Please read these instructions carefully before using the device.

GOOD MEDICA

Automatic tourniquet

CuffMedF1

USER MANUAL

USER MANUAL

Automatic tourniquet

Please read these instructions carefully before using the device.

User Manual in English

The product name:

Automatic tourniquet

Model:

CuffMedF1

Manufacturer:

Good MedicaSp. z o. o.
ul. Opolska 149
52-013 Wroclaw, Polska

Contents:

page

3 - SPECIFICATION FOR USE
3 - INTENDED USE
3 - CONTRAINDICATIONS
4 - PRECAUTIONS
4 - PRECAUTIONS FOR USE
5 - ADVERSE EVENTS
5 - TECHNICAL SPECIFICATION AND PERFORMANCE PARAMETERS
6 - PACKAGE CONTENTS
7 - INITIAL VISUAL INSPECTION
8 - CHARACTERISTICS AND OPERATING PRINCIPLES
9 - GRAPHICAL USER INTERFACE WITH A TOUCH PANEL
10 - INTRODUCTION
11 - PATIENT PREPARATION
11 - STARTING THE AUTOMATIC TOURNIQUET
15 - PRECAUTIONS
16 - TRANSPORT AND STORAGE
16 - CLEANING, DISINFECTION
17 - SAFETY DURING USE
18 - NOTES
20 - LABELS
20 - SYMBOLS USED
21 - SERVICE

SPECIFICATION FOR USE

This specification applies to the use of an automatic tourniquet, model CuffMed F1. The instructions contain descriptions related to the use of the device, its intended use, conditions of use and operating principles.

The CuffMed F1 automatic tourniquet, is a medical product developed and designed by Good Medica sp. z o.o., used for surgical procedures on the upper and lower limbs.

INTENDED USE

The CuffMed F1 automatic tourniquet is intended for use by qualified medical personnel to temporarily inhibit blood flow in the patient's limbs during limb surgeries.

Tourniquets are used to create a bloodless surgical field during surgical procedures such as:

- Open reposition and stabilisation of limb fractures
- Removal of connectors after open reposition and stabilisation of limb fractures
- Other limb trauma surgeries
- Alloplasty of lower and upper limb joints, especially the knee joint
- Surgical oncology treatments of limbs
- Amputations
- Reconstruction of tendons, vessels and nerves
- Surgical treatment of CTS (Carpal Tunel Syndrome) or Dupuytren's disease.

CONTRAINDICATIONS

Contraindications to the use of a tourniquet include relative contraindications. Medical literature presents possible and relative contraindications:

- Open limb fractures
- Post-traumatic reconstruction of the long extensor of the thumb
- Severe crushing injuries
- Elbow surgery (for large swelling)
- Severe hypertension
- Diabetes
- Skin transplantation
- Systemic diseases and disorders that impair vascular circulation, e.g., peripheral arterial diseases
- Sickle cell disease.

PRECAUTIONS

The decision to use a tourniquet belongs to the doctor conducting the surgery (operator). By temporarily blocking the blood flow in the vessels, the automatic tourniquet creates a clinical situation that facilitates conducting the surgery.

Before the procedure, the operator must assess whether the potential risk of inhibiting the blood flow does not outweigh the potential benefits of obtaining a bloodless surgical field.

PRECAUTIONS FOR USE

- During normal operation, the CuffMed F1 automatic tourniquet must be permanently connected to the AC mains supply via a power cord. CuffMed F1 is equipped with a battery used only to maintain power in the event of an emergency mains supply failure.
- A self-test should be carried out before each use of the automatic tourniquet. The self-test is started automatically, directly after turning on the power.
- The tourniquet cuff must be applied in a proper position on the limb, taking into account the anatomy of the upper and lower limbs. (e.g., a tourniquet should not be used near the peroneal nerve)
- The tourniquet cuff must be used for the shortest possible time and in the lowest possible pressure range.
- Do not move, e.g. rotate the inflated cuff, as it releases shear forces that can damage lower tissues.
- Long-term ischaemia can lead to temporary or permanent damage to blood vessels and nerves, as well as to other tissues and anatomical structures placed distally to the cuff and directly under the cuff.
- Using too much pressure can lead to temporary or permanent damage to blood vessels and nerves, as well as to other tissues and anatomical structures placed distally to the cuff and directly under the cuff.
- Using too low pressure may cause limb reactive hyperaemia (venous outflow stopped with arterial inflow preserved).
- The extended duration of use of the tourniquet can cause changes in blood coagulation by increasing the coagulation time.
- Before inflating the cuff, it is recommended to make tight unidirectional bandaging (with an elastic bandage) from the circumference of the limb in the proximal direction to expel the largest possible amount of blood accumulated in the venous bed to the outside of the ischaemic area. In case of infection, fractures and before amputations for oncological reasons, it can be performed without the use of an elastic bandage by holding the limb up for 3-5 minutes (elevation of the limb above the heart level with preserved flow direction). Expelling blood from the venous bed in the ischaemic area improves conditions of the surgery by minimising residual reactive hyperaemia.

- It is necessary to choose the appropriate cuff size; its edges should overlap by 8 to 15 cm. Too large overlapping area can cause the cuff to curl or stretch and lead to undesirable distribution of pressure exerted on the limb.

- The skin under the tourniquet cuff should be protected from mechanical injuries, ensuring that the cuff surface is smooth and free from creases. It is recommended to use soft pressed cotton wool routinely as a base under plaster bandages.

- Transient pain felt after deflation of the tourniquet can be reduced by raising the limb.

- If the skin colour does not return to normal within 3 to 4 minutes after deflation, the limb should be placed slightly below the body level.

- In case of using IVRA (Bier block anesthesia), it is recommended to leave the tourniquet inflated for at least 20 minutes after injecting the medicine.

ADVERSE EVENTS

When using a tourniquet without general anesthesia or regional blockade, after inflating the cuff, a dull pain combined with itching may appear in the limb.

After about 1.5 hour after using the tourniquet, the risk of complications and pathophysiological changes associated with excessive pressure and ischaemia (hypoxia, hypercapnia and acidosis of tissues) increases significantly.

The use of the tourniquet may be associated with symptoms such as paralysis, touch and pressure disorder, as well as loss of kinaesthesia.

Despite the use of an automatic tourniquet, bleeding during surgery can be caused by:

- Insufficient inhibition of blood flow due to too weak pressure exerted by the cuff. Pressure in the cuff is maintained, but inappropriate application of the cuff prevents the cuff pressure from affecting the limb.
- Put on the tourniquet correctly. The tourniquet, after putting on but before inflating, should adhere tightly and embrace the circumference of the limb. The protective velcro should be fastened.
- Insufficient inhibition of blood flow due to too low pressure of the tourniquet.
- Increase the cuff operating pressure.

Despite the use of a tourniquet, bleeding out of the nutrient vessels of the long bones is possible.

TECHNICAL SPECIFICATION AND PERFORMANCE PARAMETERS

Power line voltage range ~ AC	100-240 V ~(AC), 50/60 Hz. Automatic switching

Input power	90 VA
Battery type	Lithium-ion battery, 14.8 V, 1600 mAh
Time of the first charging of the battery and recharging after discharging	The device should be connected to the power supply for 10 hours before the first use. In the event of a deep discharge of the battery, it is recommended to recharge it for 10 hours. **Note!** **After reducing the charge level to 10%, the device will not allow to change or set parameters, in which case the device should be immediately connected to the external power supply.**
Fuses	2 pcs 1.0 Amp 250 V
Output pressure range	30 mmHg/4 KPa - 750 mmHg/100 KPa
Alarm setting range	3-240 minutes
Dimensions	Height: 28.5 cm Width: 21.5 cm Depth: 25 cm Weight: 5 kg (with power cord)
Display	LCD touch panel - 8.4"
Clamp for attaching to the IV stand	Adjustable in the range of 1.5 cm - 2.5 cm
Operating conditions	Operating temperature range: 5℃ - 40℃ Air humidity: ≤ 85% Air pressure: 860 hPa - 1060 hPa

PACKAGE CONTENTS

1.	CuffMed F1 automatic tourniquet	1 pcs.
2.	Tourniquet cuffs	1 pcs.
3.	Power cord	1 pcs.
4.	Battery	1 pcs.
5.	Instructions for use: CuffMed F1	1 pcs.
6.	Instructions for use of the tourniquet cuff	1 pcs.
7.	Delivery and acceptance report	1 pcs.
8.	Warranty card	1 pcs.
9.	Technical passport	1 pcs.

When using the CuffMed F1 automatic tourniquet for the first time, check the device for any visible damage that may have been caused during transport. We recommend that this type of inspection be carried out by qualified personnel responsible for the administration and management of medical equipment in a given medical entity. If the device is damaged, inform the supplier and the manufacturer's service centre as soon as possible. If the initial inspection results are satisfactory, perform a self-test after charging the battery for 10 hours.

PRECAUTIONS

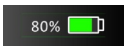
The CuffMed F1 automatic tourniquet has been designed for use outside the sterile operating field.

The device is a ready-to-run product, it does not require software installation. It should be operated by qualified medical personnel with medical knowledge on the effects of a tourniquet. Check the device for proper operation before each use.

The CuffMed F1 automatic tourniquet consists of a lot of components, which are described below:

Component	Description
1. Cuff connection ports	The left cuff port is marked in RED. The right cuff port is marked in BLUE. PRECAUTIONS: The automatic tourniquet has been designed and tested for use with Good Medica cuffs and cords connected to the port. Good Medica does not recommend the use of cuffs or cords of other companies.
2. Touch screen	Graphical interface for controlling the device functions.
3. Network connection indicator	Lit when the device is connected to the power supply.
4. Clamp for attaching to the IV stand	The clamp is used to attach the device e.g. on the IV stand.
5. Power socket	Power socket, plugs into power cord (not shown).
6. On/ off button	Turns the device on and off.
7. Place for a battery	The flap under which the battery is placed.
8. Handle	The handle for carrying or holding the automatic tourniquet.

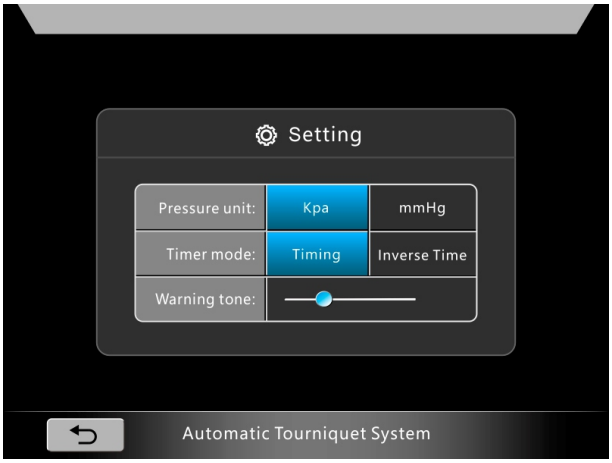
START-UP SCREEN

Graphical component of the interface	Description
"Menu" button in the bottom left corner	Displays image with technical parameters
	Activates the device self-test. If no errors are detected, the screen will switch to pressure and time parameter settings. The self-test should be done before connecting the cuffs!
	Shows percentage and graphical battery charge status.

PARAMETER MANAGEMENT PANEL

Graphical component of the interface	Description
Red / blue panel	The red panel corresponds to the parameters of the left channel, the blue panel corresponds to the parameters of the right channel.
	Change pressure and time parameters.
	Enables / disables the Bier block (IVRA).
	Enables / disables the automatic deflation after the end of the preset time.
	Activates the settings management panel.
	Displays the elapsed time.

SETTINGS MANAGEMENT PANEL



Graphical components of the interface	Description
„Pressure unit”	"Kpa" / "mmHg" pressure unit change
"Timer mode"	"Timing" - time counted from 0, "Inverse Time" - time counted to 0
"Warning tone"	Alert volume setting (10 levels of adjustment)
"Arrow" button	Return to the parameter management panel

INTRODUCTION

WARNING!

To avoid the risk of electric shock, the device must be connected to the AC mains supply with protective grounding.
The device should be connected to the AC mains supply for 10 hours before performing the initial configuration to ensure that the battery is fully charged. During transport and storage the battery may discharge.

WARNING!

To disconnect the device from the AC mains supply in case of emergency, pull out the power cord from the AC outlet or from the outlet at the back of the device housing. Place the device in such a way that access to the electrical outlet or the power cord of the device is not difficult.

DECISIONS MADE BY THE OPERATING SURGEON (operator)

The surgeon will decide on the following issues:

- What should be the position and location of the tourniquet on the patient's limb?
- What pressure should be applied?
- When should a tourniquet be inflated?
- How long should a tourniquet be used?
- When should the tourniquet be removed during surgery?

As part of good clinical practice:

- We recommend that the time of inflating the tourniquet, the time of deflating the tourniquet and the total time of use are recorded on an ongoing basis in the anesthesia card during the surgery.
- We recommend to clearly emphasize and pay attention to the time of inflation and the planned duration of use of the tourniquet before starting the surgery. A person should be appointed to monitor the duration of using the tourniquet. We recommend that the designated person give information at regular intervals (e.g. every 15 minutes) about the elapsed time of ischaemia. This will allow the surgeon to assess the need for any further prolongation of the duration of using the tourniquet. Information on the parameters of using the tourniquet (ischaemia time and pressure applied) should also be repeated in the operating protocol prepared by the operator after the surgery.

PATIENT PREPARATION

- Care should be taken that the tourniquet cuff is applied to the widest part of the limb, so that as much tissue as possible is between the cuff and the nerves or vascular structures susceptible to damage.

- The optimal place is the closer one third of the shoulder or thigh.

STARTING THE AUTOMATIC TOURNIQUET

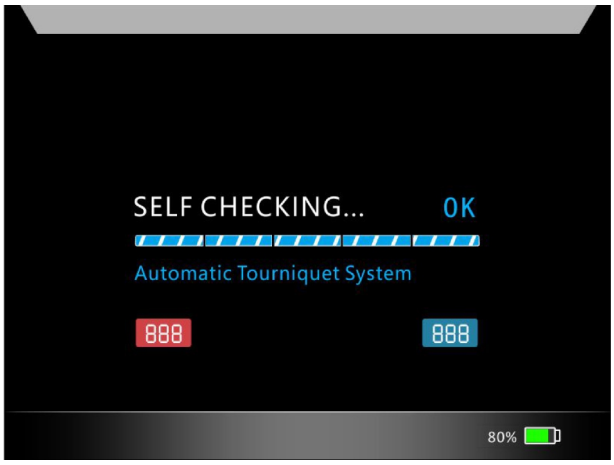
1. The device must be connected to the AC power supply.

2. Turn the device on using the ON/ OFF button at the back of the device.

3. After start-up, the "WELCOME SCREEN" will appear.

4. Make sure the cuffs are not connected to the device.

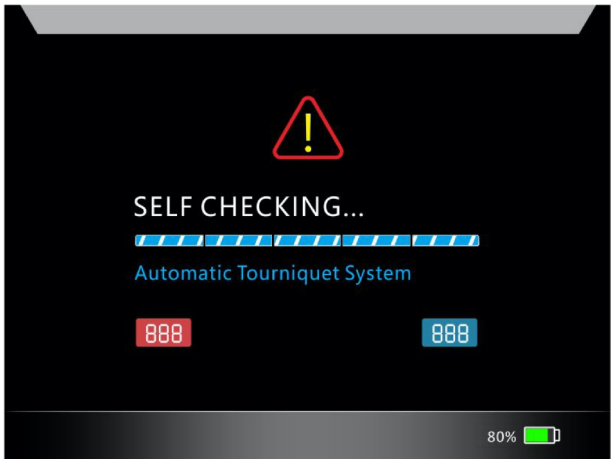
5. By pressing the "START" button, the device will automatically start "self-test".



6. After the "self-test" has been successfully completed, the device will automatically display the parameter management screen.

7. Now the cuffs can be connected.

In the event of a failure / error, the device will display the following message. In this case, please contact the service centre and do not use the device.



SETTING PRESSURE AND TIME PARAMETERS

TIME RANGE

The time adjustment range is from 3 min to 240 min, set every 1 min. The countdown time is displayed on the screen.

With the activated "Automatic deflation" the device will give 6 beeps one minute before the end of time. After the end of time, accompanied by 10 beeps, the device will deflate automatically and gradually.

With the deactivated “Automatic deflation" the device will give 6 beeps one minute before the end of time. After the end of time, accompanied by 10 beeps, the device will display the "TIME IS OVER" interface. Press the "OK" button to deflate the device. The device will return to the main interface.

PRESSURE RANGE

The pressure regulation range is 30 mmHg/4 KPa - 750 mmHg/100 KPa, set every 1 unit. The preset pressure is displayed on the screen.

Tip

- Time and pressure values can be set independently for both channels.
- Pressure and time values can be changed during the surgery.

PRESSURE/ TIME SETTING

Pressing the / button allows setting pressure and time. The choice of pressure and time should be determined by medical personnel and meet the patient's real clinical needs. After setting the values, press the of the channel to start inflation and timing countdown. The time to maintain the cuff pressure is counted down with a timer.

DEFLATION BEFORE THE END OF THE TIME PRESET

To deflate the cuffs before the end of the time preset, use the slow deflation mode or the quick deflation mode , by pressing the selected button.

The device will display a message confirming the deflation.

If you want to deflate the device, select YES .
If you do not want to deflate the device, select NO .

NOTE!
The tourniquet cuff may only be removed after deflating.

IMPORTANT:
- After finishing operation, turn off the power with the ON/ OFF button located at the back of the housing, otherwise the device will still be turned on.
- During the operation of the device always pay attention to whether the device does not make any unusual noises or whether there is no air leak. If so, contact the manufacturer or the supplier immediately.
- To ensure proper pressure, the tourniquet should be tightly fastened on the limb.
- The tourniquet must be used with an additional gauze pad (the product not included in the kit). The size of the gauze pad should be selected by the qualified medical personnel. Without a gauze pad, the pressure in the tourniquet may not be evenly distributed over the surface of the patient's limb.

APPLICATION OF A SINGLE CUFF

After turning on the device, a diagnostic self-test must always be carried out (pp. 13, 14). After successful completion, the device is ready for use. Pressure and time settings are remembered from the previous operation.

- Prepare the patient according to the instructions contained in the Patient Preparation section (p. 12).
- Assess the local condition of the skin and deeper layers of tissue before expelling blood from the venous bed of the limb and inflating the tourniquet cuff.
- The performance parameters of the tourniquet are determined by the surgeon as described in the section "Decisions made by the operating surgeon".
- Expelling blood from a venous bed of the limb
  1) Raise the limb for a minimum of 2-3 minutes
  2) Bandage the limb from the distal part in the proximal direction with an elastic bandage
  3) Apply cotton wool or other lining onto the limb, under the cuff
  4) Place the tourniquet cuff as close as possible to the bandage applied
  5) Fasten the cuff tightly, smoothly and without creases
- The pressure hose must be placed in such a way so that it does not bend during the surgery.
- Connect the cuff cord with connectors.
- Set the required pressure and time values.
- Touch the "right arrow" button to inflate the cuff to the preset pressure.
- Remove the elastic bandage applied to expel blood from the venous bed.
- Perform a surgical procedure.
- At the end of the procedure, deflate the cuff by pressing "right arrow" (slow deflation), "double right arrow" (fast deflation). If the "Automatic deflation" is activated, the pressure will automatically drop after the preset time.
- When the deflation is complete, remove the cuff.
- Check blood circulation in the limb.
- Remove the cuff from the automatic tourniquet.

DOUBLE CUFF OPERATION

The double cuff operation is the same to the Single Cuff Operation presented above, except for the following points:

• The cuff with double ports is concurrently connected to the red and blue ports.
  The pressure and time panels (blue and red) display information about a given cuff chamber.

Each cuff chamber is operated independently and controlled separately.

(IVRA) SYSTEM OPERATION WITH BIER BLOCK

Read the "SINGLE CUFF OPERATION" section.

The device is equipped with the "IVRA" function, both pressure and time are the same in both channels in this setting.

- After activating the "IVRA" and "Automatic deflation", the message "TURN ON" will appear. Confirm the choice of activation by pressing the "YES" button.
- Set pressure and time on one of the channels and press the left (or right) channel arrow. The left (or right) channel begins to inflate the cuff. A three-time beep indicates that the preset pressure has been reached.
- After the end of the preset time, the second channel begins to inflate the cuff. When the cuff inflation is completed, both tourniquets achieve equal pressure.
- The left (or right) channel begins to lower the cuff pressure, then the cycle repeats.

PRECAUTIONS

Deflation of the chamber is not possible when the other chamber is inflated.
For Bier block, follow the inflation/ deflation procedure applicable in the hospital or as requested by the doctor.

NOTE!

During the surgery, the "IVRA" and "Automatic deflation" buttons are inactive.

During the operation of the device always pay attention to whether the device does not make any unusual noises or whether there is no air leak. If so, contact the manufacturer or the supplier immediately.

The tourniquet should be fastened tightly on the limb, otherwise it will cause excessive pressure in the inner membrane, which can lead to its damage.

The tourniquet must be used with an additional gauze pad (the product not included in the kit). The size of the gauze pad should be selected by the qualified medical personnel.

TRANSPORT AND STORAGE

During transport, the device must be carefully secured, packed into a cardboard box lined inside with a protective foam.

Transport and storage conditions:

- Storage temperature: -25°C - 70°C
- Air humidity: ≤ 80%
- Atmospheric pressure: 700 hPa - 1060 hPa

The device should be stored in adequate humidity to prevent corrosion.

Before using the device after prolonged storage or transport, check that all functions of the device work properly.

Do not expose the device to sunlight, excessive low and high temperatures as well as shocks.

CLEANING, DISINFECTION

WARNING!

Risk of electric shock, damage to the device.

Disconnect the power plug before cleaning and disinfecting. Do not allow any liquid to enter the device. The device should be cleaned with non-alcohol wipes having disinfecting and washing properties, e.g. Sani-Cloth Active by Ecolab Sp. z o. o. Ready-to-use non-alcohol wipes are bactericidal, yeasticidal and mycobactericidal.

Wipe the external side of the device, including the touch screen and ports thoroughly with the above mentioned or similar wipe. It is forbidden to disinfect the device by high temperature and high pressure. The surface of the device should be cleaned after each use.

Do not clean switches or electrical contacts.

To avoid discolouration on the device, only colourless disinfectants should be used.

RISK!

Risk of explosion - The device may not be used in medical rooms where there is a risk of explosion. Risk of explosion can occur after contact with flammable anaesthetic agents or skin disinfectants.

Risk of electric shock - To avoid the risk of electric shock, the following warnings must be strictly observed. Non-compliance can lead to a risk to life and health of the patient and/ or the splint operator.

WARNING!

Before each use the user should check the condition of the device for safe use, in particular: the power cord and pressure hoses for possible damage. In the event of damage, contact the service centre immediately. Before the surgery, a test start-up of the device should be carried out without the patient's limb.

Do not use the device in a room without ventilation or sufficient light source.

NOTE!

The device should be operated by trained personnel according to the doctor's instructions.

If it is necessary to transport the device in sub-zero temperatures, the device should be warmed up to room temperature before turning on. Leave the device for approx. 2h until any possible condensate has dried.

The device may only be used in dry rooms at room temperature.

When disconnecting the device from the mains, first remove the plug, and then the cord from the device.

Do not leave the device connected to the mains unattended. When not in use, unplug it from the power source. Be careful not to pull the cord when disconnecting.

Do not use the device near a fire source.

The device should be inspected at least once a year for possible damage and loose connections.

The CuffMedF1 automatic tourniquet system should be connected to the power supply for at least 10 hours before putting it back into service to ensure that the battery is fully charged in the event of a loss of emergency power supply.

Make sure that the mains parameters match the voltage and frequency on the device label.

Do not expose the device to sunlight, excessive low or high temperatures.

Take special care when transporting the device.

In the event of damage to the device, stop its operation and contact the manufacturer for repair.

The device should be connected to the power supply for 10 hours before the first use.
In the event of a deep discharge of the battery, it is recommended to recharge it for 10 hours.

Note!

After reducing the charge level to 10%, the device will not allow to change or set parameters, in which case the device should be immediately connected to the external power supply.

NOTES

• I. Electromagnetic compatibility:

The device is designed to provide resistance to external electromagnetic factors. However, during operation, the device generates electromagnetic waves that may affect the operation of other devices.

• I. Care for the environment:

After the end of the product lifetime, the device can be fully utilised (electronic, metal and plastic components).

Common failures

Cuff leakage is a typical failure of an automatic tourniquet. Leakage reveals in the inability to inflate the cuff to the required pressure.

- If the cuff collars are delaminated or its cords are cracked, replace it with a new one.
- It is advisable to check tightness of the system by attaching a new kit of cuffs.
- If the above steps have not solved the problem, contact the supplier or the manufacturer of the device.

If the device will not work:

- First, check the AC power cord connection. Then check if the power button is in the ON position and then check if the manufacturer's logo appears on the display.
- If the AC power supply is properly connected and the device will still not work, contact the supplier or the manufacturer.

The device is powered, but the screen does not display any image:

- In this situation, most likely, there may have been problems with the internal systems, contact the manufacturer to repair the failure.

If the tourniquets are tight, the device is properly connected to the power supply, the screen displays the image and the device does not work properly, contact the manufacturer to repair the failure.

Electromagnetic recommendations

Modifications to the device are not allowed.

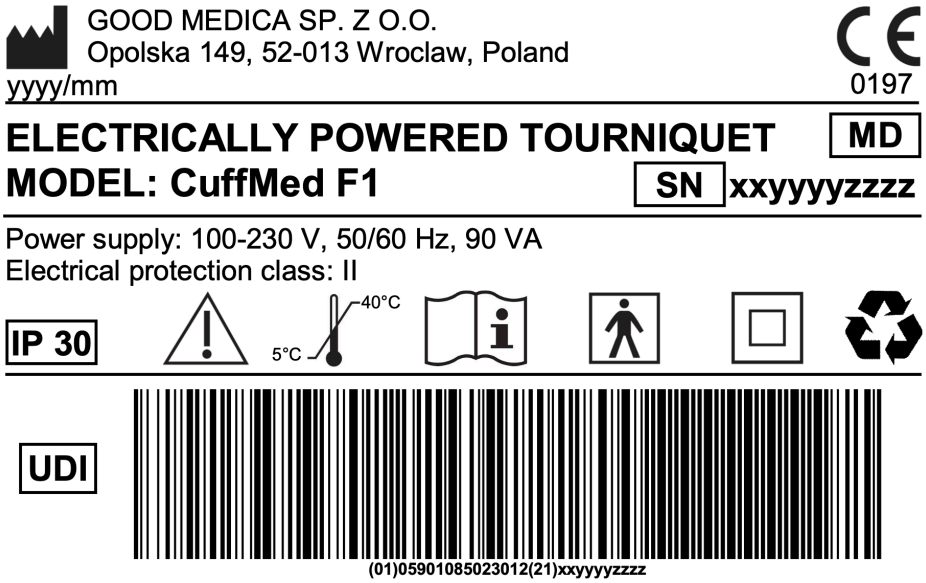
The CuffMed F1 automatic tourniquet does not contain internal service parts for the user. Do not uninstall, modify or repair internal components. Incorrect or poorly maintained device may cause a threat to the user and the patient.

Every CuffMed F1 device should be reviewed once a year in Good Medica Sp. z o. o. service centre. In the event of any failures please contact the service centre.

Guidance and manufacturer's declaration – Electromagnetic emission		
THE UNIT is designed to be used in electromagnetic environment as specified below. The customer as well as user of THE UNIT is to make sure that it is used in such environment.		
Emission tests	**Compliance**	**Electromagnetic environment – information**
Radio Electric - Frequency emissions according to CISPR 11	Group 1	THE UNIT 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.
Emisja w zakresie RF zgodnie z CISPR 11	Class B	THE UNIT 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.
RF – frequencies in the electromagnetic spectrum that lie in the range extending from around 3 kHz to 3000 GHz between the lower range of radio long waves and infrared range; frequencies used for radio transmission and communication.		

Labels

Product Label



Symbols Used

Symbol	Description	Symbol	Description
	Manufacturer	IP30	Degree of protection provided by enclosures
CE	93/42/EEC, CE Mark	40°C 5°C	Minimum and maximum temperature of storage areas
SN	Serial number		Follow/refer to the user manual
	Applied parts type BF		Equipment of class II
	Uwaga, zagrożenie, ostrzeżenie		Recycling

Modifications to the device are not allowed.

The CuffMed F1 oscillating plaster saw does not contain any internal service parts for the user. Do not uninstall, modify or repair internal components. Incorrect or poorly maintained device may cause a threat to the user and the patient.

Every CuffMed F1 device should be reviewed once a year in Good Medica Sp. z o. o. service centre. In the event of any failures please contact the service centre.

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