GB **Instruction Manual**

DIGITAL TOURNIQUET 9000

Tourniquet with dual channel for Bloodless Field,
Bilateral Surgery and I.V. Regional Anesthesia (Bier's Block)

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CE 0123

G1050GB - 10 / 04.2010

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1 General Information

Intended Use

The **Tourniquet 9000** is an electric unit for use with two single cuffs for Bloodless Field or Bilateral Surgery and also with double cuffs for Intravenous Regional Anesthesia (IVRA).

Instruction Manual

Before use, review this manual with safety instructions carefully.
This device may only be used by trained medical personnel.

Medical Device Directive

This Tourniquet Device complies with the requirements of the European Directive 93/42/EWG for medical devices.

CE 0123

EC-certificate

The design, development, production and distribution of the devices is covered by a quality system according to ISO 13485. This is confirmed by the EC Certificate issued by TÜV SÜD Product Service GmbH. For more information regarding the certificate please contact VBM or refer to the internet:
http:\\www.vbm-medical.de
\Download
\QM-Certificates
\EC-Certificate Device Class IIa

Note

- Technical modifications reserved!
- Within the EU waste management has to be carried out according to regulation 2002/96 EG (WEEE-Regulation)
- In case of interference with other devices, proceed as follows:
  1. Increase the distance between both devices.
  2. Contact the manufacturers of the devices.
- Each Tourniquet device is checked for electrical safety according to IEC 601-1 (DIN EN 60 601-1).
  We confirm to keep within the limits of device class I, BF-type:

Protective Earth Resistance	< 0.1 Ohm
Earth Leakage Current N.C.	< 0.5 mA
Enclosure Leakage Current N.C.	< 0.1 mA
Patient Leakage Current N.C.	< 0.1 mA

- Repairs, which are not described in this Manual, have to be effected by VBM or by an authorized service.

2 Device Delivery

Device Delivery complete with:

- battery in case of power failure
- power cable 4 m long
- colour coded extension hoses to Tourniquet Cuff
- alarm system

Availability:

REF 13-12-900
Table unit

REF 13-13-900
Table unit with universal clamp

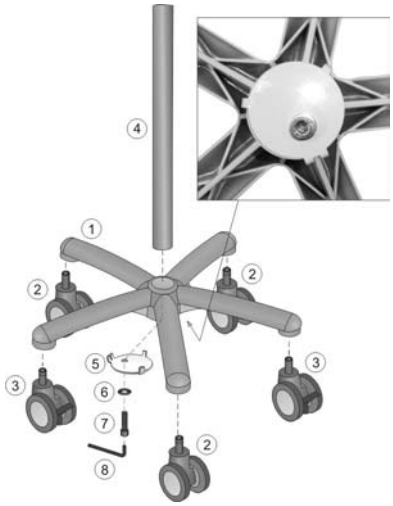
REF 13-22-900
Table unit on mobile stand with basket

Tourniquet Cuffs and further accessories are not included in the device delivery and have to be ordered separately. Detailed product information is available at VBM.

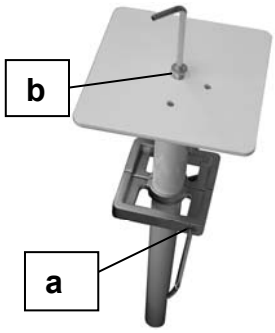
3 Assembly and Preparation for Use

Assembly of mobile stand with basket
REF 13-22-900

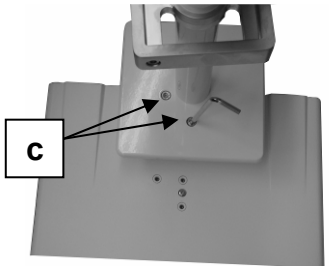
- Attach the lock-type rollers (3) opposite of each other to the base (1).
- Attach the ordinary rollers (2) to the base (1).
- Insert the support rod (4) into the base (1).
- Insert cylinder hat screw M8x40 (7) with washer (6) and distortion lock (5) from below into the base (1). Fasten with hexagon socket wrench (8).



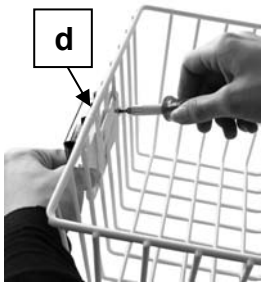
- Fix the square rail by means of the two hexagon socket screws to the support rod **(a)**
- Screw the fixation plate with hexagon socket screw M6x10 to the support rod **(b)**



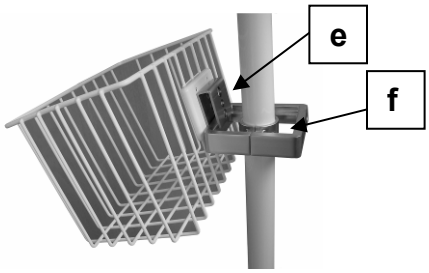
- Screw the fixation plate with the 2 hexagon socket screws M6x10 to the lower device housing **(c)**



- Attach the steel hook with fixation plate **(d)** to the basket using two countersunk screws M5x12.



- Attach the basket to the square rail **(f)** with the steel hook **(e)**



Mains Connection

Plug the power cable into the back of the device and then plug the other end of the cable into the mains socket. Always use a shockproof mains socket.

If local safety regulations require, connect the device to a potential equalisation mains supply or an earth connection (see the Potential Equalisation Terminal on the back panel of the device).

To disconnect the mains supply, unplug the power plug.

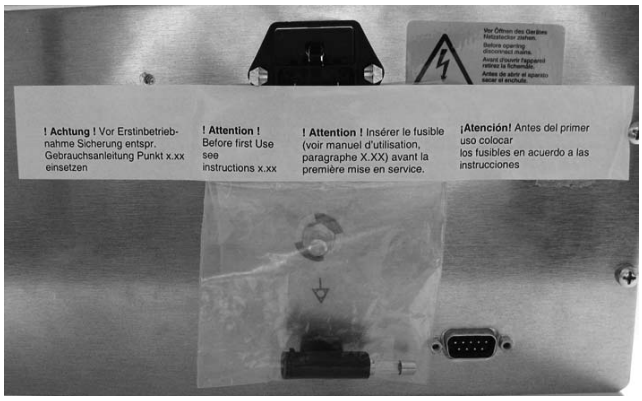
Should the good conditions of the set up or the position of the protection conductor be doubtful, the device has to be used only in battery mode (without mains supply).

3.1 Assembly of the battery

As protection of the battery there is a fuse 6,3 A (T) REF 10-50-120-51 at the back panel which should be inserted prior to first use of the device – follow below instructions with photos.

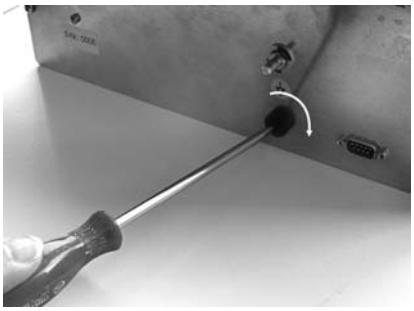
!! Attention !!
To avoid a discharge and also a drain of the battery, the fuse should be removed in case that the device is put out of operation for more than 4 weeks.

1) Fuse and fuse holder are originally packed and fixed to the back panel via an adhesive tape.

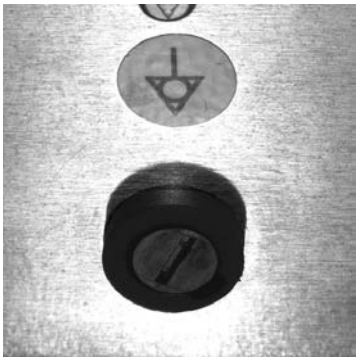


2) Remove the tape and insert the fuse into the fuse holder. Put the fuse with the holder into the device.

3) Turn the fuse holder with a screw driver 90° clockwise until it is locked.



4) Fuse in locked position.



5) After insertion of the fuse, the Tourniquet must be connected to power for 12 hours (battery will be charging). The Tourniquet can be used during charging.

For further information about the battery, see "Trouble Shooting / Battery" **page 14**.

The 12 Volt NIMH battery is charged using NIMH charging technology. The charging circuit is active anytime the unit is plugged into an acceptable V~ outlet. The charger automatically sequences through several charge states based on the battery voltage and battery temperature conditions. Based on a charger test, the best charge mode is selected. No maintenance is required of the battery charging circuit.
The life of the battery depends on the type of service and the storage method. Battery replacement will need to be more frequent with continued cycles of discharge/charge sequences and in case of a higher environment temperature. Infrequent short-term use of the battery and storage in a room-temperature environment will result in maximum life.

Should the good conditions of the set up or the position of the protection conductor be doubtful, the device has to be used only in battery mode (without mains supply).

4 Technical Data

Weight (table unit)	5.5 kg
Dimensions	
Height	150 mm
Width	320 mm
Depth	200 mm
Mains voltage	100-240 VAC
Mains frequency	50 – 60 Hz
Power consumption	75 VA
Mains fuse	2 x 2 A (T)
Battery fuse	1 x 6.3 A (T)
Battery type	NiMH 12V – 3000 mAh
Protection class (IEC 601-1)	I, type BF
Operating pressure	2 bar
Regulation range	0 – 600 mmHg (5 mmHg Steps)
Regulation accuracy	+3/– 2 mmHg
Pressure accuracy	± 5 mmHg
Timer Alarm	every 30 minutes after cuff inflation (audible signal)
Pressure Alarm	audible and visual alarm indicates leak in the Tourniquet system
Noise level	< 60 dB (A)
Connection	blue / red hoses with positive locking connectors (PLC)
Data port	RS232 for optional printer for patient report

Environmental conditions:

Transport/Storage	-10 ... +60°C
Operation	+10 ... +40°C 30 ... 95% atmospheric humidity without condensation

5 Tourniquet Cuffs

VBM offers a complete range of reusable and disposable **single and double cuffs** for **Tourniquet 9000**.

VBM single and double cuffs are colour coded. Single cuffs are blue. Double cuffs are blue (proximal chamber) and red (distal chamber).

Attachment and Securing of the cuff

See instructions for use included with each VBM Tourniquet Cuff.

Warning

Choose the adequate cuff pressure depending on cuff size and systolic blood pressure of the patient to guarantee a safe bloodless field and to avoid harm to the patient.
Cuff must not be inflated for more than **two hours**!

In case of a malfunction of the Tourniquet the cuff can be deflated by disconnecting the extension tube.

6 Operating Instructions Tourniquet Device

After securing the Tourniquet Cuff the Tourniquet device has to be operated as follows:

1. Press the ON/STANDBY switch to turn the unit on. The unit will make a self-check. In case of no mains supply the yellow Battery-indicator light illuminates. Additionally the Software Version will be displayed on the PRESSURE display, afterwards 0 will be displayed on the PRESSURE display and 0:00 on the TIME display.

2. Connect the single cuff via the positive locking connectors to the Tourniquet. For I.V. Regional Anesthesia connect the red connecting tube to the distal (red) Cuff.

3. Inflate the single cuff by turning the pressure regulator clockwise to the desired value. During pressure adjustment the symbol * is added on the PRESSURE display. For I.V. Regional Anesthesia inflate the blue proximal chamber first. The right Timer (blue side) starts automatically. The actual cuff pressure is displayed constantly on the PRESSURE display of the device.

4. The cuff pressure in the Tourniquet Cuff can be regulated via the pressure regulator at any time.

5. During I.V. Regional Anesthesia the distal chamber of the double cuff has to be inflated (considering that analgesia already takes place). Therefore turn the distal (red side) pressure regulator to the already selected proximal pressure value. The proximal chamber can now be deflated via the pressure regulator on the right (blue) side.

6. After the operation, the cuff has to be deflated slowly by turning the pressure regulator anticlockwise to zero. The corresponding Timer stops and displays the elapsed time.

Alarm System

The possible Alarm conditions will be displayed on the corresponding PRESSURE display and additionally by an audible signal.

Possible Alarm conditions:

LEAK
- No Tourniquet cuff is connected, although a pressure higher than 0 mmHg is set; the alarm is activated within 8 seconds.
- In case of leakage inside the Tourniquet system, which means a pressure decrease of 5 mmHg compared with the nominal value for longer than 10 seconds.

LOPR
- In case of disconnection of the cuff the alarm is activated within 5 seconds if a pressure higher than 0 mmHg is set.

HIPR
- In case of high pressure inside the Tourniquet system, which means a pressure increase of 15 mmHg compared with the nominal value for longer than 5 seconds.

If an alarm is activated, please operate according to the safety instructions.

The audible signal can be switched off temporarily for 30 seconds by pressing the alarm button.

Safety System

The Tourniquet device can also be operated without mains supply. The unit switches automatically to the battery mode. This offers two advantages:

- It is possible to disconnect the Tourniquet device from the mains supply in order to transport the patient with the Tourniquet in situ.

- In case of a power failure the operation can be continued safely.

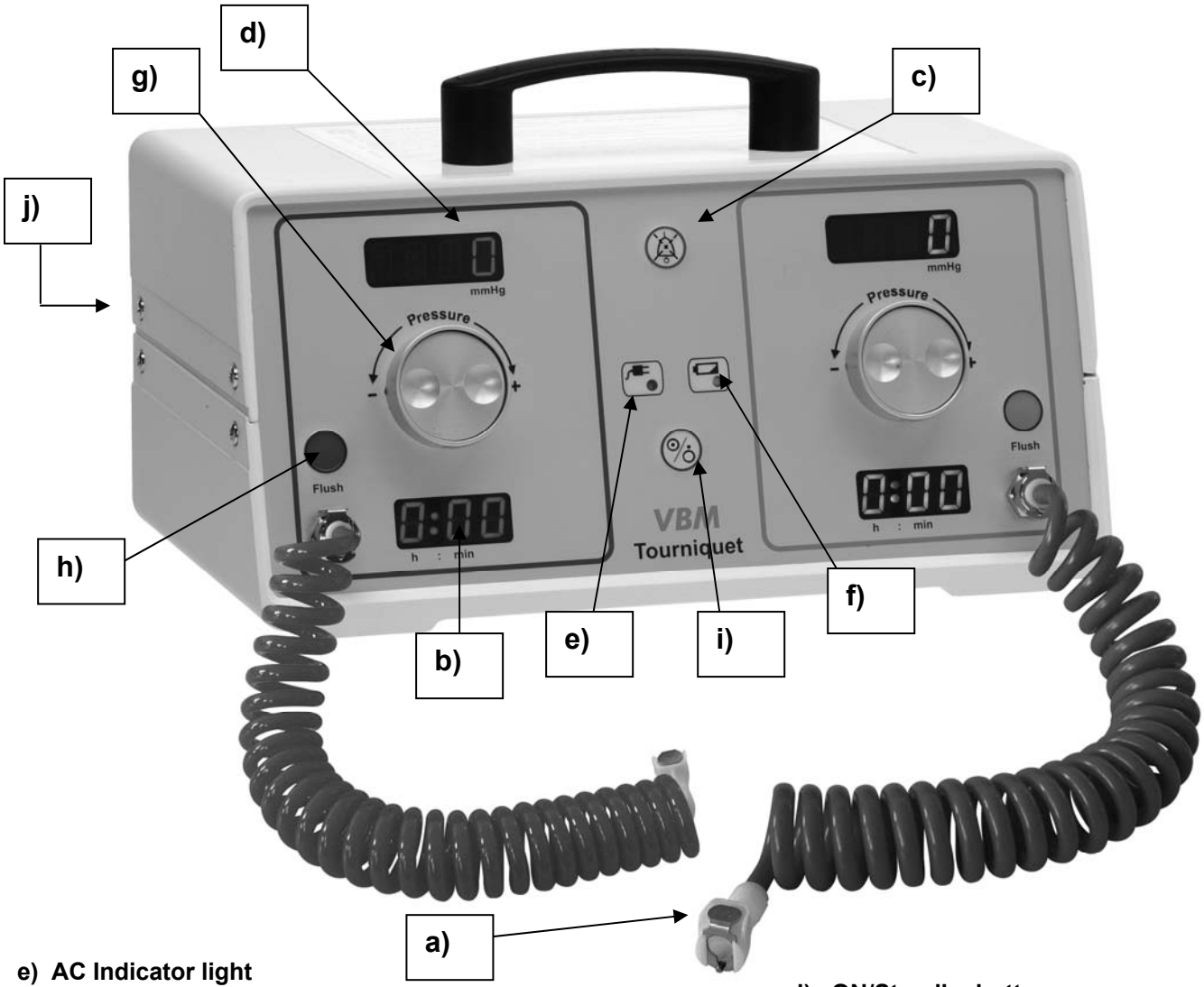
6 Operating Instructions Tourniquet Device

a) Color Coded hoses (blue/red) with Positive Locking Connectors
easy attachment and detachment; for safe and leak-free inflation

b) Automatic Timer
automatic time recording after cuff inflation; Provides elapsed inflation time for each cuff

c) Alarm silence button
to switch off audible alarm for 30 seconds

d) Pressure Display
independent pressure readings for each cuff; Large color coded LED display is easy to read; Precise monitoring, shows actual cuff pressure



e) AC Indicator light
input Voltage from 100-240 VAC

f) Battery Indicator light
Flushing light means charging
continued light means battery mode
unit operates for 4 hours with fully charged batteries

g) Precision Pressure Regulator
fast cuff inflation and deflation; automatic pressure compensation, safety knob prevents accidental movement, pressure range from 0 to 600mmHg

h) Flush Button (red and blue)
to check for bleeding after surgery; to release drug slowly after I.V. Regional Anaesthesia

i) ON/Standby button
battery charging also in Standby mode if unit is connected to the mains. To disconnect the mains supply, unplug the power plug.

j) Built-in Data port RS232
supports optional printer for patient report; Reports cuff pressure adjustments and total elapsed cuff time on a self-adhesive label

7 Safety Instructions

Mains Connection
Connect the Tourniquet device only to a grounded AC mains supply that complies with IEC requirements. Always use a three-pole cable.
Connect the device to a power supply that corresponds to the input requirements indicated on the ratings plate on the back panel of the device.

Should the good conditions of the set up or the position of the protection conductor be doubtful, the device has to be used only in battery mode (without mains supply).

Warning
Do not use the Tourniquet in explosion hazarded areas, which can be caused by flammable anaesthetics and disinfectants.

Splashing Water
Protect the Tourniquet device from splashing water. The power socket on the back of the device has to be kept dry. Do not use the device if any liquid has entered the unit.

Attention
- Make sure to select the correct cuff size. VBM offers a complete range of Tourniquet Cuffs.
- Ensure that damaged cuffs and connectors are no longer used.
- Make sure that the red chamber of the Double Cuff is put on distally.

Before Use
Check the functionality and air tightness of the Tourniquet system before each use. Put the cuff around a bottle and inflate to the maximum pressure of 600 mmHg. The alarm should not be activated within 2 minutes. Else see page 13 “Device Check”.

Check the function of the alarm system. Switch on the device. Disconnect the cuff and set the pressure regulator to a value higher than 150 mmHg. The pressure alarm has to be activated within 8 seconds.

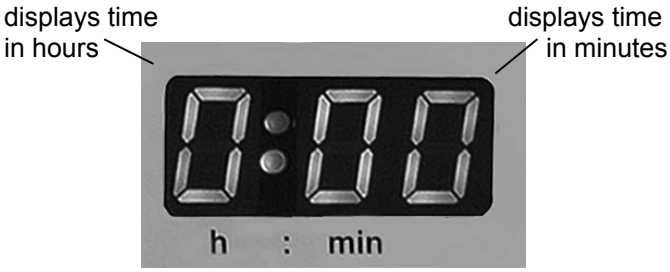
Operating
- Never occlude the hoses between device and cuff
- Make sure that the cuff inflates properly by manual palpation.
- Check the cuff pressure continuously during the operation. The PRESSURE display of the device always displays the exact cuff pressure. Any pressure deviation is indicated on the display and activates the alarm.

If the alarm is activated, operate as follows:
- Check the pressure constancy on the PRESSURE display.
- Inspect the cuff, hoses and connections for damage. Check for firm connection.
- If the alarm is still activated the device has to be inspected as described in "Service“.

Battery Recycling
There are rechargeable batteries inside, which are needed for special function.

Batteries should not be disposed of into ordinary household waste. Instead, they must be recycled properly to protect the environment and also to cut down the waste of precious resources. Contaminated batteries are marked with beside symbol. The city council, the waste management authority and also local dealers inform about recycling details.
Do not dive batteries into water or do not throw batteries into fire!

8 Operating Instructions Automatic Timer



Time controlling

- The timer is a fully automatic timer receiving its activation from the pressure regulator. The timer starts automatically after inflation of the cuff (pressure regulator ≥ 100 mmHg). This is indicated by the flashing colon. The timer now shows the elapsed time (minutes and hours only).

- Every 30 minutes an audible signal and flashing display reminds the operator regarding the elapsed time.
  The blood occlusion time must not exceed two hours.

- After cuff deflation, the timer stops automatically and the colon stops to flash. Now the total elapsed inflation time can be recorded.

9 Cleaning Instructions

Tourniquet Device

Switch off the device (ON/Standby button) and disconnect the power cable before cleaning the device!

Cleaning
Wipe the device with a soft and damp cloth.

Disinfection
Wipe the device with a cloth that has been dampened with commercially available disinfectants in low concentration.
Never immerse the Tourniquet unit in liquids!

Sterilisation
Do not sterilise the Tourniquet unit!

Tourniquet Cuffs

Cleaning, Disinfection, Sterilisation
Follow the instructions for use included with each VBM Tourniquet Cuff.

10 EMC Tables

Guidance and manufacturer's declaration – electromagnetic emissions		
The Tourniquet 9000 is intended for use in the electromagnetic environment specified below. The customer or the user of the Tourniquet 9000 should assure that it is used in such an environment		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Tourniquet 9000 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class B	The Tourniquet 9000 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

10 EMC Tables

Guidance and manufacturer's declaration – electromagnetic immunity			
The Tourniquet 9000 is intended for use in the electromagnetic environment specified below. The customer or the user of the Tourniquet 9000 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±4 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Tourniquet 9000 requires continued operation during power mains interruptions, it is recommended that the Tourniquet 9000 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

10 EMC Tables

Guidance and manufacturer's declaration – electromagnetic immunity			
The Tourniquet 9000 is intended for use in the electromagnetic environment specified below. The customer or the user of the Tourniquet 9000 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Tourniquet 9000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommend separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3Vrms	$d = 1,2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	10 V/m	$d = 0,35\sqrt{P}$ 80 MHz to 800 MHz $d = 0,7\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the "Non Ionizing Radiation" symbol

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Tourniquet 9000 is used exceeds the applicable RF compliance level above, the Tourniquet 9000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting relocating the Tourniquet 9000

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

10 EMC Tables

Recommended separation distances between portable and mobile RF communications equipment and the Tourniquet 9000			
The Tourniquet 9000 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Tourniquet 9000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Tourniquet 9000 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

11 Symbol definitions

Symbols and abbreviation	Definitions	Symbols and abbreviation	Definitions
	Refer to Instruction manual		Unit ‚ON' (only for a part of the unit)
	Equipotential		Standby Mode
	Attention		Temporary acoustic signal switch off
	Signal output		Battery condition indicator
	Electrical device, which is delivered after 13.08.2005 in the EU.		Power supply operation indicator
	Electrical Hazard		Type BF Equipment
	It is not allowed to dispose batteries in the domestic refuse.		Sign, that a material is a part of a recycling process.
			Grounding symbol, Protection class I, according IEC 60417-5019

12 Device Check

Function and Leak test

Execute following test if necessary (see "Safety Instructions - Before use" or "Troubleshooting"):

1. Connect the device to the mains supply. The AC Indicator light illuminates green.
2. Put the cuff around a bottle.
3. Connect the red extension hose to the cuff.
4. Switch on the device.
5. Now it must be possible to adjust any desired pressure value (5 mmHg steps) with the pressure regulator. The pressure value has to be displayed.
6. Set the pressure to 600 mmHg. The corresponding Timer starts automatically.
7. Press the red flush button and the pressure decreases immediately. Release the red flush button and the pressure goes back to 600 mmHg.
8. The alarm should not be activated within 2 minutes. In case of a leak alarm follow the instructions on page 14.
9. Set the pressure to 0 mmHg. The corresponding Timer stops automatically and shows the elapsed time.
10. To check the right (blue) side, repeat the steps 2-9 analogous.

Repairs

Repairs which are not described in this Manual may only be carried out by **QUALIFIED SERVICE PERSONNEL**. Otherwise VBM cannot be held responsible for safety, reliability and performance of the device.

VBM does not accept any warranty claims if the user or an unauthorised service agency has attempted to effect repairs which are not described in this Service Manual.

To ease repair of the device return it together with a detailed description of the defect.

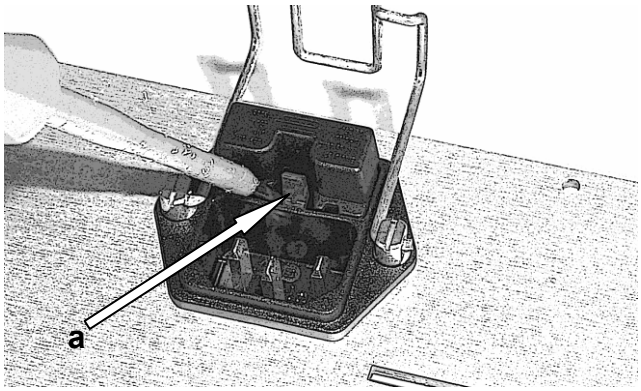
As a protective measure for the safety of VBM staff return the device or cuffs completely cleaned and disinfected (see “Cleaning, Disinfection and Sterilisation”). The VBM Service is entitled to refuse repairs of contaminated items for safety reasons.

13 Trouble shooting

Failure/Defect	Cause/Removal
Mains Switch	
• AC Indicator light does not illuminate • “defl cuff” is shown in the pressure display	➢ Fuses on the rear panel are defective. Check the fuses and replace them if necessary **(page 15)**. ➢ It is not possible to switch off the device while the cuff is inflated. In order to switch off the device the cuff needs to be deflated.
LEAK-Alarm	
• Leakage (LEAK/LOPR) in the system (device with cuff).	➢ No cuff is connected, although a pressure higher than 0 mmHg is set (both sides). Turn the pressure regulator to 0 mmHg. ➢ Cuff is damaged. Check the device with another cuff (**page 13** “Function and Leakage test”). Replace the cuff if necessary. ➢ See “Leakage inside the device”.
• Leakage inside the device	➢ Washer of male locking connector is porous or missing. Replace the washer.
Battery	
• BATT LOW • BATT FAIL	➢ Battery voltage is too low to ensure an operation time of 2h 30 min. Press alarm button to confirm that the procedure can continue. (charge battery) ➢ Fuse at the back panel is defect or missing. Please see instructions at **page 3**. ➢ Battery defective. Charge battery for at least 12 h. In case that the signal still appears, an **QUALIFIED SERVICE PERSONNEL** has to replace the battery.
Pump	
• Pump does not start	➢ Set the device in motion again. If the failure persists, the device needs to be returned.

14 Replacement of Parts

Replace the fuses



1. Pull off the mains plug.
2. Push up the shackle at the power socket on the rear panel with a screw driver **(a)**.
3. Fuse socket is loose and can be removed.
4. Replace only with the same type and rating of fuse.

Mains fuse
2 A(T) 20x5 mm
REF 20-15-772

15 Spare Parts List

Coil Extension Hose, max. stretch length 3.0 m,
with positive locking connectors

– colour: red REF 20-20-742
– colour: blue REF 20-20-744

REF SLZM30
Positive Locking
Connector, male

REF SLZF40
Positive Locking
Connector, female,
self-locking