PROFESSIONAL MEDICAL PRODUCTS

AUTOMATIC TOURNIQUET DEVICE

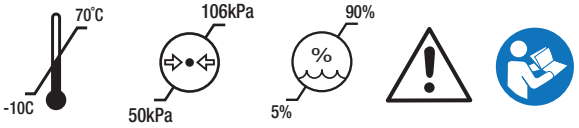
User manual

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

Gima 33108

Avrasyamed Mediikal Tıbbii Ciihazlar Ve Ürünler Pazarlama
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CE 1984



REF **TRQ-2020**

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

CE
1984

Manufacturer:

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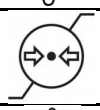
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1. General Information

1.1. Used Symbols

Symbol/Description	Definitions
	Follow instructions for use
 F1,F2:2A T; 250 V	Fuse
	Protective earth ground
	Manufacturer
	Date of Manufacture
REF	Product code
LOT	Lot number
SN	Serial number
CE 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.
IP20	Covering Protection rate
	WEEE disposal
~AC	Alternating current
Hz	Hertz
VA	Volt-Amper
IVRA	Intravenous Regional Anesthesia
	Class II applied
	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 B applied part**
	**Medical Device**
	**Imported by**
	**Warning** -It is given when special instructions must be followed. Disregarding this information could result in permanent damage being caused to the tourniquet or injury in patients or other persons.

1.2. About this document

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

Read the user manual before using the product.

Always keep the user manual near the product or in an easily accessible place for access.

User manual is translated according to the language of the country of export by sworn translation offices that are experts in labels and user manuals.

1.3. Applicability

The user manual is valid only for TRQ-2020.

2. Intended Use

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

The device is designed for continuous use. Adjustable

pressure ranges from 20 to 650 mmHg.

Medione TRQ-2020 Tourniquet Device is used for following surgery operations:

- The leg – arm fractures
- Implant insertion and removal for upper /lower extremities
- Finger, wrist, knee, elbow joint replacements
- Leg and arm implant insertion and removal
- Tendon modification
- Arthroscopic Surgery
- Carpal Tunnnel Syndrome
- Mallet Finger therapy
- Amputations
- Varicosity surgery
- Tumor excisions
- Cyst excisions

2.1. Contraindications

An automatic tourniquet device should also be avoided in patients who have the following cases:

- At location having swollen, infected or inflamed areas
- At location having malignant tumors
- Severe crushing injuries
- Severe arteriosclerosis
- Severe hypertension
- Thrombosis
- Open fractures on the extremities
- At location having dermal implants recently
- Severe brain injury
- Neuromuscular injuries
- Compromised vascular circulation, e.g., peripheral artery disease
- The presence of sickle cell disease
- Diabetes mellitus



In all cases, the final decision whether to use a tourniquet rest with the attending physician.

2.2. Adverse Effects / Possible Complications

- Hyperemia with risk of bleeding
- Muscle edema
- Paralysis
- Irregularity in acid-base balance
- Accumulated metabolites causing shock as a result of sudden restoration of blood flow
- Injury of nerves (especially peroneal or ulnar nerve)

3. Patient and User Profile

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

The product can be applicable to adult and child patients.

4. For Your Safety

Medione tourniquet devices should only be used by trained personnel in accordance with the information in this user manual.

For safe use of the tourniquet device, please consider the warnings and safety information in this manual.

4.1. Warnings and Safety Information

4.1.1 User Manual for Accessories



Misuse of accessories may cause harm on the patient and / or the tourniquet device..

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

4.1.2. Using the Tourniquet Device in Explosion Hazard Environments

WARNING! Using the tourniquet device and all accessories in environments where there is a danger of

explosion or flammable anesthesia agents or cleaning materials may cause serious injuries to patients / user and damage to the tourniquet device.

Use the Medione Tourniquet device and all accessories only in environments where there are no explosion hazard or flammable anesthetic agents or disinfectants.

4.1.3. Safety Inspection After 2-years Usage

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

4.1.4. User Training

The tourniquet device should be used in accordance with the required instructions in the user manual. The user can request training from Avrasyamed Medikal or people authorized by the manufacturer.

User manual information and user regulations after training will be valid. All national regulations regarding the installation, training, documentation and use of a medical device should be followed.

4.1.5. Maintenance and Repair of Tourniquet Device

Repairing this device 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.
- During device maintenance, 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 with the pressure measured can be made with suitable calibrators.
- It is recommended to perform device maintenance and calibrations once a year.
- The user should avoid tampering with the device.

5. Medical Device Directive and Notified Body

The device meets all requirements of 93/42/EEC Medical Device Directive. Class II a
Notified Body: Kiwa Certification Services Inc. Notified Body ID No: 1984

6. Storage and Transport Condition Before Use

Do not leave the package outside, avoid mechanical shaking.

Storage and transport conditions: Temperature; -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, avoid dropping it.

7. General Warnings

Any modification on the device could damage the patient or the device. Please never modify the device.

To avoid the risk of electric shock, the tourniquet device should be connected to only a protective grounded power source.

The device should be used only in the environment with the required conditions in this manual.

The device should be connected to the power source with a 3 m. Grounded power cord to avoid the risk of electric shock. An extension cable should not be used.

To protect the patient from electric shock, do not use the medical device right next to the patient (distance should not be less than 2 meters).

The device must be plugged in during the use of the device, the battery will only be activated in case of power failure for safety purposes. Also, if there is any suspicion of grounding in the system, a battery should be used in the installation.

The automatic tourniquet device and especially the electrical connection must be protected from water and moisture. If water is spilled on the device, never operate the device. Disconnect it from power and get support from your authorized after sales service.

Do not touch the front panel of the device with metal or sharp objects, it may cause damage. Do not pull-

on AC power cords or Pneumatic extensions.

The device should not be moved while the power cable is connected.

Make sure that the power cables are far enough away from the patient against the risk of strangulation.

Do not push the stand while the device is located on it against the risk of falling, there is a handle on the top for the safety of the device in such push / pull maneuvers. Please push/pull the standby holding the handle of the device.

The trolley wheels should be locked during operation.

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

The connector slot acts like a jumper. Therefore, it should always be accessible to disconnect in case of danger.

Always use a grounded socket to minimize electromagnetic and other interference.

The purpose of grounding is to reduce the generation of radio frequency voltages that can cause electromagnetic interference. Another measure that can be taken is filtration. Filters can be designed to prevent electromagnetic interference through conductors. In this direction, a special filter circuit can be applied to each circuit. In the device this measure has been taken using the power filter.

7.1. Cleaning and Disinfection

Before cleaning and disinfecting, unplug the power cord of the device, wipe the device surface and accessories with a suitable disinfectant.

In severe contamination, wipe with a damp cloth for 5-15 minutes depending on the desired antimicrobial effect. There are no restrictions in this application. No need to rinse.

There is a risk of short circuits and electric shock when using large amounts of water, cleaning agents, or disinfectants.

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

Do not spray disinfectants directly on the device. Automatic tourniquet devices and accessories must be dry before use.

7.1.1. Recommended Cleaning Agent

Alcohol-based disinfectants and cleaning agents can be used.

7.2. Safety of User & Patient

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 the started surgery is completed safely. If a malfunction occurs, the tourniquet device gives an audible and visual warning. Take immediate action to resolve the issue as surgical personnel responsible. In case of a malfunction in the battery, the tourniquet device can also be operated with AC power. However, it is recommended to change the battery as soon as possible to always ensure maximum safety and the tourniquet device is in good condition.

Before starting the application, make sure that your tourniquet device and accessories are in good

condition.

Make sure that the accessories to be used are compatible with the automatic tourniquet device, it is strictly forbidden to use a cuff with incompatible connectors and change connectors.

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

As a precaution, check whether the medical device works properly by connecting the cuff as stated below.

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

Display the set pressure level on the screen, e.g. 300 mmHg.

The duration and amount of pressure applied is under the physician's responsibility and is based on available knowledge from research and technology.

Too high pressure and too long a tourniquet application may harm the patient.

Apply the minimum required pressure to create a safe tourniquet on application field.

7.2.2. Children and Tourniquet

For you to control the tourniquet time during the operation, the elapsed or remaining time until the end of the countdown / forward count entered is displayed on the screen. After the countdown / forward count is over, the device will alert you audibly and you will have the opportunity to set the time again.

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

8. Explanation of Tourniquet Device

Automatic tourniquets are used on the lower and upper extremities during surgical procedures. Device; It consists of an On / Off button, the membrane keypad where pressure, time and visual alarms are displayed and settings are made, and the LED screen showing the status screens, the cuff connection connector, the carrying handle and the device case.

Power Source

The tourniquet device is supplied with 100-220V AC voltage and can be operated using the power supply unit or internally powered battery.

Self-test

Every time the tourniquet device is operated, it performs a self-test. This first system check ensures safe operation and function check of all important components. Thus, you will always be working with a safe tourniquet device. Before starting the self-test, the device cuff connections should be left open.
Connection hoses and couplings must not be attached! If the test is successful, the device is ready for use. If the test fails, an error code will appear on the screen.

Troubleshooting

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

If a malfunction occurs, a visual warning is given on the tourniquet device screen and the error code appears on the screen.

For more information. Chapter 21, p. 24

9. Front Panel



Icon No	Function
1	Proximal Pressure Display Screen
2	Proximal Pressure Adjust Button (+/-) ⇧⇩ mm-Hg
3	Proximal Time Counter Screen
4	Proximal Time Adjust Button (+/-) ⇧⇩
5	Proximal -Inflate/Deflate Button
6	Proximal Tourniquet Cuff Connecting Socket
7	Distal Pressure Display Screen
8	Distal Pressure Adjust Button (+/-) ⇧⇧ mm-Hg
9	Distal Time Counter Screen
10	Distal Time Adjust Button (+/-) ⇧⇩
11	Distal Inflate/Deflate Button
12	Distal Tourniquet Cuff Connecting Socket

Medione tourniquet device has two connection sockets to use two cuffs. With this device, you can apply a tourniquet on to two extremities at the same time in different ways as follows.:

2 X Upper Extremities 2

X Lower Extremities

Upper and Lower Extremity

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

Operating for single channel:

Left (Proximal) connection socket (channel) is always used for arm and **right (Distal) connection socket** (channel) is always used for leg.

To use tourniquet connection channels correctly.

To the left, left channel: red (Proximal) connection - arm To

the right, right channel: blue (Distal) link – leg

When using both channels:

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

9.1. Color Coded Connections for IVRA Application

With the 2-channel tourniquet device, tourniquet connections are color coded to make IVRA application easier.

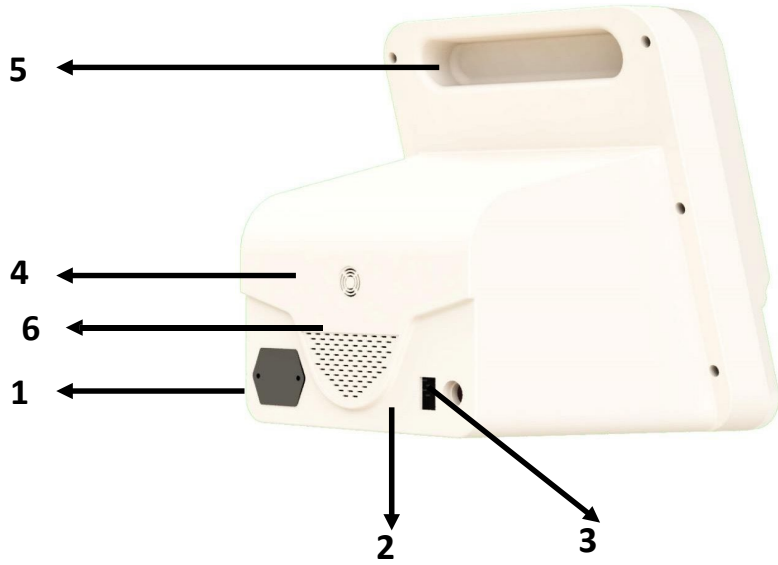
When using a double chamber cuff for an IVRA application, connect the distal and Proximal cuff chambers as described below.:

Left connection point is red and shows Proximal cuff chamber. Right

connection point is blue and indicates the Distal cuff chamber.

Red and blue colors display error codes on the corresponding display. Thus, you can quickly detect a possible malfunction in which channel.

10. Back Panel



1 Power socket 100-240V
2 On/Off Button
3 Battery fuse 2A
4 Speaker
5 Handle
6.Fan

Buttons and icons	Functions
	On/off button (2 s)
	Regional Intravenous Anesthesia (IVRA) selection
	Battery charge status (information in percentage is displayed on the Proximal time screen)
	Alarm limits (alarm time limit e.g. Warn 5 minutes before)
	Timer (count down or count up)
	Volume limit setting (8 levels)
	Alarm silence reset
	Charge indicator
	AC indicator
	Visual alarm line (Critical Alarms will alert by flashing on the line on the keypad.)
	Proximal part DEFLATE (Stops the tourniquet application)
	Proximal part INFLATE (Starts tourniquet)
	Distal part DEFLATE (Stops tourniquet)

	**Distal part INFLATE (Starts tourniquet)**
	**Proximal Display**
	**Distal Display**
	**Cuff connection socket (2)**

12. Power Source

The tourniquet device can be supplied with voltage and can be operated using the power supply or internally powered battery. The manufacturer recommends that the power supply is always used to operate the Medione Automatic Tourniquet Device. In case of a malfunction in the battery, the tourniquet device can be operated with a power supply.

The safe operation of the battery will be checked only when the device is operated under AC mode.

13. AC Mode

Under AC mode, please pay attention to the following information! Automatically

switch to battery mode at power failure.

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

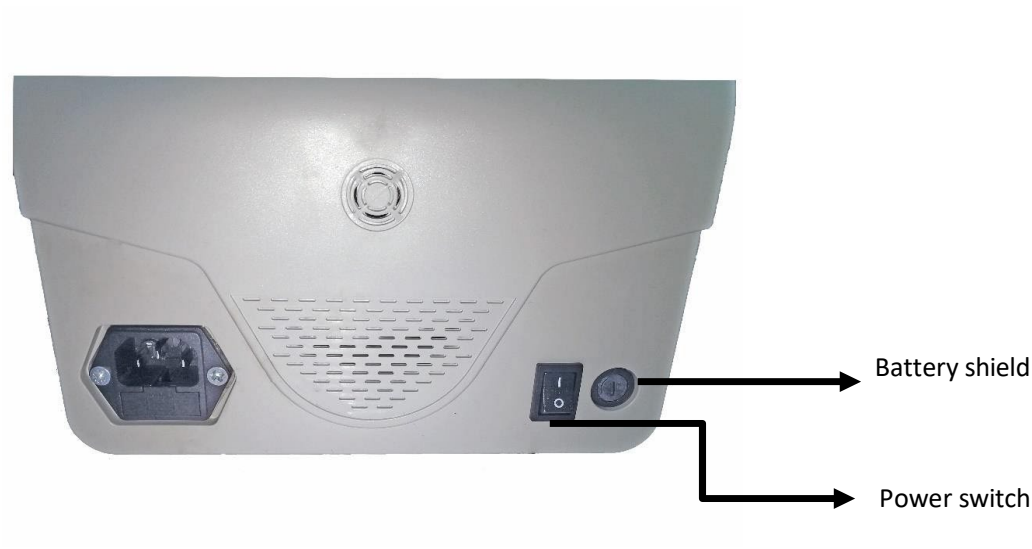
14. Battery Maintenance and Storage

There is battery protection to prevent the battery from being fully discharging during transportation or when not used for a long time. The device is delivered without this battery protector installed.

If the tourniquet device is being transported, the battery should be fully charged, and the battery protector should be removed.

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

The battery of the tourniquet device should only be charged with the battery shield attached and the switch on the back of the device in position I.



Installation of battery shield

1. Open the battery shield with the help of a flat screwdriver and properly insert the fuse.
2. Turn the battery shield to the direction of 12 o'clock with your finger.

Removing the battery protection

1. Turn the battery cover anticlockwise to 11 o'clock with the help of a flat screwdriver.

2. Remove the battery shield from its holder.

3. Keep the battery shield next to the tourniquet device.

15. Battery Charging

1. During charging of the battery, On/Off switch on the back panel of the device should always be ON position.

2. Confirm that the battery charge indicator (orange LED) is always on and not flashing.

3. If the charge indicator (orange LED) is flashing, the device warns that it is below 50% battery capacity and needs to be charged.

4. Be sure to charge the battery after using the device (regardless of the current battery status).

5. Confirm the battery is fully charged before use.



LED indicator	Charging state	Explanation
LED off	Battery is full	-
LED on	AC power is on. Battery is charging	-
LED flashes	Charging level is less than 20%	-connect the device to power supply. -Please charge the battery
E11 error and LED flashes	Charging level is less than 20%	-Connect the device to power supply. -Device will allow use with error code due to critical battery level -Connect the device to the power source or terminate the use within 5 minutes.

By pushing  battery key, battery capacity is shown as percentage%.

16. First Use

Follow the below-mentioned instructions for the first use:

16.1. Opening the package and installation

1. Open the packaging and take out the device and accessories.
2. Keep the packaging in a suitable location.
3. Install and fix the device as mentioned in this manual.
4. If required, wait for the room temperature conditions.

Content of packaging

1. Power cable
2. User manual
3. Cuffs 3 pc. single chamber + 1 IVRA cuff
4. Cuff Hose- 2 pc.
5. Main Device

16.2. Connecting the device to the power supply

Use the power cable suitable with AC power requirements in your country.

Consider the information for the power source in the manual and on the label. (See section 22, .27.)

16.3. Checking the battery charging level

Check the steps in Chapter 15 for the battery charge indicator. The battery charge case and your battery condition should be in a good situation for a safe operation.

16.4. Turning the device on

Connect the power cable of the device, switch 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.

- Automatic test starts

- If the device fails to perform the self-test, an error message is shown (E 1, E6, E2 etc.). See. chapter 21, p.26-27

- Tourniquet device is ready to use when SELF CHEC text disappears from the screen.

16.5. Turning the device off

When the tourniquet device on / off button is pressed once, OFF text will flash on the screen (5 times) and the device will turn off when it is pressed again. If no action is taken, the device becomes active.

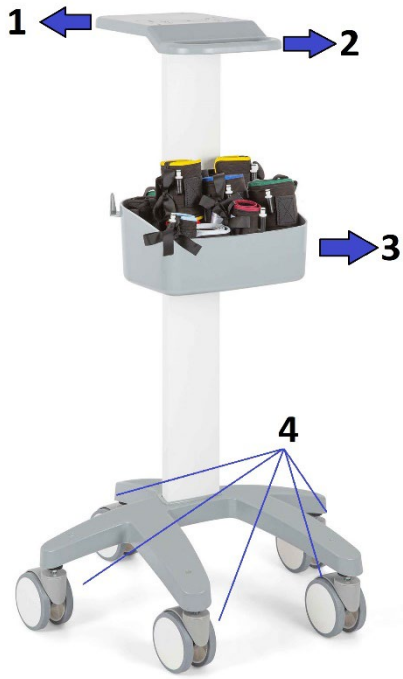
For AC mode: We recommend that you always leave the device connected to the power source (power socket) after turning it off.

16.6 Installation

Medione Tourniquet device is delivered as ready to use. The user can read the user manual and make the device suitable for operation according to the instructions for use and start using it.
Make sure the first use has been carried out properly.
Install and / or fix the tourniquet device at the desired location:
- Using it as a stationary device
- Standard rail mounting
- Attachment to the movable stand

Using as a stationary device

Tourniquet device can be used as fixed.



Make sure that the surface where the device will be positioned is solid and flat. Protect the tourniquet device from sunlight and moisture.

Do not place the tourniquet device in front of heating devices or other heat sources.

Attachment to movable stand (optional)

You can connect the tourniquet to the mobile stand by using the optional accessory (AVR- ST001). The movable stand has a basket where you can store connection hoses, cuffs and accessories.

1.Positioning Tray 2.Handle 3.Accessory Box(to keep the cuffs and power cord) 4.Wheels with fixing brake(5 pcs)

Using the fixing brake

- - Before moving the tourniquet device, disable the parking brake.
- - Activate the parking brake to prevent unwanted movements of the tourniquet device.

17. OPERATING THE DEVICE

17.1. STARTING THE DEVICE

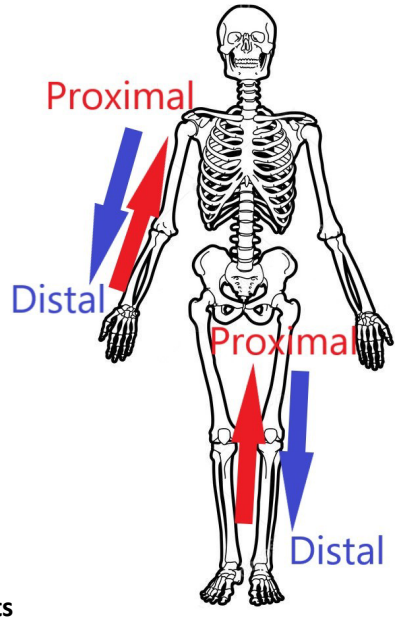
Automatic tourniquet device is an operational device, and it is turned on/off by pushing button on front panel of the device. When the lights turn on, the text (8888) will appear on the device screen. The device is ready for use after self-testing and SELF CHECK is extinguished.

17.2. Setting the device

17.2.1. Setting the pressure

When choosing the pressure, consider the information on the tourniquet cuff user manual..





Color codes for distal and proximal parts

The device has dual outputs, PROXIMAL and DISTAL. These circuits are completely separated. Pressure settings and timers are independent, the setting procedure is the same.

All keys highlighted in red will be used to adjust the PROXIMAL part.

All buttons highlighted in blue will allow adjustments to the DISTAL part.

17.2.2. Changing the Pressure (pre-operation)



Pressure level is selected with the keys, adjusts the value in mm-Hg and the adjusted value is permanently displayed on the PRESSURE screen.

17.2.3. Changing the pressure (during operation)

During the operation, the measured pressure is displayed on the PRESSURE screen, and when the pressure is desired to be changed, the pressure can be increased or decreased with keys in the relevant section. The changes will be saved automatically.

In 2-channel application, the pressure of each channel can be adjusted separately. In IVRA application, the entered pressure values are always considered valid for both channels. (see Section 20 p. 24)

17.2.4. Timer setting (before surgery operation)

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. For this setting, follow the steps below.:



With the +/- buttons under the TIME screen on the PROXIMAL and DISTAL section Time can be adjusted. The time counter can be changed as countdown and countdown.

This is realised with 

button.

Information of tourniquet application period

You can monitor the remaining and past tourniquet time from the TIME screen throughout the entire tourniquet application.

Before the entered tourniquet time expires, the alarm will alert once, the time can be extended during the operation by pressing the +/- keys on the TIME screen of the relevant section.

Setting the duration of the alarm

Before the tourniquet time ends, the tourniquet device gives the user an audible alarm close to the end of the set time. You can increase or decrease the time when the alarm will start to sound by pressing the alarm button on the device with the +/- keys on the Proximal screen. The changes you make will be saved automatically.

Connecting the cuffs

To connect to the tourniquet cuff port, insert the connectors on the tourniquet cuff end into the port. For more information, please see the tourniquet cuff user guide..



i.e.; protective bandage



i.e : application of protective bandage tourniquet cuff

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

Apply the appropriate limb protection material to the limb in the area selected for the cuff, unless it is 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 size of the tourniquet cuff and should cover the wrapped cuff on it.

Esmark bandage application is recommended to drain the existing blood in the limb in tourniquet applications.

High pressures applied to the skin and soft tissues under a tourniquet 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, under-cuff padding, underlying bandage, and lower extremity protective covers that match specific limb sizes and cuff sizes. The study results provide evidence that limb protection covers improve safety by protecting the tourniquet cuffs of the bandage wrapped during tourniquet use and also provide evidence that the greatest safety is achieved by the use of limb protection cuffs and protective bandages that match the limb size and cuff size.

Now, you can start the tourniquet

Starting the tourniquet

The pressure to be adjusted on the PROXIMAL or DISTAL extremity is adjusted from the Pressure screen on the appropriate channel.

The required time adjustment is made on the time screen, and the countdown or forward countdown is determined.

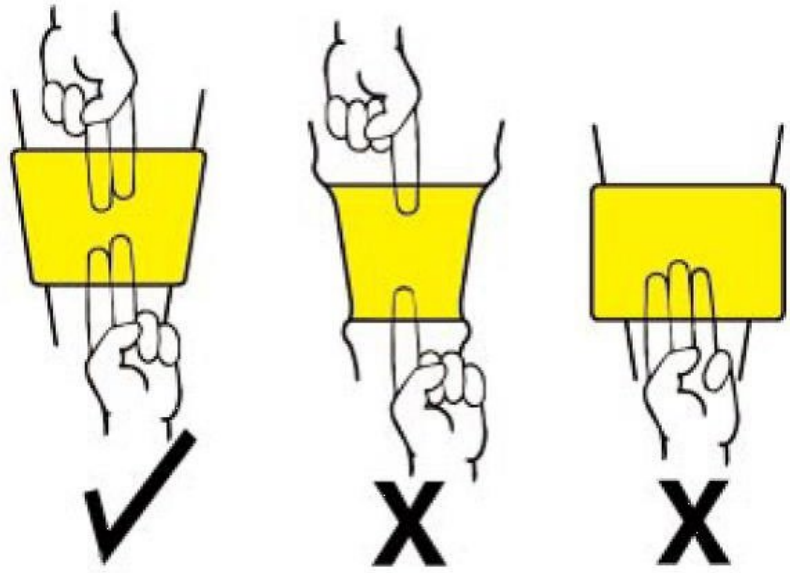
tourniquet is started by pushing the 

INFLATE key at related section.

With the information you will monitor on the screen, the tourniquet pressure and the time counter is active, you will have successfully started a tourniquet.

To rotate the inflated cuff injures the patient.

Do not forcibly change (do not rotate) the position of an inflated cuff.



Make sure that the tourniquet cuff is air-filled and that there is counter pressure when you put two fingers under the inside of the cuff (Proximal).

Check the cuff pressure regularly during tourniquet application.

18. Stopping the tourniquet

Before the entered tourniquet time expires, the device gives a warning alarm. In the finished section, DEFL is monitored, after the alarm sound, decide with the responsible physician whether to continue or end the tourniquet.

By pushing the 

DEFLATE key at related section, the tourniquet application can be stopped.

Re-applying tourniquet

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

19. Turning the device off

To turn off the tourniquet device, press the "On / Off" button and see the flashing off text on the screen 2 times and press the off button again, the device will turn off. (In order to avoid accidental key presses, you have to perform critical operations by pressing the keys twice.)

20. IVRA

Regional Intravenous Anesthesia (IVRA) is a regional anesthesia application and is mostly used during outpatient surgeries on extremities.

In Regional Intravenous Anesthesia, the extremity to be operated on is first evacuated and tied. Then, a local drug is injected into the veins to prevent pain from spreading in the ligated limb.

To connect the power cable to the plug

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

The system is activated by pushing 

key. When the system is activated, the pressure and time screens on the device will work at the same time. After making the necessary time and pressure adjustments, the double tourniquet cuff can be safely operated.

Skin protection application to the skin covering the limb Skin

protection application to the skin covering the limb **Interruption of**

limb blood flow

With the Esmarch bandage, stop the blood flow to the extremity**. Attaching the**

connection hose to the automatic tourniquet device

Make sure that the tubing is not folded to ensure that the pressure created by attaching the connection hose of the proximal sac to the left port (red area) and the connection hose of the distal sac to the right port (blue area) to the cuff smoothly.

Adjusting the pressure point

Fill the proximal sac with air pressure, following the procedure specified in section 17.2.2. Set the time as described in section 17.2.4.

After anesthetic injection and its effect

Inflate the distal pouch and make the tourniquet cuff pressurize the area over the anesthesia**. Deflating the**

upper bladder of the cuff

Pressing the "Deflate" button of the relevant pressure circuit, the upper pouch (Proximal) is vented**.**

Deflating the lower pouch of the cuff

After the operation, vent the distal pouch by pressing the "Deflate" button, disconnect the cuff from the tourniquet and turn the device off by pressing the ON / OFF button**.**

Deflating the upper bladder of the cuff

Pressing the "Deflate" button of the relevant pressure circuit, the upper sac (Proximal) is vented.

Deflating the lower pouch of the cuff

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

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



Double chamber cuff

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

Stopping the tourniquet

1. Turn off the tourniquet device. Remove all accessory parts.
2. For AC mode: Unplug the mains plug, wrap up the power cord and store it with the accessories of the device.
3. For long periods of transportation or non-use: Remove the battery protection. (See chapter 14 p.17.)
4. Store the tourniquet device in accordance with the transport and storage conditions.

21. Troubleshooting

Detecting faults

If a deviation from the standard device operation is detected, an error code is shown on the Display screen.

Error

If a fault occurs and the message is not displayed, there is a fault in the device.

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 a button. In continuous alarms, the reset button is used to silence the alarms for 25 seconds. At the end of the period, the device will give an alarm again, since it is necessary to intervene in the faulty source.

Error Code:	Reason:	Solution:
Self test errors		
E1	Battery Error	The device will make an error because the battery level is critical. 1. Turn the power switch on the back of the device to ON position and let it charge for at least 1 hour. 2. In case of recurrence of the fault, contact the technical service. Request a replacement of the battery.
E2	Leakage- Proximal Section	1. Make sure the proximal tourniquet cuff is not attached. 2. Turn the tourniquet off and on again 3. If the device gives the same error message again, contact your authorized service.
E3	Leakage – Distal Section	1. Make sure the tourniquet cuff at the distal part is not attached. 2. Turn the tourniquet off and on again 3. If the device gives the same error message again, contact your authorized service.
E4	Drain valve defective Proximal	1. Make sure the tourniquet cuff on the proximal part is not attached. 2. Turn the tourniquet off and on again 3. If the device gives the same security message again, contact your authorized service.
E5	Drain valve defective Distal	1. Make sure the tourniquet cuff at the distal part is not attached. 2. Turn the tourniquet off and on again 3. If the device gives the same error message again, contact your authorized service.
E10	Motor fail Motor is defective or disconnected	The compressor was not operating properly during the self-test. 1. Turn off the tourniquet device with the on / off button. 2. Disconnect the tourniquet device from the power supply. Wait 3.10 seconds and reconnect the mains plug. 4. Turn the tourniquet device with the on /off button. If the error message reappears: Turn off the tourniquet device and turn it on again. If the tourniquet message is still displayed: Contact your authorized service.
E14	Proximal Section High Pressure alarm	During self-test There is a malfunction at the tourniquet device. The pressure in the air tank is too high and cannot be reduced by the tourniquet device. 1. Visually check the pressure on the screen. 2. Check the error code 3. Turn the tourniquet device OFF. Turn the device on after 5 minutes. If the same fault continues, contact the authorized service.
E15	Distal part high pressure alarm	During self-test There is a malfunction at the tourniquet device. The pressure in the air tank is too high and cannot be reduced by the tourniquet device. 1. Visually check the pressure on the screen. 2. Check the error code 3. Turn the tourniquet device off. 4. Turn the device on again after 5 minutes. If the same fault continues, contact the authorized service.
Errors during operation		

E6	Cuff is not disconnected – leakage – Proximal line	1. Make sure the cuff / hose is attached to the correct port. 2. Make sure the cuff and hoses are seated correctly in the connection points. 3. Make sure that the cuff is not placed too loosely on the patient's extremity. Change the cuff size if necessary. 4. Eliminate the error message with the "Turn off alarm sound" button. Tourniquet can be restarted immediately. If the error message is still displayed: Contact your authorized service.
E7	Cuff is not disconnected – leakage – Distal line	1. Make sure the cuff / hose is attached to the correct port. 2. Make sure the cuff and hoses are seated correctly in the connection points. 3. Make sure that the cuff is not placed too loosely on the patient's extremity. Change the cuff size if necessary. 4. Eliminate the error message with the "Turn off alarm sound" button. Tourniquet can be restarted immediately. If the error message is still displayed: Contact your authorized service
E8	Deflating valve defective or blocked - Proximal	1. Make sure the cuff / hose is attached to the correct port. 2. Make sure the cuff and hoses are seated correctly in the connection points. 3. Make sure that the cuff is not placed too loosely on the patient's extremity. Change cuff size if necessary. 4. Eliminate the error message with the "Turn off alarm sound" button. Tourniquet can be restarted immediately. If the error message is still displayed: Contact your authorized service
E9	Deflating valve defective or blocked – Distal	1. Make sure the cuff / hose is attached to the correct port. 2. Make sure the cuff and hoses are seated correctly in the connection points. 3. Make sure that the cuff is not placed too loosely on the patient's extremity. Change the cuff size if necessary. 4. Eliminate the error message with the "Turn off alarm sound" button. Tourniquet can be restarted immediately. If the error message is still displayed: Contact your authorized service
E11	Battery almost empty	1. Connect the tourniquet device to the power supply. 2. Fully charge the battery until the orange LED on the front of the device turns off. 3. The device cannot be used with this error code without being connected to the power supply, turn off the device.
E12	Too High cuff pressure - left	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 held constant. 1. Visually check the actual pressure in the cuff. 2. Turn off the tourniquet.

E13	Too High cuff pressure - right	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 held constant. 1. Visually check the actual pressure in the cuff. 2. Terminate the tourniquet and turn off the tourniquet device.

22. Technical Information / Parameter

Power / frequency		100–240 V / 50–60 Hz; 70 VA	
Minimum / maximum cuff pressure		20 mmHg / 650 mmHg	
Class for applied part		Type B	
Classification for MDD		Class II a	
Protection Class		IP20	
Classification of electric protection		class II	
Sensitivity		±5 mmHg	
Size		275 x 235 x 268 (H x W x D, mm)	
Weight		4 kgs	
Screen		Indicator, LED display	
Microprocessor		Yes, (Central Processing Unit - CPU)	
S/W Classification		Class A	
Fuse		Power: F1,F2: 2 A 250 V Battery: F3: 2 A Cut off capacity 2 A Type: connection 5 mm x 20 mm	
Internal Power Source		12 V, 2,6 Ah Closed Lead Battery	
Nominal compressor value		12 V, max. 1,5 bar	
Temperature range		**Humidity**	
Operation	+15 °C–+40 °C	Operation	%5–%90, non-condensing
Storage/Transport	-10 °C–+70 °C	Storage/Transport	%5–%90, non-condensing
Atmospheric Pressure			
Operation		50 KPa–106 KPa	
Storage/Transport		50 KPa–106 KPa	

23. Accessories List

Tourniquet device movable stand is optional.
The power cord is available in the box. It can be supplied again as required.
Couplings and hoses are available in the box - 4 ea. (AVR-CUFF-S012 / S018 / S030 / AVR-CUFF-2XD20 others are offered as an option.
All accessories are available from the manufacturer, labeled and packaged.







Product Ref	Description
Reusable cuffs with single hose	
AVR-CUFF S008	8” Reusable child - short 8”L x 2”W single chamber – single hose
AVR-CUFF S012	12” Reusable – child medium 12”L x 3”W single chamber – single hose
AVR-CUFF S015	15” Reusable – child – long 15”L x 4”W single chamber – single hose
AVR-CUFF S018	18” Reusable standard- arm 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 – leg 30”L x 5”W single chamber – single hose
AVR-CUFF S034	34” Reusable long - leg 34”L x 5”W single chamber – single hose
AVR-CUFF S038	38” Reusable long - 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
Reusable cuffs with dual hose	
AVR-CUFF D008	8” Reusable – child - short 8”L x 2”W single chamber – dual hose
AVR-CUFF D012	12” Reusable – child medium 12”L x 3”W single chamber – dual hose
AVR-CUFF D015	15” Reusable – child – long 15”L x 4” single chamber – dual hose
AVR-CUFF D018	18” Reusable standard – arm 18”L x 4”W single chamber – dual hose
AVR-CUFF D024	24” Reusable standard – leg 24”L x 4”W single chamber – dual hose
AVR-CUFF D030	30” Reusable – medium – leg 30”L x 4”W single chamber – dual hose
AVR-CUFF D034	34” Reusable – long - leg 34”L x 4”W single chamber – dual hose
AVR-CUFF D042	42” Reusable – extra long - leg42”L x 4”W single chamber – dual hose
Reusable IVRA cuffs – dual chamber dual hose	
AVR-CUFF 2XD014	14” Reusable bier block cuff- short 14”L x 4”W Dual Chamber – Dual Hose
AVR-CUFF 2XD020	20” Reusable bier block – medium 20”L x 6”W Dual Chamber – Dual Hose
AVR-CUFF 2XD26	26” Reusable bier block long 26”L x 6”W Dual Chamber – Dual Hose
AVR-H003	Connection Tube/Hose 5m
AVR-P220	Power Cable
AVR-ST001 / TRQ-75	Mobile Stand (Optional)

24. Electromagnetic Compatibility (EMC) Declaration

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

This device has been tested and found to comply with the limits specified in the EN 60601-1-2:2015 standard for medical devices. These limits are designed to provide reasonable protection against electromagnetic interference (EMC) when the equipment is operated as instructed in the manual.

This device may be affected by portable and mobile RF communication devices. It should not be used in close proximity to other equipment.

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

Manufacturer's Declaration – Electromagnetic Emissions		
This device is designed for use in the electromagnetic environment specified below. The customer or the 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 functions. 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	This device is suitable for use in all establishments, including domestic establishments and those directly connected to the 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	

Manufacturer's Declaration – Electromagnetic Immunity			
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 covered with synthetic material, relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for I/O lines Repetition frequency: 100 kHz	±2 kV for power supply lines ±1 kV for I/O lines Repetition frequency: 100 kHz	Mains power quality should be that of a typical commercial or hospital environment.
Surge Between Lines IEC 61000-4-5	±0.5 kV, ±1 kV, ±2 kV	±0.5 kV, ±1 kV, ±2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge Between Line and Ground IEC 61000-4-5	±0.5 kV, ±1 kV, ±2 kV	±0.5 kV, ±1 kV, ±2 kV	
Voltage Dips on Input Power Lines IEC 61000-4-11	0% Ut; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°	0% Ut; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°	Mains power quality should be that of a typical commercial or hospital environment.

	0% Ut; 1 cycle and 70% Ut; 25/30 cycles Single phase: 0°	0% Ut; 1 cycle and 70% Ut; 25/30 cycles Single phase: 0°	
Voltage Interruptions on Input Power Lines IEC 61000-4-11	0% Ut; 250/300 cycles	0% Ut; 250/300 cycles	
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m 50 Hz / 60 Hz	30 A/m 50 Hz / 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: *Ut is the a.c. mains voltage prior to application of the test level.*			

Manufacturer's Declaration – Electromagnetic Immunity			
This device is intended for use in the electromagnetic environment specified below. The customer or the user of the 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 at 3 Vrms 6 Vrms (in ISM and amateur radio bands)	150 kHz to 80 MHz at 3 Vrms 6 Vrms (in ISM and amateur radio bands)	Portable and mobile RF communications equipment (including cables) should not be used closer to any part of the device than the recommended separation distance calculated using the equation applicable to the frequency of the transmitter. **Recommended separation distances:** **d = 0.35√P** for 150 kHz to 80 MHz **d = 1.2√P** for 80 MHz to 800 MHz **d = 2.3√P** for 800 MHz to 2.7 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 meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. **Symbol below may appear near equipment indicating potential RF interference:**
Radiated RF IEC 61000-4-3	10 V/m 80% AM at 1 kHz	10 V/m 80% AM at 1 kHz	

Note 1: 80 MHz and 800 MHz are included in the frequency range.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Additional Guidance:

a. Portable and mobile RF communications equipment such as cordless phones, walkie-talkies, amateur radio transmitters, AM/FM radios, and television transmitters may not be accurately predicted in theory due to variations in emissions. In such cases, electromagnetic site surveys may be necessary to evaluate the environment.

b. Conducted RF immunity above 80 MHz must apply only to frequencies where field strengths reach 3 Vrms.

c. For ISM (Industrial, Scientific, and Medical) frequency bands, appropriate calibration must be applied using a 150Ω system impedance.

d. If abnormal operation is observed, it may be necessary to relocate or re-orient the device.

e. Devices powered from a fixed-line supply should not share circuits with high-power medical devices exceeding 16 A per phase.

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

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

Rated Maximum Output Power of Transmitter (W)	**Separation Distance by Frequency of Transmitter (m)**			
	150 kHz to 80 MHz outside ISM and amateur bands *d = 1.2√P*	**150 kHz to 80 MHz** outside ISM and amateur bands *d = 0.6√P*	**80 MHz to 800 MHz** *d = 1.2√P*	**80 MHz to 2.7 GHz** *d = 2.3√P*
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

For transmitters rated at maximum output power not listed above, the recommended separation distance ***d*** in meters (m) can be estimated using the applicable formula for 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: 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 bands within 150 kHz to 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.

Note 3: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Manufacturer's Declaration – Electromagnetic Immunity

RF Wireless Communication Equipment Immunity Test Characteristics (IEC 61000-4-3)

This device is intended for use in electromagnetic environments as described below. The user of the device should ensure it is operated in such an environment.

Radiated RF (IEC 61000-4-3) (Immunity to wireless communications devices)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Modulation Power (W)	Distance (m)	Test Level (V/m)
	385	380-390	TETRA 400	Pulse modulation at 18 Hz	1.8	0.3	27
	450	380-390	GMRS 460, FRS 460	FM^c, ±5 kHz deviation 1 kHz sine wave	2	0.3	28
	710 745 780	704-787	LTE Band 13	Pulse modulation at 217 Hz	0.2	0.3	9
	810 870 930	800-960	GSM 800/900, TETRA 800, IDEN 820, LTE Band 5	Pulse modulation at 18 Hz	2	0.3	28
	1720 1845 1970	1700-1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Bands 1, 3, 4, 25, UMTS	Pulse modulation at 217 Hz	2	0.3	28
	2450	2400-2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation at 217 Hz	2	0.3	28
	5240 5240 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation at 217 Hz	0.2	0.3	9

Note:

- The **TEST LEVEL** is the field strength in V/m that must be met at the indicated test distance.
- A minimum test distance of 1 m is permitted per IEC 61000-4-3.
- Some services use only transmit frequencies.
- Carrier signal: modulated with 50% duty cycle square wave unless otherwise stated.
- **FM modulation**, **18 Hz pulse**, and **50% duty cycle** represent worst-case scenarios for EMC testing.

Manufacturers or **risk managers** should avoid using lower immunity test levels unless they are supported by a justification of reduced separation distances and risk mitigation.

For higher test levels, the following formula can be used to calculate the immunity field strength:

$E = 6 / d \times \sqrt{P}$

Where:

- **E** is the immunity level in V/m
- **d** is the distance in meters
- **P** is the transmitter power in watts

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