Solar GI Manometry™

User Manual

Laborie

MMS
Medical Measurement Systems

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1.1 Solar GI Measurement System

The Solar GI measurement system was developed by Medical Measurement Systems (MMS) to perform stationary gastrointestinal investigations in hospitals and private clinics.

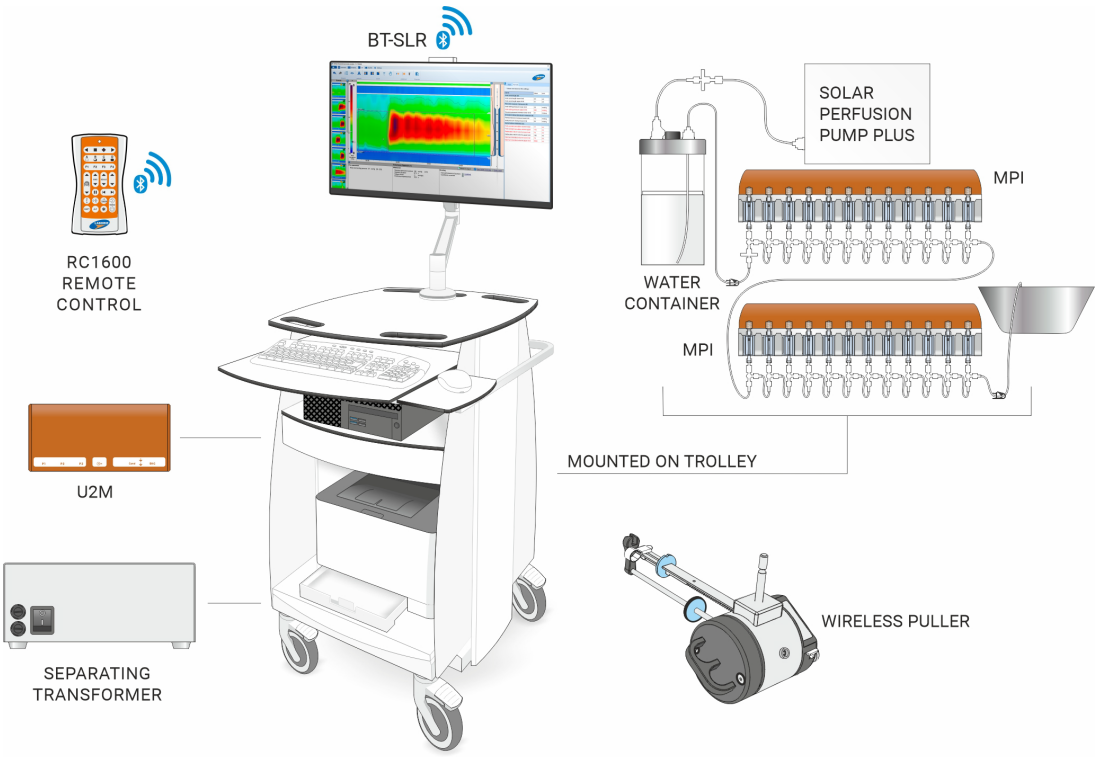


Figure 1.1 Example of a Solar GI trolley configuration[1]

The Solar GI measurement system has a modular setup on a movable Solar trolley or compact pole. The models of the Solar GI system are:

- Solar LGI H_2O, Trolley system (catalogue code G3-6)
- Solar HRM H_2O, 24p, Compact pole system (catalogue code G3-7)
- Solar G3-7 Air, Compact pole system (catalogue code G3-7 Air)
- Solar HRM H_2O, 24p, Trolley system (catalogue code G3-8)
- Solar HRM H_2O, 36p, Trolley system (catalogue code G3-12)
- Solar HRAM H_2O, 24p, Trolley system (catalogue code G3-14)
- Solar HRM Solid State, Trolley system (catalogue code G3-9)
- Solar HRIM Solid State, Trolley system (catalogue code G3-10)
- Solar HRAM Solid State, Trolley system (catalogue code G3-15)

[1] Actual product may vary slightly from image

The Solar GI system is a prescription device to be used only by physicians or individuals who have been trained and authorized by a physician or by a medical institution, under the supervision of a physician. The Solar GI system must be purchased under the supervision of a physician.

⚠ **CAUTION** For U.S. only: Federal law restricts this device to sale by or on the order of a physician.

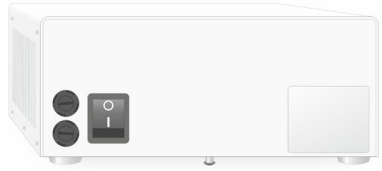
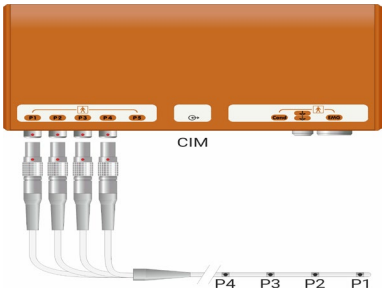
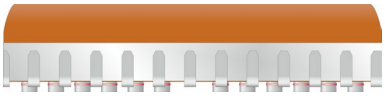
The Solar GI system is used in combination with a computer and the Laborie software program. To run the program, you will need Windows 7 Professional Edition (32 or 64 bit) or Windows 8 (8.1) Professional (32 or 64 bit), or Windows 10 Professional Edition (64 bit).[2]

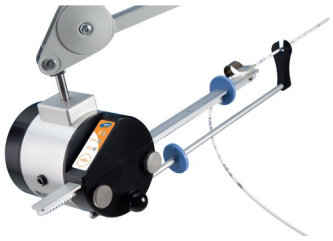
The Solar GI system can be supplied with trolley, pole or as standalone system. The Solar GI is a modular system which allows the users to design a system meeting their requirements. Laborie offers custom made modules for measuring pressures, EMG, swallow and respiration. Software modules are available for different types of investigations and offer different levels of functionality.

In the *Solar GI New Service & Installation Manual* (document code: MAN-00046) you will find a description of all Solar GI modules. The most common modules are described in the table on the next page.

After receiving new Solar GI manuals, always keep the old manuals as supplied with your Solar GI system. Descriptions and images may be different because of Solar GI hardware and software changes.

[2] Windows 7, Windows 8, and Window 10 are trademarks of Microsoft Corporation, USA. The Microsoft Office user interface is subject to protection under U.S. and international intellectual property laws and is used by Medical Measurement Systems under license from Microsoft.

	Module	Description
	Solar U2M module	Interface (main module) between computer and Solar GI modules.
	Separating Transformer	Power insulation, standard supplied with Solar GI trolleys.
	Safety module (300VA)	Power insulation standard supplied with Solar GI HRM compact systems.
	Combination Interface Module (CIM)	Measures pressures, EMG (optional), swallow (optional) and respiration (optional).
	Multi Pressure Interface	This module contains 12 pressure channels for High Resolution Manometry (HRM) with water perfused catheters.
	Wireless Patient Module (WPM)	This module can measure one pressure and two EMG signals via a wireless connection.

	Module	Description
	Catheter puller	Withdraws the catheter with constant speed to obtain anorectal or LES pressure profiles; withdraws the catheter stepwise with esophageal manometry studies. Laborie can supply you with a wireless Bluetooth puller (Mk III).
	Perfusion Pump Plus	This manometric perfusion pump is used for intraluminal manometric studies of the gastro-intestinal tract by using water perfused catheters.
	Remote control	Controls the Solar GI during an investigation.
	Bluetooth® Smart Long Range USB dongle (BT-SLR dongle)	The BT-SLR dongle is used for communication between the computer and Bluetooth Smart modules like the RC-1600 (Remote control).

1.2 Intended Use

The Solar GI system is intended to record, store, view, and analyze pressure, EMG, swallow, respiration, and impedance data online, gathered from anywhere in the gastrointestinal tract (pharynx, esophagus, stomach, duodenum, Sphincter of Oddi, small bowel, colon, and anorectal area, including rectum and pelvic floor) to assist in the diagnosis and evaluation of gastrointestinal and swallowing disorders.

1.3 Indications for Use

The Solar GI system is indicated for use in male and female adult and pediatric patients with common gastrointestinal conditions,such as swallow

disorders, reflux, irritable bowel syndrome (IBS), slow transit (small bowel and/or colon), fecal incontinence and constipation.

1.4 Contraindications

The Solar GI system has no known contraindications.

1.5 Clinical Benefit

Solar GI devices have a positive impact on patient management by facilitating diagnosis of gastrointestinal and swallowing disorders by means of gastrointestinal (GI) motility investigations, the purpose of which is to reproduce symptoms while making precise measurements to aid the healthcare professional in identifying the underlying causes for the symptoms, and to quantify the related pathophysiological processes.

1.6 Performance Characteristics

The Solar GI system allows stationary gastrointestinal measurements with up to 36 pressure channels, depending on the system configuration. Healthcare professionals using the Solar GI system can choose to use solid-state catheters, water-perfused catheters, or air-charged catheters, depending on the system configuration. Designated catheters and accessories are required for measurement in each specific area of the gastrointestinal tract. Additional modules may be configured for wireless measurement, EMG measurement, swallow measurement, respiration measurement, impedance measurement, and biofeedback. The Laborie software application provided as a part of the system generates diagnostic reports and utilizes contour plots during both measurement and analysis. The Solar GI device cannot render a diagnosis on its own.

1.7 Safety Information

The Solar GI Manometry User’s Manual is intended for users performing investigations by using the Solar system. Before working with the measurement system and its manuals, please take notice of the safety information as described in Appendix A. Safety information for users who install, test and maintain the Solar GI system can be found in the Solar GI New Service & Installation Manual (document code: MAN-00046). Safety information of the EGG module and Neuro module (HEM) can be found in the Solar EGG User’s Manual (Document Code: 0075-MAN-088-EN) and Neuro Module User’s Manual (Document Code: 0075-MAN-056-EN).

1.8 Connecting the Solar GI to an IT-Network

The Solar GI requires a connection to an IT-Network to allow the system to interface with the hospital EMR or network functionality.

For information and guidance on how to set up and configure the Solar GI to properly operate on your facility's IT-Network, refer to the *Network User's and Installation Manual* (LBL-001005).

⚠ **CAUTION** Connecting the Solar GI system to an IT-Network that includes other networked equipment can result in previously unidentified risks to patients, operators, or third parties. Laborie recommends that you work with your facility's network administrator to identify, analyze, evaluate, and control these risks. Subsequent changes to the IT-Network to which the Solar GI is connected (e.g., configuration, connection/ disconnection of customer-supplied items, updates or upgrades of other equipment connected to the network) could introduce new risks and require additional analysis. For additional information, refer to the section 1.9 "System Security."

1.9 System Security

To protect patient data and ensure the integrity of your Solar GI system, you should always employ IT-industry security best practices. The Solar GI system incorporates data security features that work in conjunction with the security practices in use by your heathcare facility.

⚠ **IMPORTANT** Only connect the Solar GI system to a managed and secure IT-Network.

To ensure the integrity and security of patient data and the Solar GI system, do the following:

- Ensure that Windows automatic updates is always turned on.
- To comply with applicable standards regarding data privacy and security (e.g., Health Insurance Portability and Accountability Act of 1996 [HIPAA] and General Data Protection Regulation [GDPR]), be sure that BitLocker is active on the Solar GI system at all times.
- Update all access information (username and password) upon first use; do not use the temporary login credentials that were provided to you during the initial system installation as your permanent access information.

- Never leave the computer unattended after you have logged in. Manually lock the computer if you expect to be away from it for an extended period of time.
- Be sure to follow all security policies, as specified by your healthcare facility's IT security department.

If you suspect a cybersecurity threat, contact your IT security department for guidance.

1.10 Accessories

Many different accessories can be used with the Laborie measurement systems. For detailed information, Laborie can supply you with the document "Declaration of compatibility for Accessories" (Document code: 0060-DEC-007). Contact your Laborie representative for information.

1.11 Troubleshooting

In case of malfunctioning or unexpected behaviour of the system please check the connection of all cables and restart the system. If you are not able to solve the problem, please contact your Laborie representative.

1.12 Laborie Software Program

The Laborie software program is supplied with your Solar GI to make the complete system function. For an overview of the software messages which require an action to resolve, see Appendix C. The program contains four parts:

- **Database** program. When you start the program, you will enter the database in which all available patient information, investigations, reports and memos are stored. Selection of a patient will give easy access to all information for that patient.
- **Measurement** program. This program is started from the database. The software guides the user through the investigation procedure and saves the measured data under the relevant patient name.
- **Analysis** program. This program is started from the database. Graphs and parameters can be displayed, printed in investigation reports and exported to other text editor and database programs.
- **Hardware test (diagnostic)** program. This maintenance program is started from the database. See the *Solar GI New Service & Installation Manual* (document code: MAN-00046) for information.

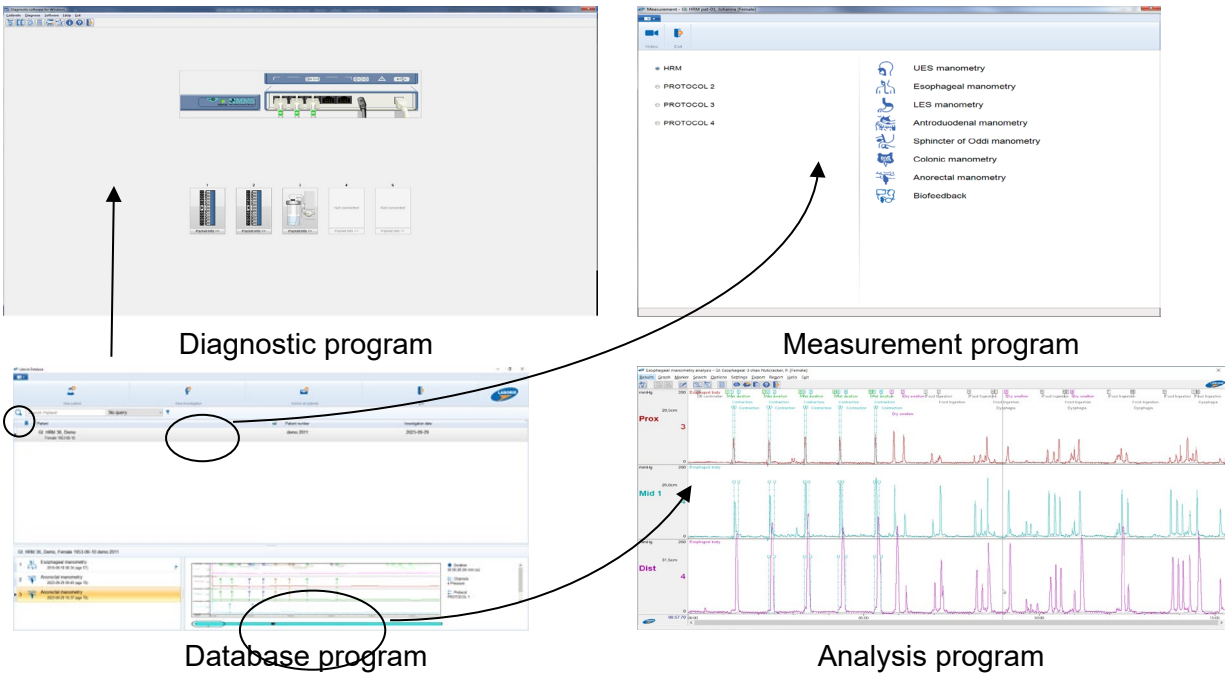


Figure 1.2 Laborie software program

1.13 Laborie Assistant

The Laborie assistant is an intelligent feature that can provide context-sensitive advice to you in a popup message box, according to your preferences. All message boxes displayed by the Laborie assistant close when you click the **OK** button. You can configure the behavior of the Laborie assistant in the Database module and the Measurement module. Or, you can turn off the Laborie assistant altogether if you prefer.

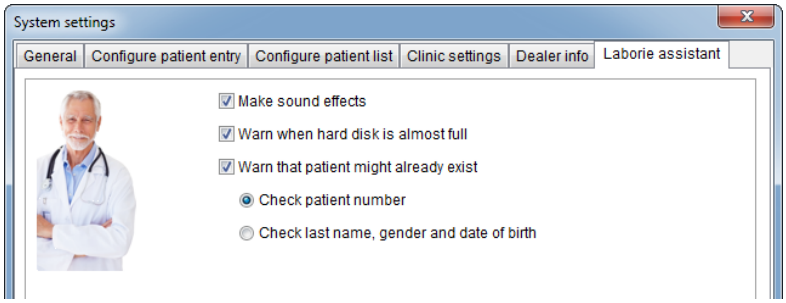


Figure 1.3 Laborie Assistant

1.14 Computer Requirements

The **minimum** computer requirements for the Laborie Windows software for the Solar GI system (including Solar GI HRM) are[3]:

- Processor: Intel Core i5-12500,
- Internal memory: 16.0 GB.
- Operating system: Windows 10 Professional 64bit (Windows build ≥10240)
- Solid-State Drive: 500 GB.
- 17 inch TFT monitor. Minimum Screen resolution 1280x1024
- USB ports: 7 to 8 (Solar U2M module, Solar infrared receiver, USB protection key, Bluetooth dongle, printer, memory stick, keyboard, mouse).

1.15 To Report Product Complaints or Incidents

To register a complaint or report a serious incident related to this product, please contact the manufacturer and the competent authority of the Member State where the incident occurred.

North American Technical Support:

Telephone: +1.800.333.1039 extension 1 *or* +1.800.522.6743 extension 1

Email: service@laborie.com

Outside North America:

Telephone: +31 (0) 53.4803777

Email: helpdesk@laborie.com

1.16 Contents of the Solar GI Manual Set

The *Solar GI Manometry User Manual* is intended for all users of the Solar GI measurement systems. This manual provides you with detailed information (step-by-step) about the GI manometry investigations. The *Solar GI New Service & Installation Manual* is intended for all technical users who install, test and maintain the measurement system.

Below you will find an overview of the manuals supplied with the Solar GI system.

[3] In case HRM software is used, the following additional specifications are applicable: onboard VGA resolution: max. 1280x1024, no ATOM processor.

	Manual	Laborie document code
Solar GI	Solar GI Manometry User's manual	LBL-001011
	Solar GI Service & Installation manual	MAN-00046
	Perfusion Pump Maintenance Instructions	MAN-00005
	Perfusion Pump Maintenance Instructions for SOM (Sphincter of Oddi Manometry)	LBL-001026
Neuro add-on	Neuro Module User's manual	LBL-001000
EGG option	Solar EGG Module User's manual	LBL-001007
Video option	Video User's Manual	LBL-000984
Network option	Network User's & Installation manual	LBL-001005
HIS option DICOM option	HIS/EMR Integration User's & Installation manual	MAN-00028

1.17 About This Manual

The *Solar GI Manometry User Manual* is intended to provide important information and instruction regarding the use and care of the Solar GI system.

1.17.1 Manual Conventions

In this manual, the name of a button, dialog box, menu, tab, or any label that appears on the user interface of the application as well as the computer keyboard appears in bold; for example, "Click the **New** patient button to add a new patient to the database."

1.17.2 Describing Interactions with the Application

In this manual, we distinguish between using the application (clicking buttons and choosing menu items) and pressing keys on your keyboard.

"Click," "double-click," right-click," and "drag"

Actions that you need to carry out using the mouse are described as follows:

- When you are instructed to *click* an item on the user interface, press the left mouse button once while your mouse pointer is over the item.
- When you are instructed to *double-click* an item, click the left mouse button twice, in rapid succession, while your mouse pointer is over the item.
- When you are instructed to *right-click* an item, press the right mouse button once while your mouse pointer is over the item.
- When you need to click a series menu items in sequence, the commands will appear in the order in which you must select them, separated by a *greater-than* (>) symbol. For example, “Choose **Settings** > **System settings** and then click the **Configure patient entry** tab” means that you must click **Settings** (in this example, on the menu bar) and then choose **System settings** from the menu that opens.
- When you are instructed to drag an item from one location to another on the user interface, this means to click the item and continue to hold down the left mouse button while you “drag” the item to its intended location. When the item is where you want it, release the left mouse button.

Pressing a keyboard key

When you need to press a specific key on the computer’s keyboard, you will be instructed to “Press a **key**”; for example, “press the **F1** key.”

1.17.3 Step-by-Step Instructions

Procedures that must be performed in a specific sequence are presented in numbered (ordered) lists, as shown here:

1 In the Database module, double-click the investigation name to start the Analysis module.
2 Click the **Reporter** button to open the **Reporter** dialog box.
3 Click **Print** to output the report.

Some procedure descriptions include a large depiction of the button that you need to click, which appears on the left side of the page. Adjacent to that is the screen that appears as a result of clicking the button. Figure 1-4 demonstrates how this looks.

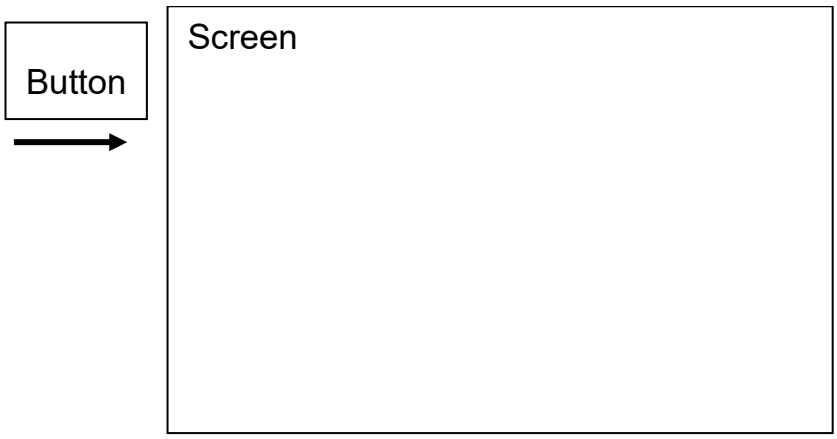


Figure 1.4 An Example of a User Interface Button and the Screen That It Opens

1.17.4 Symbols Used in This Manual

This manual provides important information to help you understand the features and safe use of the Solar GI system. This information is provided in boxed text elements that display one of three symbols, depending on the information being presented. The examples that follow show these symbols and describe the associated text elements.

⚠	**CAUTION/ WARNING**	Caution/Warning boxes present information that the user needs to know to prevent patient injury, product damage, or other serious adverse reactions associated with the use or misuse of the device.
❗	**IMPORTANT**	These boxes offer important information about using the device.
✓	**NOTE**	Notes present additional, helpful information about using the device.

1.17.5 Accessing Previous Versions of This Manual

Previous versions of this and other Laborie user and owner's manuals and Instructions for Use (IFU) are available on the Laborie website. You can access these documents by visiting the following web address:

https://www.laborie.com/document-library

On the **Document Library** page that opens, scroll down to the **Access to Archived Instruction Manuals** section and then select the link that applies to the product documentation you want.

1.17.6 Feedback on the Manual

Laborie welcomes your opinions and ideas to improve our manuals. Please send your questions and remarks to our Training & Education department:

education@laborie.com

2. Investigation Procedure

2.1 Introduction

The information in this chapter is a quick start guide to perform GI manometry investigations. Besides software instructions you will find instructions for using catheters, preparing the Solar perfusion pump plus or the pressure-cuff perfusion system, positioning EMG electrodes and preparing the catheter puller.

In chapters 3 to 10 you will find a detailed description of the following investigations:

- Upper Esophageal Sphincter (UES) manometry.
- Esophageal body manometry (includes UES & LES manometry).
- Lower Esophageal Sphincter (LES) manometry.
- Antroduodenal manometry.
- Sphincter of Oddi manometry.
- Colon manometry.
- Anorectal manometry.
- Biofeedback.

The investigation procedure can be as follows:

- Start the database program.
- Enter the database password and select the patient.
- Start the measurement program.
- Prepare the investigation (pre-test).
- Perform the investigation.
- Print the investigation report.
- Clean system and catheters.
- Exit the database program.

Detailed information about the database program and the reporter program can be found in separate manuals in PDF format, which can be opened via the **Manuals** menu in the database program.

Detailed information about the measurement program and analysis program can be found in the chapters 11 to 12.

2.2 Start the Database Program

Double-click the **Laborie-Login** button on your desktop to log into the Laborie database.

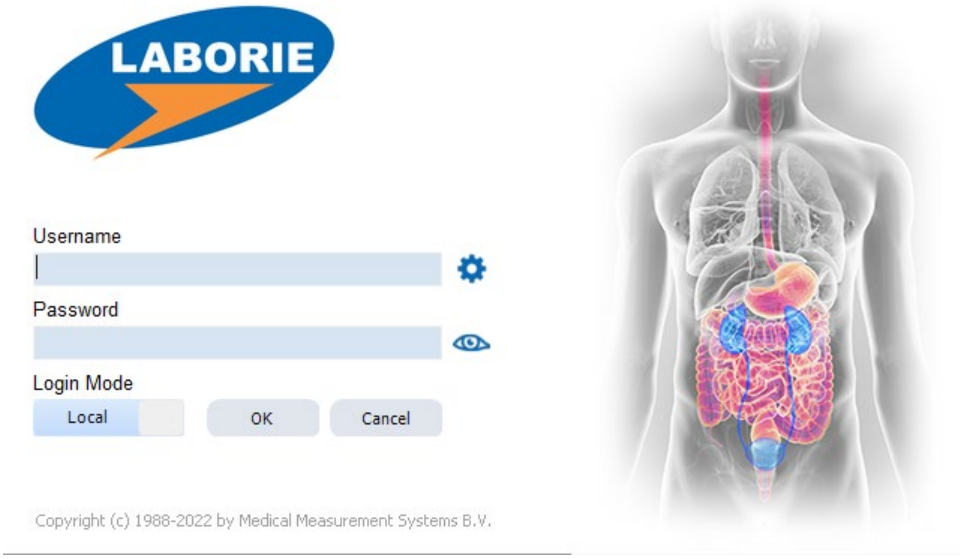


Figure 2.1 Login

2.2.1 Laborie Patient Database

From **Login** window, input **Username** and **Password**, then click **OK** button to start the Laborie patient database program.

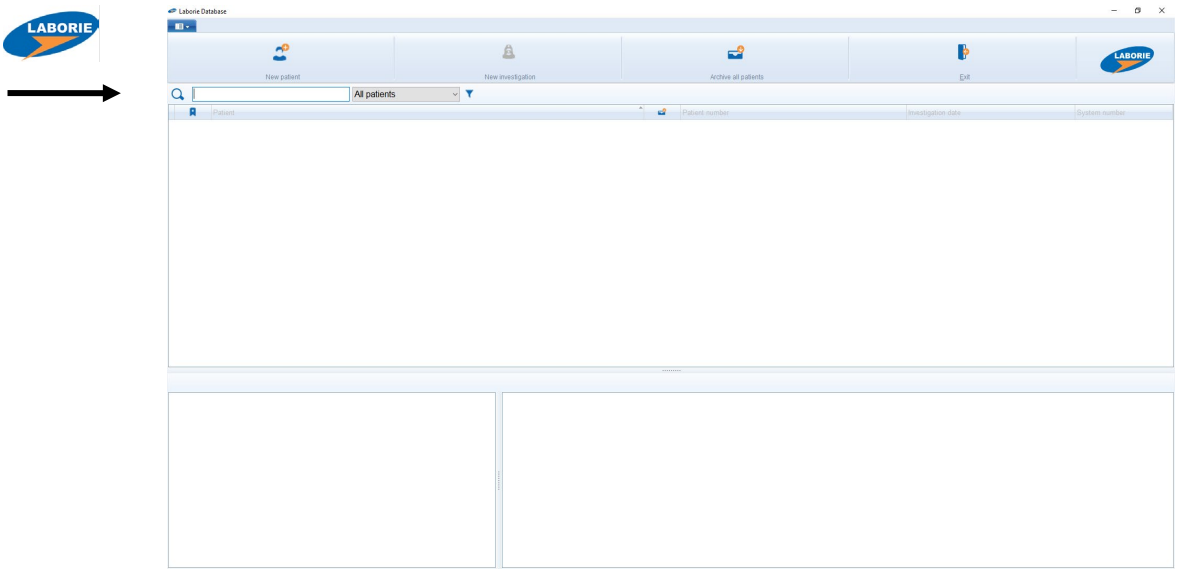


Figure 2.5 Database module - initially no patients are listed

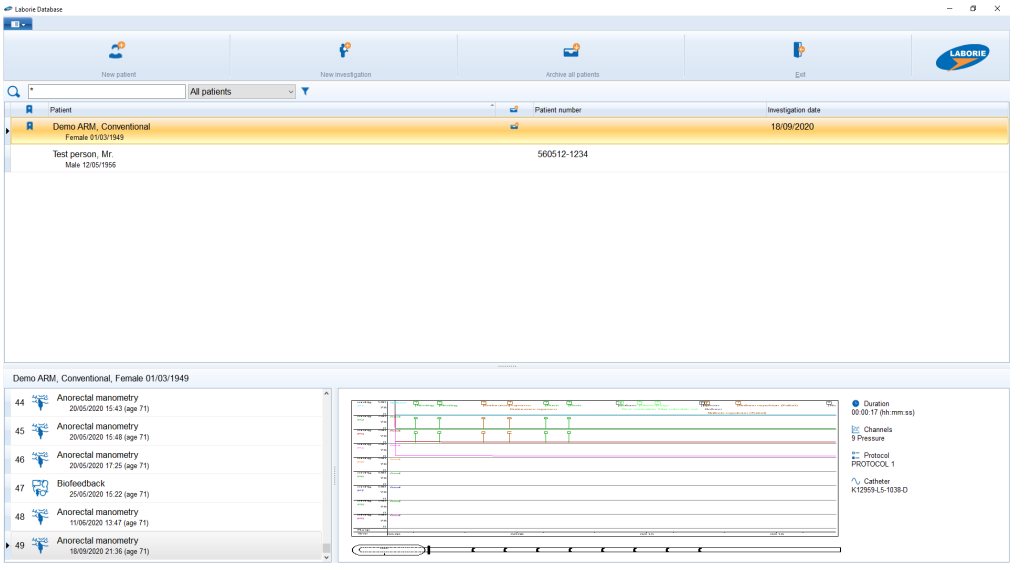


Figure 2.5.1 Database program

Initially the patient database will show no patients. In order to show all patients, you can type the "*" symbol in the search field. To find a particular patient, you can start typing the patient name in the search box, then patient will appear in the table. Select the patient by clicking once with the left mouse button on the name of the patient. All the studies performed on the selected patient are displayed in the investigation list. When you select the investigation, you will see a preview of the investigation graph (when analysis has been performed).

Enter and select the patient

Click the **New patient** button to add a new patient to the database.

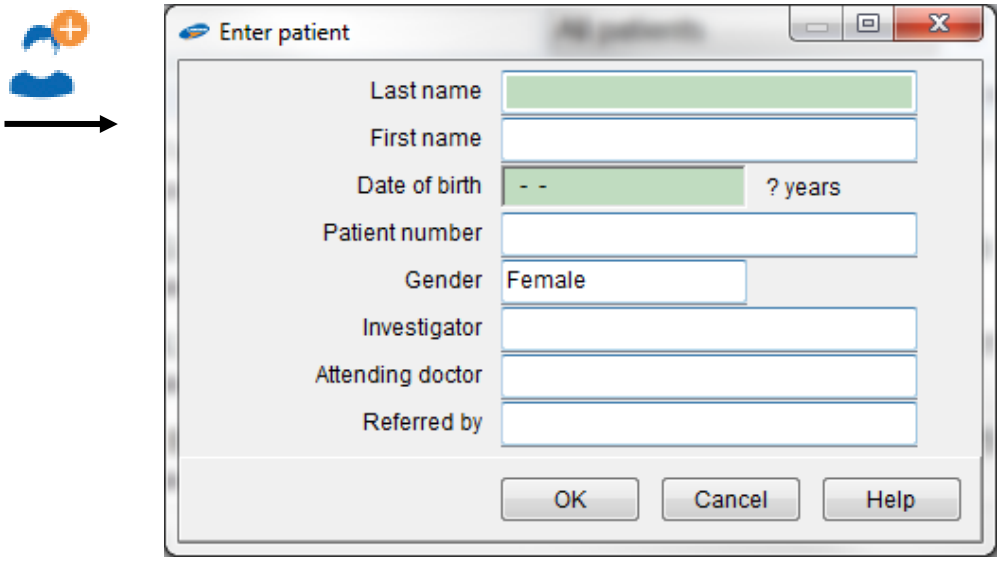


Figure 2.6 Enter new patient

Enter the patient information before starting a new investigation. You can switch to the next field by pressing the **Tab** key on your keyboard, or by clicking on the field with your mouse cursor.

Click the **OK** button to save the information of the new patient. The patient is now displayed and selected in the patient list. To abort the entry of demographics, click the **Cancel** button. The program will ask you to save the modified data.

Default, the entries last name and date of birth are obligatory. Choose **Settings > System settings** and the TAB **Configure patient entry** to select the entries patient number and date of birth.

Before starting a new investigation, you must select the name of the patient from the patient list.

2.3 Start the Measurement Program

Click the **New investigation** button in the database program to start the measurement program. When more than one system is installed, you need to select the stationary measurement system.

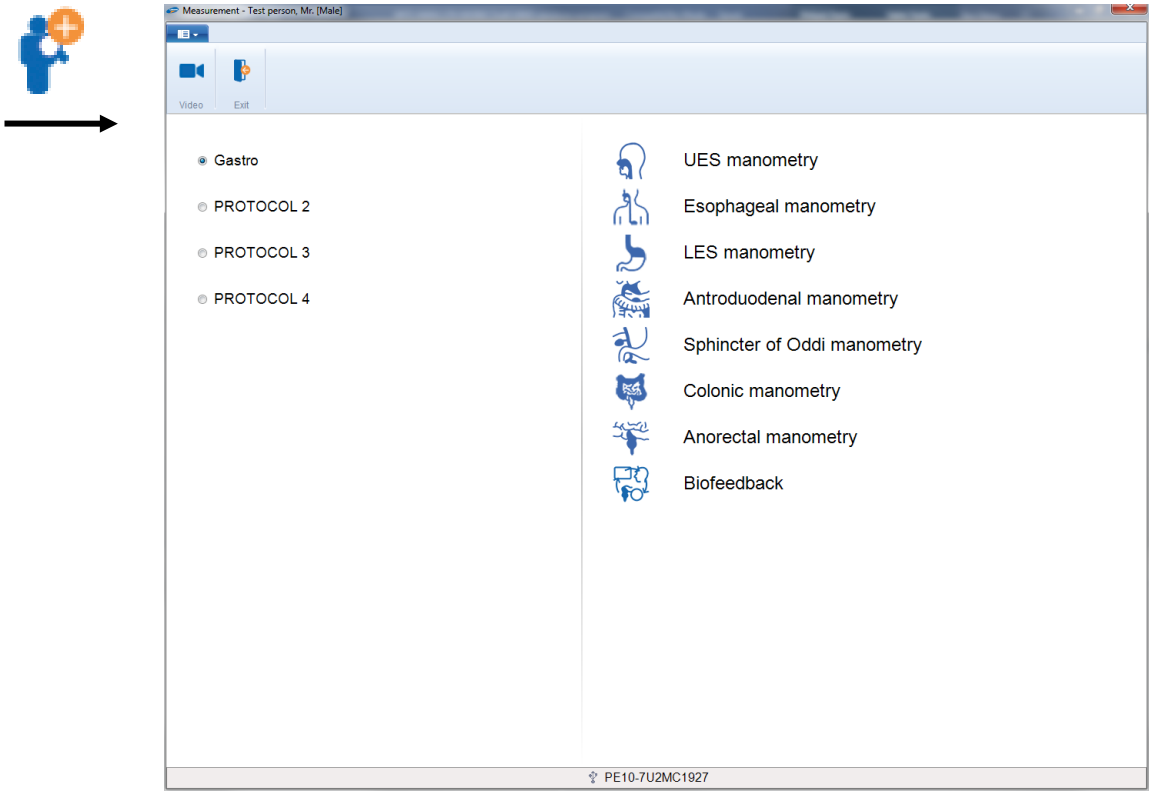


Figure 2.7 Measurement program

The measurement program shows all available investigations.
Select the appropriate investigation protocol and click on the investigation name to start the pre-test of the selected investigation.

2.4 Prepare the Investigation (pre-test)

2.4.1 Start the Pre-Test

After selecting the investigation name in the measurement program, the pre-test will start.

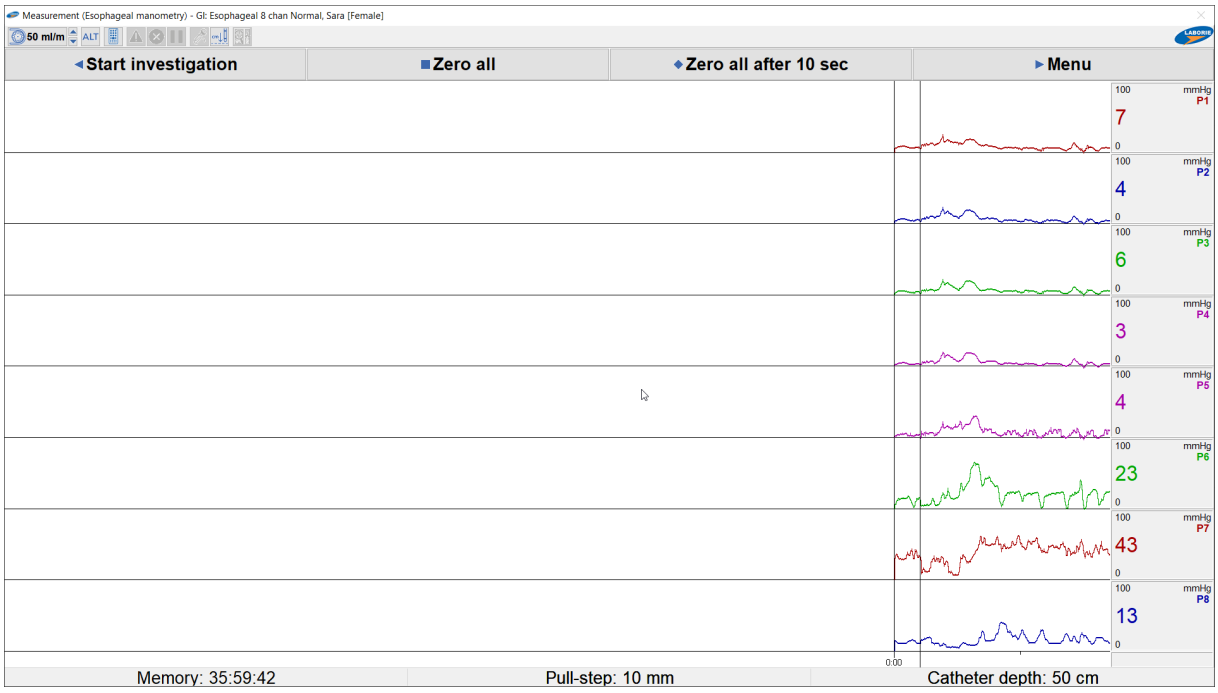


Figure 2.8 Pre-test Esophageal measurement

In the pre-test, you will prepare the patient and the measurement system, e.g. prepare the perfusion system with water perfused catheters, zero the pressures and insert the catheter. Note that data will not be stored and markers cannot be placed. After finishing the pre-test, you will start the actual investigation.

The preparations during the pre-test depend on the investigation type and the catheters which are used. More information can be found in the following subparagraphs.

2.4.2 Prepare the Perfusion Pump Plus

The Perfusion Pump Plus (MPP Plus) is an accessory device to be used with the Solar GI system for intraluminal studies of the gastrointestinal tract (pharynx, esophagus, stomach, duodenum, Sphincter of Oddi, small bowel, colon, and anorectal area including rectum) to perfuse demineralized or distilled water through the lumen of a multilumen catheter to measure pressures. Designated catheters and accessories are required for measurement in each specific area of the gastrointestinal tract.

The perfusion pump can be used for manometry investigations with water perfused catheters. The figure below shows the setup of the perfusion system.

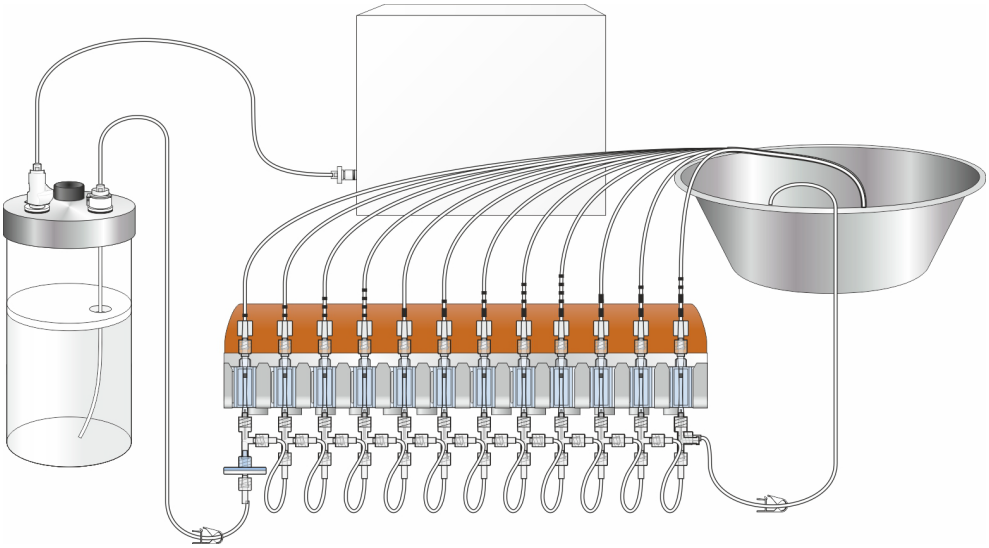


Figure 2.9 Perfusion system

Use the water perfused catheter and pressure transducers according to the manufacturer's specifications.

The perfusion pump is switched on automatically after starting the pre-test.

You can also start perfusion prior to the pre-test by using the on/off switch on the pump. After 30 minutes (default setting), the pump will be switched off automatically (this can be changed in the hardware test (diagnostic) program. The procedure for using the perfusion system can be as follows:

- Check that the setup of the perfusion system is complete and correct. If applicable you must connect the pressure transducers, the flow resistors and a water filter.
- Remove lid and float from the water container.
- Ensure that the inside of the water container is clean and fill the container with demineralized or distilled water which contains a biofilm reducing agent.
- Put the float on the water and screw the lid on the water container; the tube must be placed through the hole of the float.
- Reconnect the tubes to the water container.

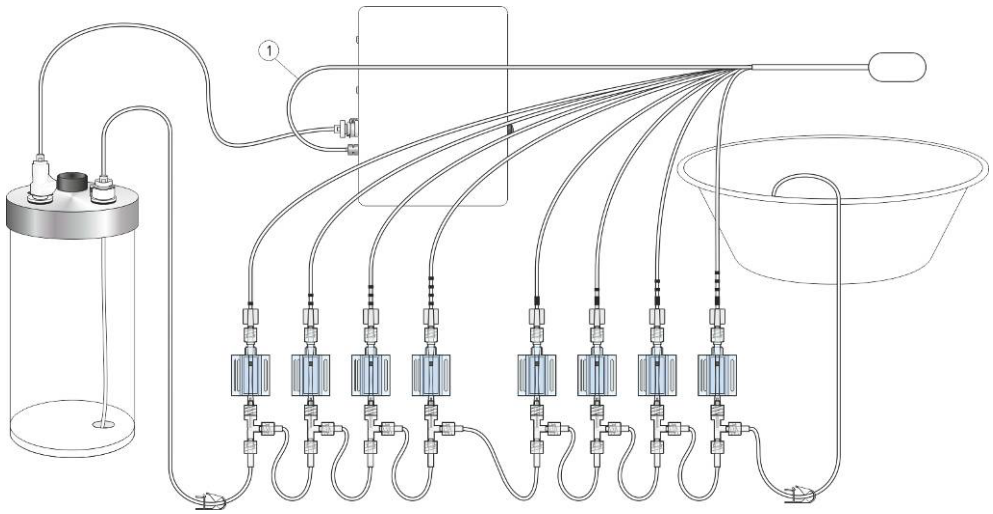


Figure 2.10 Connection of the filling lumen to the perfusion pump

- Connect the catheter to the pressure transducers (note: inspect the numbering of the channels). If applicable, connect the filling lumen (with extension line) of the anorectal manometry catheter to the male luer connection of the perfusion pump.
- Put the catheter and the flushing tube both on the dish.
- Start the pre-test of the investigation in the software program. The software switches on the perfusion pump.
- Wait until the perfusion pressure equals the pressure as set in the investigation protocol.

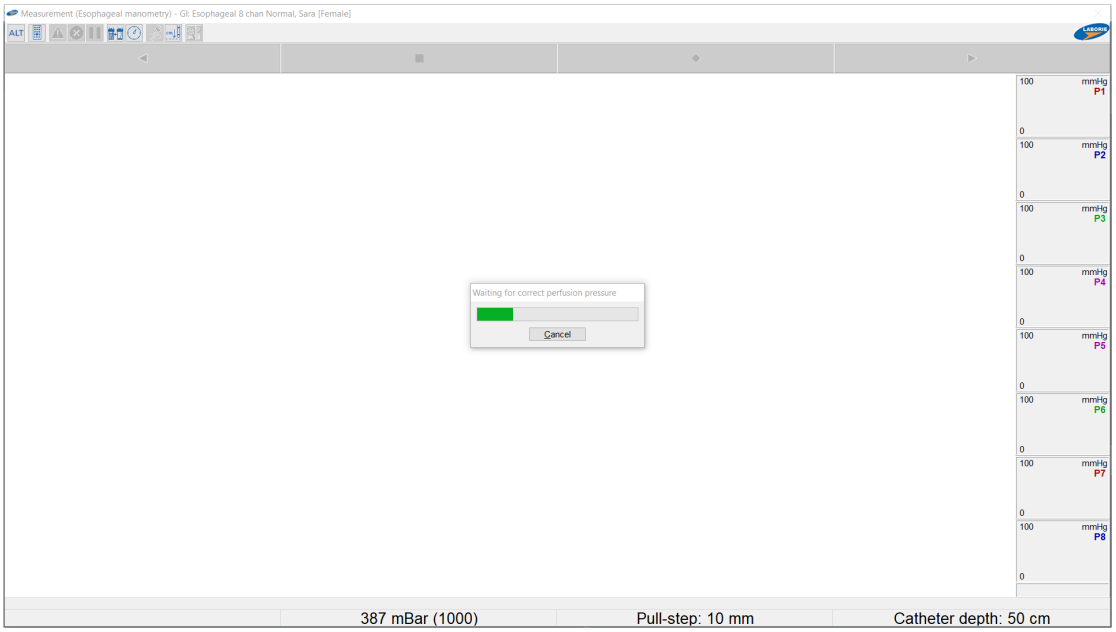


Figure 2.11 Perfusion pressure

- Use the clamp of the tube (from water container to water filter) to start (and stop) the flow of water immediately.
- Use the clamp of the flushing tube until water drops out on the dish.

- Close the clamp of the flushing tube and flush the complete system. Wait 1-2 minutes until all lumen of the catheter are filled with water.
- Inspect all wetted parts on air bubbles. Flush again if necessary.
- Keep the catheter at patient level and zero the pressures. Lift the catheter to check proper operation of perfusion pump and pressure recording.
- Insert and position the catheter in the patient. Let the patient swallow or squeeze to check proper operation.
- Perform the investigation. After finishing the procedure pressure can be released from the pump (investigation protocol setting).
- Disconnect the catheter and prepare the system for the next investigation.
- After conclusion of the last manometry procedure for the day, maintain the Solar perfusion pump Plus as described in the Perfusion Pump Maintenance Instructions (Document code: MAN-00005).

It is not recommended to refill the liquid container during an investigation. If necessary, the best way is to refill is through the refill cap with the aid of a funnel.

2.4.3 Prepare the Air-Charged Catheter

Air-charged catheters can be used for 4-channel esophageal and anorectal studies. The air-charged catheter is connected to the CIM module via air charged pressure transducer cables.

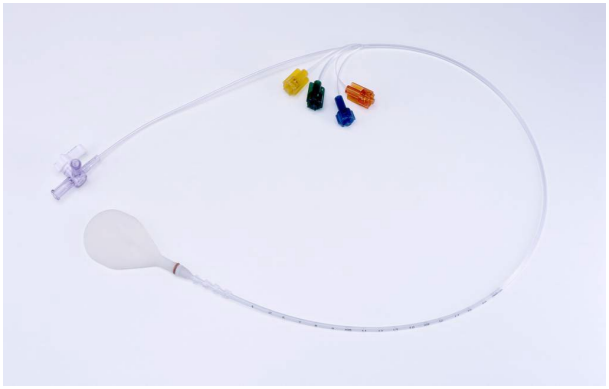


Figure 2.12 Air-charged catheter for anorectal manometry studies

The procedure to prepare the investigation is as follows:

- Connect the pressure transducer cables (in OPEN position) to the CIM module. For anorectal manometry, the GIM-60000A air charged catheter and transducers, the connection is as follows:

Color pressure transducer	CIM module
Yellow (distal)	P1
Green (medial distal)	P2
Blue (medial proximal)	P3
Orange (proximal)	P4

- Connect the catheter to the pressure transducers (follow the colors). Be sure to connect in the OPEN position.
- Calibrate the catheter as instructed by the manufacturer (follow the instructions to calibrate the catheter and charge the sensors). Press the **Zero all** button before charging the sensors in the calibration tube.
- Release pressure from the calibrator and remove the catheter. After calibration, do not slide the switch to the OPEN position.
- Insert the catheter gently in the anal canal of the patient and position the balloon in the rectum.

Figure 2.13 Charge catheters

- Ask the patient to cough to check the registration of the pressures.
- Press the **Start investigation** button to start the investigation. Follow the procedure for the tests as described in chapter 9.

2.4.4 Prepare the Solid-State Catheter

Solid state catheters can be used to perform pressure measurements in the gastro-intestinal tract.

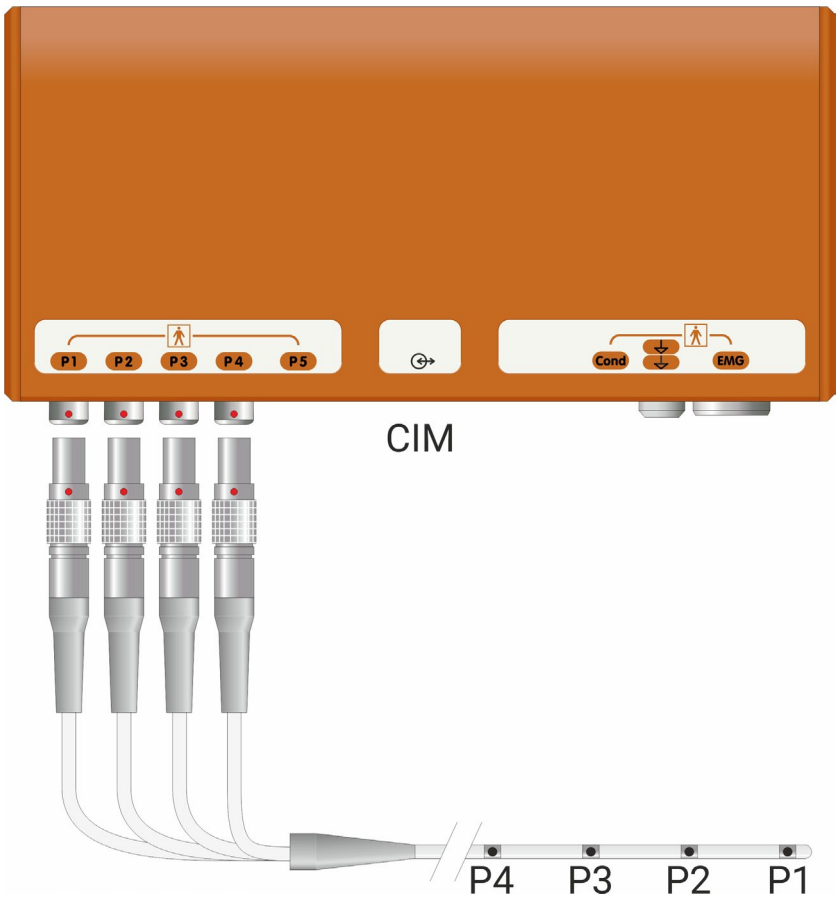


Figure 2.14 Example solid state catheter

The procedure to prepare the investigation is as follows:

- Pre-wet the catheter in distilled sterile water as described in manual of the manufacturer (the minimum period is two minutes).
- Start the pre-test in the software (for example **Esophageal manometry** or **Anorectal manometry**).
- Connect the pre-wetted catheter to the CIM module.
- Press the **Zero all** button to zero all pressures (the pressure sensors must be covered with approx. 1 cm of water).
- Insert and position the catheter. Ask the patient to cough or squeeze to check the registration of all pressures.
- Press the **Start investigation** button to start the investigation. Follow the procedure as described in the next chapters.

2.4.5 Prepare the Wireless Patient Module (WPM)

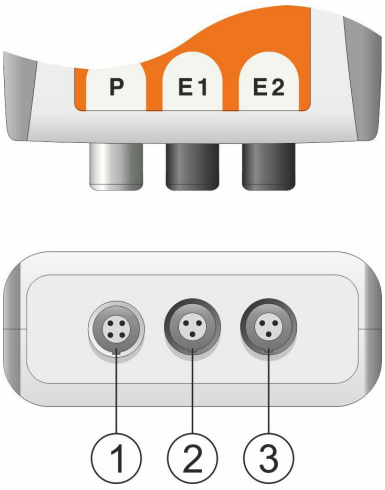
The Wireless Patient Module (WPM) can be used to measure one or two EMG channels and one pressure channel. The module is supplied with a carrying pouch (shoulder belt) or can be used with a strap to fix it to arm or leg of the patient.

Figure 2.15 Wireless Patient Module

The module can be used as standalone system for biofeedback training and anorectal manometry investigations. The wireless patient module communicates through a wireless Bluetooth connection with the computer. The module is powered by two batteries (type AA alkaline 1.5 Volt, or NiMH 1.2 Volt).

In the figure below you will see the wireless patient module. The module is supplied with a carrying bag (shoulder belt) or can be used with a strap to fix it to arm or leg of the patient.

The WPM has one status LED [1] indicating the battery and the Bluetooth connection. The WPM has one pressure connector [1] and two EMG connectors [2] and [3].



1. Lemo 4 pressure transducer receptacle
2. Lemo 3 EMG receptacle (EMG 1)
3. Lemo 3 EMG receptacle (EMG 2)

Figure 2.16 Wireless Patient Module

In the table below you will find a description of the battery indications.

LED	Indication
One green flash	Indicates proper startup of WPM electronics during battery placement.
Green blinking	Batteries are fully depleted (temporary status). Replace the batteries.
Blue blinking	Indicates a wireless Bluetooth connection.
Orange blinking	Indicates almost depleted batteries. Replace the batteries within 15 minutes.
Red blinking	Indicates depleted batteries. After 5 minutes the WPM switches off or sooner if batteries are depleted.
Off	No or empty batteries. Replace the batteries.

2.4.6 Prepare EMG Cables and Electrodes

EMG of the pelvic floor can be measured with surface electrodes. Surface electrodes are applied to an epithelial surface as close to the muscle under study as possible. Surface electrodes detect the action potentials from groups of adjacent motor units underlying the recording surface. Clean the skin first before applying the surface electrodes. Apply the electrodes as shown below.

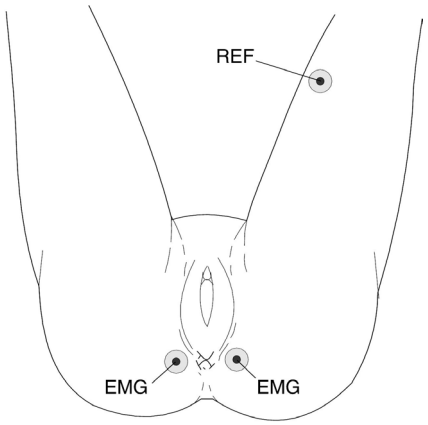


Figure 2.17 Surface EMG electrodes

The procedure is as follows:

- Connect the EMG cable to the CIM (or the WPM module).
- Position two EMG surface electrodes on either side of the anal sphincter:
    - With a gloved hand, spread the buttocks until the entire anal sphincter is visualized. Any hair that might be under the patches should be removed.
    - Thoroughly clean the anal sphincter area with alcohol. NOTE: it is extremely important that all oil, hair and foreign material be removed from this area before electrodes are placed.
    - Without releasing the buttocks, dry the area free of any remaining moisture from the alcohol pad.
    - Place the EMG electrode patches directly ON opposing sides of the sphincter. The patch should be placed ON the darker skinned area of the anus.
- Position the reference electrode on the upper leg, after cleaning the area.
- Connect the surface electrodes to the guarded EMG cable.
- Ask the patient to squeeze the pelvic floor muscles and check the quality of the EMG signal.
- If necessary, adjust the EMG sensitivity scale by pressing the **EMG sensitivity** buttons in the software or on the remote control. This can be done during the pre-test and the measurement. The default EMG sensitivity is determined by the setting for the EMG scale in the investigation protocol.

EMG cables and electrodes

The following types of EMG cables/leads and electrodes are recommended to use with the Combination Interface Module (CIM):

- EMGC-D5-SUR (= guarded EMG cable with DIN-5 connector and integrated DIN 42 802 and 3 electrodes with press studs, 180 cm).
- EMGC-TP-SUR (= guarded EMG lead wires with press studs and DIN-42802, set of 3), to be used with EMGC-D5-TP (= guarded EMG cable for 3 electrodes with DIN-42802 and DIN-5 connector, 180 cm).
- MMS EMG-PE (= disposable waterproof protected EMG surface electrodes including lead wires) to be used with EMGC-D5-TP (= guarded EMG cable for 3 electrodes with DIN-42802 and DIN-5 connector, 180 cm).

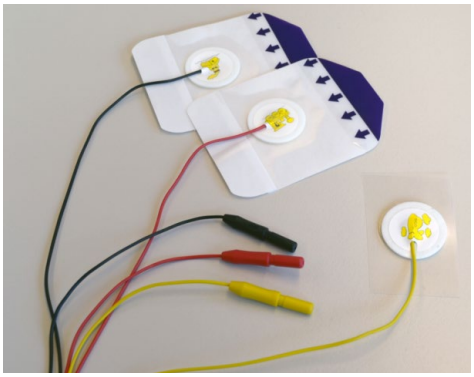


Figure 2.18 MMS EMG-PE

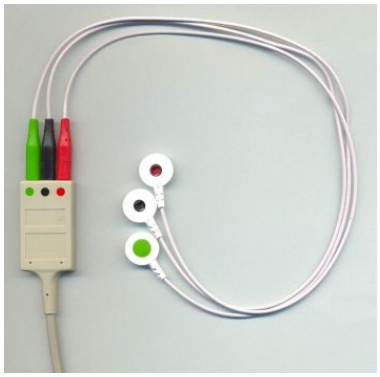


Figure 2.19 EMGC-D5-TP with EMGC-TP-SUR lead wires (for CIM)

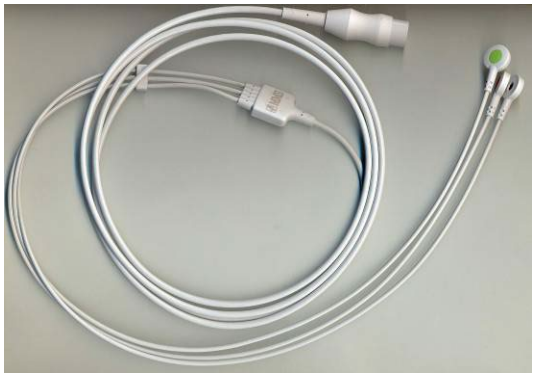


Figure 2.20 EMGC-D5-SUR cable (for CIM)

The color coding is as follows:

Signal +	Red
Signal –	Black
Reference	Green / Yellow

The recommended EMG cable to use with the WPM is the UD 597 A6 (= guarded EMG cable for 3 surface electrodes with press studs, 60 cm).

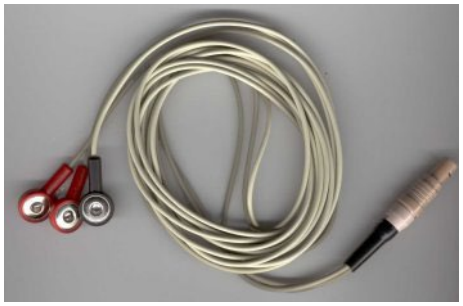


Figure 2.21 EMG cable (for WPM)

The color coding is as follows:

Signal +	Red
Signal –	Red
Reference	Black

2.4.7 Swallow / Respiration

Swallow can be detected by using EMG surface electrodes or by using a catheter and the air channel on the Perfusion pump. For using the air channel on the Perfusion pump consult the Solar GI New Service & Installation Manual (Document Code: MAN-00046).

Surface electrodes are applied to the skin on both sides of the Adam's apple. Surface electrodes detect the action potentials from groups of adjacent motor units underlying the recording surface.

Respiration can be detected by placing a Piezo sensor with a belt on the patient's abdomen. The Piezo sensor measures the movement of the abdomen, caused by respiration.

2.4.8 Prepare the Catheter Puller

The catheter puller can be used to aid in making pressure profiles of the LES and anorectal sphincter. During esophageal manometry, the catheter can be withdrawn step-by step. The catheter will be withdrawn with a predetermined speed and/or over a predetermined distance by a puller.

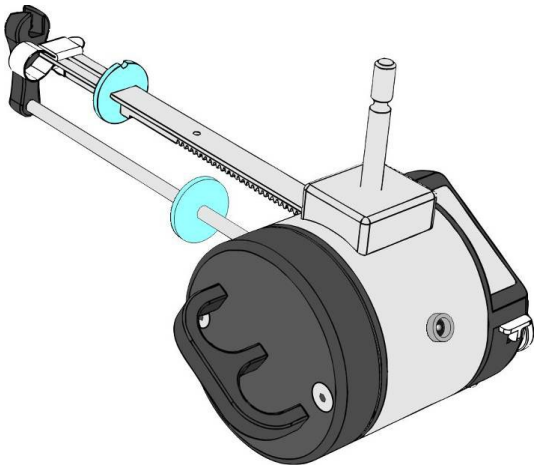


Figure 2.22 Wireless catheter puller

There are two types of catheter pullers: the wireless puller or the wired puller. The wireless catheter puller communicates through a Bluetooth connection with the computer. The puller is powered by four AA type rechargeable

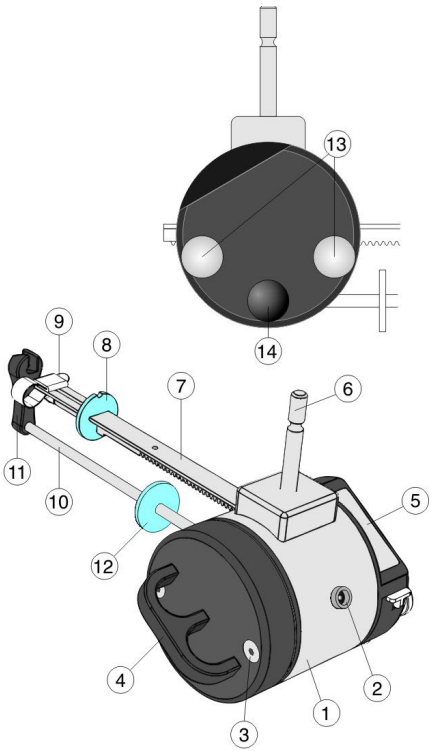
batteries (NiMH) or the supplied medical grade dedicated power adapter. While powered by the adapter the batteries are being charged also.

The wired catheter puller can only be connected to the Solar measurement system via a cable.

For more information, see the Solar GI New Service & Installation manual (Document Code: MAN-00046).

Prepare the wireless puller

In the figure below you will find an overview of the puller parts.



1. Puller motor enclosure
2. DC receptacle for the power adapter
3. Battery compartment (can be opened by removing the screws)
4. Handle to position the puller
5. Control panel
6. Pin to mount the puller on the carrying arm
7. Slider
8. Slider protection disk
9. Catheter clamp
10. Guider
11. Catheter guide
12. Guider protection disk
13. Lock-screws to secure the cover of the motor enclosure
14. Lock-screw to secure the guider

Figure 2.23 Wireless puller parts

To mount the catheter on the puller, proceed as follows:

- Move the slider [7] to the catheter guide [11], until the catheter clamp [9] is positioned close to the catheter guide [11].
- Move the catheter through the catheter guide [11] to secure the catheter in position during puller operation.
- Place the catheter under the rubber compression piece of the spring clamp [9].

The control panel of the wireless puller contains three LED's: for Bluetooth [1], Status [2] and Battery [3] indication, and one membrane button [4] to unlock the slider.

1. Bluetooth LED
2. Status LED
3. Battery LED
4. Unlock slider button

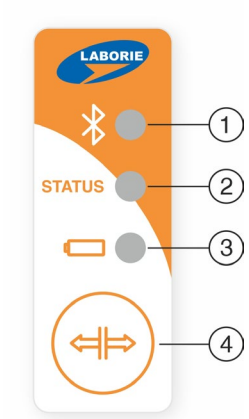


Figure 2.24 Control panel

LED's and button wireless puller

In the table below you will find a description of the LED's.

LED	Color	Indication
Bluetooth	Blue blinking	The Bluetooth catheter puller has a wireless connection with the computer.
Status	Green on	The puller is switched on and is functioning well.
	Orange on	IPL mode and/or downloading firmware.
	Red on	The puller has detected an internal failure. Contact your Laborie representative.
Battery	Green on	The rechargeable batteries are fully charged.
	Green blinking	The power adapter is connected to the puller (and charging the batteries).
	Orange blinking	The batteries are almost empty, please connect the power adapter (within 5 minutes).
	Red blinking	The batteries are depleted. You can connect the power adapter to perform the investigation and to charge the batteries. If you don't follow up the instruction, then the puller will be switched off and lose the wireless connection with the computer.

During the pre-test and the actual investigation, the slider is locked in position. To unlock and reposition the slider manually, you must press the **Unlock slider** button [4] at the control panel. Please note that the automatic return will become unavailable.

2.5 Perform the Investigation

After finishing the pre-test, click the **Start investigation** button to start the actual measurement.

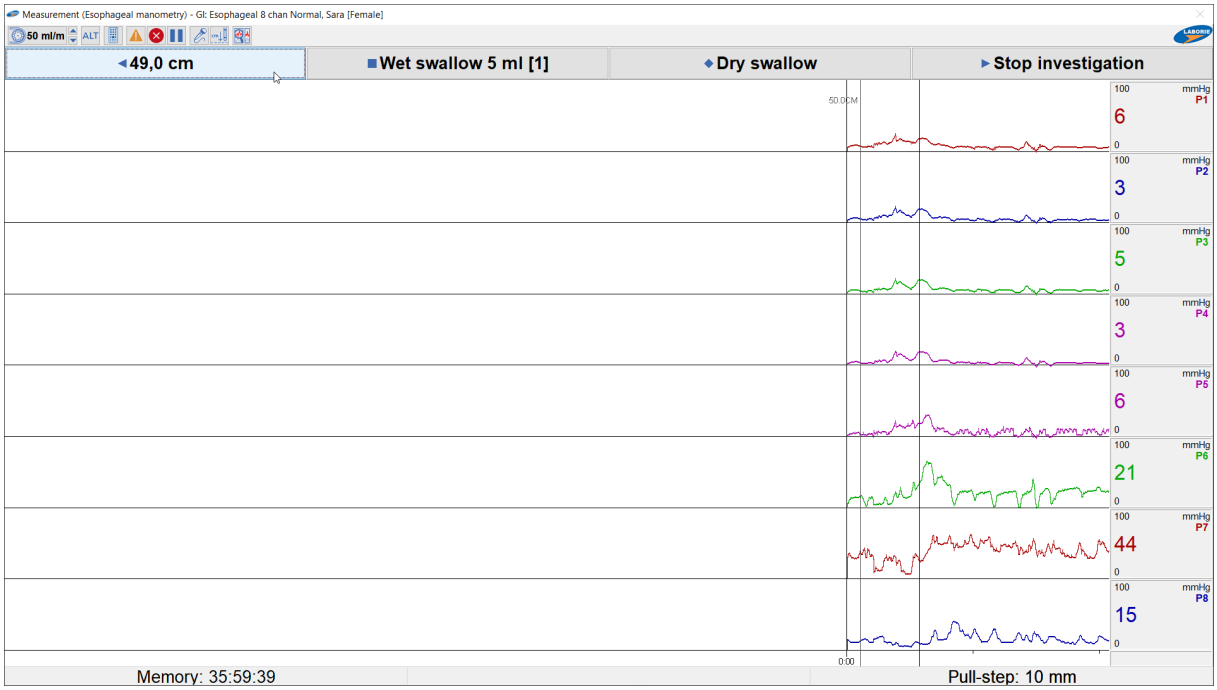


Figure 2.25 Esophageal investigation

Graphs start to scroll and all data is measured and stored. During the investigation, you can mark e.g. insertion depth, wet swallows, events and coughs.

The investigation instructions depend on the investigation type and the protocol settings. See the investigation specific instructions as described in the following chapters:

- Upper Esophageal Sphincter (UES) manometry see chapter 3.
- Esophageal body manometry (includes UES & LES manometry) see chapter 4.
- Lower Esophageal Sphincter (LES) manometry see chapter 5.
- Antroduodenal manometry see chapter 6.
- Sphincter of Oddi manometry see chapter 7.
- Colon manometry see chapter 8.
- Anorectal manometry see chapter 9.

- Biofeedback see chapter 10.

2.6 Print the Investigation Report

Double-click the **Investigation name** in the database program to start the analysis program. Click the **Reporter** button to open the Reporter dialog; click **Print** to print the report.

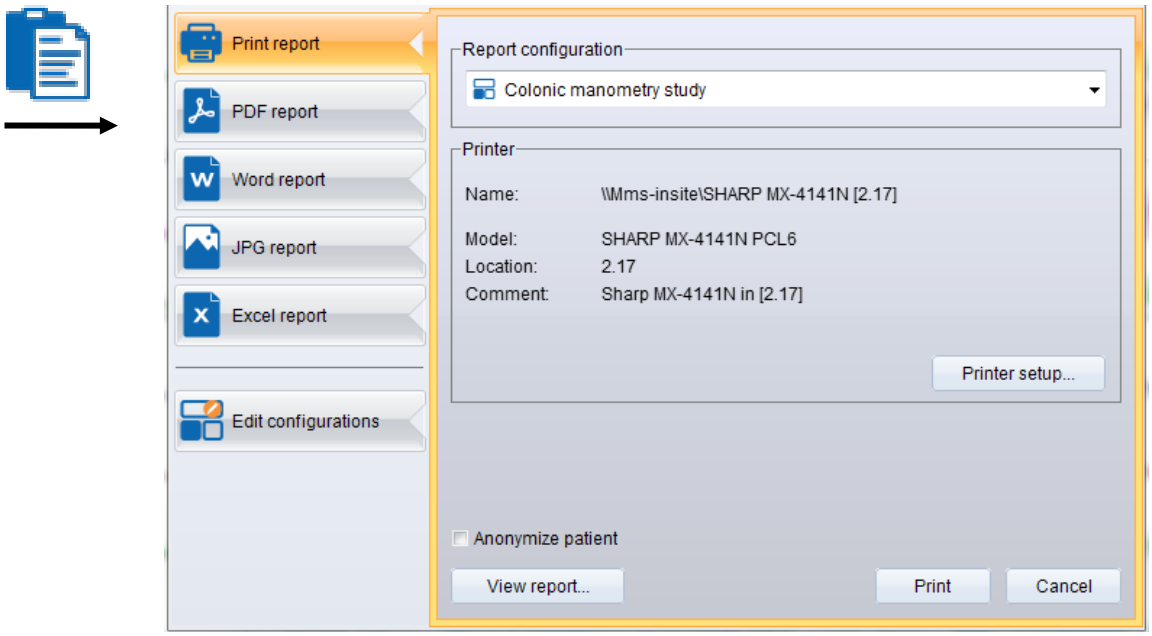


Figure 2.26 Print report dialog

Besides printing the report, it is possible to export the report to different formats, for example PDF or Word. Also, user-defined configurations of reports can be made. More information about the reporter program can be found in the separate Reporter manual in PDF format, which can be opened via the **Manuals** menu in the database program.

2.7 Cleaning Instructions

After each investigation, we recommend cleaning/replacement of the following parts:

- Re-usable catheters must be cleaned and sterilized after each investigation and kept sterile until the next investigation is done.
- Discard single use catheters, domes and pressure transducers.
- Clean the EMG cables with a moisturized cloth.
- Discard single use EMG electrodes.
- Re-usable EMG needle electrodes must be cleaned and sterilized after each investigation and kept sterile until the next investigation is done.
- Remove water from the Solar GI trolley, the Solar GI pole and its devices with a soft, dry cloth.

On a daily, we recommend cleaning of the following parts:

- Low level dis-infect the slider and the guider of the wireless puller in an instrument washer with a maximum temperature of 80°C (176°F). Cleaning and disinfection of the slider, guider, plastic pinion and the cover of the motor house can be done with 70% alcohol.
- Clean the outside of the puller and the carrying arm with a moisturized cloth.
- Clean the CIM with a slightly moisturized cloth.
- Clean the MPI with a slightly moisturized cloth.
- Release the air out of the perfusion pump.
- Clean the perfusion system according to the manufacturer's instructions. Maintain the Perfusion pump as described in the Solar GI New Service & Installation manual (document code: MAN-00046) and in the Perfusion Pump Maintenance Instructions (document code: MAN-00005) or Perfusion Pump User & Maintenance Instructions for SOM, Sphincter of Oddi Manometry (document code: LBL-001026).

Clean and maintain the pressure-cuff perfusion system

On a daily, we recommend replacing of the following parts:

- Water bag
- 4-way catheter flushing set
- DT-NN pressure transducers

When changing from anorectal manometry to esophageal manometry, it is also recommended to replace the wetted parts as mentioned above.

In case contamination with body fluids is suspected, all wetted parts must be replaced before the next investigation: water bag, four-way catheter flushing set, DT-NN pressure transducers.

NOTE For cleaning and sterilization of the catheters or accessories (e.g. EMG needle electrodes), see the manufacturer's instructions.

Trolley cover

The polyester trolley cover and pouch can be cleaned in a washing machine at 95°C. Disinfection of the trolley cover can be done with a 70% isopropyl alcohol or a chloride (1,000 ppm)-based disinfectant.

2.8 Exit the Database Program

To exit the program, you must return to the database program first. Click the **Exit** button to close the analysis program and to return to the database program.

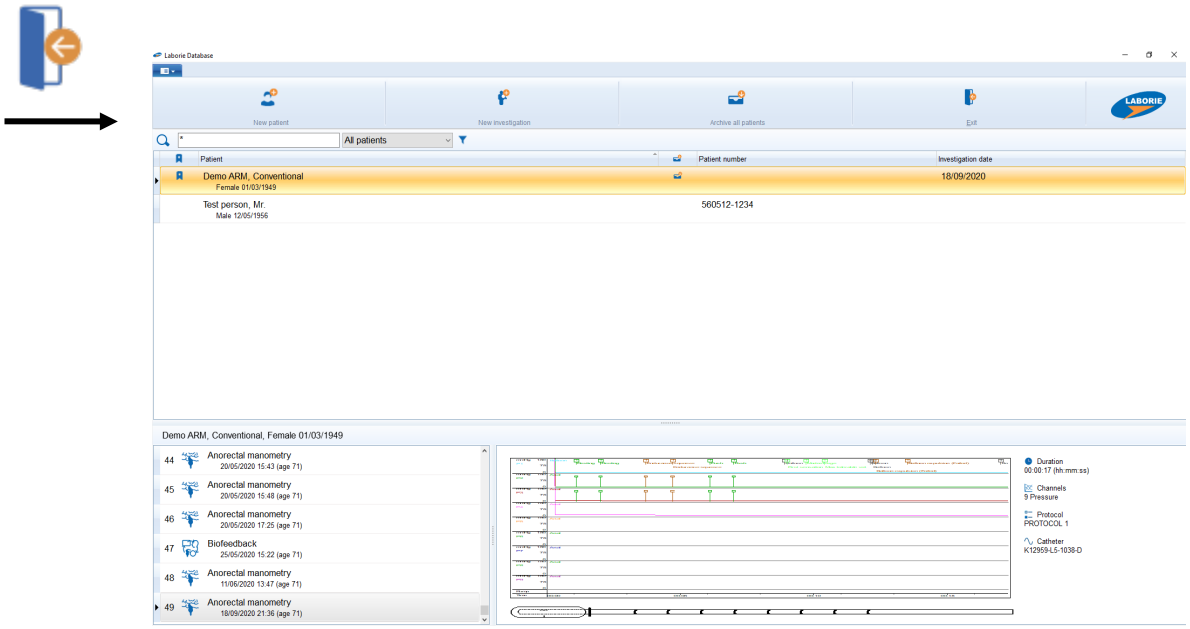


Figure 2.27 Return to the database program

Click the **Exit** button in the database program to close the database program.

Shut down computer

After clicking exit in the database program you can shut down the computer by clicking on the **Start** button of the Windows **Start** menu. Select **Shutdown** to exit Windows and turn off the system.

CAUTION Never turn off the computer when the Laborie software program is still active. You may lose data.

3. UES Manometry

3.1 Introduction

Upper Esophageal Sphincter (UES) manometry studies are often performed if oropharyngeal swallowing disorders are suspected. These studies can be performed also as part of a standard esophageal manometry study (refer to chapter 4).

Because of the rapid relaxation phase of the UES, a high sample frequency should be chosen in the investigation protocol (preferably 100Hz). Only solid state catheters are suitable for these high sample rates.

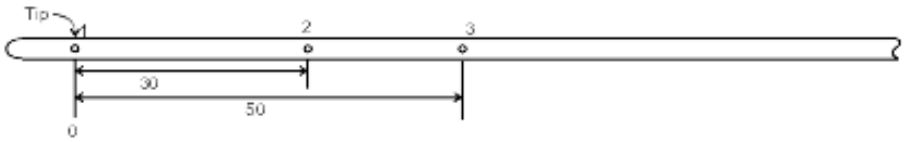


Figure 3.1 UES manometry catheter

You can use a catheter with two or three transducers. The distal transducer should be about 3 cm apart from proximal transducer. In case of a three transducer catheter is used, the third transducer should be 2 cm apart from the medial transducer.

During the investigation, the distal transducer should be placed in the UES. The second transducer will then be in the pharynx. Whenever a third transducer is present, it will be approximately at the tongue base.

UES	0 mm from tip
Pharynx	30 mm from the tip
Tongue base	50 mm from the tip

3.2 Prepare the Investigation

The procedure is as follows:

Select the **patient name** in the database program and click the **New investigation** button.

Click the **UES manometry** button to start the pre-test.

Connect the pre-wetted solid state catheter and press the **Zero all** button to zero all pressures (the pressure sensors must be covered with approx. 1 cm of water).

- ❑ Search for the best nose opening. Insert the well-lubricated catheter through the patient's nose into the esophagus. The catheter should be inserted in such a way that the medial transducers clears the UES and is in the pharynx, while the distal transducer is in the High-Pressure Zone (HPZ) of the UES. The proximal sensor measures the tongue base pressure.+
- ❑ Find the maximum pressure in the HPZ by moving the catheter slowly up and down.
- ❑ Ask the patient to swallow to check the registration of all pressures and if applicable the registration of the swallow channel.

3.3 Measurement

The procedure is as follows:

Press the **Start investigation** button. Ask the patient not to swallow on his own. Measure the pressure in the HPZ for about 20 seconds. During this time the patient should not swallow!

Give the patient a 5 ml water bolus in the mouth. Using a syringe is most convenient. Ask the patient to swallow the bolus at once. Press the **Wet Swallow** button when the patient swallows. Do a series of 10 wet swallows. Wait at least 30 seconds before the next swallow. Let the patient also swallow different boluses. Mark these swallows with the appropriate swallow markers.

Whenever the patient inadvertently swallows without a bolus, you should mark that swallow with the **Dry swallow** button. This will aid in understanding the tracings when reviewing the investigation. Let the patient also swallow different bolus compositions and volumes. Mark these swallows with the appropriate swallow markers (pre-defined in the investigation protocol).

Press the **Stop investigation** button to stop recording.

Remote control buttons

The following buttons can be pressed during the study.

Buttons	Description
	**Change the catheter insertion depth** Press the **Previous** or **Next** button to change the insertion depth of the catheter in steps of 1 cm (manual pull only).
	Press the **Alt** button first and then press the **Catheter depth xx cm** button. Enter the new depth and click **OK** (or use the keyboard keys **Page up/down** and **Arrow up/down** to change the depth in steps of 10 and 1 cm).
	**Change the pressure scale** Press the **Scale up** or **Scale down** button to adjust the scale of the pressure channels.
	**Select swallow markers** Press the **Up** or **Down** button to select another pre-defined swallow marker (default 5 ml wet swallow).
	**Zero all pressures during measurement** Press the **Alt** button on the remote control first and then press the **Zero all** button.

3.4 Analysis

Before the results of the individual swallows can be calculated, the swallows should be marked with UES swallow markers. Also, the UES resting pressure should be marked with two UES resting pressure markers.

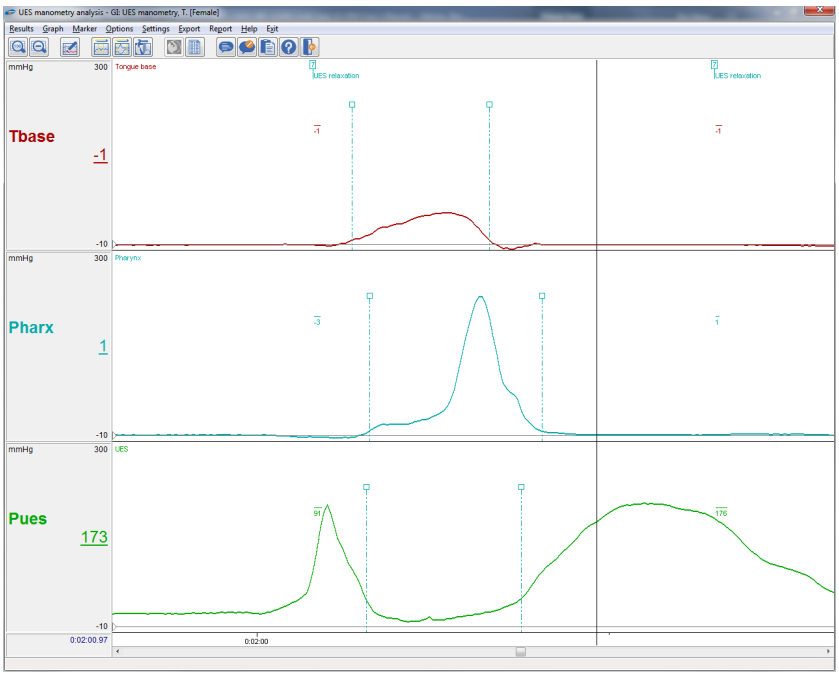


Figure 3.2 Analysis screen

UES resting pressure

An important parameter in the UES assessment is the UES resting pressure. This is the pressure in the HPZ (High Pressure Zone) of the UES at rest. Mark the HPZ of the UES as follows

- ❑ Select the **UES resting pressure marker** or click the **UES resting pressure marker** button.
- ❑ Select on which channel you want to place the marker.
- ❑ Place two markers around the UES resting pressure. This is the (high) pressure in the UES when the UES is in rest. After placing the UES resting pressure markers, the software calculates the resting pressure and uses this pressure for subsequent (channel) markers placement for UES relaxations.

UES relaxation

To mark the UES relaxations:

- ❑ Select the **UES swallow** marker or click the **UES swallow marker** button.
- ❑ Select on which channel you want to place the marker.
- ❑ Position the cursor just before the UES relaxation and press the left mouse button to place the first marker.
- ❑ Position the cursor after the UES relaxation and press the left mouse button to place the second marker. The software will now search for UES relaxation and the pharyngeal contractions and places channel markers at the appropriate position.

When the UES markers are placed, the software will search for a relaxation on the UES channel and a contraction at the pharyngeal (and if present tongue base) channel. UES channel markers will be placed, indicating the start and end of the UES relaxation on the UES channel. The software searches from the nadir of the UES relaxation towards the start and end of the relaxation until the pressure rises to half of the resting pressure. At that pressure level (half the resting pressure) channel markers are placed which indicate the start and end of the UES relaxation.

On the pharyngeal channels, the software will search from the peak to the start and end of the pharyngeal contraction and places channel markers when the pressure has dropped below a certain value. This value can be set in the UES settings. When shoulder marker insertion is enabled (see UES settings) an additional third marker is placed in the contraction. Often when the patient swallows a bolus, there will be a rise in the pharyngeal pressure caused by the bolus hitting the transducer. This is not due to muscle activity and can often clearly be distinguished from the actual contraction, which is quite steep compared to the pressure caused by the bolus. The shoulder marker can be placed in the transition, and the software will then calculate additional parameters for both the bolus area and the pharyngeal contraction. However, the software will place this marker in the middle, and you must position it to the correct position.

3.5 Results

In the analysis program, choose **Results** > **Display results** from the menu to display the calculated parameters. The following parameters can be calculated:

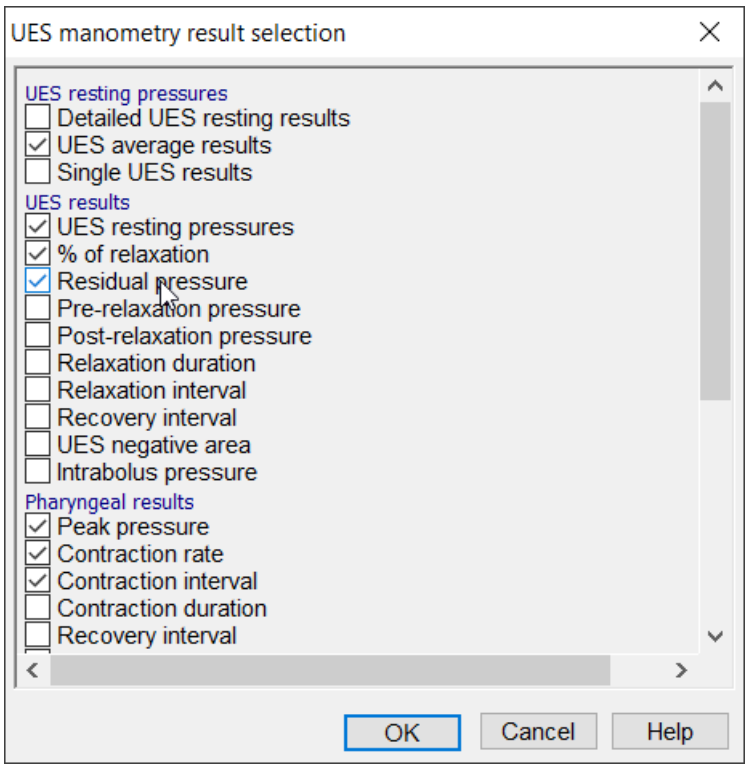


Figure 3.3 UES results selection

All calculated pressures are relative to the baseline.

UES resting pressures

The UES resting pressure is calculated as the average pressure between the two Resting pressure markers. These two markers should be placed in the High-Pressure Zone of the UES.

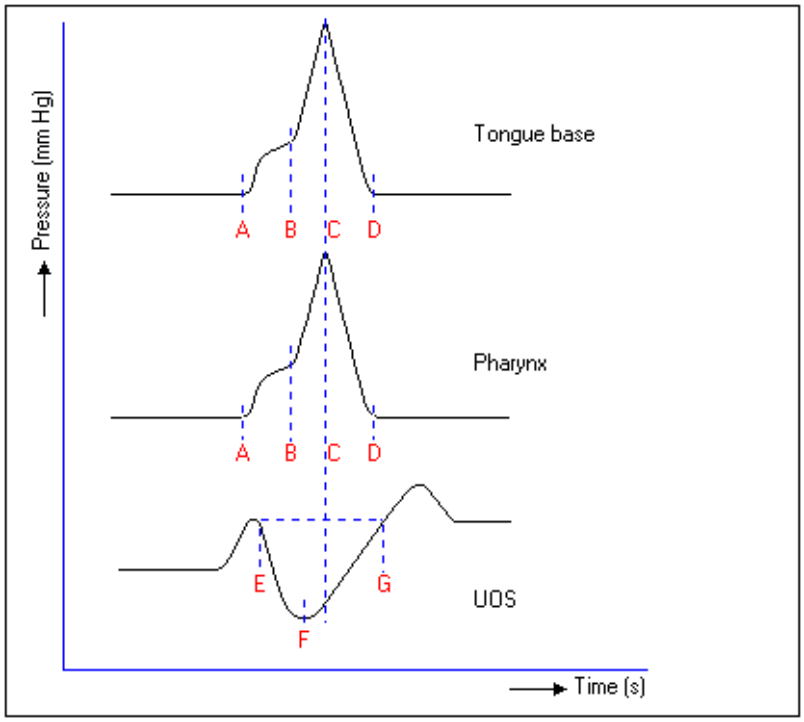


Figure 3.4 UES Results

% Relaxation
The percentage is calculated by determining the lowest pressure during the relaxation phase (=Residual pressure). This drop in pressure, is calculated as a percent of the full drop from the UES resting pressure to the (gastric) baseline.

Residual pressure
The residual pressure is the lowest pressure measured on the UES channel during the swallow [F].

Relaxation duration
The relaxation duration is the time (in ms) between the start [E] and end [G] of the relaxation.

Relaxation interval
The relaxation interval is the time (in ms) between the start of the relaxation [E] and the nadir of the relaxation [F].

Recovery interval
The recovery interval is the time (in ms) between the nadir [F] of the relaxation and the end [G] of the relaxation.

UES negative area
The UES negative area is the area in mmHg.s of that part of the UES relaxation which drops below the baseline.

Intrabolus pressure
The Intrabolus pressure is the pressure in the UES during bolus passage. It can only be measured accurately when UES measurement is performed with simultaneous X-ray recording with the cine-loop option. It is only calculated when an Intrabolus channel marker is placed on the UES channel. To place Intrabolus channel markers you should enable Insert intrabolus pressure markers in the UES settings.

Pharyngeal (and Tongue base) results

Peak pressure
The peak pressure is the highest pressure during the pharyngeal contraction [C] relative to the baseline.

Contraction rate
The contraction rate (mmHg/s) is the rate at which the pressure rises during a contraction. It is calculated as: (P[c]-P[b]) / (T[c]-T[b])

Contraction interval
The contraction interval is the time (in ms) between the onset of the pharyngeal contraction [A] and the peak of the pharyngeal contraction [C].

Contraction duration
The contraction duration is the time (in ms) between the start [A] and end [D] of the pharyngeal contraction.

Recovery interval
The recovery interval is the time (in ms) from the peak [C] of the pharyngeal contraction to the end [D] of the pharyngeal contraction.

Bolus peak amplitude
The bolus peak amplitude is the maximum pressure between the onset of the pharyngeal contraction [A] and the end of the bolus area [B]. This result is only calculated when shoulder markers are placed.

Bolus duration
The bolus duration is the time (in ms) between the onset of the pharyngeal contraction [A] and the end of the bolus area [B]. This result is only calculated when shoulder markers are placed.

Tongue driving force
The Tongue driving force is the area between the pharyngeal pressure curve and the baseline between the onset of the pharyngeal contraction [A] and the end of the bolus area [B]. This result is only calculated when shoulder markers are placed.

Contraction area
The contraction area is the area (mmHg.s) between the pharyngeal pressure curve and the baseline for the duration of the contraction.

Coordination
Following timings are all calculated in ms and are measured between the indicated points.

Beginning of Pharyngeal contraction to:

- Beginning of UES relaxation [A]-[E]
- Nadir of UES relaxation [A]-[F]
- End of UES relaxation [A]-[G]

Peak of Pharyngeal contraction to:

- Beginning of UES relaxation [C]-[E]
- Nadir of UES relaxation [C]-[F]
- End of UES relaxation [C]-[G]

End of Pharyngeal contraction to:

- Beginning of UES relaxation [D]-[E]
- Nadir of UES relaxation [D]-[F]
- End of UES relaxation [D]-[G]

Normal values
Normal values can be entered for the UES assessment. In the results window, there is an additional normal values menu.

- **Normal values > Show**
  Toggles normal values on/off.
- **Normal values > Edit**
  Enter or edit the normal values for swallows.

3.6 Settings

In the analysis program, choose **Settings > UES manometry settings** to edit the UES manometry settings.

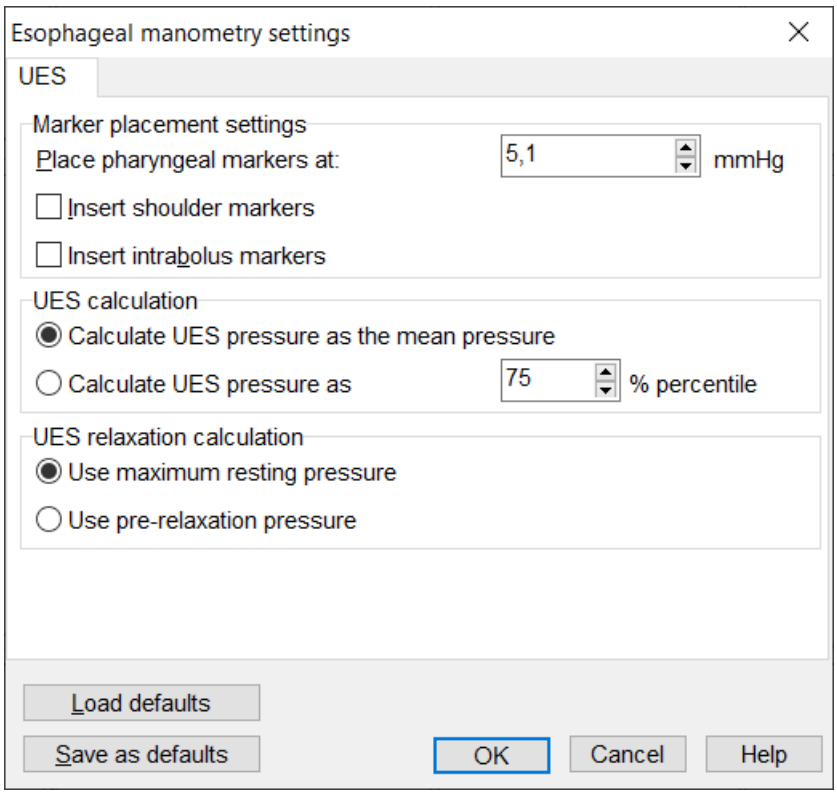


Figure 3.5 UES manometry settings

The software automatically places several channel markers when UES swallow markers are placed. The UES manometry settings control which markers are placed and where these markers are placed.

Place pharyngeal markers at [5.1 mmHg]
The pressure value, relative to the baseline, where the pharyngeal channel markers are placed. The software will search from the peak of the pharyngeal contraction towards the start and end of the contraction for the specified pressure. At that position the channel marker are placed.

Insert shoulder markers
Check this field when the software should also insert shoulder markers. The esophageal pressure rises before the actual contraction as a result of the ingested water bolus This pressure rise is also called the shoulder of the contraction. The software can automatically place shoulder markers, at the end of the shoulder and beginning of the actual contraction.

Insert Intrabolus markers
When this option is activated, the software will insert an intrabolus pressure marker on the UES channel. This marker should be moved by the user to the correct position, where the bolus passes the pressure sensor. The marker can only be accurately placed when the UES manometry is combined with X-ray recording by means of a cineloop.

Calculate UES pressure as the mean pressure
When this option is activated the UES resting pressure is calculated as the mean pressure between the UES resting pressure channel markers.

Calculate UES pressure as [75% percentile]
When this option is activated the entered % percentile of the pressure between the UES resting pressure channel markers is calculated.

Use maximum resting pressure
When activated, the % relaxation will be calculated relative to the maximum UES resting pressure calculated on this channel.

Use pre-relaxation pressure
When activated, the software will calculate the pre-relaxation pressure and use this value to calculate the % relaxation. The pre-relaxation pressure is the mean or x% percentile pressure over 5 seconds prior to the first UES relaxation channel marker. The UES resting pressure calculation setting will determine how the pre-relaxation pressure will be calculated.

4. Esophageal Manometry

4.1 Introduction

The study of the esophageal body evaluates the response of the muscles to a swallow and the relaxation of the LES. Normally the muscles contract in an orderly sequence from top to bottom (peristalsis) to transport the swallowed bolus into the stomach.

The major purpose of esophageal manometry is to diagnose esophageal motility dysfunction. The esophageal manometry study can be split up in three parts:

- Esophageal body manometry.
- Lower esophageal sphincter (LES) manometry.
- Upper esophageal sphincter (UES) manometry.

To assess the LES and the esophageal body in one investigation, you can best use a catheter with four or more transducers in the esophagus. For the LES you can have a sleeve transducer or four radial transducers.

The catheter that is used must be selected in the investigation protocol (see § 11.5.6). The investigation protocol for esophageal studies has some settings which are specific for the esophageal studies (see § 11.5.5).

HRM

For the High-Resolution Manometry (HRM) software option, a separate manual is available which describes the preparation of a HRM investigation and the HRM software program (measurement program and analysis program, Document Code: 0075-MAN-089-EN Solar GI HRM User's manual).

4.2 Prepare the Investigation

The procedure is as follows:

Select the **patient name** in the database program and click the **New investigation** button.

Click the **Esophageal manometry** button to start the pre-test.

❑ Prepare the perfusion system and connect the catheter to the pressure transducers. Turn on the water flow and flush the transducers and catheter. Be sure that there are no air bubbles left.

Press the **Zero all after 10 seconds** button. Keep the catheter horizontally at the level of the esophagus of the patient to zero-balance the pressures.

- ❑ Move the catheter up to 40 cm. Check the registration of the transducers. 40 cmH_2O is approximately 30 mmHg.
- ❑ Search for the best nose opening. Insert the well-lubricated catheter through the patient's nose into the esophagus. The LES sensors must be positioned in the stomach. Insert as far as the default insertion depth shown on the screen.
- ❑ Ask the patient to breath deep in and out in order to check the registration of all pressures.

4.3 Measurement

The procedure is as follows:

Press the **Start investigation** button.

Press the **xx cm** button to mark the insertion depth of the catheter.

Catheter insertion depth

The xx cm on the catheter insertion depth button is the default insertion depth. When the catheter is inserted into the patient, you can read the insertion depth from the markers on the catheter. You can mark this insertion depth in the software by means of xx-cm markers, where xx stands for the insertion depth. When the real insertion depth differs from the default catheter insertion depth entered in this field, you can change the insertion depth during the investigation, by means of the **Prev** and **Next** keys on the remote control.

Withdraw the catheter step-by-step until the radial transducers (or the sleeve) are in the LES. Press the **xx cm** button each time when the catheter is withdrawn 1 cm. Ask the patient not to swallow on his own.

Give the patient a 5ml water bolus in the mouth. Using a syringe is most convenient. Ask the patient to swallow at once. Press the **Wet Swallow** button when the patient swallows.

Do a series of 10 wet swallows. Wait at least 30 seconds before the next swallow. Press the **Wet Swallow** button when the patient swallows.

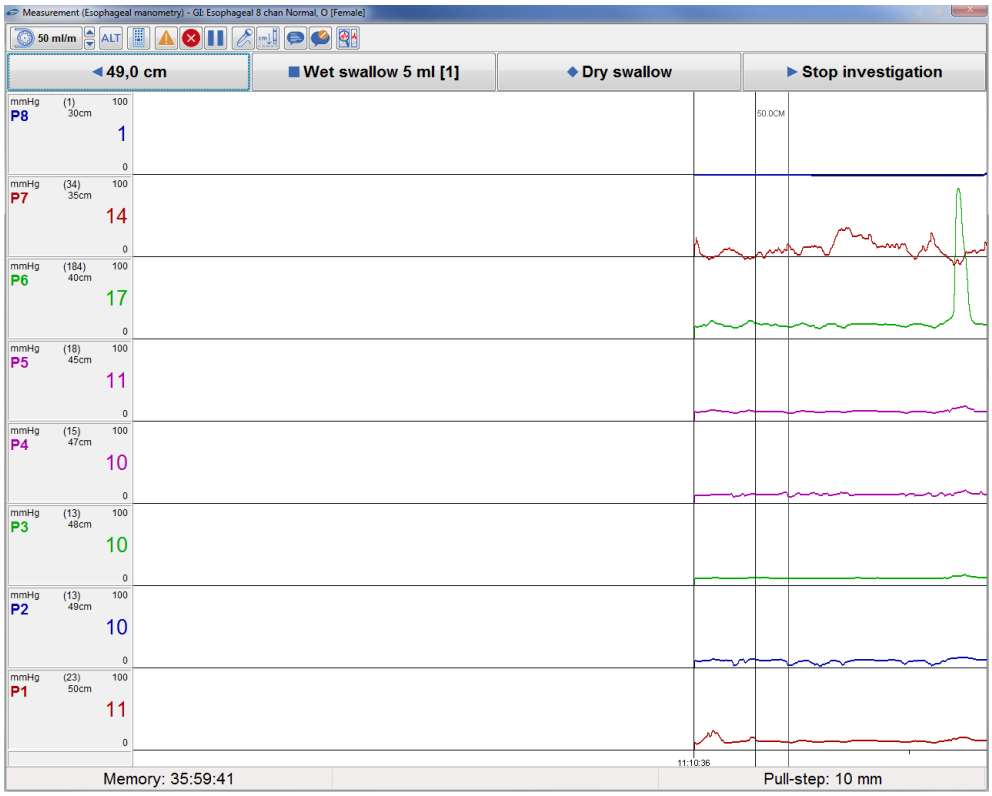


Figure 4.1 Esophageal manometry

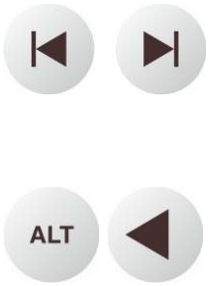
Whenever the patient inadvertently swallows without a bolus, you should mark that swallow with the **Dry swallow** button. This will aid in understanding the tracings when reviewing the investigation. Let the patient also swallow different bolus compositions and volumes. Mark these swallows with the appropriate swallow markers (pre-defined in the investigation protocol). You may also withdraw the catheter to analyze pressures in the esophagus at different levels, or in the UES.

Press the **Stop investigation** button to stop recording.

Remote control buttons

The following buttons can be pressed during the study.

Buttons	Description

	**Change the catheter insertion depth** Press the **Previous** or **Next** button to change the insertion depth of the catheter in steps of 1 cm (manual pull only). Press the **Alt** button first and then press the **Catheter depth xx cm** button. Enter the new depth and click **OK** (or use the keyboard keys **Page up/down** and **Arrow up/down** to change the depth in steps of 10 and 1 cm).
	**Change the pressure scale** Press the **Scale up** or **Scale down** button to adjust the scale of the pressure channels.
	**Select swallow markers** Press the **Up** or **Down** button to select another pre-defined swallow marker (default 5 ml wet swallow).
	**Zero all pressures during measurement** Press the **Alt** button on the remote control first and then press the **Zero all** button.

4.4 Analysis

4.4.1 Introduction

An esophageal manometry investigation is analyzed as follows:

1 Check the position of the wet swallow markers.
2 Search for contraction markers automatically.
3 Check the position of the contraction markers.
4 Set baselines to the gastric pressure.
5 Measure the LES resting pressure.
6 Measure the LES relaxation.
7 Measure the LES location.

Besides the contraction analysis, the software can also calculate LES and UES parameters. LES markers should be placed as described in this paragraph. UES markers are described in previous chapter.

4.4.2 Check Position Wet Swallow Markers

Check the positions of all wet swallow markers. Wet swallow markers **must** be placed **before** the onset of a contraction. To move (reposition) a marker, click with the left mouse button in the marker square and drag.

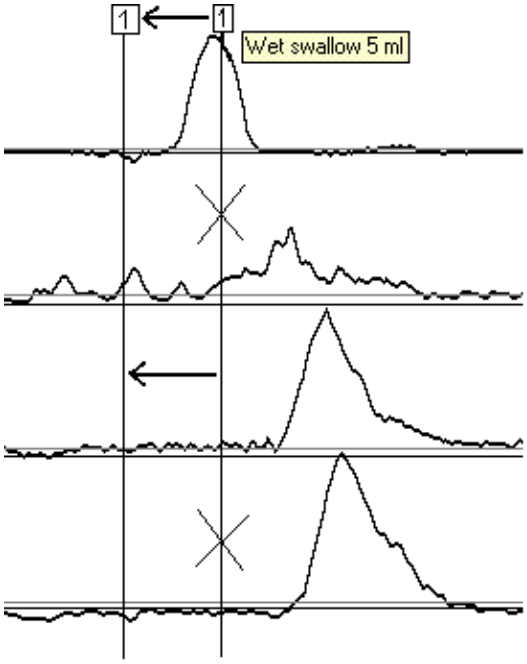


Figure 4.2 Move markers before onset of wet swallow

To add a marker, click with the right mouse button on the curves and select **Insert marker**. To delete a marker, click with the right mouse button on the marker square and select Delete.

4.4.3 Search Contraction Markers

The contraction markers can be placed automatically for each (marked) wet swallow. To mark the contractions, click the **Search esophageal contractions** button.

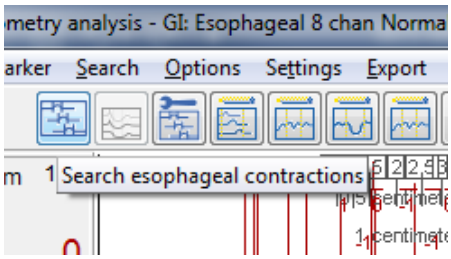


Figure 4.3 Search contraction markers

When a wet swallow marker is found, the software will search in a specific time window (default 20 seconds) after the wet swallow marker for a contraction wave. When a contraction wave is found, it will be marked with contraction markers. The software will search through the whole test and marks all contractions found.

You can also place the markers one by one around a contraction. Select the Contraction marker from the list. Whenever two markers are placed around a contraction, channel markers will appear around the actual contraction on each channel. These two channel markers indicate the start and end of the contraction as used in the calculation.

NOTE Wet Swallow markers indicate the position in the investigation where the patient swallowed. Usually these markers are placed during the study, however it is also possible to place them during the analysis.

4.4.4 Check Position Contraction Markers

It is recommended to check all contraction markers before the software calculate results for the swallow waves. When placed, the software will search for a contraction peak on each channel.

If a contraction peak is found, the software will place two channel markers around the peak. These two markers indicate the start and end of the contraction peak as used in the result calculation. If these two markers are not correct, you can reposition them.

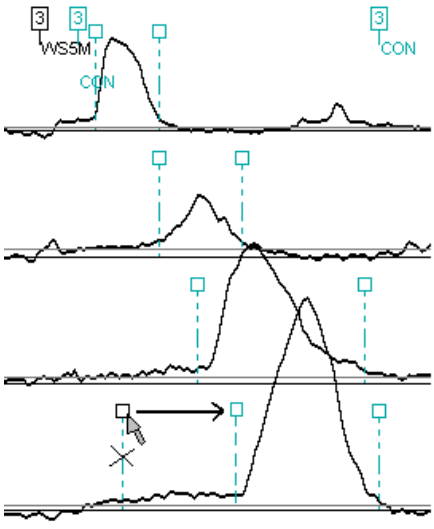


Figure 4.4 Wrong location channel marker

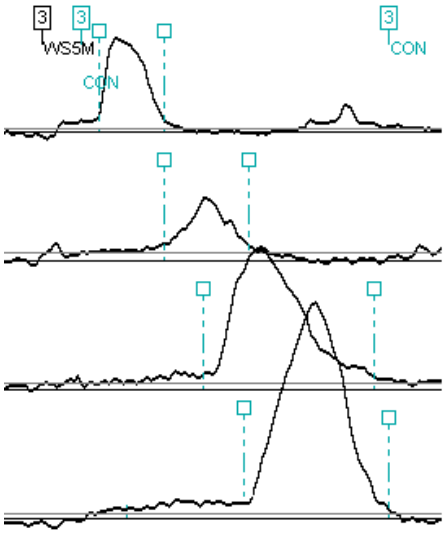


Figure 4.5 Repositioned channel marker

Move the markers by placing the mouse in the square of the marker.
With the left mouse button pressed, drag the marker to the correct position.

4.4.5 Set Baselines to the Gastric Pressure

To calculate the LES resting pressure and the LES relaxation, you must set the gastric baseline for the LES channels. To set the gastric baseline, click

with the left mouse button on the triangle (the baseline). Move the baseline to the required position.

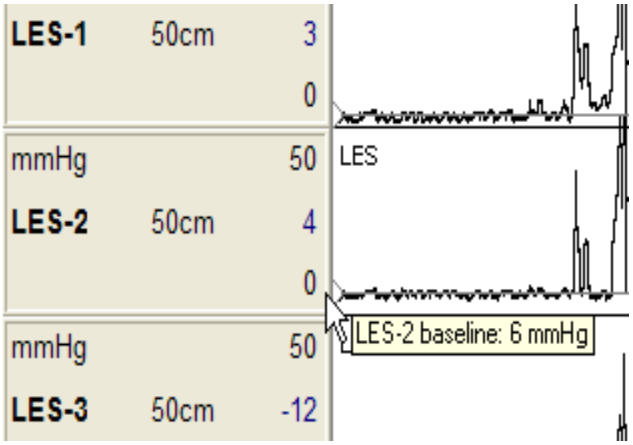


Figure 4.6 Set gastric baseline

The baseline can never be outside the min/max scale (in this example between 0-50).

If you want to move the gastric baseline below zero, you must first change the minimum scale to -10 mmHg by clicking on the minimum scale number. Then the baseline can go negative to -10.

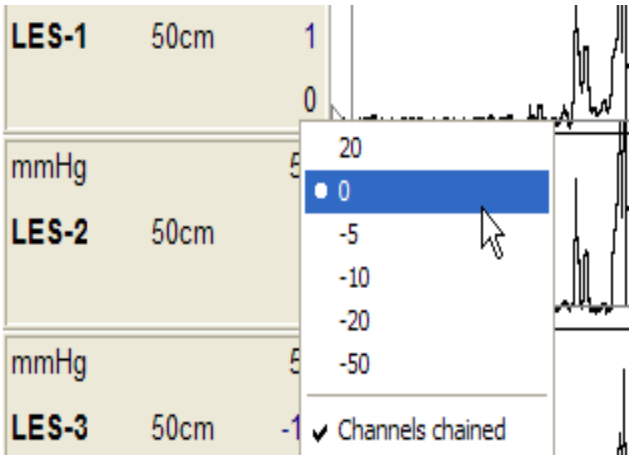


Figure 4.7 Set scale

4.4.6 Measure the LES Resting Pressure

Before the software will calculate results for the LES relaxations, you must set the gastric baseline and mark the LES resting pressure. First you must select the **LES resting pressure** marker. Then you must select on which channel(s) you want to calculate the LES resting pressure. In this example, P5..P8 are radial sensors in the LES.

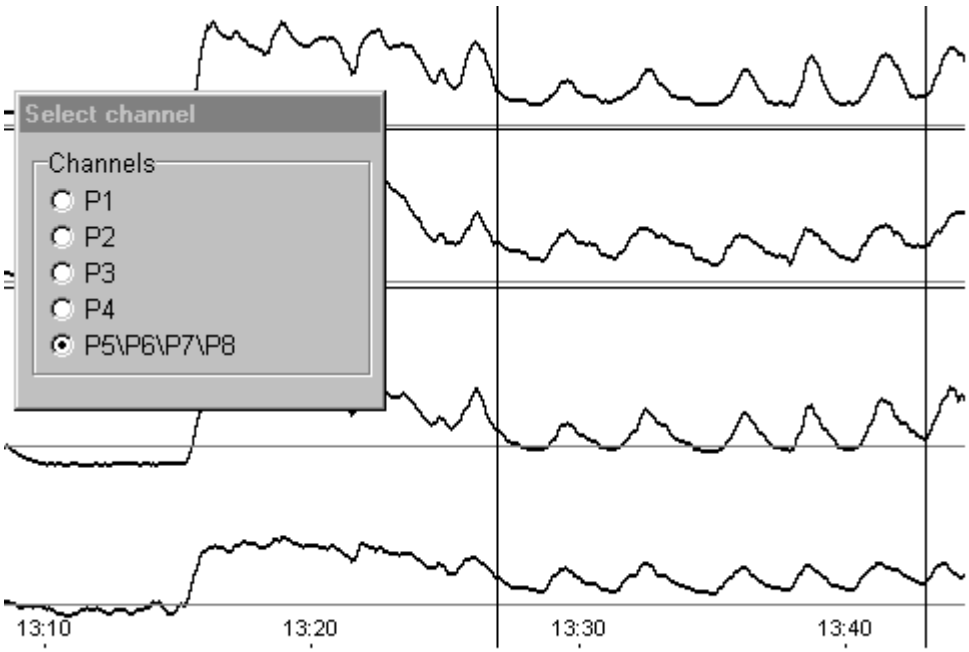


Figure 4.8 Select the channels

Mark the begin and end of the LES resting pressure (around the LES high-pressure zone). Usually, this is between two swallows. The pressure on the LES channels will be averaged and displayed in the results as the LES resting pressure.

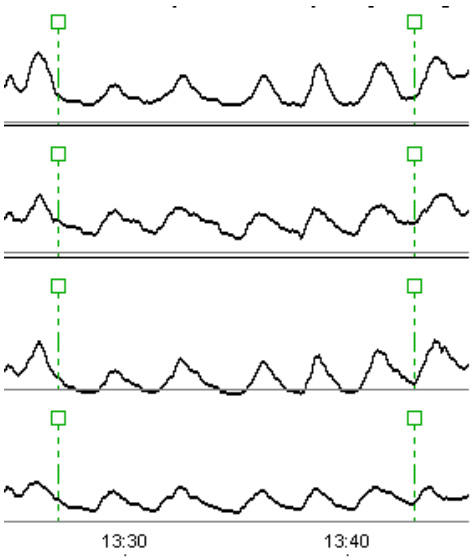


Figure 4.9 LES resting pressure markers

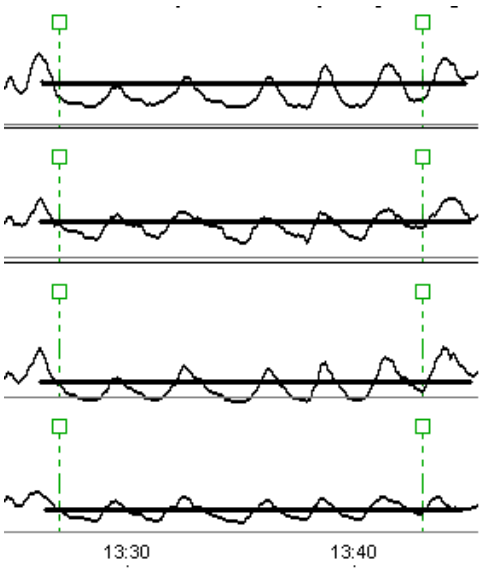


Figure 4.10 Software calculates average Pressure

4.4.7 Measure the LES Relaxation

Select the LES relaxation marker by clicking the corresponding **LES relaxation** button or via the menu **Marker > Insert marker**. Place two markers around the LES relaxation. When placed, the software will search for the trough of the LES relaxation. When the trough is found, the software will

search towards the start and end of the relaxation for the resting pressure. When the resting pressure is found, the software will place a LES relaxation channel marker at that position.

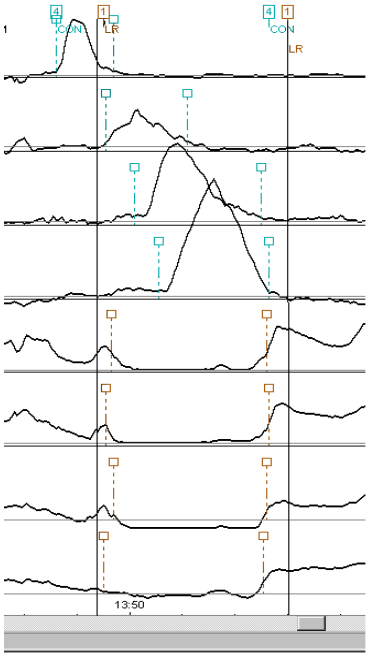


Figure 4.11 LES relaxation

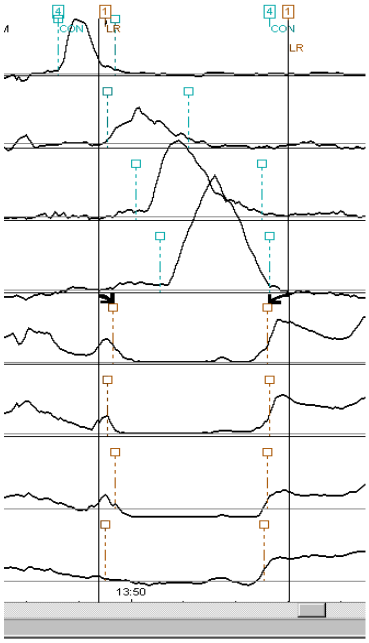


Figure 4.12 LES relaxation

4.4.8 Measure the LES Location and Length

You can measure the LES location and the LES length by placing LES location markers. Select the LES location marker and click **OK** as displayed below.

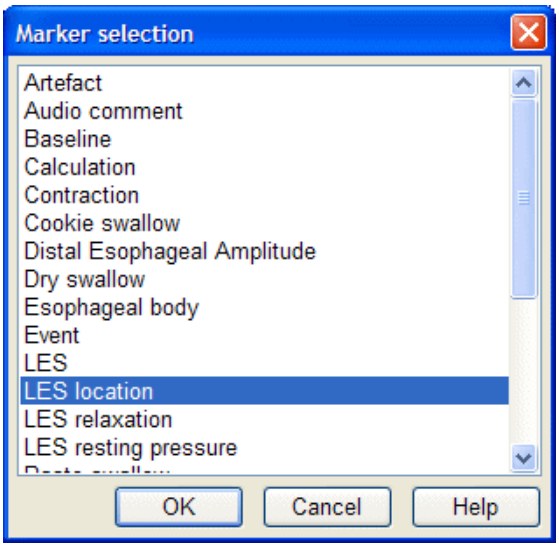


Figure 4.13 LES location marker

Select on which channel you want to place the LES location markers. Place the first marker at the position that the channel enters the LES (the LES lower border). Place the second marker at the position that the channel leaves the LES (the LES upper border).

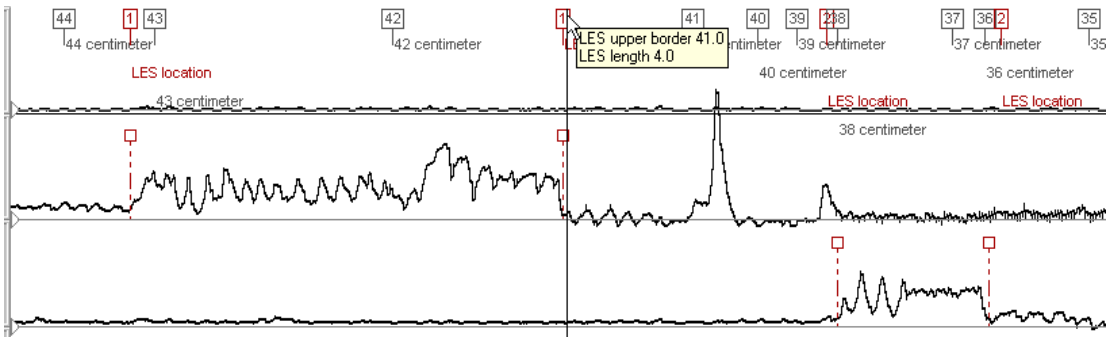


Figure 4.14 LES location

In the figure above, the LES location markers are place on the channels P2 and P3. The LES upper border and the LES length are both printed in the report. The upper border may be used for positioning the pH probe for a pH study (Upper border minus 5 cm). In the example above the pH sensor is positioned at 41 – 5 = 36 cm.

4.5 Results

In the analysis program, choose **Results** > **Display results** from the menu to display the calculated parameters. The following parameters can be calculated:

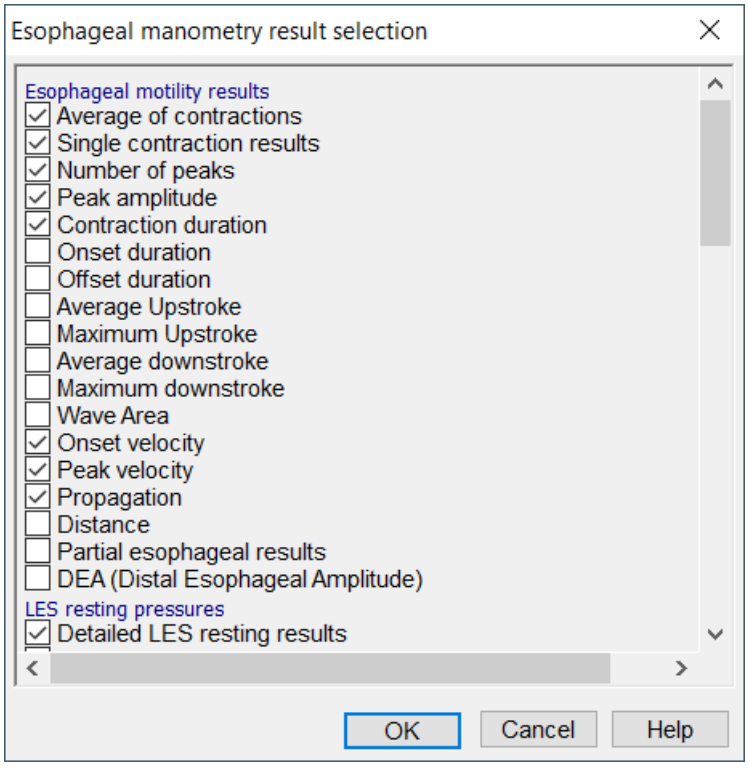


Figure 4.15 Esophageal manometry results selection

Esophageal results are calculated for each (marked) wet swallow. All calculated pressures are relative to the baseline.

Number of peaks

The number of peaks that are present on the contraction. A peak is detected if it has at least 10% of the overall wave amplitude and 1 second in duration. Peristaltic contractions that have two pressure peaks are called double peaked contractions and are considered a variant of the normal contractions. Triple peak contractions are considered abnormal.

Peak amplitude

Contraction amplitude [A] is measured from the baseline to the peak of the pressure wave. The amplitude is a measurement of how tightly the muscles of the esophagus are squeezing during a contraction.

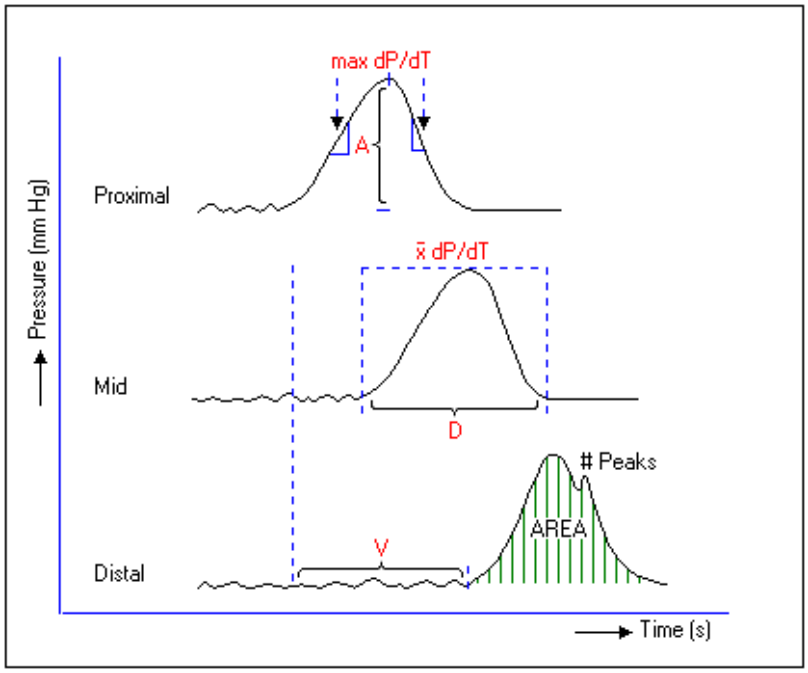


Figure 4.16 Esophageal contraction

Contraction duration

The duration is the time, in seconds, the muscles of the esophagus are squeezing during a contraction. The duration is determined as the time between the two channel markers indicating the contraction.

Onset / offset duration

The onset duration is the duration from the beginning of a contraction to its peak. The offset duration is the duration from the peak to the end of the contraction. The results can be selected in the ‘results selection’ window.

Average slope

The average slope [x dP/dT] is determined as the change in pressure (eg. the peak amplitude minus the baseline) divided by the time from the onset of the wave to the peak (dP/dT up) or by the time from the peak to the end of the wave (dP/dT down).

Maximum slope
Maximum up- and down slope [max dP/dT] is determined by calculating the maximal change in pressure of the contraction in 1/3 second.

Wave area
The area under the wave [AREA] is found by integrating pressure values from the begin to the end of the wave.

Onset velocity
The onset velocity [V] is defined as the distance between the two recording sites, divided by the elapsed time from the onset of the wave at the first recording site to the onset of the wave on the second recording site.

Peak velocity
The peak velocity is also calculated and is defined as the distance between the two recording sites divided by the elapsed time from the peak of the proximal channel to the peak of the distal channel.

Propagation
The propagation section gives an overview of the onset velocity and Peak to Peak velocity between all measured channels.

Contraction categories
Contractions are divided in 6 different categories; Peristaltic, Simultaneous, Retrograde, Dropped, Interrupted and Non-transmitted contractions. Following overview explains how the software categorizes the contractions.

Onset velocity
The onset velocity [V] is defined as the distance between the two recording sites, divided by the elapsed time from the onset of the wave at the first recording site to the onset of the wave on the second recording site.

Peak velocity
The peak velocity is also calculated and is defined as the distance between the two recording sites divided by the elapsed time from the peak of the proximal channel to the peak of the distal channel.

Propagation
The propagation section gives an overview of the onset velocity and Peak to Peak velocity between all measured channels.

Contraction categories
Contractions are divided in 6 different categories; Peristaltic, Simultaneous, Retrograde, Dropped, Interrupted and Non-transmitted contractions. Following overview explains how the software categorizes the contractions.

Contraction	Description
Peristaltic	A contraction is considered peristaltic when the proximal esophagus contracts before the distal esophagus. The contraction wave moves from the UES to the stomach, and propels the bolus downwards into the stomach. For a wave complex to be marked as peristaltic following criteria are used: 1. Contraction peaks are marked in all esophageal body channels 2. Onset velocity >1 cm/s and <= 20 cm/s
Non-peristaltic	The occurrence of nonperistaltic contractions after the patient wet swallowed is abnormal. Nonperistaltic contractions are either simultaneous or retrograde. A simultaneous contraction indicates that large portions of the esophagus are contracting at the same time, instead of in the normal, peristaltic sequence. A contraction is considered simultaneous when the onset velocity > 20 cm/s.
Retrograde	A contraction is considered retrograde when the distal esophagus contracts before the proximal esophagus. For a wave complex to be marked as retrograde following criteria are used: 1. Contraction peaks are marked in all esophageal body channels 2. Onset velocity < -1 cm/s and >= -20 cm/s
Dropped	A contraction is considered dropped when the proximal esophagus contracts normally but in the distal esophagus no contraction occur. For a wave complex to be marked as dropped following criteria are used: 1. Absence of contractions is most distal channel(s) 2. Contractions in most distal channels are simultaneous

Contraction	Description
Interrupted	A contraction is considered interrupted when contractions occur in the proximal and distal esophagus, but are absent in the channels in between. For a wave complex to be marked as interrupted following criteria are used: 1. Absence of contractions is most medial channel(s) while contractions are present in the proximal and distal channels 2. Contractions in most proximal channels are simultaneous
Non-transmitted	Sometimes a wet swallow will be followed by no activity in the distal esophagus. This phenomenon is known as a non-transmitted wave. Also 'peristaltic' waves with a onset velocity < 1 cm/s are considered non-transmitted.

4.6 Esophageal Contraction Identification

Esophageal swallow waves need to be marked before the contraction results are calculated and included in the report. This marking can be performed either automatically or manually. This paragraph will describe how you can mark the contractions and how the software can help to identify the contractions.

4.6.1 Search for Contraction Markers Automatically

The software can search automatically for contractions and mark them if found. Click the **Search esophageal contractions** button. The software will scan the investigation for contractions:

1. On esophageal body channels (the type of the channels can be set in the channel definition **Settings > Channel definition**).
2. A time window, around wet swallow markers. The contraction search window can be set in the contraction search settings as time before and time after swallow marker. Default 0 seconds before the wet swallow marker and 20 seconds after the wet swallow marker.
3. Optionally the software can also search for contractions around dry swallow markers (when corresponding option is activated).

4. From the start of the investigation, unless an esophageal body marker is placed. In that case the software will start searching from the esophageal body marker.
5. Until the end of the investigation, unless a UES marker is placed. In that case the software will stop searching at the UES marker.
6. If the option search and mark contractions from cursor option is activated, then the search will start from the current cursor position.

The software uses the contraction identification method which will be described in the next paragraph to detect contractions. If a contraction is found, then the begin and the end of the contraction are marked with channel markers. It is always possible to correct the position of channel markers manually, by dragging them on their labels to the correct position.

Note: Wet swallow markers (and dry swallow markers) indicates the position in the investigation where the patient swallowed. Usually these markers are placed during the investigation, however it is also possible to place them during the analysis.

4.6.2 Contraction Identification

When the software is searching for a contraction in a specified area it will first look for the highest peak in that area (C). The software then searches the curve backwards and forwards from the peak to the first crossings (points B and D) of the contraction threshold (E). The software will then check if the contraction time (D-B) meets the defined minimum duration and the amplitude (C) meets the defined minimum amplitude.

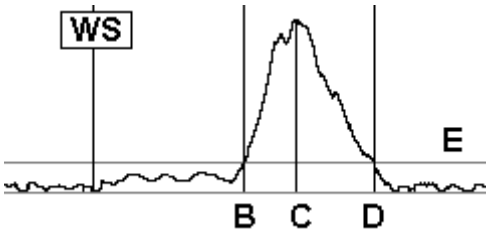


Figure 4.17 Contraction identification

Unwanted ramp between two points

Sometimes, esophageal contractions do have an unwanted ramp that should not be used for calculations. In the figure below this is the case between points A and B. The software provides an option *Use maximum upstroke method* (see next paragraph*)*, that in this kind of situation will identify point B as the start of the contraction.

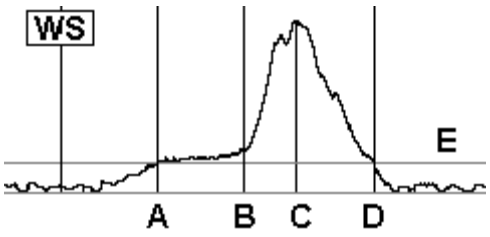


Figure 4.18 Contraction identification

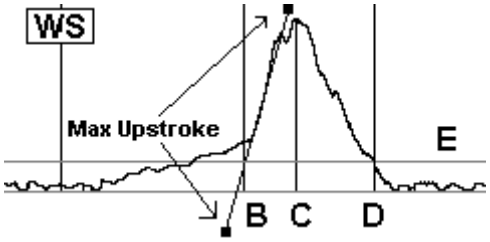


Figure 4.19 Contraction identification

The maximum upstroke method determines the beginning of the contraction as follows:

1. The software determines the points A and B using the threshold setting.
2. If the time between A and B is more than the minimum contraction duration the software proceeds, otherwise no contraction is found.
3. The software will calculate the best line (using linear interpolation, least square method) for a window of 0.5 seconds. This window will slide from the starting point A towards the peak moving the window sample by sample until the end of the window reaches the peak.
4. For each step 3, the software will check if the slope of the line is greater than the current maximal slope in which case this line is used for determining the beginning of the contraction.
5. If the maximum slope > 1 (45 degrees) then the software will determine the beginning of the contraction as the intersection of the line with maximum slope and the threshold.
6. In all other cases the threshold method is used to locate the beginning of the contraction.

4.6.3 Contraction Identification Settings

All setting related to finding and marking esophageal contractions can be set in the esophageal manometry settings dialogue. Click on the **Esophageal manometry settings** button or choose **Settings > Esophageal manometry settings**.

Minimum contraction amplitude [9.6 mmHg]
Minimum contraction amplitude which a contraction should have (from the baseline) to be marked.

Minimum contraction duration [1 s]

The minimum duration of a contraction at threshold. When a contraction last shorter as specified is found, it is ignored and not marked. This is used to prevent artifacts being marked as contractions.

After wet swallow marker [20 s]

Time after west swallow markers where the auto-search for esophagus contractions should end.

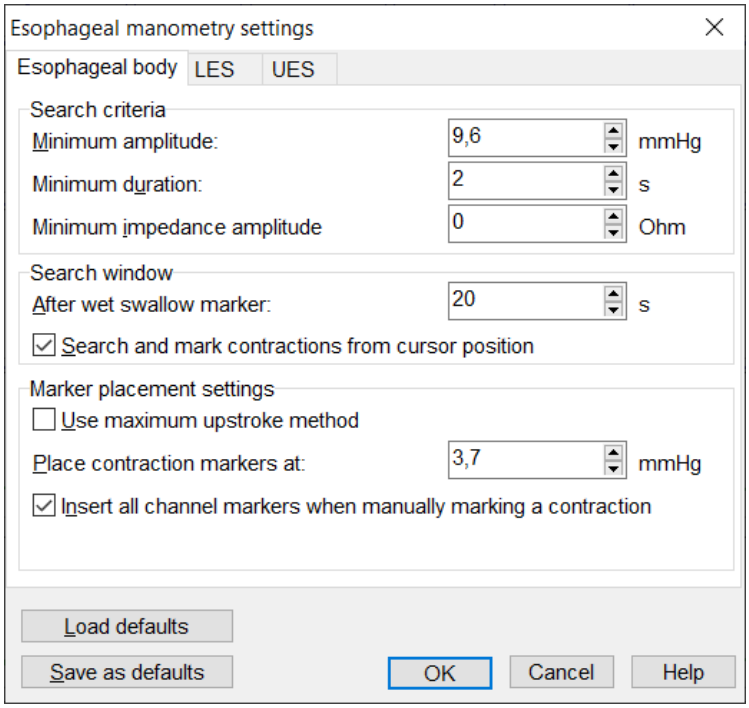


Figure 4.20 Contraction search

Search and mark contractions from cursor position

When this option is active, the software will start searching for contractions from the current cursor positions. No contractions will be marked left of the cursor position.

Find and mark dry contractions as well

When this option is active, the software will start searching and marking contractions also after Dry Swallow markers.

Use maximum upstroke method

When this option is activated the software calculates the begin and end points in following manner: Determines the points where the tracing and the level of the contraction threshold setting intersect.

If the time between these two point is below the minimum contraction duration, then the contraction is rejected. The software calculates the slope over a 0.5 second window from the start point towards the peak until the end sample of the window reaches the peak.

The place where the slope is maximal is determined. If the maximal calculated slope is < 1 (45 degrees) then the beginning of the contraction is determined by the threshold. When the maximal slope > 1 then the software determines the beginning of the contraction as the intersection of this line (with maximum slope) and the threshold.

Place contraction marker at [3.7 mmHg]
The pressure value, relative to the baseline, where the contraction channel markers are placed. The software will search from the peak to the onset and end of the contraction for the specified pressure. At that position the channel markers are placed.

Insert all channel markers on manual insert marker
When this option is activated, the software will place contraction channel markers on all esophageal body channels, regardless whether a contraction was found or not. In case a contraction was found, the channel markers will surround it. If no contraction was found, the channel markers will be placed at the same position as the parent markers and can be moved or deleted by the user.

When the option is inactive, the software will only mark contractions with contraction channel markers. If no contraction is present, the contraction channel markers are not placed.

4.6.4 Mark Contractions Manually

It is always possible to mark contractions manually by clicking the **Place Esophageal contraction marker** button. Now you can mark the contraction period by placing one marker at the begin of the Wave complex and the other marker at the end of the Wave complex.

The software will search on all esophageal channels in the marked period for contractions using the contraction identification method as described before. If contractions are found these contractions are marked. When no contraction is found whether the software will insert channel markers or not depends on the setting *Insert all channel marker when manually marking a contraction* (see previous paragraph). When this option is disabled, no channel markers are inserted for the channel where no contraction has been found. If the option is enabled however the software will insert channel markers at the begin and end of the marked period. In the latter case these markers need to be positioned manually, or should be removed (right click on the channel marker label and choose **Delete**).

5. LES Manometry

5.1 Introduction

The Lower Esophageal Sphincter (LES) consists of smooth muscles which are normally contracted to maintain closure. On swallow, the LES opens and relaxes. To investigate the LES, a pressure catheter is pulled from the stomach through the LES into the esophagus.

Lower Esophageal Sphincter (LES) studies are usually performed as a part of a standard esophageal manometry study (refer to chapter 4). A separate LES manometry study is primarily intended to perform the Rapid Pull Through technique, where the catheter is pulled out of the stomach into the esophagus at a constant speed by means of a catheter puller. When more than four channel are measured radially, the obtained data can be used to create a three-dimensional image of the LES.

Catheters

There are many different types of **water perfused catheters** suitable for measuring LES pressure. To assess the LES accurately it helps to use a catheter with radially orientated orifices, because the LES often has an asymmetrical pressure profile. You can also use a Dent sleeve manometry catheter, which is a water infusion catheter with a specially constructed tip. One side of a 6-cm segment at the tip is covered with a thin flexible membrane. A constant infusion of water occurs under this membrane, what produces a pressure-sensitive area along the segment. During manometry, the Dent sleeve is placed in the LES.

Instead of water infused catheters, **solid state catheters** can also be used. For LES assessment, it is best to use a catheter with a transducer which measures pressures radially, or a catheter with multiple transducers placed radially.

A catheter definition should be created for the used catheter. This catheter should be selected in the investigation protocol (see § 11.5.6)

5.2 Prepare the Investigation

The procedure (for water catheters) is as follows :

Select the **patient name** in the database program and click the **New investigation** button.

Click the **LES manometry** button to start the pre-test.

- ❑ Position the puller catheter clamp at the end of the puller arm, by means of the puller buttons in the software.
- ❑ Prepare the perfusion system and connect the catheter to the pressure transducers. Turn on the water flow and flush the transducers and catheter. Be sure that there are no air bubbles left.

Press the **Zero all after 10 seconds** button. Keep the catheter horizontally at the level of the LES of the patient to zero-balance the pressures.

- ❑ Move the catheter vertically up to 40 cm. Check the registration of the transducers. 40 cmH_2O is approximately 30 mmHg.
- ❑ Search for the best nose opening. Insert the well-lubricated (radial) catheter through the patient's nose into the esophagus. The LES transducers must be positioned in the stomach. Insert as far as the default insertion depth shown on the screen.
- ❑ Place the catheter on the puller head.
- ❑ Ask the patient to breath deep in and out in order to check the registration of all pressures.

5.3 Measurement

The procedure is as follows:

Press the **Start investigation** button.

Press the **Start puller** button. The catheter is withdrawn by the puller.

Press the **LES profile [1]** button to mark the start of the profile.

Press the **Profile end** button to mark the end of the profile. Repeat this procedure if necessary.

 Press the **Stop investigation** button stop recording.

As the catheter is pulled through the LES, it will soon reach a point where tracing goes *down* rather then *up* with inspiration. This is called the Pressure Inversion Point (PIP), also known as the point of respiratory reversal. If the pressures in the sphincter are very low, this reversal point may be the only way to locate the LES.

Remote control buttons

The following buttons can be pressed during the study.

Buttons	Description
	**Change the pressure scale** Press the **Scale up** or **Scale down** button to adjust the scale of the pressure channels.
	**Select swallow markers** Press the **Up** or **Down** button to select another pre-defined swallow marker (default 5 ml wet swallow).
	**Change the catheter insertion depth** Press the **Alt** button first and then press the **Catheter depth xx cm** button. Enter the new depth and click **OK** (or use the keyboard keys **Page up/down** and **Arrow up/down** to change the depth in steps of 10 and 1 cm).
	**Zero all pressures during measurement** Press the **Alt** button on the remote control first and then press the **Zero all** button.

5.4 Analysis

To assess the LES you should mark the LES resting pressure and the LES relaxations. Before the software will calculate results for the LES relaxations, you must to set the gastric baseline as described in § 4.4.5.

5.4.1 Place LES markers

To mark the LES resting pressure, place two LES resting pressure markers around the LES high-pressure zone as described in § 4.4.6. The pressure on the LES channels will be averaged and displayed in the results as the LES resting pressure.

The relaxations can be marked by placing two LES relaxation markers around each LES relaxation as described in § 4.4.7. After you placed the LES relaxation markers around the relaxation, the program will automatically insert LES relaxation channel markers. These channel markers will be placed at the level of LES resting pressure (determined by the program as the average pressure on the LES channel between the LES resting pressure markers), one before and one after the relaxation.

5.5 Results

In the analysis program, choose **Results** > **Display results** from the menu to display the calculated parameters.

The following lower esophageal sphincter results are calculated for each (marked) wet swallow. All calculated pressures are relative to the baseline.

LES relaxations summary
The LES relaxations summary gives an overview all LES relaxations categories.

%Complete LES relaxations
The % of complete relaxations in the investigation. A LES relaxation is considered complete when the relaxation >= 80 %.

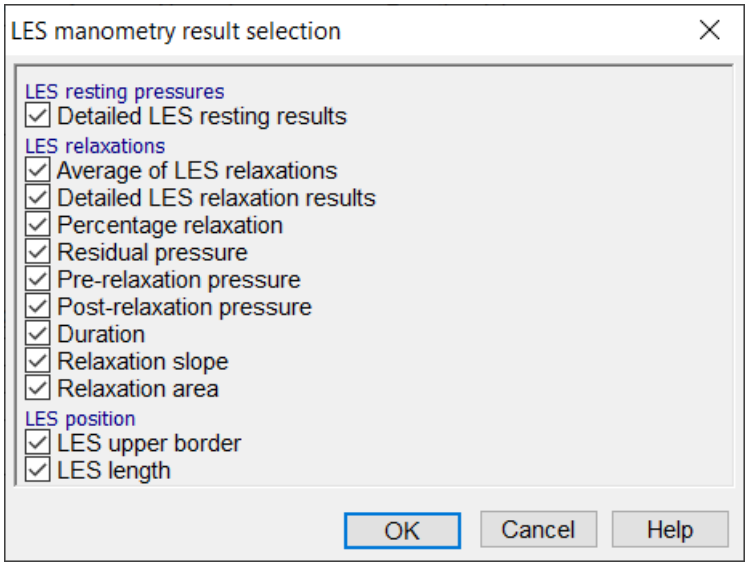


Figure 5.1 LES manometry results selection

%Partial LES relaxations

The % of partial relaxations in the investigation. A LES relaxation is considered partial when the relaxation >0% and < 80 %.

%Absent LES relaxations

The % of absent relaxations in the investigation. A LES relaxation is considered absent when the relaxation =0%.

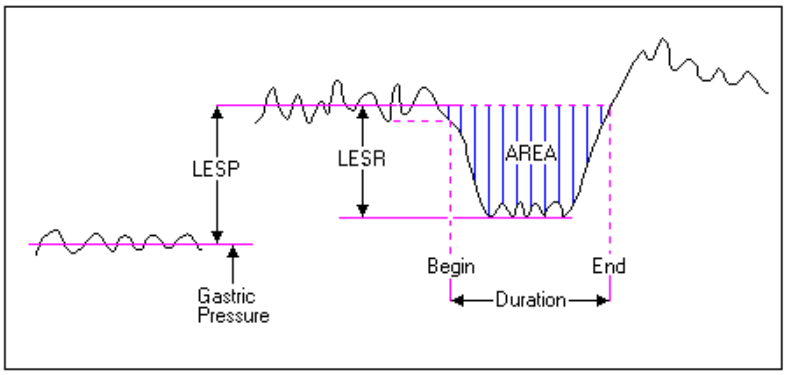


Figure 5.2 LES results

LES resting pressures

Detailed LES resting pressure results

The LES resting pressure [LESP] is calculated between the LES resting pressure channel markers on the LES channel(s). The resting pressure is determined by averaging the LES pressure between the two channel markers.

LES relaxations

Detailed LES relaxations results

LES relaxation results will be calculated for each (marked) LES relaxation. The LES relaxation channel markers indicate the start and end of the relaxation. Following results will be calculated for each relaxation.

%relaxation

The percentage relaxation is calculated as the percentage of drop from LES resting pressure to LES residual pressure to the LES resting pressure.

Percentage relaxation = ([LESR] / [LESP]) * 100%
where [LESR] = [LESP] - Residual pressure

Whenever the LES residual pressure is lower than the (gastric) baseline, the percentage relaxation will be considered 100%.

Residual pressure

The LES residual pressure is the lowest pressure during a relaxation relative to the baseline. This lowest pressure calculated as the minimum 2 second sliding average pressure between the two channel markers.

Relaxation duration

The duration in seconds between the start of the relaxation to the end of the relaxation.

Relaxation area

The area of LES relaxation is calculated as the integral from the relaxation curve to the LES resting pressure.

5.6 Settings

In the analysis program, choose **Settings > LES manometry settings** to edit the LES manometry settings.

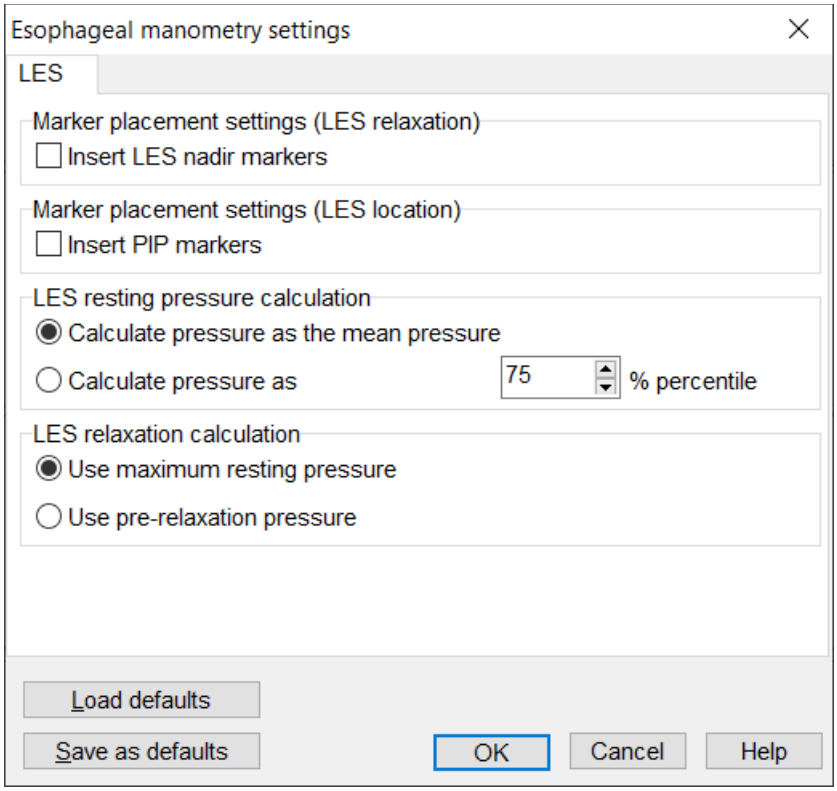


Figure 5.3 LES manometry settings

The software automatically places several channel markers when LES relaxation or LES location markers are placed. The LES manometry settings control which markers are placed.

Insert LES nadir markers

Activate this setting when the software should also insert LES nadir markers. When a LES nadir marker is present the software will use the pressure at this marker as the residual pressure. The software places the LES nadir marker at the point of the lowest pressure between the LES relaxation markers.

Insert PIP markers
Activate this setting when the software should also insert PIP markers. When a PIP marker is present the software will also calculate Intra-abdominal length and the PIP position. The software will insert the PIP marker between the LES location channel markers. You should visual determine the exact position of the PIP and move the PIP marker to that position.

Calculate pressure as the mean pressure
When this option is activated the LES resting pressure is calculated as the mean pressure between the LES resting pressure channel markers.

Calculate pressure as [75% percentile]
When this option is activated the entered % percentile of the pressure between the LES resting pressure channel markers is calculated.

Use maximum resting pressure
When activated, the % relaxation will be calculated relative to the maximum LES resting pressure calculated on this channel.

Use pre-relaxation pressure
When activated, the software will calculate the pre-relaxation pressure and use this value to calculate the % relaxation. The pre-relaxation pressure is the mean or x% percentile pressure over 5 seconds prior to the first LES relaxation channel marker. The LES resting pressure calculation setting will determine how the pre-relaxation pressure will be calculated.

6. Antroduodenal Manometry

6.1 Introduction

With the stationary antroduodenal investigation, phase I, II and III of the MMC (migrating motor complex) cycles can be recorded. It can be used for investigating the mechanisms of delayed gastric emptying. The investigation can take several hours to determine motor activity of the gastroduodenal motor unit after taking a meal.

Solid state or water perfusion catheters with 4 to 36 pressure channels (optionally in combination with impedance channels) can be used.
During the study the sensors in the antrum can move into the duodenum. An optional TMPD recording channel can be used to check the position of the catheter around the pylorus. Fluoroscopy is also an accurate method to aid and verify catheter placement.

6.2 Prepare the Investigation

The procedure is as follows:

Select the **patient name** in the database program and click the **New investigation** button.

Click the **Antroduodenal manometry** button to start the pre-test.

(For solid state catheters) connect the pre-wetted solid state catheter and press the **Zero all** button to zero all pressures (the pressure sensors must be covered with approx. 1 cm of water).

Or (for water perfused catheters):

- ❑ Prepare the perfusion system and connect the water catheter to the pressure transducers. Turn on the water flow and flush the transducers and catheter. Be sure that there are no air bubbles left.

Press the **Zero all after 10 seconds** button. Keep the catheter horizontally at the level of the guts of the patient to zero-balance the pressures.

- ❑ Move the catheter vertically up to 40 cm. Check the registration of the transducers. 40 cmH_2O is approximately 30 mmHg.
- ❑ Intubate the catheter through the nose into the stomach. For an easy passage of the pylorus let the patient lie on his/her right side. Optional a guidewire can be used. If the pylorus passage fails an endoscope can be used to place the catheter. Move the catheter beyond the ligament of Treitz. At least 3 or 4 sensors must be in the duodenum/jejunum. If the antral pressure is also recorded at least 2 or 3 sensors must be in the antrum.

6.3 Measurement

The procedure is as follows:

Press the **Start investigation** button.

Press the **Meal** button to mark the start of a meal period.

Press the **Meal End** button to mark the end of a meal period.

Press the **Stop investigation** button to stop recording.

Remote control buttons

The following buttons can be pressed during the study.

Buttons	Description
	**Change the pressure scale** Press the **Scale up** or **Scale down** button to adjust the scale of the pressure channels.

6.4 Analysis

6.4.1 Introduction

When an antroduodenum investigation is reviewed for the first time, information about the channels needs to be entered. The type of the channel (antrum, duodenum, jejenum) and the distance of the transducers on the catheter need to be set correctly for analysis.

This information can be stored in the analysis protocol and can be loaded when reviewing an investigation for the first time, but for some investigations it can be necessary to adjust the channel type, since a channel might be antrum in the loaded protocol, but in the investigation, it became a duodenum channel. This information can be set in the *Channel definition* (see § 6.6.3).

NOTE It is always necessary to look at the curves to determine the types of the channel and to set the channel types in an investigation that is reviewed for the first time!

After the channel types are set correctly, the contractions are searched automatically (detect peaks).

6.4.2 Markers

Besides the standard markers, the following markers can be placed in an antroduodenum investigation:

- Manometry markers
- Phase 3 markers

Manometry marker

Manometry markers are used to mark parts of the investigation for *Manometry results* (see § 6.5.1).

Phase 3 marker

Phase 3 markers are used to mark phase 3 parts of an MMC cycle. Phase 3 markers also have channel markers that are placed on the channels to mark in that channel the phase 3 waves. Numerous calculations are done for Phase 3 markers in the *Marker analysis results* (see § 6.5.2).

6.4.3 Detect Peaks

The software automatically searches for peaks of the contractions on the antroduodenal channels.

Motion artefacts (simultaneous pressure rises occurring at all transducers with similar amplitude and identical duration) are eliminated. This is done by calculating the minimum pressure curve, which consists of the minimum value for each set of samples taken simultaneously. The minimum curve is then subtracted from the individual curves.

In the contraction detection algorithm, a contraction is defined as an increase in pressure exceeding baseline pressure with more than the contraction threshold, lasting longer than the Minimum contraction duration (this is different for antral and duodenal channels), see § 6.6.1.

6.5 Results

6.5.1 Manometry Results

The manometry results will display the results for manometry markers that are placed in the investigation. For a set number of time windows calculations on the antroduodenal channels will be done (see also § **Error! Reference source not found.**). For each channel, the calculations for the time windows will be listed, so that the calculations can be compared.

For each time window the following is calculated:

- Contraction incidence
- Contraction frequency (2 ways)
- Summed contraction amplitude
- Mean contraction amplitude
- Motility index

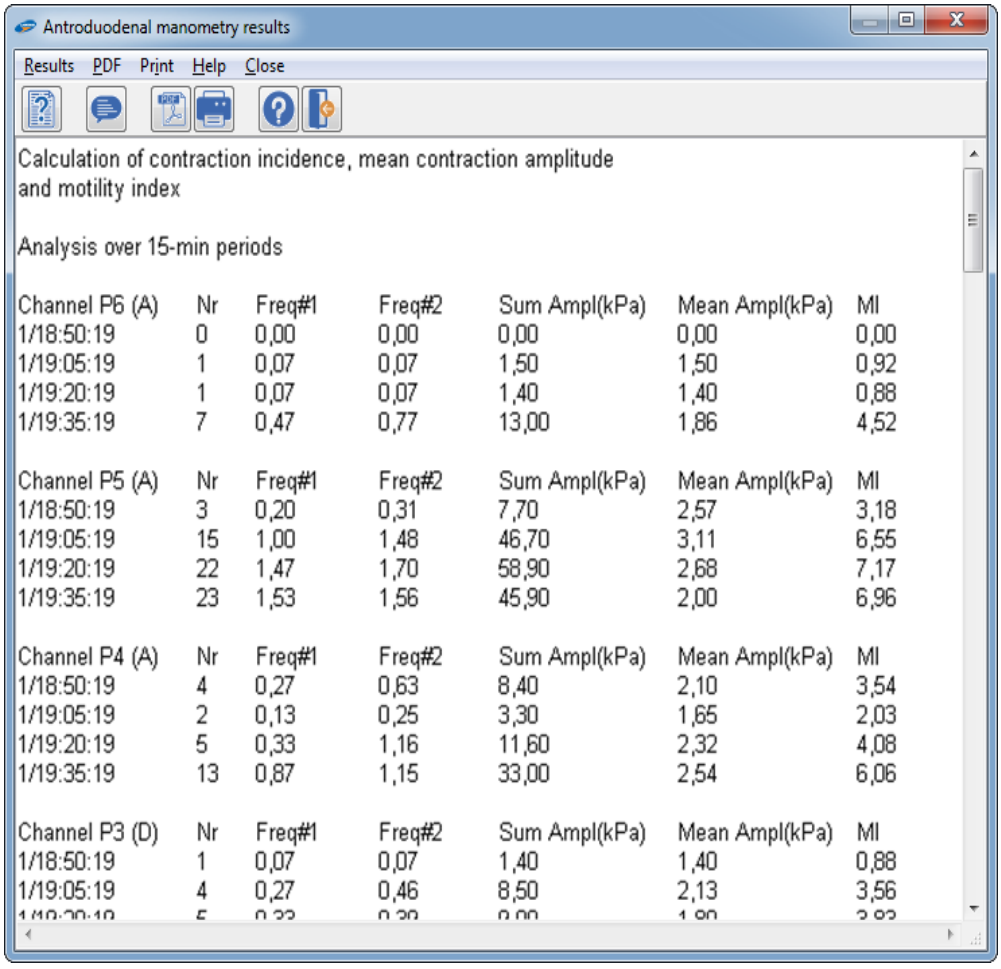


Figure 6.1 Manometry results

Contraction incidence

The number of contractions that occurred in the time window on the channel.

Freq#1
This frequency is *number of contractions / period duration*.

Freq#2
This frequency is *number of contractions / (end time of last contraction - start time of first contraction).*

Sum contraction amplitude
This is the sum of the amplitudes of the contractions.

Mean contraction amplitude
This is *Sum contraction amplitude / number of contractions*.

Motility index
This is *LN ((number of contraction * Sum contraction amplitude)+1)*.
This logarithmic calculation depends on the used pressure unit (mmHg, cm H_2O, kPa). See § **Error! Reference source not found.** to set the MI fixed to kPa units.

6.5.2 Marker Analysis Results

Select **Results > Display marker results** to show the results for Phase 3 markers that are placed in the investigation.

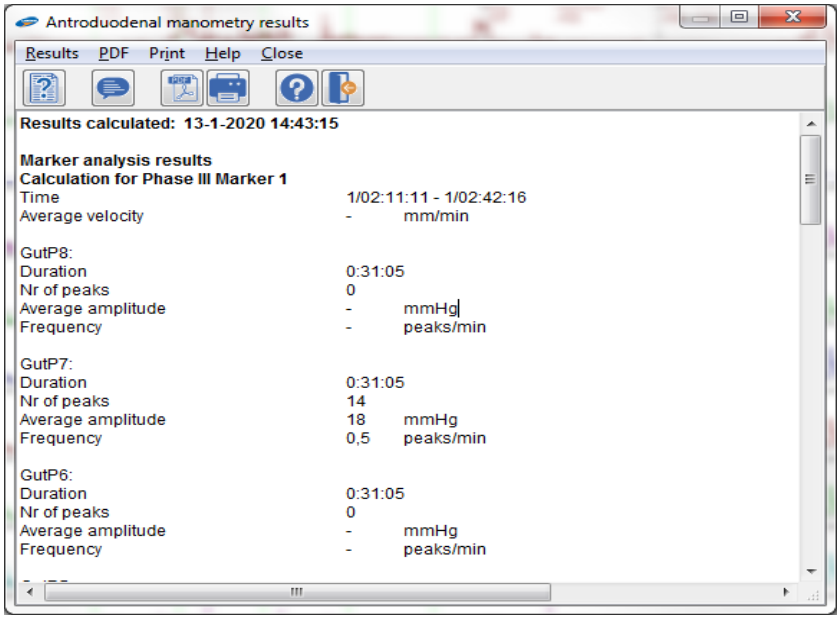


Figure 6.2 Marker analysis results

For each Phase 3 marker the following will be calculated:

- Begin time and end time.
- Average velocity.

For each channel marker of the Phase 3 marker:

- Duration: This is the time between the begin and the end channel marker.
- Number of peaks.
- Average amplitude.
- Frequency: *Number of peaks / Duration*.

6.5.3 Frequency Plot

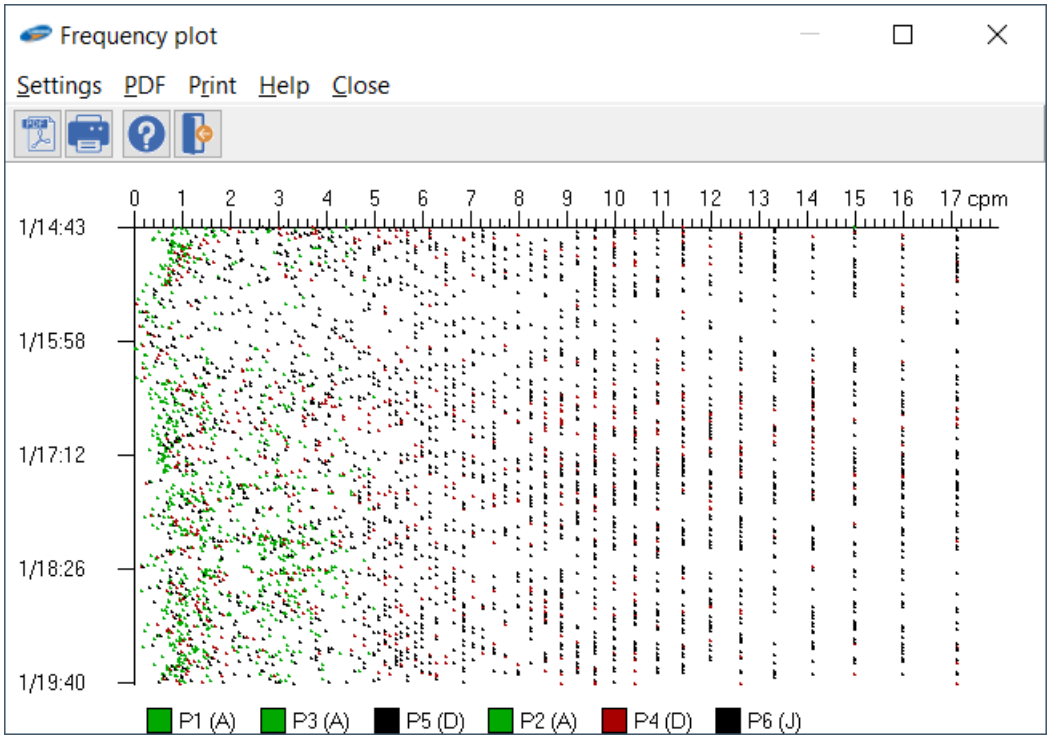


Figure 6.3 Frequency plot

The frequency plot displays the frequencies of the contractions in cycles per minute (CPM) over the investigation.

6.6 Settings

6.6.1 Antroduodenal Settings

The ADM parameters contain the settings for the antroduodenum analysis algorithms used in the peak detection and phase 3 analysis.

They can be changed by selecting **Settings > Antroduodenal settings**.

Artefact removal TAB

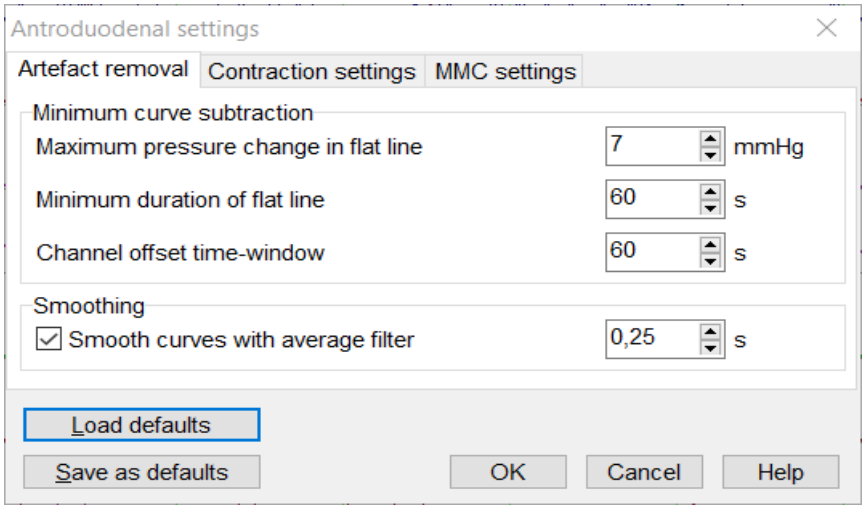


Figure 6.4 Antroduodenal settings

The software can automatically remove artefacts like coughing or movement artefacts. Is uses the minimum curve subtraction algorithm, which basically finds the minimum pressure on all channels for each sample and subtracts this pressure from the data. So, in case of a cough, the pressure on all channels will increase and this will be subtracted, eliminating the cough.

In case there is an issue with a channel not being measured (i.e., flat line) the algorithm would fail. The software will detect non-working channels and exclude these channels from the algorithm. The minimum curve subtraction settings set the parameters for finding flat lines. For example, in the dialog above, all curves with less than 7 mmHg change over any 60s period will be excluded.

The Smoothing option will give the curves a smoother appearance by applying an average filter over the enter time period of each sample. The longer the duration here, the smoother the curves.

Contraction Settings Tab

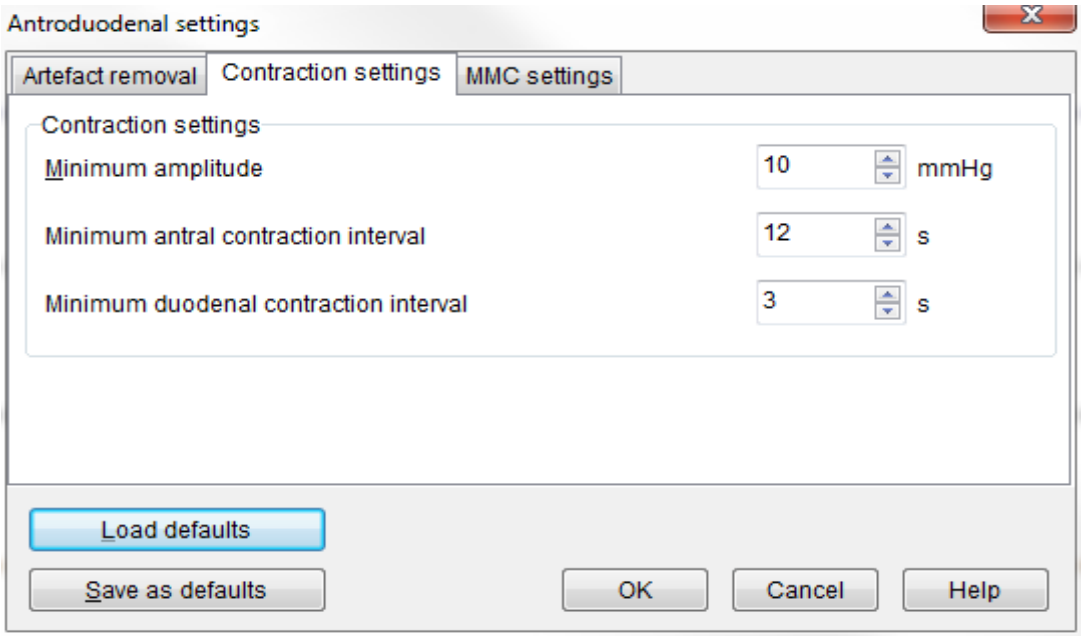


Figure 6.5 Antroduodenal settings

Minimum Amplitude

For a contraction to be found, at least a rise in pressure greater than this threshold should occur.

Minimum duration of antral contractions

This value is used with an antral channel to determine whether a rise in pressure greater than the contraction threshold should be marked as a contraction.

Minimum duration of duodenal contractions

This value is used with a duodenum channel to determine whether a rise in pressure greater than the contraction threshold should be marked as a contraction.

Default ADM parameters

Parameter	Default
Minimum Amplitude	10 mmHg
Minimum duration of antral contractions	12 s
Minimum duration of duodenum contractions	3 s

6.6.2 Manometry marker settings

For each manometry marker in the investigation, the antroduodenal channels are analyzed for numerous of consecutive time windows. Here you can set the length of a time window and the number of time windows to analyze.

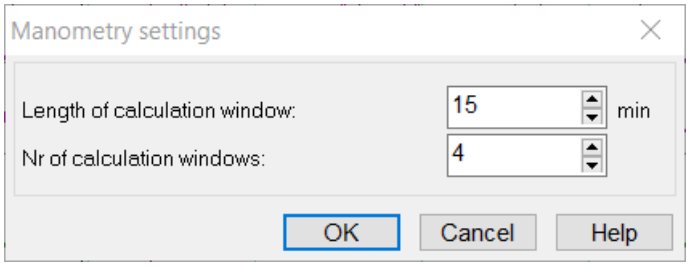


Figure 6.6 Manometry settings

The above dialog is shown when a Manometry marker is placed during the analysis of the study.

6.6.3 Edit Channel Definition

In the channel definition, you set the channel type (antrum, duodenum or jejunum) and the distances on the catheter for the channels that are used. To set the channel definition, select **Settings > Channel definition**.

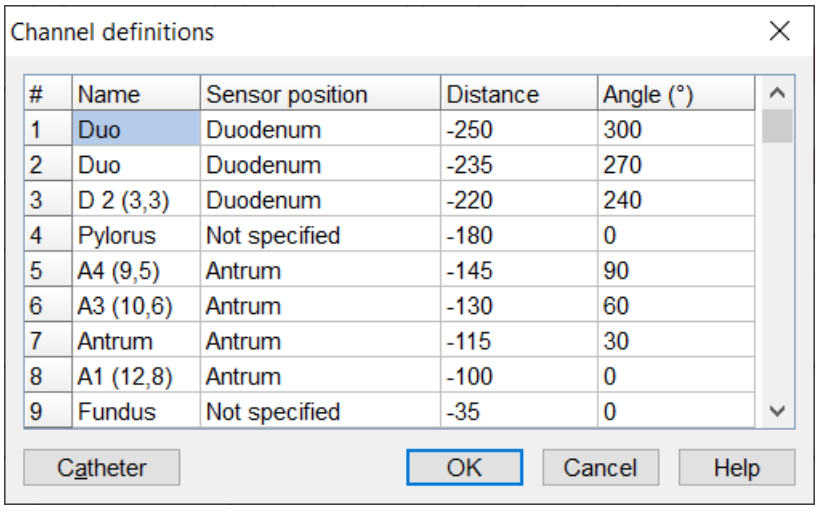


Figure 6.7 Channel definition

7. Sphincter of Oddi Manometry (SOM)

7.1 Introduction

The sphincter of Oddi manometry (SOM) is used to study the motility in the sphincter of Oddi. Indications for sphincter of Oddi manometry can be patients with biliary pain and one of:

- Elevated liver function
- Dilatation of the CBD (Common Bile Duct) (> 12 mm)
- Delayed contrast drainage from the CBD (> 45 min) during ERCP

For Sphincter of Oddi manometry, a special solid state or perfusion catheter with three pressure sensors, with or without aspiration channels, must be used. SOM is performed during an endoscopic session.

7.2 Prepare the Investigation

The procedure is as follows:

Select the **patient name** in the database program and click the **New investigation** button.

Click the **Sphincter of Oddi manometry** button to start the pre-test.

❑ (For water catheters) prepare the perfusion system and connect the water catheter to the pressure transducers. Turn on the water flow and flush the transducers and catheter. Be sure that there are no air bubbles left.

Press the **Zero all after 10 seconds** button. Keep the catheter horizontally at the level of the guts of the patient to zero-balance the pressures.

❑ Move the catheter vertically up to 40 cm. Check the registration of the transducers. 40 cmH_2O is approximately 30 mmHg

Or (for solid-state catheters):

Connect the pre-wetted solid state catheter and press the **Zero all** button to zero all pressures (the pressure sensors must be covered with approx. 1 cm of water).

- ❑ Before introduction of the catheter, the patient can be sedated and the throat can be anesthetized.
- ❑ Insert and position the catheter in the CBD (by passing it through the biopsy channel of the duodenoscope and manipulating it through the papilla. Catheter position can be verified by using a small amount of contrast injected through the catheter lumen. After positioning the catheter, wait a few minutes before starting the investigation.

7.3 Measurement

With the sphincter of Oddi manometry, the following parameters can be recorded:

- Common bile duct pressure.
- Basal pressure of the sphincter of Oddi.
- Phasic waves.
- Duodenal pressure.

After recording the common bile duct pressure for a few minutes the catheter is withdrawn until located in the high-pressure zone of the sphincter. Now the phasic waves will be recorded. The 2 or 3 pressure ports can be used to detect peristaltic or retrograde contractions. After recording these waves the catheter is withdrawn until it reaches the duodenum and the duodenal pressure is recorded.

This procedure will be repeated to check the reproducibility.

The procedure is as follows:

- ❑ Position the patient on the left side.

Press the **Start investigation** button.

Record the **Common bile duct** pressure for a few minutes and a stable baseline is obtained.

- ❑ Withdraw the catheter slowly, 2 mm at the same time, every 2 minutes.

- ❑ When all 3 ports are in the HPZ (High Pressure Zone) record the **Baseline** sphincter pressure for at least 3 minutes. Propagated phasic waves are seen in the HPZ.
- ❑ Withdraw the catheter into the duodenum.
  When all recording channels reach the duodenum, the pressure falls below the pressure in the common bile Wait until a stable baseline is recorded. Record duodenal pressure for a few minutes.
- ❑ If necessary, the procedure can be repeated.

Press the **Stop investigation** button to stop recording.

Remote control buttons

The following buttons can be pressed during the study.

Buttons	Description
	**Change the pressure scale** Press the **Scale up** or **Scale down** button to adjust the scale of the pressure channels.
	When pressed for the first time: Common bile duct comment marker. When pressed for second and subsequent time: comment marker with number 1-10. When right clicking on the button, you can reset to initial state (Common bile duct marker).
	When pressed for the first time: Pancreatic duct comment marker. When pressed for second and subsequent time: marker with number 1-10. When right clicking on the button, you can reset to initial state (Pancreatic duct marker).
	The **Baseline** button is used to (re)zero pressures in the duodenum.

7.4 Analysis

The sphincter of Oddi results calculation takes place on different pressure channels. In the channel definition, you can set the sensor position for each

channel. The software uses the sensor position to calculate specific results on the appropriate pressure channels.

For sphincter of Oddi manometry following sensor positions can be set:

- Sphincter of Oddi: Sphincter of Oddi pressure channel.
- Duodenum: Duodenum pressure channel

In the analysis, you can place the following markers.

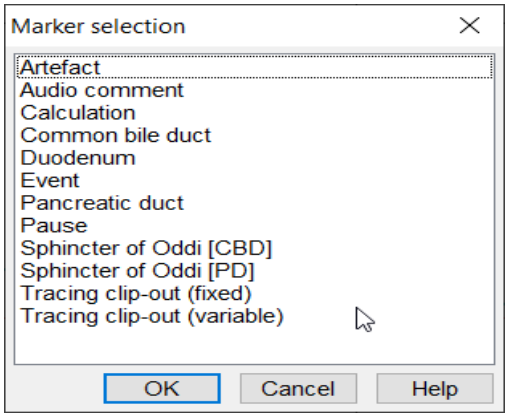


Figure 7.1 Markers for Sphincter of Oddi manometry

In the curves, the 40 mmHg line is shown as a red line. The 40 mmHg line is important for the diagnosis of the investigation of patients with Sphincter of Oddi dysfunction caused by stenosis and/or smooth muscle disorder (Dyskinesia).

Below you can find a table which indicates wave and pressure abnormalities.

	Stenosis	**Dyskinesia**	**Normal**
Phasic waves		> 8 per min	3-6 per min
Retrograde waves		> 50%	5 – 20 %
Basal SO pressure	>40 mmHg		10 – 20 mmHg
Decrease basal SOP after given CCK (CholeCystoKinin)	NO	YES	YES

8. Colon Manometry

8.1 Introduction

The colonic manometry is used to study the motility of the colon (optional in combination with impedance). To assess the colon, use a catheter with eight (or more) recording sites, with 5 cm to 15 cm apart from each other. Before the start of the investigation, create a catheter definition and select this catheter definition in the protocol.

Colonoscopy should be used for placement of the catheter. Advance the colonoscopy beyond the splenic flexure and pass an appropriate guide wire through the endoscope. Withdraw the endoscope and place the motility catheter over the guide wire. Remove the guide wire when the catheter is in place and tape the catheter securely to the patient's buttock.

8.2 Prepare the Investigation

The procedure is as follows:

Select the **patient name** in the database program and click the **New investigation** button.

Click the **Colon manometry** button to start the pre-test.

- ❑ (For water catheters) prepare the perfusion system and connect the water catheter to the pressure transducers. Turn on the water flow and flush the transducers and catheter. Be sure that there are no air bubbles left.

Press the **Zero all after 10 seconds** button. Keep the catheter horizontally at the level of the guts of the patient to zero-balance the pressures.

- ❑ Move the catheter vertically up to 40 cm. Check the registration of the transducers. 40 cmH_2O is approximately 30 mmHg.
- ❑ Insert the catheter in the patient.

8.3 Measurement

The procedure is as follows:

Press the **Start investigation** button.

- ❑ Record baseline motility while fasting for 1 hour.
- ❑ Give the patient a meal, place a meal marker (you can define this marker in the investigation protocol or you can use the event marker), and continue recording for another 3 hours.

Press the **Stop investigation** button to stop recording.

Remote control buttons

The following buttons can be pressed during the study.

Buttons	Description
	**Change the pressure scale** Press the **Scale up** or **Scale down** button to adjust the scale of the pressure channels.

8.4 Analysis

8.4.1 Contraction Detection

The software searches for contraction peaks on all colon channels. By default, found contraction peaks are indicated by a vertical line. Contraction indication can be toggled on/off via **Options > Display contractions**.

Peak detection

Peaks are detected and marked as follows by the software:

1 Software scans the channel until a peak is found has amplitude greater or equal to the minimum contraction amplitude.
2 Software will check if previous peak found was within the contraction interval time before the currently found
   a) If another peak was detected within the contraction interval before the current peak, then the peak will be ignored.
   b) If no other peak was detected in the contraction interval, then this peak will be marked.

Settings

In the colon settings dialogue (choose **Settings > Colon settings**) on the 'Contraction settings' TAB, you can change the following settings that affect the peak detection:

- Minimum contraction amplitude. This is the minimum amplitude that a peak should have to be detected.
- Contraction interval. This is the minimum time between peaks before the peak is marked by the software. This should prevent multi-peaked contractions to be marked more than once.

NOTE Peaks in artefact and pause areas are ignored and not included in the results.

NOTE When a peak is marked with HAPC markers, it is not included in the manometry results.

8.4.2 Artefact Removal

Artefacts caused by coughing or other body movements can be removed by the software. This will prevent that the software thinks these artefacts are contractions and that these artefacts would be included in the results. Artefact removal will be performed when the analysis is started and the curves are initially displayed without the artefacts. Raw data can still be displayed, by activating **Settings > Display raw data**. By toggling between showing raw data curves and curves with artefact removed you can see what artefacts are removed by the software.

Minimum curve subtraction

Artefacts can be removed by means of a method called Minimum curve subtraction. This method will remove subtract a pressure change that occurs on all channels simultaneously, like for instance cough peaks.

The minimum curve subtraction consists of following steps:

1 For all the pressure channels the software will look for flat lines, which are parts of the recording where the pressure is stable. Segments of channels where the pressure is stable will not be included for calculating the minimum curve. This step ensures that when one of the channels, for some reason, did not function for a while during the investigation, it does not influence the minimum curve subtraction.
2 For all pressure channels the software will now, for a fixed time frame, determine the pressure offset. The pressure offset is the minimum pressure of a channel that occurs during this timeframe. This step is necessary since

the channels can have a different offset pressure, for instance because of sensor position.

3 The minimum curve is now calculated which is the minimum pressure of all the pressure channels. For each sample, the minimum pressure is determined from all channel pressures minus their offset pressure. Channels that have a flat-line at a sample, are excluded from the minimum curve calculation.
4 The minimum curve calculated in the previous step is now calculated from all channels, except when on a channel a flat-line was detected.

In the colon settings dialog (choose **Settings > Colon settings**) on the 'Artefact removal' TAB you can change following settings that affect the minimum curve subtraction:

- Minimum flat line duration. This is the minimal duration of a flat line. When a flat line, shorter than this duration is detected it is not marked as a flat line for the minimum curve subtraction. The default the minimum flat line duration is 60 seconds.
- Maximum pressure change. This is maximum pressure change that may occur for the minimum flat line duration to be marked as a flat line. When the pressure change is more than this value during the minimum flat line duration, the software will not mark it as a flat line. The default Maximum pressure change is 4 mmHg.
- Channel offset window. This is the duration for which the offset of the channel is determined by the software, before the minimum curve is calculated. The default offset window is 60 seconds.

Curve smoothing

Optionally the curves can be smoothed with a running average filter. This will remove the noise from the curves.

By default, a running average filter of 0.25 seconds is used. However, in the colon settings, the average time can be changed. Also, the smoothing filter can be disabled completely in the settings dialogue.

8.5 Results

In the analysis program, choose **Results** > **Display results** from the menu to display the calculated parameters. The following parameters can be calculated:

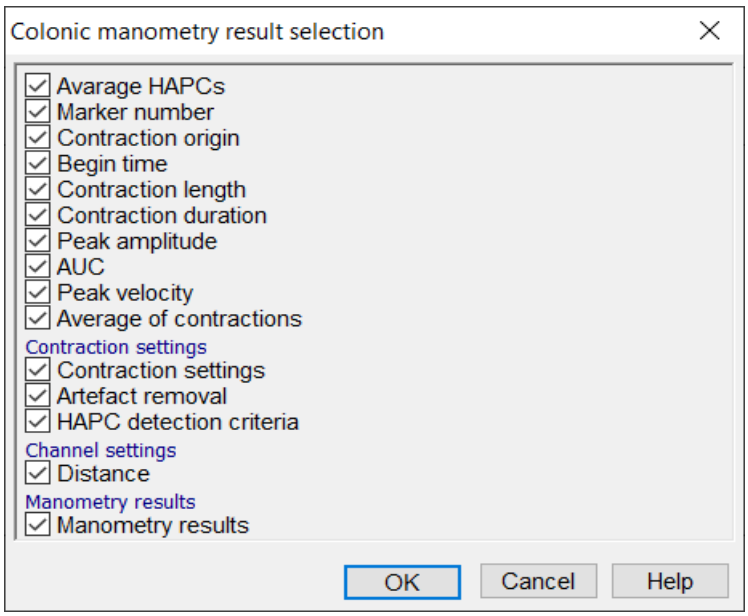


Figure 8.1 Colon manometry results selection

9. Anorectal Manometry

9.1 Introduction

Anorectal manometry is used to objectively assess the apparatus and defecation provided by the anorectal sphincter. With anorectal manometry, you can measure resting and squeeze pressure, as well as the length of the functional anal canal. More detailed assessment of radial and longitudinal pressure profiles can be obtained from a vector volume plot. With use of an intra-rectal balloon it is also possible to assess the recto-anal inhibitory reflex (RAIR), rectal sensitivity, capacity and compliance.

For the anorectal manometry investigation, the following tests are available:[4]

- Resting pressure
- Squeeze
- Endurance squeeze
- Cough
- Push
- RAIR (Rectal Anal Inhibitory Reflex)
- Sensation
- Anal rest profile
- Anal squeeze profile
- Rectal compliance
- Balloon expulsion

In this chapter, you will find information about the investigation protocol settings, selection and preparation of catheters and transducers, the anorectal manometry tests and analysis.

HRAM

For the High-Resolution Anorectal Manometry (HRAM) software option, a separate manual is available which describes the preparation of a HRAM investigation and the HRAM software program (measurement program and analysis program, document code 0075-MAN-157 HRAM User's manual).

[4] In case of a 1-channel ARM software option not all tests and results are available

9.2 Investigation Protocol

9.2.1 Edit the Anorectal Manometry Protocol

In the measurement program, click with the right mouse button on the protocol name, and choose **Edit protocol**. Select the **Anorectal manometry** TAB in the 'Edit investigation protocol' window.

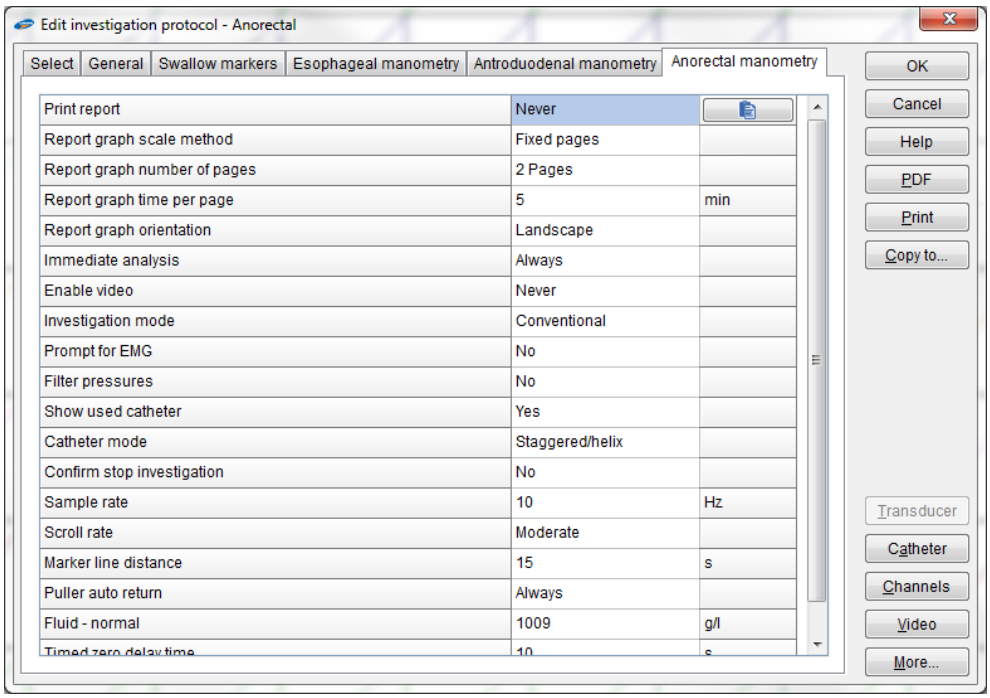


Figure 9.1 Anorectal manometry protocol

A page is shown with settings, regarding the use of the printer, storage on disk, initial pump speed, sample rate, marker line distance, etcetera. Under normal circumstances the default settings are sufficient.

For anorectal manometry, you must select the catheter which will be used (see § 9.2.2). You can also edit the channels to be measured (for example add EMG) and the connections. Use the buttons **Catheter**, **Channels** and **Connections** to set this information.

Under the **More** button you will find all settings specific to the anorectal manometry tests (see § 9.2.3 to § 9.2.12).

9.2.2 Select the Catheter

Anorectal manometry investigations can be performed by either using (a) water catheters with DT-NN pressure transducers, (b) air-charged catheters with external pressure transducers or (c) solid state catheters. Laborie advises to use catheters with 4 pressure channels for the most accurate results.

The layout of the two most common 4-channel catheters is displayed in the figures below:

- one cm spacing between the 4 pressure channels (spiral) and a balloon at the tip to test the anorectal reflex (RAIR) and sensations.
- 4 pressure channels at the same location (radial) with an angle of 90 degrees and a balloon at the tip to test the anorectal reflex (RAIR) and sensations.

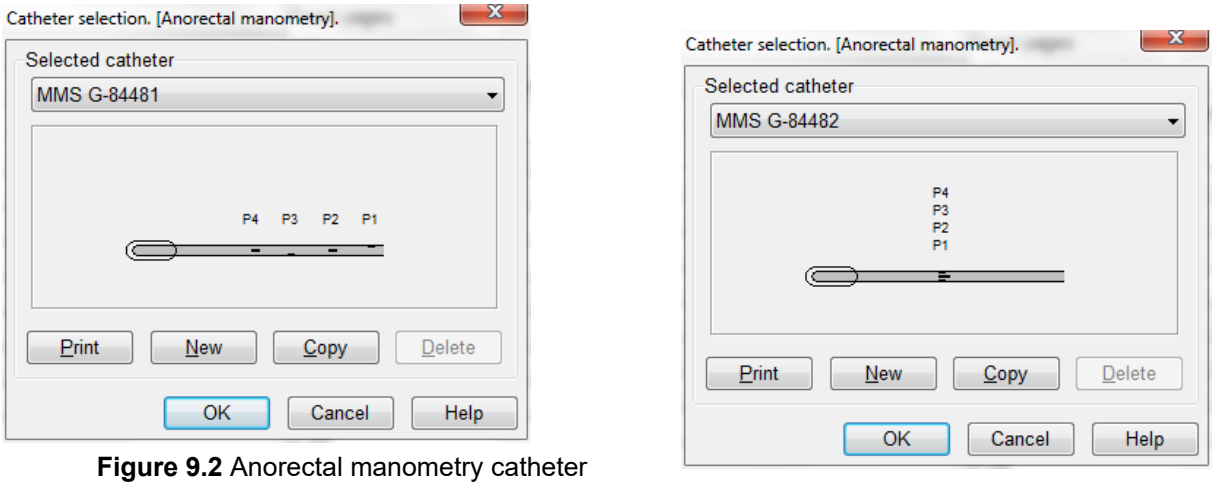


Figure 9.2 Anorectal manometry catheter spiral (left) and radial (right)

Click the **Catheter** button to display the Catheter selection window. Select your catheter from the list, for example the disposable water catheter 'MMS G-84481' or the 'MMS G-84482'.

Radial catheter mode

In the 'Edit investigation protocol' window you can select the catheter mode: staggered/helix (default selected) or radial mode. When radial mode is selected, on the **Test selection** TAB, the resting pressure test, the squeeze test and the push test are combined in one sequence. When the rest, squeeze or push test is ended, the next test in the combined sequence will be activated. When the cm marker is inserted during the sub sequence, the sub sequence will start from the beginning. If you want to change the catheter insertion depth during the investigation, you can use the **Go to x cm** button (puller) or the **Mark x cm** button (manual pull).

When right clicking on this button, the x cm is reset to initial value (when a puller is used), or the insertion depth is increased with 1 cm (when manual pull is used).

When radial mode is selected, the software will ask if RAIR is present or absent when inserting the RAIR end marker. In the results this is shown in the marker name and it is added to the report. The balloon volume is shown in the RAIR marker hint.

When the investigation has been performed, and the analysis program is started, the results are calculated on all channels.

9.2.3 Select the Anorectal Manometry Tests

In the protocol settings, you can select which tests can be performed during the investigation, as well as adapt the order of the selected tests. Click the **More** button and select the **Test Selection** TAB. The following window is displayed.

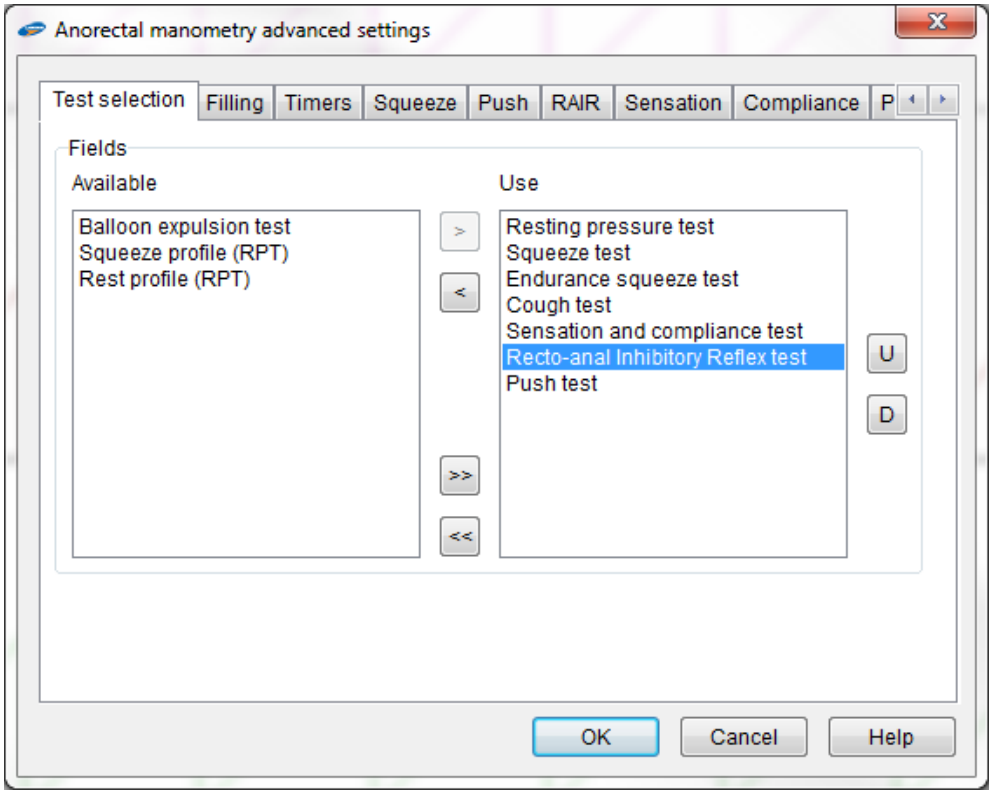


Figure 9.3 Anorectal manometry protocol, test selection

In the 'Use' column you will see the tests which will be available during the investigation. Use the arrow buttons to add or remove a test. You can adapt the order in which the tests appear during the investigation: use the **U** button to move the selected test in the 'Use' column up. Use the **D** button to move it down.

NOTE Most tests can be combined in one single investigation. It is up to the investigator to decide which tests should be performed.

9.2.4 Filling

Click the **More** button and select the **Filling** TAB to set the balloon filling method (for the RAIR test, for the sensation test and for the balloon expulsion test). You can select syringe or urodynamic pump (filling with water) or (if

available) Perfusion pump (MPP Plus). It is recommended to enable the Vin channel (balloon volume) in the channel settings of the anorectal manometry protocol (see § 11.5.7).

The urodynamic pump (automatic, H_2O) is only available for urodynamic systems and is not suitable for RAIR test, but can be used for the sensation test or the balloon expulsion test. Contact your Laborie representative for safety information and installation of the urodynamic pump.

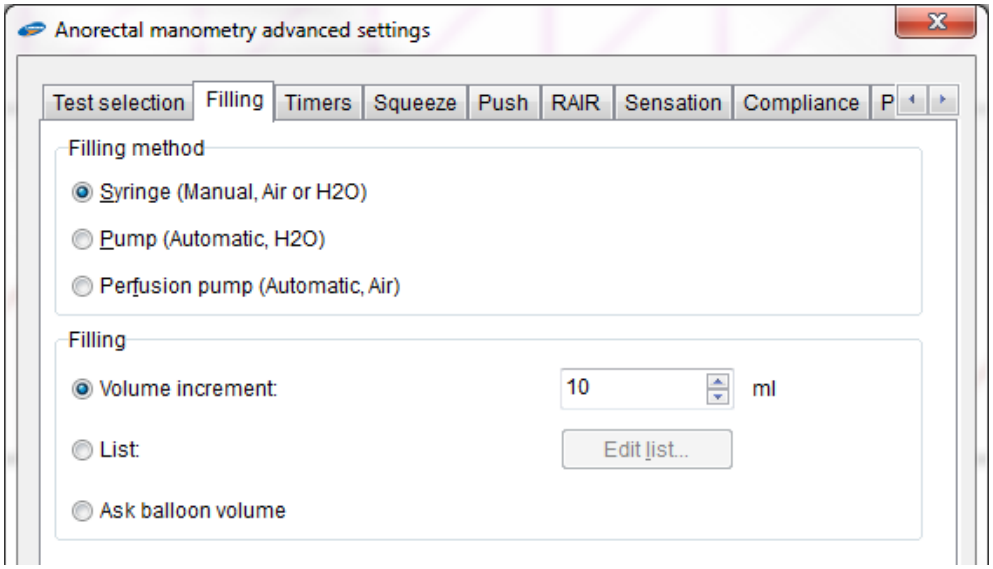


Figure 9.4 Filling Tab, Syringe settings

Ask balloon volume is available for the syringe filling method (most common method) and can be used for the push test, RAIR test, sensation test and balloon expulsion test. After inserting the end marker during the test the software will ask to enter the balloon volume.

The Volume increment setting and the List selection is applicable for the syringe filling method for the Sensation test. You can enter the volume increment (e.g. 10 ml) or edit a complete list (e.g. 10-10-10-20-20 etcetera).

9.2.5 Timers

On the Timers TAB, you can enable timers and set the duration. Timers will help you to perform the test with a certain duration and to show this to the patient. During the test, a progress bar will appear on the screen as soon as the start of test has been marked. When the time is elapsed, the progress bar will disappear and the end marker is automatically placed.

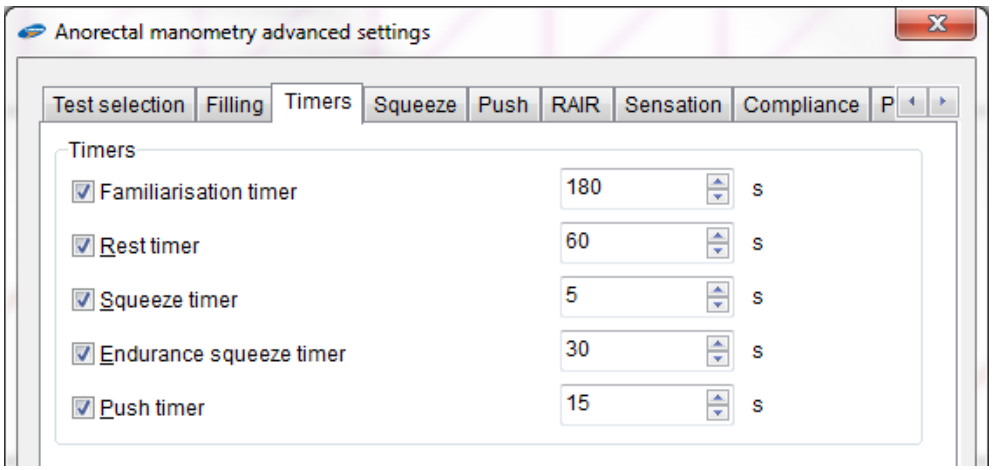


Figure 9.5 Timers TAB

The familiarization timer (default on) is used to let the patient get used to the catheter at the beginning of the investigation.

9.2.6 Squeeze

Click the **More** button and select the **Squeeze** tab. The following window is displayed.

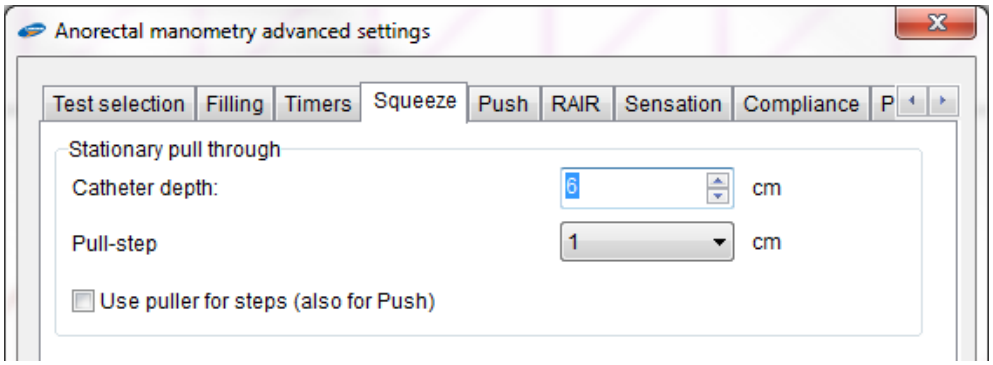


Figure 9.6 Squeeze settings

During the squeeze test you can mark the catheter position (insertion depth). This setting is often used for investigations with radial catheters. The puller can be used to withdraw the catheter step-wise (default 1 cm).

9.2.7 Push

Click the **More** button and select the **Push** TAB. The following window is displayed.

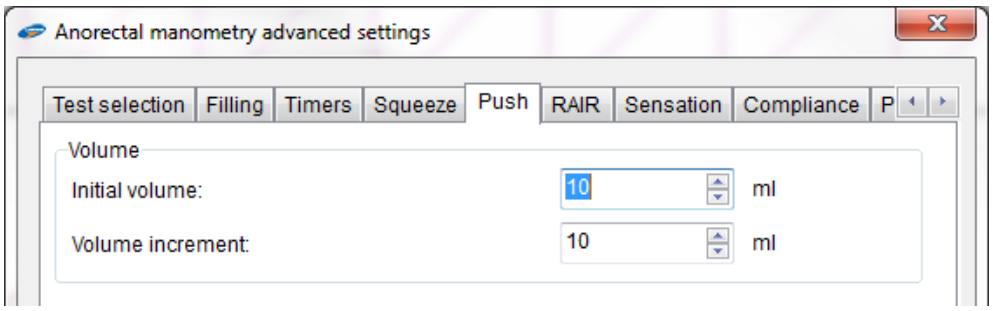


Figure 9.7 Push settings

During the push test, you can mark the catheter position (insertion depth). This setting which be found on the **Squeeze** TAB, is often used for investigations with radial catheters. The puller can be used to withdraw the catheter step-wise (default 1 cm).

Balloon filling settings

You can set the initial volume (default 10 ml) and the volume increment (default 10 ml) under 'Volume' on the **Push** TAB.

On the **Filling** TAB, you can set the filling method. For syringe filling method, you can select 'Ask balloon volume' on the **Filling** TAB.
After inserting the Push end marker during the test the software will ask to enter the balloon volume.

For filling the balloon with the pump (water) you can enter the pump speed (default 50 ml/min) on the **Filling** TAB.

9.2.8 RAIR

Click the **More** button and select the **RAIR** TAB. The following window is displayed.

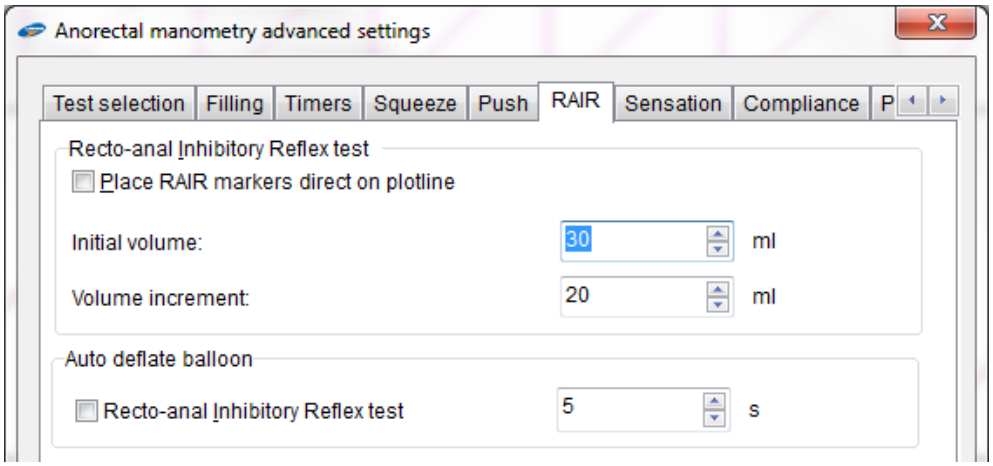


Figure 9.8 RAIR settings

You can enable the option to place markers directly on the plotline (default off). You can set the initial volume (default 30 ml) and volume increment (default 20 ml) for the RectoAnal Inhibitory Reflex (RAIR) test.

The initial inflation volume is the volume that will be inflated the first time in the balloon to assess the RAIR. You can also set the volume increment that will be added to the previous inflation volume after the balloon has been inflated.
For example: If the physician would like to assess the RAIR with the following inflation volumes: 10, 20, 30 etcetera, then both the initial volume and the volume increment should be set to 10 ml.

Balloon filling settings

On the **Filling** TAB, you can set the filling method. If you use the MPP Plus for filling the balloon automatically, you can select to auto deflate the balloon after a certain time (default not selected) on the **RAIR** TAB. Otherwise the balloon will be deflated automatically after clicking the **Next test** button.
For syringe filling method, you can select 'Ask balloon volume' on the **Filling** TAB. After inserting the RAIR end marker during the test the software will ask to enter the balloon volume.

9.2.9 Sensation

Click the **More** button and select the **Sensation** TAB. The following window is displayed.

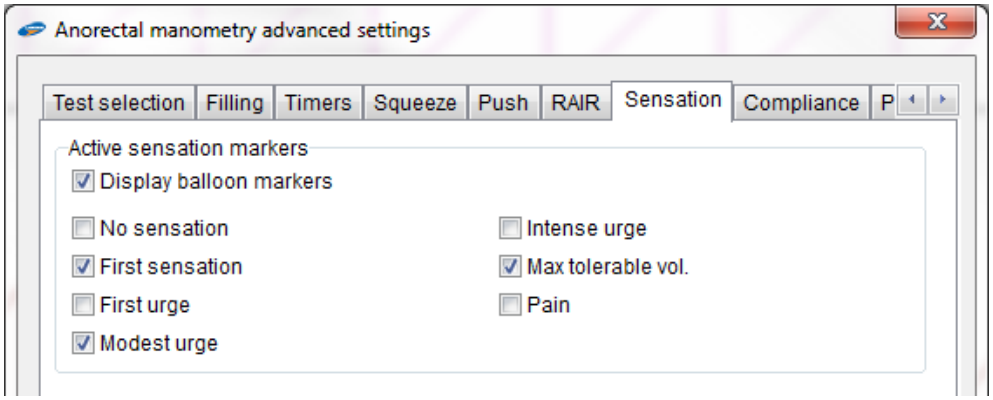


Figure 9.9 Sensation settings

During the sensation test, different sensation markers can be placed. The following markers can be enabled in the protocol: no sensation, first sensation, first urge, modest urge, intense urge, maximum tolerable volume and pain. The setting 'display balloon markers' can be (de)selected.

Balloon filling settings

On the **Filling** TAB, you can set the filling method. For the syringe filling method, you can enter the volume increment (e.g. 10 ml) or edit a complete list (e.g. 10-10-10-20-20 etcetera) on the **Filling** TAB. You can also select 'Ask balloon volume'. After inserting a sensation marker during the test the software will ask to enter the balloon volume.

For filling the balloon with the pump (water) you can enter the pump speed (default 50 ml/min) on the **Filling** TAB.

9.2.10 Compliance

Click the **More** button and select the **Compliance** TAB. The following window is displayed.

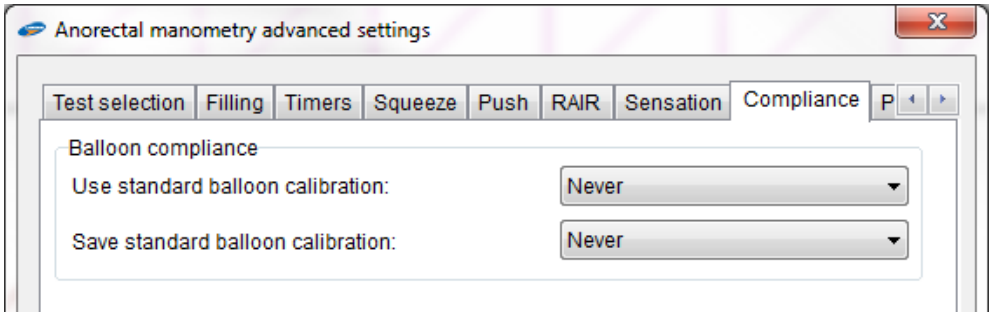


Figure 9.10 Compliance settings

Rectal compliance

Rectal compliance can be calculated after the sensation test. A catheter with a balloon mounted on the tip and a filling lumen (opening at the tip), can be used to determine the compliance.

If you want to perform a rectal compliance test, you need to select a catheter in the protocol with balloon pressure (Pbal).

Balloon compliance can be determined each time at the start of the test, or determined once and saved if you always use the same type of balloon.

Use standard balloon calibration

Since the balloon has a compliance of its own, the calculated compliance should be compensated to obtain the actual compliance of the rectum. If the physician always uses the same balloon type, its compliance needs to be determined only once. When this has been done, and the compliance is saved as the standard balloon compliance, subsequent investigations can use this balloon compliance. This can be achieved by this setting.

Save standard balloon calibration

When a balloon calibration has been performed, it can be saved as the standard balloon calibration. This settings controls whether this will be the case.

Balloon filling settings

On the **Filling** TAB, you can set the filling method. Filling automatically with the MPP Plus is recommended.

9.2.11 Balloon Expulsion

Click the **More** button and select the **Balloon expulsion** TAB. The following window is displayed.

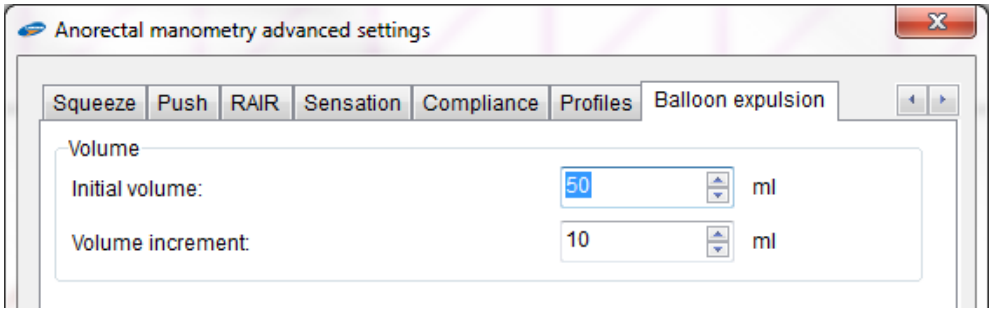


Figure 9.11 Balloon expulsion settings

Balloon filling settings

You can set the initial volume (default 50 ml) and the volume increment (default 10 ml) under 'Volume' on the **Balloon expulsion** TAB

On the **Filling** TAB, you can set the filling method. For the syringe filling method, you can select 'Ask balloon volume'. After inserting the Balloon expulsion end marker during the test the software will ask to enter the balloon volume.

For filling the balloon with the pump (water) you can enter the pump speed (default 50 ml/min) on the **Filling** TAB.

9.2.12 Profiles

Click the **More** button and select the **Profiles TAB**. The following window is displayed.

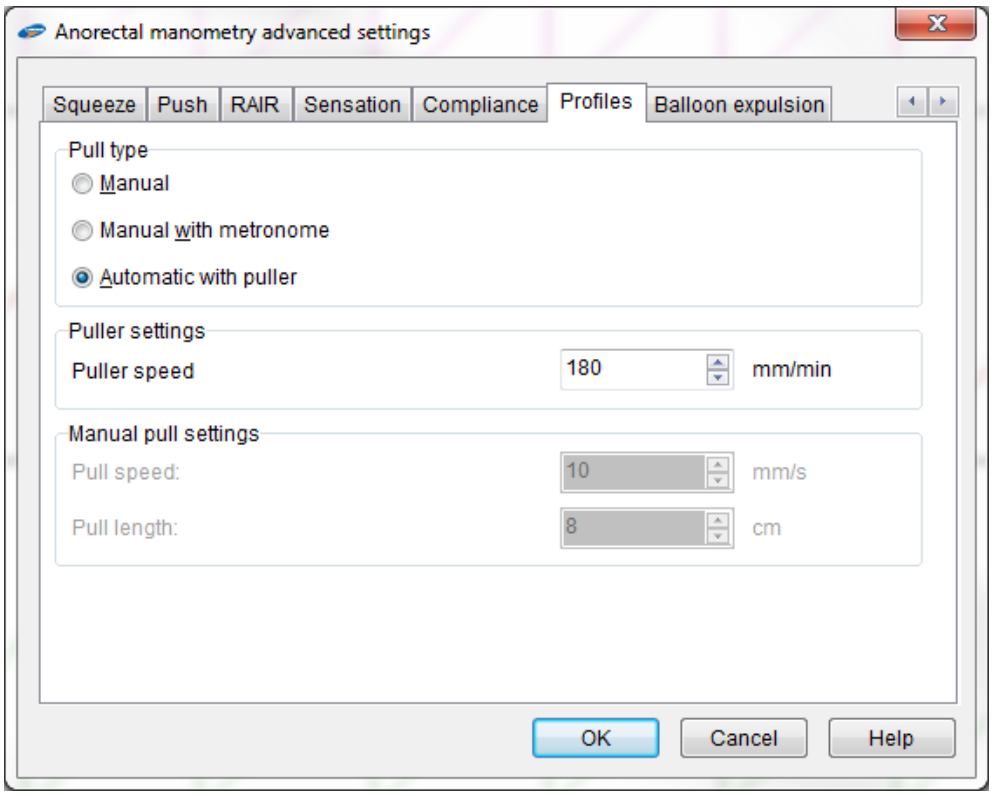


Figure 9.12 Profile settings

Rest and squeeze profile tests can be performed during anorectal manometry. A 4-channel radial catheter is most accurate for these tests. In the profile settings, you can select how to withdraw the catheter, automatically by using the puller or manually with your hand.

When you want to create 3D vector volume plots of the anal-canal, you need a catheter with at least four radially oriented channels. When more channels are available, a more detailed vector volume plot can be reconstructed. The anal channels should all be marked with sensor positioning *Anal* in the catheter definition.

When automatic is selected, the puller pulls constantly at the set puller speed. The recommended speed is 60 mm/min. The puller is required for continuous longitudinal profile manometry. Settings are enabled when a puller is connected. When manual is selected, you must pull the catheter through the anal canal at a constant speed. A metronome function can be activated in the protocol to aid in withdrawing the catheter. You must set the pull (withdrawal) speed and length (distance). During the investigation, each step will be displayed on the screen at the set speed. The metronome makes a sound at each step. The software automatically places the profile end marker.

9.3 Prepare the Investigation

9.3.1 Water Catheters

For measuring with water perfused catheters and pressure transducers, perfusion of the channels is needed. The procedure to prepare the investigation is as follows:

❑ Enter and select the **patient name** in the database program.

Click the **New investigation** button in the database program.

Click the **Anorectal manometry** button to start the pre-test. For preparing the water perfused catheter and perfusion with the Perfusion pump plus, see § 2.4.2.

Press the **Start investigation** button to start the investigation. Follow the procedure for the tests as described in the next paragraphs.

9.3.2 Air-Charged Catheters

The procedure to prepare the investigation is as follows:

❑ Enter and select the **patient name** in the database program.

Click the **New investigation** button in the database program.

Click the **Anorectal manometry** button to start the pre-test. For preparing the investigation with air-charged catheters, see § 2.4.3.

Press the **Start investigation** button to start the investigation. Follow the procedure for the tests as described in the next paragraphs.

9.3.3 Solid-State Catheters

You can use reusable solid state catheters with filling lumen and a balloon fixation point at the tip. You can use standard balloons or make a balloon catheter as follows. Use a latex condom as a balloon. Cut the top 8 centimeters (approximately 3.5") off the condom. Use a piece of stitch wire to tie the condom to the catheter. Tie in such way that the rectal transducer is inside the balloon, while the anal transducer is outside the balloon. Be careful

not to apply excessive force to the transducers or catheter. Do not bend the catheter.

The procedure to prepare the investigation is as follows:

- ❑ Pre-wet the catheter in water as described in manual of the manufacturer.
- ❑ Enter and select the **patient name** in the database program.

Click the **New investigation** button in the database program.

Click the **Anorectal manometry** button to start the pre-test. For preparing the investigation with solid state catheters, see § 2.4.4.

Press the **Start investigation** button to start the investigation. Follow the procedure for the tests as described in the next paragraphs.

9.3.4 Position of the Catheter

The position of the catheter in the anal sphincter depends on the layout of the catheter:

- If you are using the 4- or 8-channel spiral catheter with one or 0.5 cm spacing, then the sensors should be positioned in the anal canal and the balloon in the rectum. It is important not to move the catheter during the investigation and performance of all anorectal tests.
- If you are using the 4- or 8-channel catheter with radial sensors, you can position the radial sensors at the high-pressure zone and perform all tests including the profiles. Alternatively, you can position the radial sensors at the proximal level (e.g. 4 cm inside the anal canal) and perform all tests, then withdraw the catheter 1 cm and repeat these tests. The insertion depth must be marked with the cm button in the software.

9.4 Investigation

9.4.1 Introduction

For the anorectal manometry investigation, the following tests are described:

- Resting pressure
- Squeeze
- Endurance squeeze
- Cough

- Push
- RAIR (Rectal Anal Inhibitory Reflex)
- Sensation/Rectal compliance
- Anal rest profile
- Anal squeeze profile
- Balloon expulsion test

During an anorectal manometry investigation, the patient should be awake, un-anaesthetized and neither sedated nor taking drugs that affect functioning. Any variations should be specified.

The pretest is described in the previous paragraphs.

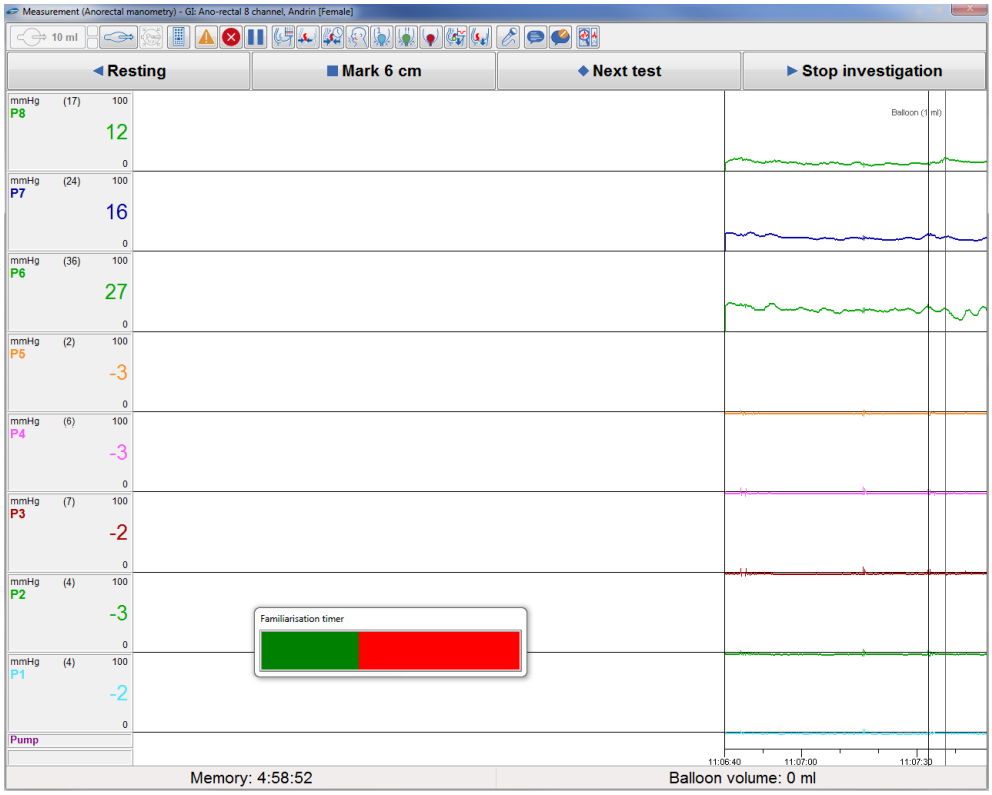


Figure 9.13 Measurement program anorectal manometry

9.4.2 Resting Pressure Test

The purpose of this test is to determine the resting pressure.

Press the **Next test** button until the text “Resting” is displayed on the left button.

Ask the patient to be quiet for 10 to 20 seconds (do not talk, move, squeeze). Press the **Resting** button to mark the start of the test.

Press the **Resting End** button to mark the end of the test. Repeat this procedure if necessary.

9.4.3 Squeeze Test

The purpose of the squeeze test is to obtain an assessment of voluntary sphincter capability at one or more levels in the sphincter.

Press the **Next test** button until the text “Squeeze” is displayed on the left button.

Ask the patient to squeeze. Press the **Squeeze** button to mark the start of the test. The endurance squeeze will cause an increase in pressure on the EAS (External Anal Sphincter) channel.

Ask the patient to stop squeezing. Press the **Squeeze End** button to mark the end of the test. This marker is placed automatically when the squeeze timer is used (see protocol settings). Repeat this procedure if necessary.

9.4.4 Endurance Squeeze Test

The purpose of the endurance squeeze test is to evaluate the effects of maintained squeeze on rectal and anal sphincter pressures.

Press the **Next test** button until the text ‘En. Squeeze’ is displayed on the left button.

Ask the patient to squeeze and to maintain the squeeze. Press the **En. Squeeze** button to mark the start of the test. The endurance squeeze will cause an increase in pressure on the EAS channel, which slowly will drop due to sphincter fatigue.

After about 20 to 30 seconds, ask the patient to stop squeezing. Press the **En. Squeeze End** button to mark the end of the test. This marker is placed automatically when the endurance squeeze timer is used (see protocol settings). Repeat this procedure if necessary.

9.4.5 Cough Test

The purpose of the cough test is to obtain an assessment of voluntary sphincter capability at one or more levels in the sphincter.

Press the **Next test** button until the text ‘Cough’ is displayed on the left button.

Ask the patient to cough. Press the **Cough** button to mark the start of the test.

Press the **Cough End** button to mark the end of the test. Repeat this procedure if necessary.

9.4.6 Push Test

The purpose of the push test is to evaluate the effects of strain on rectal and anal sphincter pressures.

Press the **Next test** button until the text ‘Push’ is displayed on the left button.

Ask the patient to push. Press the **Push** button to mark the start of the test.

Ask the patient to stop pushing. Press the **Push End** button to mark the end of the test. This marker is placed automatically when the push timer is used. Reposition the catheter and repeat this procedure if necessary.

9.4.7 Rectal Anal Inhibitory Reflex (RAIR) Test

The purpose of the RAIR test is to assess the rectal anal inhibitory reflex. You can use the Perfusion Pump or a syringe to inflate the balloon. If you use the Perfusion Pump, refer to the Solar GI service & installation Manual for safety information, installation and operation. Both methods to fill the balloon are described below.

Filling with air (Solar perfusion pump)

Press the **Next test** button until the text ‘RAIR’ is displayed on the left button. Connect the filling lumen of the catheter to the perfusion pump.

Press the **RAIR** button to mark the start of the test. This is a delayed marker and is used to determine the baseline pressure.

Press the **Balloon x ml** button to place a Balloon marker and to inflate the balloon automatically. Wait for the sphincter relaxation, indicated by a drop in the IAS pressure. Empty the balloon by clicking the **Deflate balloon** tool button to suck all air out with the perfusion pump.

Press the **RAIR End** button to mark the end of the test after the relaxation at the baseline pressure (this is a delayed marker). Wait about 40 seconds to settle all pressures before repeating this procedure.

Filling with air (syringe)

Press the **Next test** button until the text ‘RAIR’ is displayed on the left button. Fill the syringe with air to the volume displayed on the Syringe button in the upper-left corner of the screen (for example 10 ml). Connect the syringe to the 3-way stop-cock which is attached to the filling lumen of the catheter.

Press the **RAIR** button to mark the start of the test. This is a delayed marker and is used to determine the baseline pressure.

Press the **Balloon x ml** button to place a Balloon marker and inflate the balloon. Wait for the sphincter relaxation, indicated by a drop in the IAS pressure. Empty the balloon by sucking all air out with the syringe.

Press the **RAIR End** button to mark the end of the test after the relaxation at the baseline pressure (this is a delayed marker). Wait about 40 seconds to settle all pressures before repeating this procedure.

The balloon volume is always absolute, what means that the balloon is deflated and inflated with the currently selected volume.

9.4.8 Sensation Test

The purpose of the sensation test is to determine at which rectal filling the patient feels specific sensations. You can choose to fill the balloon with air (by using the Solar perfusion pump or a syringe) or water (by using a syringe or the Solar urodynamic pump module). If you use the urodynamic pump module, contact your Laborie representative for safety information and installation and operation. The methods to fill the balloon with air are described below.

Filling with air (Solar perfusion pump)

Press the **Next test** button until the text 'No sensation' is displayed on the left button. Connect the filling lumen of the catheter to the perfusion pump.

Press the **Start filling** button to inflate the balloon with air to the volume displayed on the button (default 250 ml, adapt the initial volume with the arrow buttons). On the status bar at the bottom of the screen an indication of the infused volume can be found.

Press this button when a patient (during infusion) states a certain sensation. A balloon marker and sensation marker is inserted. The sensation markers are defined in the protocol settings: No sensation, First sensation, First urge, Modest urge, Intense urge, Maximum tolerable volume and Pain. When the maximum tolerable volume is reached, stop inflating the balloon by clicking the **Inflate balloon** button again.

Press the **Stop filling** button to stop filling.

During the filling, in case the volume which is displayed on the button is reached, the pump stops automatically[5] and the button shows a new volume which can be reached. If you start filling again, the balloon will be filled until the new volume, which is displayed on the button. When the maximum filling for the catheter has been reached, the pump stops also automatically and the

[5] The pump will also stop when 250 ml filling is reached. To continue filling, increase the filling volume and click start filling again.

balloon cannot be filled more. The maximum balloon filling is predefined in the catheter definition.

Press the **Deflate balloon** button to deflate the balloon.
After deflating, the button will show **Start filling** again.

Press the **Next test** button to continue with the next test. The balloon will be deflated automatically.

Filling with air (syringe)

Press the **Next test** button until the text ‘No sensation’ is displayed on the left button. Fill the syringe with air to the volume displayed on the Syringe button in the upper-left corner of the screen (for example 10 ml). Connect the syringe to the 3-way stop-cock which is attached to the filling lumen of the catheter.

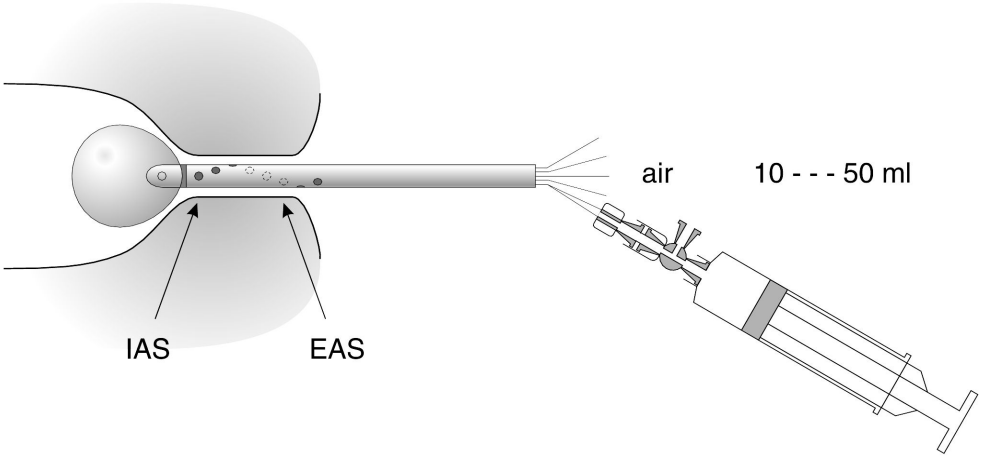


Figure 9.14 Sensation test with syringe

Inflate the balloon and press the **Balloon +10 ml** button to place the balloon marker. Repeat inflating the balloon and placing the balloon markers. On the status bar at the bottom of the screen an indication of the infused volume can be found.

Press this button when a patient (during infusion) states a certain sensation. The sensation markers are defined in the protocol settings: No sensation, First sensation, First urge, Modest urge, Intense urge, Maximum tolerable volume and Pain. When the maximum tolerable volume is reached, stop inflating the balloon.

Empty the balloon with a syringe and continue with the next test. When the anorectal manometry tests are finished, stop the measurement. To speed up deflation of the balloon you may snap the disposable catheter with a pair of scissors.

Insert more of the same sensation markers

It is possible to perform the sensation test more than once, thus insert more than one of the same type of sensation marker.

To reset (restart) the sensation test press the **Next test** button until the text 'No sensation' is displayed on the left button, or

Right-click with the mouse on this button until the sensation marker you want to insert, is displayed.

9.4.9 Rest and Squeeze Profiles Using a Puller

The purpose of the anal resting and squeeze pressure profiles is to obtain a continuous pressure profile of the entire anal sphincter. This is accomplished by withdrawing the catheter through the anal-sphincter by means of the puller or manually. In this paragraph, you will find a description of the test using the puller.

When pressures are measured radially throughout the sphincter, the software can create cross-sectional and longitudinal graphs of the sphincter (3D vector volume plots). The anal channels should all be marked with sensor positioning 'Anal' in the catheter definition (see § 9.5.3).

Prepare the catheter puller and position the catheter on the puller as described in § 2.4.8. The pressure channels of the catheter should be positioned in the rectum.

NOTE Do not position the puller too close to the anal verge. This prevents the puller head from pollution by the catheter during withdrawing.

The procedure is as follows:

Press the **Next test** button until the text 'Start puller [Rest]' is displayed on the left button.

Press the **Start puller [Rest]** button to start the puller. After a short while there should be an increase in the anal pressure.

Wait until the onset of the rise in anal pressure is at the marker line. Press the **Anal profile** button to mark the start of the test.

Wait until the drop of anal pressure to zero reaches the marker line. Press the **Profile end** button to mark the end of the test. The puller returns to its starting position automatically (protocol settings) or use the puller icon in the software. Reposition the catheter and repeat the procedure if necessary.

Press the **Next test** button until the text ‘Start puller [Squeeze]’ is displayed on the left button.

Ask the patient to squeeze and to maintain the squeeze. Press the **Start puller [Squeeze]** button to start the puller. After a short while there should be an increase in the anal pressure.

Wait until the onset of the rise in anal pressure is at the marker line. Press the **Anal Squeeze profile** button to mark the start of the test.

Wait until the drop of anal pressure to zero reaches the marker line. Press the **Profile end** button to mark the end of the test. The puller returns to its starting position automatically (protocol settings) or use the puller icon in the software. Reposition the catheter and repeat the procedure if necessary.

Instead of a rest profile it also possible to perform stress profiles to the procedure described above. To perform a stress profile, let the patient cough during the profile manometry. During the analysis, the software can calculate transmission parameters for the peaks.

9.4.10 Rest and Squeeze Profile with Manual Pull

The purpose of the anal resting and squeeze pressure profile is to obtain a continuous pressure profile of the entire anal sphincter. This is accomplished by withdrawing the catheter through the anal-sphincter by means of the puller

or manually. In this paragraph, you will find a description of the investigation with manual pull. When pressures are measured radially throughout the sphincter, the software can create cross-sectional and longitudinal graphs of the sphincter (3D vector volume plots). The anal channels should all be marked with sensor positioning ‘Anal’ in the catheter definition (see § 9.5.3).

The pressure channels of the catheter should be positioned in the rectum.

The procedure is as follows:

Press the **Next test** button until the text ‘Start profile [Rest]’ is displayed on the left button.

Press the **Start profile [Rest]** button. A window is displayed with the distance you must withdraw the catheter. Withdraw the catheter with the speed and distance as displayed (setting in the protocol).
After a short while there should be an increase in the anal pressure. The software automatically marks the start and the end of the anal profile. Reposition the catheter and repeat the procedure if necessary.

Press the **Next test** button until the text ‘Start profile [Squeeze]’ is displayed on the left button.

Ask the patient to squeeze and to maintain the squeeze. Press the **Start profile [Squeeze]** button. A window is displayed with the distance you must withdraw the catheter. Withdraw the catheter with the speed and distance as displayed (setting in the protocol). After a short while there should be an increase in the anal pressure. The software automatically marks the start and the end of the anal profile. Reposition the catheter and repeat the procedure if necessary.

Instead of a rest profile it also possible to perform stress profiles to the procedure described above. To perform a stress profile, let the patient cough during the profile manometry. During the analysis, the software can calculate transmission parameters for the peaks.

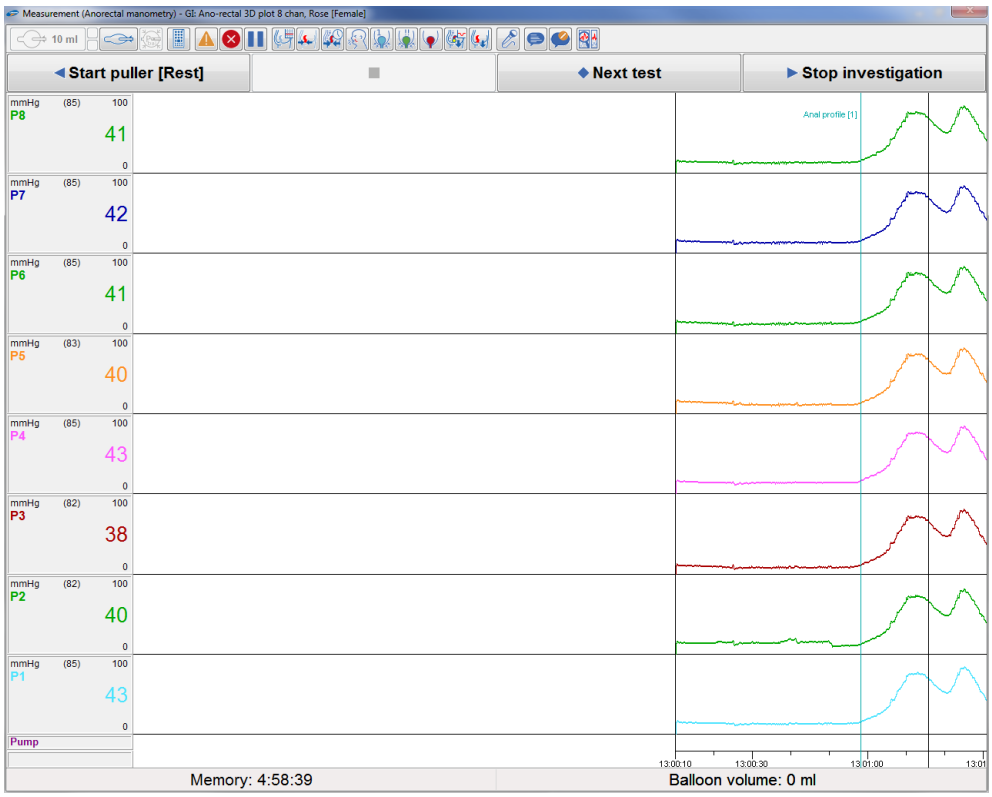


Figure 9.15 Anorectal Rest profile

9.4.11 Balloon Expulsion Test

The purpose of the balloon expulsion test is to determine if the patient can expel a balloon filled with a certain volume. The filled balloon simulates the feces. Therefore, the best way to perform this test is to use water at body temperature and a syringe to fill the balloon with water.

In case of a multi-use catheter (without replacement of the balloon), it is advised to fill the balloon with air instead of water. This is to prevent the balloon from sticking together. Use the Solar perfusion pump or a syringe.

Filling with water or air (syringe)

Press the **Next test** button until the text ‘Balloon expulsion’ is displayed on the left button. Fill the syringe with water (or air) to the volume displayed on the Syringe button in the upper-left corner of the screen (for example 10 ml). Connect the syringe to the 3-way stop-cock which is attached to the filling lumen of the catheter. Fill the balloon.

Press the **Balloon expulsion** button to mark the start of the test. A balloon marker is automatically inserted. Ask the patient to expel the balloon.

Press the **Balloon expulsion End** button to mark the end of the test. The software asks if the balloon expulsion was successful. Select ‘Failed’, ‘Partial’, or ‘Success’ and click **OK**.

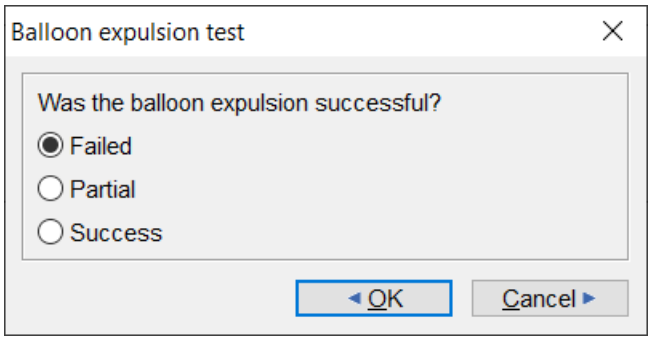


Figure 9.16 Balloon expulsion test

Filling with air (Solar perfusion pump)

Press the **Next test** button until the text ‘Balloon expulsion’ is displayed on the left button. Connect the filling lumen of the catheter to the perfusion pump. Click the **Inflate balloon** tool button (in the upper-left corner of the screen) to inflate the balloon with air to the volume displayed on the button (for example 10 ml).

Press the **Balloon expulsion** button to mark the start of the test. A balloon marker is automatically inserted. Ask the patient to expel the balloon.

Press the **Balloon expulsion End** button to mark the end of the test. The software asks if the balloon expulsion was successful. Select ‘Failed’, ‘Partial’, or ‘Success’ and click **OK**.

9.4.12 Rectal Compliance

The purpose of the compliance measurement is to objectively determine the compliance of the rectum. The compliance can be used to determine abnormalities in the elasticity of the rectum.

Balloon compliance correction

To obtain the real compliance of the rectum, it is important to determine the compliance of the balloon itself. To calibrate the balloon compliance, proceed as follows. Place the balloon in warm water at body temperature (37° C). Make sure that the following settings are set in the protocol (see § 9.2.10):

- On the Filling TAB:
  Filling method: Perfusion pump (Automatic, Air)
- On the Sensation/Compliance TAB:
  Use std. Balloon calibration Always
  Save std. Balloon calibration Always


Click the **Anorectal manometry** button to start the pre-test.


Zero the transducer in open air.

Click the **ALT** tool button and press the **Calibration begin** button  . Automatic calibration is done by the perfusion pump.


Press **OK** to continue.


Press the **Start investigation** button.

During analysis, the software will compensate the rectal pressure with the pressure built up by the balloon. If you always use the same balloon catheter, you only need to determine the balloon compliance once.

Measurement

Inflate the balloon with the perfusion pump (click the pump tool button).


This button indicates that the uncalibrated balloon pressure is displayed. Click the button to switch to calibrated balloon pressure.


During infusion, the sensation markers can be set by pressing the appropriate softkey.

When the maximum tolerable volume is reached, the pump must be stopped (click the pump tool button again).


The balloon can be deflated.

Press the **Stop investigation** button. The balloon compliance will be saved and is used by the next investigation.

9.4.13 Remote Control Buttons

Buttons	Description
	**Select the previous or next test** Press **Previous** or **Next** to select another anorectal manometry test.
	**Select another value or sensation marker** Press the **Up** or **Down** button to select another value on the **cm** or **balloon** button, or to select another sensation marker.
	**Change the pressure scale** Press Scale **Up** or **Down** to adjust the scale of the pressure channels.
	**Zero all pressures during the measurement** Press **Alt** first and then **Zero all** during the measurement to zero all pressures.

9.4.14 Stop the Investigation

To stop the anorectal manometry investigation:

Press the **Stop investigation** button to stop the investigation.

9.5 Analysis

9.5.1 Introduction

Analysis can be done by inserting channels markers or by using the channel definition settings. We recommend to use the method with the channel markers.

9.5.2 Insert Channel Markers

The channel markers should be inserted on the channels on which the specific test is registered. The results will then be calculated on these channels. When you open the investigation for the first time, the dialog window ‘anorectal manometry channel marker settings’ will be displayed automatically.

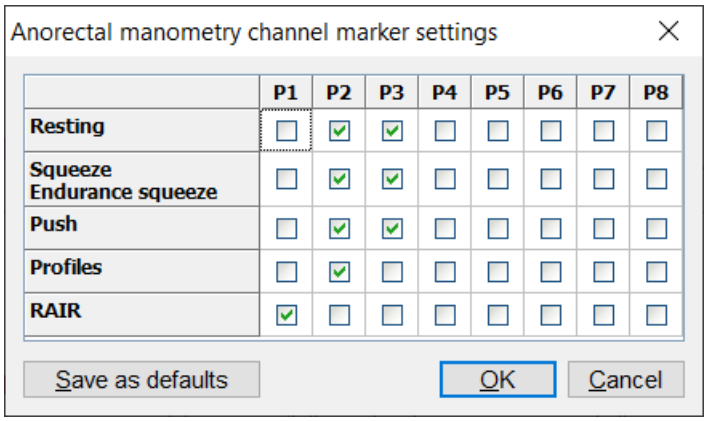


Figure 9.17 Example of anorectal manometry channel marker settings

When you performed the investigation with i.e. a spiral catheter, you must decide on which channel(s) you want to perform analysis for each test. Once you set this, you can save the settings as default. For the next investigation (if performed with the same catheter and in the same way), you can use these settings again.

When you performed the investigation with a radial catheter, you select all channels for all tests.

It is always possible to change the settings (i.e. after you reviewed the curves and decide that the settings must be changed). Choose **Settings > Anorectal manometry channel marker settings** to display the settings dialog.

9.5.3 Channel Definition

In the channel definition window, you can define which pressure channels you want to analyze. Choose **Settings > Channel definition** or click the **Channel definition** button to display the following dialog window.

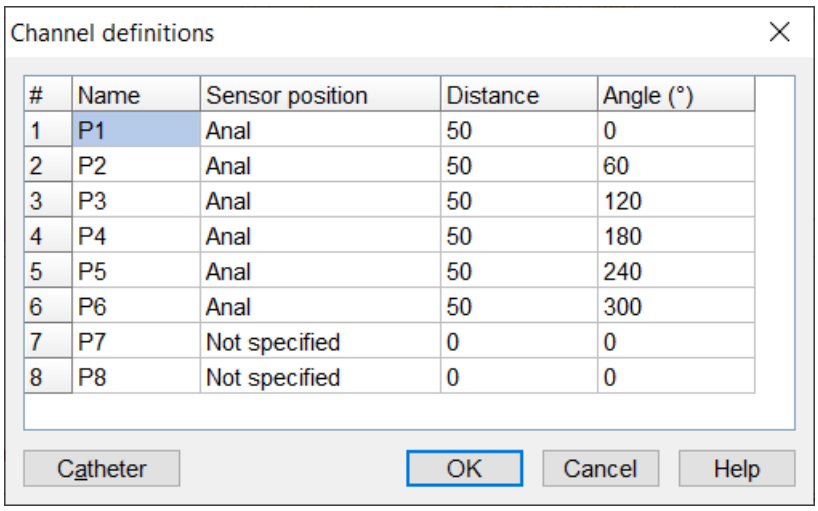


Figure 9.18 Channel definition

When using spiral catheters with one cm (or 0,5 cm) spacing between the pressure channels, you must define the sensor positions and so the channels which will be analyzed. The previous figure serves as an example.

- The RAIR test can tell you which channel measured is at the IAS (Internal Anal Sphincter). Drops in pressure after inflating the balloon indicates the internal sphincter. In the window channel P3 is defined as IAS. This implies that for the RAIR test only channel P3 is analyzed.

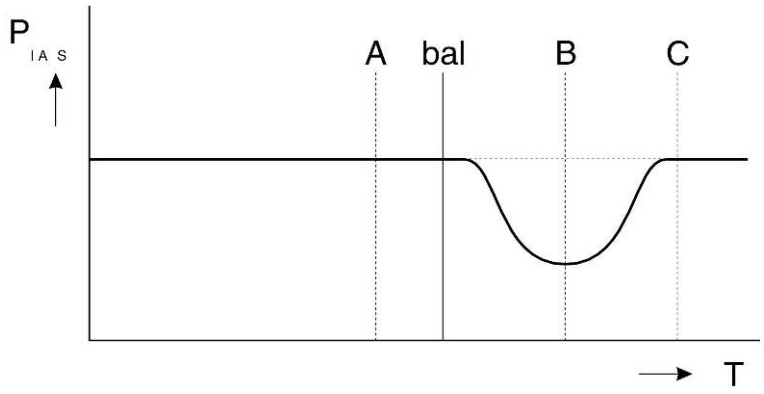


Figure 9.19 RAIR test

- The squeeze test can tell you which channel is at the EAS (External Anal Sphincter). The strongest pressure increase indicates the external sphincter. In this window channel P2 is defined as EAS.
- The tip is positioned in the rectum (in the figure above: channel 4).
- After setting the channel definition, you must check the position of all the markers.

9.5.4 Anorectal Manometry Settings

During analysis, you can define how certain results should be calculated. This can be done in the anorectal manometry settings window, that can be activated by **Settings > Anorectal manometry settings**. These anorectal

settings are stored with the investigation. This means that changes made here are only in effect for the current study.

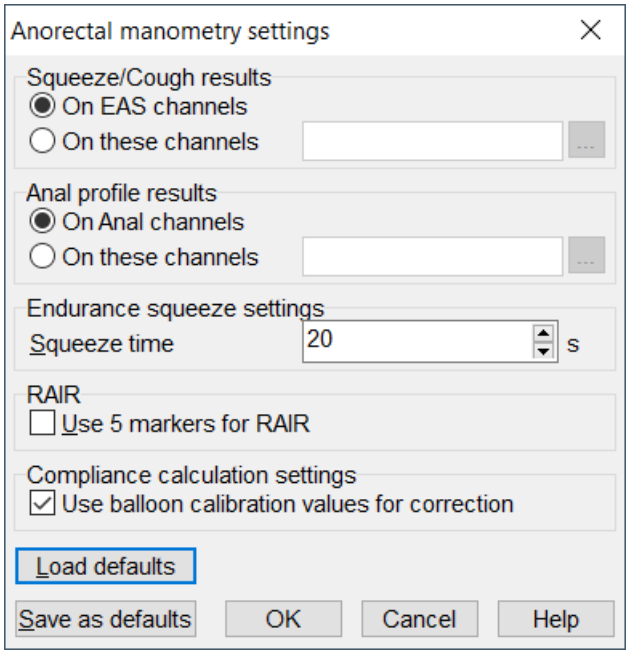


Figure 9.20 Anorectal manometry settings

Squeeze/Cough results

The squeeze and cough results are calculated either on channels that are defined as EAS in the channel definition (**Settings > Channel definition**) or on certain user-selectable channels. To select the channels yourself, click on the button with '…' and a selection window is displayed. Just check the channel you would like to include for the results.

Anal profile results

The (rest and squeeze) profile results are calculated either on channels that are defined as 'Anal' in the channel definition (**Settings > Channel definition)** or on certain user-selectable channels. To select the channels yourself, click on the button with '…' and a selection window is displayed. Just check the channel you would like to include for the results.

Endurance squeeze setting

Placing the endurance squeeze markers, two channel markers will be automatically placed on the EAS channel as defined in the channel definition (**Settings > Channel definition)**. The first channel marker will be placed on the maximum pressure between the two endurance squeeze markers. The 2nd channel marker will be placed a certain time later. This time can be specified as the squeeze time in this dialog.

RAIR settings

You can select ‘Use 5 markers for RAIR’ (instead of 2). It is not recommended, but this setting is still supported for users who are used to it.

Compliance calculation settings

When balloon compliance calibration is performed, the compliance calculation will compensate for the obtained balloon compliance. If for some reason this is not desired, you can disable the balloon compensation with this option.

Load and save defaults

The anorectal-settings dialog is enhanced with options to load and save the default settings. The default settings will also be assigned automatically to all new investigations.

9.5.5 Results

In the analysis program, choose **Results** > **display Results** from the menu to display the calculated parameters. Some parameters will be calculated after placing the corresponding markers.

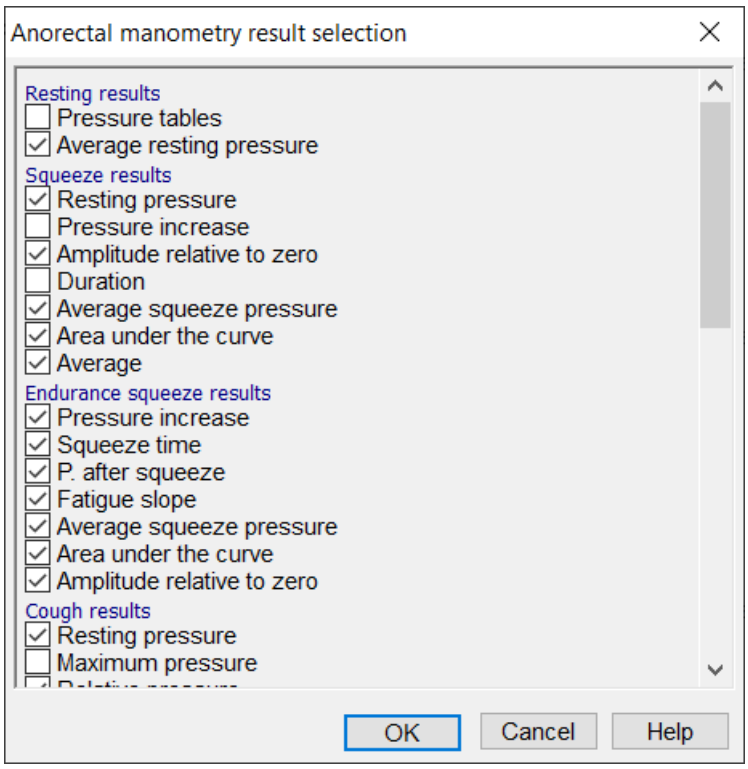


Figure 9.21 Select anorectal manometry results

Almost all results can be individually enabled or disabled. This makes the report much more flexible and you can select exactly those results that are important.

9.5.6 Resting Pressure Test

For the resting pressures, a table with the average pressure between the markers can be displayed. The level at which the resting pressures are obtained (when cm markers are placed) and the average resting pressure are also calculated. Besides the table, the average overall resting pressure for the IAS, EAS, and Anal channels is calculated. In the results selection, you can choose what results should be displayed for the resting pressure.

9.5.7 Squeeze Test

The squeezes should be marked with two squeeze markers. The first squeeze marker should be placed at the onset of the squeeze. The second squeeze marker should be placed at the end of the squeeze. Normally the markers are already placed during the investigation. You can reposition the squeeze markers, or insert new squeeze markers if squeezes are not marked during the investigation.

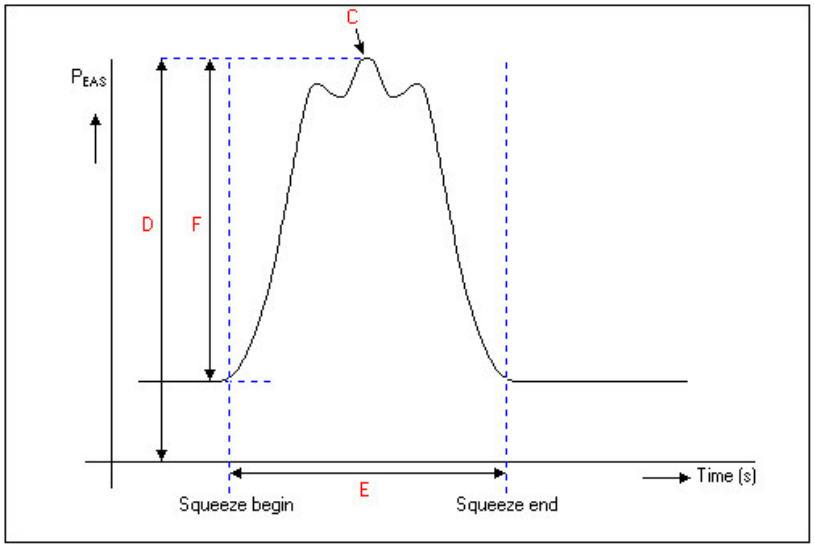


Figure 9.22 Squeeze test

The letters between square brackets refer to the corresponding letters in the above figure. During the squeeze test the patient squeezes his External Anal Sphincter. The beginning and ending of the squeeze period is marked with two squeeze markers [A] and [B] as shown in the figure above. Squeeze markers should always be set in pairs (it is a chained marker).

The squeeze results are displayed in three tables:

- Resting pressure
- Maximum squeeze pressure
- Relative squeeze pressure

Results for up to 8 channels are displayed and averaged. In the result selection, the user can select which of these tables should be included in the results. Using the squeeze markers following parameters are calculated.

Resting pressure
The resting pressure is the average pressure over a 1 second period before the squeeze begin marker [A].

Maximum squeeze pressure
The maximum squeeze pressure (i.e. the pressure increment during squeeze) is calculated as the highest squeeze pressure (between marker [A] and [B]) minus the resting pressure.

Squeeze duration
The squeeze duration is the time between the squeeze markers [A] and [B] = [E].

Average squeeze pressure
The average squeeze pressure is calculated as the average pressure between the squeeze markers minus the resting pressure.

Area under the curve
This is calculated as the integral of pressures between the squeeze markers and the resting pressure.

Vector Volume Plot (VVP): When 2 or more cm-markers are placed, a Vector Diagram can be constructed. The VVP will use the maximum pressure on each channel between the cm-markers to create a squeeze VVP.

9.5.8 Endurance Squeeze Test

The squeezes should be marked with two endurance squeeze markers. The first endurance squeeze marker should be placed at the onset of the squeeze. The second endurance squeeze marker should be placed at the end of the squeeze. Normally the markers are already placed during the investigation. You can reposition the endurance squeeze markers, or insert new endurance squeeze markers if squeezes are not marked during the investigation.

In the anorectal settings dialogue (**Settings > Anorectal manometry settings**), you can specify the endurance squeeze time (see § 9.5.4). The endurance squeeze time is the time for which the fatigue slope of the external anal sphincter pressure is determined. The time starts at the maximum squeeze pressure (between the endurance squeeze markers) and ends squeeze time later. Two channel markers will be placed to indicate this positions.

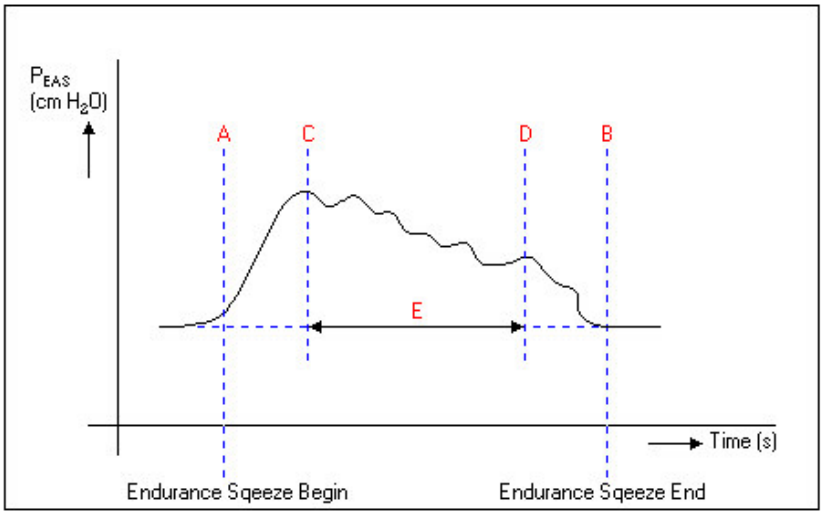


Figure 9.23 Endurance Squeeze test

The letters between square brackets refer to the corresponding letters in the above figure. During the endurance squeeze test the patient squeezes his External Anal Sphincter and maintains the squeeze for about 30 seconds. The beginning and ending of the squeeze period is marked with two squeeze markers [A] and [B] as shown in the figure above. The software will automatically insert two channel markers [C] and [D]. The first channel marker will be placed on the maximum EAS pressure between marker [A] and [B]. The second channel marker will be placed a certain time after the first channel marker.

The positions of the channel markers mark the exact EAS pressures which are used for the result calculations. They can be repositioned by the user, if they are not correctly placed by the software.

The software will calculate following results for each marked endurance squeeze:

- Maximum pressure
- Squeeze time
- Pressure after squeeze time
- Fatigue slope
- Average squeeze pressure
- Area under the curve

9.5.9 Cough Test

The coughs should be marked with two cough markers. The first cough marker should be placed at the onset of the cough. The second cough marker should be placed at the end of the cough.

Normally the markers are already placed during the investigation. You can reposition the cough markers, or insert new cough markers if coughs are not marked during the investigation.

The cough results are displayed in three tables:

- Resting pressure
- Maximum cough pressure
- Relative cough pressure

Results for up to 8 channels are displayed and averaged. In the result selection, the user can select which of these tables should be included in the results.

Resting pressure
The resting pressure is the pressure at the cough begin marker.

Maximum pressure
The maximum cough pressure is calculated as the maximum pressure between the two cough markers.

Relative pressure
The cough pressure (i.e. the pressure increment during cough) is calculated as the maximum cough pressure minus the minimal base pressure at one of the cough markers.

9.5.10 Push Test

The strains should be marked with two push markers. The first push marker should be placed at the beginning of the strain. The second push marker should be placed at the end of the strain. Normally the push markers are already placed during the investigation. You can reposition these markers, or insert new push markers if strains are not marked during the investigation.

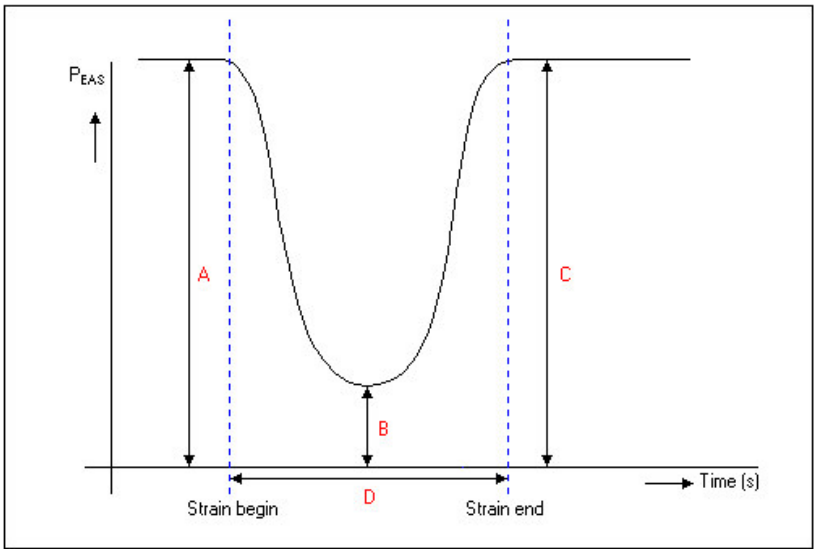


Figure 9.24 Push test

The letters between square brackets refer to the corresponding letters in the above figure. The software will calculate the following results for each marked push:

- Resting pressure
- Residual pressure
- % Relaxation
- Duration

Resting pressure
The resting pressure is the pressure at the push begin marker [A].

Residual pressure
The residual pressure is the minimum pressure between the two push markers [B].

%relaxation
The %relaxation is calculated as 100 * Residual pressure/Resting pressure.

Duration
The duration is the time in seconds between the two push markers [D].

9.5.11 Rectal Anal Inhibitory Reflex (RAIR) Test

During the analysis, additional Reflex marker can be placed. The first two markers should mark the IAS baseline pressure. The second two markers should mark the IAS relaxation pressure. The last marker marks the end of the relaxation.

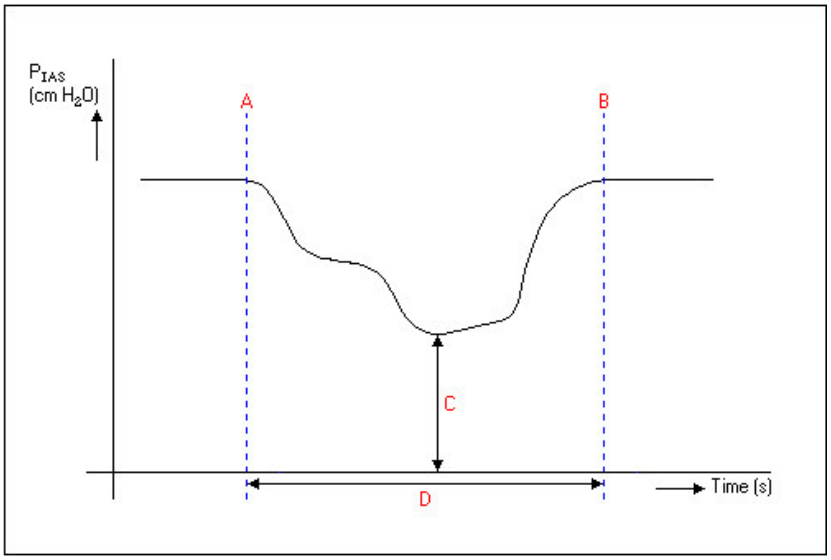


Figure 9.25 RAIR test

The letters between square brackets refer to the corresponding letters in the above figure.

Resting pressure

The resting pressure is the average pressure at marker [A].

Residual pressure

Minimum pressure between Marker [A] and Marker [B].

Amplitude of relaxation

The amplitude of relaxation is the pressure difference between the resting pressure and the residual pressure.

% of relaxation

The %of relaxation is defined as the Amplitude of relaxation divided by the resting pressure multiplied by 100%. It is the percentage of IAS relaxation relative to zero pressure.

$$\text{Calculated: \% of relaxation} = \frac{\text{Amplitude of relaxation}}{\text{Resting pressure}} * 100\%$$

Duration

The duration is defined as the time [D]. It is the time between the balloon marker and marker [C].

If no balloon marker is set between marker A and C, the reflex duration cannot be calculated.

Balloon volume

Is the volume with which the balloon was inflated. It is infused volume at the balloon marker [Bal].

External sphincter response
Is the maximum pressure on the EAS channel between marker [A] and marker [C]. This result is only calculated when an EAS channel is present.

9.5.12 Sensation Test

The sensations should be marked with sensation markers. Normally sensation markers are already placed during the investigation. You can reposition the sensation markers, or insert new markers if sensations are not marked during the investigation.

The following sensation results will be calculated:

- Sensation volume
- Pressure at sensation

Sensation results are displayed for all sensation markers present in the investigation. If multiple markers of the same sensation type are present, then the result for all these markers are displayed.

9.5.13 Anal Rest and Squeeze Profiles

When the investigation is stopped, the program will automatically insert two internal sphincter markers for each profile in the test data. These two markers will be located between the profile markers around the maximum pressure. The software will calculate the average internal sphincter pressure between these two markers. It is possible to reposition these markers, if you would like to.

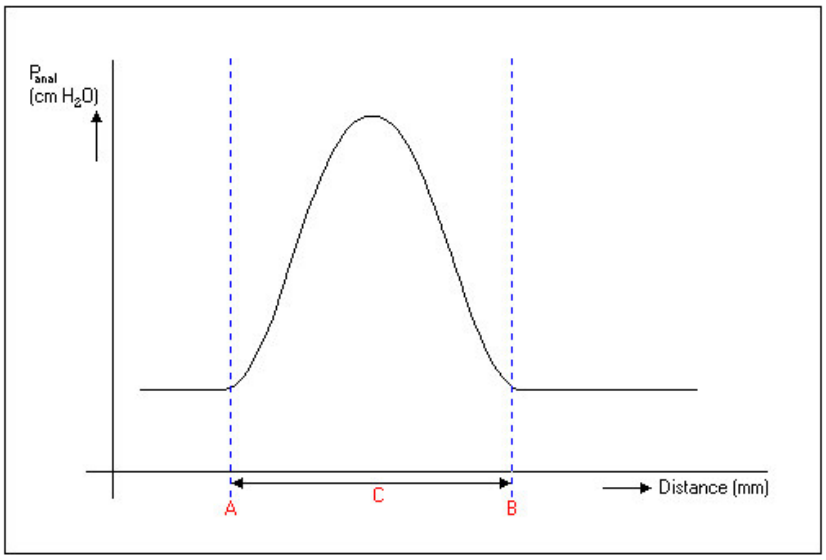


Figure 9.26 Anal profile test

Rest profile

The following results will be calculated for anal pressure profiles:

- Length of anal-zone.
- Average internal sphincter pressure.
- Pressure transmission ratios at *transmission* markers when these markers are present.
- Length of HPZ (High Pressure Zone). This is the profile area where the pressures are higher than 50% of the maximum pressure.
- Vector Volume.
- Asymmetry index.

Length anal zone
The length of the anal profile is defined as the distance [C]. This distance is measured in mm. It is calculated as the product of the puller speed and the time between the marker [A] and the marker [B].

Average internal sphincter pressure in anal zone
The average internal sphincter pressure is defined as the average value of anal pressure between the markers [A] and [B]. The pressure will be calculated on the channel marked as IAS in the channel definition.

In the profile tables, the average for each distance is also calculated and included in the table. In the results, a profile pressure table can be included. This table displays the pressures for each channel over a certain distance of the profile. In the result selection, this table can be activated or deactivated.

Squeeze profile
At this moment, only a profile pressure table can be included. This table displays the pressures for each channel over a certain distance of the profile. It is possible to display a 3D VVP for the squeeze profile. Vector Diagram can be displayed for the profile when at least 3 channels are measured radial.

9.5.14 Balloon Expulsion Test

The balloon expulsion should be marked with two balloon expulsion markers. The first balloon expulsion marker should be placed before the expulsion of the balloon. The second marker should be placed after the expulsion of the balloon. The balloon expulsion state (failed, partial or success) will be displayed in the marker name.

Normally the markers are already placed during the investigation. You can reposition the balloon expulsion markers, or insert new balloon expulsion markers if they are not marked during the investigation.

The balloon expulsion results contain if the expulsion was successful, partial or failed, balloon volume, and duration.

9.5.15 Rectal Compliance

During the analysis, the compliance can be determined by placing compliance markers. Place the compliance markers so that they surround the area over which the capacity should be determined. For each pair of compliance markers placed, the calculated compliance will be present in the result screen and in printed reports.

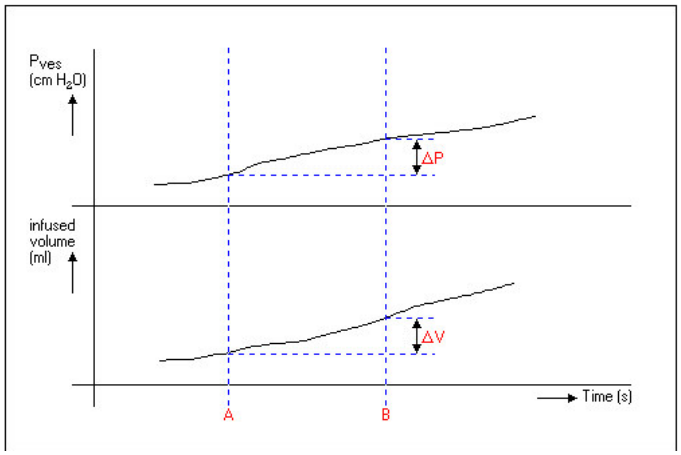


Figure 9.27 Rectal compliance test

The letters between square brackets refer to the corresponding letters in the above figure.

The compliance is the change in volume for a change in pressure. It is defined as C= dV/dP, where dV is the volume increment and dP is the change in pressure associated with this volume increment.

$$\text{Compliance} = \frac{V}{Prect} = \frac{\text{VolumeB - VolumeA}}{\text{Prect B - Prect A}}$$

Rectal filling begin compliance = VolumeA
Rectal filling end compliance = VolumeB

When the compliance calibration is performed during the test, then the compliance calculation will be compensated for the pressure caused by the balloon itself. This is done by subtracting the balloon-pressure belonging to the volume from the actual measured pressure during the test.

During the investigation, a first sensation marker was placed the sensory threshold will be determined. This parameter will be included in the result screen and in the printed reports. For each sensation marker placed during the investigation following parameters will be determined:

- Balloon volume at sensation marker
- Rectal pressure at sensation marker

- IAS pressure at sensation marker

9.5.16 3D Vector Volume Plot

When you want to create 3D vector volume plots of the anal-canal, you need a catheter with at least three radially oriented channels. Profile tests must have been performed in o display the plot. Also, the pressures should be correctly defined in the channel definition (**Settings > Channel definition**).

In the analysis software, click the **3D Vector volume plot** button to display the 3D vector volume plot. Three-dimensional imaging of the anal sphincter can be used to evaluate sphincter dysfunction.

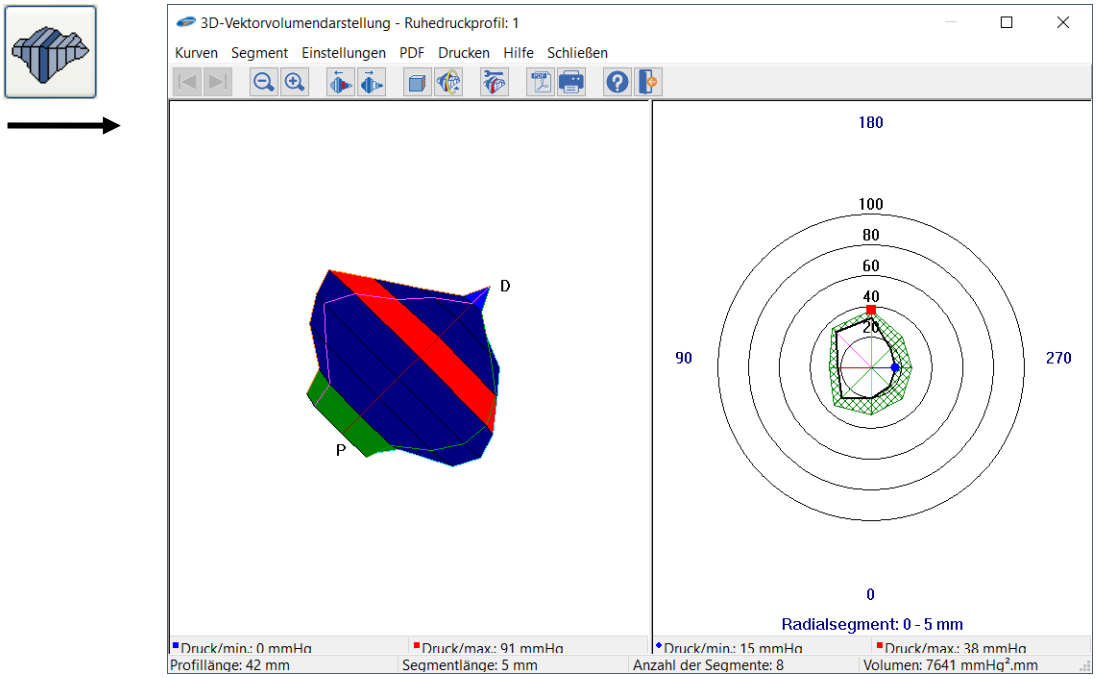


Figure 9.28 Dimensional Vector volume plot

The 3D vector volume plot is created from the pressures measured during the pull-through of the catheter through the rectum. The profile is divided in several segments of fixed length. The maximum pressure in each segment for each channel is used to draw the three-dimensional sphincter image.

The Vector Volume Plot of the sphincter is displayed in the left window. It can be rotated in any direction by means of the cursor keys or the mouse. The 3D plot consists of several segments, displayed in different colours. These colours have the following meaning:

Colour	Meaning
Red	Segment with highest pressure
Light Blue	Segment with lowest pressure
Green	Active segment
Dark Blue	All other segments

The radial cross-section of the active segment is displayed in the radial cross-section graph in the window on the right.

In the vector volume plot header, the type and number of the profile on which the VVP is based are displayed. Two buttons are added to the toolbar, with which you can select the previous or next VVP when multiple profiles are present. In the graphs and the segment menu, you will find the option to export the VVP and the Radial Segment to a BMP file (Save as).

More information can also be found in the Help information.

9.5.17 Rectal Volume Plot

Click the **Rectal volume plot** button or Choose **Options > Rectal volume plot** to display the Rectal volume plot.

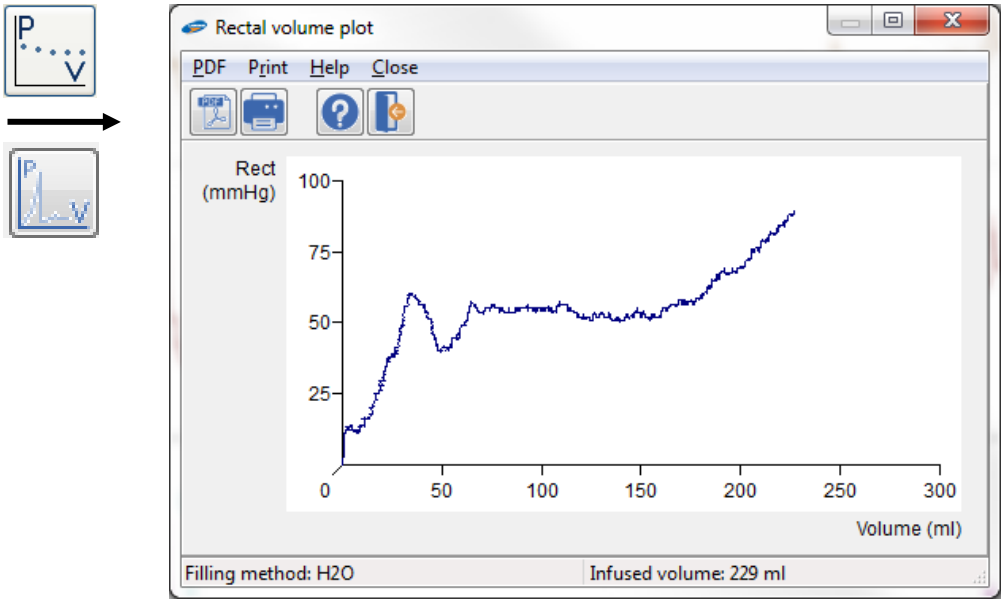


Figure 9.29 Rectal Volume plot

This plot displays the relation to the balloon volume and the rectal pressure. To include the rectal volume plot in the report, select **Rectal volume plot** in the Report setup.

The X-axis represents volume (auto scale). The Y-axis represents rectal pressure (auto scale). When filling with air, for each balloon marker a filled circle is displayed in the plot. When filling with water, a continuous line is displayed.

More information can also be found in the Help information.

10. Biofeedback

10.1 Introduction

In the management of e.g. stress incontinence, biofeedback training can be used for training of the patient's pelvic floor muscle's or anal sphincter.

During the training one or more challenges can be presented to the patient, for example the patient must squeeze the pelvic floor until a certain level. Feedback to the patient is generated by displaying the measured signal (i.e. EMG, pressure etc.) by a moving object. For example, a fish can be displayed in a sea world. When the fish is catching air bubbles, the patient is doing good.

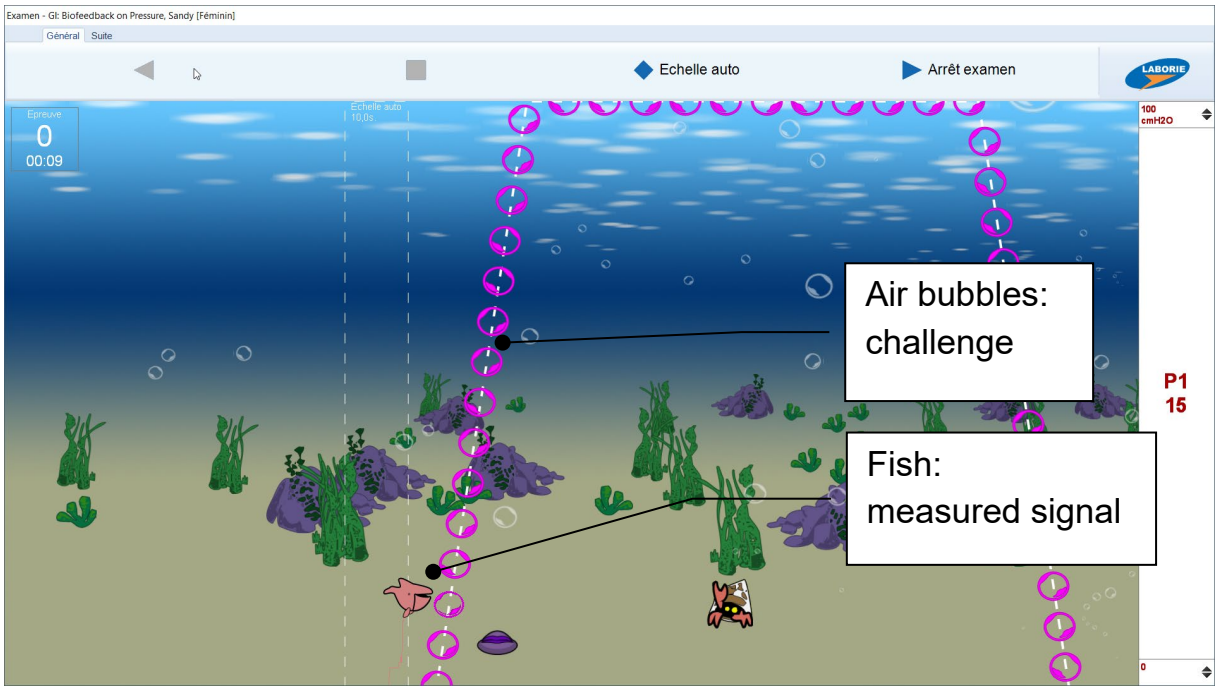


Figure 10.1 Biofeedback on EMG in the sea world

Biofeedback can react on different channels:

- Flow
- Pressure
- EMG

Different probes are available to measure different signals.

10.2 Prepare the investigation

Click the **Biofeedback** button to start the pre-test.

A window with the biofeedback settings is displayed. If the patient hasn't done a biofeedback training before, the default protocol settings are loaded. Otherwise the last applied settings for the current patient are displayed. You can change the theme, challenge time or resting time (for more information see § 10.5.2). If you want to return to the main screen of the measurement program you need to click the button **Menu**.

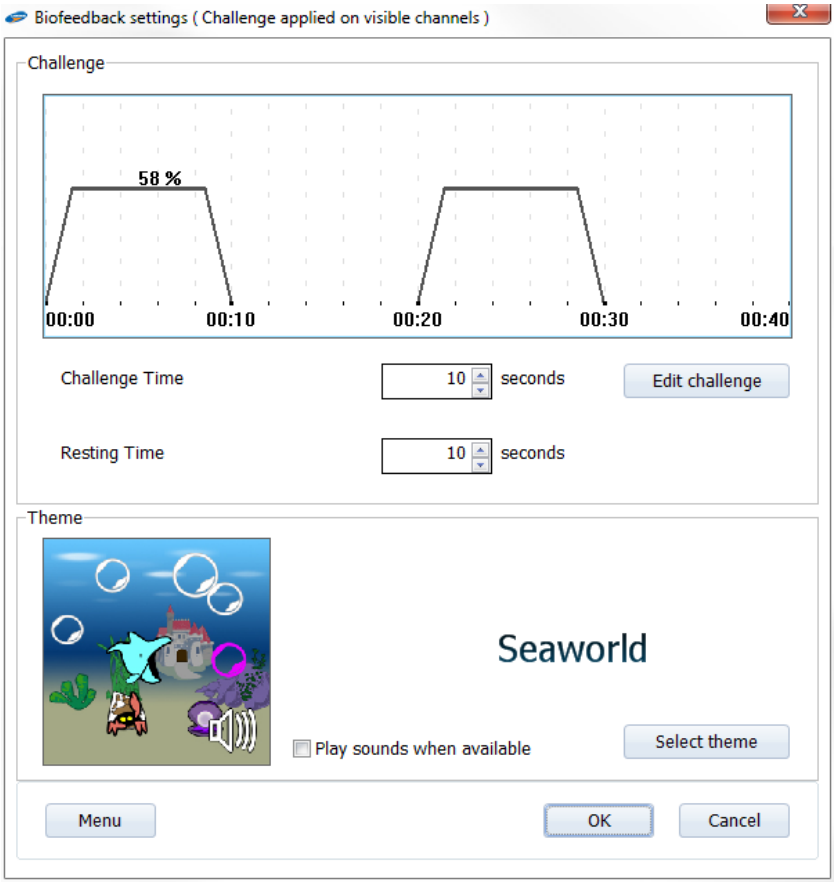


Figure 10.2 Biofeedback settings

- ❑ Click **OK** to save the new settings and to start the pretest. **Cancel** will use the current displayed settings (changes are not saved).

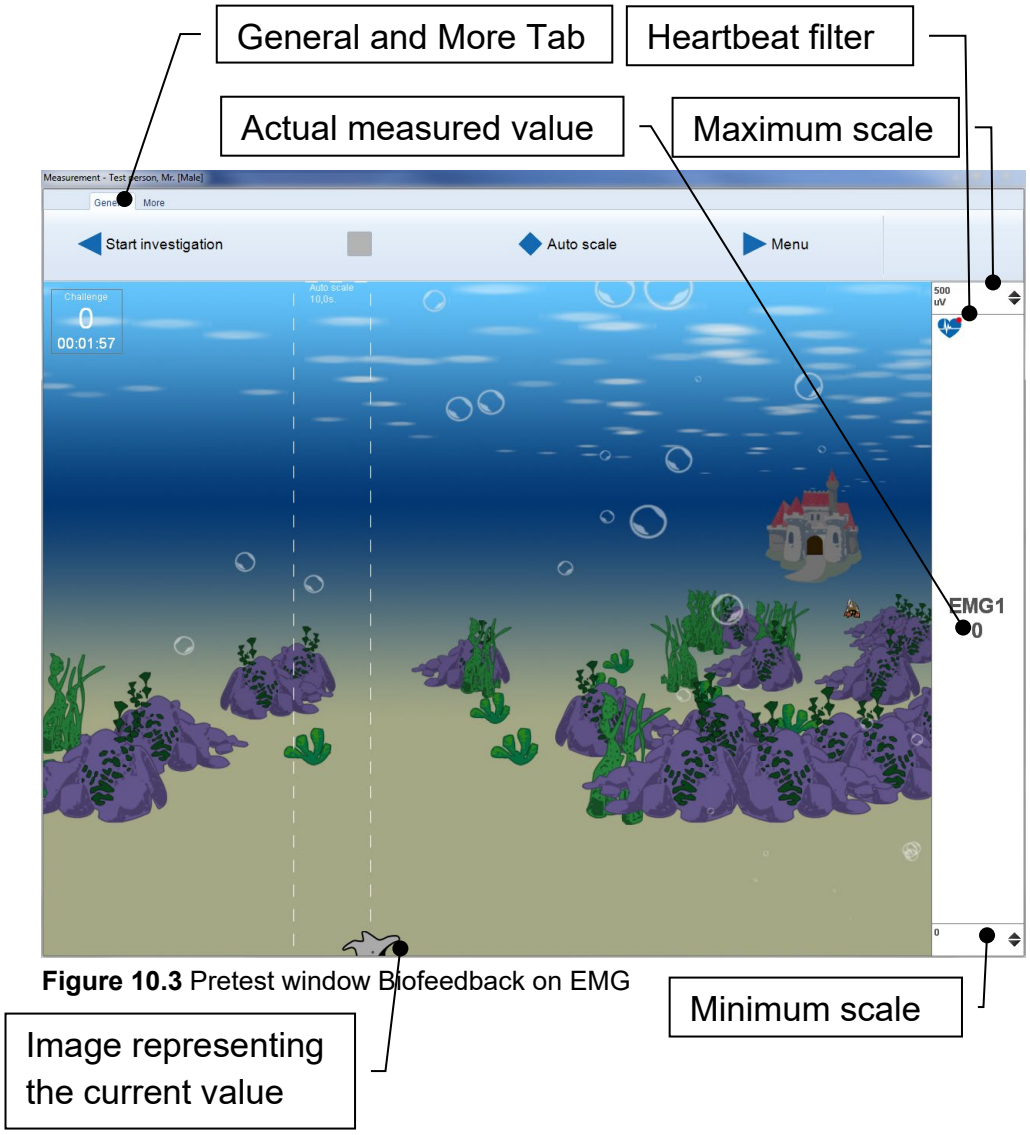


Figure 10.3 Pretest window Biofeedback on EMG

For EMG continue as follows:

- ❑ Apply EMG electrodes / insert probe.
- ❑ Ask the patient to squeeze the muscles to check the EMG signal.

For pressure continue as follows:

- ❑ Prepare the catheter / probe.

Zero the transducer in open air.

- ❑ Insert the catheter / probe.
- ❑ Ask the patient to cough to check the registration of the pressure.

Auto scale

It is possible to set the scale automatically as follows:

- ❑ Let the patient relax for a while.
- ❑ Ask the patient to squeeze e.g. the pelvic floor / anal sphincter as much as possible for a while.

Click the **Autoscale** button. The minimum and maximum values which are measured over the last 10 seconds will be used to set the minimum and maximum scale (when you move the mouse cursor over the **Auto scale** button, it will show the time window which is used).

Manually change scale

Use the triangular buttons at the maximum or minimum scale to change the scale manually. It is also possible to double click on the scale value and to enter a new value.

Heartbeat filter for EMG

A heartbeat filter can be toggled on or off for the EMG channel(s). When the filter is on, the software calculates the minimum value over a moving time window of 400msec.

Heartbeat filter disabled for the EMG channel. Click to enabled.

Heartbeat filter enabled for the EMG channel. Click to disable.

Show curves

It is possible to show curves by clicking the **More** tab, and the **Show curves** tool button. Click the **General** Tab to return to the general screen.

Change settings

It is possible to change the settings by clicking the **More** tab, and the **Edit challenge** tool button. You can change the challenge time or resting time (see § 10.5.2) or you can edit the challenge (see § 10.5.3). Click the **General** Tab to return to the general screen.

Click the **Start investigation** button to continue.

10.3 Investigation

The animation which represents the challenge, scrolls from right to left. The patient should try to follow the goal line of the challenge and collect the items of the challenge. For example, in the Seaworld theme, the items of the challenge are air bubbles and, when the ‘play sound’ setting is used, a sound

is played when touching the items. The time between two challenges is the set resting time. In the top left corner, a challenge counter is displayed.

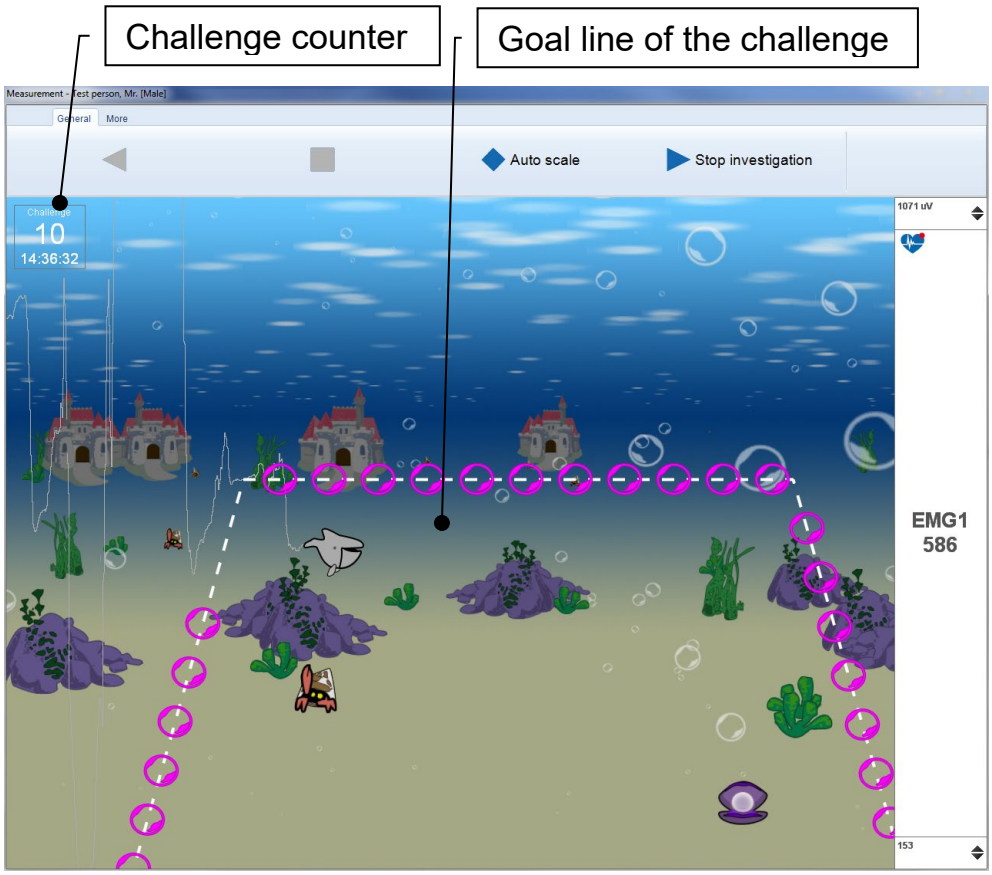


Figure 10.4 Investigation window Biofeedback on EMG

During the investigation, you can auto scale, toggle curves on/off or toggle heart beat filter on/off. Changes in the settings like challenge time and/or resting time can still be done. Editing the challenge can be applicable when you need to change the level or the rest value. The procedures to change the settings are the same as in the pretest: click the **More** Tab and the **Edit challenge** button.

EMG test

The Biofeedback EMG test uses EMG channel 1 of the measurement system to control the animated object. The higher the EMG value the higher the object appears on the screen. This means when the patient will relax the muscles, the object will descend and when the patient strains his muscles the object will ascend.

Pressure test

The Biofeedback pressure test uses pressure channel 1 of the measurement system to control the animated object. The higher the pressure the higher the object appears on the screen.

Flow test

The flow test is a normal uroflow, except instead of the curves a moving animated object appears on the screen. The height of the animated object is a direct indication of the current flow. All measured data are saved after the investigation and can be analyzed as a normal uroflow.

10.4 Analysis

In the analysis program, the measurement is shown as conventional graphs. The challenge markers show the start of a challenge. Every time a challenge has changed during the investigation, a new marker is added. This is also the case when the scale had been changed during the investigation.

With the **Show challenges** tool button, it is possible to show the challenges superimposed over the graphs.

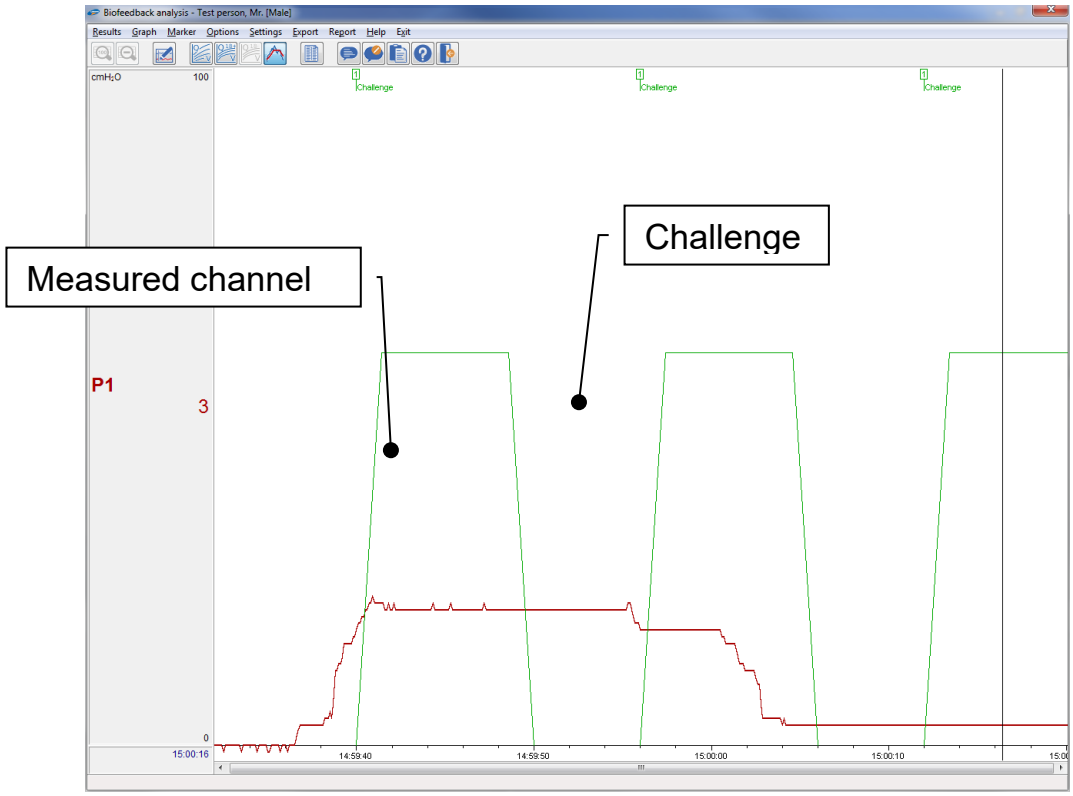


Figure 10.5 Analysis window Biofeedback on pressure

10.5 Investigation Protocol

In the protocol settings, you can define the channels to be measured, and select or edit challenges (for each channel) of the protocol. To edit the protocol, start the measurement program (select the patient in the database and click the **New investigation** button), click with the right mouse button on the protocol name and choose **Edit protocol** from the menu. Select the **Biofeedback** TAB in the 'Edit investigation protocol' window.

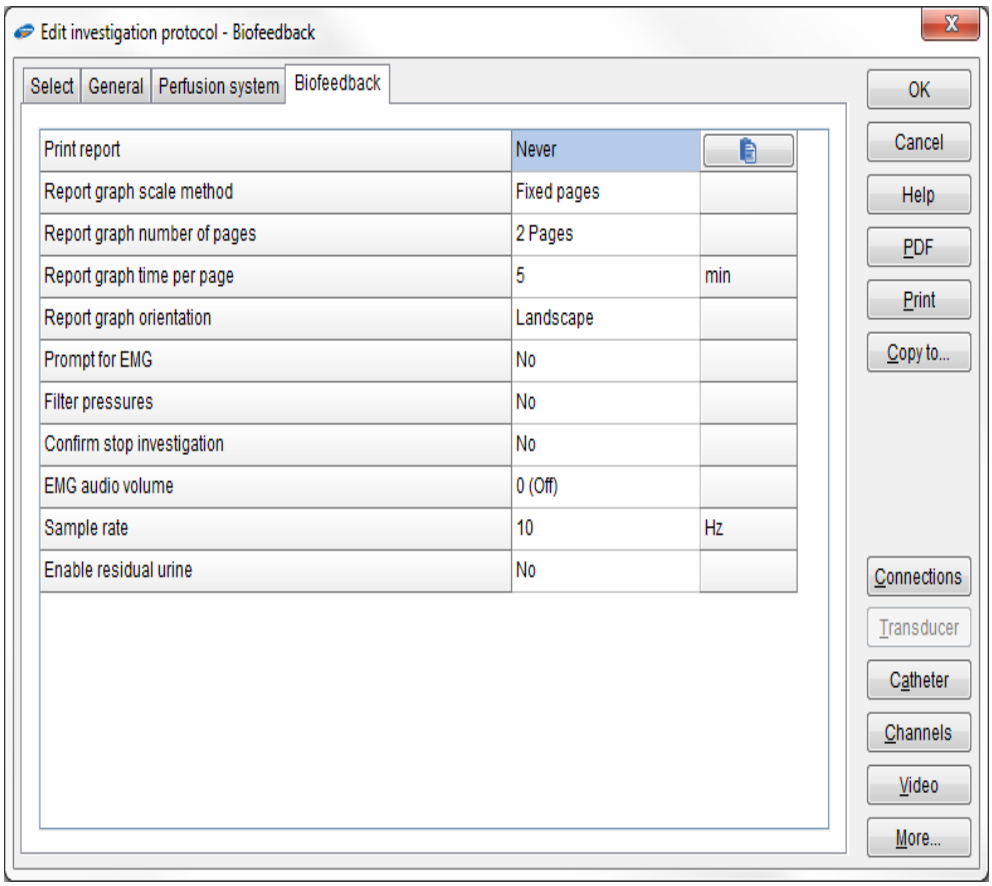


Figure 10.6 Biofeedback protocol

The changes made in the protocol settings (and saved with the **OK** button), are stored for the protocol. With the **More** button changes in the Biofeedback settings can be done (more information, see § 10.5.2). However, during the pretest or measurement the 'Biofeedback setting's dialog can also be opened, and changes are saved for the current patient then.

10.5.1 Channel Settings

In the 'Edit investigation protocol' window, click the **Channels** button to display the 'Channel settings' window.

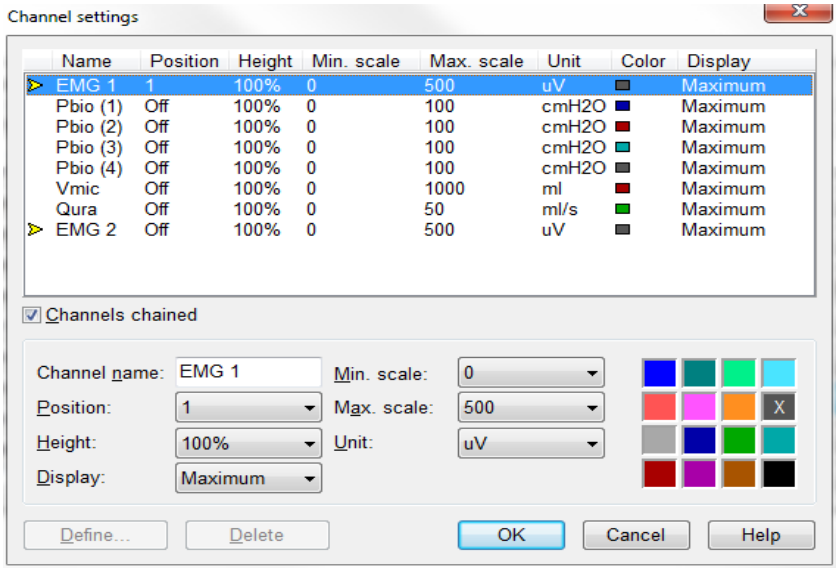


Figure 10.7 Channel settings

In this window, you can define the channels to be measured. To enable a channel, the setting ‘Off’ in the column and ‘Position’ must be set to a position on the screen, for example position 1. Click on the channel in the list and change the position in the lower part of the window. Click **OK** to save the changes and to return to the ‘Edit investigation protocol’ window.

10.5.2 Biofeedback Settings

The ‘Biofeedback settings’ window can be opened in different ways.
If you want to save the changes as default protocol settings, act as follows:

- In the ‘Edit investigation protocol’ window, click the **More** button. To save the changes, you need to click the **OK** button.

If you want to change the settings only for the current patient, act as follows:

- Start the pretest for the current patient. The Biofeedback settings window will be displayed automatically.
- During the pretest or investigation, click the **More** Tab and click the tool button **Edit challenge**.
- To save the changes, click the **OK** button.

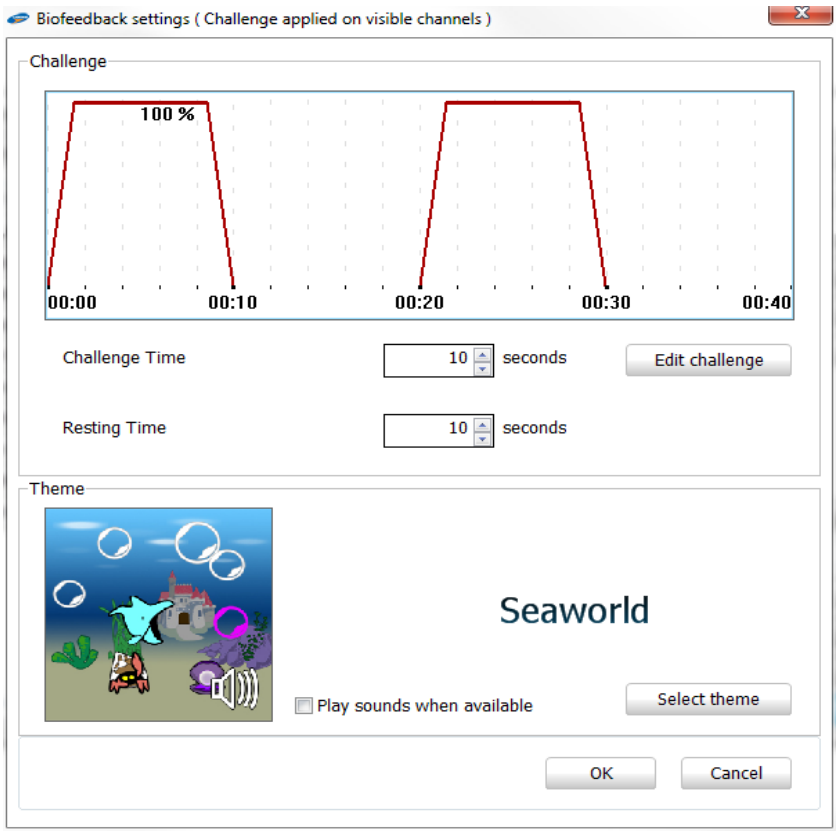


Figure 10.8 Biofeedback settings in the protocol

The ‘Biofeedback settings’ window shows a preview of the selected challenge. For each channel a preview of the challenge is displayed.

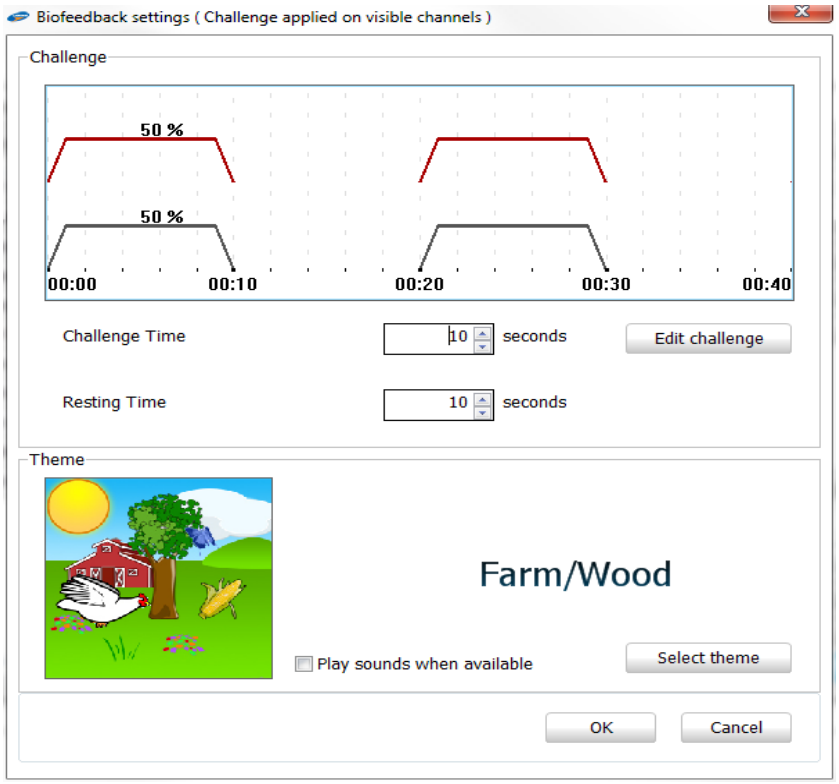


Figure 10.9 Biofeedback settings for two channels

A challenge consists mostly out of challenge time and resting time. The challenge time is the worktime with a certain workload for the patient. The resting time is the time in between two challenges and serves as a moment of rest for the patient. The challenge time and resting time can be adapted by clicking in the field and changing the time. To select another challenge or to edit an existing challenge, click the **Edit challenge** button (for more information, see § 10.5.3).

Select Theme

In the 'Biofeedback settings' window, it is possible to select another theme by clicking the **Select Theme** button or the image of the theme. This is only possible if you enter the settings from the protocol, and not during the pretest or investigation.

A window shows the possible themes. To select another theme, click on the image of your choice. Click **OK** to save the changes and to return to the 'Biofeedback settings' window.

Figure 10.10 Select theme

Play sounds

In the 'Biofeedback settings' window, it is possible to use audio feedback during the investigation by selecting 'Play sounds when available'. Playing sounds is only available for certain themes (indicated by the speaker in the theme image)

10.5.3 Challenge Editor

With the challenge editor, it is possible to select another challenge or to edit a challenge. The challenge editor consists of basic edit mode and advanced edit mode. Challenges can be selected or edited only for the enabled channels in the channel settings (see § 10.5.1).

The ‘Edit challenge’ window can be started by clicking the **Edit challenge** button in the ‘Biofeedback settings’ window, or by clicking the preview image of the challenge.

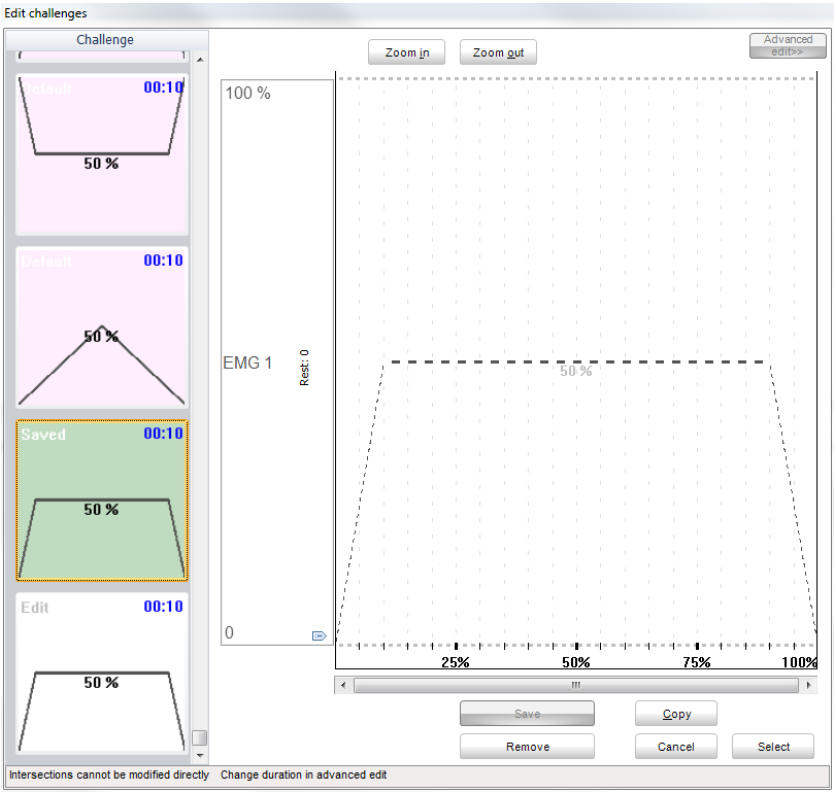


Figure 10.11 Challenge editor

All available challenges are shown on the left side. The current selected challenge can be recognized on the orange border. The default available challenges are shown at the top (the background colour is pink and the text ‘default’ is shown in the image). The other challenges in the list (if present) are custom made. The saved challenges have a green background color and the text ‘Saved’ is shown in the image. The challenges with a white background color and the text ‘Edit’ in the image are in the ‘under construction’ mode (they are not yet saved).

You can select a challenge by clicking on the challenge image. If you want to use this challenge and return to the protocol, you need to click the **Select** button and then click the **OK** button.

Remove challenge

To remove a challenge, select the challenge and click the **Remove** button. This is not possible for default challenges, and only for saved challenges.

Copy challenge

To copy a challenge, select the challenge and click the **Copy** button. The new challenge can be edited (see below).

Edit challenge

To edit a challenge, you first copy a challenge. The new challenge will be selected and is displayed with a white background color. The text ‘edit’ in the image indicated that the challenge is in the ‘under construction’ mode.

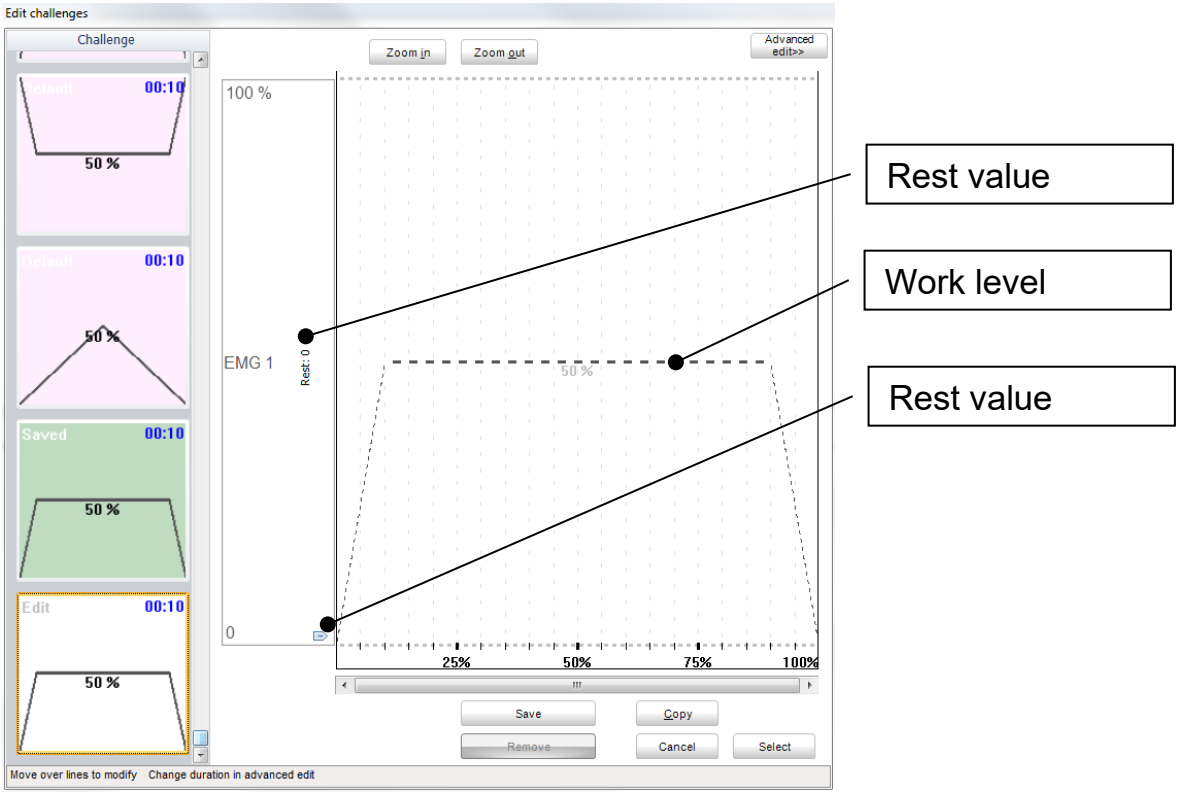


Figure 10.12 Edit challenge window

Basic edit mode

In the basic edit mode, you can adapt the work level or the rest value of a challenge. A challenge consists of one or more work levels. A work level defines a goal workload, for example the EMG level the patient must reach by contracting the pelvic floor. This is a constant level during a certain amount of time. The work level is expressed in a percentage of the scale value (100% is the maximum value). The level can be adapted by clicking and dragging the dashed line up or down.

The rest value is expressed in a percentage of the scale value (100% is the maximum value) and is the value where the challenge starts. The rest value can be changed by moving the indicator on the left. The rest value can be

used for indicating an increase or decrease of workload (for example contract or relax).

Advanced edit mode

A challenge can consist of more than one work level with transition between them. The transition is the time in between two work levels and interpolates between the preceding work level to the next work level. In the advance edit mode, you can add a new part, remove parts in the challenge and change levels of each part.

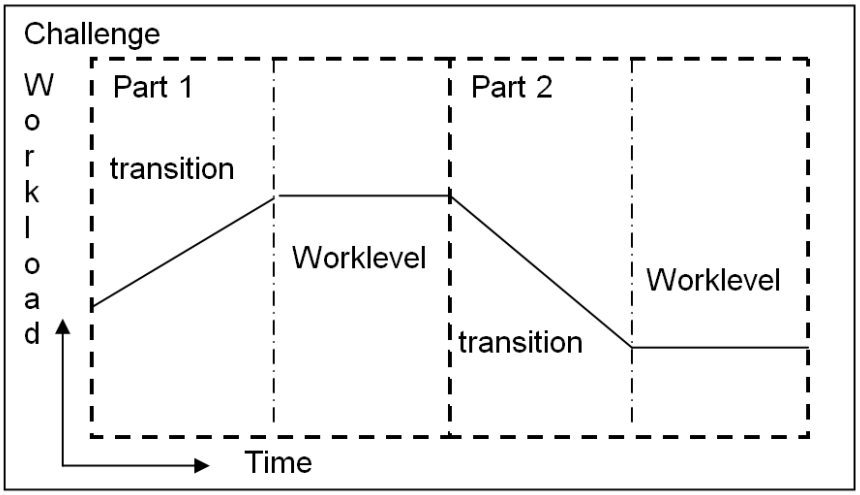


Figure 10.13 Challenge structure

Click the **Advanced edit** button to enter the advanced edit mode. All modifications can be done by clicking and dragging, or with the right mouse button. Follow the instructions as displayed on the right side in the ‘Advanced edit’ window. Also, the status bar will show a hint of the action which can be performed, based on the position and status of the mouse cursor.

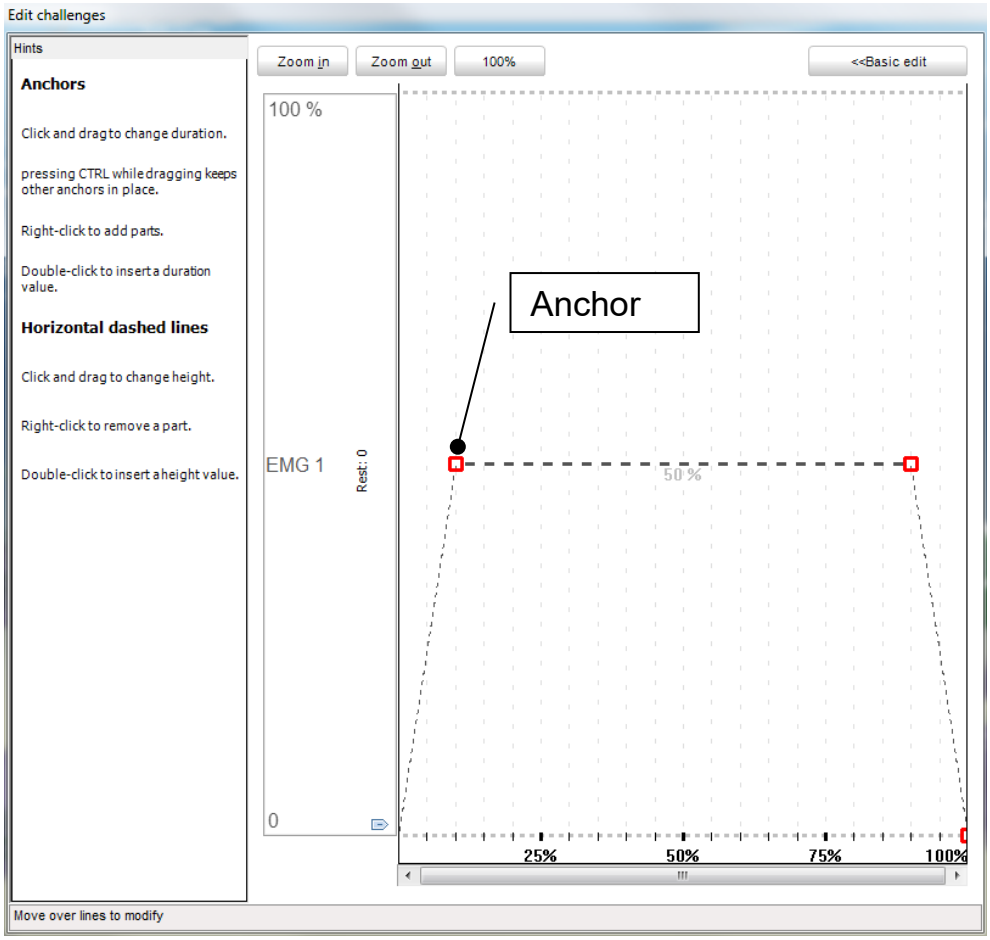


Figure 10.14 Advanced edit mode

The anchor points can be used to modify duration. To modify the height, the horizontal dashed lines can be moved. To add a part, click with the right mouse button on an anchor.

To return to the 'Basic edit' window you need to click the **Basic edit** button. In the basic edit mode you can save the challenge by clicking the **Save** button. To select this challenge you need to click the **Select** button. You will return to the Biofeedback settings window. To return to the protocol, click the **OK** button.

11. Measurement Program

11.1 Introduction

In this chapter, you will find a description of the menu items and settings in the measurement program. Click the **New investigation** button in the database program to start the measurement program. If more than one system is installed, you need to select the measurement system, for example the stationary system.

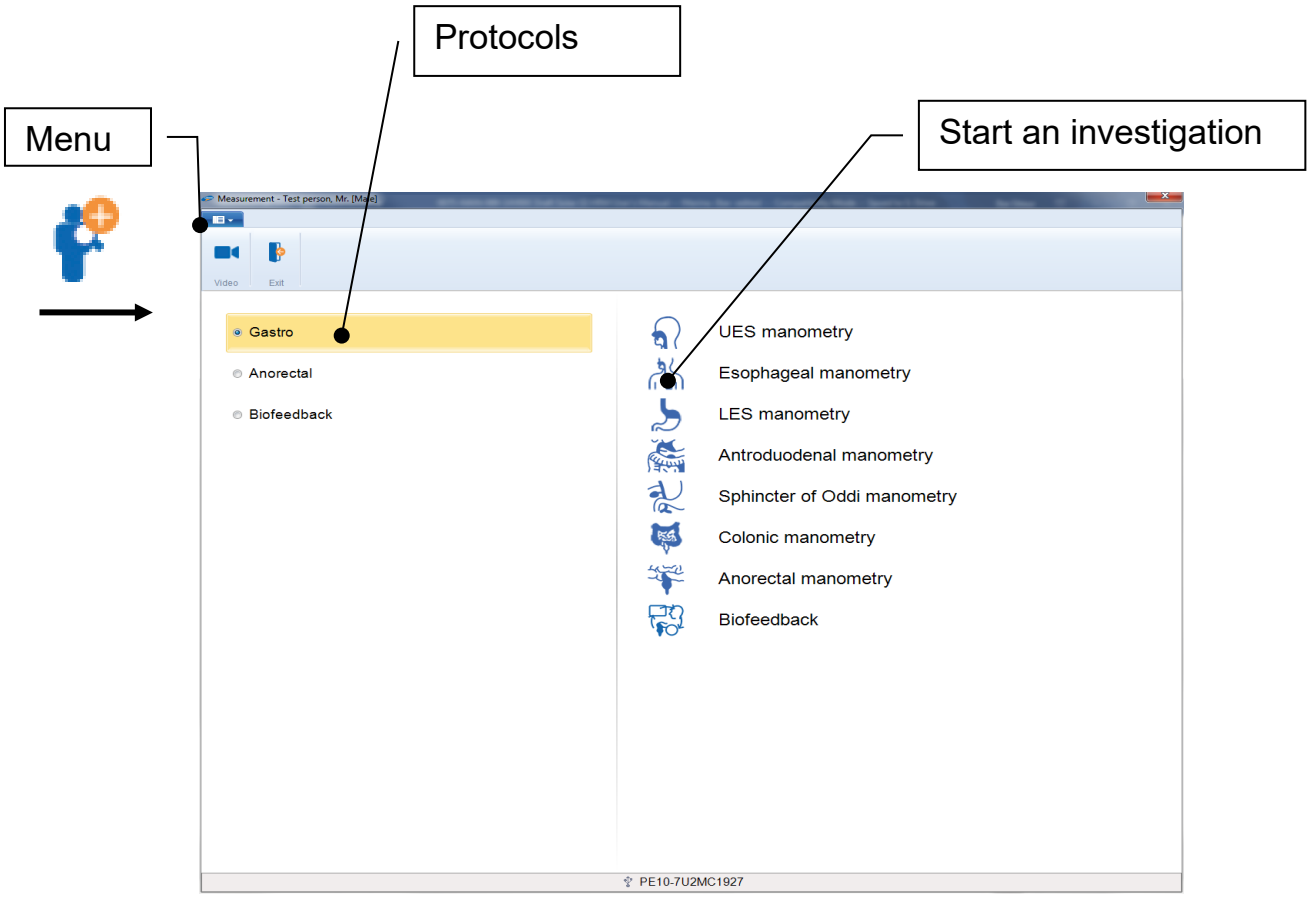


Figure 11.1 Measurement program

The measurement window displays all investigation protocols which can be selected. More information about the settings in investigation protocols can be found in § 10.5. You can change the order of the protocols by clicking and dragging the protocol name up / down. The investigations which can be selected are displayed on the right.

With the **Exit** button on the tool bar you can leave the measurement program and return to the database program. The video tool button is displayed if applicable.

11.2 Main Menu

The main menu can be activated by clicking on the menu button.

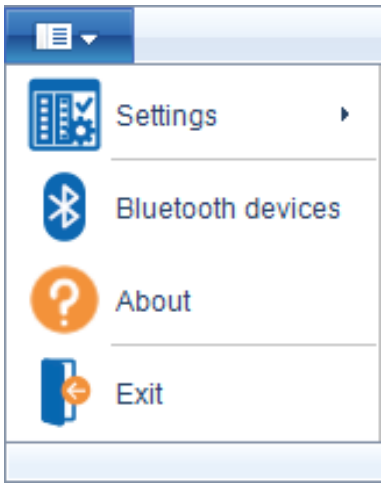


Figure 11.2 Main menu

Menu item	Function
	Settings A description of the menu items can be found in § 11.4.
	Bluetooth devices Register Bluetooth modules while installing the system. See the Solar GI Service & Installation Manual for the registration procedure.
	About View the about box with information about the software.
	Exit Exit the software program.

11.3 Investigation

Select the appropriate investigation protocol and click on the investigation name to start the pre-test of the selected investigation.

In this paragraph, you will find general information about the investigation procedures. Specific information can be found in the corresponding chapters in this manual.

11.3.1 Pre-Test

When an investigation is selected from the measurement program, the pre-test starts. The pre-test differs from the actual investigation in that data will not be stored and markers cannot be placed. In general, the pre-test is a final check and preparation before the actual investigation. The preparations depend on the investigation type and the type of catheters being used.

11.3.2 Start Measurement

In the pre-test, click the **Start investigation** button, or press the corresponding key on the remote control, to start the actual measurement. The measured values will be shown real-time in curves on the screen.

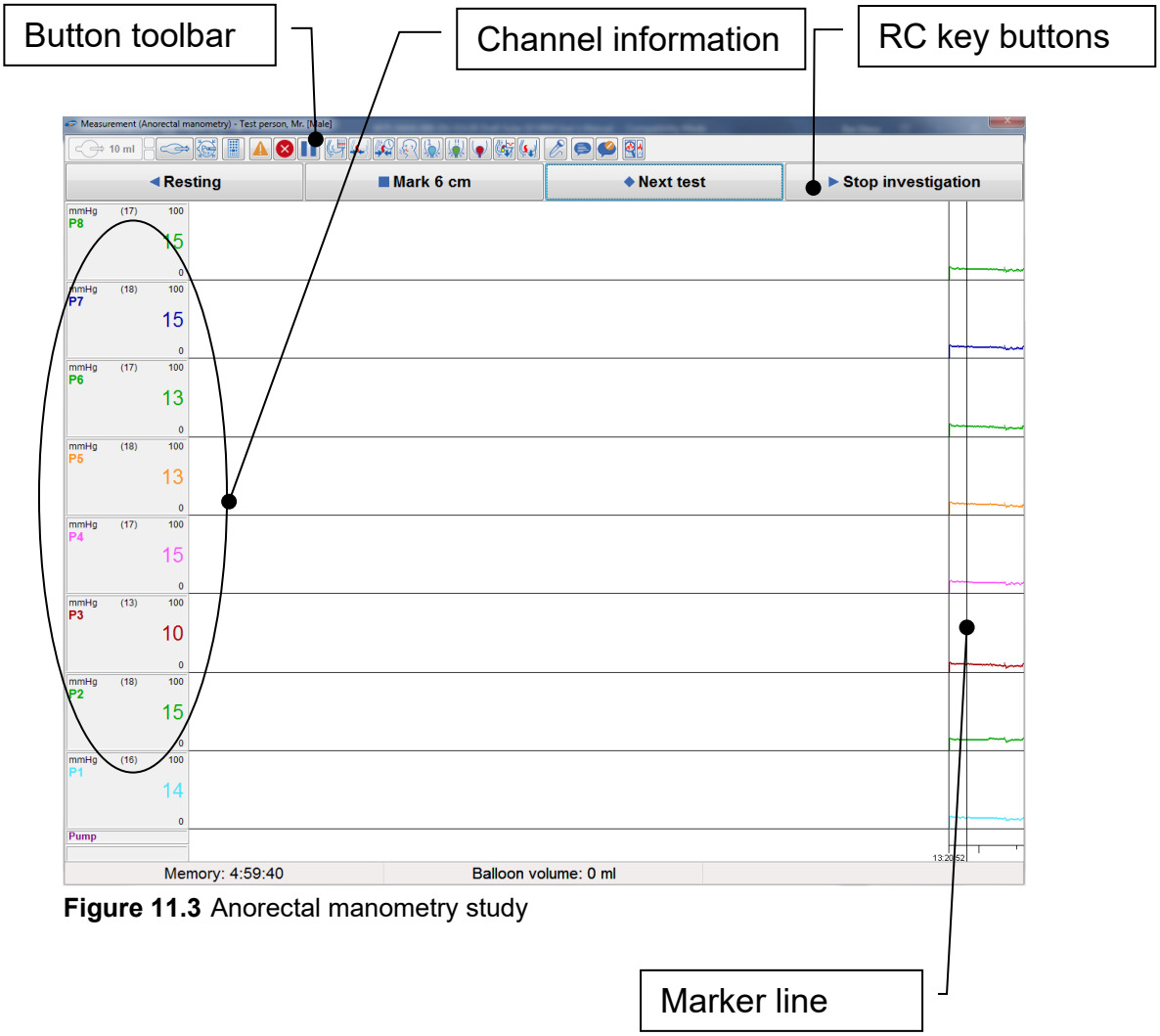


Figure 11.3 Anorectal manometry study

The name of the patient and the investigation name are shown at the top of the screen. The functions of the buttons (keys on the remote control) are indicated on the software buttons. Clicking the button will have the same effect as pressing the corresponding button on the remote control.

The main part of the screen shows the plot windows for the selected channels. Your screen may look different caused by different protocol settings or system settings. The name of each channel and the scale of the plot window is shown next to the plot window. For all channels the numerical value is shown real-time during measurement. The names of the channels are shown in the same color as the corresponding curve. This way different channels are easily identified if more curves are shown in the same plot window.

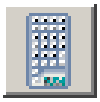
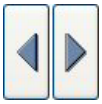
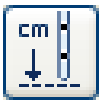
During an investigation, the status bar is displayed at the bottom of the screen. The status bar can display the following information:

- Memory: Computer memory available to store an investigation.
- Pull step: The distance over which the catheter is withdrawn each time.

11.3.3 Button toolbar

Depending on the investigation one or more of the following buttons may be available.

Buttons	Description
	Place a balloon marker and inflate balloon with Solar perfusion pump.
	Deflate balloon with Solar perfusion pump.
	Fill water container (Perfusion pump only). Release the pressure to refill the water container of the perfusion pump.
	Set perfusion pressure (Perfusion pump only). Change the pressure of the Perfusion pump.
	Place a balloon marker and inflate the balloon with syringe. By clicking on one of the arrows you can increase or decrease the inflation volume.
	Show Bluetooth quality info
	Activate/deactivate alternative menu. Change the text on the measurement buttons (e.g. change to zero all pressures or to the catheter insertion depth during the esophageal manometry investigation).

Buttons	Description
	Activate/deactivate virtual remote control.
	Insert an event marker. It is also possible to add comment for the marker.
	Insert an artefact marker (delayed marker).
	Activate the pause mode.
	Start and stop the catheter puller (wireless) during pretest and investigation.
	Move the catheter puller and the puller clamp in the direction of the patient.
	Change the insertion depth of the catheter.
	Increase insertion depth of the catheter.
	Decrease insertion depth of the catheter.
	Resting pressure marker. Insert a resting pressure marker (this in an immediate marker).
	Squeeze marker. Insert a squeeze start marker (this is an immediate marker).
	Endurance squeeze marker. Insert an endurance squeeze start marker (this is an immediate marker).
	Cough marker. Insert a cough start marker (this is an immediate marker).
	Push marker. Insert a push start marker (this is an immediate marker).

Buttons	Description
	RAIR marker. Insert a start RAIR marker (this is a delayed marker).
	No sensation marker. Insert a no sensation marker (this is an immediate marker).
	First sensation marker. Insert a first sensation marker (this is an immediate marker).
	First urge marker. Insert a first urge marker (this is an immediate marker).
	Modest urge marker. Insert a modest urge marker (this is an immediate marker).
	Intense urge marker. Insert an intense urge marker (this is an immediate marker).
	Maximum tolerable volume. Insert a maximum tolerable volume marker (this is an immediate marker).
	Pain. Insert a pain marker (this is an immediate marker).
	Balloon expulsion marker. Insert a balloon expulsion start marker (this is an immediate marker).
	Record audio comment. Add spoken comment to the investigation.
	Toggle on-line review mode on/off. The right half of the screen displays the curves and markers of the measured data up to that moment.

11.3.4 Remote Control

The GI manometry investigations on the Solar GI measurement system can be performed by using the RC-1600.

RC-1600

The RC-1600 communicates with the computer via a wireless Bluetooth connection, using a Bluetooth® Smart Long-Range USB dongle (BT-SLR dongle). Pointing is not necessary for the RC-1600. During the investigation, the LED has different functions. See the table further in this paragraph.

Note that the RC-1600 must be registered first in the measurement program before you can work with it (see the Solar GI New Service & Installation manual, Laborie document code: MAN-00046).

Figure 11.4 RC-1600 (orange)

LED information RC-1600

The status LED may show different colors; the indication is as follows.

LED	Indication
Blue blinking	Bluetooth communication remote control.
Green (steady)	NA for GI
Green blinking	NA for GI
Red light up	Bluetooth communication remote control and a key is pressed, but the batteries are almost empty. Replace the batteries.
Off	Remote control is in sleeping mode until a key is pressed. No or empty batteries. Place new batteries in the battery compartment. Bluetooth connection is lost. Check if the Bluetooth® Smart USB long range dongle is missing or broken.

Batteries RC-1600

The remote control, RC-1600 operates with 3 AAA batteries (preferably alkaline). It is recommended to replace batteries every six months to avoid leakage and because there will be no low battery indication.

RC-1600 keys

The RC-1600 contains 32 keys. The functions of the various keys are explained in the table in the next page. The key numbers in the table refer to the numbers on the remote-control diagram.

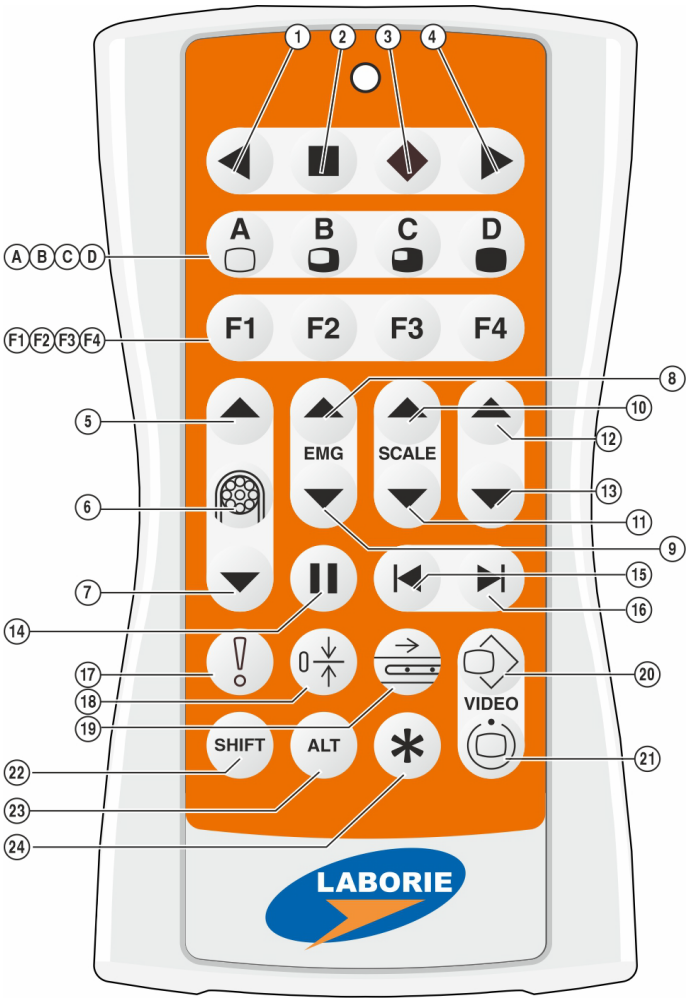


Figure 11.5 RC-1600 diagram

RC-1600 key #	Name	Function	SHIFT function
1	Arrow left	The function of this keys vary throughout the program. The function is indicated by the software	• Next sensation (anorectal sensation test)

RC-1600 key #	Name	Function	SHIFT function
2	Square	The function of this keys vary throughout the program. The function is indicated by the software	• Reload zero values during pretest. • Set puller auto forward (anorectal – relax, (endurance) squeeze, cough and push test) • Next sensation (anorectal - sensation test)
3	Diamond	The function of this keys vary throughout the program. The function is indicated by the software	• Select previous test (anorectal)
4	Arrow right	The function of this keys vary throughout the program. The function is indicated by the software	-
A/B/C/D	Marker A/B/C/D	Place user definable marker A/B/C/D immediate during investigation	Place user definable marker A/B/C/D delayed during investigation
F1..F4	F keys	No function yet	No function yet
5	Pump speed up	Increase pump speed during pre-test and investigation	
6	Pump on/off	Toggle switch to control the pump. The pump status is shown on the **Pump** button in the software.	
7	Pump speed down	Decrease pump speed during pre-test and investigation.	
8	EMG scale up	Increase the sensitivity for EMG channel 1	Increase EMG audio volume
9	EMG down	Decrease the sensitivity for EMG channel 1	Decrease EMG audio volume

RC-1600 key #	Name	Function	SHIFT function
10	Scale up	Increase the sensitivity for the pressure channels.	
11	Scale down	Decrease the sensitivity for the pressure channels	
12	Up	Increase the sensitivity for EMG channel 2	Increment filling (anorectal – expulsion, RAIR and sensation tests)
13	Down	Decrease the sensitivity for EMG channel 2.	Decrement filling (anorectal – expulsion, RAIR and sensation tests)
14	Pause	To activate or de-activate the Pause mode during an investigation	Stop investigation (same as key 4)
15	Previous	• Select previous test (anorectal)	Decrease EMG audio volume
16	Next	• Select next test (anorectal) • Skip squeeze command (biofeedback)	Increase EMG audio volume
17	Event	Place an event marker during the investigation.	Place an audio comment marker during the investigation.
18	Zero all	Zero all channels during pretest. Set balloon marker during investigation (0 ml anorectal)	• Zero infused volume (anorectal)
19	Puller on/off	Toggle switch to control the puller. The puller status is shown on the **Puller** button in the software.	Set puller auto forward
20	Video	Store video (single image, cineloop or loop to disk).	
21	Video	Grab video (cineloop).	
22	SHIFT	Press this key together with another key to	

RC-1600 key #	Name	Function	SHIFT function
		activate the SHIFT function for that key.	
23	ALT	To activate or de-activate ALTernate functions (anorectal)	
24	Asterics	No function yet	No function yet

Zero pressures of separate channels

When you press the **Shift** key on the keyboard during pre-test or investigation, some extra buttons become available which are not available in the software or on the remote control:

Shift + click with Mouse : Zero pressure channel 1

Shift + click with Mouse : Zero pressure channel 2

Shift + click with Mouse : Zero pressure channel 3

Shift + click with Mouse : Zero pressure channel 4

11.3.5 Virtual Remote Control

The virtual remote control is a tool, which is useful when the remote control has depleted batteries, is malfunctioning or when it is lost. The tool ensures that the user can always proceed the investigations.

A tool button is available which controls the display of the virtual remote control during pre-test and measurement. By clicking the keys with the mouse, the keys on the remote control will be activated.

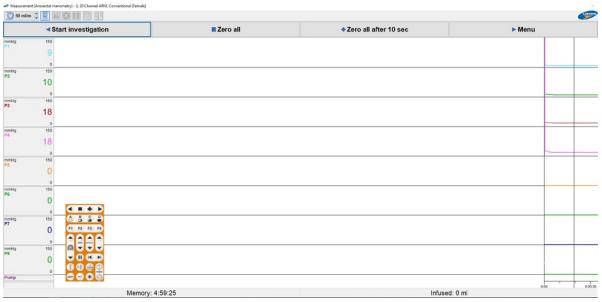


Figure 11.12 Virtual remote control

The position of the remote-control window can be changed during pre-test by dragging the window with the mouse. The position of the remote-control window will be saved and will be default for the next software startup. During measurement, the remote control cannot be moved. By clicking the keys with the mouse, the keys on the remote control will be activated.

11.3.6 Markers

During an investigation, markers can be placed to indicate interesting events or to invoke calculation of parameters. Markers are displayed as colored vertical lines on the screen.

There are two types of markers:

- **Immediate markers** are placed at the plot line. This is the line where the curves start.
- **Delayed markers** are placed at the marker line. This allows some time to consider where the marker should be placed. The marker line is the vertical line in the plot window at a certain distance from the plot line. In the investigation protocol, the marker line distance (time for the curves to reach the marker line) can be set.

Some markers are used for all investigations and other markers are specific to one investigation.

Artifact marker (delayed marker) 

Coughing or movement by the patient can cause an undesired change in the pressures. For that, you can place an *artifact* marker before and after the artefact. The data between the two *artifact* markers will be excluded from the calculations. Artifact markers can be placed with the **Artifact** button on the screen or with the **Artifact** key on the remote control.

In the investigation protocol, you can specify **automatic artifact detection**. The software will then automatically place artefact markers around an artefact. When artifact is active, the **Artifact** button will be down and the curves show red borders.

Event marker 

An event marker marks a point of interest during an investigation and has no influence on parameter calculations. Event markers can be placed with the **Event** button on the screen or with the **Event** key on the remote control. By default, event markers are delayed markers and the option ‘Enter comment at event markers’ is default enabled. Choose **Settings > System settings** to enable ‘Plaats event markers direct’ (see § 11.6).

Audio comment marker (immediate marker) 

When a sound card is present you can add spoken comment to the investigation. This is done by adding an audio comment marker. After the marker has been placed, a bar appears which indicates the recording time. During this time, you can talk in the microphone. During analysis, you can replay the spoken comments. Audio recording can be started by clicking the **Audio comment** button on the screen.

11.3.7 Pause Mode

 During an investigation, you can activate the pause mode by clicking the **Pause** button on the screen. This mode can be used when the patient is repositioned. In the pause mode, the screen keeps scrolling. Data which has passed the marker line is not recorded and is therefore excluded from the calculations. The pause mode can be de-activated by clicking the **Continue** button or the **Pause** button again.

11.3.8 Stop Measurement

Click the **Stop investigation** button to stop the investigation. In the analysis program, you may analyze the results and print the report. When in the investigation protocol the field '*Confirm stop investigation*' is set to '*Yes'*, the investigation is not immediately stopped. You may continue or confirm stop investigation. After performing an investigation, there are two ways to start a new study:

- Review the curves immediately after the investigation. Set the field *Immediate analysis* in the investigation protocol (see § 11.5) to *Always*. A new investigation can be started by selecting the investigation name from the Measurement menu in the analysis screen.
- Skip analysis and select a new investigation from the measurement menu. Set the field *Immediate analysis* in the protocol to *Never*.

11.4 Settings Menu

When you click the main menu button and choose **Settings**, the following menu items are available.

Menu item	**Function**
Edit protocol	Configure the measurement protocol for each study. For more information see § 11.5.

System settings	Configure the measurement program to your wishes. For more information see § 11.6.
Laborie assistant	Configure the assistant to your wishes.

11.5 Investigation Protocol

11.5.1 Edit the Protocol

The investigation protocol can be set in the measurement program. Start the measurement program by clicking the **New investigation** button in the database program.

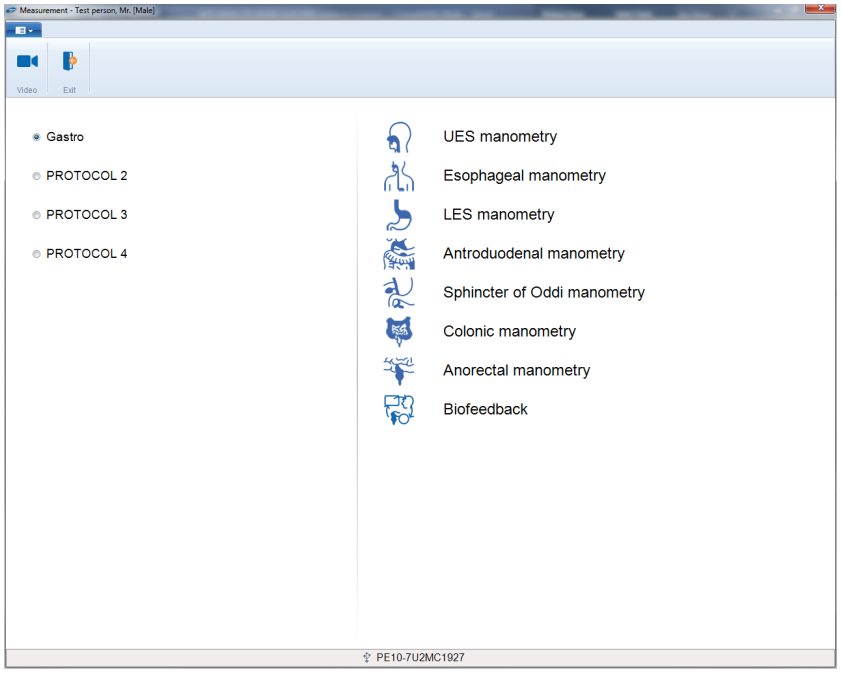


Figure 11.13 Select protocol

When the measurement program is started, the window shows default one investigation protocol. More protocols can be added (see below). The investigation protocol contains different settings. The last used protocol is selected as default. To select another protocol, click the radio button in front of the protocol name. You can also change the order of the protocols by clicking and dragging the name of the protocol up/down. Protocols can be edited, copied, added, or deleted, as described below.

Edit investigation protocol

Click with the right mouse button on the protocol name and choose Edit protocol (or choose **Settings > Edit protocol** from the main menu and select the protocol you want to edit).

Add investigation protocol

An unlimited amount of protocols is available. Click with the right mouse button on the protocol name and choose **Add protocol** (or choose **Settings > Add investigation protocol** from the main menu). A new protocol with all investigations will be created. The new protocol will contain the default values.

Copy investigation protocol

An entire protocol with all settings can be copied. Click with the right mouse button on the protocol name and choose Copy protocol (or, if you are in the protocol, use the Copy all button).

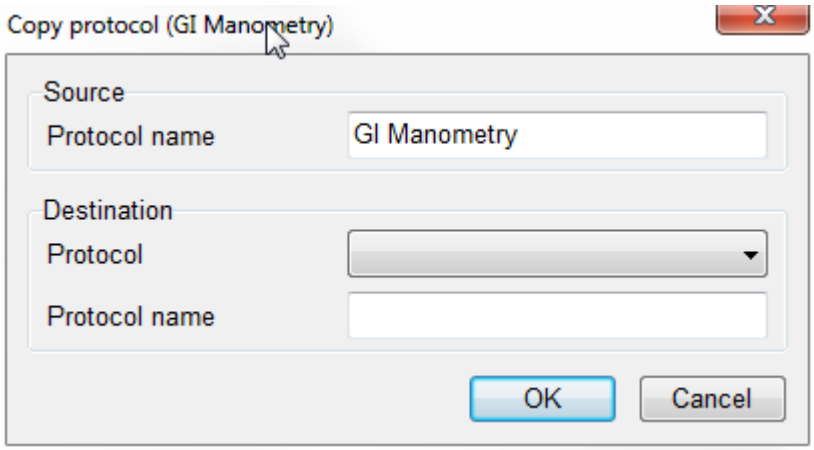


Figure 11.14 Copy protocol

Via the drop-down menu you need to choose the destination for the copied protocol. In the field ‘Protocol name’ you can enter a name for the copied protocol.

Delete investigation protocol

Click with the right mouse button on the protocol name and choose **Delete protocol** (or choose **Settings > Delete investigation protocol** from the main menu and select the protocol you want to delete). The protocol file will be deleted.

11.5.2 Include/Exclude Investigations for Protocol

When you choose to edit a protocol, the ‘Edit investigation protocol’ window is displayed, with the Select Tab on top.

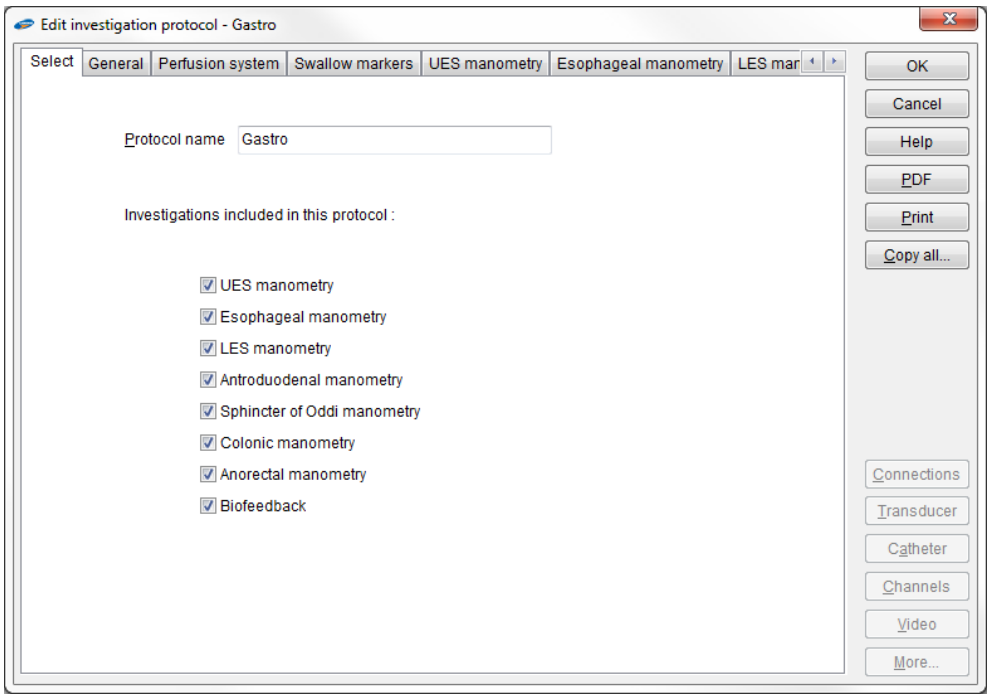


Figure 11.15 Select investigations for protocol

On the Select Tab you can exclude investigations from the current protocol (or include them if they were excluded). This can be done by clicking the check box in front of the investigation type. When an investigation is excluded, the corresponding Tab with investigation specific settings will be invisible.

Protocol name

Here you can enter the name of the protocol.

11.5.3 General Protocol Settings

Click the TAB **General** to display the general protocol settings.

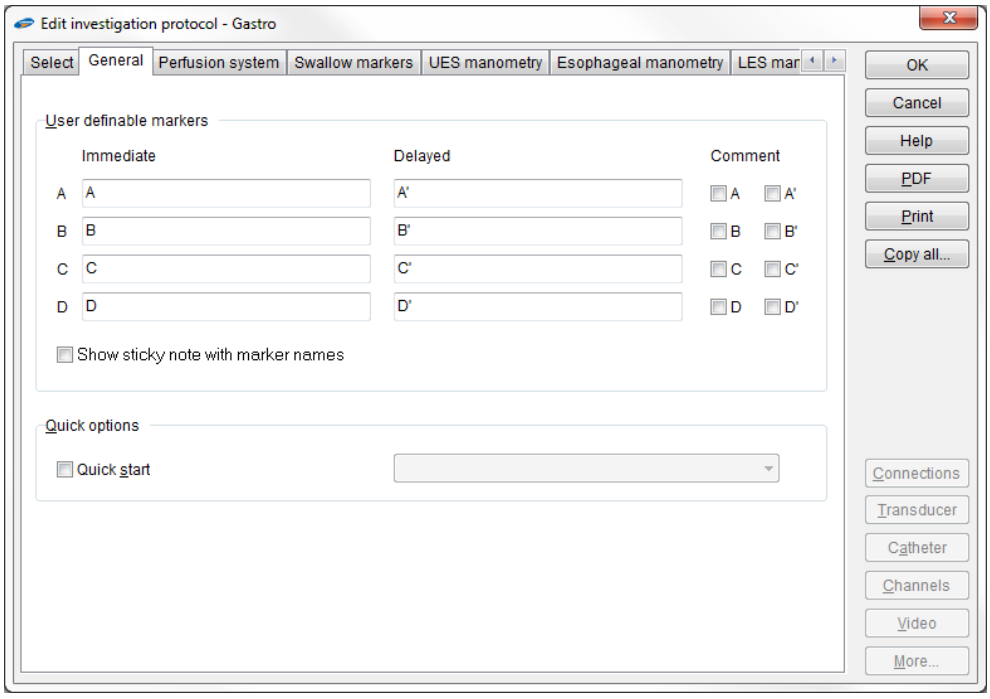


Figure 11.16 Edit investigation protocol

User definable markers

On the ‘General’ page you can change the names of the user definable markers. Immediate markers (A, B, C, D) are placed by pressing **A**, **B**, **C** or **D** on the keyboard or the remote control. Delayed markers (A’, B’, C’, D’) are placed by pressing the **SHIFT** key simultaneously with the keys **A**, **B**, **C** or **D**. More information about the use of immediate or delayed markers can be found in § 11.3.6.

Show sticky note

Will show the user definable markers as a sticky note on the screen during a measurement.

Quick options

Quick start allows immediate start of an investigation when the measurement program is started. In the quick options select **Quick start** and select the investigation to be started from the drop-down list.

11.5.4 Swallow Markers

During the esophageal investigation, the patient will need to swallow. Often the patient will swallow different boluses to investigate the influence on the motility. During the investigation, these swallows can be marked with swallow markers.

In the investigation protocol, you can enter up to four different swallow markers. During the investigation, these swallow markers can be placed by clicking on the appropriate softkey. To select a defined swallow marker during the investigation, press the **Up**/**Down** keys on the remote control.
Select the ‘Swallow timer’ checkbox to enable the Swallow timer and to set the duration of that timer. During the esophageal manometry study, a progress bar will appear on the screen as soon as a swallow marker is placed. When the time is elapsed, the progress bar will disappear.

11.5.5 Investigation Specific Settings

To change the settings which are specific for an investigation, click on the TAB with the name of the investigation.

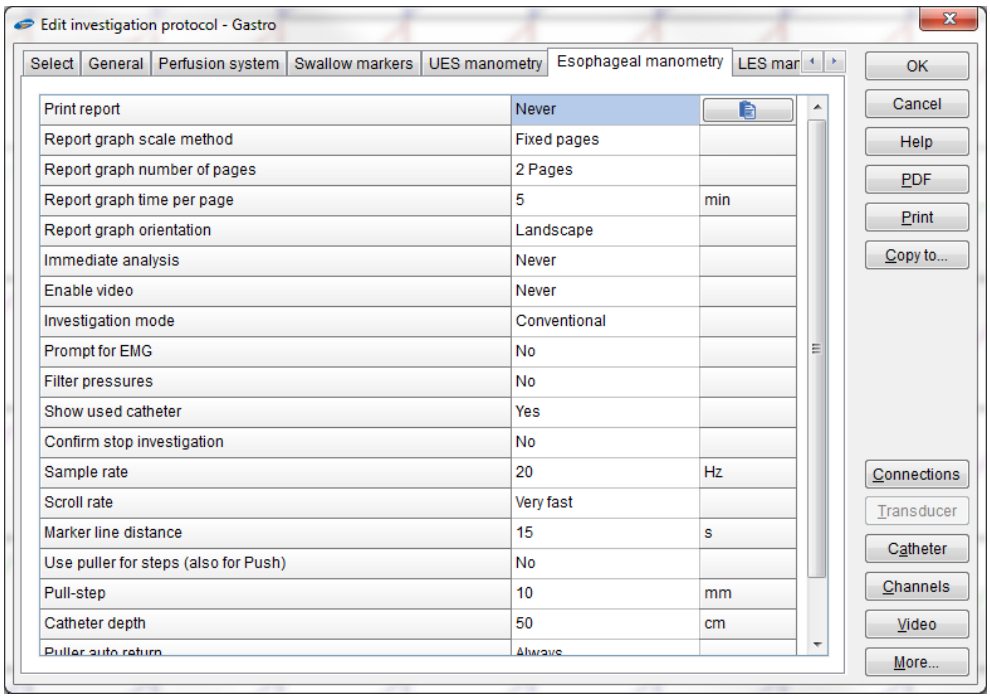


Figure 11.17 Edit investigation protocol, Esophageal manometry TAB

A page is shown with settings, regarding settings for printing the report, storage on disk, initial puller speed, catheter depth, sample rate, marker line distance, etcetera.
Some settings are:

- Print report,
- Settings for the graph automatically generated at the end of the investigation:
    - Report graph scale method,
    - Report graph number of pages,
    - Report graph time per page,
    - Report graph orientation.

Create report immediately after the investigation

When the setting Print report is set to ‘always’ or ‘optional’, the report can be created immediately after the investigation, using the report configuration which is selected in the protocol. To select the configuration, click the **Reporter** button behind ‘Print report’ or behind ‘Save report to PDF’. In the dialog window, you can also edit the printer settings / PDF settings for the report. The selected report configuration will be saved per protocol, per investigation type. The printer and PDF settings will be saved globally for all protocols, but only for the reports which will be created after the measurement. More information about the reporter program can be found in the separate Reporter manual in PDF format, which can be opened via the **Manuals** menu in the database program.

Channels and connections

In the protocol, you must set the channels for each investigation (e.g. EMG, swallow, respiration) to be measured and the connections for each channel. Use the buttons **Channels** and **Connections** to set this information. For more information see § 11.5.7 and § 11.5.8.

Click the **Transducer** button to choose the transducers used during the investigation. In most cases just select standard pressure transducers. Only change this setting when using user-calibrated transducers.
Click the **More** button to set the CIM-AUX settings (Show connector configuration or use pH on Impedance channel).

11.5.6 Select Catheter

Click on the button **Catheter** to display the following dialog window.

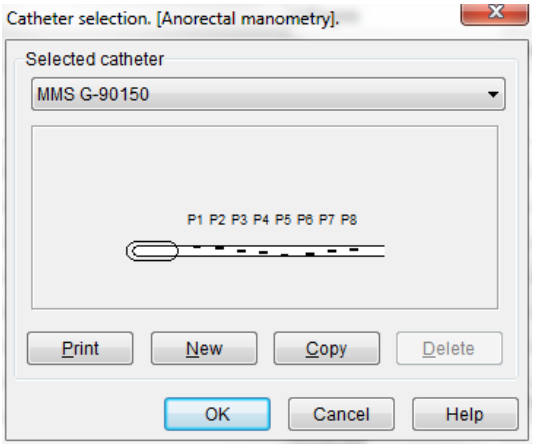


Figure 11.18 Select catheter

Select the type of catheter you are going to use for the selected protocol. You can choose one of the pre-defined catheters by Laborie.

It is also possible to define a catheter yourself.

NOTE

A catheter definition defines exactly what a catheter looks like. The information in the catheter definition:

- instructs the Solar which channels should be measured.
- contains the information of the transducers connected to the channels.
- is used to display the channels correctly.
- may be needed for some calculations.
- is needed for vector volume plots.

Define your own catheter

To define your own catheter, you can select one of the pre-defined catheters and change the sensor positions. The following example explains how to add one pH channel to your catheter definition.

- Select an investigation tab, for example Esophageal manometry.
- Click the **Catheter** button to display the window Catheter selection.
- Select the catheter from the list.
- Click the **Copy** button to display the window Copy catheter.
- Enter a name for the catheter and click **OK**.

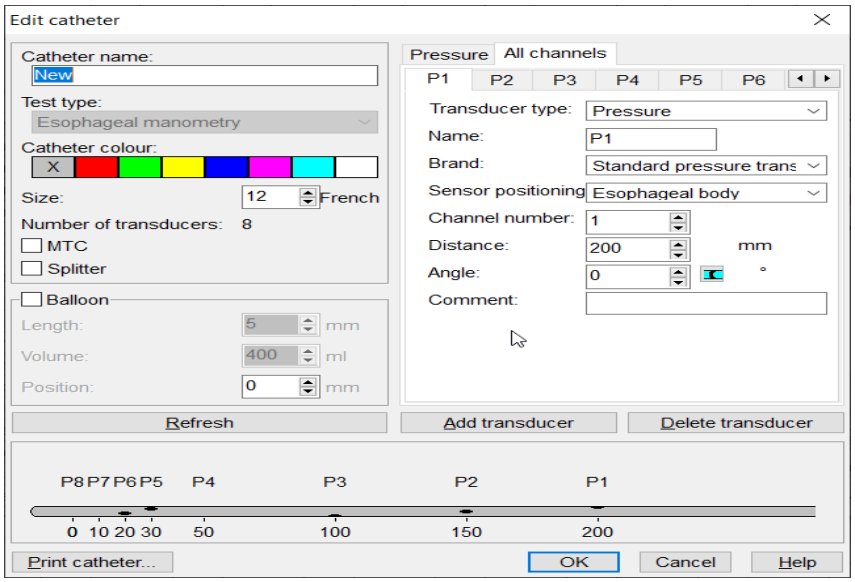


Figure 11.19 Edit catheter

- Click the **Add transducer** button.
- Enter the name of the transducer, e.g. pH.
- Enter the transducer type pH.
- Click **OK**. The window Catheter selection is displayed.
- Click **OK**. The catheter is selected and the window Edit investigation protocol is displayed.
- Click the **Channels** button to display window Channels settings.
- Select the pH channel and enter the position.
- Click **OK** to save the settings.

11.5.7 Channel Settings

Click on the button **Channels** to display the following dialog window.

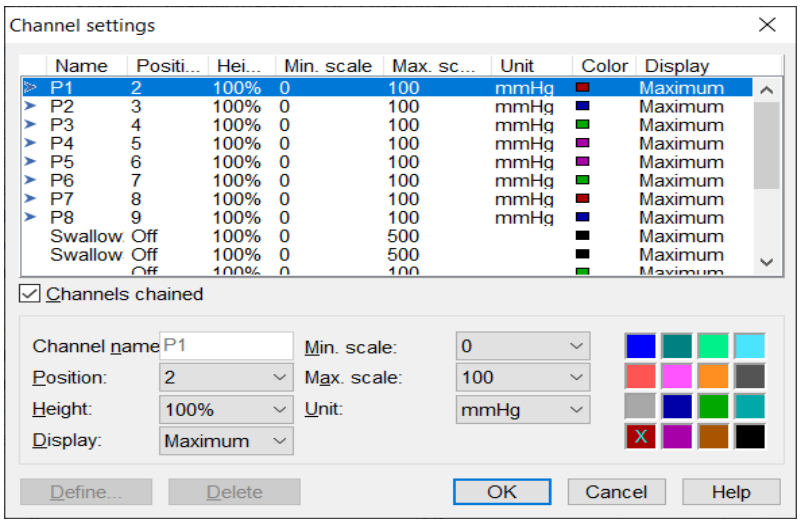


Figure 11.20 Channel settings

The ‘channel settings’ window shows an overview of all available channels.

For each investigation, you can set:

- the channels to be measured (e.g. swallow/respiration)
- the layout of these channels (for example color, position, scale).

Put the cursor on the channel you want to change. In the lower part of the window you can now change the settings of the selected channel.

11.5.8 Connections Solar

For each investigation, you can set the channel numbers for the channels (signal) to be measured with the Solar GI measurement system. Select the investigation TAB in the ‘protocol settings’ window and click the **Connections** button set the connections for that investigation. The following window will be displayed:

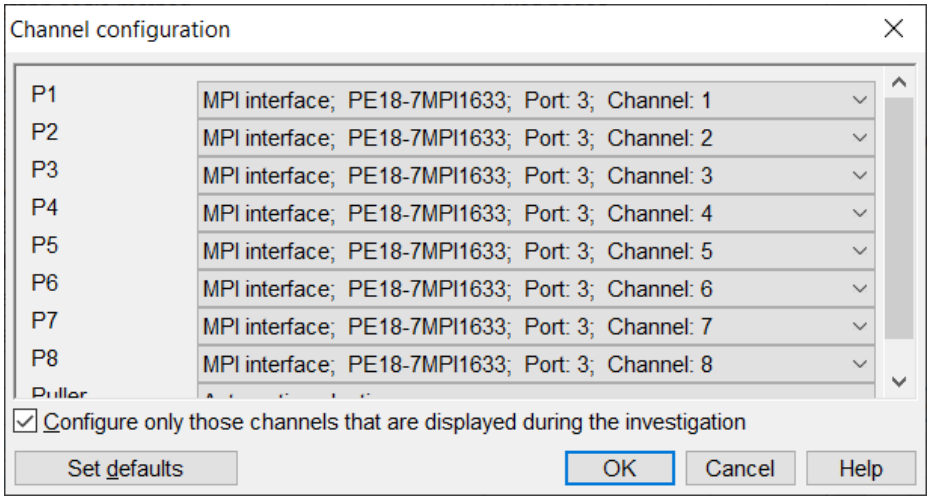


Figure 11.21 Connections Solar, Channel configuration

In the left column, you will see the channels which have been selected via the **Channels** button (see § 11.5.7). For each channel (signal) to be measured, you must select the channel number.

11.6 System Settings

Choose **Settings > System settings** from the main menu to display the following dialog window.

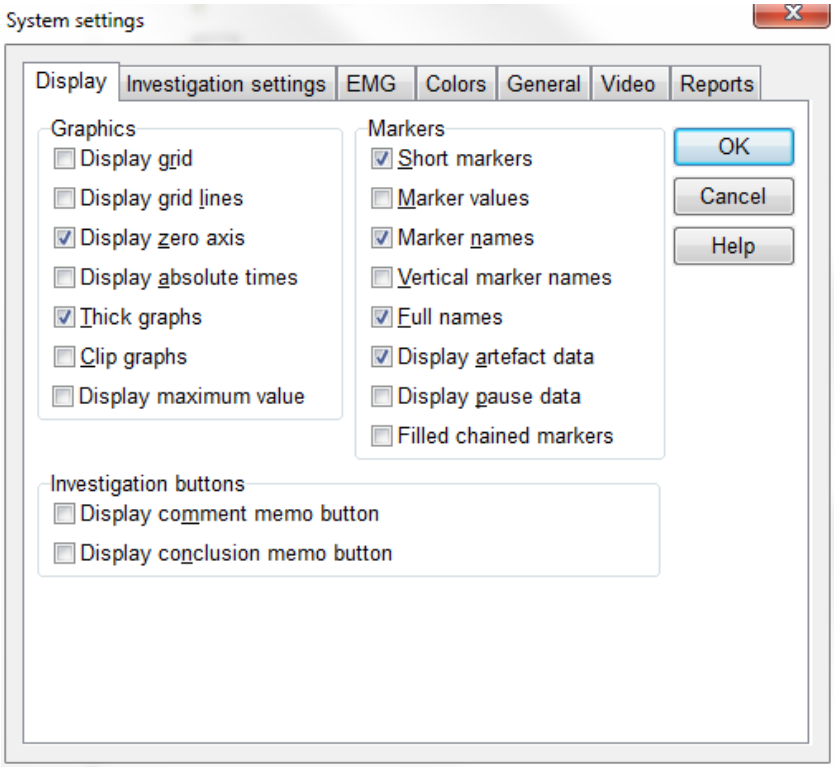


Figure 11.22 System settings measurement program

You can select some pages with settings by clicking the appropriate TAB.

The settings are described below.

Display

Specific settings for graphs and markers, for example how to display a grid and to show the markers as full names. If you select ‘Vertical marker names’, marker names will be displayed vertically instead of horizontally, which prevents marker names from overlapping. If you select ‘filled chained markers’, chained markers like begin- and end-markers for resting pressure, will be displayed with a colored background from begin- to end-marker.

If you select ‘Display maximum value’, the maximum measured value will be displayed during the investigation. All displayed maximum values can be reset to the actual value during the investigation by clicking on the maximum value.

You can also enable the memo functionality. The investigation memo and conclusion buttons will be added to the toolbar so comment can be entered during the investigation.

Investigation settings

You can save investigation data at certain intervals during the investigation to secure the data. Select the **Auto save** check box and enter during which interval the measurement data must be saved. You can also set the scroll mode and the position of the channel information.

The position of the channel information (default at the right side of the screen) can be changed.

Under ‘Options’ the options for your measurement system are enabled. More information can be found in the Solar GI Service & Installation manual.

EMG

You can set the display for the EMG graphics. Also, settings for signal processing are available. You can choose ‘Slow average’ (default), ‘Fast average’ or ‘Peak amplitude’ (in case you want the fastest response of the EMG channel without a filter).

High speed EMG settings

In case ‘High speed EMG’ is enabled, a separate window will be displayed on top of the main measurement screen during the pretest and the investigation. The window can be resized or moved (to a second monitor) during the pre-test. You can also set the time base (tracing clip out time) for the high-speed EMG window during the investigation, and (de) select ‘Save high speed EMG’ (deselecting saves hard disk space).

Colors

You can change the colors of the various items displayed on the screen: artefact, background, baselines, cursor, grid, et cetera. Select the object and click on the new color. You can also define a set of graph colors. These colors will be selectable in the channel settings. When you have defined all colors, save the colors in a color scheme. You can define more than one color scheme, so you can quickly change colors. Click the button **Markers** to change the colors of the available markers.

General

You can set some general settings, for example if hints are shown when the mouse cursor is moved over a button. In case ‘High speed EMG’ is enabled (only for anorectal manometry or biofeedback), a separate window will be displayed on top of the main measurement screen during the pretest and the

investigation. The window can be resized or moved (two a second monitor) during the pre-test. You can also set the time base (tracing clip out time) for the high speed EMG window during the investigation, and (de) select ‘Save high speed EMG’ to save hard disk space.

Video

You can set video settings as the video input signal. See for more information the Video User’s Manual.

Reports

You can set some report settings: thick graphs, tracing clip-out time, or video image.

12. Analysis Program

12.1 Introduction

In this chapter, you will find a description of the menu items and settings in the analysis program. For a detailed overview see the help information.

Double-click on the investigation name in the database program to start the analysis program.

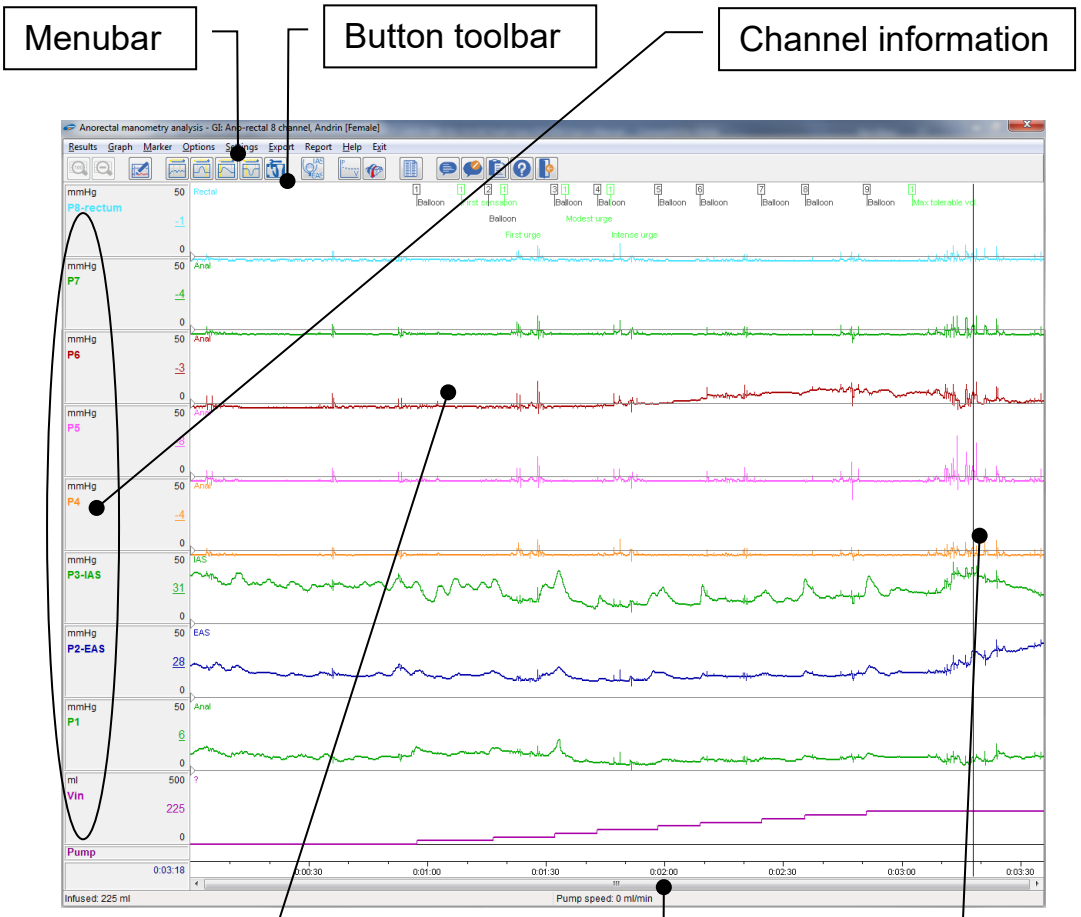


Figure 12.1 Analysis program

In the screen, a vertical line is shown. This **cursor line** can be moved through the graphs by moving the mouse. In the left column, you will see the channel name (e.g. P, EMG), the channel value which is related to the position of the cursor, the unit (e.g. cmH_2O) and minimum/maximum scale. The scale, the unit and the channel name/color can be changed by clicking on the corresponding name or number.

Below you can find a pressure unit conversion table.

Pressure unit	Conversion
1 mmHg	0,13 kPa 1,36 cmH_2O 0,54 $inchH_2O$
1 cmH_2O	0,10 kPa 0,74 mmHg 0,39 $inchH_2O$
1 kPa	10,20 cmH_2O 4,01 $inchH_2O$ 7,50 mmHg
1 $inchH_2O$	1,87 mmHg 0,25 kPa 2,53 cmH_2O

By using the mouse cursor, you can zoom in to show details. The scrollbar indicates the part of the graph which is shown on the screen. To see other parts of the graph, drag the scrollbar left or right or use the **Page Up / Down** keys on your keyboard.

(Auto) scroll
Scrolling is possible with a horizontal scrollbar and with the scroll wheel of the mouse. Auto scroll is possible by right-clicking with the mouse on the graphs (when not fully zoomed out at 100%), and choosing **Play** or **Loop**. You can speed up or slow down by using the arrow keys on your keyboard (up or down). With the escape key the auto replay will be stopped.

Toolbar
The buttons on the toolbar can be configured. Click with the right mouse button on the toolbar and choose **Configure**. How to place, move and delete buttons is described in § 12.8.

12.2 Results

12.2.1 Menu Overview

The following menu items are available.

Menu item	Function
Display results	Display the results of the selected investigation. See § 12.2.2 for more information.

Edit investigation parameters	Edit investigation parameters, for example patient weight and name of the investigator. See § 12.2.3 for more information.
Investigation info	Display information of the selected patient investigation, for example patient (demographic) information, investigation information and channel information.
Investigation memo	Open a memo-editor. The physician who performed the investigation can write down important facts about the procedure. This memo can be included in the report.
Investigation conclusion	Open a memo-editor. The physician who analyzed the investigation can write down comments concerning the conclusion. This memo can be included in the report.
Questionnaire (optionally)	Select and fill in a questionnaire which can be included in the report.

Investigation memo/conclusion
More information about the investigation memo/conclusion can be found in the separate Reporter manual in PDF format, which can be opened via the **Manuals** menu in the database program.

Templates
Templates can be defined and loaded in the investigation memo/conclusion to make standard letters, eg. For referring doctors. In these templates patient information and investigation parameters can be replaced automatically. Memo-templates are described in a separate Database manual in PDF format, which can be opened via the **Manuals** menu in the database program.

12.2.2 Display Results

Choose **Results > Display results** from the menu or click the **Results** button to display the following dialog window. You can also press the **F2** button on your keyboard.

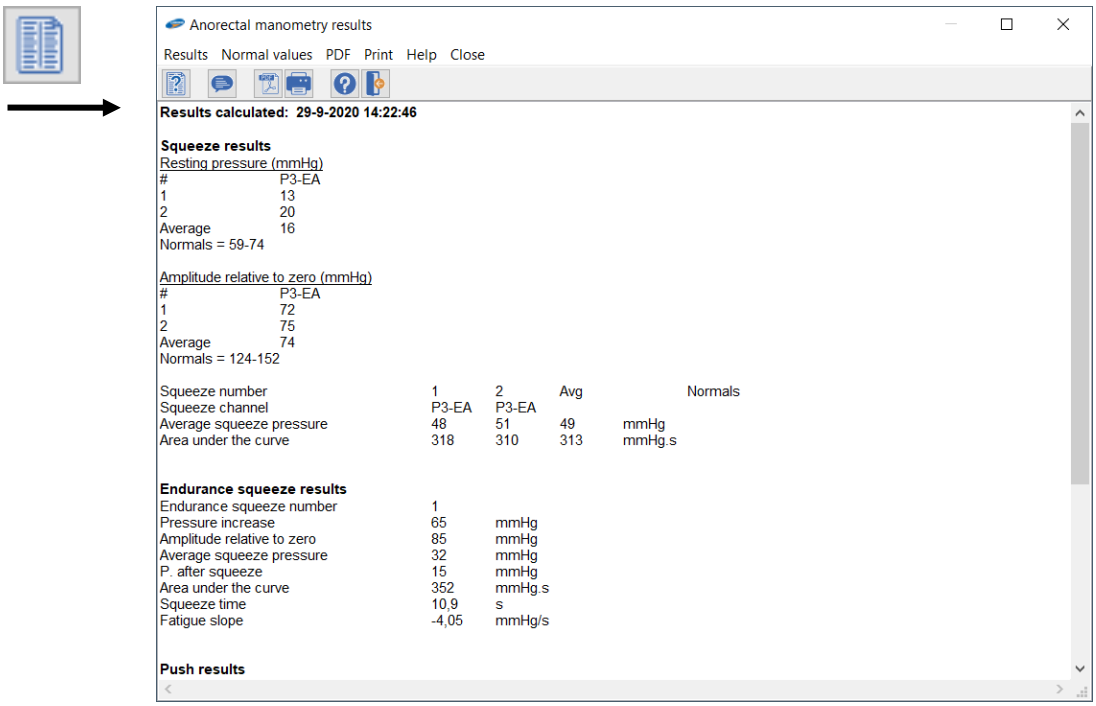


Figure 12.2 Results anorectal manometry study

Various parameters are available and can be printed in the investigation report. Note that the selection of results for the report must be done in the Reporter program. More information can be found in the separate Reporter manual in PDF format, which can be opened via the **Manuals** menu in the database program.

In this paragraph, you will find general information about results.


Click **Select results** to enable or disable parameters.


Click **Investigation memo** to add comment to the investigation.


Click **Save to PDF** to save the results as PDF file.


Click **Print** to print the selected results only.


Click **Help** to show an explanation of the investigation parameters.


Click **Close window** to return to the analysis program.

12.2.3 Edit Investigation Parameters

Choose **Results > Edit investigation parameters** from the menu to adapt the parameters Weight, Length, Complaints and/or Investigator.
These parameters can be included in the header of the investigation report.
More information about the reporter program can be found in the separate Reporter manual in PDF format, which can be opened via the **Manuals** menu in the database program.

12.3 Graph

12.3.1 Menu Overview

The following menu items are available.

Menu item	Function
100%	Display the complete investigation on the screen. See § 12.3.2 for more information.
Zoom out	Restore the previous displayed screen. See § 12.3.2 for more information.
Zoom in	Zoom in on the area around the cursor. See § 12.3.2 for more information.
Copy	Copy the currently displayed graph to the clipboard. This graph can be pasted in another program like Paint or Powerpoint.
Save as	Save the currently displayed graph in a Windows Bitmap (BMP) or JPEG file. More information about the JPG export function can be found in the separate Reporter manual in PDF format, which can be opened via the **Manuals** menu in the database program.

12.3.2 Zoom Function

Interesting parts of the investigation can be viewed in more detail with help of the zoom function. To zoom in on a certain interesting area:

- Move the cursor to the left side of the area.

- Press the left mouse button and move the cursor to the right side of the area, while you keep the left mouse button pressed. A rectangle will now be drawn around the area to be zoomed in.
- When the left mouse button is released, the investigation will be zoomed in. Repeat this until the interesting area is on your screen.

Zoom buttons

With these buttons, you can zoom in, zoom in on sample base, zoom out and zoom to 100% screen. You can also select the zoom functions via the **100% screen** software button and the keyboard buttons **F4** (zoom 100%), **F5** (zoom out) and **F6** (zoom in).

Other fixed zoom intervals

Zoom 4 minutes, 15 minutes, 1 hour and 4 hours.

12.4 Marker

12.4.1 Menu Overview

The following menu items are available.

Menu item	Function
Insert marker	Select and insert a marker in the investigation graphs. See § 12.4.2 for more information.
Lock markers	Prevent accidentally moving of markers.
Reference cursor	Insert a reference marker. See § 12.4.4 for more information.
Marker overview	Display an overview of all present markers in the investigation.

12.4.2 Insert Markers

During an investigation, different events can be marked, for example the sensations. These markers can be selected, moved or deleted in the analysis program. In this paragraph, you will find an explanation of these procedures and an overview of some important markers which can be placed in the analysis program.

To select a marker:

- Press the **Insert** key on your keyboard, or
- Choose **Marker > Insert marker** from the menu, or
- Click the right mouse button and choose **Insert marker** from the pop-up menu.

A list appears with all available markers. Select a marker and click **OK**, the cursor is changed into a pencil. Move the cursor to the place where the marker should be inserted, and click with the left mouse button to place the marker. When the marker is part of a chained marker, the next marker in the chain can now be placed by repeating this process.

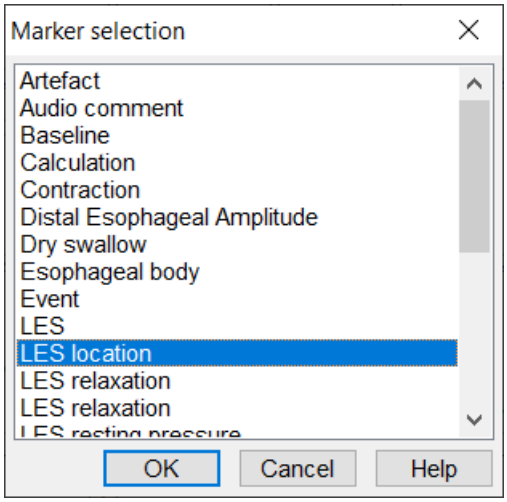


Figure 12.3 Insert marker

Marker hints

When the mouse is moved over the marker label, a hint is shown with marker information. This information contains full marker name and parameters calculated at the marker.

Delete markers

Click with the right mouse button on the marker label to display the marker pop-up menu. With this menu, you can delete the selected marker or delete all markers of the same type as the selected marker.

Moving markers

To move a marker:

- Place the cursor in the marker label and press the left mouse button.
- Keep the left mouse button pressed, move the mouse.
- Release the mouse button on the correct position.

Change the colors of the markers

There are two ways to change the color: (1) Move the mouse cursor to the top of the marker, press the right mouse button and choose **Color**, or (2) via the

system settings (§ 11.6 and 12.5.3). Changes are saved for all existing and all new investigations.

Adding comment to a marker

Move the mouse cursor to the top of the marker and press the right mouse button. Choose **Comment** from the pop-up menu.

Description of markers

In the following table, you will find a description of some markers. For a complete overview of the markers see the help information in the analysis program.

Marker name	Description
Artifact	This marker excludes data from the calculations. For example, coughing by the patient can cause an undesired change in the pressures. Artifact markers can be placed automatically (see the protocol settings) or afterward in the Analysis module.
Calculation marker	These markers are used to calculate several parameters. The calculation markers are placed in chains of two markers. The marker is inserted at the channels you select. The software will calculate for each channel marker chain: duration, minimum, average, maximum, AUC (Area Under Curve), ABS(AUC) (Absolute value of AUC), begin channel value, end channel value, delta value. For anorectal manometry studies (in case filling of balloon has been done with pump), the following values are also displayed: ▪ Infused volume (at begin channel and end channel) and ▪ the infused volume delta value. In case a puller is used for anorectal manometry studies, the puller distance (at begin and end channel) and the delta puller distance are displayed. Point the mouse on the channel marker to see the results of the calculation.
Event	This marker marks a point of interest. After inserting the marker, click with the right mouse on the marker square and choose **Comment** to add comment to the marker.

Marker name	Description
Tracing clip-out	Mark interesting parts of the investigation curves that must be included in the report.
Value marker	With this marker, numerical values of the channels are displayed at the marker position.

12.4.3 Lock Markers

Locking markers may be useful during zooming in on an investigation, because it prevents accidentally moving markers. To lock markers, choose **Marker > Lock marker** from the menu, or click with the right mouse button and select **Lock markers**.

12.4.4 Reference Cursor

A reference cursor is used to display the difference between the measured values at the position of the reference cursor and the 'normal' cursor. After setting a reference cursor, the values displayed for each channel are marked with a delta symbol to indicate that they are calculated relative to the values at the reference cursor. When the reference cursor is active, you will see a checkmark in front of this menu option.

You can place the reference cursor as follows:

- Move the cursor line to the place where you want to position the reference cursor.
- Click the button  **Reference cursor**, or choose **Marker > Reference cursor** from the menu.

To remove the reference cursor, click the **Reference cursor** button or select **Marker > Reference cursor** from the menu. You can also click the right mouse button on the graphs to de-select **Reference cursor**.

12.5 Settings

12.5.1 Introduction

In this paragraph, you will find information about the general analysis settings. Measurement specific settings can be found in the corresponding chapters in this manual.

12.5.2 Channel Settings

Choose **Settings > Channel settings** from the menu to display the following dialog window.

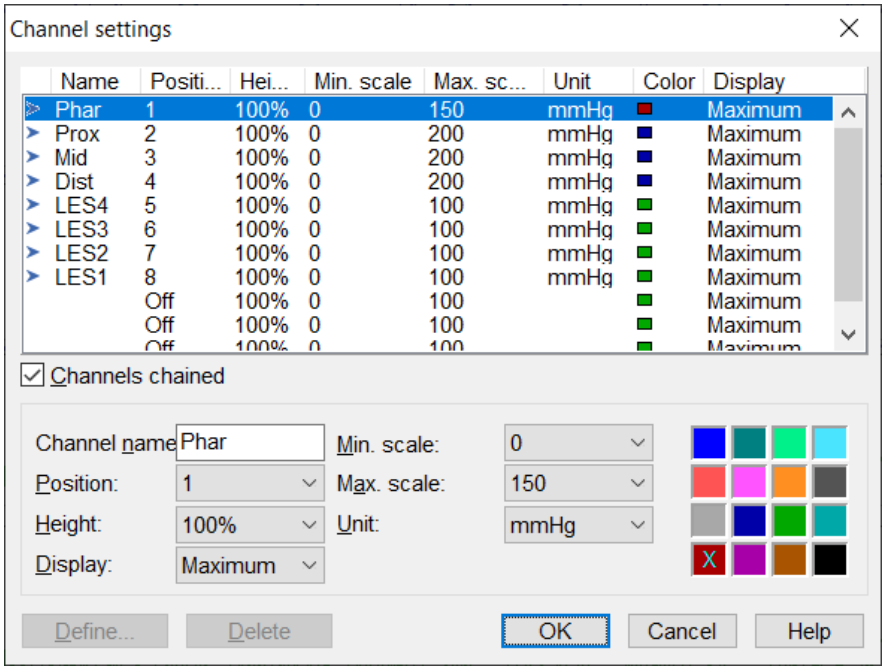


Figure 12.4 Channel settings

The ‘channel settings’ window shows an overview of all available channels.

For the **selected investigation**, you can change:

- the channels to be displayed on the screen, for example swallow, respiration.
- the layout of these channels, for example the position in the graph, the height, the scale and the color of the graph.

Put the cursor on the channel name you want to change. In the lower part of the window you can now change the settings of the selected channel.

12.5.3 System Settings

Choose **Settings > System settings** from the menu to display the following dialog window.

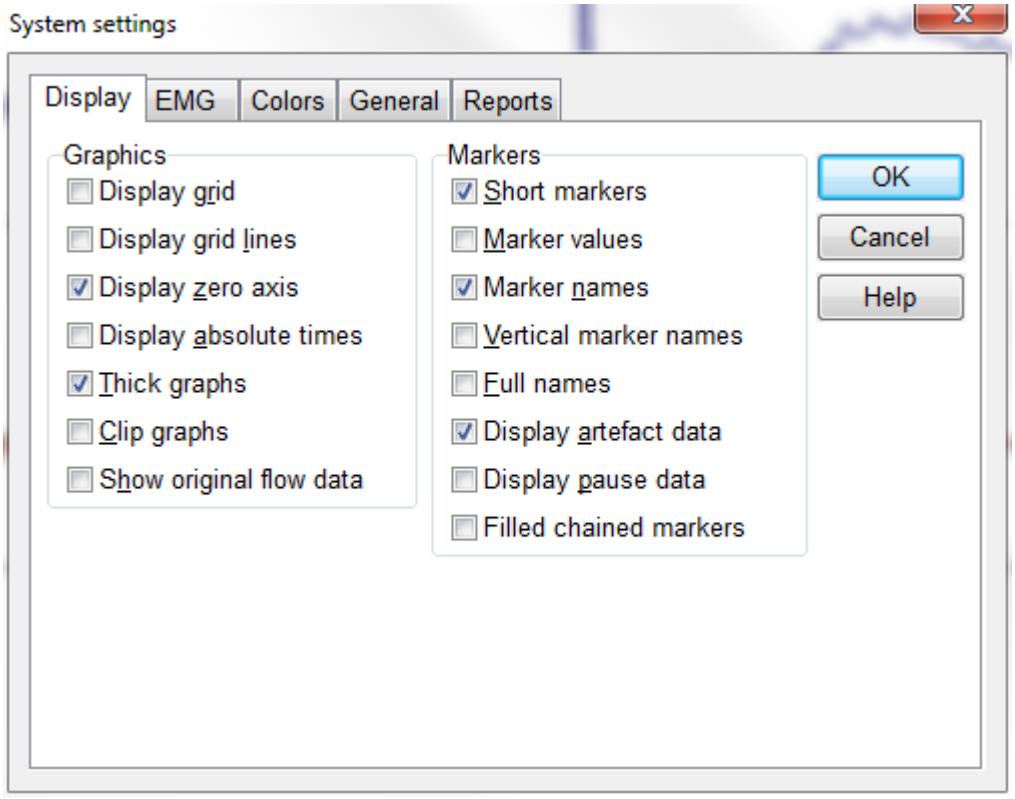


Figure 12.5 System settings analysis program

You can select some pages with settings by clicking the appropriate TAB. The settings are described below. The settings are valid for all existing investigations in the database and for all new investigations. The settings are copied to the system settings of the measurement program (see § 11.6).

Display

Specific settings for graphs and markers, for example how to display a grid and to show the markers as full names. If you select ‘Vertical marker names’, marker names will be displayed vertically instead of horizontally, which prevents marker names from overlapping. If you select ‘filled chained markers’, chained markers like begin- and end-markers for resting pressure, will be displayed with a colored background from begin- to end-marker.

‘Thick graphs’ is applicable for the graphs in the display, as well as the graphs in the plot. This can be handy when you want to copy and paste a screen capture in another application, for example in a power point presentation.

EMG

You can set the display for the EMG graphics. Also, settings for signal processing are available. You can choose ‘Slow average’ (default), ‘Fast average’ or ‘Peak amplitude’ (in case you want the fastest response of the EMG channel without a filter).

Colors

You can change the colors of the various items displayed on the screen: artefact, background, baselines, cursor, grid, et cetera. Select the object and click on the new color. You can also define a set of graph colors. These colors will be selectable in the channel settings.

When you have defined all colors, save the colors in a color scheme. You can define more than one color scheme, so you can quickly change colors. Click the button **Markers** to change the colors of the available markers.

General
You can set some general settings. The option ‘enter comment at event markers’ is default selected. In case the option ‘High speed EMG’ is available on the measurement system, you can set the timebase (default 20ms).

Reports
You can set some report settings:

- Set investigation graph height.
- Select thick graphs (also applicable for the plots in the report).
- Select settings for graphs on multiple pages: set the number of pages, time per page and select portrait/landscape.
- Set tracing clip-out time. By this option it is possible to print the graphs of interesting investigation periods in the report. Via the menu option **Marker > Insert marker**, it is possible to insert chained Tracing clip-out markers. The graphs between these markers will be printed in the report.

12.6 Export

The following menu items are available.

Menu item	Function
ASCII Binary CSV XML	Export the investigation data to other file formats.
HL/7	Create a PDF report and export the report to HL/7.

12.7 Report

The following menu items are available.

Menu item	Function
Reporter	Start Reporter. More information can be found in the separate Reporter manual in PDF format, which can be opened via the **Manuals** menu in the database program.
Print / PDF / JPG report	Print or export the report immediately. The report is printed / exported according to the report configuration and the printer / PDF / JPG settings of the reporter program.
Print / PDF / JPG graph	Print or export the graph immediately. The graph is printed / exported to the settings which can be adapted by clicking the **Printer** / **PDF** / **JPG** setup button.

12.8 Configure Button Toolbar

You can configure the buttons and the position of the buttons on the button toolbar for each type of investigation. Click with the right mouse button on the button toolbar and choose **Properties** from the pop-up menu to display the following window.

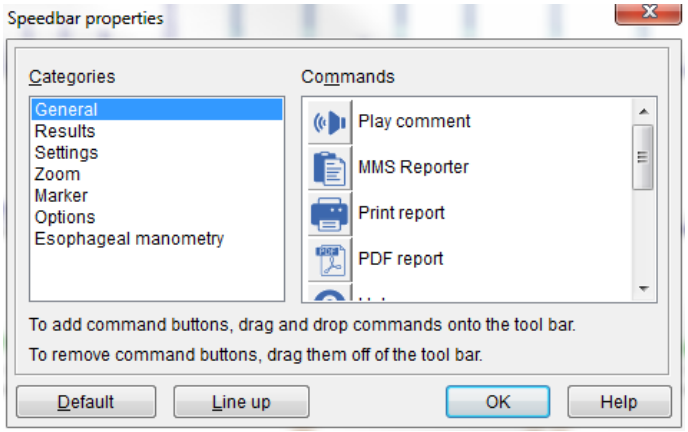


Figure 12.6 Configure button toolbar

To place a button on the toolbar, do the following:

- Select a category and click on a button in the commands list.
- Keep the mouse cursor pressed and move the mouse cursor to the toolbar. Release the mouse button on the spot you want to place the button.

To move a button on the bar, do the following:

- Click the button on the toolbar.
- Keep the mouse cursor pressed and move the button. Release the mouse button on the spot you want to place the button.

To delete a button from the bar, do the following:

- Click the button on the toolbar.
- Keep the mouse cursor pressed and move the button down.
- Release the mouse button, when the cursor is not on the toolbar anymore.

Appendix A Safety Information

The Safety information in this manual is intended for users performing investigations by using the Solar measurement system. Before working with the Solar measurement system and its manuals, please take notice of the safety information as described in this appendix.

Safety information for users who install, test and maintain the Solar measurement system can be found in the Solar GI New Service & Installation manual (document code: MAN-00046).

The Solar measurement system is a prescription device to be used only by physicians or individuals who have been trained and authorized by a physician or by a medical institution, under the supervision of a physician. The Solar system must be purchased under the supervision of a physician. For US only: Caution: Federal law restricts this device to sale by or on the order of a physician.

The Solar GI measurement system complies with the requirements as stated by

- IEC 60601-1:2005 + CORR. 1:2006 + CORR.2:2007 + A1:2012
- IEC 60601-1-2:2014
- ANSI/AAMI ES60601-1:2005 + C1:2009 + A1:2012 + A2:2012
- CAN/CSA-C22.2 No. 60601-1:2014
- local derivates and the Medical Device Directive (93/42/EEC).
- SGS contract no. 710253

The Solar measurement system conforms to the above mentioned requirements only when it is used with specified and approved Laborie modules/devices as mentioned in this document.

The instructions, precautions and warnings in this manual should be followed by the operator to ensure safe operation and to maintain the Solar measurement system in a safe condition. Therefor the use of the Solar system should be restricted to qualified personnel only.

The following signs are printed in this manual in front of important warnings, precautions and notes. It is important to pay good attention to these warnings and precautions to provide patient safety and to prevent damaging of the equipment.

WARNING A warning is a statement that alerts the user to the possibility of injury, death or other serious adverse reactions associated with the use or misuse of the device.

CAUTION A caution is a statement that alerts the user to the possibility of a problem with the device associated with its use or misuse. Such malfunctions include device malfunction, device failure, damage to the device or damage to other property.

NOTE The note sign appears when it is important to read the information.

Operating conditions:

- Condition: System is acclimatized for at least four hours prior to use
- Temperature range: +15°C to +35°C
- Relative humidity range: 30 % to 75 %, non-condensing
- Atmospheric pressure range: 700 hPa to 1,060 hPa.

Storage conditions:

- Condition: System is clean, dry, and protected by dust cover
- Temperature range: –10°C to +50°C
- Relative humidity range: 15 % to 90 %, non-condensing
- Atmospheric pressure range: 700 hPa to 1,060 hPa.

Transport conditions:

- Condition: System is clean, dry, and protected by the manufacturer’s packaging
- Temperature range: –25°C to +70°C
- Relative humidity range: ≤ 90 %, non-condensing
- Atmospheric pressure range: 700 hPa to 1,060 hPa.

Plastics and rubbers can become brittle at lower temperatures and soft at higher temperatures, this is no problem if not used.

Electronic components are selected to cope with the specified conditions.

The system can withstand the transport conditions provided it is clean, dry and protected by the manufacturer’s packaging.

Before put into storage, the system must be clean, dry, and protected by a dust cover.

Before placing the system into operation, allowed it to acclimatize to the specified operating conditions for at least four hours.

All repairs that are not performed by Laborie personnel become the responsibility of the facility or entity that owns the Solar GI system. Laborie will not give any guarantee or take any responsibility for any part that has been opened, adjusted, or replaced by non-Laborie-qualified personnel. The Solar GI system may be opened for any adjustment, replacement, maintenance, or repair by Laborie-qualified personnel only.

12.9 Disposing of Product After Use

The Solar GI system equipment and consumables should be disposed of in the following manner:

- **Contaminated single-use consumables:** Discard these products according to the standard operating procedures on medical waste handling at the institution of use.
- **Waste Electrical and Electronic Equipment (WEEE):** Ensure that any waste electrical and electronic equipment is collected separately and returned to the locally designated recycling service for these types of products.
- **Batteries:** Dispose of any end-of-life batteries according to local regulations.
- **Packaging waste:** Ensure that any packaging waste is collected separately for available national packaging collection and recycling services. Packaging is 80% recyclable/renewable by weight.

12.10 Environmental Consideration of Waste Disposal

The Solar GI system is designed to perform urodynamics studies. Laborie recommends properly disposing of waste generated from these studies, such as urine, to prevent environmental pollution. The waste should be disposed of in such a way that it will not pollute the freshwater supply system, especially the drinking water system. For facilities that outflow waste water to sewage systems that include water-treatment processes and procedures, the most convenient means of disposal is to use these sewage systems.

General

WARNING No modification of this equipment is allowed.

WARNING Safety can be compromised if the Solar GI measurement system or one of its modules shows visible damage.

WARNING Do not attempt to open any Laborie modules.

WARNING To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

WARNING All devices must be powered via the Safety module to reduce risks involving dangerous electrical currents.

WARNING Only connect items that have been specified as part of the system or that have been specified as being compatible with the Solar GI system into the Safety Module. By plugging in unapproved items the level of safety may be reduced and the IEC 60601 system requirements should be applied prior to use.

WARNING Do not use the Solar GI system simultaneously with HF Surgical equipment.

WARNING Do not loosen the Protective Earth.

WARNING Do not place the safety module/Multiple Socket-Outlet (MSO) on the floor.

WARNING Do not connect an additional Multiple Socket-Outlet (MSO) or extension cord to the Solar GI system.

WARNING Do not connect non-ME equipment that is supplied as part of this system intended to be plugged into the Safety module into a wall outlet. The Safety module is a safety component designed to ensure Touch/Enclosure Leakage currents are below the allowable limits. Operator may experience electrical shock if non-ME equipment is connected directly to the wall outlet.

WARNING Only connect equipment that has been supplied as part of the Solar GI system to the Multiple Socket Outlet provided on the Safety module.

WARNING The Solar GI system requires a connection to an IT-Network, which can present unidentified security risks related to this connection, including to patients, operators, or third parties. Laborie recommends that you work with your network administrator to identify, analyze, evaluate, and control these risks.

Solar trolley

WARNING All devices must be powered via the Separating transformer to reduce risks involving dangerous electrical currents.

Solar pole (Mk IV)

WARNING All devices must be powered via the safety module (300 VA) to reduce risks involving dangerous electrical currents.

WARNING To ensure stability and safety, do not mount/attach other devices to the Solar pole then laptop and the described Solar modules.

WARNING Do not connect the computer/laptop to a network without proper safety precautions. Take note of the applicable safety standards.

WARNING After each measurement, you have to remove water from the Solar pole and its devices with a soft, dry cloth.

CAUTION Be careful while working with the Solar pole. There is a risk to trip over of the cables laying on the floor.

CAUTION Do not place objects > 4 kg on the laptop shelf to reduce risks involving instability.

CAUTION When moving the pole, make sure that the wheel brakes are released and the cables are unplugged and stowed onto the pole to reduce risks involving tilting of the pole.

CAUTION Connect all USB devices directly to the laptop to prevent any USB/Windows related problem. Connect the U2M USB cable **directly** to the laptop. Do **not** connect the Solar U2M module via the USB-Hub!

Computer

CAUTION Please connect the U2M and Bluetooth dongle preferably directly to the computer as un-powered USB-HUBs might compromise their performance.

Solar U2M Module

WARNING Make sure that the correct dedicated power supply for the U2M module is used before plugging it into a mains socket (PS-U2M/T for trolley systems, PS-U2M/P for non-trolley systems).

WARNING Do not use a power supply other than which is specified. Doing so may cause fire leading to serious accidents.

WARNING Do not clamp the Solar U2M module up-side-down in a wet environment.

WARNING When using a Solar U2M module without safety module/separating transformer, create a safe Solar system setup for the patient. The patient must be positioned more than 1.5 meter from the computer. Take note of the applicable safety standards to reduce risks involving dangerous electrical currents.

WARNING Do not (dis)connect the U2M USB connector when a patient is connected to the Solar system to reduce risks involving dangerous electrical currents.

WARNING Always remove the power adapter from the mains first before removing the power supply cable from the Solar U2M module to reduce risks involving dangerous electrical currents.

CAUTION Be careful while working with the Solar U2M module. There is a risk to trip because of the cables laying on the floor.

CAUTION Make sure that the infrared receiver on the Solar U2M module is always visible (Solar pole version only).

Combination interface module

WARNING Do not clamp the combination interface module up-side-down in a wet environment.

WARNING When there is some friction, use a brush to put a little silicon oil on the orange rings. Never put the oil on the contacts of the connectors.

WARNING Do not connect an impedance catheter to P5 (Lemo 14) of the combination interface module.

Multipressure interface

WARNING Always mount/use the MPI with its connectors downward.

WARNING When there is some friction, use a brush to put a little silicon oil on the orange rings. Never put the oil on the contacts of the connectors.

WARNING After connecting the catheter to the TNF-R transducers, you must verify the channel mapping before starting the investigation.

Wireless patient module

The wireless patient module complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. This device contains FCC-ID POOWML-C40XX.

CAUTION Change the battery only when the patient is disconnected from the WPM (unplug catheter and all patient leads from the WPM).

CAUTION After low battery indication, exchange the batteries within 15 minutes.

CAUTION Remove the batteries when the wireless patient module is not used for a longer period (month).

NOTE Environmental conditions (as thick walls/doors, iron in walls/doors) may compromise the Bluetooth connection of the wireless patient module and battery lifetime.

Bluetooth puller Mk III (wireless)

The Bluetooth puller complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received,

including interference that may cause undesired operation. This device contains FCC-ID POOWML-C40XX.

WARNING Make sure that the Bluetooth puller is connected to the correct power adapter (PS-BT-PULLER). Do not use a power adapter other than which is specified. Doing so may cause fire leading to serious damage.

WARNING When adjusting the spring balanced arm, be aware not to pinch fingers or other objects.

WARNING Connect the power adapter whenever the Bluetooth puller is not used to prevent batteries to become depleted. Deep discharging the batteries will damage the batteries internally and shorten the lifespan.

WARNING If the slider does not move smoothly (ticking noises) during an investigation, then the results are not reliable. Solve the problem and redo the investigation.

CAUTION When using the Bluetooth puller, do not clamp the catheter at the position of a pressure transducer, as this will damage the transducer permanently.

CAUTION Use rechargeable AA batteries (≥ 2300 mAh NiMH) of good quality only and replace all four at once.

CAUTION After low battery indication, connect the power adapter within 5 minutes and charge the batteries. The Bluetooth puller is fully operational when the power adapter is connected and can be used to perform investigations.

CAUTION Remove the batteries when the Bluetooth puller is not used and the power adapter is not connected.

NOTE Environmental conditions (as thick walls/doors, iron in walls/doors) may compromise the Bluetooth connection of the puller and battery lifetime.

CIM-AUX HR(I)M Module

WARNING Do not clamp the CIM-AUX HR(I)M module up-side-down in a wet environment.

WARNING Do not rinse or immerse the connector housing of the HR(I)M catheter with water (fluid).

Perfusion Pump Plus

WARNING Always use flow resistors to guarantee an accurate measurement and to prevent that too much water is infused into the patient.

WARNING Never drop the water container. Do not use the water container in case of visible damage. The water container is pressurized and may burst in case of damage.

WARNING Ensure that the catheter and tubes are placed safely to prevent splashing the personnel during disinfection.

WARNING Do not use glutaraldehyde based disinfectants, because of (1) risk of splashing, (2) it may be difficult to remove all the glutaraldehyde from the system after disinfection, and (3) glutaraldehyde based disinfection is only short term effective.

CAUTION Water is not allowed to flow into the air compressor. This may damage the compressor. Never hold the water container upside down.

CAUTION Always use the float in the water container. Air bubbles will reduce the pressure response rate and the accuracy of the pressure recording.

CAUTION Always use demineralized or distilled water (preferable water for irrigation, distilled and sterile). Never perfuse with tap water or mineral water; minerals can cause blockages in the flow resistors.

CAUTION The tubes connected to the water container and air compressor all have a connector with locking mechanism. Do not attempt to disconnect by pulling the tubes. Loosen the lock by pressing the lever on the connector.

CAUTION Prior to each investigation, verify the proper functioning of the perfusion pump.

CAUTION Always release pressure from the water container first before removing the lid or the refill plug.

CAUTION It is only allowed to autoclave those parts and accessories described in the Solar GI New Service & Installation Manual (Document code: MAN-00046) as being autoclaveable.

CAUTION Make sure that the internal surfaces of the water container are not polluted with small particles.

Bluetooth Smart Long-Range USB dongle (BT-SLR)

The BT-SLR uses a transceiver module which complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. This device contains FCC-ID: QOQBLE121LR, IC: 5123A-BGTBLE121LR.

Catheters and accessories

WARNING Use only disinfected or sterile catheters.

WARNING Do not use the catheter if the package is damaged.

WARNING Do not reuse single-use accessories. After use, dispose of single-use accessories in accordance with local regulations.

CAUTION Always check the expiry date where applicable as this may affect the measurement results.

CAUTION To prevent drift, always pre-wet solid state catheters (sensors) to the instruction of the manufacturer.

CAUTION Only use the accessories specified in the document “Declaration of Compatibility for Accessories” (Document code: 0060-DEC-007) to prevent damage to the system.

NOTE For cleaning and sterilization of the catheters or accessories (e.g. EMG needle electrodes), see the manufacturer’s instructions.

Laborie is not liable for any damage to the perfusion pump or harm to patient or hospital personnel caused by improper use of disinfectant or procedure.

Cleaning (general)

CAUTION To prevent damage of the Solar GI measurement system do not use thinner or similar solvents.

CAUTION Do not use excessive amounts of water for cleaning the Solar measurement system to prevent damaging the electronics.

CAUTION Never allow water to get inside the Solar modules or any other part to prevent damage to the system.

Investigations

WARNING Investigation procedures as described in the Solar manuals do not pretend to be complete. How an investigation is performed and how the results are interpreted, the actual diagnosing, remains under all circumstances the responsibility of the clinician/physician performing the investigation. The description of investigation proceedings is only included to serve as an example to discuss the use of the various markers and the various transducers to reduce risks involving wrong treatment of a patient.

WARNING Safety can be violated if (e.g.) the apparatus:

- shows visible damage.
- fails to perform the intended measurement.
- has been subjected to prolonged storage under unfavourable conditions.
- has been subjected to severe stresses in transit.
- Has been handled by unqualified personnel.

WARNING Water ingress in the air compressor can cause inaccurate pressure readings, resulting in excess fluid being administered to the patient than what is indicated by the system. Excess fluid can lead to patient water intoxication, which may cause complications such as seizure.

WARNING Do not connect a patient to the Solar GI measurement system when using the diagnostic program to prevent injuries due to absence of some integral safety guards.

WARNING Do not use a defibrillator on the patient while connected to the Solar GI. The products' applied part is not defibrillator proof.

CAUTION Never turn off the computer when the Laborie software program is still active. You may lose data.

CAUTION Automatic safeguards built into the software should be seen as an aid. They are not a substitute for careful personal monitoring and an alert investigator.

CAUTION Make sure no unnecessary programs are running while performing a measurement with high speed EMG.

CAUTION In case of measurement performance problems, you can manually disable high speed EMG measurement.

CAUTION Do not carry or use a mobile telephone during the measurement to reduce risks involving electromagnetic disturbances.

CAUTION Interpretation and correct measuring cq. displaying of values by third party equipment interfaced with Laborie, is the responsibility of the user. Therefore, Laborie recommends to verify proper operation prior to each investigation.

NOTE After updating or upgrading the Laborie software, calculated parameters can be different compared to the previous software version due to changed/improved analysis techniques or changed medical opinion/insight.

Although precautions have been taken in this apparatus to prevent malfunctions due to abnormal environmental conditions and/or abnormal handling, such malfunctions can occur in some circumstances.
Abnormal environmental conditions include, but are not limited to:

- any other condition as is specified in the manual.
- (electro-)magnetic fields caused by portable equipment (as telephones, computers), X-ray equipment, (radio-)transmitters, radar-equipment, etcetera.
- Electrostatic discharge.
- mains disturbances.
- extreme temperatures, pressures, humidity, dust, etcetera.

Abnormal handling includes, but is not limited to:

- any handling other than specified in the manual.
- rough handling.
- handling by unqualified staff.

Provided such or similar conditions do not occur, this apparatus will prove to be durable and reliable.

NOTE Check the functionality of the Solar GI measurement system regularly with the hardware test (diagnostic) program.

Safety regulations Solar modules

Module	**Protection class***	**Applied part**	**Isolation protection rate**
Separating Transformer (STF)	Class I	-	IP20
Solar U2M module (U2M)	Class II	-	IPX1
Combination Interface Module (CIM)	-	BF	IPX1
Multi Pressure Interface (MPI)	-	BF	IPX1
Wireless Patient Module (WPM)	-	BF	-

Bluetooth (wireless) puller Mk III (BTP)	Class II if powered by power adapter	B	-
CIM-AUX HR(I)M module	-	BF	IPX1
Perfusion Pump Plus (MPP Plus)	-	-	IPX2

* Determined by setup.

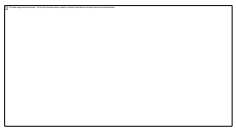
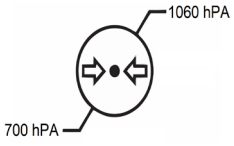
** The Solar GI HRM compact systems are standard supplied with a 300 VA safety module.

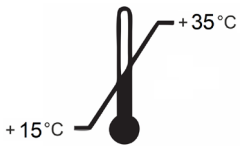
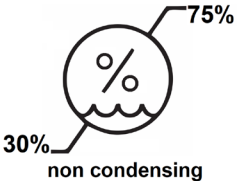
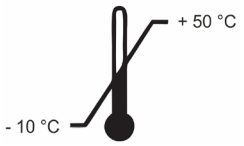
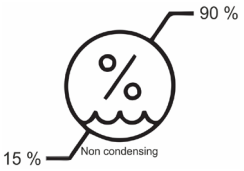
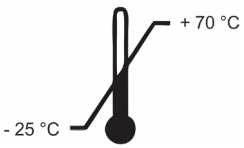
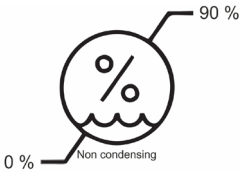
Appendix B Explanation of Symbols

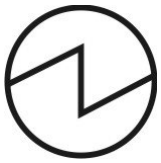
This appendix gives an explanation of the symbols on the Solar GI system.[6]

 Blue symbol	Follow instructions for use.
	Triangle with black border: Caution, consult instructions of use.
	Consult instruction for use for cautions and warnings
	Caution: Federal law restricts this device to sale by or on the order of a physician.
	Yellow triangle: General warning.
	Type BF applied part conform IEC 60601-1.

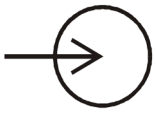
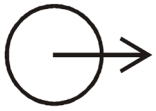
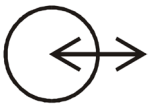
[6] Please note that some of the symbols on the measurement system are originally in color

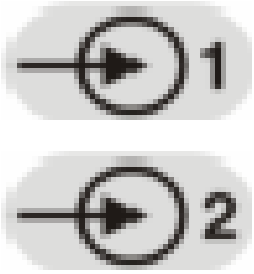
	Type B applied part conform IEC 60601-1.
IPX1	Protected against dripping water. Equipment provided with an enclosure preventing entry of such an amount of falling liquid as might interfere with the satisfactory and safe operation of the equipment.
IPX2	Provides protection against ingress of dripping water with harmful effects when tilted 15°.
	Battery symbol.
	Rechargeable battery
	Equipment can only be used indoor.
	Atmospheric pressure range 700 hPa to 1060 hPa.

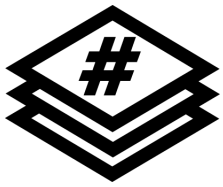
	**Operating Conditions:** Temperature range +15°C to + 35°C.
	**Operating Conditions:** Relative humidity range 30% to 75%, non- condensing.
	**Storage Conditions:** Temperature range -10 °C to + 50 °C.
	**Storage Conditions:** Relative humidity range 15% to 90%, non- condensing.
	**Transport Conditions:** Temperature range - 25°C to + 70°C.
	**Transport Conditions:** Relative humidity range ≤ 90%, non-condensing.
CE 0197 0678	0197: Complies with CE (93/42/EEC). 0687: Mitsumi BT module inside is approved by notified body 0678 on R&TTE directive.

CE 0197	CE (93/42/EEC).
SGS C US 710253	Nationally Recognized Testing Laboratories
 Symbol with red border	Never put fingers or any other body parts in the pump while it is running!
	Double insulated conform IEC 60601-1.
	This device uses a RF transceiver for data transfer purposes.
	This product is subject to WEEE directive 2012/19/EU. Contact your local authority for information about disposal and recycling.
	Energy source.

 Symbol with red border	Do not push or pull.
	Manufacturer. May be combined with manufacturing date.
	Fuse.
	Equipotentiality.
	Protective earth.
	Earth (ground).
	Signal reference

I	Class I equipment conform IEC 60601-1.
II	Class II equipment conform IEC 60601-1.
	Input
	Output
	Input/output
	Polarity of d.c. power connection.
	Solar U2M module USB port (upstream from U2M module to PC).

	Neuro module (HEM) output socket for stimulation electrode with DIN connector.
	Neuro module (HEM) output jacks for stimulation electrodes with touch-proof jacks.
	Neuro module (HEM) input sockets for connecting EMG electrodes with DIN connector.
	Solar perfusion pump plus on/off switch.
	Mass (including safe working load) in kilograms.
	Catalogue number.
	Serial number.

	Quantity symbol: Numeral in symbol (in place of #) indicates the quantity of units in package.

Explanation of PE-number

PEYY-FXXXXNNNN

PE	Peripheral Equipment.
YY	2 digit manufacturing year number.
F	Product group number.
XXXX	3 or 4 digit unique module abbreviation.
NNNN	4 digit incrementing unique number.

Explanation of SN-number

SN YYXXNNNN

SN	Serial Number.
YY	2 digit manufacturing year number.
XX	1 or 2 digit product identification number
NNNN	4 digit incrementing unique number.

Appendix C Software Messages

In this appendix, you can find an overview of the software messages with possible action(s) to resolve.

Software messages measurement and analysis

Message	Cause	Posible actions to resolve
An error occurred related to the video digitizer! Video will be disabled.	Error with video digitizer	Contact your Laborie representative
Blood pressure meter not active. Retry to connect?	Module not active	Retry connecting
Bluetooth flowmeter connection lost.	Communication problems	Contact your Laborie representative
Bluetooth puller connection lost.	Communication problems	Contact your Laborie representative
Bluetooth Puller not connected! Check the Range of the Bluetooth puller, Check the Bluetooth dongle, Replace the batteries or connect the power adapter	Module expected but not connected	Contact your Laborie representative
Bluetooth Puller not connected! Check the Range of the Bluetooth puller, Check the Bluetooth dongle, Replace the batteries or connect the power adapter. To use the manual pull option, set "Use puller for profile" in the investigation protocol to no or automatic	Module expected but not connected	Contact your Laborie representative
Bluetooth SMART dongle not found!	Communication problems	Contact your Laborie representative
Bluetooth Stack %s not initialized. File %s incompatible.	Communication problems	Contact your Laborie representative
Bluetooth Stack %s not initialized. File %s incomplete.	Communication problems	Contact your Laborie representative
Bluetooth Stack %s not initialized. File %s not found.	Communication problems	Contact your Laborie representative
Bluetooth Stack not installed. Please re-install the software to correct the problem.	Communication problems	Contact your Laborie representative
Bluetooth USB dongle not found. Possible causes: The Bluetooth software is not installed correctly, The Bluetooth USB Dongle is not connected or The Bluetooth USB Dongle might be turned off in case of a laptop	Communication problems	Contact your Laborie representative
Bluetooth USB Dongle not found. Possible causes: The Bluetooth software is not installed correctly, The Bluetooth USB Dongle is not connected, The Bluetooth USB Dongle is connected to a different USB port than was used during the installation or The Bluetooth USB Dongle might be turned off in case of a laptop	Communication problems	Contact your Laborie representative
Calibration is invalid.	Calibration is invalid	Retry calibration
Cannot move a [Markername] marker	Cannot move marker	Marker is not movable
Cannot move an Artefact marker (Display artefact data)	Cannot move marker	Artefact data is hidden

Message	Cause	Posible actions to resolve
Cannot move a Pause marker (Display pause data)	Cannot move marker	Pause data is hidden
Changes in marker data could not be written! Disk error	Error during saving of marker data	Contact your Laborie representative
Channel settings could not be written!	Error during saving of channel settings	Contact your Laborie representative
CIM not connected!	Module expected but not connected	Contact your Laborie representative
CIM-AUX not connected!	Module expected but not connected	Contact your Laborie representative
CIM-HCl not connected!	Module expected but not connected	Contact your Laborie representative
CIM-HRM not connected!	Module expected but not connected	Contact your Laborie representative
Compliance in miction phase	Compliance marker in miction phase	Remove marker
Creating a backup also failed. All changes made have gone lost. Contact your administrator.	Creating investigation file backup failed	Contact your Laborie representative
Data could not be stored within the investigation file. It is possible to store a backup file which can be imported when restarting analysis. Do you want to create a separate backup?	Saving investigation file failed	Contact your Laborie representative
Demo file not present!	Demonstration file is not available	Create a demonstration file from an analysis
Digital EMG module not connected!	Module expected but not connected	Contact your Laborie representative
Digital EMG module not connected! (Highspeed EMG)	Module expected but not connected	Contact your Laborie representative
Digital H2O interface not connected!	Module expected but not connected	Contact your Laborie representative
Digital MPI interface not connected!	Module expected but not connected	Contact your Laborie representative
Digital MTC interface not connected!	Module expected but not connected	Contact your Laborie representative
Digital Puller not connected!	Module expected but not connected	Contact your Laborie representative
Digital Puller not connected! To use the manual pull option, set "Use puller for profile" in the investigation protocol to no or automatic	Module expected but not connected	Contact your Laborie representative
Digital pump not connected!	Module expected but not connected	Contact your Laborie representative
Digital CO2 module not connected!	Module expected but not connected	Contact your Laborie representative
DT-XX transducer not connected to CO2 module	Transducer expected but not connected	Contact your Laborie representative
Due to a change in the channel configuration some approved events might have been set to not approved. It is advised to re-analyse these events	Events problem	Re-analyse events
Error during backup [Filename]	N/A	Contact your Laborie representative
Error during saving test data!	General error during saving test data	Contact your Laborie representative

Message	Cause	Posible actions to resolve
Error during saving test data! Investigation number > 99	Investigation number > 99	Contact your Laborie representative
Error during saving test data! Not enough memory available. Cannot perform investigation.	Not enough memory available	Contact your Laborie representative
Error in writing to file: [Filename]	Error during save to demo file	Retry save as demo file
Error while allocating MPEG4 buffers!	MPEG4 buffer problem	Contact your MMS representative
Error while allocating video buffers. Increase the non-paged memory size in Milconfig.	Error while allocating video buffers	Increase the non-paged memory size in Milconfig
Fatal error during reading of the testdata!	Exception during reading test data	Contact your Laborie representative
Fatal error occurred during the measurement!	Exception during measurement	Contact your Laborie representative
Flowmeter not connected!	Module expected but not connected	Contact your Laborie representative
Illegal use of Laborie software on a network	Application cannot be started from network location	Start application from database
Incorrect serial port selected. Blood pressure recording not possible. Change serial port settings and restart the test.	Incorrect serial port selected	Change serial port and restart test
Invalid character encountered - use only hex digits 0..9, A..F	Invalid character in catheter string to decode	Contact your Laborie representative
MEMORY FULL **** DATA IS NOT SAVED NOW!	Memory full, Investigation took longer than expected	Stop the investigation and start a new investigation if applicable
MEMORY FULL **** PRETEST DATA IS NOT SAVED NOW!	Memory full, Pretest took longer than expected	Stop the investigation and start a new investigation if applicable
Microsoft Bluetooth stack or Widcomm Bluetooth stack not installed. Use Windows XP with at least Service Pack 2 to use the Microsoft Bluetooth stack or re-install the software to install the Widcomm Bluetooth stack.	Communication problems	Contact your Laborie representative
Perfusion pressure too high - The pressure release valve is probably polluted. Release the tube from the water container and try to restart the pump. If the error remains, the system should be sent to MMS for maintenance. Restart or Stop and save investigation?	Perfusion problem	Contact your MMS representative
Perfusion pressure too high. The pressure release valve is probably polluted. Release the tube from the water container and try to restart the pump. If the error remains, the system should be sent to MMS for maintenance. You can restart the perfusion pump with the fill perfusion button.	Perfusion problem	Contact your Laborie representative
Perfusion pressure too low. Check Leakage. Please make sure all cables and connections on the water container are airtight.	Perfusion problem	Contact your Laborie representative
No esophageal channels defined!	No Esophageal channel defined	Define esophageal channels

Message	Cause	Posible actions to resolve
No Input signal present!	No video input signal available	Contact your Laborie representative
Oximeter is not active or within range or the COM port setting is wrong. Retry connecting?	Module not active	Retry connecting
Parameter file could not be saved!	Error during saving of parameter file	Contact your Laborie representative
Patient demographics could not be written!	Error during saving of patient information	Contact your Laborie representative
Perfusion system with balloon filling not connected!	Module expected but not connected	Contact your Laborie representative
Protocol could not be found	Protocol file is corrupt	Create new protocol
Protocol file is corrupt. Open Protocol editor to fix this problem.	Protocol file is corrupt	Open protocol editor to fix this problem
Protocol file is corrupt. Protocol [ProtocolName], [TestName] Open Protocol editor to fix this problem.	Protocol file is corrupt	Open protocol editor to fix this problem
Puller error	Puller not running at correct speed or not at all	Check puller or contact your Laborie representative
Test not present!	Investigation file is not available	Contact your Laborie representative
Test settings could not be written!	Error during saving of settings	Contact your Laborie representative
The investigation cannot be started because the perfusion pump filling method is selected but the perfusion system with balloon filling function is not connected.	Module expected but not connected	Contact your Laborie representative
The investigation cannot be started because the perfusion pump filling method is selected but the perfusion system with balloon filling function is not enabled.	Module expected but not enabled	Contact your Laborie representative
The system has lost the connection, the investigation will be saved and stopped	Communication problems	Contact your Laborie representative
The system is connected to the computer via USB but not all MMS bus ports were recognized	Not all MMS bus ports are recognized	Contact your Laborie representative
The system is not connected to the computer	System is not connected to the computer	Connect the system to the computer
The system is not powered. Please check the power connection	System is not powered	Connect the power
The WPU [Name] has lost the connection	Communication problems	Contact your Laborie representative
There are more channels available in the protocol file ([Filename]) then supported by this software version!	Protocol file comes from a later version	Install correct software version or contact your Laborie representative
This color scheme is read-only	Operator tries to change a system color scheme	Modify a different color scheme
Unable to display the Clouse contour plot	Problem displaying graphs	Contact your Laborie representative
Unable to display the graphs	Problem displaying graphs	Contact your Laborie representative

Message	Cause	Posible actions to resolve
Unable to start the investigation (perfusion pressure too high) The pressure release valve is probably polluted. Release the tube from the water container and try to restart the pump. If the error remains, the system should be sent to Laborie for maintenance.	Perfusion problem	Contact your Laborie representative
Warning: compliance marker in miction phase	Compliance marker in miction phase	Remove marker
Warning: No more Profile markers!	No more profile markers available	Remove profile marker
Warning: No more Profile markers!	No more profile markers available	Remove profile marker
Wireless patient module connection lost.	Communication problems	Contact your Laborie representative
WPM not connected! Check the Range of the Wireless patient module, Check the Bluetooth dongle or replace the batteries	Module expected but not connected	Contact your Laborie representative
WPM not connected! Check the Range of the Wireless patient module, Check the Bluetooth dongle or replace the batteries	Module expected but not connected	Contact your Laborie representative
WPU not connected! Check the Range of the Wireless patient unit, Check the Bluetooth dongle or replace the batteries	Module expected but not connected	Contact your Laborie representative
WPU not connected! Check the Range of the Wireless patient unit, Check the Bluetooth dongle or replace the batteries	Module expected but not connected	Contact your Laborie representative
Writing of channel [Channel name] to catheter file failed!	Writing to catheter file failed	Retry calibration

Software messages database

Message	Cause	Posible actions to resolve
Can not execute [application]	Application cannot be executed	Contact your Laborie representative
Chipcard error	Chipcard could not be read	Contact your Laborie representative
Could not open combination report because of a problem with following investigation: [Report file] Generate report file by re-opening the investigation and create a new combination report.	N/A	Contact your Laborie representative
Creating a backup also failed. All changes made have gone lost. Contact your administrator.	Failed to create a backup	Contact your Laborie representative
Creating safety backup failed!	Safety backup could not be copied	Software will continue to work as normal without the safety backup, contact your Laborie representative
Database could not be reindexed	N/A	Contact your Laborie representative
Deleting of test not successful!	N/A	Contact your Laborie representative

Message	Cause	Posible actions to resolve
Demographics database cannot be opened! Probably due to file corruption. Try again later or call your dealer. Closing program	Demographics database is corrupted	Try again later or contact your Laborie representative
Demographics database is busy and could not be repaired! Try again later or call your dealer. Closing program.	Repairing demographics database failed	Try again later or contact your Laborie representative
Demographics database is busy! Probably a network related problem.	Demographics database is not responding	Try again later or contact your Laborie representative
Error during copying of file	Disk is full or file size is too large	Free up disk space
Error executing program	Application cannot be executed	Contact your Laborie representative
Error in FCU file. Archive of patient aborted	FCU file is corrupted	Contact your Laborie representative
Error in FCU file. Restore of patient aborted	FCU file is corrupted	Contact your Laborie representative
Error loading quester-plugin	Quester DLL could not be initialized	Contact your Laborie representative
Error reading MMS-interface file	N/A	Contact your Laborie representative
Error writing MMS-interface file	N/A	Contact your Laborie representative
FCU database error. Restore of patient aborted	FCU file is incomplete	Contact your Laborie representative
File not found	N/A	Self-explanatory
File not found. Restore of patient aborted	FCU file is incomplete	Contact your Laborie representative
General database error, back-up failed!	Database could not be opened	Try again later or contact your Laborie representative
HIS interface module not initialized	HIS export DLL could not be initialized	Contact your Laborie representative
Incorrect version of the Borland database engine installed. Application cannot be started! [BDE version] Should be BDE v5.0.0 or higher.	Incorrect version of the Borland Database Engine	Contact your Laborie representative
Interface library [Library] [Error]	Cardreader DLL could not be initialized	Contact your Laborie representative
Investigation database cannot be opened! Probably due to file corruption. Trying to repair	Investigation database is corrupted	Try again later or contact your Laborie representative
Investigation database could not be opened! Probably due to file corruption. Try again later or call your dealer. Closing program.	Investigation database is corrupted	Try again later or contact your Laborie representative
Investigation database is busy and could not be repaired! Try again later or call your dealer. Closing program.	Repairing investigation database failed	Try again later or contact your Laborie representative

Message	Cause	Posible actions to resolve
Investigation database is busy! Probably a network related problem	Investigation database is not responding	Try again later or contact your Laborie representative
Investigation number out of range!	Maximum number of investigations for the selected patient reached	Select another patient name
License file not correct, install failed	Incorrect license file	Reinstall the software or contact your Laborie representative
Login program was not used!	Network software, but Laborie Login was not used	Use Laborie login
Maximum of investigations for patient reached	The maximum number of investigations (99) for this patient has been reached	Paste investigation with a different patient
Patient number is empty	Patient number on card is not available (using a card reader)	Use a supported card
Patient number is empty	Received patient number is not available	Contact your IT representative
Storage failure. Error in FCU file	FCU file is corrupted	Contact your Laborie representative
System number is empty. Archive of patient aborted	Patient system number is empty	Contact your Laborie representative
System number is incorrect. Archive of patient aborted	Patient system number is incorrect	Contact your Laborie representative
System numbers of databases are not identical. Index-file is corrupt, please reindex databases!	System numbers of internal databases are not identical	Reindex the Laborie database, if this does not work contact you Laborie representative
This function is not available	Network software, but Laborie login is not available	Contact your Laborie representative
Unknown user: [Username] Program halted.	Unknown login user, application stopped	Use a known user to login

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