

# AUTOMATIC TOURNIQUET DEVICE

## User manual

**ATTENTION:** The operators must carefully read and completely understand the present manual before using the product.

### Gima 33110

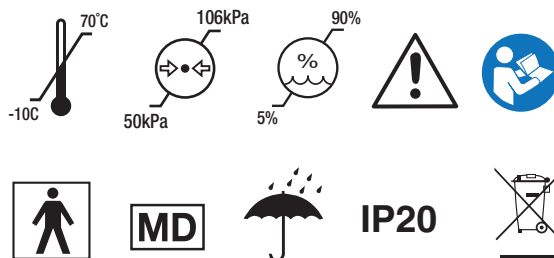


Avrasyamed Mediikal Tıbbi Cihazlar Ve Ürünler Pazarlama  
Sanayi Ve Dış Ticaret Limited Şirketi  
Cihangir Mh. Güvercin Cd. No: 4 İç Kapı No: 144 Avcılar  
İstanbul Türkiye  
www.avrasyamed.com.tr e-mail: info@avrasyamed.com.tr  
www.medione.com.tr e-mail: info@medione.com.tr  
Made in Turkey

**REF** TRQ-2024



Gima S.p.A.  
Via Marconi, 1 - 20060 Gessate (MI) Italy  
gima@gimaitaly.com - export@gimaitaly.com  
[www.gimaitaly.com](http://www.gimaitaly.com)





TRQ-2024

TRQ-2022



For clinical application, maintenance and problem solving of these devices, please read this manual carefully and understand the features and instructions before using the devices.



1984

AVRASYAMED MEDİKAL TIBBİ CİHAZLAR VE ÜRÜNLER PAZARLAMA SANAYİ VE DIŞ TİCARET LİMİTED ŞİRKETİ

TELEFONO: +90-212 590 42 40/41 FAX: +90-212 590 00 15


E-mail: [info@avasyamed.com.tr](mailto:info@avasyamed.com.tr)

E-mail: [info@medione.com.tr](mailto:info@medione.com.tr)

#### Copyright Notice

Copyright belongs to AVRASYAMED MEDİKAL TIBBİ CİHAZLAR VE ÜRÜNLER PAZARLAMA SANAYİ VE DIŞ TİCARET LTD. ŞTİ. and all rights are reserved.

This User Guide, in whole or in part, cannot be copied, distributed or published without the prior written permission of AVRASYAMED MEDİKAL TIBBİ CİHAZLAR VE ÜRÜNLER PAZARLAMA SANAYİ VE DIŞ TİCARET LTD. ŞTİ. Printed in Turkey.

**Brand Statement**  is a registered trademark of AVRASYAMED MEDİKAL TIBBİ CİHAZLAR VE ÜRÜNLER PAZARLAMA SANAYİ VE DIŞ TİCARET LİMİTED ŞİRKETİ. Names and terms used for products of other manufacturers mentioned in this User Manual may be associated with registered trademarks or trademarks. Avrasyamed Medikal recognizes the legal status of the trademarks in question without explicitly using symbols such as TM or ® that indicate their legal structure. Changes to these legal structures are accepted unconditionally.

# Contents


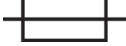














---




- 1. General information ..... 4**
  - 1.1. Symbols Used. .... 4**
  - 1.2. About this document..... 5**
  - 1.3. Applicability..... 5**
- 2. Intended Use..... 5**
  - 2.1. Contraindications ..... 5**
  - 2.2. Possible Complications..... 6**
- 3. Patient and User Profile ..... 6**
- 4. For your safety ..... 6**
  - 4.1. Warnings and Safety Information..... 6**
    - 4.1.1 User Manual for Accessories..... 6**
    - 4.1.2. Use of the Tourniquet Device in Potentially Explosive Environments ..... 6**
    - 4.1.3. Safety check after two years of use..... 7**
    - 4.1.4. Training for the person who will be responsible for the tourniquet device ..... 7**
    - 4.1.5. Tourniquet Maintenance and Device Repair ..... 7**
- 5. Medical Devices Regulation and Notified Body ..... 7**
- 6. Storage and transportation conditions before use ..... 7**
- 7. General warning ..... 7**
  - 7.1. Cleaning and Disinfection..... 8**
    - 7.1.1. Recommended cleaning materials ..... 8**
  - 7.2. User and Patient Safety..... 8**
- 8. Description of Tourniquet Device ..... 9**
- 9. Front panel..... 10**
  - 9.1. Color-coded connections for IVRA implementation ..... 11**
- 10. Back Panel..... 11**
- 11. Display and Buttons..... 12**
- 12. Power supply ..... 14**
- 13. Network mode..... 14**
- 14. Battery maintenance and storage..... 14**
- 15. Charging the Battery..... 15**
- 16. Initial use..... 15**

16.1. Unpacking and installing the appliance.....	15
16.2. Connecting the appliance to the power supply .....	16
16.3. Checking the state of charge of the battery .....	16
16.4. Switching on the appliance.....	16
16.5. Switching off the appliance.....	16
16.6 Installation.....	16
<b>17. OPERATING THE APPLIANCE .....</b>	<b>17</b>
17.1. STARTING THE DEVICE.....	17
17.2. Settings of the Tourniquet Device. ....	17
17.2.1. Presetting the pressure.....	17
17.2.2. Changing the pressure (preoperatively).....	18
17.2.3. Changing the pressure (during surgery) .....	18
17.2.4. Setting the timer (pre-operative) .....	19
18. Termination of the Tourniquet .....	21
19. Closing the tourniquet.....	21
20. IVRA.....	21
21. Settings .....	23
22. Troubleshooting.....	24
23. Technical information/Parameter .....	26
24. Accessories List .....	27
25. Electromagnetic Compatibility (EMC) Statement.....	28

## 1. General information

### 1.1. Symbols Used.

SYMBOL/TERM	Definition
	Follow instructions for use
 F1, F2, F3:2A T; 250 V	Insurance values
	Manufacturer
	Date of Manufacture
	Product code
	Lot number
	Serial number
 1984	Conformity Marking of the Council of the European Community including Notified Body ID no. The product complies with the essential requirements of the council's 93/42 / EEC (including 2007/47 / EC updates) Medical Device directives.
<b>IP20</b>	Covering Protection rate
	WEEE disposal
<b>~AC</b>	Alternating current
<b>Hz</b>	Hertz
<b>VA</b>	Volt-Amper
<b>IVRA</b>	Regional Intravenous Anesthesia
	Fragile, handle with care
	This side up
	Keep in a cool, dry place
	Atmospheric pressure limit
	Temperature limit
	Humidity limit
	Caution: read instructions (warnings) carefully

	Type BF applied part
	Medical Device
	Distribué par

### 1.2. About this document

The user manual is part of this product and contains information and instructions for the safe and proper use of the product.

Read the user manual before using the product.

Keep the instruction manual near the product or in an easily accessible place so that it can be accessed at all times.

The product is translated according to the language of the exported country by sworn translation offices specialized in labels and user manuals.

### 1.3. Applicability

The user manual applies to TRQ-2024 / TRQ-2022.

## 2. Intended Use

The Automatic Tourniquet Device is used in orthopedic surgeries in the operating room to temporarily stop or slow down the blood flow in the patient's upper and lower extremities. In addition, in the application of Regional Intravenous Anesthesia (IVRA), it prevents blood flow to that area after the blood of the extremity is drained.

The device is designed for uninterrupted use.

The usable pressure range is between 20 and 650 mmHg.

Medione tourniquet devices are used in the following surgical procedures:

- Leg arm fractures
- Insertion and removal of implants in the leg and arm
- Finger, knee and elbow prostheses
- Arthroscopy
- Tendon correction
- Carpal tunnel syndrome
- Hammer toe
- Amputation
- Varicose vein
- Removal of benign tumors in the leg and arm
- Removal of cysts

### 2.1. Contraindications

Automatic Tourniquet Devices should not be used in patients with the following defined conditions:

- Swollen, infected, or inflamed areas at the site of use
- Having malignant tumors
- Having crushes
- Severe arteriosclerosis
- Severe crush wound
- Severe hypertension
- Thrombosis

- Open fractures in the extremities
- New dermal implants in the situ of use
- Severe brain injury
- Neuromuscular injuries
- Peripheral artery disease
- Patients carrying sickle cell gene
- Diabetes



In all cases, the decision to use an automatic tourniquet belongs to the practicing doctor

## 2.2. Possible Complications

- Hyperaemia with risk of bleeding
- Muscle edema
- Paralysis
- Irregularity in acid-base balance
- As a result of the sudden restoration of blood flow, accumulated metabolites cause shock
- Nerve injury (especially the peroneal or ulnar nerve)

---

## 3. Patient and User Profile

Automatic tourniquet devices are used by specialist physicians and related health professionals (operating room nurse, anesthesia nurse) who have read the user manual.

The products can be used in adults and children.

---

## 4. For your safety

The Medione tourniquet device should only be used by trained personnel, taking into account the information in this user manual.

Heed the warnings and safety information for safe use of the tourniquet device.

### 4.1. Warnings and Safety Information

#### 4.1.1 User Manual for Accessories



**Improper use of accessories may result in damage to the patient and/or the tourniquet device.**

Only accessories provided by the manufacturer specified in this accessory list may be used.

#### 4.1.2. Use of the Tourniquet Device in Potentially Explosive Environments

**WARNING! Use of the tourniquet device and all accessories in environments where explosive or flammable anesthetic agents or cleaning materials are present may cause serious injury and damage to the tourniquet device.**

Only use the Medione tourniquet device and all its accessories in environments where there is no explosion hazard or in the absence of flammable anesthetic agents or disinfectants.

#### 4.1.3. Safety check after two years of use

Medione recommends a safety check for the tourniquet device after 2 years of use. The check can only be carried out by the manufacturer or persons authorized by the manufacturer.

#### 4.1.4. Training for the person who will be responsible for the tourniquet device

The tourniquet device can be used by following the necessary instructions in the user manual. The user may request training from Avrasyamed Medikal or persons authorized by the manufacturer.

After the user manual information and training, the user directive applies. All national regulations regarding the installation, training, documentation and use of a medical device must be followed.

#### 4.1.5. Tourniquet Maintenance and Device Repair

Repairs may only be carried out by the manufacturer or trained service personnel authorized by the manufacturer.

- Device maintenance can be done by biomedical technicians or engineers.
- When maintaining the device, the life and usability of the battery should be checked.
- The fuse on the device should be checked for soundness.
- Comparison of the pressure given by the device and the measured pressure can be made with the appropriate calibration device.
- It is recommended to perform device maintenance and calibrations once a year.
- The user must refrain from interfering with the device.

## 5. Medical Devices Regulation and Notified Body

---

It is a Medical Device Class IIa that complies with the requirements of Regulation 93/42/EEC

Notified Body: Kiwa Certification Services Inc.

Notified Body No: 1984

## 6. Storage and transportation conditions before use

---

Do not leave the package outside, avoid mechanical shaking.

Storage and transportation conditions: temperature from -10°C to +70°C; Relative humidity 5% to 90%

Ambient conditions: temperature 15°C to +40°C, relative humidity 5% to 90%

Handle the package carefully, avoiding dropping it.

## 7. General warning

---

**Any modification may cause harm to the patient or the user. At no time should changes be made to the device under any circumstances.**



**In order to eliminate the risk of electric shock, the Tourniquet device can only be connected to a supply network with a protective earthing conductor.**

Environmental conditions must be observed in use.

The automatic tourniquet device must be connected to the grounding socket with a 3 m grounding cable, especially to avoid electric shock. No multiplexer socket or extension cord should be used.

To protect the patient from electrical hazard, do not use the medical device immediately next to the patient (distance not less than 2 meters).

During the use of the appliance, the appliance must be plugged in, the battery is only activated for safety purposes in the event of a power failure. In addition, if there is a suspicion of grounding in the system, the battery should be used in the installation.

The automatic tourniquet device, and especially the electrical connection, must be protected from water and moisture. Never operate the appliance if water is spilled on it. Disconnect from the mains and get support from your authorized service.

Do not use metal or sharp objects on the front of the automatic tourniquet device, it may cause damage.

Do not pull on AC power cords or Pneumatic extensions.

The appliance must not be moved while the power cord is plugged in.

Make sure the power cords are far enough away to avoid the risk of strangulation.

Do not push the stand while it is on the device against the risk of the device falling, there is a handle on the top for the safety of the device in such push/pull maneuvers. It can be manoeuvred by holding the device while pushing/pulling.

It is recommended to lock the wheels of the stand to prevent accidental movement of the device.

Make sure that the accessories are used in appropriate conditions and on the appropriate limb.

The connector slot acts as a connecting key. Therefore, it must always be available to disconnect in case of danger.

To minimize electromagnetic and other interference, be sure to use the appliance in a grounded socket. The purpose of grounding is to reduce the generation of radio frequency voltages that can lead to electromagnetic interference. Another precaution that can be taken is filtering. Filters can be designed to prevent electromagnetic interference from conductors. In this direction, a special filter circuit can be designed for each circuit. This precaution was taken using the power filter in the device.

## 7.1. Cleaning and Disinfection

Before cleaning and disinfection, unplug the power cord of the device and wipe the device surface and accessories with the appropriate disinfectant.

In case of severe contamination, wipe with a damp cloth for 5-15 minutes, depending on the desired antimicrobial effect. There are no restrictions in this app. No rinsing is required.



**The use of large amounts of water, cleaning agents or disinfection products is a risk of short circuits and electric shocks.**

- Do not expose surfaces to large amounts of water, cleaning or disinfecting products during cleaning.
- Wipe surfaces with a cloth dampened with warm water, cleaning or disinfecting product.



**Do not spray disinfectants directly onto the appliance. The automatic tourniquet device and accessories must be dry before use.**

### 7.1.1. Recommended cleaning materials

Alcohol-based disinfection products and cleaning materials can be used.

## 7.2. User and Patient Safety

Medione tourniquet devices support you with a comprehensive safety concept. In this way, even in exceptional cases, sudden pressure loss in the cuff is prevented, and it is ensured that the surgery that has started is completed safely. If a malfunction occurs, the tourniquet device gives an audible and visual warning. As the responsible surgical staff, take immediate action to resolve the issue. However, the battery of the device should be replaced with a new one every 2 years to ensure that maximum safety is constantly ensured and that the tourniquet device is in good condition.

**Make sure your tourniquet device and accessories are in working order before starting the application.**

Make sure that the accessories to be used are compatible with the automatic tourniquet device, it is absolutely not appropriate to use cuffs with incompatible connectors and to replace connectors.

Check the condition of the connections, there should be no bends and folds to ensure air escape.

As a precaution, check whether the medical device is working properly by connecting the cuff as described below

Plug in the power cord, make sure the battery is fully charged to compensate for any interruptions.

Tie the cuff.

Display pressure instructions on the display, e.g. 300 mmHg.



**The duration and amount of pressure applied is the responsibility of the physician and is based on available information from research and technology.**

Too high pressure and longer than necessary tourniquet application can harm the patient.

Apply the minimum pressure necessary to create a safe tourniquet at the surgical site.

### **Pay attention to this issue, especially in the application of tourniquets in children!**

In order for you to check the tourniquet time during the surgery, the time entered on the main screen and the time elapsed from the start are shown on the screen. At the end of the set alarm time, the device warns you audibly and visually and you can readjust the time or terminate the process.

Decide together with the responsible physician whether the tourniquet should be continued or terminated.

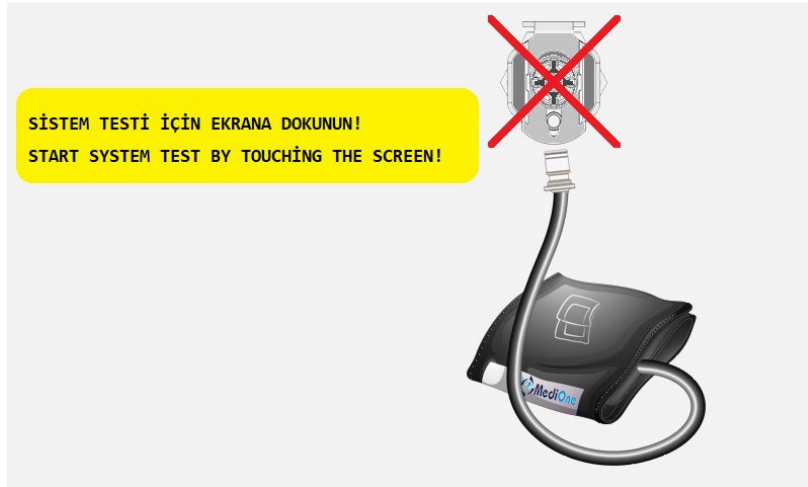
## **8. Description of Tourniquet Device**

Automatic tourniquets are used in the lower and upper extremities during surgical procedures. Apparatus; An On/Off button, a 7-inch touchscreen LCD display with pressure, time and visual alarms and settings to be made and status displays are displayed, the cuff connection connector, the carrying handle and the device case are included.

### **Power supply**

The tourniquet device can be powered by 100-240V AC voltage and can be operated using a power supply unit or an internally powered device.

### **Automatic Control Test**



Each time the tourniquet device is operated, it performs an automatic test. This initial system check ensures the safe operation and function of all important components. So you are always working with a safe tourniquet device. The device cuff connections must be left open before the self-test begins. Connection hoses and cuffs must not be plugged in! If the test is successful, the device is ready for use. If it does not pass the test, it will give an error code Error on the screen.

### **Fault Management**

Malfunctions that occur in the device are subject to different classes of severity.

If a malfunction occurs, a visual and audible warning is given on the tourniquet device screen, and the error code is also indicated on the display.

## E-06 Proximal Hava Kaçağı

Error: Alarm Code E-06

For more information, see: Chapter 21, p.31

### 9. Front panel

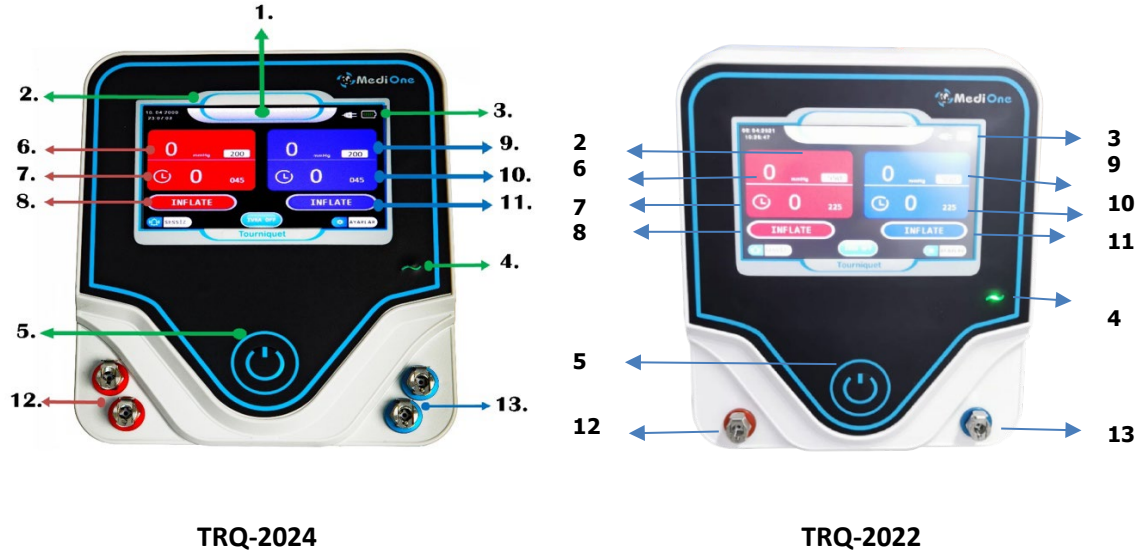


Image No.	Functions.
1	Error Code Visual Alarm Display LCD
2	LED Alarm Indicator
3	AC/DC Charging Indicator Display LCD
4	AC Led Indicator Light
5	ON/OFF Button
6	Proximal Pressure Gauge and Adjustment Screen
7	Proximal Time Display and Setting Display
8	Inflate/Deflate Button Proximal
9	Distal Pressure Gauge and Adjustment Screen
10	Distal Time Display and Setting Screen
11	Inflate/Deflate Button Distal
12	Proximal Tourniquet Cuff connection socket
13	Distal Tourniquet Cuff connection socket

TRQ-2024 Medione Tourniquet device has a total of 4 connection sockets on both sides to use a two-outlet or single-outlet cuff. With this device, you can apply tourniquets to both extremities at the same time in different ways, such as:

2 X Lever

2 x Legs

Arm and Leg

In addition, regional intravenous anesthesia (IVRA) can be applied with a double cuff.

TRQ-2022 Medione Tourniquet device has two connection sockets for using two cuffs. With this device, you can apply tourniquets to both extremities at the same time in different ways, such as:

2 X Lever

2 x Legs

Arm and Leg

In addition, regional intravenous anesthesia (IVRA) can be applied with a double cuff.

**When using a single channel:**

**The left (Proximal)** attachment point (canal) is always used in the arm and **the right (Distal)** anchor point (canal) is always used in the leg.

In order to use the tourniquet connection channels correctly;

Left-handed, left-hand channel: red (Proximal) connection – lever

Right, right channel: blue (Distal)connection – leg

**When both channels are used:**

In this case, two attachment points (channels) for the arms and legs can also be used.

**9.1. Color-coded connections for IVRA implementation**

Tourniquet connections are color-coded to make IVRA application easier with the tourniquet device.

When using a dual-chamber cuff for an IVRA application, connect the distal and Proximal cuff chambers as described below:

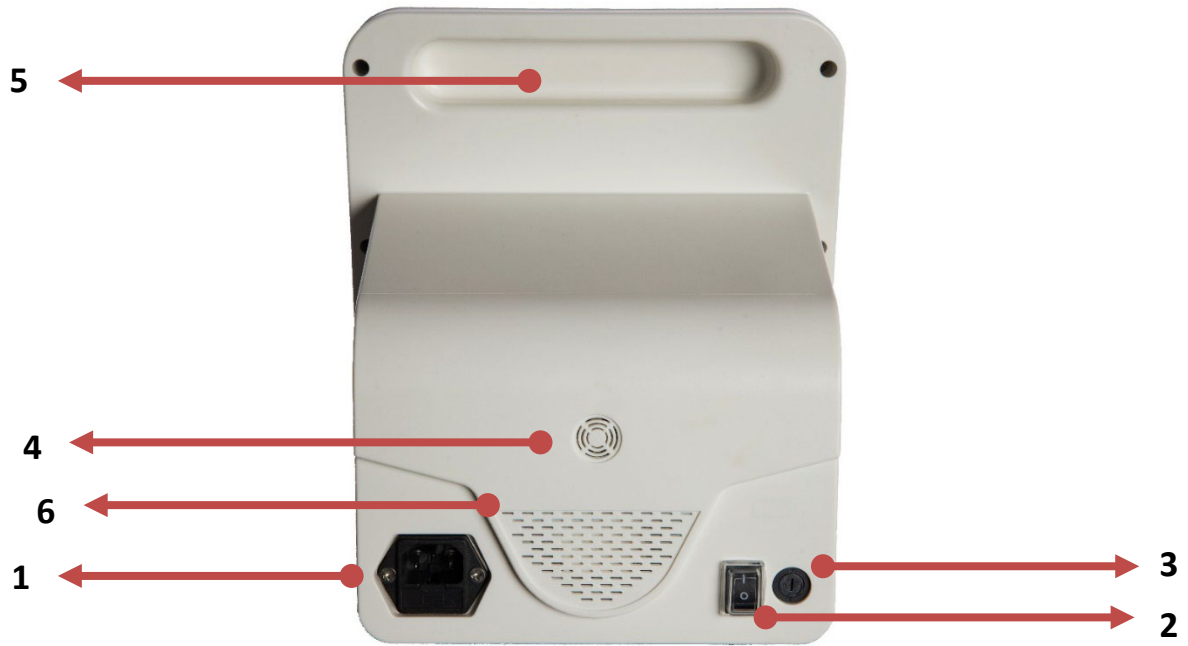
The left attachment point is **colored red** and indicates the **Proximal** cuff chamber.

The right attachment point is **colored blue** and indicates the **Distal** cuff chamber.

**An error code is shown on the screen for proximal or distal** portions. Thus, you can more quickly detect which channel has a possible malfunction.







---

















## 10. Back Panel



- 1 Power connection socket 100-240V
- 2 On/Off Switch
- 3 Battery fuse holder 2A
- 4 Speaker output
- 5 Handle
- 6. Ventilation outlet

## 11. Display and Buttons

Buttons/Icons/Connector	Functions
	Device On/Off Key (2 sec.)
	Choosing Regional Intravenous Anesthesia (IVRA)
	Setting Screen Login Button
<b>MmHg</b>	Pressure Unit
	Time Counter
	Alarm Silence Button
	Charge Indicator

	AC Indicator
	LCD Display Error Code, Information Display
	Proximal part DEFLATE (Stop tourniquet)
	Proximal Part INFLATE (Initiating the Tourniquet)
	Distal Part: DEFLATE (Stop the tourniquet)
	Distal Part: INFLATE (Starting the Tourniquet)
	Distal Part setting and information display
	Proximal Part setting and information display
	Tourniquet Cuff Connection Connector (4 pcs)
	Volume
	Alarm Timer
	Date Time Setting
	Screen Brightness Adjustment
	Language Setting
	Alarm Log
	Backspace

## 12. Power supply

---

The tourniquet device can be powered by voltage and can be operated using a power supply or an internally powered battery. The manufacturer recommends always using a power supply to operate the Medione Automatic tourniquet device. In the event of a malfunction of the battery, the tourniquet device can be operated by power supply.

The safe operation of the battery will only be checked in mains mode when the tourniquet device is switched on.

## 13. Network mode

---

**In mains mode, please pay attention to the following information!**

### **Automatically switch to battery mode in the event of a power failure**

If there is a power failure in the power supply unit, the battery must always be fully charged, even in mains mode, when starting a tourniquet application, in order to ensure the safe operation of the device. In the event of a power failure, the tourniquet device automatically switches from mains mode to battery mode. Current work is not interrupted.

## 14. Battery maintenance and storage

---

There is a battery protection to prevent the battery from being completely discharged during transport or when not in use for a long time. The device is delivered without this battery protection installed.

If the tourniquet device is being transported, the battery must be fully charged and the battery protection must be removed.

Observe the information on the label on the back of the tourniquet device.

The battery of the tourniquet device can only be charged with the battery protection installed, the switch on the back of the device is in the 1 position, the device is in standby and use.



### **Installing the battery guard**

1. Open the battery protection with the help of a flat screwdriver.
2. Insert the replacement glass fuses supplied with the appliance into the fuse holder properly.
3. After the glass fuse is installed, close the fuse holder.

4. Turn on the device and confirm whether the device is running on the battery.

### Removing the battery protection

1. Open the battery guard with the help of a flat screwdriver.
2. Remove the battery guard from its chamber.
3. Store the battery protection next to the tourniquet device.

## 15. Charging the Battery

1. When charging, the On/Off switch on the back of the appliance should always be in the **On (1)** position and the AC indicator light should be green when the power cord is plugged in.
2. Check the full or full status in the upper right corner of the battery charge indicator on the LCD screen.
3. Charging indicator (5 step bar) indicates that if the charge step lights are moving, it is below 90% battery capacity and is charged. (Each stage bar indicates a 20% charge level)
4. Be sure to charge the battery after using the device (regardless of the current battery condition).
5. Make sure the battery is fully charged before use.



Display Indicator	Charging Status	Explanation
The gauge stage is fully charged	Battery fully charged 100%	-
Indicator stage flashing	Ac power on, battery charging, battery below 90%	-
The gauge stage is at the lowest level	Battery charge level is below 50%	-Connect the device to the power supply -Charge the battery
Indicator flashing with error E11	Battery charge level is below 10%	-Connect the device to the power supply -The device will allow use with the error code due to the critical battery level -Connect the device to the power supply or stop using it within 5 minutes.

The battery charge level is displayed on the LCD screen  with 5 level bars. Each bar slice indicates a 20% charge level.

## 16. Initial use

Make the first use by following the steps below.

### 16.1. Unpacking and installing the appliance

1. Unpack the tourniquet device and accessories.
2. Store the packaging in a convenient place.
3. Install and/or fix the tourniquet device in the desired location.
4. If necessary, wait for the tourniquet device to reach room temperature.
5. Insert the battery protection fuse that comes with the device into its socket.

### Device Packaging contents

1. Power Cord

2. Instruction manual
3. Tourniquet cuff in different sizes (3 pieces standard, 1 piece IVRA )
4. Cuff connection hose 2 pcs
5. Tourniquet device main unit
6. Glass fuse

### 16.2. Connecting the appliance to the power supply

Use a power cord specific to your country to connect the tourniquet device to the power supply (power outlet).

Observe the information on the power supply manual and on the label. (See chapter 22, p. 27.)

### 16.3. Checking the state of charge of the battery

Check the steps in Chapter 15 for the battery charge status. For safe use, the battery charge and your battery must be intact.

### 16.4. Switching on the appliance

Connect the power cord of the device, turn the power switch on the back of the device to position 1. Turn on the tourniquet device by pressing the On/Off button on the device for 2 seconds.

– For automatic system testing, the test of system functions is performed by touching the screen.



– If the device fails to perform the self-test, a safety message is issued (E1, E6, E2, etc.). See chapter 21, p.31

– The tourniquet device **is ready for use when the SELF TEST (OK) text disappears from the screen.**

### 16.5. Switching off the appliance

When the On/Off button is pressed for 2 seconds, an intermittent warning sound will be heard, then the tourniquet device will turn off.

For mains mode: It is recommended that you always leave the appliance connected to the power supply (power socket) after switching it off.

### 16.6 Installation

The Medione tourniquet device is delivered ready for use. By reading the user manual, the user can make the device suitable for operation according to the instructions for use and start using it.

Make sure that the first use is carried out properly.

Install and/or fix the tourniquet device in the desired location:

- Using as a stationary device
- Attaching to movable stand

#### Using it as a stationary device

The tourniquet device can be used stationary.

Make sure that the surface on which the device will be positioned is firm and level.

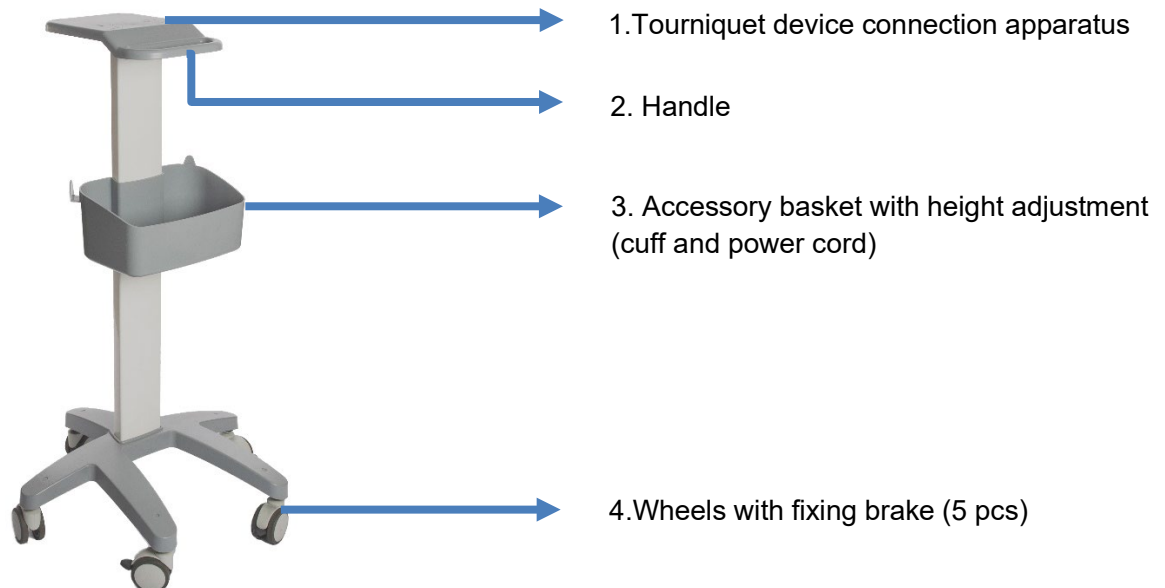
Protect the tourniquet device from sunlight and moisture.

Do not place the tourniquet device in front of heating appliances and other heat sources.

### **Attaching to movable stand (optional)**

You can connect the tourniquet to the movable stand using the optional accessory (AVR-ST001).

The movable stand has a basket where you can store the connecting hoses, cuffs and accessories.



### **Using the fixing brake**


- Disable the stabilization brake before moving the tourniquet device.
- Engage the stabilizing brake to prevent unintentional movements of the tourniquet device.

## **17. OPERATING THE APPLIANCE**

---

### **17.1. STARTING THE DEVICE**

The automatic tourniquet device is operational and is turned on and off from the On/Off button on the front

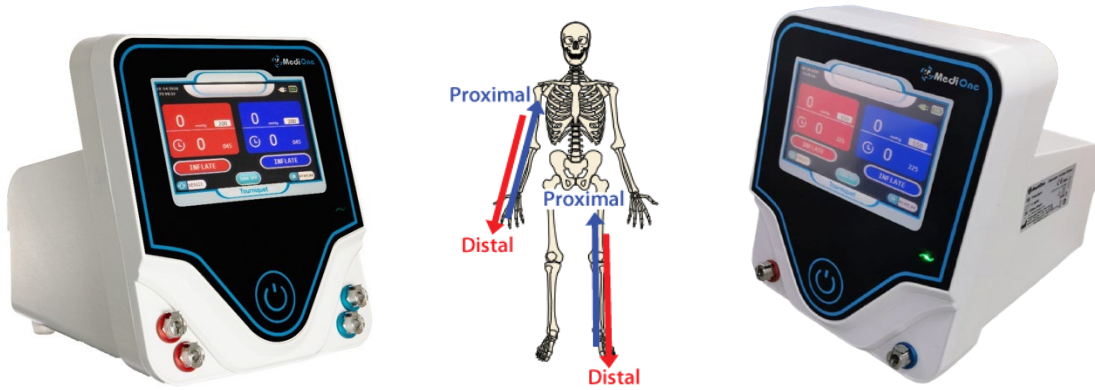
panel . On the start screen, the user is prompted to perform a system test. After the device has tested itself, it is ready for use after the SELF TEST (OK) screen.

### **17.2. Settings of the Tourniquet Device.**

#### **17.2.1. Presetting the pressure**



When selecting the pressure, take into account the information on the tourniquet cuff operating manual.



### Separation of the proximal and distal parts from each other by colors

The device is divided into two parts, PROXIMAL and DISTAL, in each section, TRQ-2024 has 4 outputs and TRQ-2022 has 2 outputs.

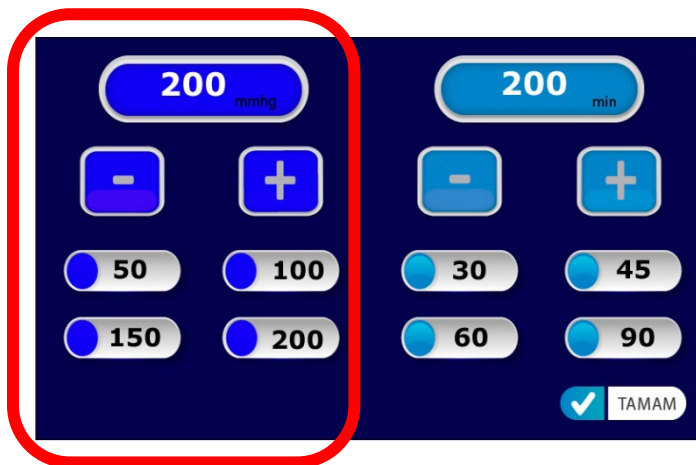
These circuits are completely separated. Pressure settings and timers are independent, the adjustment procedure is the same.

All keys colored in red will be used to make adjustments to the PROXIMAL part.

All keys colored in blue will be used to make adjustments to the DISTAL part.

#### 17.2.2. Changing the pressure (preoperatively)

The user can set the pressure parameter on the PROXIMAL or DISTAL portion.



It selects with the keys, sets the value in mm-Hg, and the set value appears on the PRESSURE screen as fixed on the display.

#### 17.2.3. Changing the pressure (during surgery)

During the surgery, the measured pressure is shown on the PRESSURE screen, and when the pressure is desired

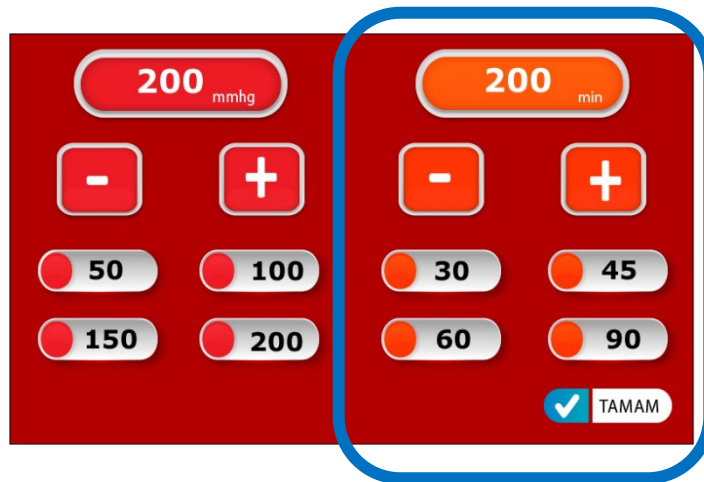


to be changed, the pressure can be increased or decreased by clicking on the relevant part and using the buttons. Changes will be saved automatically when OK is pressed.

In the 2-channel application, the pressure of each channel can be adjusted separately. In IVRA, the entered pressure values are always considered valid for both channels.

### 17.2.4. Setting the timer (pre-operative)

It is possible to set the timer to the default position separately for each circuit before surgery. This setting will be repeated automatically after surgery. Follow the steps below for this setting:





Time adjustment can be made via the PROXIMAL or DISTAL part pressure time setting menu with the buttons

at the bottom of the (min) screen   or with the times stored in the device memory.

#### Tourniquet time information


You can see the remaining and set time information along the entire tourniquet on the main screen.

The alarm will give a warning once before the end of the tourniquet period, the **time can be extended during**

the surgery with   the keys on the time setting screen of the relevant part.

#### Setting the alarm time.

The tourniquet device gives the user an audible alarm close to the end of the set time before the tourniquet

time expires, you  can increase or decrease the duration of this alarm by using the alarm button from the device settings menu. Your changes will be saved automatically with the return button.

#### Attaching the cuff

Insert the connectors at the end of the tourniquet cuff into the port to connect to the tourniquet cuff port.

For more information on the placement of the cuffs, refer to the tourniquet cuff instruction manual.



Example: Protective bandage



Example: Tourniquet cuff and protective bandage application

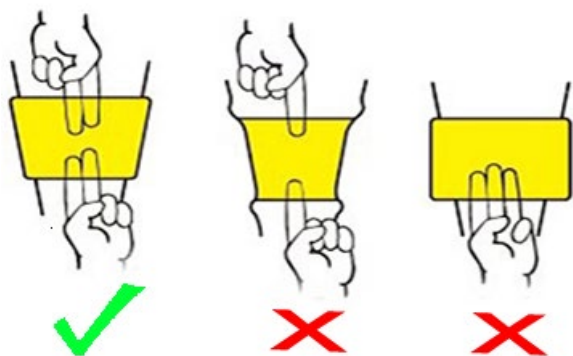


The Tourniquet Cuff should not be used without a protective bandage. Before application, it is recommended to wrap the tourniquet area with a protective bandage.

Apply the appropriate limb protection material with the limb in the area selected for the cuff, unless it is specifically recommended to use the selected cuff without limb protection. Make sure that the limb protection material and the skin under the cuff are not wrinkled. The protective bandage should be larger than the dimensions of the tourniquet cuff and cover the cuff wrapped around it.

In tourniquet applications, it is recommended to apply an esmark bandage to drain the blood from the limb.

High pressures applied to the skin and soft tissues under a tourniquet cuff can cause injuries to the skin and soft tissues. To reduce these injuries, studies have been published evaluating the relative effectiveness of no protective material, padding under the cuff, bandage located underneath, and lower extremity protective sheaths that fit specific limb sizes and cuff sizes. The study results provide evidence that extremity protection cuffs improve safety by protecting tourniquet cuffs of the bandage wrapped during tourniquet use, and also provided evidence that greatest safety is achieved by the use of limb protection cuffs that are specifically matched to the limb size and cuff size, and with a protective bandage.



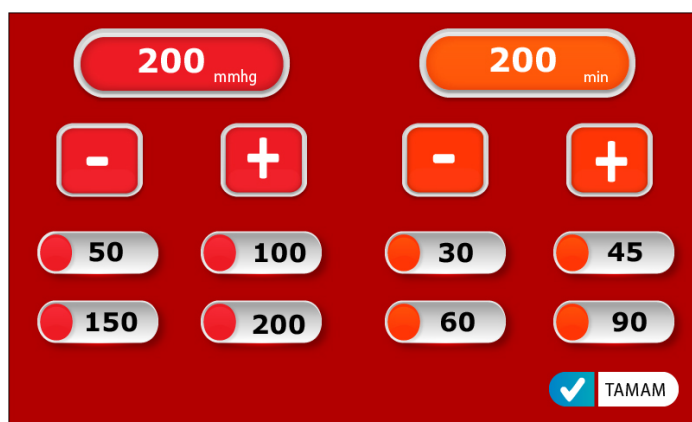
When you put two fingers under the inner part of the cuff (Proximal), make sure that the tourniquet cuff is filled with air and that there is a back pressure.

Check the cuff pressure at regular intervals during tourniquet application.

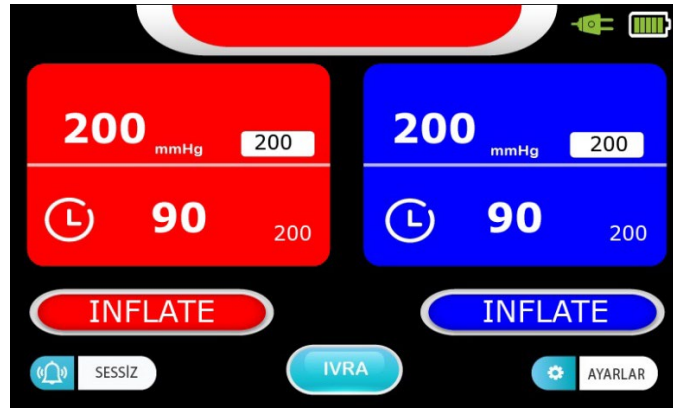
**Now you can start the tourniquet.**

### Starting the tourniquet

The pressure to be adjusted in PROXIMAL or DISTAL extremity is adjusted from the time and pressure screen over the appropriate channel. Device connections and patient connections are reviewed. After the information is entered on the setting screen, the information is saved with the OK button.



Pressure and Time Setting Display



Tourniquet Device Home Screen



The tourniquet is started with the

**INFLATE button** in the relevant section on the main screen.

With the information you will watch on the screen, the tourniquet pressure and the time counter being active, you will have a successful tourniquet start.



Forcibly turning a filled cuff can harm the patient.

Do not forcibly change (rotate) the position of a filled cuff.

## 18. Termination of the Tourniquet

Before the time of the entered tourniquet expires, the device gives a warning alarm, writes **PROXIMAL DEFLATE or DISTAL DEFLATE for the finished part**, and after the alarm sound, decide together with the responsible physician whether the tourniquet should be continued or terminated.

When the DEFLATE button in the relevant part of the device is pressed 1 time on the device



, the relevant part will be DEFLATE, you can terminate the tourniquet by pressing the DEFLATE button again. The tourniquet can be terminated before the end of the time period set for the tourniquet.



### Repetition of tourniquet application

If the cuff needs to be re-inflated in the same patient, the application can be restarted at any time

## 19. Closing the tourniquet

In order to turn off the tourniquet device, the device will give a closing warning sound by pressing the "On/Off" button for 2 seconds while the operation is terminated on the main screen of the device, and then the tourniquet device is safely closed. (You have to perform critical operations by pressing the keys twice to avoid accidentally pressing the keys on the device.)

## 20. IVRA

Regional Intravenous Anesthesia (IVRA) is a regional anesthesia application and is mostly used during short-term surgeries on the extremities.

In Regional Intravenous Anesthesia, the extremity to be operated on is first drained and ligated. Then, a local drug is injected into the veins to prevent the spread of pain in the ligated limb.

### Using Ivra Mode

After plugging in the power cord, turn on the device by pressing the ON / OFF switch.



The system is activated by pressing the button on the device. When the system is activated, the pressure and time display on the device will work the same. After the necessary time and pressure adjustments are made, the operation can be performed safely with the double tourniquet cuff.

- **Applying skin protection to the skin covering the limb**

Applying skin protection to the skin covering the limb

- **Interruption of blood flow to the limb**

Cut off the blood supply to the extremity with an Esmarch bandage

- **Attaching the connection hose to the automatic tourniquet**

Ensure that the connection hose of the proximal cuff is attached to the left port (red area) and the connection hose of the distal cuff is attached to the right port (blue area), and make sure the hose is not folded or twisted to ensure the pressure is transmitted to the cuff without any issues.

- **Setting the point to be pressurized**

Make pressure and time adjustments following the procedure set out in Section 17.2.2. Fill the proximal sac with air pressure.

- **Anesthetic injection and after its effect**

Inflate the distal sac so that the tourniquet cuff presses on the area above the anesthesia

- **Venting the upper pouch of the cuff**

By pressing the "Deflate" button of the relevant pressure circuit, the air of the upper sac (Proximal) is evacuated.

- **Venting the lower pouch of the cuff**

After the intervention, evacuate the air from the distal sac by pressing the "Deflate" button, disconnect the cuff from the tourniquet and turn off the device by pressing the ON/OFF button.



For this, use accessories suitable for IVRA applications (Double cuff)



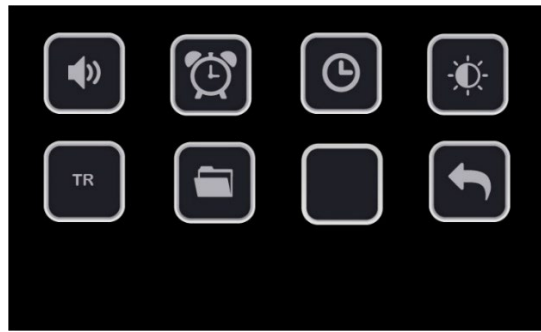
Double Tourniquet Cuff



Tourniquet users should be aware of the safe inflation-deflation sequence when using a dual chamber cuff or when using two single-chamber cuffs together. If the wrong chamber or cuff is accidentally released, it can be dangerous for the patient. Never leave the patient unattended for any reason during intermittent deflation.


### Removal of the tourniquet device from the surgery

1. Turn off the tourniquet device. Remove all accessory parts.
2. For mains mode: Remove the mains plug, wrap the power cord and store it with the accessories of the appliance.
3. In case of long-term transportation or inactivity: Remove the battery protection. (See chapter 14, p. 17.)
4. Store the tourniquet device in accordance with the shipping and storage conditions.



Settings Menu

**Volume Adjustment.**


The volume adjustment key is  pressed by entering the settings menu via the settings button on the LCD screen.



In the volume adjustment menu, the volume level is specified as 4 levels. The device volume can be adjusted using the up and down buttons. The volume will be audibly heard when the up and down keys are pressed. You just need to return to the main menu with the back key so that the settings are automatically saved.

**Alarm setting.**

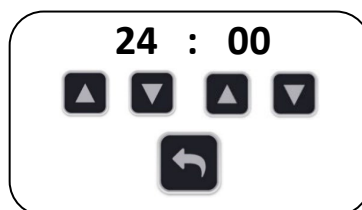
The tourniquet device gives the user an audible alarm close to the end of the set time before the tourniquet

time expires, you  can increase or decrease the duration of this alarm by using the alarm button from the device settings menu. Your changes will be saved automatically with the return button.

**Clock Date Setting.**



Date Setting: Day/Month/Year



Time Setting: Hours:Minutes

### Screen Brightness Adjustment.

The screen brightness setting of the device can be adjusted to 8 steps. When the button is pressed on the settings menu, the screen brightness ratio can be adjusted as desired. Screen vision in dark and bright environments will be easier thanks to this setting.



Screen Brightness Adjustment

### Language Setting.

The device language can be changed to TURKISH and ENGLISH with the option to change the language through the device settings menu.



When the current key is pressed, the language can be selected as TR (Turkish) and EN (English). The settings will be saved automatically.

### Alarm Log.

The device can record the current alarm information in its historical memory.

Alarm information consists of alarm error code date and time information. The last 20 error codes can be seen on the screen. By pressing the Alarm log button on the settings menu, the error codes given by the retrospective tourniquet device will be seen on the screen retrospectively. (Error Code Section 21.)



## 22. Troubleshooting

### Detection of faults

If a deviation from standard device operation is noticed, an error code is shown on the LCD display.


### Mistake

If a malfunction occurs and the message is not displayed, **then there is** an error in the device.

The errors are described below

### Alarm sound

Depending on the priority of the error and the message, a visual and audible **alarm** sounds.

All alarm sounds  can be temporarily turned off using the button (120 seconds.), and at the end of the period, the device will alarm again because it is necessary to intervene at the source of the fault.

## Troubleshooting

### Notification category

Error Code:	Reason:	Solution:
<b>Self-test fault group</b>		
E1	Battery failure	The device will give an error because the battery level is at a critical level. <ol style="list-style-type: none"><li>1. Turn the power switch on the back of the device to position 1 and allow it to charge for at least 1 hour.</li><li>2. In case of recurrence of the malfunction, contact the technical service. Request a replacement of the battery.</li></ol>
E2	Leakage Proximal part	<ol style="list-style-type: none"><li>1. Make sure that the tourniquet cuff on the proximal part is not attached.</li><li>2. Turn off the tourniquet device and turn it on again</li><li>3. If the device repeatedly displays the same safety message, contact your dealer.</li></ol>

E3	Leakage Distal part	<ol style="list-style-type: none"> <li>1. Make sure that the tourniquet cuff on the distal part is not attached.</li> <li>2. Turn off the tourniquet device and turn it on again</li> <li>3. If the device repeatedly displays the same safety message, contact your dealer.</li> </ol>
E4	Drain valve defective Proximal	<ol style="list-style-type: none"> <li>1. Make sure that the tourniquet cuff on the proximal part is not attached.</li> <li>2. Turn off the tourniquet device and turn it on again</li> <li>3. If the device repeatedly displays the same safety message, contact your dealer.</li> </ol>
E5	Distal drain valve defective	<ol style="list-style-type: none"> <li>1. Make sure that the tourniquet cuff on the distal part is not attached.</li> <li>2. Turn off the tourniquet device and turn it on again</li> <li>3. If the device repeatedly displays the same safety message, contact your dealer.</li> </ol>
E10	Motor fail, motor defective or not plugged in	<p>During the self-test, it was found that the compressor was not working correctly.</p> <ol style="list-style-type: none"> <li>1. Turn off the tourniquet device with the On/Off button.</li> <li>2. Unplug the tourniquet device from the power supply.</li> <li>3. Wait 10 seconds and plug the mains plug back in.</li> <li>4. Reopen the tourniquet device with the On/Off button.</li> </ol> <p>If the security message appears again: Turn off the tourniquet device and turn it back on. If the security message is still displayed: Contact your authorized service center.</p>
E14	Proximal part high pressure alarm	<p>During the self-test There is a malfunction in the tourniquet device. The pressure in the air tank is too high and cannot be reduced by the tourniquet device.</p> <ol style="list-style-type: none"> <li>1. Visually check the pressure on the screen.</li> <li>2. Check the error code</li> <li>3. Turn off the tourniquet device.</li> <li>4. Turn the device back on after 5 minutes, and if the same malfunction persists, contact the authorized service.</li> </ol>
E15	Distal part high pressure alarm	<p>During the self-test There is a malfunction in the tourniquet device. The pressure in the air tank is too high and cannot be reduced by the tourniquet device.</p> <ol style="list-style-type: none"> <li>1. Visually check the pressure on the screen.</li> <li>2. Check the error code</li> <li>3. Turn off the tourniquet device.</li> <li>4. Turn the device back on after 5 minutes, and if the same malfunction persists, contact the authorized service.</li> </ol>
<b>Error codes in operation</b>		
E6	The cuff is not connected leakage Proximal	<ol style="list-style-type: none"> <li>1. Make sure the cuff/hose is plugged into the correct port.</li> <li>2. Make sure the cuffs and hoses are seated correctly at the connection points.</li> <li>3. Make sure that the cuff is not too loosely attached to the patient's limb. Change the cuff size if necessary.</li> <li>4. Turn off the security message with the "Mute the alarm" button.</li> </ol> <p>The tourniquet can be restarted immediately. If the security message is still displayed: Contact your authorized service center.</p>
E7	The cuff is not connected to the leakage Distal	<ol style="list-style-type: none"> <li>1. Make sure the cuff and hose are plugged into the correct port.</li> <li>2. Make sure the cuffs and hoses are seated correctly at the connection points.</li> <li>3. Make sure that the cuff is not too loosely attached to the patient's limb. Change the cuff size if necessary.</li> <li>4. Turn off the security message with the "Mute the alarm" button.</li> </ol> <p>The tourniquet can be restarted immediately. If the security message is still displayed: Contact your authorized service center.</p>

E8	Drain valve defective or clogged Proximal	<ol style="list-style-type: none"> <li>1. Make sure the cuff and hose are plugged into the correct port.</li> <li>2. Make sure the cuffs and hoses are seated correctly at the connection points.</li> <li>3. Make sure that the cuff is not too loosely attached to the patient's limb. Change the cuff size if necessary.</li> <li>4. Turn off the security message with the "Mute the alarm" button.</li> </ol> <p>The tourniquet can be restarted immediately.</p> <p>If the security message is still displayed: Contact your authorized service center.</p>
E9	Distal drain valve defective or clogged	<ol style="list-style-type: none"> <li>1. Make sure the cuff and hose are plugged into the correct port.</li> <li>2. Make sure the cuffs and hoses are seated correctly at the connection points.</li> <li>3. Make sure that the cuff is not too loosely attached to the patient's limb. Change the cuff size if necessary.</li> <li>4. Turn off the security message with the "Mute the alarm" button.</li> </ol> <p>The tourniquet can be restarted immediately.</p> <p>If the security message is still displayed: Contact your authorized service center.</p>
E11	The battery is almost empty	<ol style="list-style-type: none"> <li>1. Connect the tourniquet device to the power supply.</li> <li>2. Wait for the battery to charge on the device test screen, then perform the self-test process.</li> <li>3. If the device cannot be used without being connected to the power source with this error code, turn off the device.</li> </ol>
E12	Very High Cuff Pressure Proximal	<p>There is a malfunction in the tourniquet device. The pressure in the cuff is too high and cannot be reduced by the tourniquet device. The valves are closed and the cuff pressure is kept constant.</p> <ol style="list-style-type: none"> <li>1. Visually check the actual pressure on the cuff.</li> <li>2. Terminate the tourniquet and turn off the tourniquet device.</li> </ol>
E13	Very High Cuff Pressure Distal	<p>There is a malfunction in the tourniquet device. The pressure in the cuff is too high and cannot be reduced by the tourniquet device. The valves are closed and the cuff pressure is kept constant.</p> <ol style="list-style-type: none"> <li>1. Visually check the actual pressure on the cuff.</li> <li>2. Terminate the tourniquet and turn off the tourniquet device.</li> </ol>

## 23. Technical information/Parameter

Technical Specifications		
Model	TRQ-2024	TRQ-2022
Power voltage / Power frequency	100–240 V / 50–60 Hz / 30 VA	100–240 V / 50–60 Hz / 30 VA
Minimum / maximum cuff pressure	20 mmHg / 650 mmHg	20 mmHg / 650 mmHg
Class of the applied part	Type BF	Type BF
Product class according to the Medical Device Regulation	Class IIa	Class IIa
Protection class	IP20	IP20
Electrical protection class	Class I	Class I
Sensitivity	±5 mmHg	±5 mmHg
Dimension	275 x 235 x 268 (H x W x D, in mm)	275 x 235 x 268 (H x W x D, in mm)
Weight	3,650 grams	3,650 grams
Screen	7 inch Touch LCD Screen	7 inch Touch LCD Screen
Microprocessor	Yes, (Central Processing Unit)	Yes, (Central Processing Unit)
Software class	Class A	Class A
Insurance	Mains power: F1,F2: 2 A 250 V Battery: F3: 2 A Breaking capacity 2 A	Mains power: F1,F2: 2 A 250 V Battery: F3: 2 A Breaking capacity 2 A

		Type: Fused connection 5 m x 20 mm	Type: Fused connection 5 mm x 20 mm
Built-in power Supply		14.4V, 5.8Ah Lithium Ion Rechargeable Battery	14.4V, 5.8Ah Lithium Ion Rechargeable Battery
Nominal compressor values		12 V, max. 1.5 bar	12 V, max. 1.5 bar
Pneumatic Outlet Connector		4 pcs.	2 pcs.
<b>Temperature range</b>		<b>Moisture</b>	
Usage environment	+15 °C / +40 °C	Usage environment	5% / 90%, non-condensing
Storage/Shipping	-10 °C / +70 °C	Storage/Shipping	5% / 90%, non-condensing
<b>Air pressure</b>			
Usage Environment		50 KPa–106 KPa	
Storage/Shipping		50 KPa–106 KPa	

## 24. Accessories List

Tourniquet device trolley is optional.

The power cord comes out of the box. It can be resupplied as desired.

Cuffs and hoses come out of the box 4 pieces (AVR-CUFF-S012/S018/S030/AVR-CUFF-2XD20, others are offered as an option.

All accessories are available from the manufacturer with labels and packages.



Item Number	Explanation
<b>Reusable Single Hose Cuffs</b>	
AVR-CUFF S008	8" Reusable Kids Cuff 8"L x 2"W Single chamber Single hose
AVR-CUFF S012	12" Reusable Kids Cuff 12"L x 3"W Single chamber Single hose
AVR-CUFF S015	15" Reusable Kids Cuff Long 15"L x 4"W Single chamber Single hose
AVR-CUFF S018	18" Reusable standard Cuff 18"L x 4"W Single chamber Single hose
AVR-CUFF S024	24" Reusable Standard Leg 24"L x 4"W Single chamber Single hose
AVR-CUFF S030	30" Reusable Medium size Leg 30"L x 5"W Single chamber Single hose
AVR-CUFF S034	34" Reusable Long size Leg 34"L x 5"W Single chamber Single hose
AVR-CUFF S038	38" Reusable Long size Leg 38"L x 5"W Single chamber Single hose
AVR-CUFF S042	42" Reusable Extra long Leg 42"L x 6"W Single chamber Single hose
AVR-CUFF S044	44" Reusable Extra long Leg 44"L x 6"W Single chamber Single hose
<b>Reusable Double Hose Cuffs</b>	
AVR-CUFF D008	8" Reusable Kids Cuff 8"L x 2"W Single chamber Double hose
AVR-CUFF D012	12" Reusable Kids Cuff 12"L x 3"W Single chamber Double hose

AVR-CUFF D015	15" Reusable Kids Cuff Long 15"L x 4" Single Chamber Double Hose
AVR-CUFF D018	18" Reusable standard Cuff 18"L x 4"W Single chamber Double hose
AVR-CUFF D024	24" Reusable Standard Leg 24"L x 4"W Single chamber Double hose
AVR-CUFF D030	30" Reusable Medium size Leg 30"L x 4"W Single chamber Double hose
AVR-CUFF D034	34" Reusable Long size Leg 34"L x 4"W Single chamber Double hose
AVR-CUFF D042	42" Reusable Extra long Leg 42"L x 4"W Single chamber Double hose
<b>Reusable Dual chamber Double Hose IVRA Cuff</b>	
AVR-CUFF 2XD014	14" Reusable bier block cuff short 14"L x 4"W Double chamber Double hose
AVR-CUFF 2XD020	20" Reusable bier block medium 20"L x 6"W Dual chamber Double hose
AVR-CUFF 2XD26	26" Reusable bier block long 26"L x 6"W Dual chamber Double hose
<b>ACCESSORY</b>	
AVR-H003	Connection hose 3m
AVR-P220	Power Cord
AVR-ST001 & TRQ-75	Tourniquet device trolley (Optional)

## **25. Electromagnetic Compatibility (EMC) Statement**

This device generates, uses, and radiates radio frequency (RF) energy. If not installed and used in accordance with the instructions in the manual, it may cause electromagnetic interference.

This device has been tested and determined to comply with the limits for medical products in accordance with the EN-60601-1-2:2015 standard. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation when the device is used according to the instructions in the manual.

This device can be affected by portable and mobile RF communication devices. This device should not be stored or used together with other equipment.

For more information about this device and EMC, please refer to the tables below


<b>Guide and Manufacturer's Declaration - Electromagnetic Emissions</b>		
This device is designed for use in the electromagnetic environment specified below. The customer or user of this device should ensure that it is used in such an environment.		
Emission Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	This device uses RF energy only for its internal function. Therefore, RF emissions are very low and are not expected to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class B	This device 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	

<b>Guide and Manufacturer's Declaration - Electromagnetic Immunity</b>			
This device is designed for use in the electromagnetic environment specified below. The customer or user of this device should ensure 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	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 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 ± 1 kV for input/output lines Repetition frequency 100 kHz	± 2 kV for power supply lines ± 1 kV for input/output lines Repetition frequency 100 kHz	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV line(s) to line(s) ± 0.5 kV, ± 1 kV, ± 2 kV line(s) to earth	± 0.5 kV, ± 1 kV line(s) to line(s) ± 0.5 kV, ± 1 kV, ± 2 kV line(s) to earth	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	0% $U_T$ ; 0.5 cycle 0°, 45°, 90°, 135°, 180°, 225° 270° and 315° 0% $U_T$ ; 1 cycle 70% $U_T$ ; 25/30 cycles 0% $U_T$ ; 250/300 cycles	0% $U_T$ ; 0.5 cycle 0°, 45°, 90°, 135°, 180°, 225° 270° and 315° 0% $U_T$ ; 1 cycle 70% $U_T$ ; 25/30 cycles 0% $U_T$ ; 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50/60 Hz	30 A/m 50/60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
<b>Note:</b> $U_T$ is the AC mains voltage prior to application of the test level.			

**Guide and Manufacturer's Declaration - Electromagnetic Immunity**

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	150 kHz to 80 MHz 3 Vrms 6 Vrms (in ISM and amateur radio bands)  80% AM at 1 kHz	150 kHz to 80 MHz 3 Vrms 6 Vrms (in IS and amateur radio bands)  80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of this device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  <b>Recommendations for separation distance:</b> $d = 0.35\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 1.2\sqrt{P}$ 800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$ 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 meters (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 following symbol: 
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz 80% AM at 1 kHz	10 V/m 80 MHz to 2.5 GHz 80% AM at 1 kHz	

**Note 1:** At 80 MHz and 800 MHz, 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

- 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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.
- b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
- c. Immunity requirements for devices containing components susceptible to magnetic interference.
- d. Separation distances for transmitters specified to be used near the device should be determined based on the frequency and output power of the transmitter.

**Recommended Separation Distances Between Portable and Mobile RF Communication Equipment and This Device**

This device is intended for use in an electromagnetic environment where RF interference can be controlled. To protect against electromagnetic interference, the owner or user of this device should maintain a minimum distance from portable and mobile RF communication equipment (transmitters) as specified below, according to the maximum output power of the communication equipment.

Rated Maximum Output Power of Transmitter (W)	Separation Distance Based on Frequency of Transmitter (m)			
	150 kHz to 80 MHz (Outside ISM and Amateur Radio Bands) <b>d=1.2√P</b>	150 kHz to 80 MHz (Inside ISM and Amateur Radio Bands) <b>d=0.6√P</b>	80 MHz to 800 MHz <b>d=1.2√P</b>	800 MHz to 2.7 GHz <b>d=2.3√P</b>
0.01	0.12	0.06	0.12	0.23
0.1	0.38	0.19	0.38	0.73
1	1.2	0.6	1.2	2.3
10	3.8	1.9	3.8	7.3

100	12	6	12	23
<p>The above table may be used to calculate the recommended separation distance in meters (m) for transmitters with a rated maximum output power not listed above using the applicable equation based on the frequency of the transmitter, where PPP is the maximum output power rating of the transmitter in watts (W) as given by the transmitter manufacturer.</p> <p><b>Note 1:</b> For frequencies between 80 MHz and 800 MHz, a higher frequency range is applicable.</p> <p><b>Note 2:</b> The ISM (industrial, scientific, and medical) frequency bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio frequency bands between 150 kHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz, and 50.0 MHz to 54.0 MHz.</p> <p><b>Note 3:</b> The guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p>				

Manufacturer Declaration - Electromagnetic Immunity							
This device is designed to be used in the electromagnetic environment specified below. The user of this device should ensure that it is used in such an environment.							
IEC 61000-4-3 RF Wireless Communication Equipment Immunity Test Specifications	Test Frequency (MHz)	Band (MHz)	Service a)	Modulation b)	Modulation Power (W)	Distance (m)	Immunity Test Level (V/m)
	385	380-90	TETRA 400	Pulse Modulation b) 18 Hz	1.8	0.3	27
	450	380-390	GMRS 460, FRS 460	FM c) ±5 kHz deviation 1 kHz Sine	2	0.3	28
	710	704-787	LTE Band 13, 17	Pulse Modulation b) 217 Hz	0.2	0.3	9
	745						
	780						
	810	800-960	GSM 800/900, TETRA 800, iDEN 820, LTE Band 5	Pulse Modulation b) 18 Hz	2	0.3	28
	870						
	930						
	1720	1700-1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Bands 1, 3, 4, 25, UMTS	Pulse Modulation b) 217 Hz	2	0.3	28
	1845						
	1970						
	2450	2400-2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation b) 217 Hz	2	0.3	28
	5240	5100-5800	WLAN 802.11 a/n	Pulse Modulation b) 217 Hz	0.2	0.3	9
5240							
5785							
<p><b>Note:</b> IMMUNITY TEST LEVEL: If the necessary test level is to be reached, the distance between the transmitter antenna and the medical device or equipment should be reduced to 1 meter. According to IEC 61000-4-3, a test distance of 1 meter is allowed.</p> <p>a. Some services have only the transmission frequencies included. b. Carrier signal; 50% duty cycle square wave signal is modulated. c. FM modulation is an alternative to 18 Hz pulse modulation with 50% duty cycle, as it represents the worst-case scenario.</p> <p>MANUFACTURER, RISK MANAGEMENT NOTE: To reduce the separation distance, higher IMMUNITY TEST LEVELS should be used. To calculate the recommended separation distances using higher IMMUNITY TEST LEVELS, the equation below should be used: <math>E=6/d\sqrt{P}</math>. 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 meters (m). The immunity level is represented in volts per meter (V/m).</p>							



**Disposal:** The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment.

**GIMA WARRANTY TERMS**

The Gima 12-month standard B2B warranty applies