

<p>SPHINCTOMETER</p> 	<p>Manual</p> <p><i>(waterfilled sensor, except Trainer)</i></p>	<p>MSM ProMedico GmbH Jülicher Str. 338 a 52070 Aachen Tel.: 0049-(0)241-96 82-10 Fax: 0049-(0)241-96 82-122 e-mail: zentrale@msm-aachen.de</p>
<p>Sphinctometer Instruction Manual New.doc</p>	<p><i>Manual</i></p>	

SPHINCTOMETER

- System -

- **Measurement device for analtonometrie and perineometrie**
- **Trainings device for incontinence therapy and
Therapy of pelvic floor insufficiency**

Version 1.51



Please see all accompanying documents before first use!



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1 Introduction

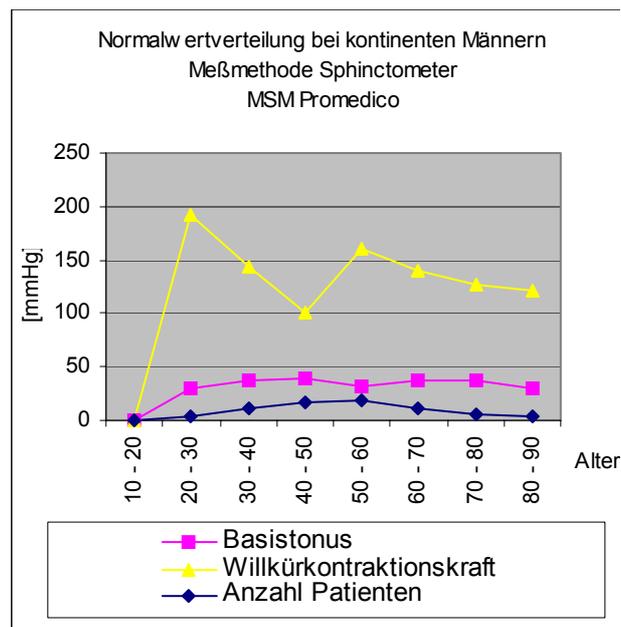
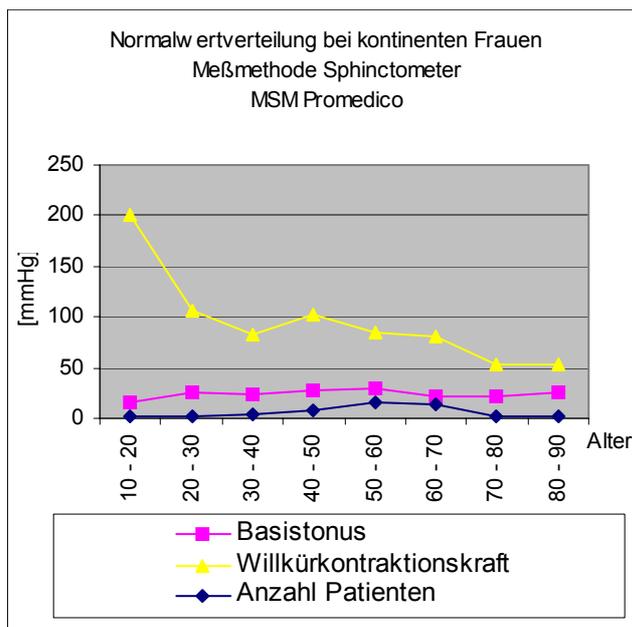
1.1 Measured values with the Sphinctometer

The Sphinctometer allows the evaluation of the pelvic floor muscles through vaginal and of the sphincter muscles through anal tension measurements.

The measured values can be read off the device after inducing the specific sensor in the anus (sensor A)/ the vagina (sensor B).

The following table shows norm values of healthy persons of different age.

Pressure ca.	Females	Males	Elucidations of device display
Tension / mmHg	40 - 60	60	ARD: relaxed anal pressure
Contraction pressure / mmHg	100	150	AMD: maximum anal pressure



The Sphinctometer effective range is between 0 and 300 mmHg.

Please use the Sphinctometer-Trainer for patient training. The effective range of this device is up to 250 mmHg.

Please see also chapter XXX of this instruction manual for detailed information on the Sphinctometer-Trainer.

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1.2 Intended use

The system Sphinctometer is meant to be used in doctor's surgeries, clinics and sanatoriums. The handler has to know the instruction manual, and has to be introduced to the device. In case the device is used together with a computer and the program SphinctoDat the patient has to be alluded that his data can be saved. Handicaped persons may need further support during the examination. Please keep the Sphinctometer away from children.

2 Medizinproduktegesetz

Das System Sphinctometer unterliegt als Medizinprodukt der Richtlinie 93/42/EWG über Medizinprodukte und dem Medizinproduktegesetz.

Durch die Klassifizierung gilt folgende Einordnung:

Der Meßsensor (Anwendungsteil) des Sphinctometers ist **Klasse IIa** (Regel 5) zuzuordnen.

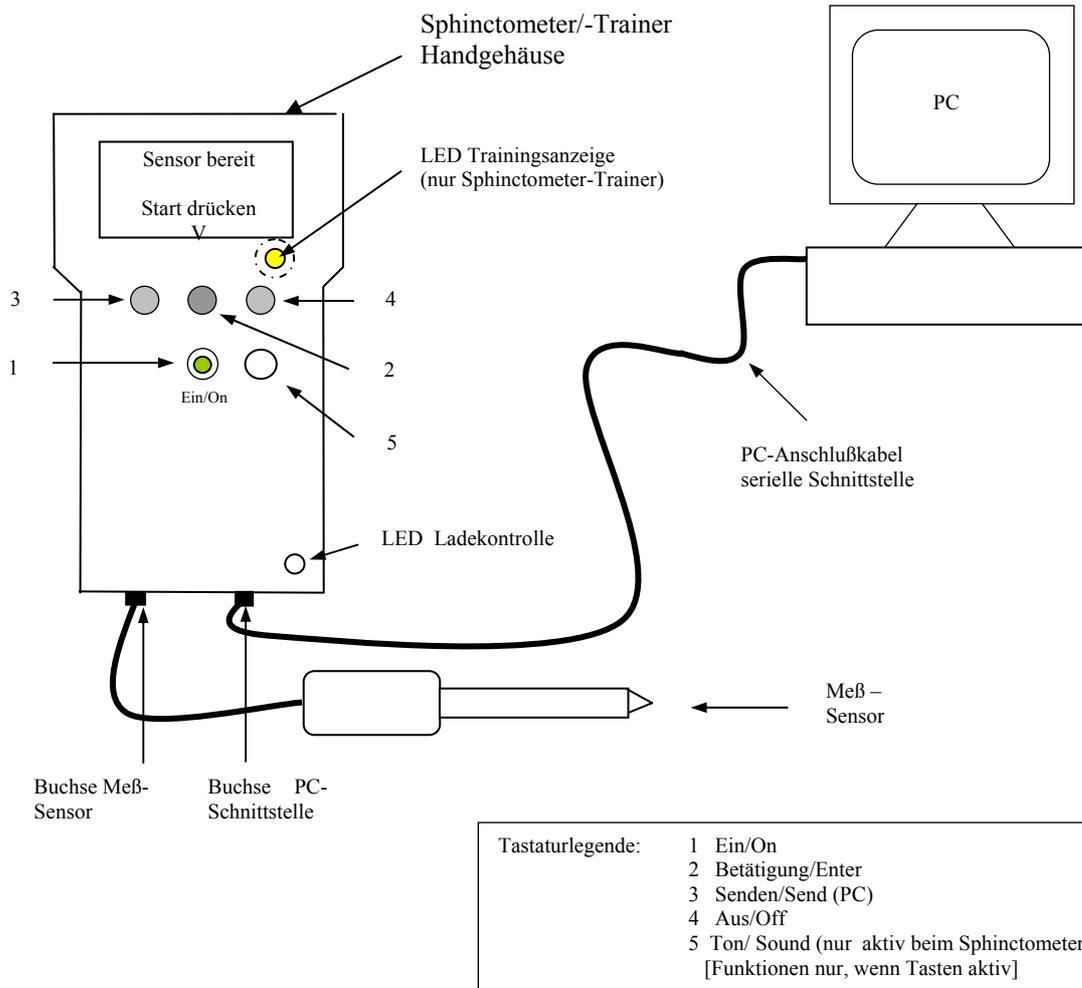
Der Meßsensor wird mit dem Grundgerät betrieben, das der **Klasse I** zuzuordnen ist (Regel 12).

Unsere Geräte werden nach der Richtlinie 93/42/EWG in Einzelprüfung einer EG-Prüfung unterzogen, die von der Benannten Stelle RWTüV Essen durchgeführt wird und uns zum Anbringen des CE-Zeichens berechtigt.

Damit stellen wir Ihnen optimal vorbereitete Geräte zur Verfügung.

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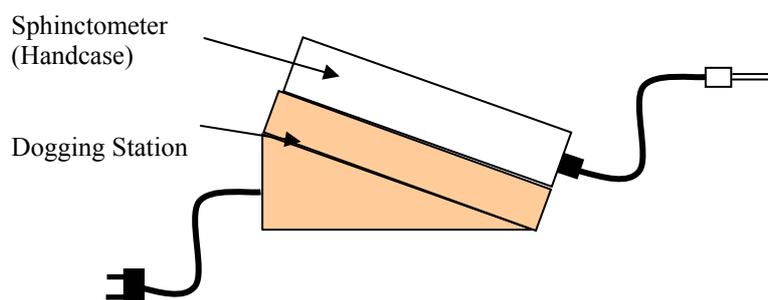
3 System overview Sphinctometer/ Sphinctometer-Trainer



3.1 Overview

The image shows the Sphinctometer hand device, the sensor and a serial connection to a computer. The sensor is connected to the left connector. The data cable is connected to the right connector. Both connections are designed to fit only in the right way. The Sphinctometer is delivered with a desk stand with an integrated power supply unit. The battery is charged automatically when the hand device is in the desk stand. All this is applicable on the Sphinctometer-Trainer, too.

3.2 Dogging Station



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4 Description of the system Sphinctometer

The Sphinctometer is composed of the hand device with the sensor. The associated desk stand is concipated a storage place where the battery is recharged.

Types:

The Sphinctometers is offered in two versions:

1. **Sphinctometer (doctor's diagnosis device)**
2. **Sphinctometer-Trainer (Therapy device)**

To 1.: The Sphinctometer as a diagnosis device allows quick and precise measurements. The measured values can be transferred to a PC. This allows easy documentation and data storage. To use this function the software „SphinctoDat“ by MSM is needed. Of course the Sphinctometer can be used without the software.

To 2.: The Sphinctometer-Trainer in concipated as a training device. It can be used ambulant, at home, in rehabilitation centres, etc. The device is based on a Biofeedback-base. It has a light signal and an optional audio signal asking the patient to squeeze. It does also have a PC interface, which allows the user to enter training data into the Trainer, and to transfer the training results from th trainer to the PC.

Sphinctometer and Sphinctometer-Trainer are strukkturally identical but differ in function.

Hand device:

The Sphinctometers/ Sphinctometer-Trainers is handled with the five-button-keyboard. The integrated display shows enter requests as well as measured data.

The device has the following interfaces:

- LCD – Display
- Button ON (lower middle)
- Button ENTER (upper middle)
- Button SEND PC (upper left)
- Button OFF (upper right)
- Button SOUND (lower right, active only at the Trainer)

To switch on the device please press the “ON” button. All active buttons are marked with a “V”. Please follow the screen notifications. The display leads automatically through the measure or training programme. You handle the sensor and meanwhile press the particular buttons as indicated by the screen.

Working with the Sphinctometer always follows the same course:

- Connect the sensor
- Sensor ready (the sensor is calibrated now – please make sure no pressure is applied to it)
- Insert sensor
- Start measurement
- Measure rest tonus and maximum contraction force
- Read off measured values
- If applicable: Send data to the PC
- Start new measurement or switch off device

The button marked with a speaker symbol turns the sound on or off.

It is not possible to cancel the procedure once started. This makes sure no data is lost accidentally.

Note: When the screen shows the notification “Sensor Not Ready” the pressure inside the sensor is too high. . ,In this case please see the brief instructions “refilling the sensor with water”.

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Sensor A for analtonometric:

The sensor A is the component used for analtonometric and training.

It is made of a plastic handle and a silicon tube. This sensor with a cone head is inserted into the patient's anus after a one way protection has been applied to it.

The protection avoids a pollution of the sensor. It has to be renewed with every new patient. The sensor is connected with a flexible cable to the hand device.

Sensor V for perineometric:

The sensor V is another component of the Sphinctometers/-Trainers used for Perineometric and training of the pelvic floor muscles.

The only difference to sensor A is its form. It is used in the same way.

Control measurements with the measure clips:

To perform a control measurement to check the full function of the Sphinctometer (doctor's device) please use the enclosed measure clips. For further information please see paragraph 6.5 of this manual.

Power supply:

Sphinctometer and Sphinctometer-Trainer are run by the integrated battery. Both devices have an automatic switch-off-function to save power. Completely charged the device is operable for at least two hours. To make sure the Sphinctometer is always operable please put it back to the desk stand where it is recharged when your measurement is done. The desk stand has the necessary qualification according to DIN EN 60601.

Datatransfer from/to the PC:

The Sphinctometer/ -Trainer is designed for a use with the PC (although it can as well be used without one). For further information please see paragraph 9 – 9.7

Desk stand

Sphinctometer and Sphinctometer-Trainer werden are delivered with a desk stand. This desk stand has a power connector (230V) and functions as charging device. Please put the Sphinctometer/ -Trainer back on the desk stand when you finished using it.

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5 Handling of the Sphinctometers (diagnostic device)

In the following paragraph you will find some instructions on the handling of the Sphinctometer and the Sphinctometer-Trainer.

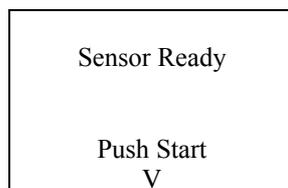
For information on the measure procedure please see paragraph 5.2

5.1 Preparation of the measurement (diagnostic device only)

Please connect the sensor cable to the left connector of the hand device. Now please check if the battery of the hand device is charged sufficiently. The green light in the lower right corner indicates the state of charge. New or long time unused devices have to be charged for at least 4 hours before use. Please make sure the desk stand is connected to a socket (230 V).

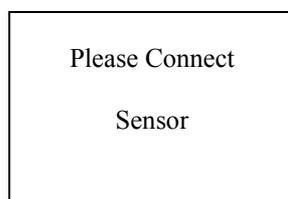
5.1.1 Check on water level of the Sensor

Before measuring is has to be checked if the sensor is filled with water sufficiently. In order to do so please open the screw top located at the handle of the sensor. Please use a syringe to fill in tap water (better distilled water) as bubble free as possible. It should be at room temperature. It may help to squeeze the tube in order to get the last bubbles out. Please close the screw top slowly, so the superfluous water can pour out. Please check if the gasket is in the right position. While closing the sensor make sure to hold it at the white handle, only. Now you can switch on the Sphinctometer (Button EIN/ON). If the pressure in the tube is small enough the display shows that the sensor is ready.



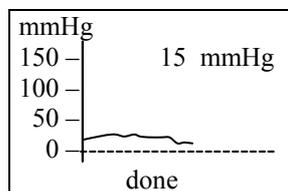
5.1.2 Correct the water fill level

If the pressure in the tube is too high it may occur that the Sphinctometer is not able to ‘find’ the sensor. In this case the following notification will be displayed:



Please loose the screw top at the handle of the sensor, so that the tube can release the superfluous pressure. Now hold the sensor so, that no pressure is in the tube, and that no water can pour out. Now the sensor can be ‘found’ by the Sphinctometer. Please press the Enter button twice (please ignore the notifications “Sensor ready“ and “Induct Sensor“). Now you can see the measured values on the display.

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The current pressure is now 0 mmHg. Now please slowly fasten the screw top again. The pressure may rise to maximum 25 mmHg. Should the pressure be too high please consider to loosen the screw a little or to slightly squeeze the tube before closing it. These measures help to adjust the sensor to a value of 10-15 mmHg when lying horizontal on the desk. Now please switch of the device by ending the measurement, then select “no“ and finally press the off button.

5.1.3 How to control the effective range

To assure that the whole pressure range is measurable please check the maximum pressure that can be measured. To do so perform a measurement as described in paragraph 6.2 “Performing measurements”. At the same time please check the tightness of the system. Use your fingers to squeeze the tube. Please try to cover a similar area the sphinctermuscle would cover. A pressure of about 300 mmHg should be displayed to cover the full range. No water must pour out of the whole system. If the pressure is to low please repeat the filling ob the sensor as air bubbles may be the reason for low pressure. Another potential source of error is that the pressure after fastening the screw top is higher that 25 mmHg (sensor lying horizontally). After long time use the silicontube may also change its elasticity. In this case the sensor has to be renewed. Please send the whole device back to the manufacturer.

5.2 Performing measurements

5.2.1 Applying the single use protection

To perform a measurement please apply a sinlge use protection on the sensor. Please make sure the whole sensor is covered, to avoid a contamination. As protection latex hulls for ultrasonic sensors can be used (e.g. by the company MAPA, Zeven, Art.-Nr. 11.150.023). You can find further hints in paragraph 9.2

5.2.2 Handling sequence for measurements

Connect the sensor to the hand device and press the “on” button.

The display shows:



If the sensor is not connected yet you are now asked to do so. In case the device still show “connect sensor” please proceed as described in paragraph 5.1.2

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Please Connect

Sensor

When the sensor is connected properly the display shows:

Sensor Ready

Push Start

V

To proceed press the enter button. It is marked by the “V”.

IMPORTANT: The sensor must not undergo any external pressure as in this phase the sensor is calibrated. Please put the sensor into a horizontal position, or to a similar position in which the measurement will later be performed.

By doing so you avoid a value falsification through the own weight of the water.

Please wait until the display shows a new notification.

Measurement

Insert sensor

done

Now stick the latex tube part of the sensor which is covered by the single use protection up to the handle into the anus.

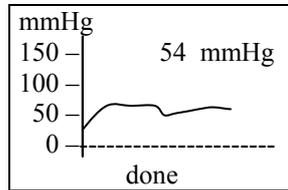
Hold the sensor now, and keep it in a neutral position so the values are not falsificated by the own weight of the sensor.

Start the measurement whent the sensor is in the right position.

To do so press the enter button (the middle one) over which the display shows “proceed”.

Now the values are measured continuously. You can now read the current values off the display. The unit is mmHg. The values of the last 15 seconds are displayed as a curve for orientation purposes. Please ask your patient to squeeze in order to create pressure..

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When the patient has applied his maximum pressure let him relax again to see the course of pressure on the display. Is the minimum tone reached end the measurement by pressing the enter button.

Note: The minimum and maximum values are being saved. In practice it turned out to be useful to first measure and document (either by hand or PC) the relaxed and maximum pressure, and then in a second measurement all other functions (e.g. pressure during coughing, pressure over a certain period of time etc.)

IMPORTANT:

During the whole measurement process the position of the sensor must not be changed! When the measurement is finished press the enter button BEFORE you begin to remove the sensor. Otherwise the data can be falsified.

Now you have the option to do a mean value measurement. By pressing “yes” the pressures applied in the next 10 seconds are averaged.

Please see also paragraph 5.2.4 “10 second mean value measurement”

Mean Value	
Averaging 10 sec	
yes	no

If you do not wish a mean value measurement simply press the “no“ button. On the display you can now see the minimum pressure (ARD) and the maximum pressure (AMD) of the current measurement:

ARD:	mmHg
AMD:	mmHg
Mean:	mmHg
Send	New	off
V	V	V

This is the result of your measurement.

To check the result a second measurement can be conducted. Simply press the “new” button.

Please make sure the sensor is in the right position.

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5.2.3 Other buttons and functions

To send the measured data to a PC you have to connect the data cable to the Sphinctometer (you can do it after the measurement or before). If you do not use a PC for data storing please note the values and proceed to the next measurement or switch off the device.

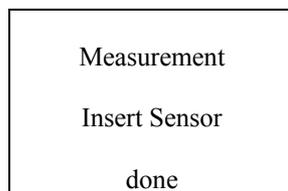
The buttons you can see in the display have the following meaning:

Send PC (Button SENDEN/SEND PC):

Current measured data can be saved on a PC. To do so please use the data cable and the Software "SphinctoDat".
Please see paragraph 8 for more information.

new (Button ENTER):

You get back to the start display and can start a new measurement after pressing the enter button.



off (Taste AUS/OFF):

Pressing this button switches the Sphinctometer off. Please put it back to the desk stand.

If no other measurements are necessary please remove the sensor and the protection hull. For cleaning and disinfecting please see the clean and care paragraph of this manual (10.10)

Important information:

The measurement has to be started and ended while the sensor is in the anus. Otherwise the measured data can be falsified.

Furthermore we recommend to do several measurements to obtain reproducible results. Doing so please check the correct fit of the sensor, again.

You will be familiar with the procedure within short time

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5.2.4 10 second mean value measurement

Subsequent to the normal measurement it is possible to do a 10 second mean value measurement. If you wish to perform such a measurement simply press the “yes” button when the display shows “Mean value 10 sec”

Mean Value	
Averaging 10 sec	
yes	no

All values measured within the next ten seconds are now being averaged. The result is presented in the third line under “Average”.

ARD:	mmHg
AMD:	mmHg
Mean:	mmHg
Send	New	off
V	V	V

Information on the 10 second mean value measurement:

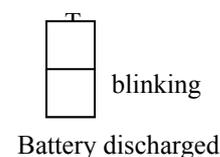
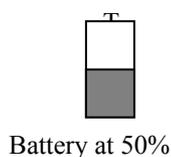
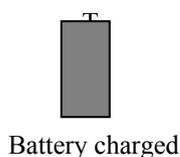
Unusually low values for the rest tonus can have the following cause:

When the patient is asked to relax in order to measure his rest tone he may reflectively detente his sphincter muscles and due to this let the values sink. As the Sphinctometer always takes the lowest value as rest tone it may be useful to do a 10 second mean value measurement in order to get an objective rest tone value

5.3 Charge level and recharging of the battery

5.3.1 Charge level display

You can see the charge level of the battery in the upper right corner.

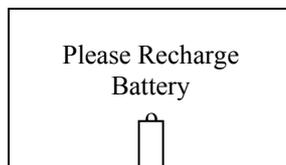


If the battery is discharged the Sphinctometer is no longer operable. The device has to be put back on the desk stand and recharged. It is advisable to keep the device charged. Otherwise it may not be operable for long time use.

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5.3.2 Automatic switch off at discharged battery

When the akkumulator is discharged too much the display will show a notification that charging is necessary and following the device will switch off automatically.



The device is operable again when the battery is recharged.

5.3.3 Recharging the battery

Put the Sphinctometer (or the Sphinctometer- Trainer) on the desk stand when the measurement is finished and the device is switched off. To recharge the device please check if the desk stand is connected to the electric circuit (230V).

Please disconnect the desk stand from the power supply when the Sphinctometer is charged and you are not going to use it in short time. When long time unused the Sphinctometer has to be recharged before reuse.

When the charge control LED (green light) in the lower right corner of the desk stand is on, the Sphinctometer is currently being charged.

Charge control LED

After putting the Sphinctometer on the desk stand the green light in the lower right corner of the desk stand indicates the state of charge.

1. LED blinking: **Normal-charge:** Battery is charged normally.
If the light does not stop blinking within 5 hours and still is discharged the battery is defect.
2. LED shines steadily: **Quick-charge:** Battery is charged quickly.
3. LED blinking: **Battery is charged:** Battery is charged completely.

If the battery is not discharged completely it will recharge in quick charge mode.

Important:

If the light should stay blinking without shining steady for more than 5 hours the device has to be returned to the manufacturer. You can recognize the state of complete dischargement at the almost invisible output on the display.

Possible sources of error when LED does not shine:

- The desk stand is not connected to a 230V electric circuit.
- The Sphinctometer has not been put on the desk stand correctly.

IMPORTANT: Opening the Sphinctometer or the desk stand must only be done by the manufacturer or authorized personel. Batteries must not be taken out or changed by the user.

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5.4 Unit of measurement

The Sphinctometer measures the pressure in mmHg. The following table shows some conversion factors.

Pa (Pascal) = 1 N/m²

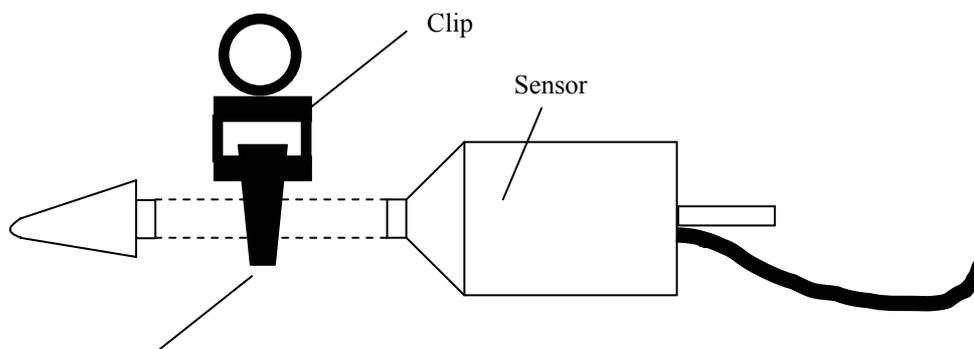
mmHg	10	50	100	150	200	250	300
hPa	13,33	66,66	133,32	199,98	266,64	333,31	399,97
Pa = N/m ²	1333	6666	13332	19998	26664	33331	39997

5.5 Checking the measure function

The Sphinctometer is delivered justified and calibrated. The measure precision is ± 4 mmHg. The high quality mechanical components guarantee properly used a high durability and precision. Nevertheless it is usefull to check the correct function of the Sphinctometer from time to time. To do so please use the enclosed measureclips and compare the measured values with those given in the table (13.7). Is there a high deviation of the values there Is not enough fluid in the sensor. Please refill the sensor as described in paragraph 13.4 “refilling the sensor with water“.

Note: The Sphinctometer-Trainer does not has to be checked, as it is filled with air.

Sketch of the check with the measure clip:



The clip is positioned in the middle of the tube!

Course of control measurement:

1. Check the sensor on air bubbles. Refill water if necessary.
2. The sensor must lie freely, or be in the desk stand.
3. Now switch on the Sphinctometer. Please do not touch the sensor in this phase.
4. Start a measurement with the Sphinctometer.
5. Apply the clip in the middle of the tube during a measurement.
6. Please note down the measured value and compare it to the values given in table 13.7

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The measured value must equal the reference value range within the scope of measure precision given by the manufacturer. **See table (13.7).**

Should there be higher deviations that can not be corrected by refilling the sensor it has to be send back to the manufacturer to be checked. In case of asymmetric sensor tubes there can occur deviations due to sensor position.

The values apply for water and oil filled systems.

The control measurement is meant to debare a malfunction of the Shinctometer and is an optional additional security.

6 Specifics of the Sphinctometer-Trainer

6.1 Trainings device

The Sphinctometer-Trainer is concepted as trainings device for the patient. It allows the patient to do an effective training programme with an included performance check. Easy handling and patient specific programmability through the doctor excel this device.

6.2 Signalisierung zur Unterstützung des Trainings

The trainings device has a yellow light right under the display and a vibration feature. These acoustic and visual signals indicate when the patient has to squeeze and when he can relax. Additionally the display shows a bar which enlarges proportionally to the contraction power. After some training sessions the patient should not concentrate on the bar but on the training process itself. The acoustic and optic signals are ment to indicate the durance of squeezing. The achieved squeeze power remains visible on the display. This sort of training helps to sensitize the patient for his pelvic floor and sphincter muscles.

6.3 Enter the training parameter

The doctor can enter patient specific training parameter.

To do so press the left and the right upper button at the same time, and hold them for about 3 seconds. If you now choose "enter training parameter" and subsequently "manual" you can enter the specific training data.

Another way to enter the training data is by PC. This happens with the help of the software "SphinctoDat" and will be explained in paragraph 8.

Training data that is entered is:

- Squeeze durance / Sec.
- Rest durance / Sec.
- **Training pressure / mmHg**
- Number of squeeze cycles

To enter the training pressure please note:

You have to enter the desired pressure between rest tone and target pressure (100%). Please note that the effective increase of pressure is between rest tone and target pressure.

Example:

- Rest tone: 20 mmHg
- max. contraction power: 70 mmHg
- Trainingszieldruck: 35 mmHg
- **Training pressure: 15 mmHg** This value has to be entered for 100%!

To let the patient train with 50% of his maximum contraction power, what is in this example 35 mmHg **as training pressure 15 is entered.** This is the difference between rest tone and the desired training pressure.

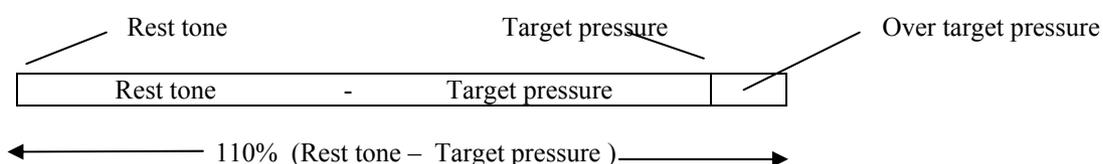
<p style="text-align: center;">SPHINCTOMETER</p> 	<p>Manual</p> <p><i>(waterfilled sensor, except Trainer)</i></p>	<p>MSM ProMedico GmbH Jülicher Str. 338 a 52070 Aachen Tel.: 0049-(0)241-96 82-10 Fax: 0049-(0)241-96 82-122 e-mail: zentrale@msm-aachen.de</p>
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6.4 Training procedure

The training procedure follows this course:

- Connect the sensor to the hand device. (left connector)
- Switch on the device
- Follow the menu
- Stick the sensor in.
- Squeeze and relax according to the given cycle an target value

The device switches off automatically when the training is finished. The instructions given to the patient must be to try to push the bar (which fills almost the complete display when the target pressure is reached) up to the last third. The sketch shows the bar. Pressures a little higher than the target pressure are displayed, too.



The performed squeeze power remains visible throughout the training procedure for orientating purposes.

6.5 Data transfer to the PC

The training parameter can be transferred directly from the patients file to the Sphinctometer-trainer with the help of "SphinctoDat".

Furthermore it is possible to transfer the training log files from the Sphinctometer-trainer to the PC. This allows the doctor to check the training and evaluate the success of the training procedure. Statistics and graphs contribute to cleanliness and allow a good evaluation.

6.6 Brief instruction for patients

Enclosed you will find a brief instruction that shows the most important steps in the course of the training procedure. Apart from that all points you find in the Sphinctometer manual account for the Sphinctometer-trainer. One important feature is that the trainer's sensor is not filled with water, but with air.

The patient has to be introduced to the device by the doctor or an assistant. All relevant points of the manual have to be motioned to guarantee a successful and safe treatment. Especially safety guidelines have to be explained. The patient can get a full length manual if he desires to have one, which does not contain e.g. the programming guidelines.

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6.7 Entering training parameter manually in programming mode

After switching on the device you can enter the programming mode. To do so please press the upper left and right button at the same time and hold it for about 3 seconds.

In the programming mode you see the following displays. (The values are for explanation purposes only)

First you see the number of training session the patient performed. In the second column you see how many sessions have been successful.

Number:	14
positive:	12
done	
V	

Number: 14 14 training sessions have been performed by the patient.
positive: 12 At 12 of 14 sessions he achieved more than 50% of the target pressure (Training target (100%) – rest tone).

With the "done" button you come to the next screen.

Send Training Results ?	
yes	no

By pressing "Yes" the saved data is send to the PC. For more information please see the following paragraph. If no PC is connected please press "no".

"Yes" the saved data is send to the PC

"No" proceeds to the next screen

Enter training data:	
receive	manual
V	V

Now you can choose between:

"receive" If the PC is connected the training parameter can be transferred from the patient's file to the training device.

"manual" If you choose manual input you see the following screen:

Squeeze durance:	6 s	
-	done	+
V	V	V

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By pressing “+” or “-“ the squeeze durance is changed in steps of one second. When the desired squeeze durance is reached please press “done” to proceed.

The other parameters are entered in the same way:

Relax durance:

Relax:	3 s
- done +	
V V V	

Training pressure:

(Target pressure (100%) – rest tone)

Tr. pressure:	50 mmHg
- done +	
V V V	

Please note that the training pressure is the difference between rest tone and target pressure (100%).

Squeeze cycles:

Squeeze cycles:	20
- done +	
V V V	

Finally you can delete the training results that are saved in the trainer:

Delete training results?	
yes	no
V	V

When you are done the device switches off automatically.

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7 Handling of the Sphinctometer-trainers during a training session

7.1 Preparation

Important information for the preparation of a training can be found in the “brief guidelines for the Sphinctometer trainer”, which you find enclosed. It is meant to be given to the patient. After the patient has come to his exercise position an the trainer and sensor is prepared the training can start.

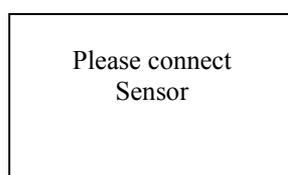
7.2 Switching on the trainer an connecting the sensor

Single use protection and optional attachment clips have to be applied to the sensor. The trainer with the connected sensor is taken off the desk stand. The sensor has to lie freely without any pressure being applied to it. Now the device is switched on with the green “On” button.

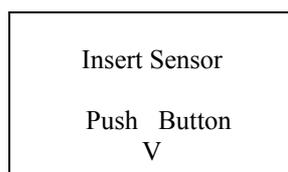
Now the start screen appears.



Now it is checket if the sensor is connected properly.



When the device is ready this screen appears:



Now please insert the sensor. To start press the middle upper button.

Note:

In case the sensor is not found please check if the correct sensor has been connected. To do so please compare the serial number which you find in the packaging note. Furthermore you can try to open the screw top of the sensor for a short time and then close it carefully. If the sensor is still not found please phone our service line.

Note:

After two minutes the device swches off automatically, thus the training should start within those two minutes.

After an automatic switch-off the sensor has to be removed again.

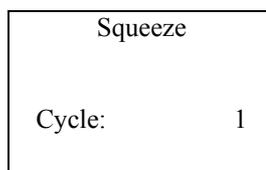
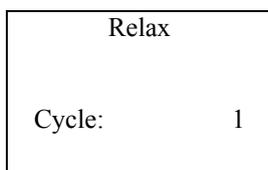
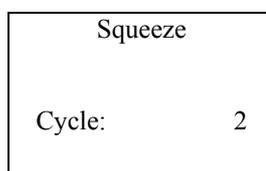
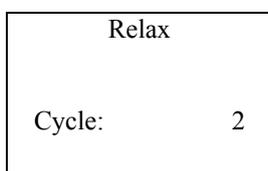
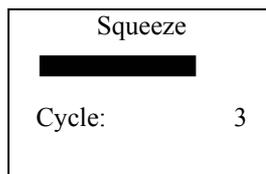
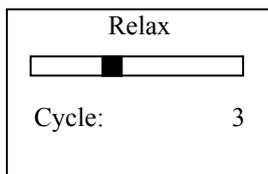
To restart the trainer please put the sensor on a plain surface.

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7.3 Displays during a training session

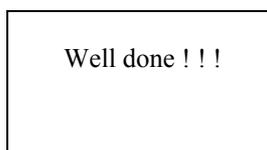
The training session follows the trainings data entered by the doctor. The number of training cycles is displayed and counted down in the course of the training session. Each cycle comprimese of one relax- and one catraction phase. The patient can recognize the contraction phase by the yellow light an the sound. The sound can be turned off as well. To switch it off or on press the speaker button right to the “on“ button.

This is how the last three cycles of a training session look like:



During the relax phase a bar signalises the reached compression. The bar length during the squeeze phase should be more than 50% of the full length. Each cycle fulfilling this criteria is marked a “passed”.

If more than 50% of the trainings cycles were “passed” the display shows a praise before it switches off automatically:



Important:

If a second training session shall be performed at once the sensor first has to be removed from the body as the sensor is calibrated before each session. Again it has to lie on a plain surface.

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8 Using the Sphinctometer/Sphinctometer-Trainer with a PC

8.1 Introduction

The Sphinctometer allows to perform measurements without using a PC. For further diagnostics and to build up a patient database we recommend to use the Sphinctometer with a PC. The Sphinctometer-trainer can also be connected to a PC. Here you can send the training parameter from the patient's master file to the trainer, and in the other direction get the training data of the training sessions the patient performed into your PC database. The trainer can save 200 training sessions with up to 250 cycles that can be transported to the PC at the doctor's. The documentation duty can be dealt with by simply printing the result protocol.

You can perform measurements while the Sphinctometer is not connected to a PC and thus move around freely. Simply connect the cable when you want to transport the measured data to the PC. In normal surroundings the cable length should be enough to use the Sphinctometer stationary.

8.2 Hard- and Software requirements

To use the software you need at least:

- Windows 95/98 compatible PC,
- Windows 95/98 or WIN NT- operating system,
- Software „SphinctoDat“ by MSM,
- Sphinctometer and a data cable for a serial PC connection,
- Optionally: A printer to print the results.

The Sphinctometer is delivered with the data cable for the serial COM-interface of the PC if the software “SphinctoDat” has been ordered.

8.3 Connection to the PC

The structure and installation of the necessary components is very easy.

- First install the Software ”SphinctoDat“ which is located on the floppy-disk.
- Connect the enclosed Cable to the Sphinctometer and the serial COM-interface of your PC
- Connect the sensor to the Sphinctometer.

Start the installation by opening the file “setup.exe” located on the floppy-disk. Now following files are copied to your computer:

- SphinctoDat.exe (Programme file)
- Pat-db.scd (Patient database)

The installation program runs self-reliant. Please follow the notifications and enter the needed data into the window.

Please connect the data cable to the Sphinctometer (right connector) and the Computer (serial COM port).

Please start the program by opening “SphinctoDat.exe“ either directly from the desktop or the explorer. After starting the software you have to fill in which com port you use. To do so please click on => EDIT => SETTINGS and fill in e.g. “COM1” or “COM2”.

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8.4 Menu and symbol bars in “SphinctoDat”

In the menu bar you adjust all necessary settings and execute the different program functions.



You can execute the following actions among others:

Command in the menu bar		Description
File	-Database	
	-New	Create new patient database.
	-Open	Choose and open patient database (patient database contains data of many patients.)
	-Save	Save current database under a current name.
	-Save as ...	Save database under a different (new or old) name.
	-Print	Print database on the connected printer.
	-Seitenansicht	Preview of the printable pages with adjustment options.
	-Install printer	Installation of a printer
Edit	-Settings	Please enter here which COM port you use (COM1 or COM2)
	-neuen Eintrag anlegen	Creates a new patient file in the current patient data base.
	-akt. Eintrag löschen	Deletes the current patient file. Attention: All measurements are deleted!
	-erster Patient	Here you can choose a patient from your patient list. The commands “first patient”, “next entry”, “previous entry” and “last patient” can also be activated with the four arrow keys.
	-Eintrag zurück	
	-Eintrag vor	
	-letzter Patient	
View	-Symbolleiste	Show/hide symbol bar
	-Statusleiste	Show/hide status bar (comment at the window bottom)
	-Patientenliste	Show/hide additional window with the patient list.

Some commands can be activated with the help of buttons placed under the menu bar. Following functions can be activated this way:



Save



New patient file



Delete patient file (ATTENTION: All measurements are deleted!)



Arrow keys to choose patient from the patient list

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Show/hide patient list



Search patient by name



Print patient data (including measurements)

8.5 Entering patient data / Measurements with the Sphinctometer

In general sending measured data from the Sphinctometer to the PC looks like this:

8.5.1 Eintragungen am PC

In the patient database “pat-db.scd“ you first have to create a patient file. To do so please click on this button:



Please enter all needed data into this file. If you created the specific patient file before you can of course open this one. Please use the arrow keys in the symbol bar or the search function.

Pat-db - SphinctoDat

File Edit View ?

msm ProMedico 3/3

Name: test First Name: tester

Date of birth: 01.01.1999 Health Insurance Company: ABC Insurance

Other Data: Insurance Number: 1234567890

Diagnosis:

Measurements:

Number of measurements: 4

No.	Date	Rest Pressure	Anal Maximal Pressure	Tr. Results
1	03. 31. 2006 , 10:55:38	34	147	no
2	03. 31. 2006 , 10:59:08	29	157	no
3	03. 31. 2006 , 11:55:52	60	235	no
4	03. 31. 2006 , 12:33:43	0	0	yes

New Measurement Edit Measurement Delete Measurement

Ready NUM

After clicking “NEW MEASUREMENT” a window called “Measurement” opens. Now you can carry out your measurement with the Sphinctometer.

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8.5.2 Measurements with the Sphinctometer

Now you perform a measurement on the patient. When all data is measured please connect the data cable to PC and Sphinctometer if this did not already happen.

Please click on the “READIN” button. Now the PC waits for about 30 seconds for data coming from the Sphinctometer. You should also see a counter next to the button “READIN” counting down from 60. If you could not transfer any data until this counter reached zero please click „READIN“ again.

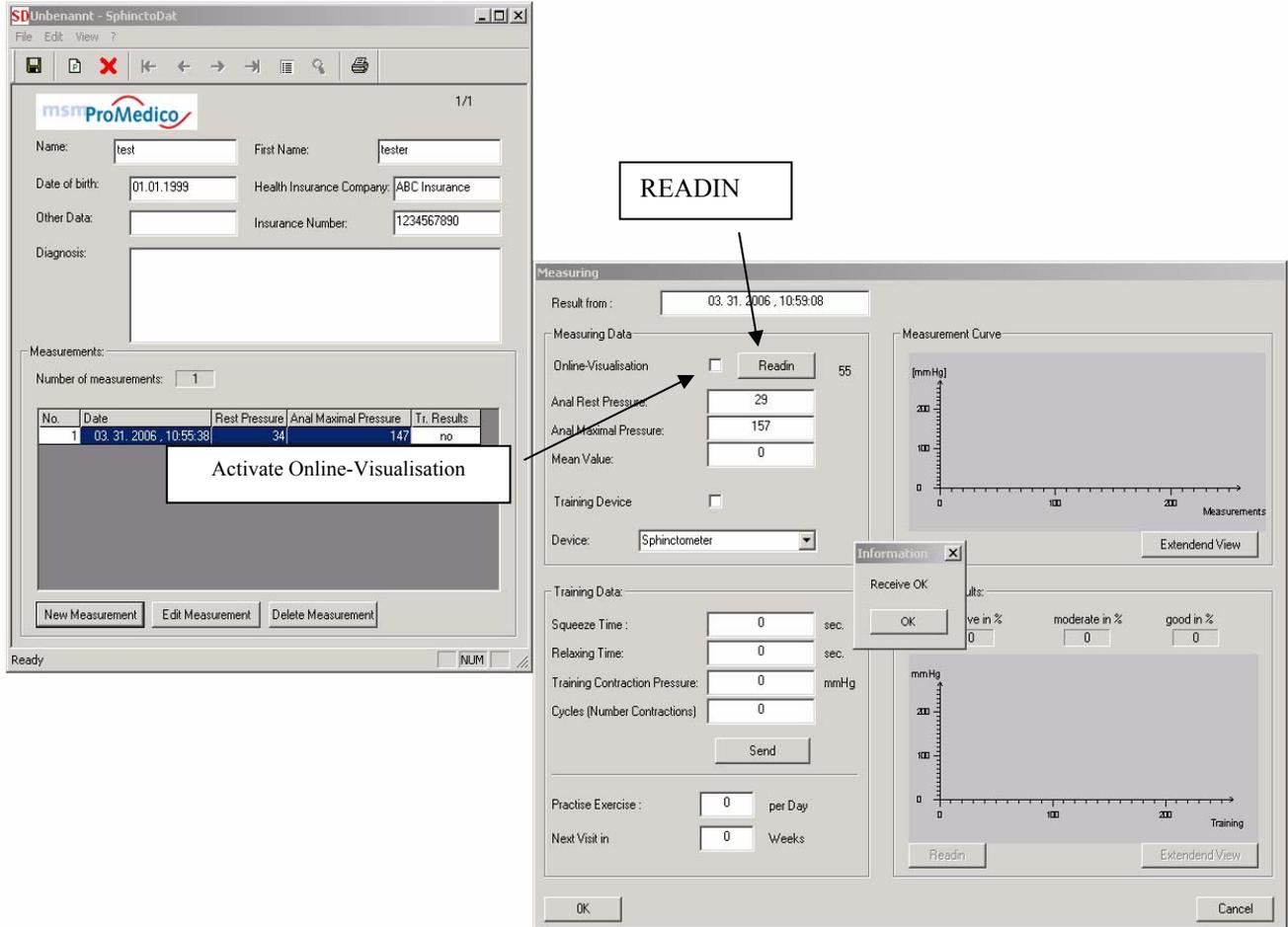
On your Sphinctometer you have to press the “SEND” button after the measurement.

AMD:mmHg		
ARP:mmHg		
Mean:mmHg		
send	new	off	
V	V	V	

8.5.3 Measure data transfer (rest tonus and maximum contraction)

The data transfer is carried out automatically Both PC and Sphinctometer show a notification when the data has been transferred successfully.

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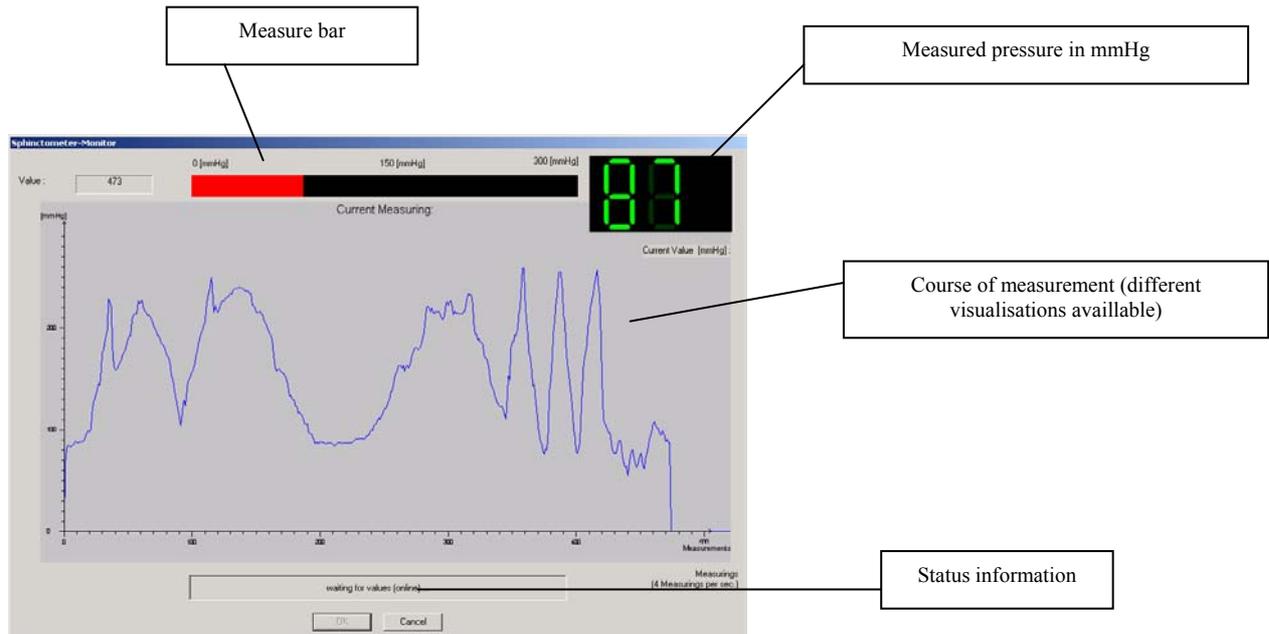


If the current measured data is not useful simply perform a second measurement to overwrite the measured data. Are the measured values ok you can finish the value entry by clicking the “OK” button.

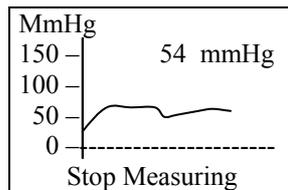
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8.5.4 Tranfering measure data (Online-Visualisation und Kurvenverlauf)

During a measurement you can visualise the values on the PC. To do so please make sure that you activatet “Online-Visualisation” before clicking on “reading”. Please click “reading” next. After starting the measurement on the Sphinctometer you have to can now see the graph of the measured values on the screen. The bar and the number in the upper right corner show the current pressure.



To finish a measurement please press the “Stop Measuring” button on the Sphinctometer.



While the PC ist waiting for the final results you can choose to do a mean value measurement on the Sphinctometer.

Mean Value	
Averaging 10 sec	
yes	no

ARD:	mmHg
AMD:	mmHg
Mean:	mmHg
Send	new	off
V	V	V

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When you finished measuring please press “send“ on the Sphinctometer. The PC monitor will show a notification that the data has been transferred successfully. You can finish the data transfer by clicking “Ok” If you want to perform further measurements please press “new” on your Sphinctometer. The procedure is now the same.

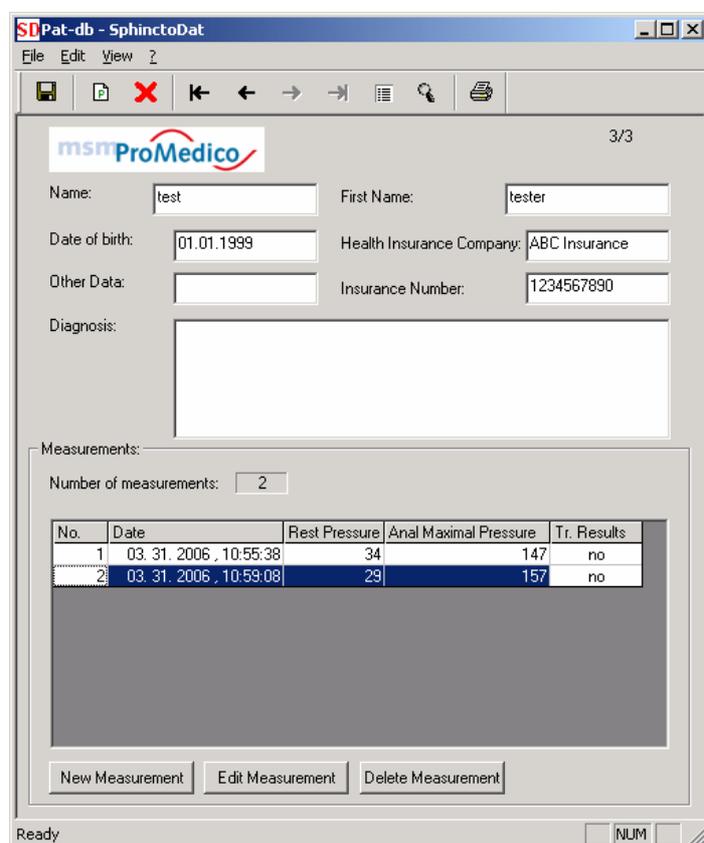
8.5.5 Editing measurements

Click on a measurement in the lower subwindow.

For better orientation the data base entry are marked by:

- Running numbers
- Date of measuring resp. date of data transfer
- Rest tonus and maximum Contraction force
- Availability of training results (yes/no)

To edit a measurement simply double click it, oder click “Edit Measurement”.



Above: Patient file

The button “Delete Measurement” allows you to delete the selected, or the active measurement.

Attention: Please do not mix up this delete function with the command “delete current patient” which deletes the current patient file including all measurements!

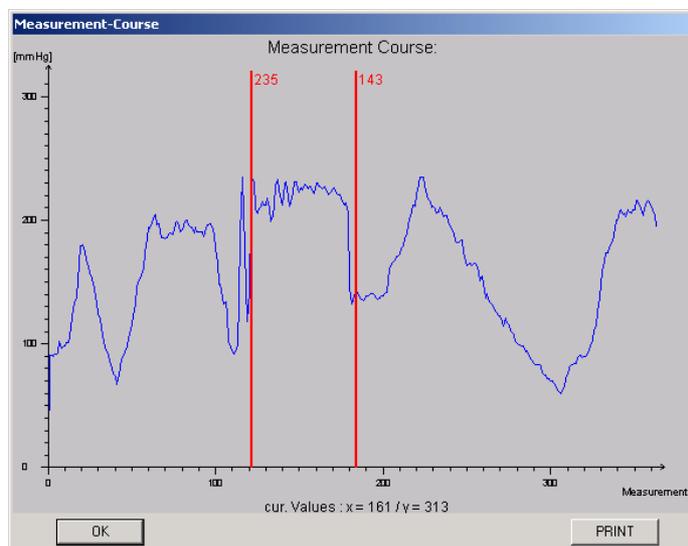
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8.5.6 Analysis and graphical display of the course of pressure

You can open and analyse any saved measurement at any time. If the values have been recorded in the online visualisation mode you will also see the course of the measurement. To open a certain measurement please select it in the patients file and click on “Edit Measurement”.

To get a better impression of the measurement course please click on “Extended View”. You can now read off any value with the help of the mouse. If you move the mouse to a specific point in the graph you will find the current values displayed under the x-axis named “Measurements”. The pressure value in mmHg can be read off the y-axis. Another feature are the red bars which help you reading of the exact values. Please double-click on the desired position a little below the x-axis and a red bar will appear. You can grab it with the left mouse button and move it to any position you want. If you should need a second bar please proceed as before.

To zoom in grab one corner of the window and stretch it until it serves your needs. To move the window grab it at the bar at the top (next to “Measurement-Course”).



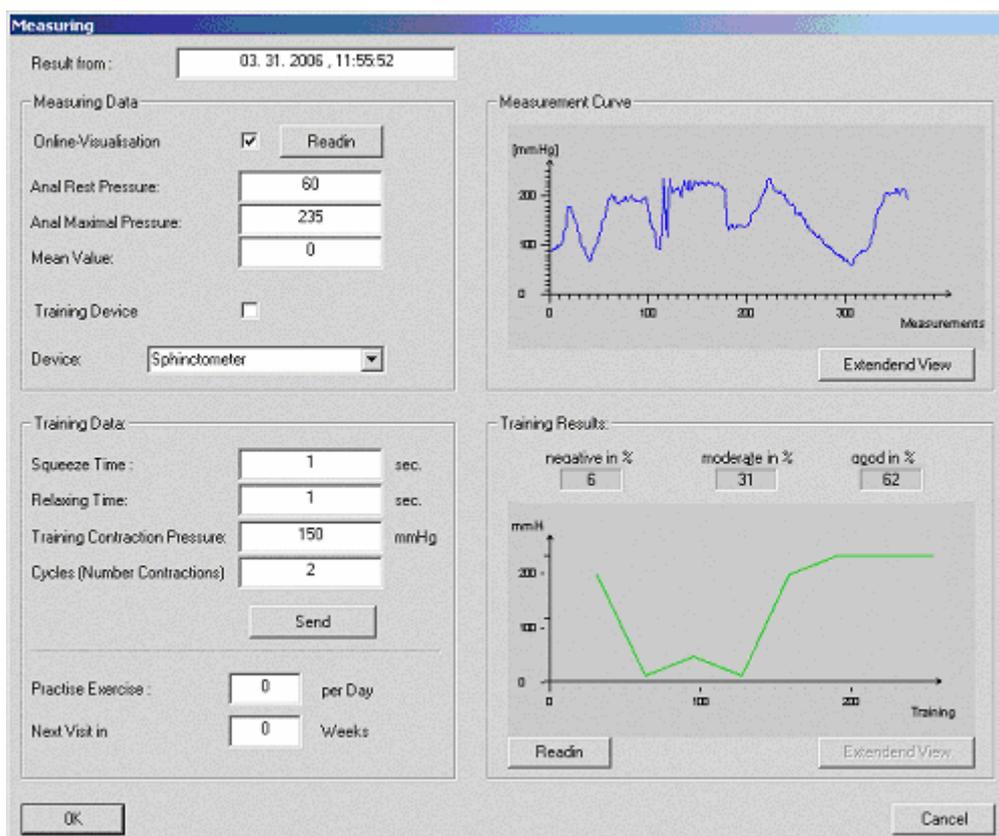
The next paragraph will inform you about the possibilities the Sphinctometer-Trainer offers to you.

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8.6 The Sphinctometer-Trainer connected to the PC

8.6.1 Data of the Sphinctometer-Trainers on the PC

If you select and edit a measurement you will see the data recorded in the specific measurement. The lower part of the window is used for the Sphinctometer-Trainer entries. On the left side the doctor can enter the training parameter, while the right side displays the training results.



The screenshot shows a software window titled "Measuring" with the following sections:

- Result from:** 03. 31. 2006, 11:55:52
- Measuring Data:**
 - Online-Visualisation: **Readin**
 - Anal Rest Pressure: 60
 - Anal Maximal Pressure: 235
 - Mean Value: 0
 - Training Device:
 - Device: Sphinctometer
- Measurement Curve:** A line graph showing pressure (mmHg) over time (Measurements). The y-axis ranges from 0 to 200 mmHg, and the x-axis ranges from 0 to 300 measurements. The curve shows several peaks and troughs. A button "Extendend View" is at the bottom right.
- Training Data:**
 - Squeeze Time: 1 sec.
 - Relaxing Time: 1 sec.
 - Training Contraction Pressure: 150 mmHg
 - Cycles (Number Contractions): 2
 - Send** button
 - Practise Exercise: 0 per Day
 - Next Visit in: 0 weeks
- Training Results:**
 - negative in %: 6
 - moderate in %: 31
 - aged in %: 62
 - A line graph showing pressure (mmHg) over time (Training). The y-axis ranges from 0 to 300 mmHg, and the x-axis ranges from 0 to 200 training. The curve shows a sharp drop followed by a rise and then a plateau. Buttons "Readin" and "Extendend View" are at the bottom.

At the bottom of the window are "OK" and "Cancel" buttons.

The training device Sphinctometer-Trainer is connected to the PC in the same way as the Sphinctometer. The data connection allows you to transfer the training parameter from the PC to the device, and on the other way the training results from the Device to the PC.

8.6.2 Sending training parameter to the Sphinctometer-Trainer

The patient specific training parameter can be transferred with the PC-Software „SphictoDAT“ from the PC to the „Sphinctometer-Trainer“. The following data is transferred:

- Squeeze durance /s
- Relax durance /s
- Training goal /mmHg (= Zieldruck – Ruhetonus, zur Einstellung s. Abschnitt 6.4)
- Number of training cycles per training session

The picture above shows the window where the data is entered (lower left part).

To carry out the data transfer please select “receive” when you are asked to enter the training data in the programmers mode in the Sphinctometer trainer.

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Enter training data:

Receive	manual
V	V

Note: To get into the programmers mode please press the upper left and the upper right button at the same time shortly after you turned the device on.

When the Sphinctometer trainer is ready to receive the training data please click the send button. There will be a notification on the PC that the data transfer was successful if everything was done correctly:

8.6.3 Transferring the training results to the PC

The data transfer from the Sphinctometer-trainer to the PC is quite similar. You will find a screen showing “send training results“ in the programmers mode of the Sphinctometer-Trainer. By pressing yes the data transfer to the PC is started.

Send training results ?

yes	no
-----	----

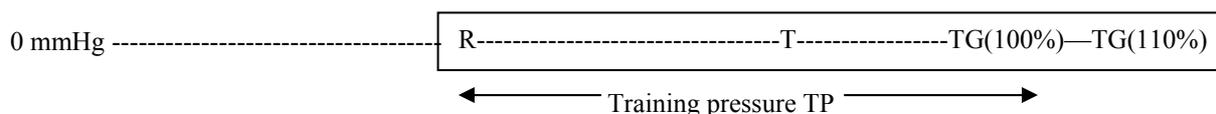
Now please press the “readin” button on the PC. Shortly after this there should appear a notification that the data transfer was successful.

Please make sure that you associate the training results to the right measurement by selecting the correct one before transferring the training results.

8.6.4 Analysing the training results on the PC

The results are visualised in a graph. The results are subdivided in three classes. The criteria is the achieved pressure during the squeeze procedure.:

Classes:	Good:	$T > 75 \% \times TP$
	Moderate:	$T > 40 \% \times TP$
	Bad:	$T \leq 40 \% \times TP$

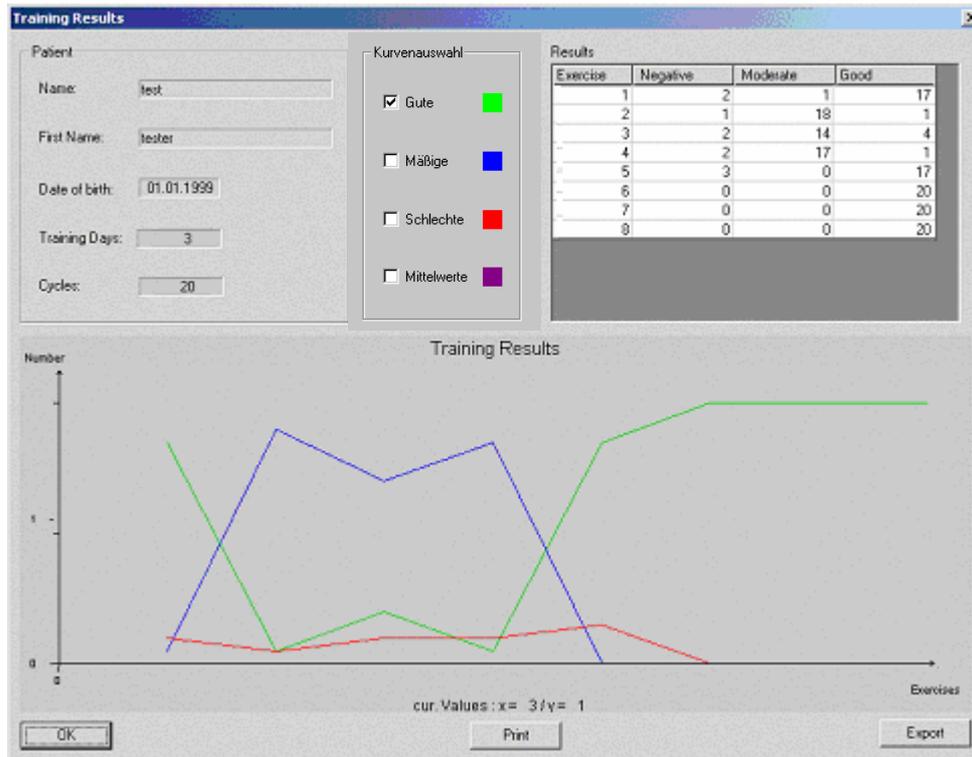


T = Achieved training pressure (Difference to the rest tonus)
 R = Rest tonus
 TG(100%) = Training goal (100%-Value of the bar in the display)
 TP = Training pressure (entered parameter = effective measured pressure = TG(100%)– rest tonus R)

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Remember: TP = entered training goal parameter for the Sphinctometer-Trainer.
The parameter TP is the difference between the measured Value TG(100%) and the rest tonus R

The result of this evaluation is displayed on the PC monitor.
If you click on “extended view” a new window will open where you can differentiate the training result more exactly.



Picture: Graph showing the training results. Differentiation according to the three classes (good, moderate and bad)

The extended view shows how successful the different training sessions were. You can also choose which classes are displayed.

The value training days is calculated automatically. It shows the time difference between the doctor’s measurement and the incoming data from the Sphinctometer-Trainer.

This function gives a survey over the period of time the training results have been achieved.

8.7 Printing the results for documentation

To document the measured values you can print the patient files. Please press the print button in the symbol bar or use the extended view function in the menu. Now you can change several setting e.g. high or horizontal format, choose pages etc.

On your print-out you will find the measurements you performed as well as the training results. Also the course of measurement will be printed if the measurement has been carried out and saved in online mode.

SD pat-db.scd - SphinctoDat

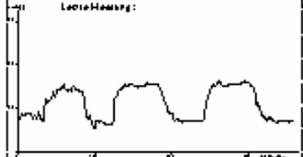
Drucken Nächste Vorherige Zwei Seiten Vergrößern Verkleinern Schließen

by Handelt

Name:	M Villa	Vorname:	Toni
Geburtsdatum:	18.02.22		
Krankenkasse:	B IKK	Versicherungs-Nr.:	1234567890
Stamm-Nr.:	12345		
Diagnose:	wertlos		

Messdaten:

Nr.	Messzeit	SD [min]	SD [max]	Markierung	Tätige Zeit	Inaktiv Zeit	Ergebn [min]	Ergebn [max]	Ergebn [avg]	Ergebn [std]	Ergebn [err]
1	24.02.2006, 10:09	75	130		22	3	2	26	56		
2	22.03.2006, 15:08	75	119		22	3	6	26	116		
3	25.03.2006, 06:06	6	6	nicht verfügbar	nach	6	6	6	6	nicht verfügbar	
4	28.03.2006, 18:16	16	150		22	2	*	26	116		
5	31.03.2006, 19:18	*6	163		22	2	*	26	166		

Leistungsleistung: 

Leistungsleistung: 

Unterschrift: _____

Seite 1 NUM

The documentation print out contains:

- Patient data (Name, insurance number, ...)
- Diagnosis
- Measured data (including date of measurement)
- Graphic of the course of measurement
- Training data
- Course of last measurement (left graph)
- Last training results (right graph)
- Space for signature

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9 Important notifications

9.1 Permissible device combinations

The device Sphinctometer/-Trainer and the sensor are delivered as a unit and must only be used in this combination, as the device is calibrated for this specific sensor. Using other sensors than the one delivered with the device will lead to false measure data.

Both device and sensor have a serial number which must correspond. The two serial numbers are the same except the two letters at the end.

Example: Device STM-0001-G is run with the sensor STM-0001-A or STM-0001-V.

Enclosed you find a table (13.7) which is designed specially for your device.

Important note: Water filled sensors must not be filled with oil or vice versa.

9.2 Single use protection and lubricant

As protection latex hulls for ultrasonic sensors can be used (e.g. by the company MAPA, Zeven, Art.-Nr. 11.150.023) or other fitting protection hulls used for analtonometrie. In case of latex allergy silicon hulls can be used as well (Acquireable at the company Medesign GmbH, Partnachplatz 7, 81373 Münschen).

At proctological (analtonometrie) use we recommend Recto-Lyss as lubricant. Used vaginally we recommend Gyn-Lyss empfohlen (both by Medesign).

In case of skin irritation or a rejection by the patient vaseline or water can be used as well.

9.3 Operating conditions

The Sphinctometer and all associated components are designed for indoor-use only. Please keep the device away from highly flammable substances. The sensor may be cleaned with hot water and cleaning substances that are hand neutral. Antiseptics for endosonographical devices may be used as well. Please make sure to keep the connector dry during the cleaning process. Please use easy approachable sockets only.

9.4 How to handle damaged devices

In case of damage, corrosion, or wearout of housing, cable or other parts of the Sphinctometer the device must not be used any longer to avoid disfunction and potential dangers. Especially if connectors or cables are damaged practise is not safe anymore. Please make sure to disconnect the power supply of the desk stand in such cases. A damaged device has to be returned to the manufacturer.

9.5 Steady non reproducable control measurements

In case of a negative control measurement, or obvious mismesurements that do not result from wrong use please contact manufacturer. Please dicribe the state, the storing conditions and other remarkabilities.

9.6 Battery care and exchange

To keep the battery intact it has to be recharged from time to time if the Sphinctometer is not used for a longer period. The battery must only be changed by the manufacturer. Opening the house leads to expiration of the warranty.

Please keep the battery away from children. At annual inspections the battery is checked and changed if necessary.

9.7 Protection off heat sources and electromagnetically sensitive devicec.

Storing the Sphinctometer/Sphinctometer-Trainer above heat sources (e.g. heater) should be avoided for reasons of wearout and disfunction. Please do not store the device in the direct sunlight. Cleaning the housing with hot wet cloth is possible in case the interior electronic components do not get warmer than 50°C. The device must in no case be immersed in water!

Important:

The sensor element is located in the handle of the sensor. It is encapsulated from the environment so that hot water may be used for a short time to clean the outer sensor.

Inside the sensor the measuring unit is hardly proteced, so refilling must only be carried out with room temperature water.

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The device is manufactured with a permanent magnet. Please make sure that no electromagnetically sensitive devices are around (e.g.: floppy discs, electric devices, check cards...). Please keep all devices away from children.

9.8 Contra indicators

Performing measurements is interdicted in following cases:

- Rotundity or injury of the anus or vagina area.
- Danger of irritation of polyps, tumors or Gefahr der Reizung oder Verletzung von Polypen, Tumoren, ggf. offene innere/äußere hemorrhoids,
- Incompability to the patient (e.g. in size)

In any case the doctor has to evaluate if the Sphinctometer is applicable.

9.9 Side effects and risks

For the exception of the cases listed under contra indicators (10.8) using the Sphinctometer/-Trainer is not dangerous for the patient. Side effects are not known. In case of harmful interactions the manufacturer has to be informed.

If there are loose parts especially at the sensor the Sphinctometer must not be used. In general the components are not dangerous.

9.10 Clean and care

The Sphinctometer/-Trainer can be cleaned with a wet cloth and detergents. Please dry the device before reuse. The device must not be held under running water. High air humidity can damage the device. Please do not use aggressive antiseptics.

The sensor may be cleaned with hot water and cleaning substances that are hand neutral. Antiseptics for endosonographical devices may be used as well.

Antiseptics must be proper for plastics.

Usable disinfectants are e.g.:

- Desonite by Merz&Co. Hygieneartikel, 60318 Frankfurt,
- or the following two substances by Dr. Schumacher GmbH, 34201 Melsungen:
- DESCOSEPT,
 - Perfektan Endo

Warning:

The electric connectors must be kept dry. Corrosion can lead to disfunction and malmeasurements. Furthermore heat can cause severe damage (see paragraph 10.7)

9.11 Control measurements

Please perform control measurements regularly (e.g. once per month). Please see paragraph 5.5 for further information.

9.12 Check by manufacturer

Sphinctometer/-Trainer are affected by natural wearout effects. To keep the device in good condition please send it in for a general check once per year. Worn out components are exchanged at this opportunity. Please use the original cartilage and please fill in the delivery note including the disinfection confirmation. Please inform about the current fees.

9.13 General safety guidelines

If there is a suspicion about damage or disfunction of the device please send it back to the manufacturer before using it again.

9.14 Dispose guidelines

To dispose the device please pay attention to the local rules for electronic waste. Sending the device back to the manufacturer is possible as well.

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Batterys must not be disposed in the trash, but be given back to the reseller or manufacturer. This applies for both Sphinctometer and Trainer.

10 Warranty/Certificates

10.1 Warranty and liability

The manufacturer gives a warranty of 24 months in case of proper use. Damage caused by leaking batteries or use of an external power supply as well as intervention on the device by non authorized personel cause an expiration of warranty.

A liability for any damage caused by faulty software or its application is debared. Non proper use debares any kind of liability and warranty. Liabilities of deliverers remain unaltered.

As area of jurisdiction it is herewith agreed on Aachen

10.2 CE-Sign

Sphinctometer/ –Trainer have undergone an EG-check according to 93/42/EWG for medical products (appendix. IV). The check of the device has been performed by: RWTüV Essen.
You will find the certificate enclosed.

11 Technical information

11.1 Function and structure

Battey mode:	Sphinctometer and Sphinctometer-Trainer operate in battery mode. The battery is recharged in the desk stand.
Power save function:	existent
Display:	fluid crystal-grafic-Display
Sensorunit:	Piezo-pressure sensor element Measure sensor with water/oil filling (Doctor’s device) Measure sensor with air filling (Training device)
Housing material:	Sphinctometer: ABS
	Sensor: Silicon-tube Stainless steel POM (Polyacetal) Interior silicon sealing agent Interior rubber gasket
Appurtenance:	PC data cable (serial) Software „SphinctoDat“ for patient specific data storing

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11.2 Technical data

Measure precision:	Doctor's device:	± 4 mmHg
	Trainer:	± 6 mmHg (± 10 mmHg if values are < 30 mmHg)
	Bar display (Trainer):	± 10 mmHg
	Range of bar display: Difference:	(110% Training goal – rest tonus)
Measure range:	0 to 300 mmHg (Doctor's device)	
	0 to 250 mmHg (Trainer)	
Nominal voltage:	230 V~/ 12 V DC (Power supply unit)	
Power supply:	Integrated NiMH-Akku (9,6 V)	
	Power supply unit (12 V DC) (desk stand)	
Protection class:	III, II with power supply unit	
Kind of protection:	masked	
Sensor:	Typ BF	
		
Store temperature:	5 – 40 °C	
Working environment temperature:	20 – 40 °C	
Air humidity:	35-80 %, Sensor: 100%	

12 Manufacturer/Reseller

12.1 Manufacturer

If nothing else is given the device has been manufactured and sold by:

MSM ProMedico GmbH
Jülicher Str. 338 a
52070 Aachen

CE0044

12.2 Reselling / maintenance/ sending back

12.2.1 Sphinctometer (doctor's device)

The Sphinctometer is delivered to surgeries, clinics etc as a diagnostic device. For maintenance the device has to be returned to the manufacturer where it will be checked, and if necessary repaired or exchanged.

12.2.2 Sphinctometer-Trainer

The Trainer is send to the doctors' when prescribed, where it is handed over to the patien for the period of rent. When the period is over the device and all appurtenance has to be returned to the manufacturer where it will be checked. The ensures a proper disposal of the components

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12.2.3 Appurtenance

The Sphinctometer/ -Trainer is delivered with:

- Sensor A or sensor V
- Desk stand with power supply
- Starter pack protection hulls
- Lubricant (Tainer)
- Controle kit
- Manual incl. Brief instructions

Optional available:

- PC-Software „SphincDat“
- PC data cable

12.2.4 Rent devices

Rented devices have to be handled proper and with care. The remain in possession of the manufacturer and have to be returned after the stipulated period. Sensors remain in possession of the patient

12.2.5 Returning used or defect devices

If a device is defect or not used anymore it has to be returned to the manufacturer. In case a new device is ordered th desk stand can remain at the doctors’.

Should a new sensor be needed the device and the sensor have to be returned.

The patient will receive a new device that will be send to the doctor who has to check on the training data, promptly.

Note: **Please use the original cartonage for return and fill in delivery note and disinfection confirmation**

12.3 Serviceline

If you have any questions that can not be answered by this manual feel free to phone us: +49-241-96 82-10

12.4 Declaration of conformity by manufacturer

12.5 Certificate (EG-check) by RWTüV

12.6 Brief instructions on the Sphinctometer (Doctor’s device)

12.7 Brief instructions „refilling the sensor with water“

12.8 Brief instructions on the Sphinctometer-Trainer (enclosed if applicable)

12.9 Manual Sphinctometer-Trainer (enclosed if applicable)

12.10 Value table (separate paper)