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EZO-02 ELECTRONIC DUAL TOURNIQUET CONTROL UNIT
Cat. No. 30.0026.000

www.chm.eu

All comments should be addressed to

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Read the Instructions for Use prior to the first use.

1. INTRODUCTION

1.1. GENERAL INFORMATION

1.1.1. INTENDED USE

Please remember that **ChM**'s EZO-02 electronic dual tourniquet control unit is a device that is powered by electricity. Take all precautions necessary when using the product to avoid the risk of electric shock.

EZO-02 electronic dual tourniquet control unit is a device that generates and controls the pressure in two independent cuffs or one dual cuff applied on an extremity to produce a bloodless operating field, along with the measurement of the duration of the applied pressure. The built-in compressor and DC battery allow for functioning of the device without its connection to the compressed air and electric AC 230V networks. Thanks to that, EZO-02 can be used during patient's transportation, power supply AC 230V failure and when there is a lack of compressed air network in the facility.

DO NOT use the unit in the presence of oxygen, nitrous oxide or a mixture consisting of flammable anesthetics and air.

1.1.2. PRECAUTIONS IN USE[1]

The EZO-02 electronic dual tourniquet control unit can only be used after careful consultation of the product's Instructions for Use. It is recommended that an alternative *(spare)* device and mating elements be available during the surgery since unexpected technical problems can occur.

The EZO-02 control unit can only be used by qualified medical personnel familiar with the operation of the device, such as anesthetists, who control the device outside the operating field.

To ensure proper operation of the device, use only **ChM** original accessories. Using accessories of another manufacturers may result in unplanned functioning of the device and loss of warranty rights. The device and its accessories must be in an operable condition. Check them regularly for leaks and other defects.

The EZO-02 control unit is designed to work with two single tourniquets or one dual tourniquet. However, it is still possible for EZO-02 to work with one single tourniquet. In such case, the tourniquet should be connected to the selected terminal *(red or blue)* of the control unit.

1 Should the above-mentioned information be insufficient, please, contact the manufacturer

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Prolonged ischemia caused by tourniquet use may lead to temporary or permanent damage to tissues, blood vessels and nerves. Tourniquet paralysis may result from excessive pressure. Prolonged tourniquet time can also produce changes in the coagulability of the blood with increased clotting time. Insufficient pressure may result in passive congestion of the limb with possible irreversible functional loss.
After the tourniquet has been fully deflated and removed from the patient, the unit should be set to STAND BY mode. Even the slightest impedance of venous return may lead to congestion and pooling of blood into the operative field.

The tourniquets are not deflated in STAND BY mode. Before switching the device to STAND BY mode, ensure that the tourniquets are fully deflated.

DO NOT modify any system components yourself. Failure to follow the above-mentioned can result in injury to the medical staff or operator.

Before each use:

- visually inspect the product,
- check the basic functions of the unit *(inflating, deflating, etc.)*,
- check the battery charge *(use only the fully charged battery for a surgical procedure)*,
- perform the test in accordance with section 2.7 of this manual.

Before using the EZO-02 control unit in surgical procedure for the first time, the device should be cleaned in accordance with section 3 of this manual.

For the EZO-02 control unit to function properly, **ChM** recommends that the device be cleaned after each use in accordance with the instructions provided in the chapter *"CLEANING AND DISINFECTION"*, and if necessary, more often. Following the recommendations provided can considerably extend the serviceable life of the product.

The user of the product is fully responsible for the proper use of the device during the surgery.

DO NOT dismantle or service the product yourself. The product should be sent to the manufacturer for repair. Failure to follow the above-mentioned can result in electric shock or fire.

DO NOT plug in or use the EZO-02 control unit with a voltage other than that indicated on the back panel of the unit.

DO NOT use the device with a damaged cord or plug. The power cord of the unit should be connected to the power supply socket equipped with protective grounding.

Prior to cleaning, ALWAYS unplug the device from the power supply to minimize the risk of electric shock.

For information on electromagnetic compatibility *(EMC)*, go to section ELECTROMAGNETIC COMPATIBILITY of this Instructions for Use.

The application part of the product has a BF-type of protection against electric shock. This product is suitable for use in patients according to EN 60601-1.

To ensure proper functioning of the EZO-02 control unit, **ChM** recommends its annual maintenance. Only trained and experienced personnel of the manufacturer can perform such inspections. The manufacturer shall not be liable for any damage resulting from improper operation or maintenance of the product performed by unauthorized persons.

The main power source of the EZO-02 control unit is an external power supply AC 230V. The internal battery power supply should only be used in case of external power supply failure and for patient transportation. Due to the fact that the battery is a consumable element, it is recommended that the battery be replaced at least once a year, or ad hoc when its reduced functional properties are detected.

The EZO-02 electronic dual tourniquet control unit and its accessories cannot be sterilized. This process can destroy the product.

1.1.3. ACCESSORIES SUPPLIED WITH EZO-02 DUAL TOURNIQUET CONTROL UNIT

The EZO-02 control unit is delivered to a client with the following accessories:

	name	pcs.
	Power cord AC 230V 1.8 m	1
	Tourniquet control unit air hose – blue Cat. No. 30.0035.010	1
	Tourniquet control unit air hose – red Cat. No. 30.0035.020	1

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1.1.4. ADDITIONAL ACCESSORIES OF EZO-02 CONTROL UNIT

1. Tourniquets

No	Product name	The range of use *(limb circumference in cm)*	Dimensions	Cat. No
1	Single arm tourniquet	25÷40	64x13	30.0009
2	Single tourniquet for children	14÷20	50x6	30.0010
3	Single tourniquet for children	14÷20	50x11	30.0011
4	Single femoral tourniquet	38÷58	85x14	30.0012
5	Single femoral tourniquet	38÷58	120x13.5	30.0013
6	Single femoral tourniquet	38÷58	140x13.5	30.0008
7	Conical single femoral tourniquet	40÷60	110x11	30.0014
8	Single arm tourniquet long	38÷58	82x8	30.0015
9	Single arm tourniquet	25÷40	62x7	30.0016
10	Single tourniquet for babies	10÷17	30x3	30.0017
11	Dual tourniquet	38÷58	84x16	30.0018
12	Dual tourniquet	25÷40	64x13	30.0019

2. Mobile stand for tourniquet control units – Cat. No. 30.0040.000

The stand is used as a mobile platform for the tourniquet control unit, as well as the accessories needed to be used with the device, such as tourniquets, skin protection padding, power cords and other accessories.

Technical parameters	
Dimensions *(H/W/D)*	900 x 570 x 570 mm
The height with the control unit	1100 mm
Weight	9 kg

Tourniquets and stand are additional accessories of the EZO-02 control unit and are offered as a separate accessory. Prior to use, consult Instructions for Use supplied with these products.

1.2. TECHNICAL PARAMETERS

Power supply	100-240 [V], 50/60 [Hz]
Power consumption	65 [VA]
Battery Type	Li-Ion 14.8V *(fully charged battery is sufficient for approximately 120 minutes of the device work)*
Output pressure *(in tourniquet)*	100-600mmHg with 10mmHg increments
Work factor	Compressed air *(compressed by built-in compressor)*
Mode of operation	Continuous operation
Degree of protection against electric shock	Type BF applied part, EN 60601-1
Ingress Protection Rating	IPX0, EN 60529
Directive 93/42/EEC classification	IIa
Pressure accuracy	± 8mmHg
Alarm time setting range	1-240min *(counting down/ counting up)* with 1min. increments
Type of protection against electric shock	Class I or Internally Powered Equipment *(When the unit is operating on backup battery, the type of protection against electric shock changes to internally powered equipment)*
Internal Diagnostics	pressure system, emergency power supply
EMC	EN 60601-1-2
Applicable standards	EN 60601-1
Dimensions-base	21cm x 21cm
Height	21 cm
Weight	3.8 kg
Volume of sound signals	45-85 dB

1.3. FUNCTIONAL PARAMETERS

- fast inflation and deflation of a tourniquet,
- emergency power from the internal battery activated at the time of external power supply failure,
- the microprocessor monitors the pressure in the tourniquets and alerts the operator about the potential hazards to the patient using audible and visual means,
- alarms: leakage of the pneumatic system, discharged battery,
- the elapsed time is signaled every second,
- large display for controlling the parameters from a distance,
- possibility of performing pressure test with tourniquets,
- automatic timer activated at tourniquet inflation and deactivated at its deflation,
- compact, robust housing,
- easy to keep clean.

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1.4. ADVERSE EFFECTS

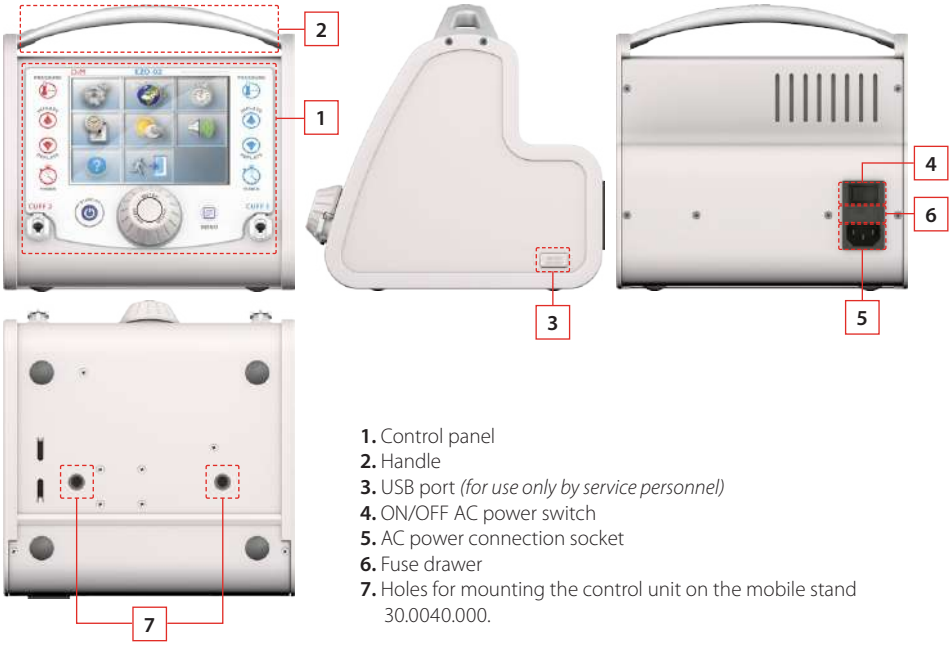
A dull aching pain may develop throughout the limb following the use of tourniquet. Pathophysiologic changes due to pressure, hypoxia, hypercarbia, and acidosis of the tissues occur and become significant after about 1.5 hours of tourniquet use. Symptoms of tourniquet paralysis are motor paralysis and loss of sense of touch, pressure, and proprioceptive responses.

Intraoperative bleeding may be caused by:

- the slight impeding effect exerted by an unpressurized tourniquet *(and its padding, if used)* which prevents venous return at the beginning of the operation.
- blood remaining in the limb because of insufficient exsanguination.
- inadequate tourniquet pressure *(between systolic and diastolic blood pressure of the patient)*, or slow inflation and deflation that allow arterial blood to enter while preventing venous return.
- blood entering through the nutrient vessels of the long bones, such as the humerous.

2. OPERATING THE EZO-02 CONTROL UNIT

2.1. CONSTRUCTION



1. Control panel
2. Handle
3. USB port *(for use only by service personnel)*
4. ON/OFF AC power switch
5. AC power connection socket
6. Fuse drawer
7. Holes for mounting the control unit on the mobile stand 30.0040.000.

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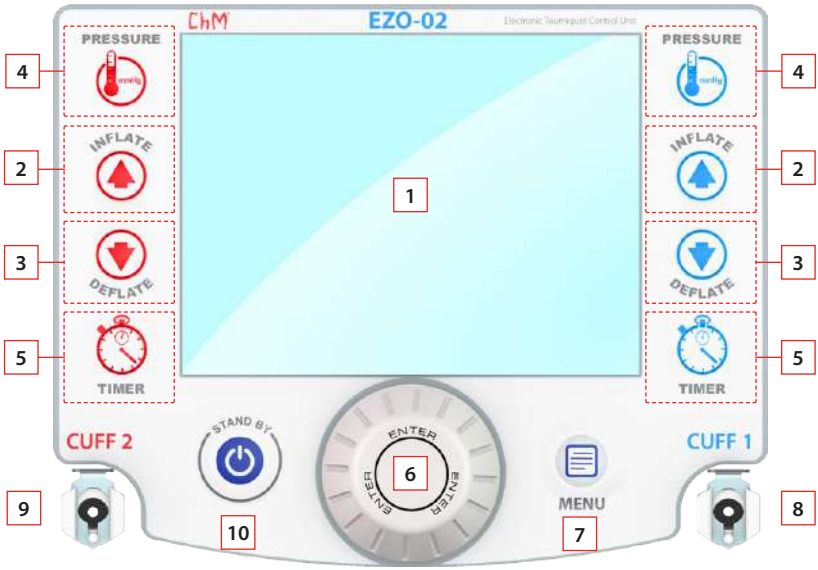
2.2. CONTROL PANEL



1. LCD display
2. INFLATE button – inflate tourniquet 1 or 2
3. DEFLATE button - deflate tourniquet 1 or 2
4. PRESSURE button - set the pressure for the tourniquet 1 or 2
5. TIMER button – set the time alarm set point for the tourniquet 1 or 2
6. Control knob – set the parameters and confirm *(ENTER)*
7. MENU button – EZO-02 control unit options
8. Tourniquet 1 connection port
9. Tourniquet 2 connection port
10. STAND BY button

2.3. INITIAL CONTROL

Unpack the EZO-02 dual tourniquet control unit upon receipt and inspect the unit for any obvious damage that may have occurred during shipment. If the unit is damaged, notify the carrier and your **ChM** representative immediately. If the initial inspection results are satisfactory, an auto-test should be performed after a 3-hour charge.

If, after 3 hours of charging, the battery level does not exceed 90%, the battery should be considered defective. EZO-02 control unit should be sent to the manufacturer for repair.

Have the spare device prepared prior to the surgery. In case of failure of the EZO-02 control unit, pressure drop or uncontrolled operation, the device should be disconnected from the tourniquet, unplugged and another functional device or the tourniquet control system should be used. Send the defective unit to the manufacturer.

To avoid the risk of electric shock, the unit must only be connected to a power supply with protective grounding.

If there are doubts as to the continuity of the power cord or the protective earth system in the electrical system, do not use the control unit due to the risk of electric shock as a result of the lack of basic safety measures. Carefully use the power cord and plug to avoid damaging the cord and socket which could result in electric shock. In case of any damage to the power cord and/ or the plug, do not use the device.

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2.4. CONTROLS AND INDICATORS

The display is divided into two parts, distinguished by colours, to facilitate reading and setting parameters for an individual tourniquet:

- The left, red side of the screen displays the values for the tourniquet attached to the left red connection port labeled CUFF 2.
- The right, blue side of the screen shows the values for the tourniquet attached to the right blue connection port labeled CUFF 1.

Such marking ensures that the EZO-02 control unit operator does not make an error at the moment of reading or setting parameters of the device.

- Set pressure section – 0 mmHg
- Set inflation duration section – 0min ^{00sec}
- Timer mode - count up, - count down

Power source		
1		mains ~230 VAC
2		internal *(battery)*

Control panel elements		
	STAND BY button	Turns the device on or switches the unit to standby mode. The button does not switch the unit to standby mode until the pressure in the tourniquets is zero. Before switching the unit to standby mode, make sure that the tourniquets are fully deflated and removed from the patient along with the possible underlying bandages or protective sleeves. **NOTE: In STAND BY mode, the power supply and all functions of the unit** *(e.g., inflating, deflating)* **are off, but the battery is charged at all times when the unit is connected** *(plugged)* **to the mains supply ~ 230VAC and the power switch is ON.**
	MENU button	The button allows for changing device options.
	Control knob	Changes the inflation duration or pressure introduced. Turn the knob clockwise to increase the value; turn the knob counterclockwise to decrease the value. Press the knob to confirm the selected value. The knob is also used to navigate through menu options.
	PRESSURE buttons	Press to modify the introduced pressure for the respective tourniquet
	TIMER buttons	Press to modify the introduced inflation duration for the respective tourniquet.
	INFLATE buttons	Tourniquet inflation begins by pressing the INFLATE button assigned to the selected tourniquet.
	DEFLATE buttons	Tourniquet deflation starts by pressing the DEFLATE button assigned to the selected tourniquet. **NOTE: For safety reasons, the DEFLATE buttons function with delay and must therefore be held pressed for at least 2 seconds before the unit starts to deflate the tourniquet.**

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LCD display elements		
	External power supply indicator ~230V/50Hz	The mains power icon located on the right top of the display indicates that the device is connected and powered from the external power supply. This is normal operational mode *(battery power is considered emergency power used only in the case of external power failure or patient transportation).*
	Battery charging indicator	External power supply indicator on the right top of the display gradually fills when the battery is being charged while the unit is connected to the mains and the switch is in the ON position.
	Battery indicator	When: • the external power supply fails or • the EZO-02 control unit has not been plugged in to the power supply or • the switch on the back panel of the device is OFF, the unit will automatically switch into the battery power mode. The battery icon in the right upper corner of the display indicates that the unit is operating on the emergency power supply. The charge level of the battery is shown as a bar inside the battery symbol. The bar changes its length with the change of the battery charge level. When the battery charge level exceeds the <40% threshold, the color of the bar changes from green to red.
	Battery charge level	battery charge level 100%
		battery charge level about 75%
		battery charge level about 50%
		battery charge level <40%
		battery charge level below 15%
		The *„empty"* icon indicates that the battery charge level is low which means that the device may switch off at any time. The user of the unit is informed about this condition cyclically through an audible *(short signal)* and visual *(the control knob light begins to flash)* alarm. Plug the EZO-02 control unit to the ~230VAC power supply and start the charging process.

LCD display elements

Pressure display

Display area showing the current air pressure in two pneumatic channels. In other operating modes, depending on the alarm conditions and active functions, the display may show other information such as alarm messages or pressure settings.

Time display

Display area showing the current tourniquet inflation duration when the device is in the mode of tourniquet pressure holding. In other situations, the display may show other information, such as alarm messages or time settings.

Other elements of the device

Tourniquets connection ports CUFF1 and CUFF2

Tourniquets connection ports allow for fast connection of dedicated tourniquets.

ChM does not recommend using other than ChM tourniquets.

USB port

USB port for maintenance purposes only.

NOTE: it is forbidden to remove the plug and perform any operation during normal use of the control unit.

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2.5. MENU

MENU button

Press the button to change the device options.

Having positioned the option indicator, press the knob that functions as ENTER.

NOTE: It is not possible to enter the Menu when the tourniquet is inflated.

Menu window

2.5.1. DESCRIPTION OF AVAILABLE MENU OPTIONS

Icon	Description	Window
	**Testing** It is possible to check the tourniquets: • left, • right, • both.	
	**Language** It is possible to select the language used in the device. The options are: • Polish, • English, • Russian, • German, • Spanish.	

Icon	Description	Window
	**Timer** It is possible to change the inflation duration settings. Options are: • count down *(from set value to zero)*, • count up *(from zero to the set value)*.	
	**Date / Time** It is possible to change the date and time displayed on the device screen.	
	**Screen brightness** It is possible to adjust the brightness of the screen from 0 *(minimum screen brightness)* to 35 *(maximum screen brightness)*.	
	**Alarm volume** It is possible to adjust the volume of the alarms from 0 *(minimum volume)* to 16 *(maximum volume)*.	

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Icon	Description	Window
	**Information about the set parameters of the device** Displays information about the basic parameters of the device: • screen brightness, • alarm volume, • timer *(count down or count up)*, • time *(time and date)*.	
	**Exit menu** Allows to exit the menu, go to the working screen, and start using the device.	

2.6. INITIAL SETTINGS

To avoid the risk of electric shock, the unit must only be connected to a power supply with protective grounding.

The unit is equipped with an IEC power supply socket with an integrated fuse socket *(fuse type: 2 x 250V T2.0A)*. Before using the unit for the first time, plug the unit in for 3 hours to the power supply *(AC)* and set the power switch of the device ON.

During transportation and storage, the battery of the device may become discharged.

2.7. TESTING

Connect the power cord AC *(provided with the device)* to the socket on the back of the control unit and then to the power supply socket equipped with protective grounding and of specification *(voltage and frequency)* according to technical data. Set the power switch of the device ON. Turn on the device by pressing the STAND BY button located on the control panel. Internal auto-test will be activated. Afterwards, the main window will be displayed.

If an internal auto-test result is negative, an error message will appear on the screen. Further work with the device will not be possible. Contact the device manufacturer.

Connect the **ChM** tourniquets using spiral air hoses supplied with the EZO-02 control unit to the tourniquet

connection ports located on the control panel. Roll up the tourniquets tightly and secure against unrolling. Then enter the Menu and select Testing. During the testing, the tourniquets will be inflated and the device will check the tightness of the system: control unit – tourniquet*(s)*. If the system is tight, the testing will end with a PASS sign - the control unit and tourniquet*(s)* can be used during the procedure. Displayed FAILD sign indicates that the system is not tight. Check the condition of the tourniquets, air hoses, pneumatic connectors and their connection. Eliminate leaks if possible *(e.g. replace defective tourniquet or air hose)*. Run the test again. Once the system has passed the test, the device is ready to work. If the system testing fails again, contact the manufacturer.

Should it be impossible to remove or detect the leaks, it is strictly forbidden to use the set: control unit-tourniquet for surgery. Only the set with positive test results *(PASS displayed)* **can be used for surgery.**

For testing, use tourniquet*(s)* **that will be used during the procedure. When replacing the tourniquet, the testing should be repeated.**

2.8. WORK WITH A TOURNIQUET

Press the STAND BY button to turn on the device. Connect the tourniquet to the control unit using appropriate tourniquet connection port.

Perform the diagnostic test *(tightness of the system)* as described in Section 2.7 of this manual. Successful completion of the diagnostic test means that the device is ready for use.

When switching on the EZO-02 control unit, the most recently set pressure and inflation duration are loaded from the device memory. Apply the tourniquet on a limb, keeping in mind that the pneumatic air hose must be free of bends. Set an occlusion pressure required to close the blood flow to the operating site as the minimum effective pressure for each patient individually. The minimum effective pressure should be determined on the basis of such factors as:

- the location of the tourniquet applied *(upper or lower limb)*,
- the patient's systolic blood pressure before surgery and
- the maximum predicted increase in systolic blood pressure during surgery.

Press INFLATE button in the control panel section to which the tourniquet is attached *(red or blue)* to start inflate the cuff. The device will inflate the selected tourniquet to the set pressure and will activate the time elapsing until the alarm is triggered. If change in pressure or inflation duration is required, these modifications can be introduced when the tourniquet has been inflated. The information on the inflation level of the selected cuff will be displayed on the LCD screen. If the device cannot inflate the tourniquet within ± 15 mmHg from the set value in less than 10 seconds, a leak alarm will be emitted. For information on possible alarm conditions, see Section 2.10. When the set time has elapsed, a sound alarm will be activated. If the cuff is not deflated or the new inflation duration is not set, the clock will start counting up from 00.

At the end of the surgical procedure, deflate the tourniquet by pressing the DEFLATE button of the corresponding cuff and holding it pressed for at least 2 seconds. The PRESSURE display of the respective cuff will indicate its deflation process and the inflation duration alarm will stop.

Immediately, when completely deflated, remove the tourniquet along with the underlying bandages or protective sleeve from the patient and disconnect it from the device. Switch the unit to STAND BY mode.

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Work with two tourniquets

Work of the device with two tourniquets does not differ in any significant way from working with one cuff. Connection of the other tourniquet, adjustment of the pressure parameters and further operation is the same as for the first cuff.

The only difference is that the operator is obliged to carefully and correctly connect the tourniquets to the defined connection ports. To facilitate this task, the tourniquet connection ports are marked CUFF1 and CUFF2 respectively. In addition, the display screen has been divided into two parts distinguished by colors corresponding to the connection ports, and the functional buttons have been also marked with colors.

Inflation of a loose, not applied on a limb or tightly rolled up tourniquet may result in its damage.

This is the surgeon that decides on the parameters to be set *(pressure, pressure duration, etc.)*, the location of the cuff to be applied, the inflation and deflation time, and other parameters.

2.9. TIMER

The duration of the occlusion applied can be controlled in two modes:

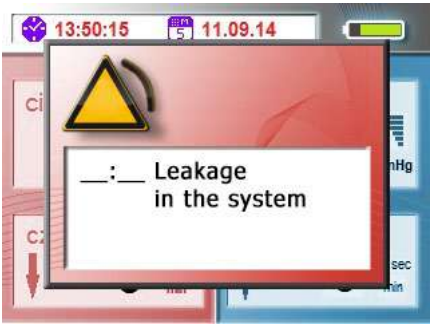
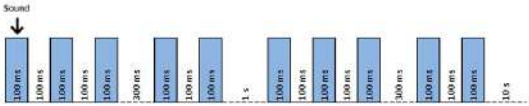
- countdown mode – range from 240 min. to 1 min., with sound alarm when the set time has elapsed. If the tourniquet is not deflated after 240 minutes, the timer will switch into count up mode.
- count up mode – from 0 to 240 min.

To change the timer mode, enter Menu.

Elapsed occlusion time does not deflate the tourniquet

2.10. ALARM AND INFORMATION SYSTEM

The EZO-02 dual tourniquet control unit has been equipped with an alarm and information system informing the user of important parameters or abnormalities occurring during operation of the device.
Tables below list the reasons for a message, the type of a message, and the action to be taken.

Alarm	Description	
Alarm **Leakage in the system**	During operation of the unit and maintaining the pressure, the selected pressure may not be reached or changes rapidly. This condition may be caused by: improper installation of the tourniquet, damaged tourniquet, damaged air hose or internal leakage of the pneumatic system. If the system is not able to reach the set pressure within more than 10 seconds since beginning of inflation, the device will generate an alarm signal in the form of a message on the display and a sound. The alarm is emitted without delay. The graphic message includes a general alarm symbol, information about the state, possible solutions, and the time of the alarm. The alarm must be cleared by the operator's conscious decision - by pressing the control knob *(ENTER)*.	
	Graphic message	
	Sound message	
	Appropriate action	Check the tightness of the hoses, tourniquets and all connections between the tourniquets and the control unit. Remove the leaks. If it is not possible to remove the leaks, depending on the location of the leakage, use a different tourniquet or device.

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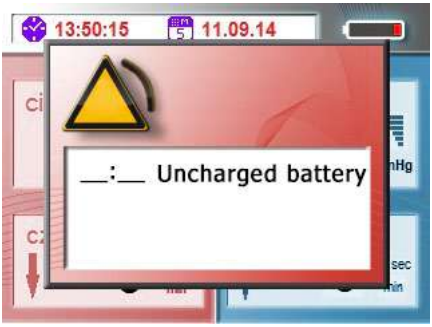
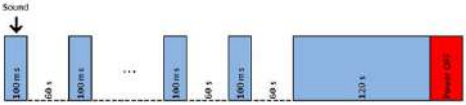
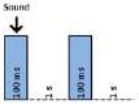
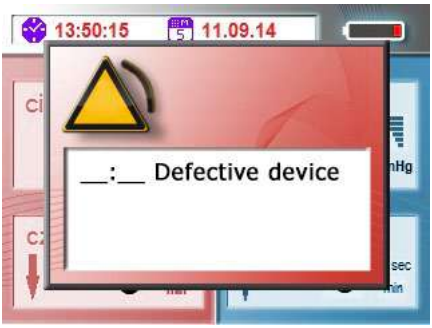
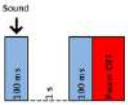
Alarm	Description	
Alarm Uncharged battery	When the device is powered from the internal power source and the low battery level is detected, the device will notify of this state 60 seconds after its detection by displaying a graphic message and emitting a sound. The graphic message includes a general alarm symbol, information about the state, possible solutions, and the time of the alarm. The sound alarm cannot be turned off and is repeated every 60 seconds. When the battery is exhausted, a signal lasting 120 seconds is emitted and the unit turns off. When connected to the external power supply, the alarm must be cleared by the operator's conscious decision- by pressing the control knob *(ENTER)*.	
	Graphic message	
	Sound message	
	Appropriate action	Start the process of battery charging; plug in the unit to the AC 230V 50Hz power supply, set the switch on the back panel of the device ON. If not plugged in, the device will switch off in safe mode with all valves closed.

Information	Description	
Information Occlusion time has elapsed	During operation of the device and when the occlusion time has passed, the device signals the operator by issuing sound messages. An audio message can be muted or its volume can be modified in the device settings.	
	Sound message	
	Appropriate action	The action depends on the surgeon's decision - it is possible to continue the occlusion applied or to deflate the tourniquet.

Information	Description	
Information Defective device	At each startup, an internal test is performed to verify the correct operation of the critical components of the device. If the result of the internal test is negative, a message will be displayed and a sound signal will be emitted. Pressing the control knob - ENTER - turns the unit off. If the result of the internal test is positive, the device will automatically go to the main menu and be ready to work. At the same time, during the internal test, the device activates the sound generator for about 1 second to determine its functioning - the result is positive when the operator has heard the sound. If the operator has not heard the sound, repeat the test *(turn the unit off and on again)*. Contact the manufacturer of the device if the test fails again.	
	Graphic message	
	Sound message	
	Appropriate action	Should this information appear, contact the manufacturer of the device.

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3. CLEANING AND DISINFECTION

Before cleaning or disinfection, disconnect the device from 230V network!

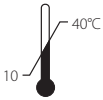
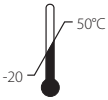
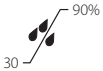
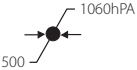
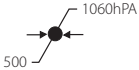
The outer surfaces of the device should be cleaned with a soft, moistened *(not dripping)* with a mild detergent solution cloth then wiped dry. In case of contaminating the housing of the device with infectious agents *(blood, body fluids, etc.)*, disinfection using disinfectants with a neutral pH is recommended. In such cases, soak a soft cloth in disinfectant, wipe the housing and allow it to dry.

Do not allow the detergents or disinfectants to enter inside the device housing. Should the detergents or disinfectants enter inside the device housing, switch the device off, disconnect from 230V network and send it to the manufacturer for cleaning processes.

The EZO-02 unit control should NOT be sterilized.

4. STORAGE

Store and use the product under the conditions provided below:

Environmental Conditions		
	Operation	Transportation and storage
Temperature		
Relative humidity		
Atmospheric pressure		

5. WARRANTY AND SERVICE

When servicing, warranty and post-warranty repairing is concerned, please contact the manufacturer's representative or **ChM** directly:

ChM sp. z o.o.
Lewickie 3b
16-061 Juchnowiec Kościelny, Polska
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fax: +48 85 86 86 109
e-mail: chm@chm.eu
www.chm.eu

Do not repair or replace parts of the EZO-02 electronic dual tourniquet control unit by yourself! The changes made will render the warranty void.

The warranty does not include product damage due to: negligence, inappropriate usage, usage not in accordance with the intended purpose, mechanical damage.
Accessories and spare parts are presented in **ChM**'s catalogues.
Warranty and non-warranty services are to be handled solely by the manufacturer - **ChM**.

It is recommended to perform technical inspection and calibration of the device at the manufacturer's site at least once every 12 months.

6. THE LIFETIME AND DISPOSAL

ChM sp. z o.o. does not define the maximum number of uses for the EZO-02 dual tourniquet control unit. The useful life of the device depends on many factors including the method and duration of each use, applied cleaning and disinfection and the handling between uses. Nontheless, the lifetime of the EZO-02 control unit is assumed for 10 years. After this period, the product should be sent to the manufacturer in order to: determine the device further suitability for use, perform maintenance works, repairs or to recommend the user to purchase a new unit. The device should be disposed of in accordance with the applicable electrical and electronic equipment law.

The battery is a consumable element that is subject to gradual wear even when used properly. It is recommended that the battery be replaced at the manufacturer's service at least once every 12 months, or ad hoc when its reduced functional properties are detected.

Worn-out lithium-ion battery must be disposed of in accordance with the current law on waste electrical and electronic equipment.

7. TROUBLESHOOTING

The following table lists some potential problems that may occur while using the device. For each problem, the most likely causes are provided.

If any other problems than the ones listed below have occurred or if the suggested actions have not solved the problem, please contact the manufacturer.

DO NOT perform repairs on your own unless otherwise stated in this manual.

Problem	Possible causes	Solution
Accidental or unintended operations of the device	Device driver wet due to improper cleaning	Send to **ChM** service
	System error	Send to **ChM** service
	System failure	Send to **ChM** service
	Overheating of the device	Send to **ChM** service
	Strong electromagnetic interference	Turn off all electrical equipment not in use.
		Change the location of electrical equipment.
		Plug in electrical equipment to other available outlets.
	Exceeding the declared lifetime of the device *(10 years)*	Send to **ChM** service for checking the further usefulness of the product
No response of the device to the set parameters	System failure	Send to **ChM** service
	System hang-up	Turn the device off and then back on
	Overheating of the device	Send to **ChM** service
Tourniquet does not inflate	The air hose may be bent or incorrectly connected	Check the hose and the connection
	Damaged tourniquet	Replace the tourniquet for a new one
	Damaged pneumatic circuit	Send to **ChM** service.
	Damaged air hose	Replace the air hose for a new one
	System failure	Send to **ChM** service
Tourniquet does not deflate	The air hose may be bent or incorrectly connected	Check the hose and the connection
	Damaged tourniquet	Replace the tourniquet for a new one
	Damaged air hose	Replace the air hose for a new one
	System failure	Send to **ChM** service
Dropping of the device	System failure	Send to **ChM** service
	Display damage	Send to **ChM** service
	Battery damage	Send to **ChM** service
	Appearance of dangerous voltage on the device housing	Send to **ChM** service
	Damage to the power cord	Replace the power cord for the new one
	Damage to the air hose	Replace the air hose for the new one

Problem	Possible causes	Solution
Unit does not turn ON.	Unit not plugged in and battery fully depleted	Plug in the unit
	The unit is plugged in but the switch is OFF and battery is fully depleted	Turn the switch ON
	Damaged power cord	Replace the power cord for the new one
	Battery failure	Send to **ChM** service
	System failure	Send to **ChM** service
The device does not maintain the set pressure	The air hose may be bent or incorrectly connected	Check the hose and the connection
	Damaged tourniquet	Replace the tourniquet for the new one
	Damaged air hose	Replace the air hose for the new one
	System error	Send to **ChM** service
	Exceeding the declared lifetime of the device (10 years)	Send to **ChM** service for checking the further usefulness of the product
Tourniquet cannot be connected to the unit	Damaged air hose	Replace the air hose for the new one
	Non-**ChM** tourniquet used	Use only **ChM** tourniquets
Discoloration and scratches on the surface of the device	Use of detergents other than those recommended by the manufacturer	Consult the Instructions for Use of the unit
	Overheating of the device	Send to **ChM** service
	Exceeding the declared lifetime of the device (10 years)	Send to **ChM** service for checking the further usefulness of the product
Unit switches off	Battery fully depleted	Charge the battery
		Replace the battery for the new one in the manufacture's service
	System error	Send to **ChM** service
	System failure	Send to **ChM** service
	Strong electromagnetic interference	Turn off all electrical equipment not in use
		Change the location of electrical equipment
		Plug in electrical equipment to other available outlets
Too short battery life	End of battery life	Send to **ChM** service
		Consult the Instructions for Use of the unit
	Failure to follow manufacturer's instructions	Send to **ChM** service
		Consult the Instructions for Use of the unit
	Exceeding the declared lifetime of the device (10 years)	Send to **ChM** service for checking the further usefulness of the product
Information cannot be read from the device display	Display failure	Send to **ChM** service
	System failure	Send to **ChM** service
	System error	Send to **ChM** service
Unit cannot be set to STANDBY	Pressure sensed in tourniquet	Deflate the tourniquet
	System failure	Send to **ChM** service
Alarm indicating a leaking system	The air hose may be bent or incorrectly connected	Check the hose and the connection
	Damaged tourniquet	Replace the tourniquet for a new one
	Damaged pneumatic circuit	Send to **ChM** service
	Damaged air hose	Replace the air hose for a new one
	System failure	Send to **ChM** service

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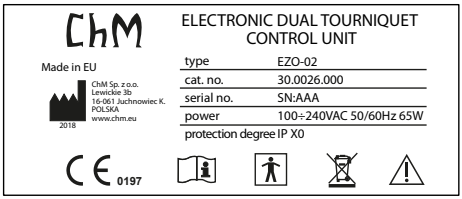
Problem	Possible causes	Solution
Alarm indicating discharged battery	Battery fully depleted	Charge the battery
	Battery failure	Send to **ChM** service
	System failure	Send to **ChM** service
No external power supply icon when the device is plugged in	The device is not plugged in	Plug in the device
	Damaged power cord	Replace the power cord for the new one
	The switch is OFF	Switch ON
	No mains voltage	Check the voltage in the mains
	System failure	Send to **ChM** service
The battery does not charge	The device is not plugged in	Plug in the device
	The unit is plugged in but the switch is OFF	Turn the switch ON
	Battery failure	Send to **ChM** service
	System failure	Send to **ChM** service
Possible electrical shock	Damage to the power cord	Send to **ChM** service
Electrical interference	Occurrence of electrical noise	Turn off all electrical equipment not in use
		Change the location of electrical equipment
		Plug in electrical equipment to other available outlets
The unit has been sterilized	Staff negligence	Send to **ChM** service
	Negligence of Instructions for Use supplied with the product	

8. EXPLANATION OF SYMBOLS USED

Symbol	Meaning	Description
	Do not discard the product with household waste	Worn devices and other electrical products must be collected separately and disposed of in accordance with the applicable electrical and electronic equipment law.
	Classification Type BF	Degree of protection against electric shock.
CE 0197	European conformity mark with the notified body number	Conform to the European Medical Device Directive 93/42/EEC for class IIa medical devices *(notified body number)*
	Instructions for Use	Prior to first use, consult Instructions for Use
IPxx	Protection degree	Ingress protection degree
	Caution	Read the provided Instructions for Use before operating the device.
	General alarm	Alarms emitted while operating the device
	Manufacturer/ Date of manufacture	The address of the device manufacturer and the date of manufacture of the device.

9. LABELS AND WARNINGS



Name plate

Warnings on the housing

Danger!
Risk of electric shock.
Do not remove the cover.
Repairs may be performed by qualified service personnel only.

Danger!
Explosion hazard.
Do not use in the presence of flammable gases.

Caution!
Use in the safe place and avoid any accidental damage.

Notice!
To be used by trained personnel only.
Power supply 230V/50Hz.
Battery only for use during power emergency or patient transportation.

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10. ELECTROMAGNETIC COMPATIBILITY

The EZO-02 unit is intended for use in an electromagnetic environment specified below. The customer or the user of the product should assure that it is used in such the environment.

10.1. ELECTROMAGNETIC EMISSIONS

Emission test	Compliance	Electromagnetic environment – guidance
RF emissions, CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emission is very low and it is not likely to cause any interference in nearby electronic equipment.
RF emissions, CISPR 11	Class B	The 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	Comply	

10.2. ELECTROMAGNETIC IMMUNITY

Immunity test standard	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge *(ESD)* IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be made from wood, concrete or ceramic tile. If floors are covered with a 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 in/ out lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±1 kV line to line ±2 kV line to earth	
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	<5% Ut *(0.5 cycle)* 40% Ut *(5 cycles)* 70% Ut *(25 cycles)* <5% Ut *(5 seconds)*	<5% Ut *(0.5 cycle)* 40% Ut *(5 cycles)* 70% Ut *(25 cycles)* <5% Ut *(5 seconds)*	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires its continuous use even during power outages, it is recommended that the device be connected to an emergency power supply. Ut - mains supply voltage
Power frequency *(50/60 Hz)* magnetic field IEC 61000-4-8	3A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Immunity test standard	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	V1 = 3V/m 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = 1.20 √P d = 1.20 √P 80 MHz to 800 MHz d = 2.30 √P 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts *(W)* according to the transmitter's data provided by the 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	3 V/m 80 MHz to 800 MHz 3V/m 800 MHz to 2.5 GHz	E1 = 3V/m 80 MHz to 800 MHz E2 = 3V/m 800MHz to 2.7GHz	

a) Field strengths from fixed transmitters, such as base stations for radio telephones *(cellular/ cordless)* 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, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

b) For the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

10.3. SEPARATION DISTANCES

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters *(m)* can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts *(W)* according to the transmitter's data provided by the manufacturer.

Rated maximum output power of transmitter *(W)*	Separation distance according to frequency of transmitter *(m)*		
	150 kHz to 80 MHz d = 1.20 √P[m]	80 MHz to 800 MHz d = 1.20 √P[m]	800 MHz to 2.5 GHz d = 2.30 √P[m]
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.20	1.20	2.30
10	3.80	3.80	7.30
100	12.00	12.00	23.30

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