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1. Introduction

2. Basic technical parameters

Power supply:	9V DC batteries /type 1604,6F22/
Size:	120 x 60 x 35 mm
Weight:	120g
Basic energy consumption	15mA \pm 25%
Impulse amplitude regulation	fluent (0-max.)

3. Important warning

- for your safety and for the correct functioning of this device.

Any manipulation with a dismantled device is forbidden. In addition to that, the device is sealed and any violation of it during the guarantee time causes lost of your right to free repair.

4. Control elements

4.1 Switching on and off

You can switch the monitor on using a button marked (ZAP-VYP) (ON-OFF) which is placed on the right side of the device. The ON position is signalled by a LED marked (BATÉRIA)(Battery).

4.2 Button 1 x / s

After pushing this button, the device will produce a chain of impulses each after 1s \pm 25% time delay.

4.3 Button S T O P

will finish the function 1X/s. The device is in the stand-by position.

4.4 Button TOF - 4x

After pushing this button, the device will produce a chain of four impulses , each after 0.5s \pm 25%.

4.5 Button 100 Hz

Pushing of this button will start a series of impulses at a frequency of 100Hz \pm 25% .

4.6 Output impulse level regulation

Pushing a potentiometer marked (INTENZITA) you can regulate the output impulse amplitude fluently from 0 to maximum level.

5. Signalisation elements

(BATÉRIA) red coloured LED signalizes the power supply condition. In case of twinkling it is necessary to change the battery./cca 6.6 V/.(IMPULZ) yellow LED signalizes the course of output impulse.

6. Block-scheme description

Driving impulses for the executive component are produced by the IO NA 556 impulse generator. This generator is capable to produce three kinds of impulses. Pushing the 100 Hz button it will start to produce a series of impulses at a certain frequency of 100 Hz. The 1X/s button activates a special bistable /BKO/ circuit, which subsequently activates the generator producing a series of impulses at 1 Hz frequency. The (STOP) button is capable to wipe out the BKO circuit and thus to stop the generator. Pushing the TOF button you will activate a monostable /MKO/ circuit which will subsequently activate the generator, producing impulses at a frequency 2 Hz. The MKO circuit will be exhausted after four impulses and the generator will be then set to stand-by position. The executive component is equipped with a PNP (Darlington) transistor which rouses up the output transformer which secondary part is connected with an output impulse amplitude regulator.

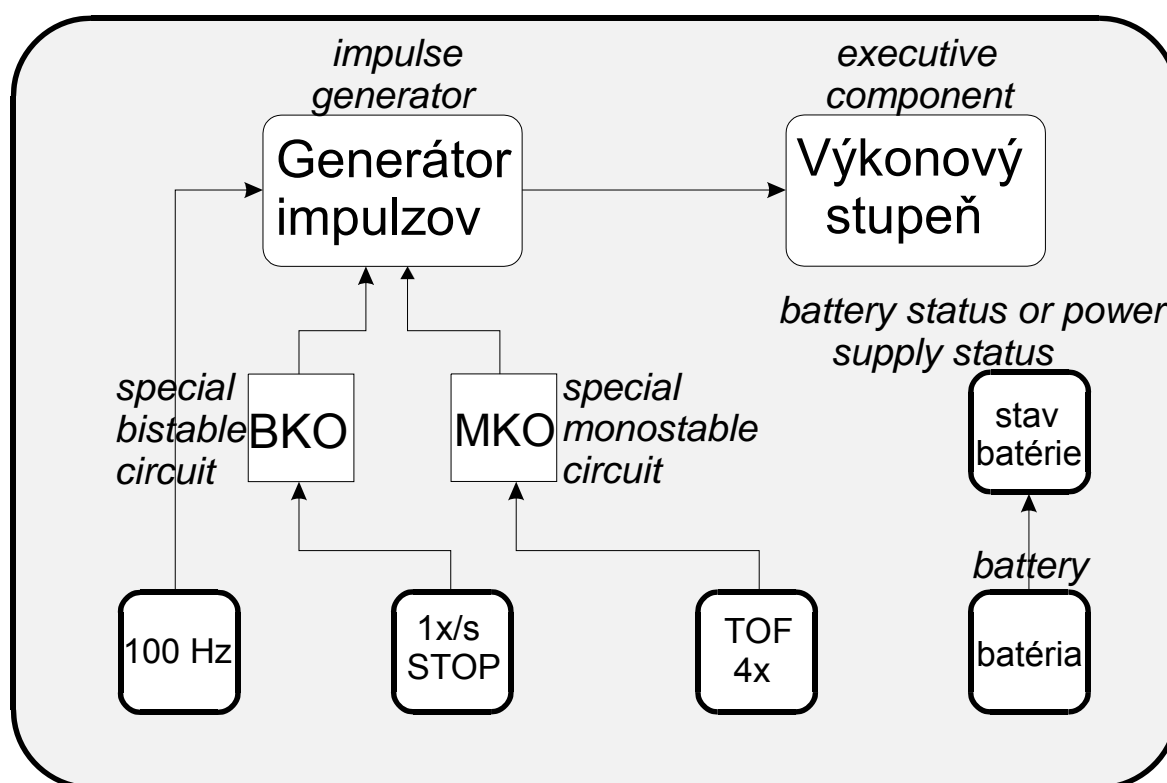
Battery status signalisation is created by a NE 556 circuit and it signalizes the battery voltage decrease to the level of cca 6.6 V.

7. Accessories

Double bicolour wire, lenght of 1 m, its crossection is 0.75 mm^2 , ended with a Jack , and a patent connector on the opposite end. The patent connector should be attached to disposable ECG electrodes. These electrodes should be positioned somewhere above the course of a thick nerve, which is easy to stimulate electrically /see the clinical direction for use/.

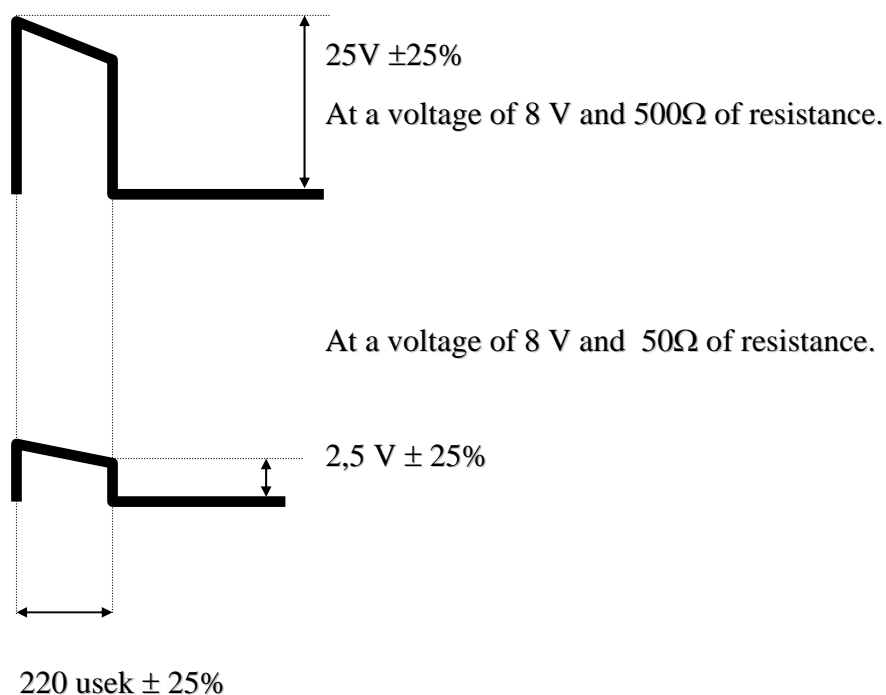
8. BLOCK SCHEME

Appendix No 1



9. Output impulse course

Appendix No 2



10. Completeness list, guarantee and post-guarantee service

Name	Quantity-pieces
Relaxation monitor	1
Attaching cable	1
Battery 9V	1
Electrodes	50
Direction for use	1

The guarantee and post-guarantee service is provided by KALAS-Považska Bystrica / according to conditions published in the guarantee certificate/.

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Kliniccal **direction for use**

11. General considerations

The MR 1095 muscle relaxation monitor is in matter of fact a programmable generator of electrical impulses / width $0.2 \pm 25\%$ ms/, their amplitude is 10-100 Volts /or their several multiplications/. The value of electrical current ranges from several tenths of mA to several mA-s / according to the level of loading/. Its level depends on the electrical resistance of the skin, thickness of the skin, etc./.

The device itself is supplied by a 9 V battery and it cannot be attachad in any case to AC current. One battery can be used up to 14 days at 5-6 anesthized patients per day. It is also possible to use a rechargeable Ni-Cd battery which can be repeatedly used up to 300 times.

This device is designed for use in the clinical practice and its use is indicated according to the decision of a specialist in anaesthesia or critical care medicine, familiar with nerve-stimulation.

The producer as well as the distributor do not respond to damages caused by its use in other than above listed indications.

Every physician who decide to use this device should read this direction for use and to follow it strictly.

This device may not be connected to AC power supply under any condition!!!

W A R N I N G

Patients with an implanted electronic device cannot be submitted to muscle stimulation without an approval of a specialist physician.

12. Introduction

Monitoring of the relaxation level during and after the general anaesthesia where muscle relaxants have been applied, is one of the basic conditions of safe anaesthesia application.

In routine practice without relaxation monitor, the administration of muscle relaxants is more or less empirical and many times unnecessary., causing overdosage which can further cause avoidable complications in the post-operative period. On the other hand underdosage can worsen working conditions of the surgeon as well as anaesthetist.

The solution is to use a relaxation monitor in his most simple form- that means mechanoscopic observation of the stimulated muscle, its response to the electric stimulating impulse.

Most frequently in clinical practice used to be stimulated n.ulnaris, or n.radialis. It is necessary to observe the response of the stimulated forearm, or hand muscles.

It is possible to apply a single impulse or a system of TOF /train of four/ , which is an application of 4 subsequent stimulating impulses at a frequency of 1-2 Hz, eventually a

series of impulses at a frequency 50-100 Hz . The last mentioned kind of stimulation will cause a muscle cramp /tetania = tetanic stimulation/.

Usually a TOF, followed by a tetanic stimulation lasting 2-3 seconds and another TOF is the most frequently used way of diagnostic nerve stimulation.

Mechanomyoscopic observation of the muscle stimulation accomplished following the way described above enables to evaluate the relaxation level during anaesthesia as well as during weaning from artificial lung ventilation.

Using the above listed sequence of stimulation it is possible to distinguish several kinds of muscle response which represent different levels of relaxation.

1.Normally responding muscle without curarisation -responds to each impulse as well as to tetanic stimulation.

2.Supramaximal block-usually after the administration of a muscle relaxant. There is no reaction at all.

3.Posttetanic potentiation-it is possible to distinguish several levels-the muscle responds to individual stimuli of TOF but only after tetanic stimulation.

4.Non depolarising block-different levels-muscles respond only to TOF impulses, no response to tetanic stimulation, if any, only minimal.

Those above mentioned kinds of response indicate adequate relaxation level which enable comfortable surgery and a problem-less artificial lung ventilation for anaesthetist.

5.Residual relaxation-different level. Muscle responds to the TOF, but after tetanic stimulation becomes exhausted very quickly. After another TOF reacts well again.

6.Satisfactory decurarisation-muscles respond similar way as they used to do before the relaxant administration.

Separate levels of blockade are schematically shown on fig. No.1.

13. Practical application of relaxation monitor.

The MR 1095 relaxation monitor (fig. No.2) consists of the device itself attaching cables and electrodes.

Cables are distinguished by different color, **the red one should be attached to the positive electrode, and the black to the negative electrode.** Electrodes should be stuck on the palmar side of the forearm approximately in a distance of 3-7 cm above the course of n. ulnaris (fig. No 3).

It is possible to stimulate also different nerves, in accordance to anaesthesia literature.

After you have unpacked the monitor, open the back-cover and insert a 9 V battery (R 622 type), then close the cover. Take the attaching cable and its jack connector push into the plug in the upper part of MR 1095.

Switch on the device, the LED signalling the monitor functioning will start to light. In case that the battery power decreases under the acceptable limit, it will start to twinkle. In such case change the battery.

Push the 1X/s button. You will hear an acoustic signal/click/ at a frequency of 1 Hz, indicating stimulation. At the same time the MR 1095 will apply stimulating impulses at the same frequency till the time you decide to push the STOP button.

Each stimulating impulse is accompanied by a twinkle of (IMPULZ) LED

Push the STOP button and the stimulation will stop

Push the 4X button and the MR will apply 4 sequent impulses / TOF/ and stop automatically. Stimulating impulses are indicated optically and acoustically.

Push the 100 Hz button . The MR will apply stimulating impulses at 100 Hz frequency during all the time of pushing the button.

After you have tested the relaxation monitor the way described above, and you had found all the functions O.K. you can stick on electrodes, attach cables (fig.No 3).

Adjust the intensity regulator (potentiometer on the right side of the device, marked INTENZITA) to minimum and switch ON. Then push the 1X/s button and slowly increase the intensity till visible muscle respons occurs (gentle jerking of flexors or fingers movement). The intensity regulating button let in the same position for further applications.

Stimulation depends on many factors and each patient needs different level of stimulation intensity. It is necessary to adjust the intensity of stimulation to individual needs, using a way described above.

After you have adjusted the correct intensity, try TOF and tetanic stimulation application. If there is evrything correctly functioning, adjust MR to STOP regime.

After introduction of anaesthesia and administration of a relaxing agent, the level of relaxation should be verified every 5-10 minutes, depending on what kind of relaxant had been administered.

It is advisable to proceed using a sequence TOF, tetanic stimulation, TOF, as described in the theoretical part of this booklet. **The mechanomyoscopic response should be observed according to fig.No 1**

The MR should be switched OFF between particular stimulations in order to save the battery.

!!! Do not change the position of intensity regulating button once the patient relaxed. The stimulation intensity should be tested before muscle relaxation !!!

Patient must be informed before switching the monitor ON, that he will feel paresthesia as well as gentle jerking and movements of his fingers.

Switch the device OFF before detaching cables and electrodes, then pull the jack connector out.

14. Desinfection and decontamination.

Electrodes which come into the direct contact with patient's skin, are disposable, do not use them repeatedly because of the possible defect of function of the device as well as possible transfer of infection. !!!

MR 1095 could be cleaned using a dampen piece of fabric and detergent solution. Desinfection can be provided by e.g. Sekusept, glutaraldehyd, Cidex, Chloramin etc.

Cables can be also submitted to cleaning and desinfection but after it they should be dried.

It is unacceptable to soak neither the monitor, nor the cables or to pour them over with any liquid.

The surface and the membrane keyboard resist common disinfection agents. Do not use liquids containing organic diluents and or alcohol because they damage the device surface.

15. Fig.No 1. Schematic figure of muscle response to TOF, tetanic stimulation, TOF.

