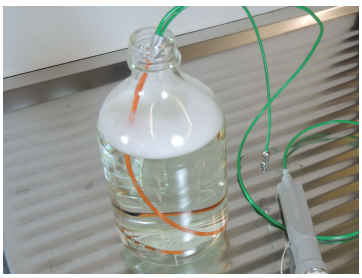
Step 2





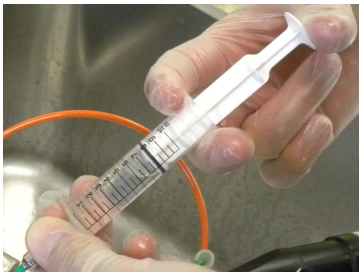
At the beginning and the end of the immersion time the lumen must be rinsed through at least three times with cleaning solution using a 10-ml syringe.

Step 3



The catheter should be immersed into the cleaning solution for the minimal time period that is recommended by the manufacturer, but not longer than 45 minutes.

Step 4



After the immersing time the catheter must be washed again with distilled water and the lumen must be rinsed through with distilled water using a 10-ml syringe at least three times (the rinsing liquid must be clean while it flows out).
Then the catheter, including sensors, should be wiped dry carefully with a soft tissue.

4.4 Disinfection (Manual Procedure)

The disinfection must be made after the cleaning. Especially if a disinfectant is used which fixates protein residues.

Disinfection should only be made with solutions which, in principle, are considered to be effective.
Only freshly prepared solutions should be used. Their respective concentrations must comply with the manufacturer's instructions.

The UniTip HR Catheter must be immersed, apart from the connector, into the disinfection solution according to the immersion time specified by the manufacturer.

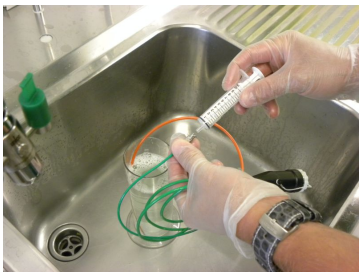
The UniTip HR Catheter must be dried prior to packing and sterilization.

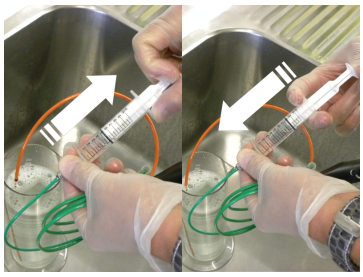
After disinfection wipe the catheter dry with a soft tissue.

The connectors can be cleaned with 70% cleaning alcohol.

The UniTip HR Catheter should be immersed into the disinfection solution for the minimal time period that is recommended, but not longer than 45 minutes.
After the immersing time the catheter must be washed again with distilled sterile water.

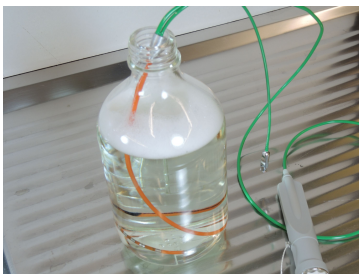
Step 1





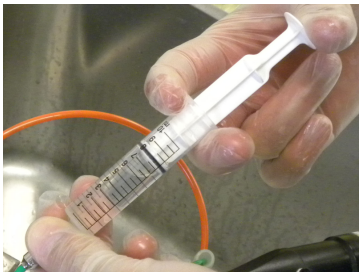
At the beginning and the end of the immersion time the lumen must be rinsed through with disinfection solution using a 10-ml syringe at least three times.

Step 2



The catheter should be immersed into the disinfection solution for the minimal time period that is recommended by the manufacturer, but not longer than 45 minutes.

Step 3

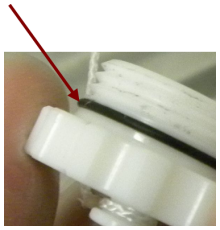


After the immersing time the catheter must be washed again with distilled sterile water and the lumen must be rinsed through with distilled sterile water using a 10-ml syringe at least three times (the rinsing liquid must be clean while it flows out).
Then the catheter, including sensors, should be wiped dry carefully with a soft tissue.

4.5 Cleaning / Disinfection (Mechanical Procedure)

The connector's cap must be completely closed before reprocessing with a mechanical procedure. There must be no gap between the connector's cap and the connector housing!
Failure to do so will result in water ingress and damage of the UniTip HR Catheter.

Before every cleaning the connector's cap has to be examined for defects. Particular attention has to be paid to the o-ring (see Picture).



Should the connector's cap get lost/damaged, the o-ring be defect or missing or should there be a leakage suspected, the connector's cap has to be replaced with the provided replacement cap (see also Chapter 7.5).
Additional replacement caps are available through your sales partner: REF RP-00-1041.

The catheter must not get in contact with any movable parts of the disinfection machine! The movable parts may cause mechanical damage to the catheter.

Disinfection should only be carried out with solutions which, in principle, are considered to be effective.
Only freshly prepared solutions should be used. Their respective concentrations must comply with the manufacturer's instructions.

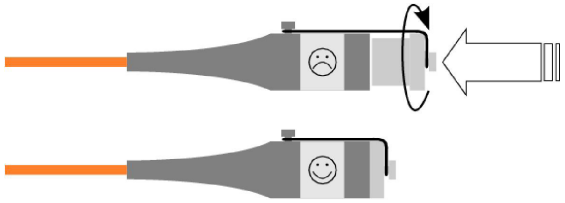
Since some automated reprocessors cannot generate the pressure required to force fluid through the lumen, manual cleaning & disinfection is the safest method to effectively reprocess this area of a lumened device.
After manual cleaning and disinfection of the lumen, mechanical reprocessing of the catheter is subsequently possible.

Catheters with lumen cannot be reprocessed in a reprocessing machine without an appropriate interface for lumen reprocessing!
The lumen must be connected to an appropriate lumen interface for mechanical reprocessing.

Only disinfectants, which do not harm the material of the UniTip HR Catheter, should be used for disinfection purposes (see also Chapters 4.1 and 4.2). The applied method should be conducted with a low temperature cycle (max. 70 °C / 160 °F).

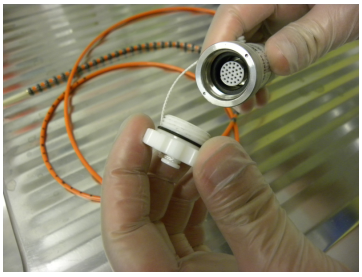
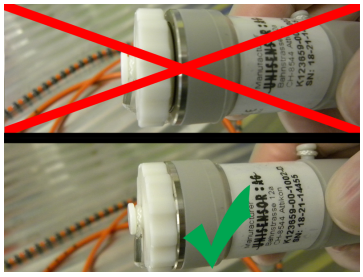
No thermal disinfection!

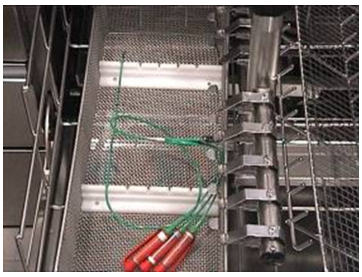
For further information see also the instructions for use of the manufacturer of the disinfection machine.



Only UniTip HR Catheters with an original protective cap at the connector are permitted to be cleaned and disinfected using the mechanical method. Please close the connector's cap and put the catheter into the machine. Place the catheter into the machine safe from movable parts in order to prevent the catheter from being damaged during the procedure!

After the cleaning / disinfection the catheter, including the connector, has to be wiped carefully dry. The thread of the connector must also be wiped dry.

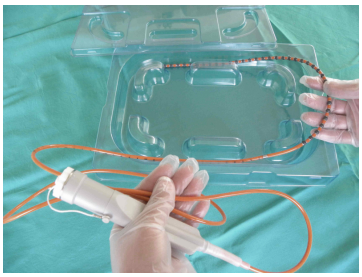
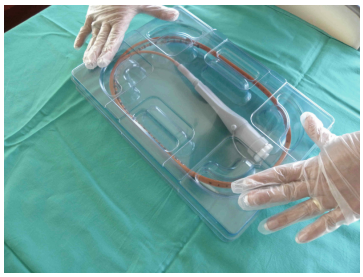
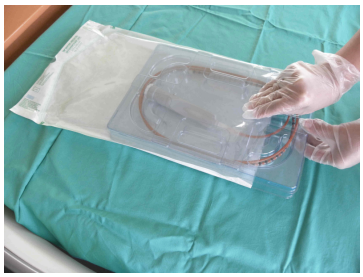





4.6 Sterilization

4.6.1 Allowed Sterilization Method

UniTip HR Catheters must be cleaned and disinfected prior to sterilization.

Prior to sterilization, the catheters must be placed in a suitable sterilization pack (one-way sterilization packing or an adequate sterilization container for the applied sterilization method).

Ethylene oxide (EO)-sterilization is allowed (up to maximum temperature of 70 °C / 160 °F).
High temperatures reduce the life time of the catheter. Unisensor recommends gas sterilization with a 'cold cycle', this means at max. 50 °C / 122 °F!

Sufficient de-gassing is necessary to minimize the EO-residues in the sterilized catheter.

For further information see also the instructions for use of the manufacturer of the sterilization machine.

4.6.2 Prohibited Sterilization Methods

Steam sterilization and other methods of sterilization with a temperature above 70 °C / 160 °F are not permitted. Do not use any autoclave or (gamma) irradiation, and no low-temperature plasma sterilization STERRAD® (due to high hydrogen peroxide (H_2O_2) concentration).

5 Application on Patients

5.1 Intended Use (Indications for Use)

UniTip HR Catheters are intended for performing static and dynamic pressure and impedance measurement in the gastrointestinal tract. Impedance rings are used to assess bolus transit dynamics during swallow challenge testing by detecting the direction and the transition time of the fluid or food bolus in the oesophagus. It is for example possible to detect a reflux from the stomach into the oesophagus through the impedance rings. Impedance rings make use of the natural conductivity of the fluid or food bolus for this purpose.

UniTip HR Catheters are intended only for connection to a suitable measurement / recording system.

5.2 Contraindications

The UniTip HR Catheter is contraindicated in patients with the following conditions:

- Near complete obstruction
- Severe coagulopathy
- Cardiac conditions in which vagal stimulation is poorly tolerated
- Oesophageal varices
- Nasal septum deviation

5.3 Warnings and Safety Precautions

Do not use the measuring signals for diagnosis during the operation of HF-devices and similar devices.

Do not perform MRI examinations on patients with inserted UniTip HR Catheters.

Do not use electrocautery and defibrillation equipment on patients with inserted UniTip HR Catheters.

The application of the catheter may lead to irritation, injuries and pain to nose, pharynx or oesophagus. Additionally, it may cause epistaxis, nausea, vomitus (risk of aspiration!), the latter particularly for non fasting patients.

5.4 Application

Functionally test the whole measurement chain according to Chapter 3 a few days prior to the application.
Preparation / reprocessing must be carried out according to Chapter 4 prior to the application.

5.4.1 Pressure Sensors

Fill a basin with distilled sterile water and place it close to the patient so that the sensors can be moistened and the 'zero-point' adjusted before the catheter is inserted.

Remove the disinfected / sterilized catheter from the packing, connect it to the measuring device, and lay it into the prepared basin with distilled sterile water.
The pressure sensors should be covered with approx. 1 cm of water. After a minimum period of about two minutes the zero-point of the pressure sensors should be adjusted according to the operating manual of the measurement device (Sensors are still immersed in the water basin! See also Chapter 3.1). For better evaluation of the measurement, you may write down and compare the value of the zero point directly before the insertion of the catheter and directly after removing the catheter (at the most a few seconds in the dry; see also Chapter 3.1). In case of uncertainties repeat the zero-point adjustment directly before the insertion of the catheter.

Now, the catheter can be inserted. The measurement signals can be influenced by the drying surface of the sensor during the transfer of the UniTip HR Catheter from the basin of water to the patient.

The catheter must be cleaned immediately after the application and prior to the storage. If you are not able to clean the catheter directly after the application, lay the catheter in a basin filled with water, so that the residues do not dry in prior to cleaning.
Maximum soaking time in water: 4h

5.4.2 Electrodes for Impedance Measurement

The electrodes are measuring an electrical resistance (impedance). The resistance must be very high if the sensor is dry, and must become much lower when any liquid or other conductible medium contacts the two electrodes.

Application of the Electrodes:

Please follow the instructions of the manufacturer of your measurement device.

The electrodes are only intended for impedance measurements. They are NOT approved for electrical stimulation!

5.4.3 Lumen

Rinse the lumen at least three times with clear water using a 10ml-syringe immediately after the application.

The lumen can be flushed with 70% alcohol, followed by forced air drying. But the catheter must not be immersed into alcohol!

Balloons for anorectal applications must be deflated before extraction of the catheter!

The lumen is NOT meant for administration of drugs or other compounds, other than water.

Cleaning of the lumen with a wire is strictly forbidden!

Only the following guide wires can be used with UniTip HR Catheters:

- REF GW00-18-0308 - SINGLE-Use Guide Wire 0.018", length: 500cm (only for lumen L3 and above)
- REF GW00-21-0308 - SINGLE-Use Guide Wire 0.021", length: 500cm (only for lumen L4 and above)
- REF GW00-35-0507 - Hydra Jagwire ST (only for lumen L5 and above)

(available through your sales partner)

Guide wires must have a floppy end on both sides!

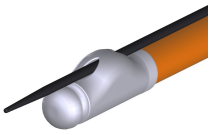
Guide wires must not be cut!
A cut edge could damage the catheter or harm the patient.

Guide wires must not be forced in or out of the lumen!

Application of Guide Wires:

1. Only insert the floppy end of the guide wire into the catheter's guide wire lumen.
2. To avoid lumen damage, if significant resistance is felt while attempting to remove the guide wire while the catheter is *in vivo*, keep the guide wire in the catheter during the study. Remove the catheter with the guide wire still in the lumen, lay the catheter on a table or counter so that it is straight, then gently remove the guide wire from the lumen.
3. Rinse the lumen at least three times with clear water using a 10ml-syringe immediately after removing the guide wire.
4. Dry the lumen by blowing a few syringes of air through the lumen, until no water drops come out of the lumen.

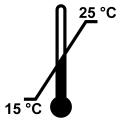
For monorail catheters that are inserted using a guide wire, it is mandatory to remove the guide wire first before the catheter can be extracted!



6 Storage

UniTip HR Catheters should always be stored in the original storage box after cleaning / disinfection / sterilization according to the regulations.

The life time of UniTip HR Catheters depends tremendously on proper handling and proper maintenance.



Store at room temperature (15 °C - 25 °C / 59 °F - 77 °F).

Store in dry conditions.

Do not store in direct sunlight.

7 Checking / Troubleshooting

Are the results of the measurement not plausible?
If you have any doubts about the performance characteristics please send the UniTip HR Catheter with a description of the failure to the sales partner or to Unisensor for a technical check.

The most frequent reason for inaccurate measurement results of the pressure sensors is an incorrect zero-point adjustment.

7.1 Checking as a Matter of Routine

Checking as a matter of routine is described in Chapter 3. These steps are also very useful to start with for troubleshooting and should be applied, if a fault occurred or if there is any suspicion for a fault.

7.2 Recognition of Mechanical Damage (Visual Inspection)

Due to the potential danger of ingress of liquids, the catheter must be inspected for signs of defects before its application and, if necessary the catheter should not be used any more.

- The condition of the tube has to be inspected after every application of the UniTip HR Catheter. Its surface has to be examined closely for cuts, kinks, punctures and knots.
- Leaking lumen can be attributed, for example, to kinked catheter tubes.
- There should be no visible damage at the surface of the steel sensor housing.
- Check the surface of the small grey measurement windows (the pressure-sensitive zone) for signs of tearing. If recognized early, a repair is possible.
- Broken sensor membranes are frequently invisible and do not reveal any leaks in the catheter. If recognized early (Note: sensors with broken membranes show normally no pressure signal), a repair is possible.

7.3 Checking the Cleanliness

- The pressure-sensitive zone of the catheter (small grey area) must be examined for traces of blood, protein or other residues.
- Residues that are not removed completely by means of cleaning affect the functional operation of the sensor and, in dry-up state, can destroy the sensor membrane when the UniTip HR Catheter is inserted.

- If necessary, clean the catheter again according to chapter 4.3. Contamination should never be removed with mechanical tools. Rinse off the catheter after every cleaning.

7.4 Checking the Connectors

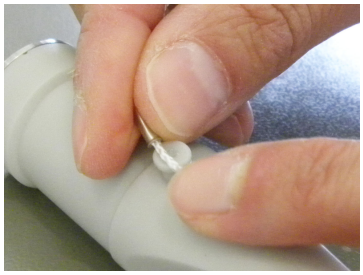
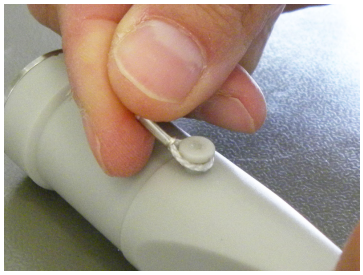
- Regularly check the connector visually for cracks or any other mechanical damages.
- If wetness is observed on the plug casing or the contact pins, the electric contacts may be corroded on the inside of the connector. This could cause leakage current which disturbs the measurement significantly. In case of continued wetness inside the catheter, this leads to a completely broken UniTip HR Catheter.
- Disinfect or sterilize UniTip HR Catheters with signs of wetness in or on the plug-connection and return them to Unisensor for examination.

7.5 Replacement of the Connector's Cap

Should the connector's cap get lost/damaged, the o-ring be defect or missing or should there be a leakage suspected, the connector's cap has to be replaced with the provided replacement cap.

Additional replacement caps are available through your sales partner: REF RP-00-1041.

1. The old connector cap, including the cord, has to be removed.
2. The replacement cap is attached to the connector by pulling the loop at the cord's end over the fixation (see pictures).

8 Materials / Specifications / Performance

The materials that can be in contact with the patient during the application are medical steel, polyurethane, Teflon, Peek®, ceramics and the silicon encapsulation of the sensor that covers the 'measuring windows'.
All the materials needed for the manufacturing of this product are carefully selected and tested according to international ISO standards and applicable regulatory requirements. Therefore, the risk of biological incompatibility is reduced to the possible extent.
UniTip HR Catheters are not manufactured from any natural latex rubber.
Reliable functional operation of the UniTip HR Catheter is only assured if it is applied in a proper manner by suitably trained personnel.
The UniTip HR Catheter is re-usable, provided that the catheter is properly cleaned / disinfected / sterilized (see also Chapter 4).

8.1 Pressure Sensors

Measurement range: -50 to +300 mmHg
Temperature range: 20 °C to 42 °C / 68 °F to 108 °F

8.2 Electrodes for Impedance Measurement

Please check the specifications of the manufacturer of your measurement device.

Resistance between electrode ring and related pin at the connector: $< 30\ \Omega$

8.3 Lumen

Size of lumen (L3-L7): Inside diameter from minimal 0.60mm to maximal 1.00mm.

Maximum allowed pressure: 5 bar

9 Packing for Service and Repair

The catheter must be cleaned / disinfected / sterilized before packing and dispatch! (See also Chapter 4)

Failure report

Please enclose a description of the failure to the catheter.

Packing

Use the original box.

Dispatcher

Please enclose your name, address, telephone- / fax-number with the catheter!

Always send the UniTip HR Catheter by certified mail!