Manual Hpm™ Tourniquet 800-20 & 800-40

English

TABLE OF CONTENTS

1 Introduction

Hpm™ Tourniquet 800-20 and 800-40 contains a micro-processor which monitors the tourniquet to act as a single cuff or as a double cuff in IVRA mode. The tourniquet is not dependent on external air pressure and works independently with a built-in pump, battery, a computer controlled system which is monitored via the touch screen. Power cord, hose/hoses and user instructions are included with the tourniquet.

Versions/models:

All models require AC power to start up.

800-20 tourniquet to be used with single cuffs. If the AC power is disconnected, the unit will alert the operator of this but can still be used in normal state until low battery status is shown.

800-40 tourniquet to be used with a single cuff on one side of the unit or with a double cuff for IVRA. If the AC power is disconnected, the unit will alert the operator of this but can still be used in normal state until low battery status is shown.

1.1 Intended clinical use

The device is intended to be used as an electronic tourniquet instrument to control venous and arterial blood circulation to an extremity for a period of time, as for operations in a bloodless field. The pressure is applied circumferentially upon the skin and underlying tissues of an extremity; this pressure is transferred to the walls of vessels, causing them to become temporarily occluded. It is generally used as a tool for a medical professional in applications such as cannulation or to stem the flow of traumatic bleeding. The device is intended for routine clinical use and should only be used by medical professionals trained in the operation of the device. If the instrument is not used correctly during operation it might cause severe harm or death.

! The operators are required to supervise the instrument during use.

Contraindications for use

Contraindications for use of the device are conditions reported, including but not limited to extremity infection, open fracture, tumor distal to the tourniquet, sickle cell anemia, impaired circulation, previous revascularization of the extremity, extremities with dialysis access, venous thromboembolism, increased intracranial pressure and acidosis.

We recommend that you always use Hpm™ cuffs with Tourniquet 800-40 and 800-20.

1.2 User Manual

This user manual contains important information for operating the Hpm™ Tourniquet 800 series. Before use of the tourniquet the user manual must be read carefully. The user manual should be treated as a part of the equipment and must therefore be available during use of the tourniquet, it is a support and reference for the clinical staff.

If the unit is moved to another operating room, the user manual has to follow the tourniquet.

The user manual illustrations are in order to simplify, understand and manage the equipment. The illustrations are not always in proper scale and can vary from the actual equipment.

! or "Warning" or combinations of both denotes instruction regarding safe use of the instrument.

1.3 Manufacturer

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1.4 Warranty

Thank you for purchasing this quality product from Hammarplast Medical AB. Our products are developed to meet high standards in both quality and technology. To further ensure quality, we grant you, the final customer, a warranty on our products in accordance with the following conditions.

The Hammarplast Medical AB product is warranted for the period of twenty-four (24) months from the original date of purchase, against defective materials and workmanship. In the event that warranty service is required, you should return the product to the dealer from whom it was purchased. In case of difficulty, details of the local dealers are available at www.hpm.se. You may also contact the service center in Sweden (email: service@hpm.se).

International warranty conditions

1. The warranty is only valid if, when warranty service is required, the warranty demand is presented with the original invoice or sales slip or confirmation, and the serial number on the product has not been defaced.
2. Hamarplast Medicals obligations are limited to the repair or, at its discretion, replacement of the product or the defective part. For this, the customer is responsible for the dispatch and insurance of the product. The transport and insurance costs shall be borne by the customer. Hammaplast Medical shall cover the costs for the materials/spare parts and the labor costs as required, as well as the return postage to the sender.
3. In case of warranty repairs, they must be carried out by authorized Hammarplast Medical AB dealers. No re-imbursement will be made for repairs carried out by non-Hammarplast Medical representative and, any such repair work and damage to the products caused by such repair work will not be covered by this warranty.

4. This product is not considered to be defective in materials nor workmanship by reason that it requires adaptation in order to conform to national or local technical or safety standards in force in any country other than the one for which the product was originally designed and manufactured. This warranty will not cover, and no re-imbursement will be made for such adaptation or any damage which may result.

5. This warranty covers none of the following:

A. Periodic check ups, maintenance and repair or replacement of parts due to normal wear and tear (such as upholsteries, hoses or reduced capacity of accumulators).
B. Cost relating to transport, removal or installation of the product.
C. Misuse, including the failure to use this product for its normal purposes or incorrect installation.
D. Damage caused by lightning, water, fire, acts of god, war, public disturbances, incorrect mains voltage or any other cause beyond the control of Hammaplast Medical AB.
E. Spillage of chemicals or liquid or use of any other hazardous or non instructed substances, which may affect the product.
F. Minor defects or deviations from the product specifications, that are immaterial or negligible as regards to the value or the functioning of the product.

1.5 Copyrights

The manual is an exclusive part of the equipment and may not be provided to or used by any third party. Pictures, text, specifications and other illustrations are protected by copyright and may not be copied without approval by Hammarplast Medical AB.

1.6 Customer service

For technical questions, contact Hammarplast Medical customer service. Contact information is found under chapter 1.3

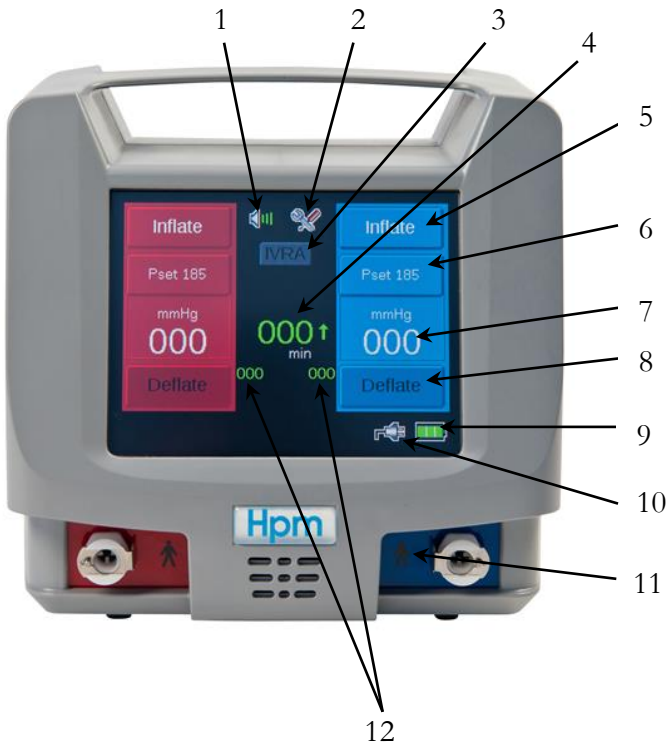
1.7 CE labeling

The equipment is manufactured in accordance to EU´s directives regarding current medical equipment 93/42/EEC.
CE labeling is located on the equipment's rear side.

! Warning: This instrument, as all medical electric equipment in general, needs special precautions regarding EMC and needs to be installed and put into service according to information in this document.

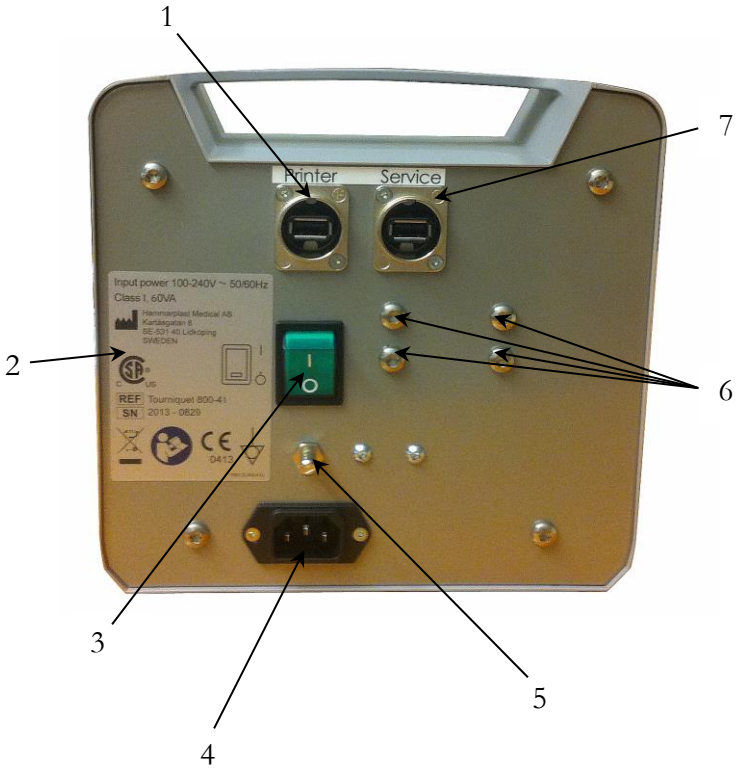
! Warning: This instrument, as all portable medical electric equipment in general, can affect other medical electrical equipment. Refer to Appendix EMC for further guidance regarding EMC.

1.8 Tourniquet front view



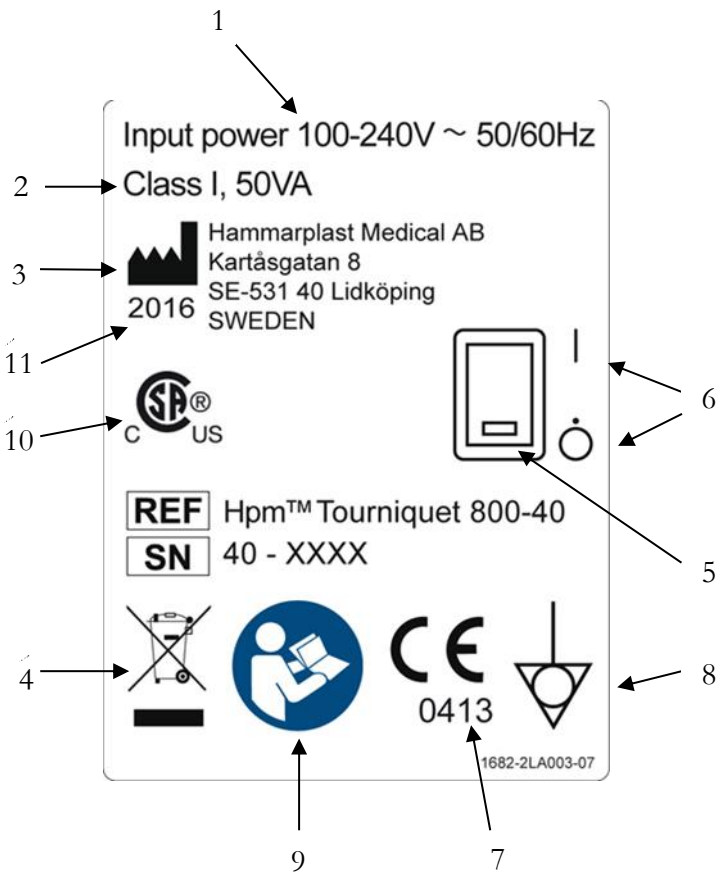
1. Volume icon. 1-5 levels shows level of volume.
2. Settings icon. Press symbol in order to open menu.
3. IVRA icon. Press symbol in order to activate.
4. Timer icon. Default setting is counting up.
5. Inflate icon. Click in order to activate pump.
6. Pset pressure.
7. Current cuff pressure in mmHg.
8. Deflate icon. Press in order to deflate.
9. Battery icon.
10. Icon for AC power connection.
11. Applied part
12. Double timers.

1.9 Tourniquet rear view



1. Printer connection.
2. Label, including serial number (ref. 1.11)
3. Power switch. Green light on power switch indicates AC power is connected.
4. Power cord outlet.
5. Potential equalization socket.
6. Attachment points for clamp.
7. Computer outlet for service.

1.10 Label



1. Operating voltage in Volts (100-240V ~50/60Hz)
2. Class 1
3. Manufactured by
4. Contains electrical components, plastic parts and battery. Return the instrument to the manufacturer or dispose it in accordance with legal regulations and local ordinances.
5. ON/Stand-by. The yellow light is on when AC power is connected and the battery stand-by charges.
6. 1/0. 1 indicates that the battery stand-by charges and the unit is active and ready to use. 0 indicates that the unit is in stand-by, and the battery stand-by charges.
7. CE-marking
8. Protective ground conductor.
9. Read instructions before use.
10. Certified to U.S and Canadian standards
11. Year of manufacture.

All labels on this equipment are supposed to be cleaned with soap water.

1.11 Shipping, packaging and storage

Transport inspection:
Check the delivery immediately for completeness and any damage during shipping.
For obvious transport damage, do the following:

- Do not accept the delivery or accept it only conditionally.
- Note the scope of damage on the shipping documents or on the shipping delivery note.
- File a complaint

In order to prevent shipping damages to the greatest extent possible, when returning a product to Hammarplast Medical or a local representative, use the original packaging. Provide the following information: Owner´s name and address, serial number (see model plate), a description of the damage.

Packaging notes:
Packaging is commensurate with expected shipping conditions. Only environmentally safe materials are used for packaging.
The packaging is intended to protect individual components from shipping damage until installation is complete. Therefore, do not destroy the packaging and only remove it immediately prior to installation.

Handling packaging materials:
Dispose of packaging materials in accordance with legal regulations and local ordinances.

- Dispose of packaging in an environmentally safe manner.
- Follow the local disposal ordinances. If necessary, hire a professional disposal service.

Storing packages:

- Do not store outdoors.
- Keep dry and free of dust.
- Do not expose to corrosive agents.
- Protect from sunlight.
- Avoid mechanical vibrations.
- Storage temperature -10 to + 50 °C.
- Relative humidity: max 80%, non-condensing.
- When storing for longer period, periodically check the general condition of all components and the packaging.

1.12 Operator profile

Incorrect use and wrong interpretation of user manual may cause severe harm or accidents, it is therefore important that you read and understand the information in this user manual.
Users of the equipment must have medical training, experience, skill and should have proper training on the equipment, for safe usage and treatment of the equipment (e.g. surgery staff, anesthesia staff).
Trained staff can in a safe way use the equipment and in good time anticipate risks and discrepancies as a protection for themselves and the patient.
Trained staffs should have obtained knowledge about rules and guidelines for operating in bloodless fields.
Trained staffs have technical and practical knowledge about how to apply cuff and set correct limb occlusion pressure (LOP).

2 Tourniquet start up

2.1 Before taking in use

Before taking in use, turn on the mains switch. **Note**: If the battery is fully depleted it will turn off the display. Connect equipment to main power supply, aknowledge a possible warning about battery low level, and charge until full battery level is displayed (normally up to 3 hours for a depleted battery).

Protect the instrument from liquids or blood. Use an original Hpm™ coiled hose to keep the instrument out-of-reach of the patient.

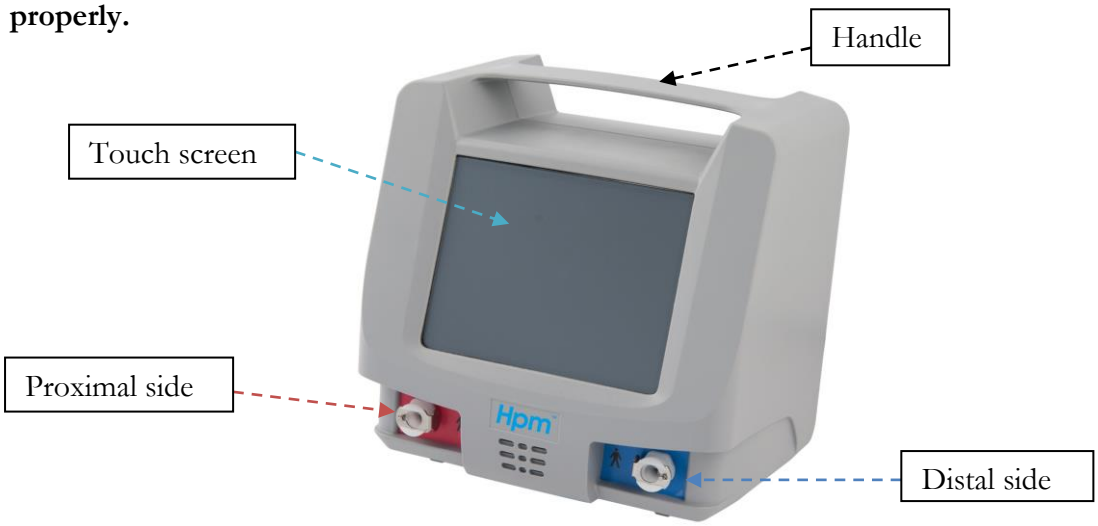
Ensure that the equipment is placed without risk to fall down.

The included coiled air hose has CPC-quick connectors in both ends. The male end fits in the device's air outlet female CPC-connector and the female connector in the other end fits with the male connector of the cuff.
The air outlets, coiled hoses and the cuffs are color coded. Blue color indicates distal side and red color indicates proximal side.

Cuff is applied parts. Make sure to place tourniquet out of reach for patient.

The touch screen acts on command from one pressure point, multiple pressure points on screen can give unwanted commands. Make sure to just press with one finger.

When moving and starting up the unit again, make sure all the connections are properly attached and perform a diagnostic test of the unit to make sure everything works properly.



2.2 AC Power Connections

The AC power cable is connected to the power cord outlet on the rear of the tourniquet (pic. 1.10, arrow 4) and the wall power outlet. Switch on the tourniquet by switching the main switch to I (pic 1.10, arrow 3). Only use included power cord (hospital grade).
A Self test will automatically be performed during start up.

To avoid the risk of electric shock, this equipment must only be connected to AC which is properly grounded.

! The power cord plug must be removed to break AC current. The wall socket outlet should be installed nearby the tourniquet and be easily accessible.

2.3 Procedure options

The Hpm™ Tourniquet has two intended options of use, single cuff procedure and double cuff IVRA procedure. When a single cuff is used, the user can inflate or deflate the applied cuff for either upper or lower limb. When IVRA procedures are performed, the proximal and distal sides are synchronized regarding set pressure and time, in order to perform safe surgeries. The "IVRA" icon is activated before the start of the surgery and will be indicated with a green illuminated "IVRA" icon.

2.4 Unit start up

- Make sure that the cuffs are disconnected.
- The Tourniquet is turned on by pressing the ON/OFF button on the backside of the Tourniquet.
- The tourniquet will then perform a Self Test of system, pump function and a leakage test.
- A sensor calibration is performed against the atmospheric pressure.
- After this you will be asked to press the green OK icon. If you tap outside of the green OK icon, you will be asked to calibrate the screen. Conduct the calibration by following the instructions on the screen.

After pressing the OK icon you will then hear two (2) beeps, one from the speaker and one from the back-up alarm.
Press OK to confirm hearing these two (2) beeps. If the user answers "CANCEL" two (2) times the tourniquet goes into an instrument error-mode (code 20) and needs to be restarted.

The tourniquet is now ready to use.

Main menu display when the tourniquet is ready for use.

The tourniquet is now ready for operation with the pressure (ref. 3.2) and time (ref. 3.1.2) earlier set by the user. Cuff inflation is done by pressing the "Inflate" icon.
To perform a manual self test, please enter the sub menu by pressing  (sub menu icon) and then press  (self test icon) (ref. 3.1.3).

2.5 Icones used

Pset indicates chosen pressure
Inflate indicates inlet of pressure
mmHg indicates pressure in cuff
Deflate indicates outlet of pressure
IVRA Grey indicates inactive IVRA
IVRA Green indicates active IVRA
min 000 indicates elapsed time
000 indicates the time on each side

Battery symbols:

 Battery fully charged
 Battery with approximately 75% power
 Battery with approximately 50% power
 < 25% battery power

Symbols:

 AC power connected
 AC power failure
 Sub Menu
 Information
 Timer
 Self Test
 Settings
 Language
 Print
 Alarm volume
 Service
 Date & Time
 Safe state, make self test to clear this state
 Critical alarm (technical error) Try to restart or contact service.

2.6 Front panel with inflated cuff

A white framework shows if cuff is inflated and green arrow indicates monitored side.
The Inflate icon is replaced by a "-5" respective "+5" icon.
In order to adjust the pressure during procedure, press "+5" icon to increase and press "-5" icon to decrease pressure.

2.7 Front panel during alarm

If an error is detected an error message and an alarm icon will show and an audio alarm will sound. Deal with error message according to user manual directions (ref. chap 4).
Reset alarm by pressing "Alarm" icon.

3 Options

3.1 Settings 

By pressing  (sub menu icon) you enter the sub menu. If no icon is pressed within 30 seconds, the main menu returns automatically.

3.1.1 Information 

By pressing  (information icon) data regarding the unit will occur (manufacturer, model, serial number and software version). Press the back icon to return to the sub menu or wait 30 seconds and the main menu will return automatically.

3.1.2 Timer 

By pressing  (timer icon) time can be set, counting up or down. The alarm time can be set by using the numeric display. ! The Timer may not be set during procedure.
When the settings are done press the "OK" icon and you will return to sub menu. If the new setting data not is confirmed within 30 seconds, the new data will not be saved and the main menu will automatically return.
By pressing "cancel data" the old timer settings will be valid and you will return to sub menu.

3.1.3 Self Test 

By pressing  (self test icon) a self test will automatically be performed. When the self test is done a new menu will occur with the text "Confirm self test OK". Confirm by pressing the "OK" icon and the main menu will return. If a cuff is pressurized the user has to confirm every step of the self test by pressing the screen as a part of the internal security mechanisms. If the self test detects errors, it stops and the device returns to the main menu and shows errors. (Ref. section 2.4)

3.1.4 Print 

When pressing  (print icon) without printer connected you will receive the message "Printer is not connected". By pressing "Cancel" you will return to sub menu or wait 30 seconds and the main menu will return automatically.
When the printer is connected and turned on the message "Printer is ready" will show and a print icon is visible. Press the "Print" icon and the details from the last run will be printed.
If an error occurs, when the printer communicates with the tourniquet, the message "Error, reconnect printer" will show.

! No printer to be connected and used together with the Tourniquet during procedure!

! During operation make sure to not touch USB port and patient at the same time.

3.1.5 Language 

By pressing  (language icon) a menu with all default languages appears on screen. Choose language and automatically return to sub menu. Chosen language will be default.

3.1.6 Settings

By pressing (settings icon) you will enter default settings menu.

- Default timer. Press to set default timer.
- Default Pset. Press to set default pressure (mmHg) in steps of 5 mmHg or use the slider and confirm with "OK".
- Restore default. Press to get factory settings and confirm by pressing "Save".

Use the "Save" icon to confirm new default settings. Use the "Cancel" icon to abort and return to sub menu.

3.1.7 Service

By pressing (service icon) you will enter service menu. Enter menu with service code, for authorized staff only.
Press "Cancel" to return to sub menu or wait 30 seconds and the main menu will return automatically.

3.1.8 Date & Time

By pressing (Date & Time icon) you will enter the page where you are able to program the tourniquet internal clock.
Date are constructed according to YY-MM-DD and the clock according to HH:MM:SS.
Use the numeric display starting with YY(year) until you finished with SS (seconds). Press OK.

3.1.9 Volume

By pressing (volume icon) the volume menu will appear. Change level of volume by pressing the "+" or "–" key. Five different levels of volume are possible to set and store. When restarting the Tourniquet volume level will be minimum medium.
1-5 stacks, next to the speaker icon, indicate the volume level. To save chosen level press "Confirm" and you will return to the main menu.
To abort press "Cancel" and you will return to main menu.
The sound volume is demonstrated during the diagnostic test that is done as a part of the initial procedure.
The sound settings can be changed before or during procedure.

3.2 Pset

Figures in the Pset box shows the pre-setting of the pressure (e.g. 200 mmHg) in the inflated cuff(s). Inflated cuff(s) can be adjusted in steps of plus (+) or minus (-) 5 mmHg by pressing the

” +” or “–“ key. After deflation the Pset automatically returns to the pre-setted value (e.g. 200 mmHg). The default value can be adjusted in the settings (3.1.6)

3.3 Accurancy of the pressure

The Hpm™ Tourniquet is designed in order to maintain the inflated cuff pressure during the time of the procedure.
When the cuff is inflated, you may change the Pset pressure in steps of + or – 5 mmHg keys, or press the “Pset” icon and use the menu (section 3.2). A change of the Pset pressure will result in a change in the inflated cuff(s).
If an unexpected change of the pressure is detected, an alarm message is shown, followed of an audio alarm. Reset the alarm by pressing the “Alarm” button and locate the cause of the alarm and take corrective measures (ref. chap. 4) .

3.4 Inflate/deflate cuff in normal mode

In order to inflate the cuff, press the ”Inflate” icon. The pressure will be achieved within seconds, meanwhile a leak test is performed. If no leaks are detected, the pump will inflate the cuff until the desired pressure is achieved. A white frame and a green arrow indicate which cuff is inflated and active. If a leak or a kink is detected during the inflation, the pump tries to inflate the cuff. If inflation fails, the user will be alerted by an error message followed by an audio alarm (ref. chap. 4). Inflation can be aborted at any time by pressing ”Deflate”. If you press ”Deflate”, you will have to confirm the deflation, by answering the question “ Deflate the distal/proximal cuff?”, by pressing “Confirm”. This will deflate the cuff in approximately 15 seconds.

3.5 Timer

A timer is built into the tourniquet. The timer is activated automatically each time a cuff is inflated. The time is noted on the display along with the cuff pressure. The time is shown on the display as YYY min (minutes). The timer counts each minute that the pressure is retained in the cuff(s). A beep alerts the operator after sixty (60) minutes, after an additional period of thirty minutes another beep alerts the operator of the time elapsed. After the thirty (30) minute beep, the operator will be alerted by a beep every fifteenth (15^{th}) minute.
After one hundred and eighty (180) minutes the alarm goes into medium priority level which means three (3) beeps repeated every twenty (20) seconds. The timer automatically stops when the cuff(s) is deflated. The total of the elapsed time that the cuff has been inflated will be shown on the display until a new procedure starts. When performing an IVRA procedure, the time shown is the total time which the proximal and the distal cuffs have been inflated. Each side has an individual timer.
The timer has the “Counting Up” or “Counting Down” options. In order to change time counting, enter the sub menu (section 3.1), timer (section 3.1.2) to make changes.
Factory default setting (090 minutes) can be restored by entering sub menu (section 3.1), press the “Settings” icon and press “Restore default” (section 3.1.6)

Icon for sub menu

Green arrow indicates time count up from zero (0)

3.6 IVRA overview

IVRA (Intravenous regional anaesthesia), also known as a Bier´s Block, is used to enable the infused aesthetic to first take effect on the distal part of an extremity. After a period of time, cuff pressure is applied on the already anesthetized part of the extremity and the cuff is deflated on the more proximal portion of the limb. To prevent the anaesthetic from leaving the extremity before it is absorbed by the tissue, it is important to have the cuffs inflated and deflated in the correct sequence.

Some of the safeguards programmed into the tourniquet for use in an IVRA procedure include:

- A special icon marked" IVRA" is located in the middle of the display. It is used to program the proximal and distal sides to communicate during the IVRA procedure. When the "IVRA" icon is activated it changes colour from grey to green to confirm that the unit is ready for IVRA procedure.
- IVRA procedure button can be engaged, even though one side is inflated, by pressing the "IVRA" icon and press confirm.
- When both sides of the tourniquet are pressurized, but one side has not yet reached the set pressure level, only the side that has not yet reached set pressure can be deflated. The operator can deflate optional side only when both sides are inflated to the set pressure level.
- The elapsed time will be stopped when both sides are deflated (ref. 3.5).

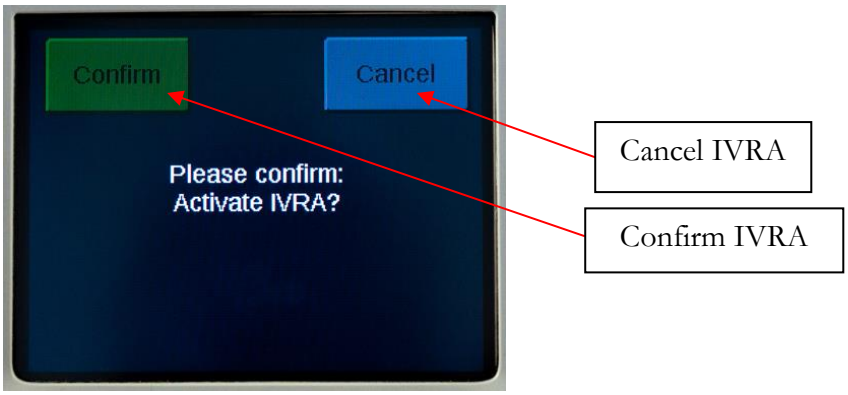
Green "IVRA" icon. Indicating IVRA active.

Green arrow, indicating active side.

3.7 Choices of IVRA during operation

If the proximal (distal) side is inflated and IVRA is not activated before, it is possible to choose IVRA even in this situation.

1. Press “IVRA” icon and the question ”Activate IVRA?” is displayed.
2. In order to activate IVRA press ”Confirm”. IVRA has now been enabled and the main menu returns, now with “IVRA” icon illuminated green.
3. If IVRA is not desired, press ”Cancel” and the main menu returns without IVRA function and the “IVRA” icon remains grey.



3.8 Change default pressures

Hpm™ Tourniquet permits the user to change the factory default pressure of 200 mmHg (ref. 3.1.6). To restore default factory settings, see section 3.1.6.

4 Alarm

The device is designed to test and supervise itself during the start up process to alert the operator of any faults or errors which might cause problems during the use of this product.
The start-up tests are performed every time the unit is activated to review the status of both the software and hardware of this microprocessor controlled device. If these tests detect any errors, the appropriate message will be shown in the display. The possible errors are listed below.

4.1 Alarm system

When something occurs in the system that must come to the operator´s attention, a message is clearly displayed on the screen and an audio alarm is emitted. This is referred to as "Raising an Alarm". If one of the cuffs is the cause to the alarm will also a red or a yellow framework indicate which cuff it is and which priority the alarm has.
The alarms consist of the following categories:

Priority	Signal color	Signal sound
High	**Red**	**10 beeps repeated every 10 second,**
Medium	**Yellow**	**3 beeps repeated every 20 seconds**
Low	**Yellow**	**1 beep**

Note: All alarms have the same sound level.

4.2 The automatic alarm safety mechanism

When a high or medium priority alarm (and even some low priority alarm) occurs, an automatic safety mechanism closes all the valves and turns off the pump.
To exit from this state the operator has three (3) options:

1. Perform a self test (ref. 3.1.3). This self test will not open the block valve (i.e. the pressure in cuffs is unaffected), but it performs a test that the internal components of the tourniquet are operating safely. It is not possible to inflate or increase the pressure during this state.
2. Acknowledge the alarm by pressing the "Alarm" icon.
3. The cause of the alarm is corrected.

4.3 Alarm priority

If a higher priority alarms occurs after a lower priority alarm, the higher priority alarm is prioritized and displayed. Lower priority alarms that occur after a higher priority alarm are queued but not displayed until the higher priority alarm is acknowledged by the operator.

4.4 Alarm reset

By pressing the "Alarm" icon you acknowledge, silence and reset the displayed alarm condition signal only. Other alarm conditions are unaffected. If more than one alarm condition exists, the operator has to reset each alarm separately. Some alarm conditions, e.g. AC power failure, resets automatically when the cause, that was generating the alarm signal, ceases.

4.5 Common alarm messages

Signal definition

Safe State Icon: 	The state when the block valve, the deflate valve and the pump all are de-energized creating independent means to prevent the increase or decrease of a cuff pressure. Monitoring of pressure values continues. Make self test to clear this state.
Instrument error Icon 	Try to restart or contact service.
critical battery	The battery capacity is less than enough for running one burst of high priority alarm and switching the system in safe state after a serious fault is detected.
low battery	The battery capacity can maintain monitoring and valve control but no pump control (pressure control) for less than 10 minutes
Invalid pressure	If the measured pressure is invalid
High pressure	If a pressure higher than 30 mmHg above Pset set value.
Low pressure	If pressure is lower than 15mmHg below Pset
Critical low pressure	If pressure is lower than Pset- 75 mmHg
Critical high pressure	If pressure is higher than 100 mmHg above Pset
Inflating leakage	If the set pressure value has not been reached within 20 seconds
Inflated leakage	The pump can not keep the set pressure in the cuff

Alarms during startup test:

The following alarms after the power-up self-test will make the instrument in-operable (instrument error).

Restart instrument, or call service!

Alarm message
Instrument error
System pressure failure
Pump failure
Pump leakage
Deflation valve failure
Cuff sensor failure
Cuff sensor failure
Distal block valve failure
Proximal block valve failure

Alarm message	*Description*	*Priority*	*Comment*
Timeout!	Timer counting down	Medium	
Time > 60	Timer 60 minutes	Low	
Time > 90	Timer additional 30 minutes	Low	
Time > 90 n* 15 min	Timer reminder every 15 minutes	Low	
Time limit	Timer after 180 minutes	Medium	Risk for harming patient
Fatal CPU failure	Instrument testing continuously	High	Instrument error: Restart instrument, or call service
Fatal pressure failure	Instrument testing continuously	High	Instrument error: Restart instrument, or call service
Mains failure	Mains failure in Idle (cuff has no pressure)	Low	Safe state until mains returns
Instrument error	Instrument testing continuously	Medium	Instrument error: Restart instrument, or call service
Mains failure	For 800-x0 model: Mains failed and cuff has pressure	Low	Clears when mains returns
Critical battery level	Battery level < 25%	Low	Safe state: Connect mains to charge battery
Critical battery level	During start up	Low	Connect mains for 0-2 hours to charge battery, until battery indicator shows full battery capacity
Low battery level	Battery level < 50%	Low	Connect mains to charge battery
System pressure failure (infl)	Instrument testing continuously	Medium	Instrument error: Restart instrument, or call service
Pump failure (inflate)	Instrument testing continuously	Medium	Instrument error: Restart instrument, or call service
Leakage (inflate)	Leakage while inflating	Low	Check tubing and cuff
Kink (inflate)	Kink while inflating	Low	Safe state: Acknowledge alarm or perform selftest to return to normal operation
Critical pressure	Pressure level < 100 mmHg below Pset if IVRA	High	Safe state: Acknowledge alarm or perform selftest to return to normal operation
Critical pressure	Pressure level < 100 mmHg below Pset if not IVRA	Medium	Safe state: Acknowledge alarm or perform selftest to return to normal operation
Low pressure	Pressure level < 15 mmHg below Pset	Low	Clears if pressure returns
High pressure	Pressure level > 30 mmHg above Pset	Low	Clears if pressure returns
Critical high pressure	Pressure level > 100 mmHg above Pset	Medium	Safe state: Acknowledge alarm or perform selftest to return to normal operation
Leakage	Leakage while inflated	Medium	
Battery fault	Battery cannot be charged properly	High	Instrument error: Restart instrument, or call service
Sensor consistency	Pressure sensor fail detected	High	Instrument error: Restart instrument, or call service
Cuff not connected	A cuff is un-connected	Low	Connect cuff

5 Battery function

Charge capacity varies highly between individual units and over time.
Note:
1) The battery is to be used only as a temporary backup in case of failing AC power.
2) Battery capacity can suddenly decrease quickly in a non-linear fashion.
3) The following is an indication only and must not be used as absolute measurement of remaining capacity:

 : Battery fully charged.
 : About 75% capacity remains.
 : About 50% capacity remains.
 : < 25% capacity remains.

Connection to AC power supply will immediately start the charging of the batteries.
The cuff(s) maintain the pressure as the tourniquet is connected to the AC power supply and the procedure can continue without interruptions. The batteries are charged automatically.

6 Care and Maintenance

Service and repair must be carried out by Hammarplast Medical service department or by an authorized service partner. Contact your local distributor for more information. When the tourniquet is returned to Hammarplast Medical, use our original box with its foam protection.

Cleaning
The Tourniquet is not intended to be sterilized. Clean the device with a damp, soft cloth. Use mild detergents, Ethanol 30%.

Warning! Only gentle pressure when cleaning the touch-screen!

The Tourniquet is not intended to be sterilized.
Only use the power cord (hospital grade) that comes with the device.

For safe use, the battery and hose kit should be frequently checked as follow:

Hose kit
-Spiral hose to be visual inspected before every new procedure:
Cracks in the hose
Discoloration of the hose
Hose is seated properly on the hose connectors

-Replace spiral hosing after fiftyfour (54) months.

-Spiral hose to be considered as consumables.

NOTE! No modification or shortening of spiral hosing is allowed! If damaged, it needs to be replaced with a new original spiral hosing!

Calibration

Perform a pressure test for internal leakage and a pressure calibration of the system each twelve (12) months or after changing any vital parts in the unit such as internal hoses, pumps or valves. Contact your local distributor for more information about leakage test.

Battery

The battery needs to be checked once a year. Check that a dis-charged battery can be charged within 3 hours. If not, the battery needs to be replaced (the battery is considered as a consumable). We recommend that the battery is replaced every twentyfour (24) months.

7 Data log

The following data are logged for each operation: Date and time of start, set pressure, actual operation duration time, mains/IVRA/cuff status description and error description.

The log for the recent operation can be printed out only after a procedure.

Note: The log is maintained during an AC power fail and after the Tourniquet is powered down.

8 Technical specifications

Electrical power input: 100-240 VAC, 50-60 Hz
AC receptacle: IEC type per CEE22V (hospital grade)
Temperature range: operating +5 till+40 °C,
Temperature range: transport & storing -10 to +50 °C.
Relative Humidity range: 20-80% non-condensing (operating, transport, storing)
Atmospheric pressure range: 75 to 106 kPa
Pressure, maximal level: 600 mmHg (emergency stop during malfunction)
Pressure, operating range: 50 mmHg to 550 mmHg
Weight: 2.5 kg
Dimensions: 200 mm (wide) x 195 mm (high) x 145 mm (deep)
Pressure output port: CPC connector
Accuracy: ±5 mmHg or 2% full scale
Inflate time: ~5 seconds
Class & type: Class 1, type B
Printer interface: USB
Backup battery: NiMh, 7.2 V 4500 mAh
Alarm sound level: 73dB

9 Accessories

Printer: Art. no 800-10 Model EPSON TM-T88V supplied with screened cable.

Clamp: Art. no 800-25.

Mobile stand: Art. no 400-45.

Basket: Art. no 400-85.

Hpm™ Reusable and autoclavable single and double cuffs, Hpm™ Disposable single and double cuffs. Hpm™ disposable cuffs are sterilized and are only to be used according to hospital procedures and regulations. The following codes are referred to as *Hpm™ Disposable cuffs*;

Hpm™ single disposable cuffs: 15-100, 15-110, 15-120, 15-130, 15-140, 15-150, 15-160, 15-170 & 15-180.

Hpm™ single disposable cuffs conical: 75-140, 75-150, 75-160 & 75-170.

Hpm™ double disposable cuffs: 25-100, 25-110, 25-120, 25-140 & 25-160.

Hpm™ Tourniquet 800-series are only to be used together with cuffs marked according to the CE standard.

We recommend that you only use Hpm™ CE-marked cuffs with Hpm™ Tourniquet 800-20 and 800-40.

10 Appendix EMC guidance

The following guidance information are required by EN 60601-1-2 (2007):

Warning
The tourniquet should not be used adjacent to or stacked with other equipment.

Warning
The use of any other printer than listed in chapter 9 may result in increased emisssions or decreased immunity of the tourniquet.

Essential performance (as defined in EN60601-1-2)

- An alarm system should signal whenever the tourniquet inflated pressure is 30 mmHg higher or 15 mmHg lower than the set pressure.
- In single fault condition the cuffs should be isolated using a block valve with a maximum leakage of 1 mmHg/min.
- The tourniquet inflated pressure should not be affected by disturbances (excluding external pressure changes) by more than +30 to -15 mmHg.
- The tourniquet inflated pressure should compensate for pressure changes due to external pressure changes on the cuff within a few seconds

Guidance and manufacturer's declaration - electromagnetic emissions		
The tourniquet is intended for use in the electromagnetic environment specified below. The user should assure that it is used in such an environment		
Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefor, its RF emmissions ar very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The tourniquet is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics IEC61000-3-2	Not Applicable	
Voltage fluctuations IEC 61000-3-3	Not Applicable	

Guidance and manufacturer's declaration - electromagnetic immunity			
The tourniquet is intended for use in the electromagnetic environment specified below. The user should assure that it is used in such an environment			
Immunity test	IEC 601 test level	Compliance level	Electromagnetic immunity guidance
ESD IEC 61000-4-2	±2 kV, ±4 kV and ±6 kV contact discharges ±2 kV, ±4 kV and ±8 kV air discharges	±2 kV, ±4 kV and ±6 kV contact discharges ±2 kV, ±4 kV and ±8 kV air discharges	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity shall be at least 30%
Radiated fields EN 61 000-4-3	3 V/m	10 V/m	Mains power quality should be of that of a typical commercial or hospital environment.
Burst IEC 61000-4-4	±2 kV	±2 kV	Mains power quality should be of that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±2 kV	±2 kV	Mains power quality should be of that of a typical commercial or hospital environment.
Conducted distrurbances IEC 61000-4-6	3 V with 80% AM @ 1 kHz	3 V with 80% AM @ 1 kHz	Mains power quality should be of that of a typical commercial or hospital environment.
Power frequency IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.
Voltage dips and interruptions IEC 61000-4-11	Reduction: > 95% for 10 ms 60% for 100 ms 30% for 500 ms > 95% for 5 s	Reduction: > 95% for 10 ms 60% for 100 ms 30% for 500 ms > 95% for 5 s	Mains power quality should be of that of a typical commercial or hospital environment. If the user of the Tourniquet requires continued operations during power mains interruptions, it is recommended that the tourniquet be powered from an uninterruptible power supply or battery.

Article number	Article
800-20	Hpm™ Tourniquet 800-20, single
800-40	Hpm™ Tourniquet 800-40, double
800-10	Printer for Hpm™ Tourniquet 800-series
800-11	Label roll for printer
400-45	Stand for systems of Tourniquets
800-25	Clamp Hpm™ Tourniquet 800-series
400-85	Basket incl. fastening devices

CE 0413

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