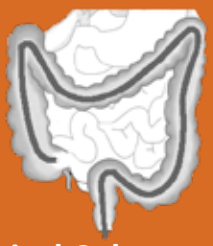
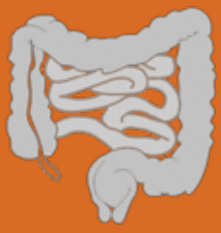
Virtual Colonoscopy

Intussusception reduction



Optical Colonoscopy



Virtual Enteroscopy

User guide/manual VMX-1020A

ORIGINAL INSTRUCTIONS

MEDICAL
CO2 INSUFFLATOR

VIMAP TECHNOLOGIES

CONTENTS

1 INTRODUCTION

Thank you for placing your trust on VIMAP TECHNOLOGIES by purchasing this product.
You are able to see marks in explaining where you must read carefully.

Text marked by the symbol  **must given particularly attention.**

Text marked by the symbol  **is provided for information.**

The words WARNING, CAUTION, and NOTE carry special meanings. Sections marked with these words must be read especially attentively.

 Abbreviations & terms frequently used in this User Guide:

- **L/min** flow in liters per minute
- **mmHg** pressure in millimeters of mercury
- **°C** temperature in Celsius
- **L** volume in liters

 **Read these instructions before using the device, especially the sections dealing with safety conditions and Environmental requirements for the equipment.**
Read the manual carefully and become familiar with the operation and function of the device and the accessories before use during examinations.

The manufacturer reserves the right to modify the appearance, graphics, and technical data of the supplied product through continued product development.

1.1 FUNCTIONALITY

This device is designed to be used exclusively for:

- Virtual Colonoscopy or CT Colonography,
- Virtual Enteroscopy,
- Intussusception reduction
- Optical Colonoscopy

with carbon dioxide gas (CO_2), medical grade, for safe means of performing colonic distension.
With this User Guide you will know device options and user modes.
The insufflator VMX-1020A has been designed to use exclusively the administration sets AS-series.

VIMAP administration sets for VMX-1020A are using specific high-performance filters that are anti-bacteria, anti-viral and hydrophobic.
Each filter provides a protection against virus is average of 99.999% (VFE) and against bacteria is average of 99.999% (BFE). The filter barrier is not one but two consecutive filters.
The administration set is single use consumable and is changed at any patient, before every new exam.
Due to this double barrier, the probability of cross-contamination between 2 patients is neglectable even in the very unlikely case of contamination of the internal device components.

Note: The VMX-1020A is the only CO2 insufflator using single use administration sets with a redundant filter barrier including 2 filters. In the eventuality of any contamination of first filter by direct contaminated liquids that would enter in contact with the filter and affect its filtration properties, the second filter in this situation would remain fully efficient and clean. The hydrophilic property of the first filters would prevent the second filter from any risk of contact by contaminated liquids.

To ensure patient safety, a VIMAP single-use tubing fitted with a viral hydrophobic filter must be used and the tube set must be replaced for each patient. It is prohibited to use other tubing which is not be produced by VIMAP.

Usable tubings and function: Reference VIMAP

- **AS-3W-H-R35A (CT Colonography, Virtual colonoscopy only)**

UDI : 08436557390059

- **AS-3W-H-R35B (intussusception reduction only, model recommended for children)**

UDI : 08436557390097

CAUTION!
Disposals are NON-sterile, therefore we do not indicate the method for sterilization.

1.2 EXCLUSION OF LIABILITY & SAFETY INFORMATION

Exclusion of liability
The manufacturer is not liable for direct or consequential damage and the warranty is null and void if:

- the device and/or the accessories are improperly used, prepared, or maintained,
- the instructions and rules in the manual are not adhered to,
- non-authorized personnel perform repairs, adjustments, or alterations on the device or accessories,
- non-authorized persons open the device,
- the prescribed inspection and maintenance schedules are not adhered to.

Receipt of technical documentation from the manufacturer does not authorize individuals to perform repairs, adjustments, or alterations on or to the device or accessories.

Authorized trained personnel: Only a technician, trained and certified by VIMAP TECHNOLOGIES, may perform repairs, adjustments, or alterations on the device or accessories and use the service mode. Any violation will void the manufacturer's warranty.
Each trained engineers" have a "hard PERSONAL password" to access to maintenance/technical functionalities of the device.

The VMX-1020A device:

- is NOT connected and must NOT be connected to a physical LAN.
- is NOT connected and must NOT be connected to a Wireless LAN.
- is NOT connected and must NOT be connected to Internet or a CLOUD service.
- does NOT record of identification data's of the patient.

It is prohibited:

- to changes any material of the device,
- to install third party software,

- to do any setup changes of the operative system,
- to do any update of the operative system,
- to connect to a wireless LAN, permanent or temporary,
- to connect to a physical LAN, permanent or temporary,
- of not to comply with the procedures defined by Vimap Technologies, for installing, using and maintaining the device.

Failure to comply with these previous rules will automatically remove all responsibility of the manufacturer Vimap Technologies, on the operation of the medical device and any possible adverse events on the patient or operator.

Intended use: VMX-1020A, CO_2 Insufflator for Virtual Colonoscopy (CTC), Intussusception Reduction and Virtual Enteroscopy (Virtual Enteroclysis) procedures.

Care and maintenance: the service and maintenance of the device and its accessories has to be carried out as per instructions to ensure the safe operation of the device. For the protection of the patient and the operating team, check that the device is properly connected and functional.

This symbol indicates that the waste of electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately instead. Please contact the manufacturer or an accordingly authorized disposal or waste management company for further information.

2 CONTRAINDICATIONS, WARNINGS AND CAUTION TO TAKE IN ACCOUNT

2.1 CLINICAL CONTRAINDICATIONS, WARNINGS AND CAUTIONS:

CAUTION! This device must be used only by a radiology physician with enough experience in this medical examination and trained for the use of this device.

CAUTION! Only the physician can evaluate the clinical factors involved with each patient and determine if the use of this device is indicated. The physician must determine the specific technique and procedure that will accomplish the desired clinical effect.

You must be careful that the patient is experiencing no pain prior to the examination.

You must ask the patient to remain quiet for improving CO_2 absorption, avoiding effects on flow and pressure.

The colon can be adequately distended by pressure in the range 15 to 25 mmHg. The selection of a setpoint pressure over 25 mmHg is justified only for particular cases and under the responsibility of the Doctor.

The patient has to be placed on the CT table for a CT scan in position “head first” and the VMX-1020A insufflator should never be placed behind the CT Scan machine. The VMX-1020A should be accessible. The displayed information on the touch screen should be visible during all exam from the room and from the CT control room.

Any colon insufflation exam with an intra-colonic pressure over 25 mmHg should be under the

control and responsibility of a Physician. If the pressure is inadequate to the patient general condition or age it can produce in some exceptional cases adverse events like:

- Decreased respiration with compromised diaphragmatic excursion
- Cardiovascular problems (venous blood return, cardiac output)
- Acidosis
- Perforations
- Pain

The pressure must always be adapted to the internal pressure of the patient and especially the patient age and the patient general condition. For patients over 70 years old and/or patients with poor general condition, it is not recommended to use the range 25-35mmHg and to keep the intra-colonic pressure under 25mmHg.
Some patient with an high internal pressure could require to be insufflated in the range 25-35mmHg. In this specific case, intra-colonic pressure in the range 25-35mmHg would represent no danger and would be required to achieve the distension. The setting of the pressure over 25mmHg has to be appreciated case by case by the Physician and under the responsibility of the Physician.


You must be careful when you practice an exam with people whom have microdrepanocytic disease, sickle cell disease or pulmonary insufficiency, since they are more susceptible to metabolic changes.


Absorption of CO2 can in some very exceptional cases cause irritation of tissues as they come into direct contact with carbonic acid.


The use of this device is contraindicated whenever virtual or conventional colonoscopy is contraindicated.


This device is contraindicated for hysteroscopic insufflation; it must not under any circumstances be used for intra-uterine distension.

2.2 TECHNICAL CONTRAINDICATIONS, WARNINGS AND CAUTIONS:

You must follow the instructions.


WARNING! During the start-up or restart of the device, to enable a good calibration procedure:
- don´t connect or disconnect the disposable/tubing
- don´t touch or move the heating hose


WARNING! To avoid the risk of electrical shock, only use this device when connected to a properly grounded power supply network.


WARNING! In case of an emergency requiring insufflation to be suspended, the technician must shut off the CO_2 supply by quickly disconnecting the administration tube from the exit port of the device.


WARNING! In the case of suspicious behavior, an extinction of the device or unplugging the power cable ensures optimal safety, by default, this action closes the supply of gas and releases the gas already present inside the device.


WARNING! No modification of the equipment is allowed.


WARNING! To prevent electrical shock, do not open this device. Never open this device yourself. Refer only servicing to qualified service personnel by your official distributor.

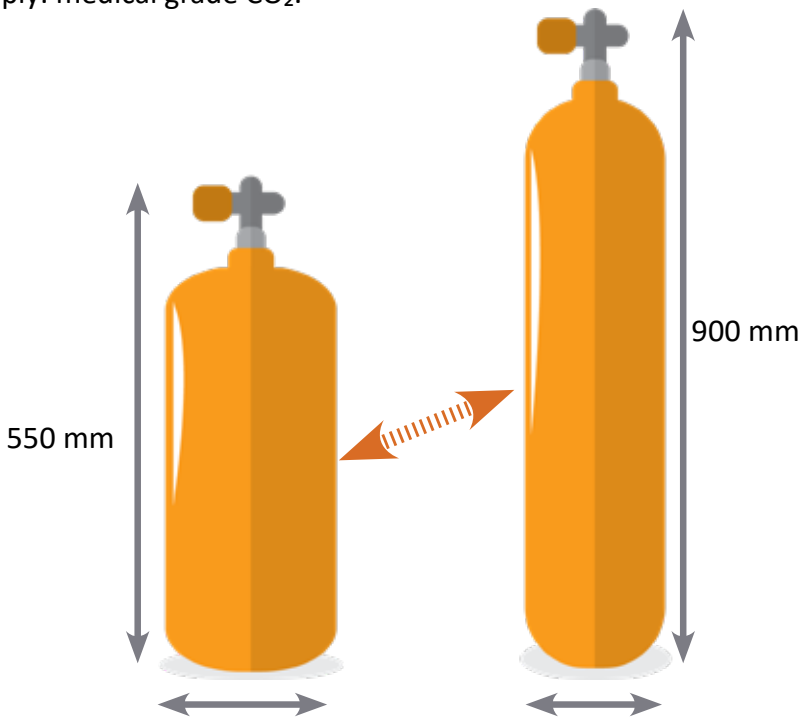
WARNING! Replacing fuse; replace the fuse only with a fuse of the same type and rating.

WARNING! Original accessories; for your own safety and that of your patient, use only original accessories.

You must perform the examination in a ventilated place, since the device has different regulation CO_2 blocks, the excessive gas will be thrown out by secure means into the ambient atmosphere.

Check before opening the CO_2 cylinder that the high pressure hose has not been damaged, and it is correctly connected to the device and to CO_2 Cylinder.
Check that you correctly use a CO_2 cylinder with indicated features.

Maximum pressure, for the gas cylinder: 70 bars.
Maximum pressure, for the gas network hospital: 6 bars.
Material supply: medical grade CO_2.



For a height up to 550mm, the maximum diameter is 174 mm

For a height between 550mm to 900mm, the maximum diameter is 140 mm

- Keep the device in cleaning rooms (without dust) with a low humidity, and normal temperature.
- This device must only be opened by a technician approved by the manufacturer.
- Not use electrical conducted materials into the device to avoid:
  - ➢ Electrocution
  - ➢ Fire
  - ➢ Short circuit
  - ➢ Hazardous emissions.
- This device must not be connected to any other disposables.
- This device must not be used in the presence of inflammable anaesthetics.
- This device was not designed for use in an ionizing environment.

3 LEGAL RECOMMENDATIONS

3.1 CONFORMITY

This device was designed and manufactured by a company with certified quality system **(ISO 13485:2016)**
It conforms to the requirements of European Directive 93/42/CEE on medical devices.
It conforms that many of the components meet RoHS certificate.
It therefore conforms in particular to specific standards on electrical safety **(IEC 60601)** and electromagnetic compatibility **(EMC)**.

3.2 ELECTROMAGNETIC COMPATIBILITY

Despite the electromagnetic compatibility, you must be careful and avoid that there will be any possible devices in close proximity to this unit, such as special radiofrequency devices (mobile phones, motors, transformers). You must be sure that you have a good ground installation. If you follow these steps you will not have any problems.

3.3 MEDICAL DEVICE CONTROL

Each year or 4500 exams (whichever comes first), the device must be sent to the manufacturer, where they will carry out preventive maintenance, checking that all functions and all measurements are correct.
Also if you experience that something is not working correctly, you must notify the distribution company, and also notify the manufacturer, informing them of any details. See last page for manufacturer's contact details.

3.4 DEVICE AND ACCESSORIES PLACEMENT AFTER END-OF-LIFE

At the end of the devices life, the device and accessories will be sent to the manufacturer. Manufacturer will take upon to recycle the device.
Device compliance is marked with the recycling symbol in compliance **with European Directive 2002/96/ on Waste Electrical and Electronic Equipment (WEEE)**.
By disposing of this device properly you are helping to prevent any harmful effects on the environment and human health.

The symbol  marked on the device and/or present in the accompanying documentation indicates that this product may not under any circumstances be treated as domestic refuse. It must therefore be taken to a waste collection centre with facilities for recycling electrical and electronic equipment. Disposal must be carried out in compliance with the waste disposal regulations applicable in the country of installation.

For further information on the processing, recovery and recycling of this equipment, please address any inquiries to your local authority, waste collection contractor, or directly to your reseller.

4 DESCRIPTION OF EQUIPMENT

The Insufflator VMX-1020A is prepared to use CO_2 as its distention media in the gastrointestinal tract when used in conjunction with a gastrointestinal endoscope under direct observation of a physician.

4.1 TECHNICAL SPECIFICATIONS:

Standards:

- ➢ Conforms to European Directive 93/42/CEE on medical devices: class IIa
- ➢ Conforms to European Directive WEEE 2002/96/EEC
- ➢ Standards: IEC 60601-1; IEC-60601-1-2; EN55011
- ➢ Conform to RoHS
- ➢ IDU: 08436557390110
- ➢ Equipment class according to electrical protection: **Class I**
- ➢ Classification of applied parts according to electrical protection : **BF- type**
- ➢ Degree of protection provided by the enclosure: **IPX0** (Not protected against falling water)
- ➢ Size, [L x W x H]: **450 x 390 x 590 mm alone**
  490 x 550 x 1640 mm with the cart CAR-XXXXD
- ➢ Weight: **20kg alone**
  65 kg with the cart CAR-XXXXD

Pneumatic:

- ➢ **Gas inlet:**
  - US 7 / 16" connector
  - Medical grade CO_2 cylinder with maximum pressure of 70 bar
  - Medical grade CO_2 Network Hospital with pressure between 2 and 6 bar.

- ➢ **Maximum flow without charge loss:** 10L/min
- ➢ **Pressure setpoint:** 5 to 120 mmHg, display accuracy of 1 mmHg
- ➢ **Flow setpoint:** 1 to 10 liters, display accuracy of 0.1 L/min
- ➢ **Heating setpoint:** 42.5 to 48.5°C, display accuracy of 0.1°C

- ➢ Two internal de-sufflation valves
- ➢ Safety relief valve on high pressure reducer: 3,8 bar (55 PSI)
- ➢ Safety relief valve on regulation block : 0,26 bars (4 PSI)
- ➢ Safety relief valve of 155 mmHg (3 PSI)
- ➢ Safety relief valve of 77 mmHg (1,5 PSI)

Operating, environment and storage:

- ➢ **Operating conditions:**
  Temperature: between +10ºC to 40ºC
  Relative humidity: between 30 % and 75%
  Atmosphere pressure: between 700hPa to 1060Hpa.

- ➢ **Transport and storage conditions:**
  Temperature: between +5ºC to 50ºC
  Relative humidity: between 20 % and 85%
  Atmosphere pressure: between 700hPa to 1060Hpa.

4.2 POWER SUPPLY

Input voltage: 100 to 250 VAC, frequency: 50-60 Hz
Power supply connection: through detachable power supply cord
Power: 300 VA, with double fuses, see fuses values on the device label.

5 SAFETY FEATURES

Our device has different safety systems for avoiding risk to the patient.

✔ **Self-test**
Auto-calibration of the device and testing of its vital functions takes just a few seconds when you initiate start-up by switching on the start button. You can scan the barcode of the KIT, and the device will set to a predetermined examination.

WARNING! During the start-up or restart of the device, to enable a good calibration procedure:
- don´t connect the disposable/tubing
- don´t touch or move the heating hose

The reference AS-3W-H-R35A is exclusively dedicated to the CTC (Virtual Colonoscopy) mode. The reference AS-3W-H-R35B is exclusively dedicated to the "Intussusception Reduction" mode. Never use the reference AS-3W-H-R35A on babies or children due to its size and to the risk of perforation. Never use the reference AS-3W-H-R35B for CTC (virtual colonoscopy). The reference AS-3W-H-R35B is not adequate to the CTC (Virtual Colonoscopy) pressure range.

✔ **Automatic control of insufflation flow**
This device automatically controls the insufflation flow to maintain a colonic distension pressure equal to the pressure set point. The selected flow is a maximum flow which will not necessarily be reached.

✔ **Additional pressure sensor**
The coherence of the measurements is monitored continuously so that, in case of a fault in the measuring circuit, the insufflation cycles can be stopped if the slightest doubt arises.

✔ **Safety valves**
In case of failure at the pressure reducer, a first safety valve limits the pressure to 3,8 bar (55 PSI). A second valve limits the insufflation pressure to 0,26 bars (4 PSI). Depending of the selected mode will have limitation of pressure to 77 mmHg (1,5 PSI) and to 155 mmHg (3 PSI).

✔ **Message display «Colon insufflated»**
When the volume of CO_2 insufflated is greater than 1,2l and according to the flow and pressure variations.

✔ **Message display «Power supply fail»**
When one of the power supplies are not within working parameters, the security of thesystem does not permit allow the performance of the colonoscopy examination.

✔ **Message display «Insufflation in process»**
After initiation of the colonoscopy examination, this message (insufflation in process) will be on the screen until the colonoscopy examination has finished.

✔ **Temperature control**
The doctor can choose the ideal temperature for CO_2 insufflation. The device has several temperature sensors for safety.

✔ **Access through password**
The device can be used only by authorized personnel through setting a password.

✔ **Message display «Cylinder empty, please contact with our CO_2 cylinder distributor»**
When the volume of CO_2 cylinder is less than 20 bar, a message is displayed to prepare or order a new cylinder.
When volume of CO_2 cylinder is less than 10 bar, a message is displayed to change the cylinder, and the device will not perform any colonoscopy examination until it will be replaced.
In Case of CO_2 Lan Hospital, when the pressure will be less than two bar, a message is displayed to contact the maintenance service of the hospital, and the device will not perform any colonoscopy exam until pressure increases to two bars.

VMX-1020A also has several filtering systems for preserving the safety between the device and the patient.

✔ **CO_2 cylinder side**
A particle filter is placed at the CO_2 inlet to prevent the ingress of dust sometimes present in the CO_2 cylinders.

✔ **Device VMX-1020A**
Inside inputs of the pneumatic proportional block, we have installed filters, preventing the entrance of impurities to the system.

✔ **Patient side**
To ensure patient safety, it is essential to use VIMAP single-use tubing fitted with viral hydrophobic filters and to replace the tube set for each patient. The use of any other tubing is prohibited.

6 CHECKING AND INSTALLATION OF THE DEVICE

6.1 CHECKING DEVICE

Any damage, malfunction or missing accessory must be reported immediately or confirmed by the carrier and/or reseller by registered letter so that it can be covered by the warranty as appropriate.

Retain the original packaging so that the device can be returned when it sent for maintenance. Attach a document giving your name, address and reason for returning the device (problem found).

6.1.1 MATERIAL PROVIDED

Your product is supplied complete with the follow ing accessories:

or

or

External High pressure filter

Optional: CAR-XXXXD

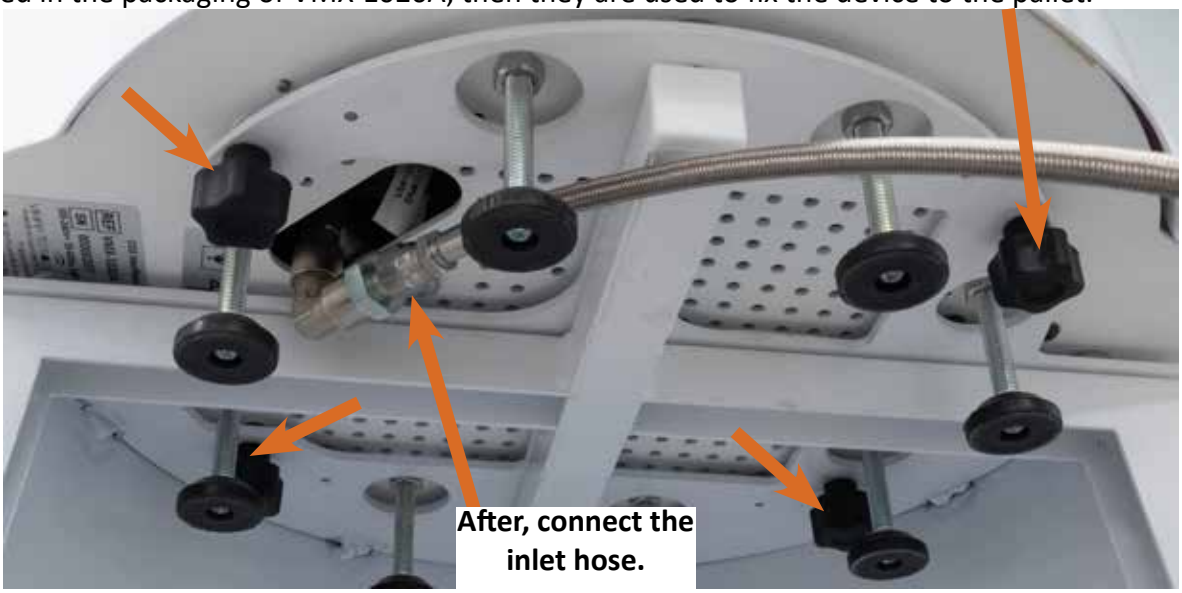
6.2 INSTALLATION OF THE DEVICE

6.2.1 CONNECTIONS OF THE DEVICE

The feet of the VMX-1020A, are adjusted and locked during manufacture, never screw more or unscrew the feet, otherwise the device may be damaged. The support cart is intended for the free passage of the feet.

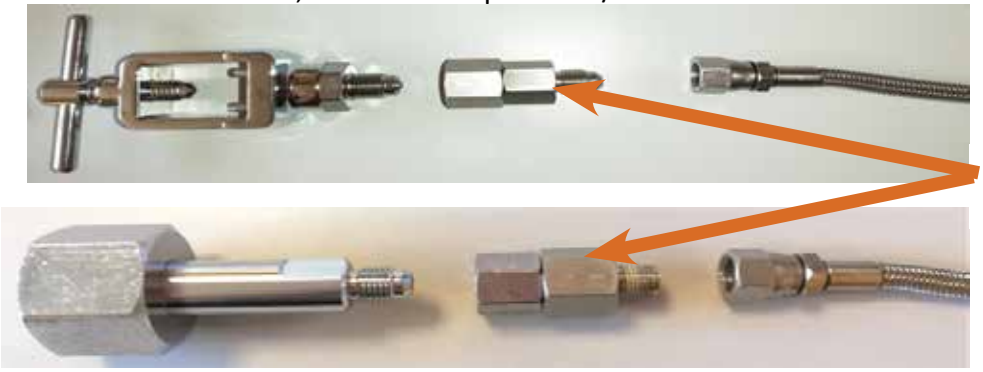
In every case, device VMX-1020A must be placed higher than the patient to prevent any backflow of liquid through the tubing.

Place the device on the top of the cart.
This apparatus must be operated in the horizontal position fixed by the 4 lobe handwheels, which are included in the packaging of VMX-1020A, then they are used to fix the device to the pallet.



To protect the devices and the components inside the device, it's essential to use a filter before the gas enters the device. By default this filter is included in all cylinder connectors provide by Vimap technologies. But it's better to check the presence in situ, of the filter:

If the pin index or the connector used to connect the device to the gas cylinder NOT include a filter, then insert an external filter, between the pin index/connector and the HP flexible, like this:



1. Electrical socket / fuses / power switch
2. Ethernet socket
3. Inlet gas
4. Equipotential bonding

6.2.2 MOUNTING AND CONNECTING THE PANEL PC.

After you mount Panel PC into the panel support, you must connect the wires fixed in panel support to the connectors indicated.

To adjust the tilt or height of the panel PC, use the supplied Allen key

Metal PanelPC:

7. Button Start cable
8. Power supply panel PC
9. USB cable
10. Ethernet cable
11. Brightness control

Plastic PanelPC:

Unscrew and re-screw by hand, the protective/cleanliness cover, to connect the cables. If necessary, you can store the excess cables inside this cover.

ELECTRICAL CONNECTIONS

1- Check that the characteristics of the main power supply are 100 to 250 v AC and 50 Hz - 60 Hz with a power requirement of 300 VA.
2- Connect the power supply cord on the specify part [1].
3- Connect the power supply cord to the electrical supply.

IEC-lock : You must have special attention, because for unplugging the IEC connector, you must move the red lock .
It is not necessary to move this lock when you plug the IEC connector to the power inlet.

ELECTRICAL PROTECTIONS

This device is protected by 2 x fuses (UR) power inlet (1). Do not use fuses with different ratings or fuses that are not UR certified.

ETHERNET SOCKET

For future options, it will be posible to connect Ethernet socket (2) to the network of your institution.

EQUIPOTENTIAL BONDING

Device is designed for avoiding electrostatic discharge (ESD), because we have equipotential bonding of all devices joined .Connect your earth wire to the connector (4).

CONNECTING TO THE GAS Cylinder

1- Maximum allowable operating pressure (70 bars)
2- Install the CO_2 gas cylinders inside the cart vertically and ensure it is secure, with the head uppermost in a good position. Afterwards, you fix the bottles with the belts installed inside the cart.
3- Check that the seal is present on the high-pressure hose on the cylinder side (DIN only).
Using the wrench provided, tighten the fitting connected to the cylinder outlet, then tighten the fitting connected to the insufflator inlet port (3).

CAUTION!
Never use the device if it is connected to a bottle placed horizontally or upside down.

7 UNINSTALLATION OF THE DEVICE

Switch off the power inlet, and then disconnect the power cord. After that, disconnect all the ports of the Panel PC to the device, and remove the panel PC. After that, you must disconnect the gas cylinder or LAN Hospital CO_2.
Before unscrewing the high-pressure hose, check that the cylinder valve is closed, and then reduce the pressure in the circuit by loosening the connector slightly.

8 CONTROLS OF THE DEVICE VMX-1020A

Depending of the manufactured version :

11. Panel PC (Touch Screen)
12. START button
13. General power switch
14. Webcam

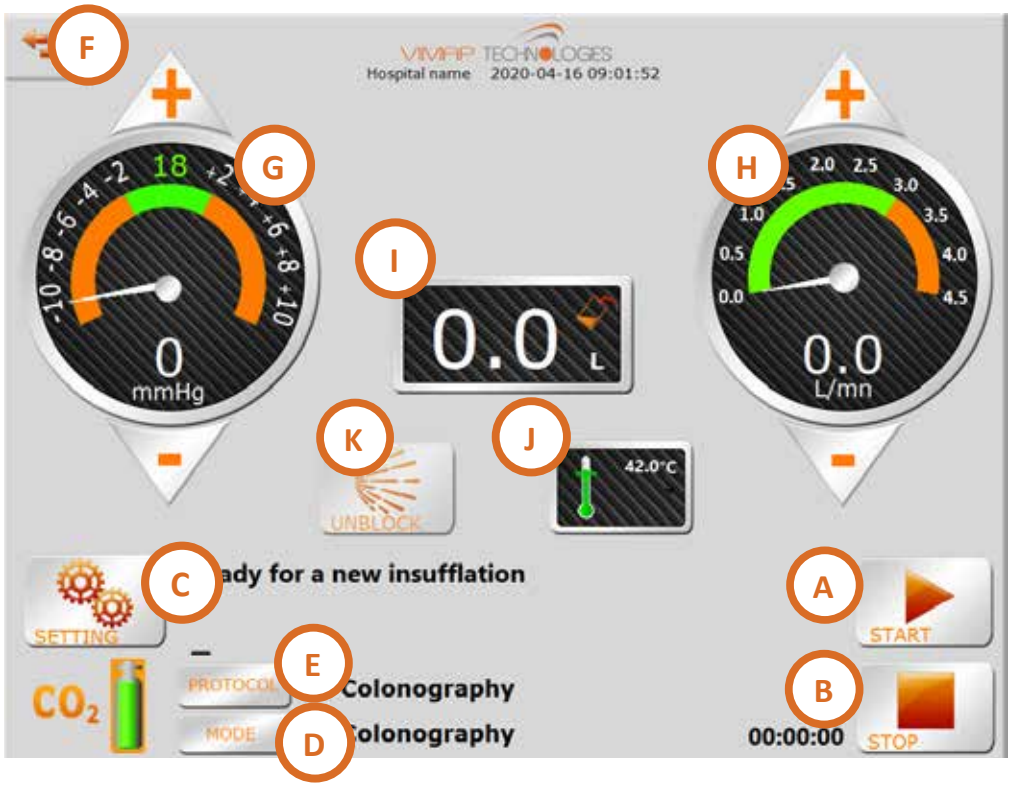
15. Stand-by led :
- orange, when the device is started
- red, when the device is in Stand-by (Panelpc shut-down)

Depending of the manufactured version :

Screen Touch controls:

T1. START button (with LED status indicator: ON: Green, OFF: dark)
T2. Volume ON/OFF
T3. Volume adjustment (-)
T4. Volume adjustment (+)
T5. Brightness (-)
T6. Brightness (+)
T7. LCD on/off (with LED status indicator: LCD ON: dark, LCD OFF: Amber)
T8. Touch Screen Lock (with LED status indicator: ON: Amber, OFF: dark)
    a. Keep on contacting 10 seconds to active
    b. keep contacting 10 seconds to release
T9. Not use
T10. Not use
T11. RFID reader

Software MAIN PAGE



A. START/PAUSE button

B. STOP button

C. SETTINGS menu

D. Set MODE

E. Set PROTOCOL

F. Show/hide colon preparation panel

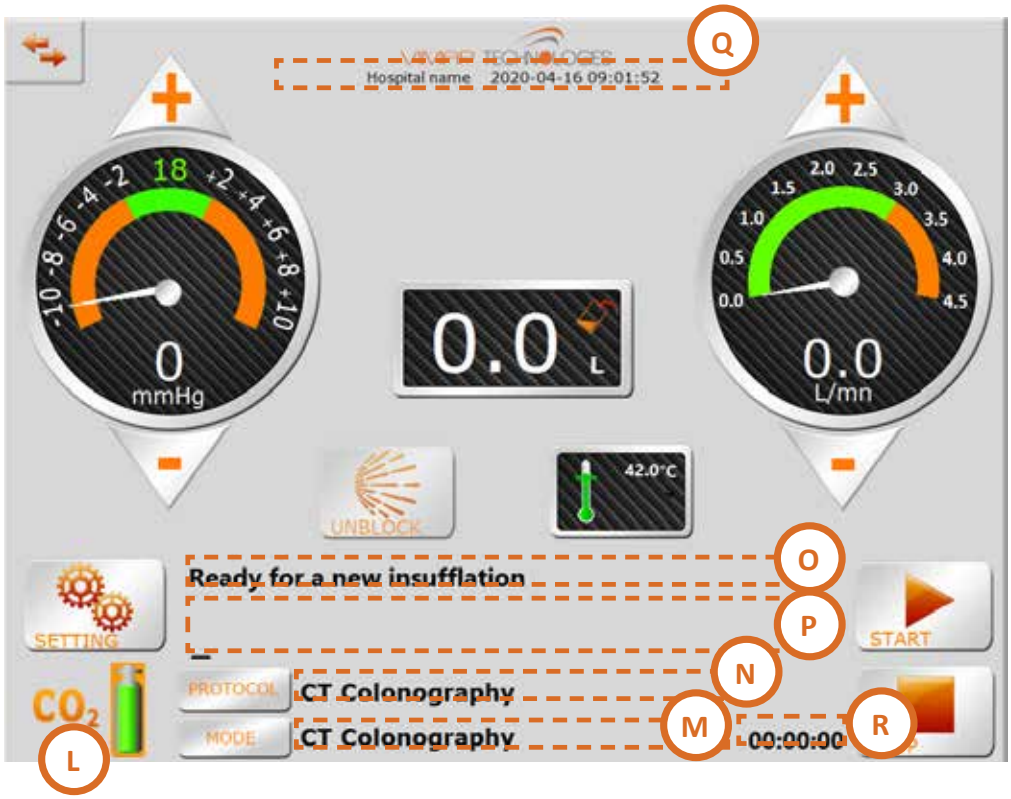
G. Pressure gauge

H. Flow gauge

I. Volume gauge

J. Temperature gauge

K. UNBLOCK button



L. Level of gas cylinder/ type gas connection

M. Actual mode

N. Actual protocol

O. Device status

P. Alert messages

Q. Name of institution & Date-time

R. Insufflation duration

9 ESTABLISHING AND MAINTAINING COLONIC DISTENSION

This device is intended exclusively for colonic distension. Any use for other purposes constitutes mis-use of the product for which the user will be liable and for which the manufacturer accepts no liability.
The safety features incorporated into this device do not in any way release medical personnel from their responsibility to monitor and keep a constant check on the patient's condition.

9.1 GETTING STARTED

CAUTION!
During the start-up or restart of the device, to enable a good calibration procedure:
- don´t connect the disposable/tubing
- don´t touch or move the heating hose

9.1.1 USER ACTIONS

✔ Open the gas cylinder
✔ Move the switch (13) to «I».

✔ Push button Start (12), and panel PC will load operative system.

✔ After that, the Panel PC automatically starts software used for colonoscopy examination showing main page.

✔ The default Mode and Protocol are automatically selected, if necessary you can enter in interface protocol/mode setup (E)/(D) and validate that all parameters are correct for your examination or you can change it.

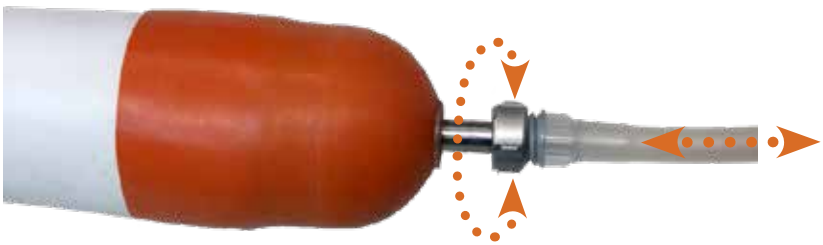
INDICATIONS FOR CONNECTING AND DISCONNECTING THE TUBING ON THE DEVICE

❖ **The manufacturer accepts no liability in case of incident or malfunction resulting from the use of damaged or unsuitable tubing.**
❖ **Do not use tubing if the packaging is damaged.**
❖ **Tubing is for single use, do not re-sterilize or re-use.**
❖ **The use of a hydrophobic bacterial and viral filter is essential to prevent patient cross-contamination.**

✔ **Only once the device is started** you can connect the disposable:
Use the reference disposable compatible with the type of examination used (mode). **Open the disposable bag carrefully to avoid damaging of the disposable or labels:**

✔ Connect the tubing to the patient outlet port of the device.

CAUTION!
The tube must be inserted freely without kinking and must not be blocked. Refer to the tubing manual for more information about the tubing.



✔ Check the selected mode (M) and protocol (N), and that they are compatible with the disposable installed

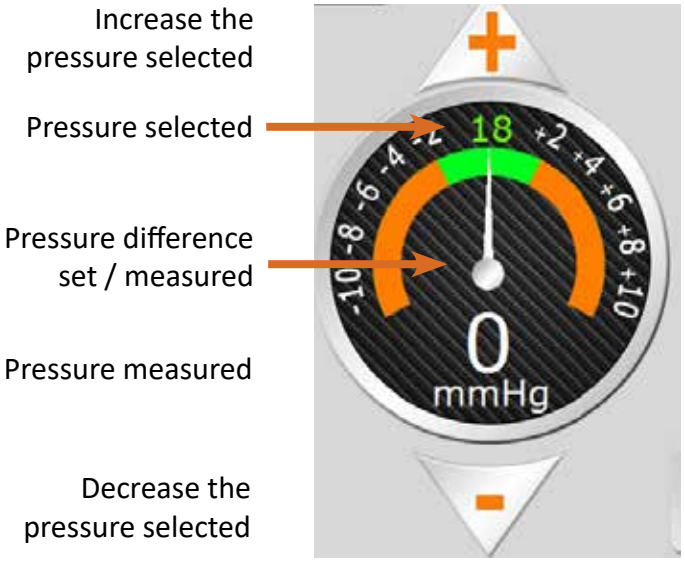
✔ Check the pressure setup and flow setup on the main page

✔ **The device is ready to start directly, or you can also adjust parameters such as pressure or flow before to start.**

9.1.2 SELECTING THE PRESSURE SET POINT

This operation must always be performed by or under the supervision of a radiology physician. Depending the protocol selected, the parameters of pressure will have different values by default.

❖ Select the colonic distension pressure. The pressure adjustment range permitted depends on the selected mode.
❖ You can set the pressure at any time of the examination insufflation.



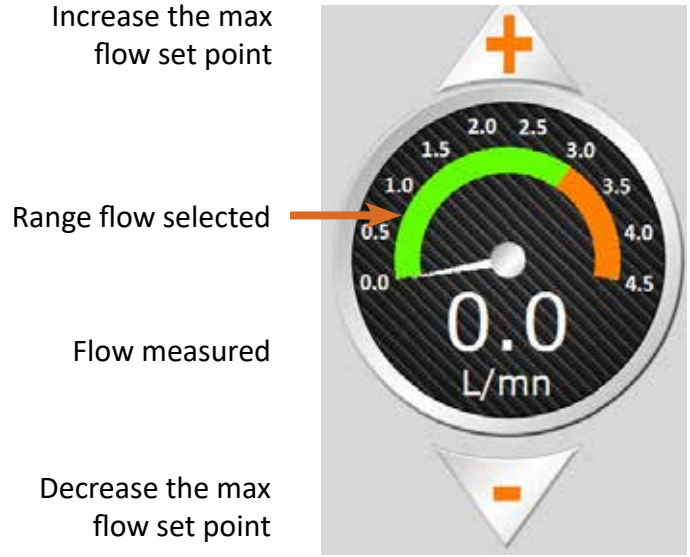
❖ Depending the selected mode, system has a safety notice, since you set, for example, a pressure above 25 mmHg, the system ask a confirmation.

9.1.3 SELECTING THE MAXIMUM FLOW SET POINT

This operation must always be performed by or under the supervision of a radiology physician. Depending on the protocol selected, the parameters of flow will have different values by default.

❖ Select the CO_2 flow. The pressure adjustment range permitted depends on the selected mode.

❖ You can set the maximum flow at any time of the examination insufflation.



❖ Depending on the selected mode, system has a safety notice, when you set , for example, a flow above 3 litres, the system will ask a confirmation.

9.1.4 REAL-TIME OPTIONS FOR THE EXAMINATION

Depending the selected mode, you can change options during the current examination:

Click in (F), to show / hide this panel

9.1.4.1 OPTION TO CHANGE THE STATE OF PREPARATION OF THE COLON (OPTION DISPLAYED DEPENDING ON THE MODE):

❖ You can set the colon preparation at any time of the examination insufflation.

9.1.4.2 OPTION TO TAKE ACCOUNT OR NOT OF THE BAG VOLUME, IN THE CASE OF NON-USE OF THE BAG (OPTION DISPLAYED DEPENDING ON THE MODE):

❖ With or without the drainage bag, depending on the composition of the administration set used for the examination. For example, for the intussusception mode, you can use an administration set with the “clamp bag” opened or completely closed during this examination.

❖ If bag is enabled, the displayed volume increases only after the bag volume (0.4 / 0.5L) has passed.

❖ If bag is disabled, the displayed volume increases directly with the gas flow.

9.1.5 INFORMATION PROVIDED DURING THE VOLUME AND TEMPERATURE MANAGEMENT

9.1.5.1 VOLUME MANAGEMENT

By default, the device take account of the drainage bag volume. So, the volume displayed on main page, works like this:

Between 0 and 0.4L (volume of the bag), the displayed "patient volume" is 0 L and the icon bag is blinking.

When the bag is full (volume equal or greater to the bag volume), the icon bag disappears.

In "Intussusception reduction" mode, you can disable the bag volume, if you not use the bag of the disposable. (See previous paragraph.) In this case the volume displayed does NOT take account of the bag volume and the icon bag is not displayed.

9.1.5.2 TEMPERATURE MANAGEMENT

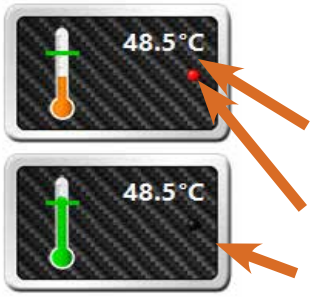
When you start the device, the flexible heater system is enabled by default. This allows, at the first examination, a quick increase in temperature.

Even if the ideal temperature is not reached you can still start an insufflation. A window "popup" appears to ask you for confirmation.

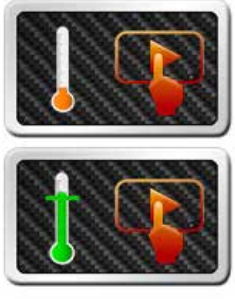
Pre-heating / Stand-by Phase: (outside the insufflation phases)

- This is the target temperature for the Stand-By/Pre-heating phase
- This is the estimated time (updated in real-time) and the waiting time temperature of heating hose to reach , the best temperature condition for the insufflation.

Heating during an examination:



- This is the target temperature set for the protocol currently used.
- This red light indicate that the heating system is actually energized.
- Here the temperature is reached



Heating when stand-by/pre-heating time is ended:

By default the device in stand-by/pre-heating phase, heat only during 45 minutes.
You can re-activate a phase of stand-by/pre-heating, by clicking the PLAY button, as indicated by this icon

9.2 STARTING THE INSUFFLATION:

Check if gas cylinder / gas input, is opened.

Insufflation will start when the START button (A) located on the main screen of Panel PC is pressed.

First, the device ask you to present and maintain few seconds the RFID label of the disposable, as show in below.

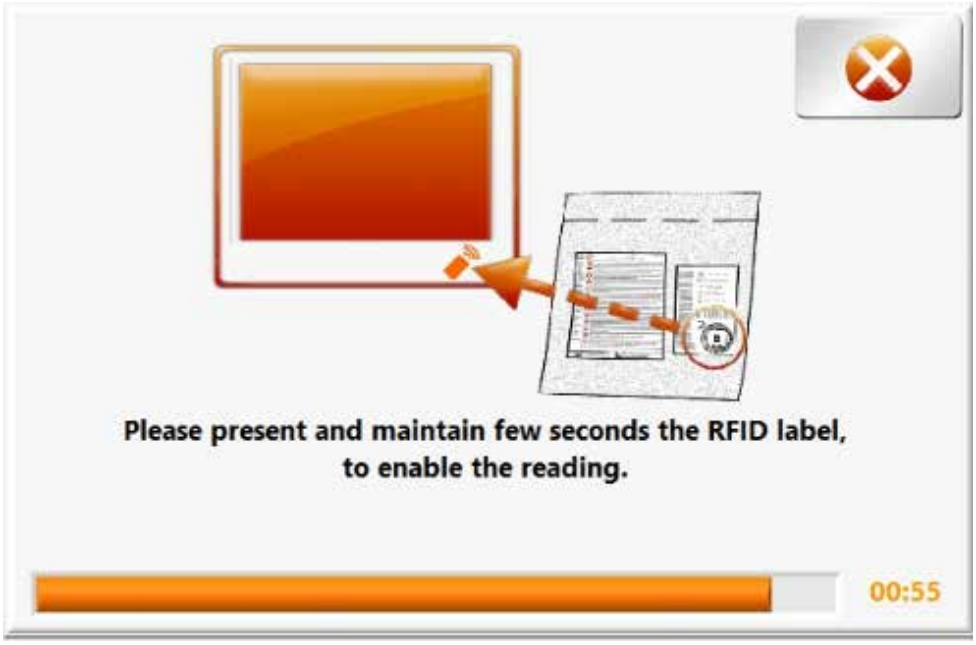
First, the device ask you to present and maintain few seconds the RFID label of the disposable, as show in below. These checks enable :

- that the disposable is adapted to the selected mode of the device
- the validy date of the disposable

prevent to use the same disposable with various patients.

CAUTION!

Do not discard the disposable bag before the end of the examination.
Do not tear off or damage the RFID tag.
The device will answer you to scan the RFID label, stuck on each disposable bag IS-IN-LL-A.
This is a security for the patient and the device.
With this RFID label, the device will verify that the disposable used is of the correct reference, has a valid date of use, and prevents the disposable from being used with several patients.



The device check if the ideal temperature target is ok, and if the ideal temperature is not reached, the software asks if you still want to start the examination.

Then after these checks, a message on the screen indicates the activation of the colonoscopy examination, displaying “Insufflation in process”

The SETTINGS button, PROTOCOL button and Mode button are disabled during the examination. It’s necessary to stop the examination, to enable these buttons.

Insufflation starts, gradually increasing the flow and pressure in the ranges of the set parameters

Once the pressure set point is reached, insufflation stops. Insufflation restarts when the intra-cavity pressure falls below the pressure set point.
The pressure, flow set-point , colon preparation can be modified at any time.

9.2.1 ELEMENTS DURING THE INSUFFLATION

9.2.1.1 OVERPRESSURE – DESSUFFLATION

When the intra-colon pressure exceeds the pressure set point dependent of the selected protocol message «OVERPRESSURE» is displayed and a dessufflation is initiated to keep the colon inflated while eliminating the overpressure.

- ❖ If pressure exceeds a bit above the pressure set point, device produces a soft dessufflation. Instead, if the pressure exceeds a lot above the pressure set point, device will produce a fast dessufflation.

- ❖ The overpressure management works at any time of the examination insufflation.

9.2.1.2 MANUAL PAUSING

It is possible to put insufflation in pause (no added pressure and flow) by pressing again the START/PAUSE button (A).
To continue insufflation, press again the START/PAUSE button.

- ❖ The overpressure management continues to remain operative during the pause.

9.2.1.3 AUTOMATIC PAUSING OF INSUFFLATION

Depending on the selected mode, the device can perform some pauses at volume levels set in the protocol of the mode.

- ❖ The overpressure management continues to operate during the pause.

To continue insufflation, confirm the validation required by the device.

9.2.1.4 MONITORING THE PARAMETERS (FLOW, PRESSURE, CO_2 VOLUME USED, TEMPERATURE)

The instantaneous flow rate is indicated in litres/minute on the Main screen. It will not exceed the maximum flow set point.
The instantaneous pressure rate is indicated in mm Hg on the Main screen. It will not exceed the maximum pressure set point.

In the Main screen you can see also, at any time:

- the CO_2 volume inside the patient (I)
- the CO_2 gas temperature at the outlet of the device (J)
- the status messages, of the device (O)
- the alert messages, of the device (P)
- the duration of the examination (K)
- the CO_2 gas level inside the gas cylinder (L)

Pressure management of the gas cylinder :

- beyond 20 bar, normal operation, no alert messages
- between 10 and 20 bar, normal operation, with an alert message to order a new gas cylinder.
- below 10 bar, the device does not allow insufflation, and displays a message to check the cylinder

In the Case of a Gas LAN Hospital, this will be noticed when input pressure will be below 2 bar.

9.2.1.5 END OF COLONIC DISTENSION

✔ Stop the insufflation by pressing the STOP button (B), a fast dessufflation is initiated.
✔ Immediately disconnect the tubing from the device to prevent any backflow of liquid or gas into the unit.

Used tubing should be disposed of in a suitable container after use.

At the end of the diagnostic procedure switch off the device :

- navigate to the device information panel, and press the shutdown button (D4) **(recommended)**
- or by pressing the START button (12)

Finally, you switch power inlet (13) to "0".

9.3 INSUFFLATION MODES

Depending on the settings of your device, you have the possibility to use the following modes:

- ❖ CT colonography / Virtual colonoscopy
  - ➢ Pressure range: 5 to 35 mmHg
  - ➢ Flow range: 1 to 4 L/ min

- ❖ Optical colonoscopy
  - ➢ Pressure range: 5 to 35 mmHg
  - ➢ Flow range: 2 to 10 L/ min

- ❖ Virtual Enteroscopy
  - ➢ Pressure range: 5 to 35 mmHg
  - ➢ Flow range: 1 to 4 L/ min

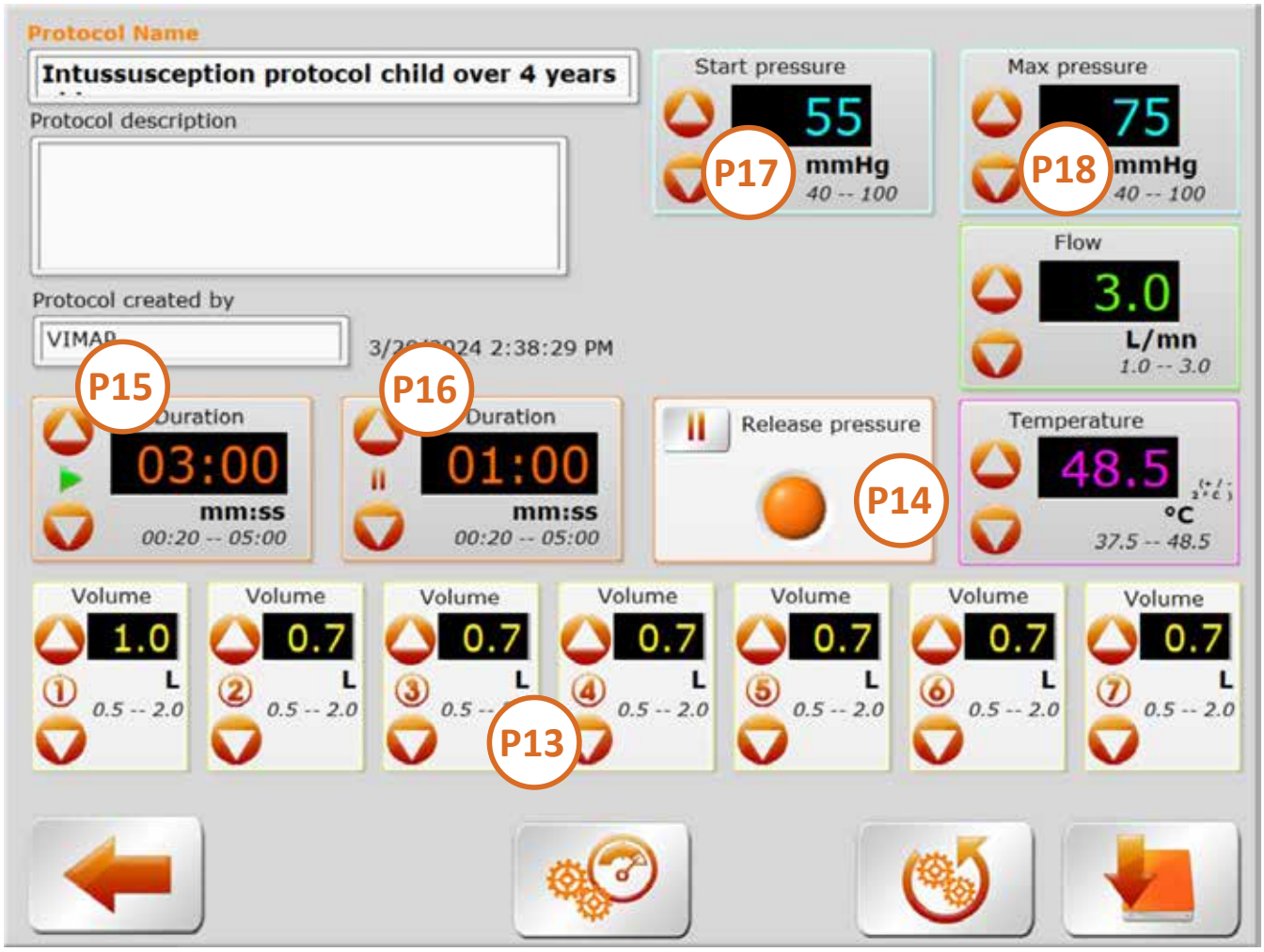
- ❖ Intussusception reduction
  - ➢ Pressure range: 40 to 120 mmHg
  - ➢ Flow range: 1 to 3 L/ min

9.3.1 DETAILS FOR THE INTUSSUSCEPTION REDUCTION MODE.

For the Intussusception reduction mode and for reasons of security for young patients, the operating principle is as follows:

- Once the maximum pressure selected, you can perform 7 trials to complete the exam.
- The increase in pressure is done gradually with pressure levels, forcing to try first, lower pressures to reduce intussusception.
- Each trial has a maximum volume and an authorized maximum duration (adjustable).
- Between each trial a minimum pause duration is imposed (adjustable).
- During the pause you can choose to release all the pressure or reduce the pressure to the minimum pressure (40 mmHg).
- if you request a Pause: once the minimum Pause time has been completed, you can go directly to the next trial and the next pressure level.

Protocol setup for Intussusception reduction :



P13. Definition of the maximal volume for each trial. Here the volume is adjustable between 0.5 and 1.5 liter.

P14. Pressure management during the pauses :

- Enabled : Pause with release of all the pressure.
- Disabled: Pause with pressure reduced at 40 mmHg

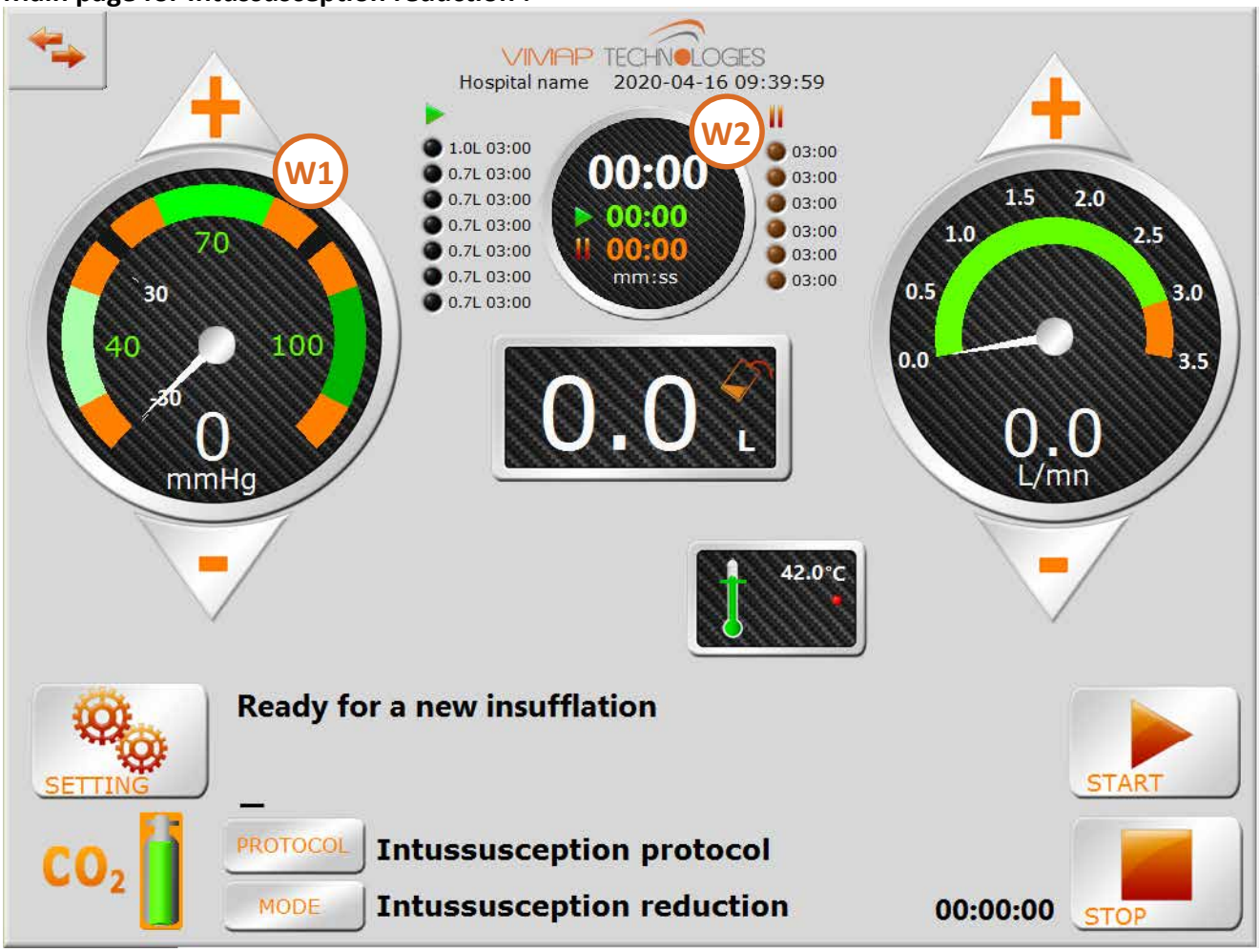
P15. Maximum duration for each trial. Adjustable between 20 secondes and 5 minutes.

P16. Minimum duration for each pause. Adjustable between 20 secondes and 5 minutes.

P17. Start pressure : Default pressure of the first trial. This pressure will be used by default, every time you use this protocol. Use the up and down arrows to set the pressure.

P18. Max pressure : Default pressure of the third trial. This pressure will be used by default, every time you use this protocol. Use the up and down arrows to set the pressure.

Main page for Intussusception reduction :



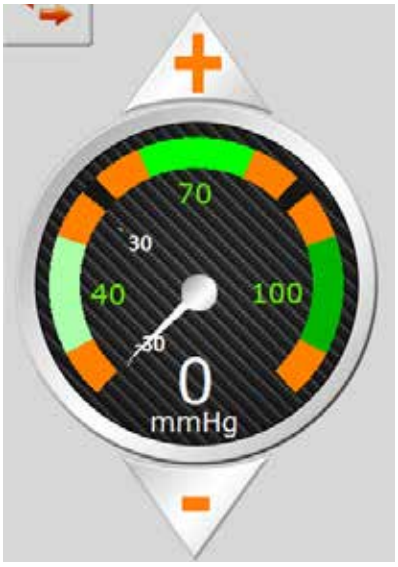
For Intussusception reduction mode, you have two specifics gauges :

The pressure gauge (W1), show you the two trials pressure levels, before the maximum pressure set inside the protocol.
The device will automatically compute intermediate default pressures for the first and second trials : the increase in pressure is done gradually with pressure levels, proposing to try first, lower pressures to reduce intussusception:

First trial: by default, use of the Start pressure**, set by the user.**
Second trial: use of the intermediate pressure = Start pressure + ((Max pressure - Start pressure)/2)
From third trial: use of the Max pressure**, set by the user.**

In this example:
The device has created pressure levels:

- a first pressure level at the Start pressure : 40mmHg
- an intermediate pressure level : 70 mmHg
- and the Max pressure level : 100 mmHg



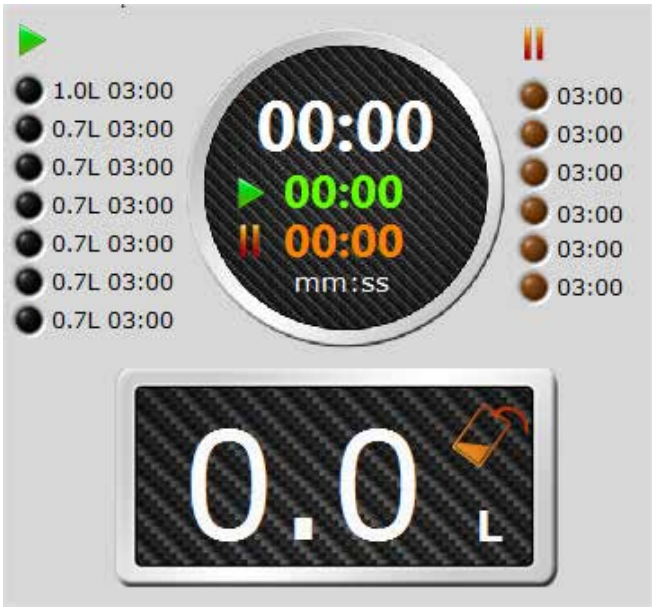
In the protocol setting page, the maximum allowed pressure is of 100 mmHg. **But you can manually set since first trial and in any trials,** a pressure up to 120 mmHg using the + and - buttons on this gauge, in this case the device ask you a confirmation to set a pressure over 100mmHg.

The trials gauge (W2), show you informations for each trial.

Column of trials:

You can see here each trials, with the maximum volume and the maximum duration set in the protocol.

When a trial is done, volume and time values change, for the volume and duration really used for the trial.



Column of Pauses

You can see here each pause, with the minimum duration set in the protocol.

When a pause is done, the duration value change, for the duration really used for the pause.

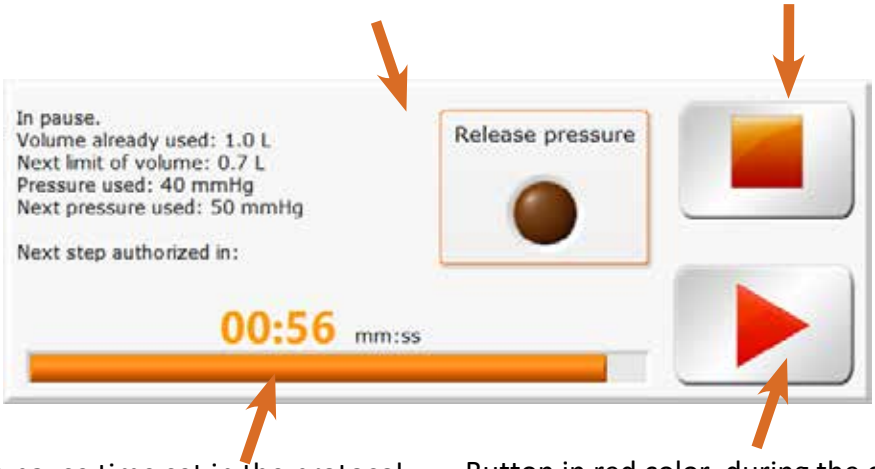
The central gauge shows 3 durations :

- The duration in white, is the total duration of the examen.
- The duration in green ▶, is the insufflation time of the actual trial.
- The duration in orange ⏸, is the insufflation time of the actual pause.

Description of the Intussuception Reduction Pause popup :

If "Release pressure" is by default disabled inside the protocol:
this button is displayed to enable you to release if necessary, the pressure during this pause.

Stop the examination.
A second popup ask you a confirmation, and the insufflation still in Pause, until you press STOP on the main screen again.



Countdown of the pause time set in the protocol.

Button in red color, during the coutdown of the pause time.
On the entire responsibility of the physician or operator, you can decide to skip the pause and go directly to the next attempt without waiting for the end of the pause time.

For safety reasons, we do not recommend to skip the minimum pause duration of the protocols that has been set to 20s . Vimap Technologies will not be responsible of any adverse event occurring if the physician or operator decides to skip the minimum 20s pauses.

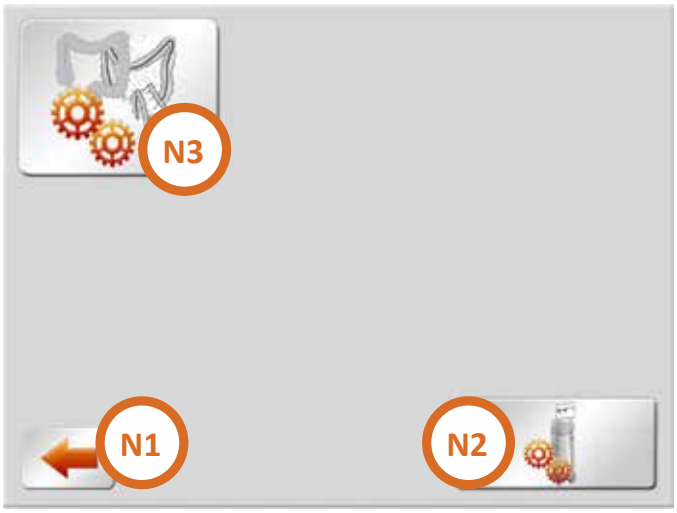
When the pause time is ended, the countdown time disappears and the button change in green.

9.3.2 OPTION TO TAKE ACCOUNT OR NOT OF THE BAG VOLUME, IN THE CASE OF NON-USE OF THE BAG (OPTION DISPLAYED DEPENDING ON THE MODE):

- ❖ With or without the drainage bag, depending on the composition of the administration set used for the examination. For example, for the intussusception mode, you can use an administration set with the “clamp bag” opened or completely closed during this examination.
- ❖ If bag is enabled, the displayed volume increases only after the bag volume (0.4 / 0.5L) has passed.
- ❖ If bag is disabled, the displayed volume increases directly with the gas flow.

10 NAVIGATE INSIDE SOFTWARE

You can navigate to other panels of the software, by clicking the SETTINGS button (C) on the Main panel.



N1. Back to the Main panel

N2. Go to the informations panel

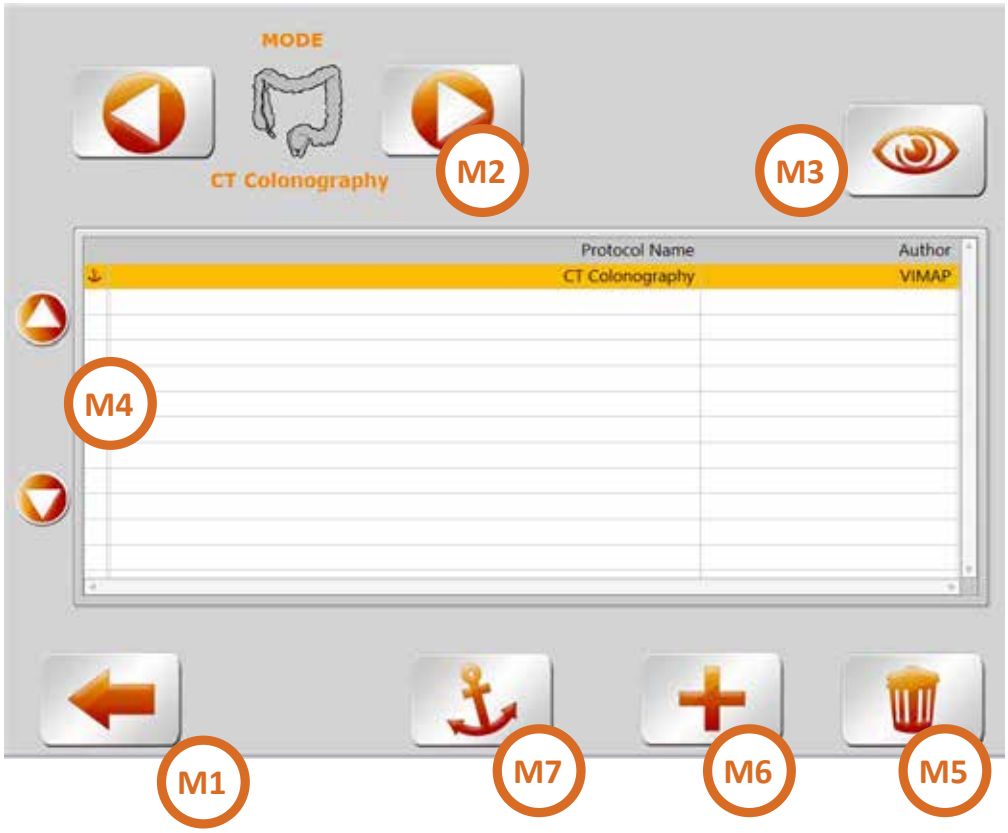
N3. Set MODE/PROTOCOL

The others buttons of this panel, are for future options.

10.1 PROTOCOLS/MODES SETUP

In this panel, you can see the actual mode used and the list of protocols attached to this mode. You can also navigate directly in this panel, by clicking on the MODE button on the Main panel.

The default protocol used in this mode is identified by the small anchor (M4) in the list.



You can change the display order of protocols list by a click in the columin header of Protocol name or Author.

M2. The actual mode is displayed here. With the right and left arrows you can change the mode used, in accordance with the setup of the device (authorized modes).

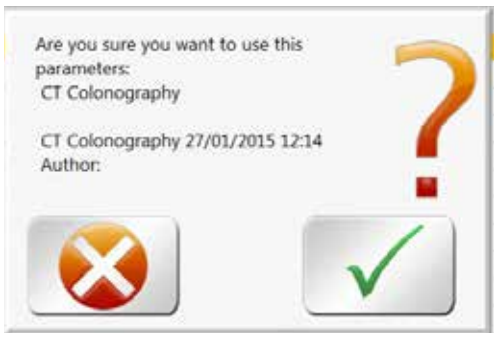
M3. Go to the details panel of the selected protocol, You can also go the detail panel of a protocol by a double click in the protocol list, or directly by clicking on the PROTOCOL button in Main panel.

M5. Delete the protocol selected in the list. A confirmation is requested.

M6. Create a new protocol for the actual mode.

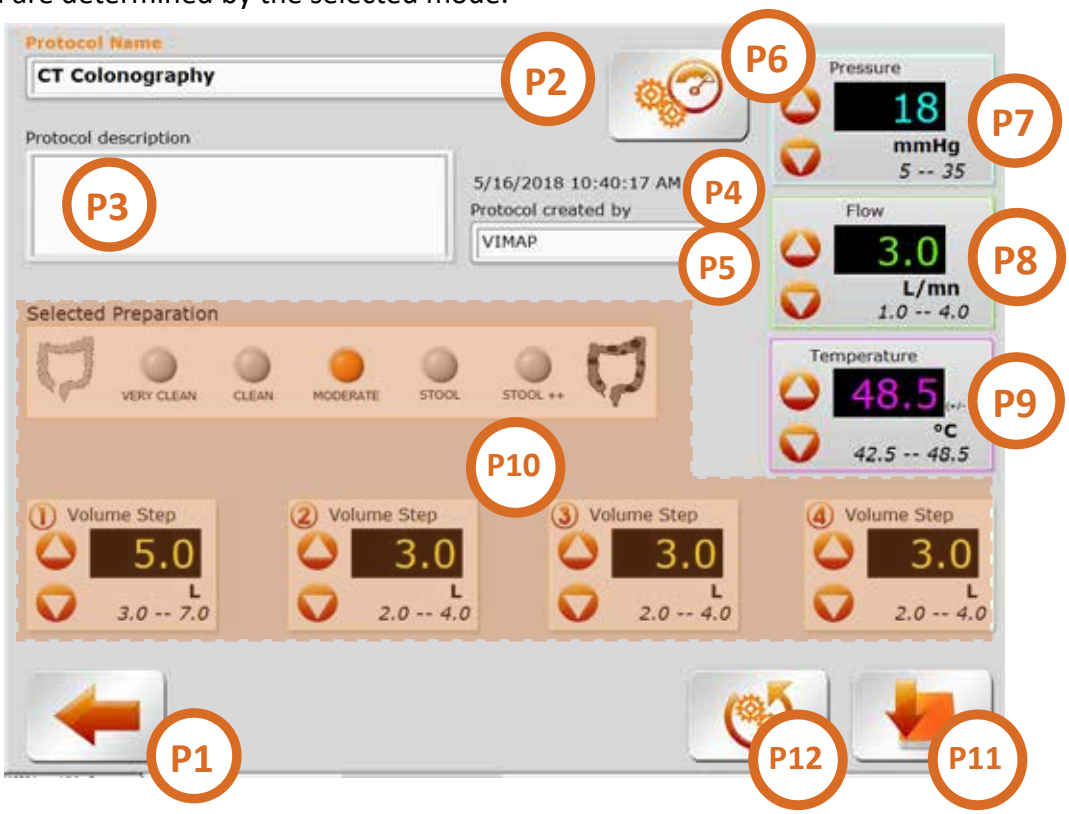
M7. Set the protocol selected in the list as the default protocol to use for this mode. This is identified by the small anchor (M4) in the list.

M1. Back to the Main panel. A confirmation is requested to use or not the protocol selected in the list.



10.2 DETAILS PROTOCOL

In this panel, you can see and change the default parameters used by the protocol.
For each of the parameters, you can set a default value to use. The minimum and maximum values authorized are determined by the selected mode.



P1. Back to the Main panel.

P2. Name of the protocol. Activate the popup keyboard, by clicking inside this field. This name is displayed on the protocol list, and on the Main page when it is selected.

P3. Description of the protocol. Activate the popup keyboard, by clicking inside this field.

P4. Displays the creation or modification date of the protocol.

P5. Name of the Author of this protocol. Activate the popup keyboard, by clicking inside this field.

P6. Interface setup. You can set an interface specific to this protocol. See the next paragraph for more detail.

P7. Default pressure. This pressure will be used by default, every time you use this protocol. Use the up and down arrows to set the pressure.

P8. Default flow. This flow will be used by default, every time you use this protocol. Use the up and down arrows to set the flow.

P9. Default temperature. This temperature will be used by default, every time you'll use this protocol. Use the up and down arrows to set the temperature.

P10. In this orange area, you can set parameters specific to the mode. The type of parameters available here can totally change from one mode to another.
Here we have for example, the possibility to choose the type of preparation of the colon, and the levels of volumes that will cause automatic pauses during the insufflation.

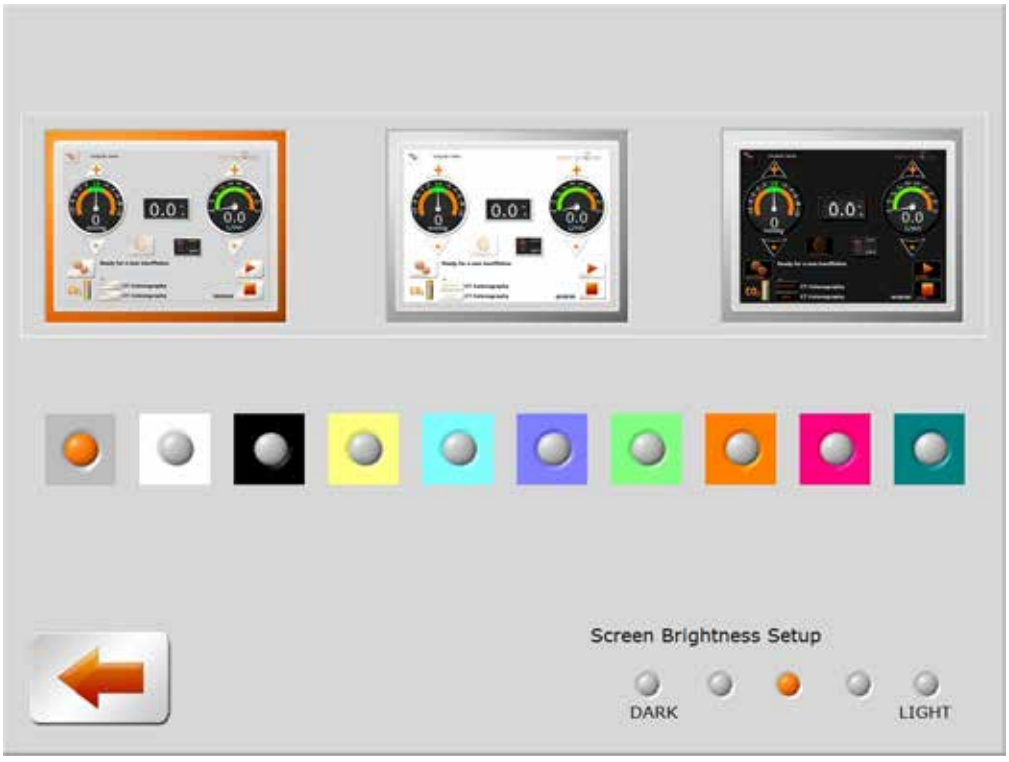
P11. Save button. Click on this button to save the changes made in this protocol.

P12. Restore the default parameters. Click on this button to load the default parameters of the protocols in relation with the mode. Don't forget to save it.

10.2.1 INTERFACE SETUP

In this panel, you can select the indicators style of each measure displayed in the Main panel.
You can also set the colour of the background and the brightness of the screen.

NOTE. You must be careful between background and indicator contrast. Select calm colours and the best way you understand and easily read the parameters easily.



10.3 DEVICE INFORMATION

In this panel, you can see some informations about the device:

- Model device
- Serial number SN#
- Various device informations
- The quantity of insufflation performed since the last maintenance
- The potential number of insufflations before the next maintenance
- The date of the last insufflation
- The date of next preventive maintenance
- Gas volume used for the last insufflation.

D1. Back to the Main panel.

D2. Password access. Used only for maintenance / advanced setup, operations.

D3. Reboot the device.

D4. Shutdown the device. **Recommended to shutdown the device correctly.**

D5. Test and actions of the pedals module **(in option)**
When a pedal module is connected you control actions of the software. Use the advanced setup to change the actions assigned to each pedal.
To test the pedal, press for one second on each pedal, successively.

10.4 POPUP KEYBOARD

This keyboard automatically appears when it is possible to write information

1. Write the new text and close the keyboard.
2. Delete character by character.
3. Delete directly all text.
4. Close the keyboard without applying the new text.
5. **Temporarily show/hide the real characters of passwords in plain text. (only for software >=V4.6)**

11 ADVANCED SETTINGS AND FEATURES

To access the advanced settings and features, you must enter the password

- **only for software <V4.5) localadmin**
- **only for software >=V4.5) localadmin@ISO13485**

in (D2) of the device information panel.

You can see more options in the tabs below :

11.1 LOCAL SETUP PANEL

11.1.1 HOSPITAL NAME

Click on the field, and change the hospital name with the virtual keyboard. Click on the button Save N1, to save the changes.

11.1.2 SET THE ACTIONS ASSIGNED TO EACH PEDAL

You can assign or not an action to the pedal, with the help of the list of proposed actions. Click on the button Save N2, to save the changes.

11.1.3 SERIAL NUMBER OF THE DEVICE

If it's not already done, you can set the serial number of the device. This serial number is recorded and used for the log of events and values sensors fo the device.

Click on the button Save N5, to save the changes.

11.2 REGIONAL SETUP PANEL

11.2.1 TIME/DATE

Select with the arrows the correct parameters, and click to the button Save N8.

11.2.2 UNITS

Units used for the display: Select the units and click on the button Save N9. Follow on-screen instructions (restart device).

11.2.3 LANGUAGE

Language used for the display: Select the language with the left and right arrows and click on the button Save N10. Follow on-screen instructions (restart device).

11.3 GAS SETUP PANEL

11.3.1 GAS INPUT TYPE

Click on the desired type of CO2 gas input, selects and click to the button Save (N11).

The two pressure displayed below this button, are the gas cylinder pressure, and Pressure after the internal High Pressure reductor. This two pressure are indicative and can facilitate identification of eventual problem of gaz input.

For gas cylinder input type: Use only cylinders containing **CO2 gas medical grade**, with a maximum pressure of 70 bar. With this entry, the device will function only if the inlet pressure exceeds 10 bar.

For network of gas of the institution: The inlet pressure of the gas must be between 2 and 6 bar. Use only **CO2 gas medical grade**.

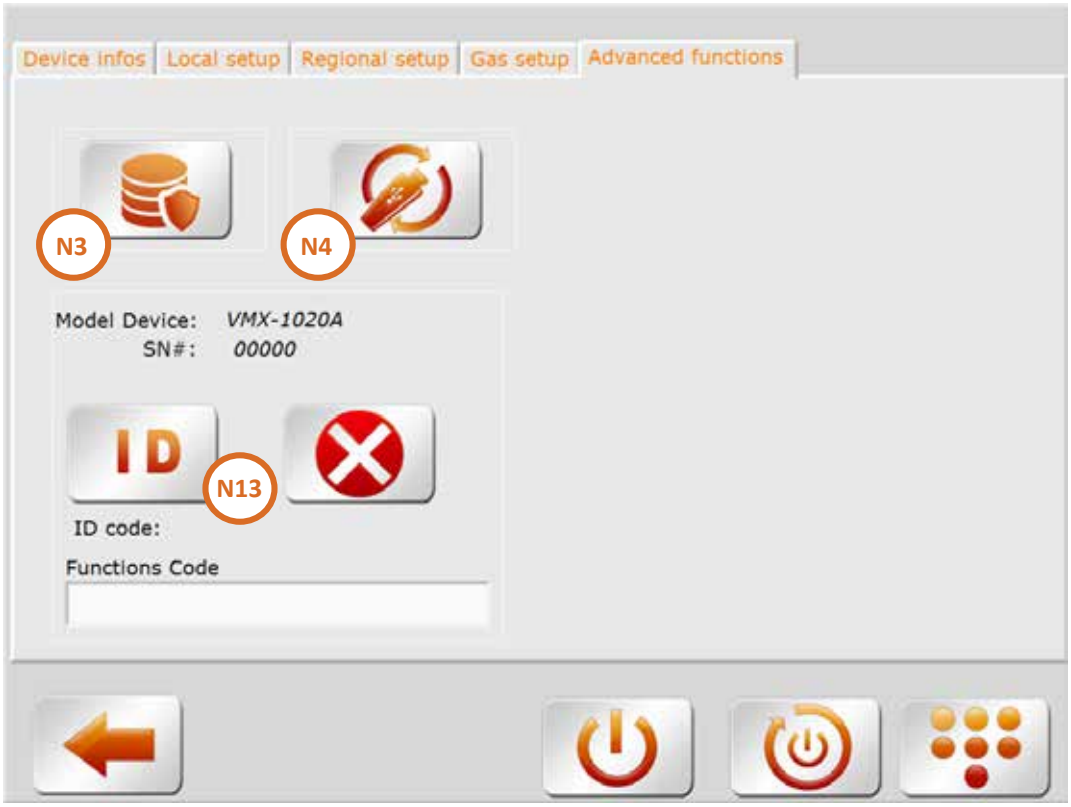
11.3.2 TIME BEFORE STAND-BY

You can set the duration (here 45 minutes) during that, the device heats the flexible outside an examination; Once that time has elapsed, the heating of the device goes into "stand-by" to the request for a new insufflation.Set the time and click to the button Save (N12).

When you start an insufflation, if the ideal temperature is not reached, the device asks if you want to wait for the ideal temperature to be reached, or if you want to start insufflation.

When you turn on the device, the heating is activated the first time, and then goes to "stand-by" if no insufflation is started after 45 minutes (the time set in this example.)

11.4 ADVANCED FUNCTIONS PANEL



11.4.1 BACKUP THE DATA

You can backup the database and data records of each insufflations performed on the device. The backup is saved on the device and you have also the possibility to save this backup on a USB drive/key.

To do this action, click on the Backup button (N3), and follow the on-screen instructions.

11.4.2 FUNCTIONS CODE

This section allows you to enable or disable certain functions of the device, temporarily or permanently.

A click on the ID button (N13) generates an "ID code" to send to your distributor / Vimap Technologies. Once this code has been verified, your distributor / Vimap Technologies will send you a function code to enter into the field "Functions code".

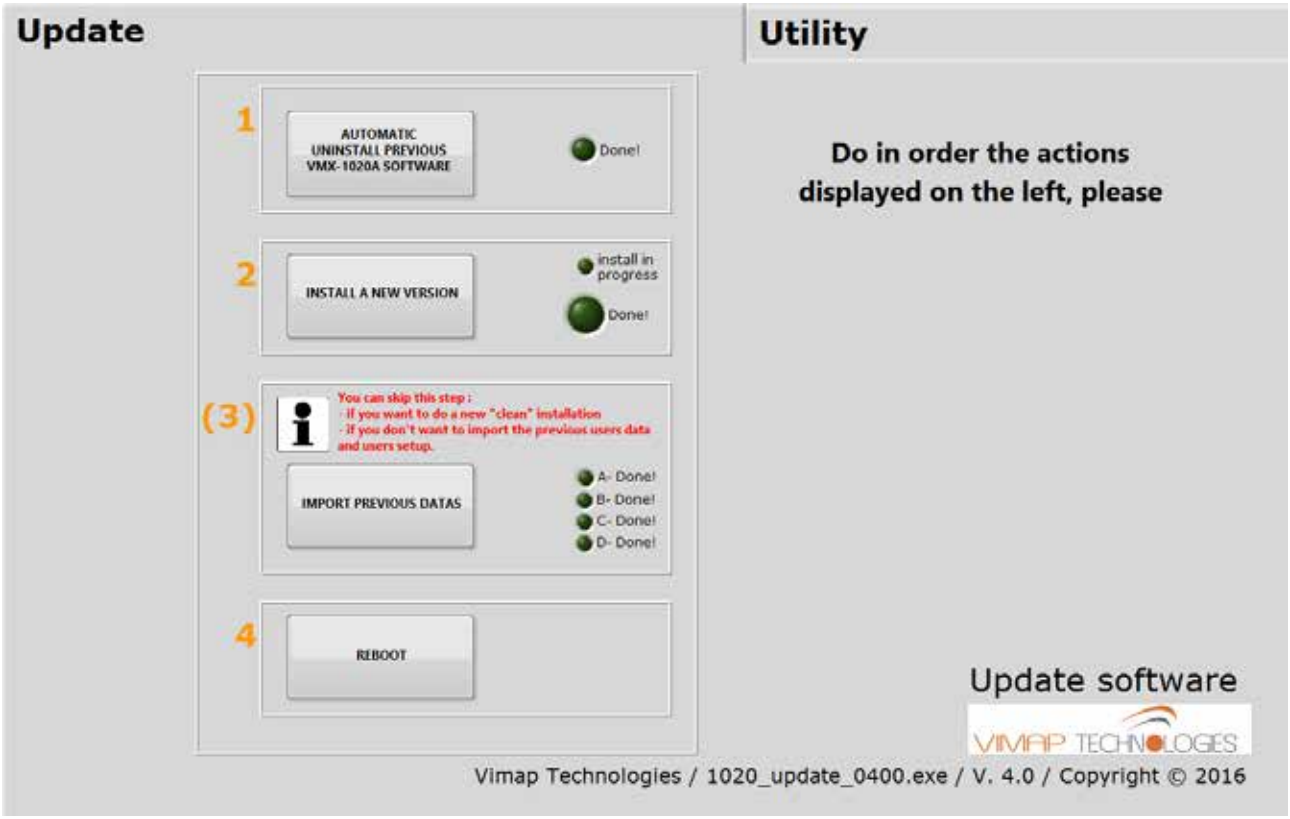
Please note that each "ID code" is specific to each request. If you click for a new "ID code", you will have to send this "ID code" again to your distributor / Vimap Technologies.

11.4.3 UPDATE SOFTWARE

Use this function, when you want to apply a software update of the device. The update is provided by your local distributor or by Vimap Technologies. The update function uses a USB drive/key, and the update process is automated, with on-screen instructions. Click to the Update button (N4) to start the procedure.

When the update procedure is initiated, the update software boots directly from the USB key.

This is the main panel of the software updater. Simply follow all the steps:

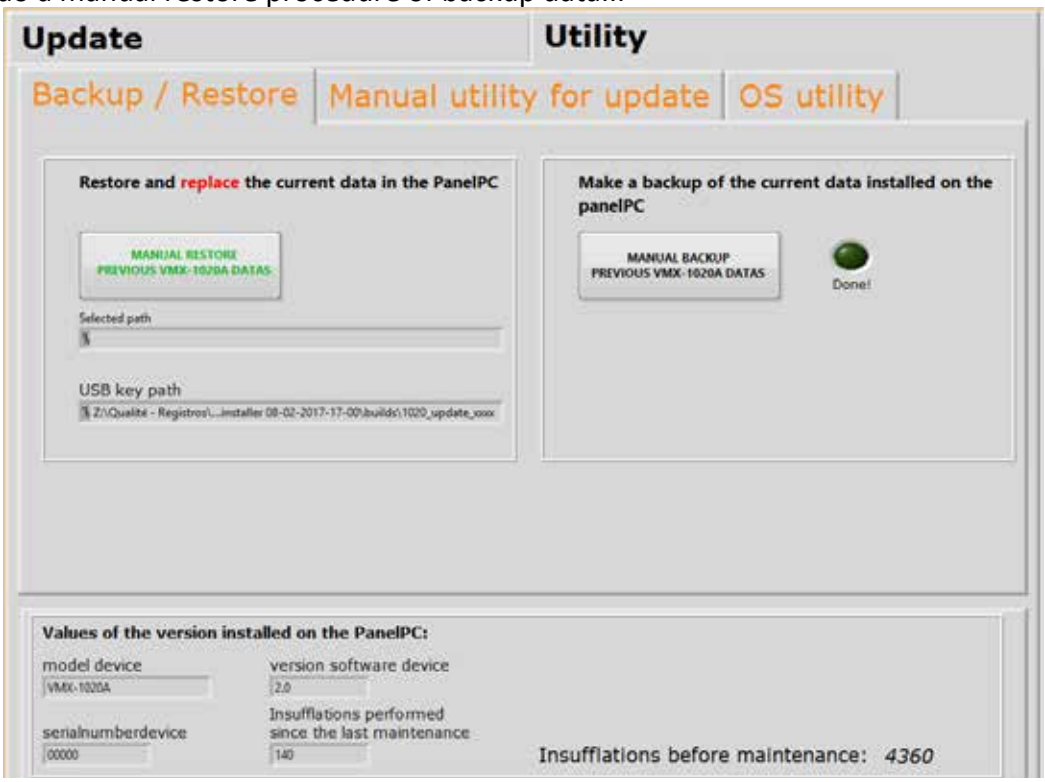


Step **3** "IMPORT PREVIOUS DATAS"**:**

- You can skip this step, if you don't want to import the previous data and user setup.
- **Skip this step if you want to install a "clean version" of the software.**

Go directly to the step 4

The "option panel", is only used in case of problem during the automated phases of the software update, or do a manual restore procedure of backup data...



12 FAULTS AND ALERTS

12.1 POSSIBILITY TO SHUTDOWN OR REBOOT THE DEVICE

- navigate to the device information panel, and press the shutdown button (D4) **(recommended)**
- or by pressing the START button (12) (If necessary a long press on this button can also initiate the shutdown of Panel PC)
- you can switch power inlet (13) to “0”.

If other previous method fail or in case of emergency, such as in the case of suspicious behavior, an extinction of the device or an unplug of the power cable ensures optimal safety, by default, this action closes the supply of gas and releases the gas already present inside the device.

IEC-lock : You must have special attention, because to unplug the IEC connector, you must move the red lock .
It is not necessary to move this lock when you plug the IEC connector to the power inlet.

12.2 DEVICE ALERTS

When an alert message is displayed on the screen, depending on the level of alert, the device will:

- ask a user action, to immediately resolve the fault.
- stop or prevent the insufflation examination, to prevent damage.
- ask you to contact your nearest after-sales service.

13 CLEANING / SERVICING / MAINTENANCE

13.1 CLEANING / DECONTAMINATION

The instructions issued by the sterilization managers of each hospital or medical centre must be followed in all cases; these instructions will take precedence over the information contained in the present manual which is provided for guidance only.

Prior to disinfecting the VMX-1020A Insufflator, ensure the power is turned off and the line cord (mains lead) is unplugged.
To disinfect the VMX-1020A Insufflator wipe down with an intermediate level disinfectant (corrosive disinfectants, such as bleach, are not recommended since they may damage or change color of the equipment) in accordance with the manufacturer’s directions.
Do not use abrasive or sharp-edged devices when disinfecting the VMX-1020A Insufflator.
Do not spray fluids directly onto the unit or allow fluids to enter the unit.
Dry all components thoroughly.
Do not sterilize or autoclave this unit.
For general cleaning, the VMX-1020A Insufflator can be wiped down with a damp cloth and mild soap.
For example, you can use wipes 2% chlorhexidine and 70% ethanol-based alcohol.
After each use:

➢ Discard the disposable tubing - do not attempt to sterilize it.
➢ Clean up any splashes of liquid present on the device by wiping with a damp cloth.

The unit must be decontaminated before sending it to the after-sales service.

13.2 SERVICE OF MAINTENANCE

13.2.1 PREVENTIVE MAINTENANCE

CAUTION!
The service and maintenance operations, not to be done while in use or connected to the patient.

The panel PC of your insufflator allows you to visualize, the number of examinations performed before service.
SERVICING MUST BE CARRIED OUT EXCLUSIVELY BY AUTHORIZED PERSONNEL FOR THE MANUFACTURER AFTER 4500 EXAMINATIONS OR EACH YEAR. The unit must be returned if the message «Contact with your distributor» is displayed continuously.

This service will include a full test/inspection checklist, reinstatement of factory settings, testing of flow and pressure measuring circuits, inspection and calibration.

13.2.2 SHIPMENT OF THE DEVICE

The device can be shipped only when you receive written approval from your distributor or VIMAP Technologies. In this case, thank you to use the original packaging of the device .

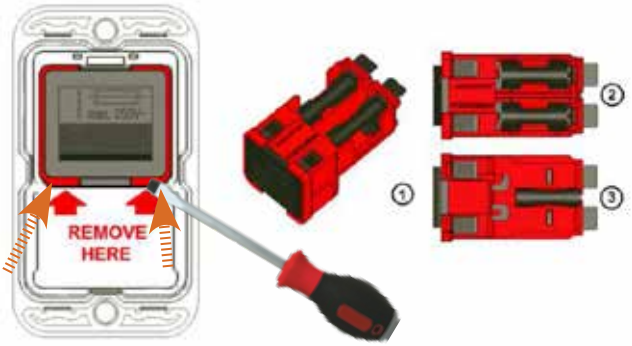
- **Please DISCONNECT / UNPLUG the metallic high pressure hose and the electric cord.**
- **Fix or block all parts.**
- **Do not let parts “free to move” inside the box pallet during the shipment.**
- **Do not remove the feet of the device.**

In case of the original packaging is not being used or the device is not properly installed in its packaging, VIMAP TECHNOLOGIES reserves the right to automatically charge for the replacement of items that have suffered damage during transport.

13.3 CHECK / REPLACE FUSES

In case of device does not start, disconnect the cord, and check that the fuse of power inlet is correct. For doing this check, see the next image and follow the steps:
Replace only with fuses, as values indicated on the device label.(5x20mm, UR slow-blow fuse, compliant with UL standard)

Removal of the combined switch / fuse holder unit:



An additional fuse mark on the switch indicates the fuses holders behind the switch. The red frame shows the outline of the removable unit.

With a simple tool like a Swiss army knife or a screwdriver No1 or smaller, the unit (1) can be removed from the filter. On the topside (2) behind the switch there are two fuse holders for each live connection. On the bottom side (3) is a clip to carry an additional spare fuse.

CAUTION!
Unplug the power cable before performing this operation

13.4 IMPACT OF MOBILE AND PORTABLE HF COMMUNICATION DEVICES

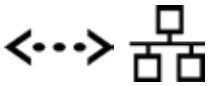
The emission of high frequency energy by mobile communication devices may affect the function of the electrical medical device. Operating such devices (e.g., cell phones, GPS phones) in the proximity of the electrical medical device is not recommended.

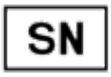
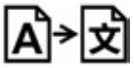
13.5 ELECTROMAGNETIC COMPATIBILITY

Medical devices are subject to special safety and protective measures concerning Precautionary measures electromagnetic compatibility (hereafter abbreviated as EMC). This device is to be used only for the purposes described in the manual and has to be installed, set up, and operated in compliance with the EMC notes and instructions, in annex.

14 ANNEX

14.1 SYMBOLS USED

Description	Corresponding SYMBOL
Class I device	Class I
Type BF device	
Important : Read the user manual	
UR slow-blow fuse, compliant with UL standard (here 8A temporized 250V)	 T 8A 250V
Ethernet / LAN plug	

Description	Corresponding SYMBOL
Conforms to European Directive WEEE 2002/96/EEC	
Equipotential earth bonding	
CO_2 inlet connection 70Bar MAx.	
Conform to European Directive 93 / 42 EEC (XXXX number of certify body CE)	 0318
Product reference of the device	
Serial number of the device	
Manufacturer of the device	
Date of manufacture YYYY	 2015
Conform to RoHS Directive 2011/65/EU and amendment 2015/863/EU. (Restriction of the Use of Certain Hazardous Substances)	
Internal connexion at protective earth	
On / Off of the device	 On Off On/Off
Data matrix UDI / GS1 (Unique Device Identification) (01) 08436557390110 UDI-DI Primary Product identifier for VMX-1020A device / (21) serial number / (11) date of manufacture	
Unique Device Identifier. Indicates a carrier that contains Unique Device Identifier information.	
Medical device. Indicates the item is a medical device.	
Conform to UK MDR 2002	
Others Translations for the user manual.	

14.2 MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS

This apparatus is intended for use in the electromagnetic environment specified below. The user must ensure that it is used in this environment.

Emissions test	Conformity	Electromagnetic environment - Guide
RF emissions CISPR 11 / EN 55011	Group 1	This apparatus uses radio-frequency energy for its internal functions only. For this reason its RF emissions are very low and are not liable to cause interference with nearby electronic equipment.
RF emissions CISPR 11 / EN 55011	Class B	This apparatus may be used in all types of premises other than domestic premises and those connected directly to the public low voltage distribution network used to supply buildings for domestic purposes.
Harmonic emissions EN 61000-3-2	Compliant	
Voltage fluctuations / flicker EN 61000-3-3	Compliant	

14.3 MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY

This apparatus is intended for use in the electromagnetic environment specified below. The user must ensure that it is used in this environment.

Immunity test	IEC 60601 Level of severity	Level of conformity	Electromagnetic environment - Guide
Electrostatic discharges EN 61000-4-2	± 6 kv on contact ± 8 kv in air	± 6 kv ± 8 kv	The floor must be wood, concrete or tile. If the floor is covered with a synthetic material, the relative humidity must be at least 30%.
Rapid burst transients EN 61000-4-4	± 2 kv for power lines ± 1 kv for input/output lines	± 2 kv ± 1 kv	The quality of the main power supply must be that of a typical commercial or hospital environment.
Voltage surges EN 61000-4-5	Differential mode ± 1 kv Common mode ± 2 kv	± 1 kv ± 2 kv	The quality of the main power supply should be that of a typical commercial or hospital environment.
Dips, short interruptions and variations of supply voltage EN 61000-4-11	<5% U_T – for 10 ms 40% U_T – for 100 ms 70% U_T – for 500 ms <5% U_T – for 5 s	<5% U_T - 10 ms <40% U_T - 100 ms <70% U_T - 500 ms <5% U_T - 5 s	**The quality of the main power supply must be that of a typical commercial or hospital environment.** If the user of this apparatus requires it to continue operating during interruptions to the main power supply, it is recommended that the apparatus be powered by an inverter or battery.
Network frequency magnetic field (50/60 Hz)	3 A/m	3 A/m	The network frequency magnetic field must be at a characteristic level for a location in a typical commercial or hospital environment.

Immunity test	IEC 60601 Level of severity	Level of conformity	Electromagnetic environment - Guide
			Portable and mobile radio-frequency communications equipment must not be used at a distance from this apparatus, including the cables, less than the recommended separation distance calculated using the applicable formula depending on the frequency of the transmitter. **Recommended separation distance**
Conducted RF EN 61000-4-6	3 vrms 150 kHz to 80 MHz	3v	$d = 1{,}16\sqrt{P}$ $d = 1{,}16\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}33\sqrt{P}$ 800 MHz to 2,5 GHz
Radiated RF EN 61000-4-3	3 v/m 80 MHz to 2.5 GHz	3v/m	In which P is the maximum output power of the transmitter, in Watts (W), assigned by the manufacturer of the transmitter and the recommended separation distance (d) in meters (m). The field levels emitted by immobile RF transmitters – which are to be established by an electromagnetic measurement at the site – must be lower than the compliance level in each frequency band. Interference can occur nearby devices bearing the following symbol:

NOTE 1: *U_T is the nominal value of the power voltage applied during the test.*
NOTE 2: *At 80 MHz and 800 MHz, the higher frequency band applies.*
NOTE 3: *These recommendations may not apply in all situations. The propagation of electromagnetic waves is modified by absorption and reflection due to structures, objects and people.*

- The field level of immobile transmitters, such as radio telephone base stations (cellular and cordless) and mobile terrestrial radio systems, amateur radio systems, AM/FM radio communication systems, and Tv systems cannot be evaluated theoretically with precision. To ascertain the electromagnetic environment due to immobile RF transmitters, a site measurement must be performed. If a field level measured within the environment in which this camera is used exceeds the above applicable compliance levels, check that this camera operates in a satisfactory manner. If abnormal operation is observed, additional measurements should be taken, such as reorientation or relocation of the reference system.
- Outside the frequency band of 150 kHz to 80 MHz, the field level should be less than 3 v/m

14.4 RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RADIOFREQUENCY COMMUNICATIONS EQUIPMENT AND THIS APPARATUS.

This apparatus is designed for use in an electromagnetic environment in which radiated RF disturbance is controlled. The user of this apparatus can help prevent electromagnetic interference by maintaining a minimum separation distance between portable and mobile radio-frequency communications equipment (emitters) and the apparatus as recommended below, depending on the maximum output power of the communications equipment.

Specified maximum output power of emitter W	**Separation distance depending on emitter frequency m**		
	150 kHz to 80 MHz	**80 MHz to 800 MHz**	**800 MHz to 2.5 GHz**
	$d = 1{,}16\sqrt{P}$	**$d = 1{,}16\sqrt{P}$**	**$d = 2{,}3\sqrt{P}$**
0.01	0.116	0.116	0.233
0.1	0.366	0.366	0.736
1	1.16	1.16	2.33
10	3.66	3.66	7.36
100	11.6	11.6	23.3

In the case of emitters for which the maximum output power is not listed above, the recommended separation distance d in meters (m) may be determined using the equation applicable to the emitter frequency, where P is the maximum output power of the emitter in watts (W) specified by the emitter manufacturer.

NOTE 1: *At 80 MHz and 800 MHz, the separation distance stated for the higher frequency range should be applied.*
NOTE 2: *These recommendations may not apply in all situations. The propagation of electromagnetic waves is modified by absorption and reflection due to structures, objects and people.*

14.5 CONFORMITY DECLARATION CE

EC Declaration of Conformity

Conformity declaration in accordance with **essential Requirements of Annex I of the Medical Devices Directive 93/42/EEC**

CE 0318

Equipment covered by this declaration:

Reference: VMX-1020A

UDI-DI: 08436557390110

Type: Medical Device class IIa,

according to the intended use and the criteria of annex IX of the directive: class IIa, rule 11

VMX-1020A: CO2 Insufflator for Virtual Colonoscopy (CTC), Intussusception Reduction and Virtual Enteroscopy (Virtual Enteroclysis) procedures.

Manufacturer's name: **VIMAP TECHNOLOGIES S.L.U.** (VIRTUAL IMAGING AND MEDICAL APPLICATIONS TECHNOLOGIES SL)

Manufacturer's address: **Paséo de la Hispanidad N°1 y N°2 Polígono Industrial 29130 ALHAURÍN DE LA TORRE, (Málaga) - Spain**

Project and quality management, for medical manufacturers and designers:
Our quality system complies to Annex II of MDD (**EN ISO 13485:2016** Quality Management System)
Our Technical file has been constructed under requirements of Annex VII of MDD

- **EN ISO 14971:2019** Application of risk management
- **510(k) for FDA clearance** for USA market

Scope of Application: All batches, lots or serial numbers, to which the Declaration of Conformity Procedure has been applied.

EC Certificate for approbation
Quality System: Annex II (except section 4) of Directive 93/42/EEC
Certificate: 2020 12 0945 CT
Notified Body: CENTRO NACIONAL DE CERTIFICACION DE PRODUCTOS SANITARIOS (CNCPS)

Notified Body:
Centro Nacional de Certificacion de Productos Sanitarios (CNCPS - CE 0318)

Date (YYYY-MM-DD): 2024-03-11
Serial number:

Signed by:
Nicolas Costovici
Manager

Nicolas Costovici

VIMAP TECHNOLOGIES
C/ Paséo de la Hispanidad N°1 y N°2 Polígono Industrial – 29130 ALHAURÍN DE LA TORRE, (Málaga)
Spain Phone : +34 952 02 65 36 - Fax: +33 (0)1 72335561 - NIF : B17878075 – TVA/IVA : ESB17878075

14.6 CONFORMITY DECLARATION CLASS II UKCA

UK Declaration of Conformity

Conformity declaration in accordance with the relevant Annexes to the Directive 93/42/EEC on medical devices (EU MDD), which have been modified by Schedule 2A to the UK MDR 2002

Equipment covered by this declaration:

Reference: VMX-1020A

UDI-DI: 08436557390110

Type: Medical Device class IIa,

according to the intended use and the criteria of annex IX of the directive: class IIa, rule 11

VMX-1020A: CO2 Insufflator for Virtual Colonoscopy (CTC), Intussusception Reduction and Virtual Enteroscopy (Virtual Enteroclysis) procedures.

Manufacturer's name: **VIMAP TECHNOLOGIES S.L.U.** (VIRTUAL IMAGING AND MEDICAL APPLICATIONS TECHNOLOGIES SL)
Manufacturer's address: **Paséo de la Hispanidad N°1 y N°2 Polígono Industrial 29130 ALHAURÍN DE LA TORRE, (Málaga) - Spain**

UK Responsible Person (UKRP): **MIS Healthcare Ltd. Unit 26-27 Capitol Way Capitol Park, London NW9 0EQ, England United Kingdom.**

Project and quality management, for medical manufacturers and designers:
Our quality system complies to Annex II of MDD (**EN ISO 13485:2016** Quality Management System)
Our Technical file has been constructed under requirements of Annex VII of MDD

- **EN ISO 14971:2019** Application of risk management
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Scope of Application: All batches, lots or serial numbers, to which the Declaration of Conformity Procedure has been applied.
EC Certificate for approbation
Quality System: Annex II (except section 4) of Directive 93/42/EEC
Certificate: 2020 12 0945 CT
Notified Body: CENTRO NACIONAL DE CERTIFICACION DE PRODUCTOS SANITARIOS (CNCPS)

Notified Body:
Centro Nacional de Certificacion de Productos Sanitarios (CNCPS - CE 0318)

Date (YYYY-MM-DD): 2024-03-11
Serial number:

Signed by:
Nicolas Costovici
Manager

Nicolas Costovici

14.7 CONFORMITY DECLARATION ROHS

Certificate for RoHS Compliant Products

The below product has been designed, manufactured and tested under the responsibility of VIMAP Technologies

In accordance with the following applicable European Directives:
Conform to RoHS Directive 2011/65/EU
and amendment 2015/863/EU.
(Restriction of the Use of Certain Hazardous Substances)

Restricted substances referred to in Article of the directive, and maximum concentration values tolerated by weight in homogeneous materials

- Lead (0,1 %)
- Mercury (0,1 %)
- Cadmium (0,01 %)
- Hexavalent chromium (0,1 %)
- Polybrominated biphenyls (PBB) (0,1 %)
- Polybrominated diphenyl ethers (PBDE) (0,1 %)
- Bis(2-Ethylhexyl) phthalate (DEHP): 0.1%
- Benzyl butyl phthalate (BBP): 0.1%
- Dibutyl phthalate (DBP): 0.1%
- Diisobutyl phthalate (DIBP): 0.1%

Equipment covered by this declaration:
Reference : CO2 Insufflator VMX-1020A

VIMAP Technologies knowledge and beliefs are based on information provided by third parties, and the company makes no representation or warranty as to the accuracy of such information and has not conducted destructive testing or chemical analysis on incoming materials.
VIMAP Technologies maintains documentation on all its RoHS compliant products, including Certificates of Compliance and/or Material Declaration from all its suppliers, including the component suppliers, the PCB suppliers and the contract manufacturers.

Date : 02/12/2020

Signed by:
Nicolas Costovici
Manager

Nicolas Costovici

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14.9 HISTORIC OF CHANGES

Version	Date	Description of changes
4.7	2024-03-11	• Added symbols and QR code to access in other translations of the user manual. • Updated the content of paragraph13.2.2 about the shipment of the device. • Updated the content of paragraph 10.4 about the virtual keybord • updated the paragraph 11, about the passwords. • updated the paragraph 13.1 abpout the cleaning • More infos about the protocol page for intussuceptions • Update the paragraph 9.2, with more infos about the RFID/ contacless reading. • UDI-DI added inside Declaration of conformity CE and UKCA
4.6	2022-09-23	• Following new version of international standard ISO 15223-1:2021 : Symbols description was added: MD (medical device), UDI (unique device identifier). • added symbol UKCA (Conform to UK MDR 2002). • Added a specific Declaration of Conformity class II for UKCA

Version	Date	Description of changes
4.5	2021-10-13	New version of IFU in relation with the VMX-1020A software version V4.5 **Be carefful since 4.0 version software, NEW BEHAVIOR/OPERATING MODE, OF THE INTUSSUSCEPTION MODE.** **Cyber-security changes :** • All password are "Hard password" from this version 4.5 • Old password localadmin, no still valid : new password localadmin@ISO13485 • Olds passwords of trained technicians not valid: new passwords. • Changes of the location of the buttons, to close, reduce the software, and show the taskbar of windows • Only button to shutdown and restart device are accessible for the local users and localadmin. • If software don't work or automatically closed, impossible for the local user/localadmin to do something in the windows session. • So only a trained technician can access to windows and PanelPC parameters. **Intussusception mode:** • In case of protocol with "keep the pressure" isset by default, during a pause the "popup pause" show a button to release the gas, to override if necessary the default set-up of the protocol. • If necessary to override or reduce the duration of the "step pause", now before the end of pause duration, the user can voluntary go to the next trial of intussusception. **Mode Virtual Enteroscopy:** • Can be only enable by validation code provided by Vimap. **Various:** • **§1.2, in pages 5&6 : EXCLUSION OF LIABILITY & SAFETY INFORMATION,** update of all informations. • **§9.3.1, in pages 26 to 29** : **DETAILS FOR THE INTUSSUSCEPTION REDUCTION MODE,** more details about the set-up of the pressure inside each trials, and about the possibilities of actions inside the "Pause steps" (Pause popup) • **§11.1, in pages 34/35**: If it's not already done, the serial number of the device can be set by the local administrator. This serial number is recorded and used for the logs of events and values sensors for the device. • **§11.4, in page 38:** Remove of the button: to close, reduce the software. **Windows 10 OS compatibility :** • Detection of windows 10 or 7 by the software. • Boot auto of the software specific for W10.
...4.5		• Windows 10 activation for the device software: to ensure us, that the device has a valid/registered W10 license and use only W10 configuration done by Vimap Technologies (for devices still in windows7, no need of activation)

Version	Date	Description of changes
4.2	2021-04-21	**Be carefful since 4.0 version software, NEW BEHAVIOR/OPERATING MODE, OF THE INTUSSUSCEPTION MODE.** • Inside Declaration of conformity : o Update of the VMX-1020A scope. o Update of the CE number, due to our new notify body CE0318. o Update of the certificate number. • In last page of IFU, update of the CE number, due to our new notify body CE0318. • In paragraph 13.1, more details about decontamination of the device.
4.1	2020-12-02	**Be carefful since 4.0 version software, NEW BEHAVIOR/OPERATING MODE, OF THE INTUSSUSCEPTION MODE.** • Expansion of section 1 merging with section 3. • Restructuring of the contraindications, warnings and cautions of section 2 in sections 2.1 and 2.2. • Revision of the declaration of conformity and RoHS. • Manufacturer's phone number update
4.0	2020-04-20	New version of IFU in relation with the VMX-1020A software version V4.0 : **NEW BEHAVIOR/OPERATING MODE, OF THE INTUSSUSCEPTION MODE.** • Section 10.3.1 (P25 at 27) Update of the description of the Intussusception reduction Protocol • Section 2.2 Add of the illustration of gas cylinder size. (same information as CAR-XXXD IFU) • Standardization in all IFU and software of same max pressure of gas cylinder: 70 bars. • Section 5.1 : update of safety valves values (same as Datasheet values) • Section 9 (P18) - main page : update of Main page pictures (date/ time and position of hospital name) • Section 10.1.4 : update of the two picture (buttons inside software more larger) • Section 12: the password “localadmin”, is clearly written. • Section 11.3 : update of the picture (aesthetic changes) • Section 12.3: update of the picture (Two indicative pressures are now displayed here) • Section 12.4.4: update of the picture of Main update software. (aesthetic changes) • Section 15.1: update of the symbols table (3 last lines added), standardization in all of all fuse values mentioned in the manual. • Section 15.5: update of the EC declaration of conformity to display only the Quality and risk standards. • Section 15.7: new section with official bibliography currently used, inside the medical technical file.
3.6	2019-05-14	• Remove of disposable references which are no longer sold (AS-H-600A ; AS-CONT-500A) • Update of the version of ISO13485 applied: ISO13485:2016, including inside the EC declaration of conformity. • Add illustration of the external filter for gas input.

Version	Date	Description of changes
3.1	2018-08-07	• **Sentence:** WARNING! Do not position this device so that it is difficult to operate the disconnection device. *Replaced by* The patient has to be placed on the CT table for a CT scan in position "head first" and the VMX-1020A insufflator should never be placed behind the CT Scan machine. The VMX-1020A should be accessible. The displayed information on the touch screen should be visible during all exam from the room and from the CT control room. • **Sentence:** Heating setpoint: 17.5 to 45°C, display accuracy of 0.1°C *Replaced by* Heating setpoint: 17.5 to 48.5°C, display accuracy of 0.1°C • **Sentence:** CAUTION! For reference AS-3W-H-R35A, the physician can perform two types of examinations, we have selected CT Colonography by default. If the physician wants to do an intussusception, he MUST manually selected that the examination will be an intussusception. *Replaced by:* The reference AS-3W-H-R35A is exclusively dedicated to the CTC (Virtual Colonoscopy) mode. The reference AS-3W-H-R35B is exclusively dedicated to the "Intussusception Reduction" mode. Never use the reference AS-3W-H-R35A on babies or children due to its size and to the risk of perforation. Never use the reference AS-3W-H-R35B for CTC (virtual colonoscopy). The reference AS-3W-H-R35B is not adequate to the CTC (Virtual Colonoscopy) pressure range. • Old numeric gauges description, eliminated • Add description on use and installation of the new PanelPC (plastic PanelPC) • Printscreens of the “interface panel” upgraded.
3.0	2018-05-16	• **New warning message :** WARNING! During the start-up or restart of the device, to enable a good calibration procedure: - don´t connect or disconnect the disposable/tubing - don´t touch or move the heating hose • Update of the “details protocol”, “interface setup”, “popup volume steps” screens • Added more details about the new protocol of the intussusception reduction mode. • Added details about the Gen2 of the VMX-1020A
For anterior changes, contact Vimap Technologies		

15 MANUFACTURER'S IDENTIFICATION

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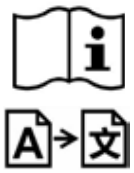

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