

REF. 700020 / 700021 REF. 800140 / 800160





USER'S MANUAL



ENI

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IMPORTANT SAFETY INFORMATION

Before using the device, carefully read through this manual in order to become familiar with the operating instructions.

1. Device and contents of packaging

When opening the cardboard box, check that all the items listed below are included and that none of them is damaged (also check the item code for future re-orders and replacements):

- 1 No. THD Anopress user manual (REF.370072)
- . 1 No. Electrical safety test report
- 1 No. THD Anopress Apparatus (Fig. 1 REF.700020 and 700021)
- 1 No. USB Memory key (Installation software and software manual) REF.760001
- 1 No. Bluetooth Dongle REF.320046
- 1 No. 12 V Power supply unit (battery charger) (REF.3621ST) and adaptors for electrical connection (5 types)
- 1 No. THD PressProbe Fig.1 (REF.800141)
- 1 No. Pressure control accessory

2. Description

THD Anopress is an apparatus which assesses average sphincter tone and is used together with the THD Press Probe.

THD Anopress may be used in conjunction with a PC to record patient details and examination results. For this purpose, the PC requires installation of a dedicated program and the insertion of the Bluetooth Dongle accessory into the USB port. For minimum PC hardware requirements, see the THD Anopress software handbook.

3. Technical Data

Manufacturer	THD S.p.A Via Industria 1 - Correggio - ITALY			
Electrical characteristics				
Power supply voltage	7.2 V provided by 6 internal 1.2 V 1200 mAh NI-MH batteries			
Max. current absorption (during battery recharging)	1A			
Protection fuse	3000 mA internal, self-resetting			
Display	3.5", colour TFT, 320x240			
Power drawn at 230 V	12W (during battery recharging)			
Dimensions	210 mm x 180 mm x 70 mm			
Weight of device	400 grams			
Electrical characteristics of the battery charger				
Power supply voltage	100-240 VAC; 50/60 Hz			
Max. current absorption	0.3 A			
Output voltage	12 VDC			
Max. output current	1 A			
Permitted environmental conditions				
Operating	Temperature: from 10°C to 30°C (see note)			
Humidity:	max. 70% Rh at +30°C			
General:	Out-patient surgery			
Storage				
Temperature:	From -5°C to 40°C			
Humidity:	max. 70% Rh at +30°C			



Electro-medical features			
Device type	Risk category: IIa (according to 93/42/EC)		
Part Applied	BF type (according to IEC 60601-1)		
Insulation	Category II (during battery recharging) Internal power supply (during operation)		
Protection rating against liquids	IPX0 (according to IEC/EN 60529)		
Use in the presence of inflammable gases	No		
Directions for use:	Continuous operation		
Basic performance features			
Measurement frequency	From 0 to 240 mmHg		
Accuracy	±10 mmHg (see note)		
Max. pressure allowed	390 mmHg		
Introducer-probe			
Diameter	16 mm		
Sensitive length (total)	50 mm (165 mm)		
Line length	1000 mm		

N.B.: The measuring accuracy falls if the ambient temperature is outside the specified range: if the THD Anopress device is left for long periods in environments outside these temperatures, wait at least one hour before use.

4. Immunity and electromagnetic emissions

Aspects of emissions				
Emissions test	Compliance	Electromagnetic environment - guidelines		
RF emissions Cispr 11	Group 1	The THD Anopress uses RF energy only for its internal operation. Therefore, its RF emissions are very low and not likely to cause interference in nearby electronic equipment.		
RF emissions Cispr 11	Class B	The THD Anopress is suitable for use in all buildings outside the home and not connected to a low voltage mains electricity supply for home use. However, the device can be used at home and in buildings connected to a low voltage mains electricity supply for home use, providing they comply with the following conditions: WARNING: this equipment should only be used by qualified medical personnel. This equipment can cause radio interference and disrupt the operation of nearby equipment. It may be necessary to adopt measures to attenuate the signal, such as facing the equipment in a different direction or relocating it or its connecting wires, or shielding the location.		
Harmonic emissions, IEC 6100-3-2	Class A Compliant	The device can be used in all buildings, including at home and in buildings connected to a low voltage mains		
Voltage fluctuations / Flicker emissions IEC 61000-3-3	Compliant	electricity supply for home use.		

Issues of immunity

The device has been designed for use in an electromagnetic environment as specified below. The customer or the user of the device should ensure that it is used in such an environment.

Immunity test	Test level EN 60601-1-2	Compliance level	Electromagnetic environment - guidelines
Electrostatic Discharge (ESD) EN 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Burst/Fast Transients EN 61000-4-4	±2 kV on power supply lines	±2 kV on power supply lines	Power supply lines should have features characteristic of a typical commercial or hospital environment.
Surge EN 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Power supply lines should have features characteristic of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines, EN 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycles 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycles 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 25 cycles	Power supply lines should have features characteristic of a typical commercial or hospital environment. If the device user requires continuous operation during power outages, a UPS unit should be used
Magnetic field at grid frequency EN 61000-4-8	3 A/m	3 A/m	Mains frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.

RF immunity aspects

The device has been designed for use in an electromagnetic environment as specified below. The customer or the user of the device should ensure that it is used in such an environment.

Immunity test	Test level EN 60601-1-2	Compliance level	Electromagnetic environment - guidelines		
Conducted RF EN 61000-4-6	3 Vrms from 150 kHz to 80 MHz	3 Vrms from 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used to place to appropriate of the		
Radiated RF EN 61000-4-3	3 Vrms from 80 MHz to 2.5 GHz	3 Vrms from 80 MHz to 2.5 GHz	be used no closer to any part of the device, including cables, than the recommended distance calculated from the equation applicable to the frequency of the transmitter. Recommended distances are as follows: d = 1.2 ⋅ √P from 150 kHz to 80 MHz d = 1.2 ⋅ √P from 80 MHz to 800 MHz d = 2.3 ⋅ √P from 800 MHz to 2.5 GHz where P is the maximum output power of the transmitter in Watts (W) as specified by the transmitter manufacturer and d is the recommended separation distance in metres (m).		

The field strengths from fixed RF transmitters, as determined by an electromagnetic survey of the site, could be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: ((v))

Recommended distance between portable and mobile RF communications equipment and the THD Anopress device

The device has been designed for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Anopress, as recommended below, according to the maximum output power of the radio communications equipment.

Rated maximum	Separation distance at the transmitter frequency			
output of transmitter (W)	From 150 kHz to 80 MHz d = 1.2 · √P	From 80 MHz to 800 MHz d = 1.2 · √P	From 800 MHz to 2 GHz d = 2.3 · √P	
0.01	0.12	0.12	0.23	
0.1	0.38	0.38	0.73	
1	1.2	1.2	2.3	
10	3.8	3.8	7.3	
100	12	12	23	

For transmitters with rated outputs not mentioned above, the recommended separation distance d in meters (m) can be calculated using the equation applicable to the frequency of the transmitter, where P is the maximum rated output power in watts (W), as specified by the manufacturer.

N.B.:

(1) At 80 MHz and 800 MHz, the higher frequency range applies.

(2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

5. Limited Warranty

THD S.p.A. guarantees the product against manufacturing defects and failure to meet the technical specifications set out in the documentation included with the device.

If the product malfunctions during the warranty period, the equipment will be repaired by THD S.p.A. at its expense.

The warranty does not cover damage caused by improper use, negligence, improper maintenance or failure to carry out maintenance as specified in the manual, changes to the equipment carried out by unauthorized personnel or the use of the equipment in inappropriate ambient conditions.

Duration of warranty: the warranty is valid for 12 months after the date of purchase.

To access support services (updating of software, additional languages, FAQ, etc.), register the device on the website: www.thdanopress.com.

6. Installation

The THD Anopress device is factory tested before delivery and the batteries are charged; however, complete recharging is recommended before using the device. To guarantee the safety of the device, only use the battery charger supplied.

THD Anopress requires special caution in relation to EMC, and it must be installed and readied for operation in compliance with the information on EMC set out in the Section "Immunity from electromagnetic emissions".

7. Intended use

The Anopress device must be used exclusively to assess the average sphincter tone due to the pressure exerted by the muscles in the anal canal on the specially designed THD Press Probe. THD AnoPress should only be used by fully trained medical personnel.

8. Environment of use and operating environment

The THD Anopress device and relative probe may be used in outpatient departments, hospitals or care homes. It does not require particular visibility conditions; just the normal lighting present in an outpatient type working environment.

It does not require particular conditions of humidity, ambient pressure, background noise pressure: just the normal conditions present in an outpatient type working environment.

The instrument is designed to be rested on a surface positioned less than a metre from the patient and the operator and within 5 metres from the PC on which the software is installed.

9. Staff authorised to use devices

The operator must be a doctor skilled in the field of general surgery and coloproctology (Proctologist, Surgeon, etc.).

The operator must have good enough vision to correctly interact both with the device and the software.

The operator must be suitably trained on the use of THD Anopress and the relative accessories.

Contraindications

Take special care using THD PressProbe where the mucous membrane is impaired. Paediatric patients

11. Limits of use

Uses other than those specified for the Intended Use.
THD Anopress must not be used for patients under the age of 14.

12. Complications

None

13. Warnings

- Read this technical manual before carrying out any operation with the device. Use the THD Anopress
 device in compliance with the instructions set out in this manual.
- Allow THD Anopress to be used only by fully trained, authorized personnel.
- The patient should normally be positioned on a horizontal bed with the part of the anatomy to be examined in the field of vision of the operator.
- Only use when ambient conditions are complied with. Specifically, use outside the specified temperature ranges may affect the measurement accuracy beyond the specified tolerance.
- Do not use high-frequency equipment (electronic instruments, cell phones, X-rays, transmitters, etc.) or
 portable/mobile radio communication equipment near the device: they could result in poor operation of
 the device. Do not use the device near to or above other equipment. If the device must be used near to or
 above other equipment, it should be monitored closely to ensure proper functioning in the configuration in
 which it is being used. After an electrostatic discharge, the device could switch off. Switch the device back
 on and repeat the measurements.
- The device can be used for examinations while the batteries are recharging. To recharge batteries, only use the battery recharger provided when asked to do so by a message on the display.
- Be extremely careful when handling the THD Anopress device and the measurement THD PressProbes, preventing them from knocking against any objects.
- Make sure the measurement THD PressProbe is properly connected to the Luer-Lock attachment of the THD Anopress before use on a patient.
- Do not inject liquids or gases other than air into the THD PressProbe or the connector of the THD Anopress device.
- There are no parts inside the device which can be repaired by the user: do not try to access internal parts
 for any reason; this invalidates the warranty.
- · It is recommended to apply a thin film of gel on the THD PressProbe before use.
- THD PressProbe is disposable: do not re-use the same THD PressProbe on different patients.
- Do not use solvents for cleaning purposes.
- Use only original introducer-probes and THD accessories.
- The THD Anopress device should be used solely for the purposes for which it was designed. Be
 particularly careful in the event of a ruptured mucous membrane.
- The THD Anopress device cannot be used as a sphygmomanometer!
- The liquid contained in the batteries is extremely corrosive and can cause burns or other skin lesions. If spilt on the skin, wash with plenty of running water and contact a doctor immediately. Do not touch the eyes with the hands or any part that has made contact with battery liquid.
 Do not use in oxygen enriched atmospheres.
- Position the device so that disconnection is easy, since the plug is the means of disconnection from the mains supply.

14. Directions for use

· Not connected to a PC

- Connect the THD PressProbe via the dedicated Luer-Lock connector to the THD Anopress attachment and screw in completely without overtightening (Fig. 2).
- Switching on the THD Anopress device: hold down the pushbutton for a few seconds (Fig. 3). The operation is confirmed by a buzzer and the appearance on the display of the THD logo; after the switch-on sequence, the "Probe authentication" message is displayed.
- Take the Probe Card included in the THD PressProbe package (Fig. 1) and fit it, by the shorter side, into the slot on the right of the display (Fig. 4). The device is now ready for the examination: the display shows a pressure diagram and the message "START inflating" (Fig. 5).
- 4. Press the START pushbutton (Fig. 5) to start inflating the THD PressProbe. The message "Inflating ..." is shown on the display. The numerical indicator and pressure diagram rise to a set pressure. When this pressure is reached, the message "Stabilization..." is displayed. After a few seconds, the THD Anopress will get ready for the examination, displaying the message "Press START and insert".
- Press the START pushbutton to begin the examination. The message "Pressure measurement" is displayed together with the time required to complete the examination. The THD PressProbe can now be inserted into the anal canal (Fig. 6).

Use a lubricant suitable for the area of application before inserting the THD PressProbe into the anal canal of the patient.

The THD Anopress display is divided into 3 sections (Fig. 6):

Upper section: graphic display of pressure on the left

Middle section: on the left the display of <u>Press.mmHg</u> in real-time, next to the pressure values measured during data acquisition, pressing the relevant pushbuttons (Re, Sq and St). Lower section: user messages

- 6. In the Press. mmHg area, the pressure is displayed in real time.
 - If the RESTING pressure is measured, press the Re pushbutton and ask the patient to carry out the action, keeping the Re pushbutton pressed throughout the action.
 - b. If the SQUEEZE pressure is measured, press the Sq pushbutton and ask the patient to carry out the action, keeping the Sq pushbutton pressed throughout the action.
 - c. If the STRAIN pressure is measured, press the St pushbutton and ask the patient to carry out the action, keeping the St pushbutton pressed throughout the action.

During the examination, the curve showing the pressure trend has the same colour as the pushbutton used, to show what is being measured. The graph covers about 30 seconds. When it reaches the right-hand side of the screen, it gradually overwrites the curve, starting from the left.

To finish data acquisition, press START. The message "Discharge pressure" is shown. If the total time for the examination has not been reached, further data can be acquired, starting the procedure once again from point 4.

IMPORTANT: without connection to a PC with a dedicated Anopress SW software procedure, the THD Anopress is unable to store any data.

Switching off the Anopress THD device: hold down the switch for about 2 seconds until the device switches off.

· Connected to a PC

Requirements:

PC WINDOWS with the installation of Anopress SW data acquisition software; for the full set of requirements see the Anopress SW software handbook.

USB communication driver installed

Anopress SW program installed

Bluetooth dongle inserted into a PC USB port

Anopress SW program started

The patient examination with THD Anopress is carried out in the same way as described above in this Manual. The pressure diagram is displayed at the same time on the PC screen, as are all the pressure values (RESTING, SQUEEZE, STRAIN). The data is stored under the patient's name (details of whom have already been entered, or selected if previously input). The patient's name is also displayed on the device.

See the software manual for details of how the software is used.

- Connect the THD PressProbe via the dedicated Luer-Lock connector to the THD Anopress attachment and screw in completely without overtightening (Fig. 2).
- Switching on the THD Anopress device: press and hold down the pushbutton for a few seconds (Fig. 3). The operation is confirmed by a buzzer and the appearance on the display of the THD logo; after the switch-on sequence, the "Probe authentication" message is displayed.

<u>ADDITIONAL INFORMATION:</u> in the top right section of the display, next to the battery, the blue Bluetooth icon is displayed, showing that the connection has been activated; the line at the bottom of the display reads "Enter patient's name".

- Take the Probe Card included in the THD PressProbe package (Fig. 1) and fit it, by the shorter side, into the slot on the right of the display (Fig. 4). The device is now ready for the examination: the display shows a pressure diagram and the message "START inflating" (Fig. 5).
- 4. Select the patient from the details in the Anopress SW software archive booted on the PC (or fill in data for a new patient) and press the EXAM pushbutton on the Anopress SW: the name of the patient is displayed in the top left section of the screen (if no patient has been selected the message "???" will appear).
- 5. Press the START pushbutton (Fig. 6) to start inflating the THD PressProbe. The message "Inflating ..." is shown on the display. The numerical indicator and pressure diagram rise to a set pressure. When this pressure is reached, the message "Stabilization..." is displayed. After a few seconds, the THD Anopress will get ready for the examination, displaying the message "Press START and insert".
- Press the START pushbutton to begin the examination. The message "Pressure measurement" is displayed together with the time required to complete the examination. The THD PressProbe can now be inserted into the anal canal (Fio. 6).

Use a lubricant suitable for the area of application before inserting the THD PressProbe into the anal canal of the patient.

During the examination, the pressure values are shown in real time both on the THD Anopress screen and the PC monitor.

The THD Anopress display is divided into 3 sections (Fig. 6):
 Upper section: graphic display of pressure on the left
 Middle section: on the left the display of <u>Press.mmHg</u> in real-time, next to the pressure values measured during data acquisition, pressing the relevant pushbuttons (Re, Sq and St).

 Lower section: user messages



- 8. In the Press. mmHg area, the pressure is displayed in real time.
 - If the RESTING pressure is measured, press the Re pushbutton and ask the patient to carry out the action, keeping the Re pushbutton pressed throughout the action.
 - b. If the SQUEEZE pressure is measured, press the Sq pushbutton and ask the patient to carry out the action, keeping the Sq pushbutton pressed throughout the action.
 - c. If the STRAIN pressure is measured, press the St pushbutton and ask the patient to carry out the action, keeping the St pushbutton pressed throughout the action.
- 9. The THD Anopress curve has the same colour as the pushbutton pressed in order to show the type of measurement made, whilst the PC monitor has the same colour for the entire measurement period; the graph covers a period of 30 sec and when it reaches the right of the screen the THD Anopress overwrites the graph starting from the left while on the PC monitor the graph runs towards the left.
- 10. To finish data acquisition, press START. The message "Discharge pressure" is shown. If the total time for the examination has not been reached, further data can be acquired, starting the procedure once again from point 4.

IMPORTANT: when connected to a PC, the entire examination session is stored by the Anopress SW data acquisition software.

 Switching off the Anopress THD device: hold down the switch for about 2 seconds until the device switches off.

<u>ADDITIONAL INFORMATION</u>: the Anopress SW software on the PC remains activated in order to record the result (analysis, remarks and print-out).

Maintenance and cleaning

Maintenance of the device may only be carried out by THD SpA.

WARNING: before cleaning, switch off the device and disconnect the battery charge wire from the mains socket

- Clean and dry all dirty parts using only a slightly damp cloth (use water with slight surfactant).
- Make sure no liquid enters the device while cleaning.
- · Do not use abrasive materials.
- No cleaning frequency is set. The cleaning frequency is at the discretion of the operator and depends on the environment of use of the device.
- It is recommended that an annual check be carried out using the control accessory included in the THD Anopress pack (see section Routine checking of device).
- Batteries cannot be replaced by the user. Do not try to open the unit to replace the batteries; it invalidates
 the warranty.
- · Read the Warnings if the batteries fail.
- THD Anopress is fitted with 6 nickel-hydride (NI-MH) batteries, without memory effect, 1.2 V, 1200 mAh, guaranteeing at least 5 hours continuous operation.
- For a correct use of the batteries, do not leave them uncharged for long periods and recharge them only
 when a message on the display signals an insufficient charge. If the charge is insufficient (battery icon
 [INDEM]), the THD Anopress unit switches off automatically to prevent the batteries losing further charge.
- To save energy, remember to disconnect the battery charger after each use. However, the THD Anopress device can remain connected to the battery charger without damage to the batteries or the device.
- Complete recharging of flat batteries takes 6-7 hours, during which time the THD Anopress can be used.
 The display shows the symbol
- Battery life is about 300 complete charging/discharging cycles.

Routine checking of device

The pressure measurement accuracy of the device should be checked regularly. To do this, proceed as follows:

- 1. Switch on the Anopress device by holding down the pushbutton for a few seconds (Fig. 3).
- When the message "Probe authentication" is displayed, press the pushbutton to access the SETUP MENU.
- Use the arrows, up (↑) and down (↓), to scroll up and down and select "Pressure", and confirm with the "START" key.
- The accessory used for checking purposes (a syringe) is included in the THD Anopress pack; move the syringe plunger to half way along its stroke.
- Fit the syringe into the Luer-Lock connector of the device (instead of a THD PressProbe Fig. 2) and make sure the connection is stable.
- 6. Press the plunger to the end of its stroke.
- 7. Check on the display that the cursor moves to within the green band.
- If the cursor moves to a position outside the green band, repeat the check, disconnecting the syringe from the Luer-Lock connector and once again setting the plunger to half way along its stroke, then repeat the procedure from point 5.
- 9. If the value is still outside the set limits, the device should be sent to THD S.p.A. for further checks.
- If the value is within the set limits, the device is properly calibrated; remove the test syringe and switch the device off.

17. Storage

The place where the device is stored must be dry, clean, well ventilated with a temperature between -5° and 40° C. Do not expose the device to direct sunlight, sudden temperature changes, excessive humidity.

Storage at temperatures outside the range specified may cause device deterioration.

Do not bend, squeeze or twist THD PressProbe cables and/or hoses with excessive force.

For the storage, use the packaging box, making sure you remove from the connector any THD PressProbe connected to the THD Anopress device.

THD Anopress and its accessories should be stored in a dry place, away from dust, in suitable environmental conditions (see Technical Data section).

18. Transport

If transporting the device to other sites, it is advisable to use the original packaging and make sure that the transport conditions are the same as those indicated for storage.

19. Disposal

When the THD Anopress electro-medical device can no longer be used, it should be properly disposed of. THD PressProbe, if used, should be disposed of as infected hospital waste; if not used, it cannot be disposed of as undifferentiated waste.

20. Settings

THD Anopress is set up for use in various languages. To select the desired language:

- 1. Switch on the Anopress device by holding down the pushbutton for a few seconds (Fig. 2).
- Use the arrows, up (↑) and down (↓), to scroll up and down and select "Language", and confirm with "START".
- Use the arrows, up (↑) and down (↓), to scroll up and down to browse the various languages available (English, Italiano, Deutsch, Francais, Español) and select the desired language, then confirm with "START".

If the language you are seeking is not present, it needs to be installed; to do so, consult the website www.thdanopress.com

Quit the SETUP MENU by going to Exit and confirm with START.

The intensity of screen luminosity can be regulated as follows:

- 1. Switch on the Anopress device by holding down the pushbutton for a few seconds (Fig. 2).
- Use the arrows, up (T) and down (↓), to scroll up and down and select "Luminosity"; confirm with
 "START".
- Use the arrows, up (↑) and down (↓), to increase or decrease the luminosity 25-50-75-100 and confirm with "START".
- 5. Quit the SETUP MENU by going to Exit and confirm with START.

21. Troubleshooting

Problem	Possible cause	Solution
The device does not switch on.	The batteries could be flat.	Recharge the batteries. If the device does not switch on after recharging the batteries, contact THD.
Pressure measurement unstable	Loss from probe	Check the Luer connector or replace the introducer-probe
Pressure remains zero	Loss from probe	Check the Luer connector or replace the introducer-probe
	Pump faulty	Contact THD

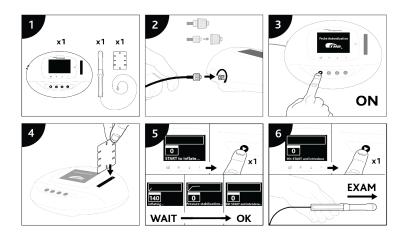
22. Operator messages

Message	Message description	Solution
"Error: move Tag closer"	Probe card not inserted correctly in the housing	Reinsert the Probe card as shown in Figure 4.
"Tag reading error, retry"	Probe card reading failed	Reinsert the Probe card as shown in Figure 4.
"TIME EXPIRED"	Time available expired	Use a new THD PressProbe and relative Probe card
"Limits of use reached!"	Probe card already used on the device	Use a new THD PressProbe and relative Probe card
"Overflow pressure"	Exceeded the 240 mmHg during a squeeze	No solution requested by operator. Return to the resting pressure value once the squeeze has been completed.
"Pressure error"	Loss greater than permissible value	Check the connection of the THD PressProbe with the THD Anopress device and restart the procedure as per Figure 5.
"Cancelled"	Press Sq button during the procedure	The action interrupts the procedure. Restart the procedure as per Figure 5.

23. Meaning of symbols used

Symbol	Meaning
2	Do not re-use
\sim	Date of manufacture
ryafx	Latex Free
	See the instructions for use
	Manufacturer
REF	Item Code
LOT	Batch number
SN	Serial number
\triangle	Warning
*	Keep dry
†	Part applied: BF type
X	Follow disposal instructions
	Ciass II
((<u>@</u>))	Radio directive 1999/5/EC

24. Images





Manufacturer: THD S.p.A.

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