RTM-01-RES

Microwave Radiometer
Breast and Multiorgan Scan System

Operating manual

res

CE 1023

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High Technology Medical Devices

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1. General Guidelines

The present Operating manual contains the description of device, operating principle, technical characteristics and operating instructions for the **Microwave Radiometer, Breast and Multiorgan Scan System "RTM-01-RES"**

This Operating manual, including specifications, is a User's manual for the **Microwave Radiometer, Breast and Multiorgan Scan System "RTM-01-RES"**

Safety Signs

 **- Refer to user manual/booklet**

 **- General safety sign**

 **- General prohibitory sign**

 **- General warning sign**

 **Read this Operating manual before using the Microwave Radiometer, Breast and Multiorgan Scan System "RTM-01-RES".**

BEFORE FIRST USE

Read and follow all the instructions in this "Operating manual" even if you feel you are familiar with the product, and find a place to keep it handy for future reference.

Your attention is drawn particularly to the section concerning "**IMPORTANT SAFEGARDS**", "**FOR YOUR SAFETY**", and the "**WARRANTY**" statements.

IMPORTANT SAFEGUARDS

When using any electrically powered product, basic safety precautions should always be followed, including the following:

- Always operate the product from a power source of the same voltage, frequency and rating as indicated on the product identification plate.
- Always position the device in a way that the appliance coupler remains easily accessible.
- Always turn the power off at the power outlet before you remove a plug. Remove by grasping the plug – do not pull on the cord.
- Do not use your appliance with an extension cord unless this cord has been checked by your electricity supplier or qualified technician.
- Do not use an appliance for any purposes other than its intended use.
- Do not place an appliance on or near hot gas flame, electric element or in a heated oven. Do not place on top of any appliance.
- Do not let power cord of an appliance hang over the edge of a table or bench top or touch any hot surface.
- Do not operate any electrical appliance with a damaged cord or after the appliance has been dropped or damaged in a manner. If damage is suspected, return the appliance to your supplier for examination, repair or adjustment.
- The device is not resistant to defibrillation.

FOR YOUR SAFETY

To reduce the risk of fire or shock hazard, do not expose this equipment to rain or moisture!

To prevent electric shock, do not remove cover!

No user serviceable parts inside!

Refer servicing to qualified service personnel!

Contents

2. Functions of Microwave Radiometer RTM-01-RES

2.1. The RTM-01-RES is intended for noninvasive measurement the averaged temperature of patients' internal tissues (Internal Tissue Sensor ITS) as well as the skin temperature (Skin Temperature Sensor STS).

It is used in oncology, urology, endocrinology and other medicine fields for the earlier detection of temperature-differentials related to diseases; the monitoring of treatment as well as drugs and physiotherapy procedure effects.

The RTM-01-RES is designed on the basis of advanced achievements in radio reception and microwave technologies. The device has a number of new diagnostic possibilities.

The use of the device is absolutely harmless for both the patient and testing personnel. Therefore, the measurement procedure could be performed repeatedly. The use of the computer enables the improvement of result measurements.

2.2. The RTM-01-RES is intended for performing examinations in health centres and clinics.

2.3. The RTM-01-RES is designed in accordance with UHL 4.2 climate conditions of national standards GOST 15150-69 and shall be used at 19-25°C temperature; atmosphere pressure of 630-800 mm Hg and relative humidity shall be not more than 80%.

2.4. Any electromagnetic interferences must be eliminated.

3. Technical specifications.

3.1. The technical specifications of the RTM-01-RES are the following:

Tab.1

Power supply	220 -240 V, Single-phase, 50-60Hz
Power consumption, VA, max	15
Internal temperature range, °C	32…38
Surface temperature range, °C	30…38
Internal temperature measurement accuracy, °C, max	±0.3
Skin temperature measurement accuracy, °C, max	±0.2
Maximum measurement time with the internal temperature sensor, when the measured temperature is 32 - 38°C, sec, max	10
Maximum measurement time with the surface temperature sensor, when the measured temperature is -30-38°C, sec, max	2
Fuses	Fast blow electric fuse, 0.16A, 250VAC, 35A (IR), 0.01 sec; INLINE/HOLDER
Dimensions:	
Data Processing Unit (DPU), mm	342x257x135
Internal temperature sensor (ITS), mm	250x65x50
Surface temperature sensor (STS), mm	250x65x50
The set weight excluding a PC and a printer, kg, max	8.6
Applied parts:	
Internal temperature sensor (ITS)	
Surface temperature sensor (STS)	

Medical Device Lifetime (ISO/TR 14969:2004 relationship to ISO 13485). "Expected shelf life of a "Microwave radiometer RTM-01-RES" means the time that a device is expected to remain functional after it is placed into use. According to the placing of initial devices on the market, the manufacturer declares minimum 5 years lifetime of the devices. Some accessories implanted to device has specified without "end of life" (EOL) dates. Other accessories or device (software) are not labeled as to their respective EOL, but are expected to remain operational through activities such as maintenance, repairs, or upgrades, for an estimated period of time."

The device complies with the requirements of the national standard GOST R 50276.0-92 class 1, type B and International standards and norms Directive 93/42/EEC, IEC 60601-1:2005-12 3rd ed., class IIa, type BF.

4. Delivered set

The device set consists of the following items:

Tab.2

Item	*Units*	*Note*
Data Processing Unit (DPU)	1	
Internal temperature sensor with antenna-applicator (ITS)	1	
Surface temperature sensor (STS)	1	
Nozzle for Surface temperature sensor	1	
Cable for DPU - PC connection	1	
Conductor cable	1	
Fuses 0,16 A	2	
Operating manual	1	
CD with RTM Diagnosis Software	1	

Also the following items may be included in the device set (as requested):

Tab. 3

Item	*Number,units*	*Note*
PC, packed by a manufacturer	1	

5. Device structure and operation principles

5.1. The device set consists of the following items:

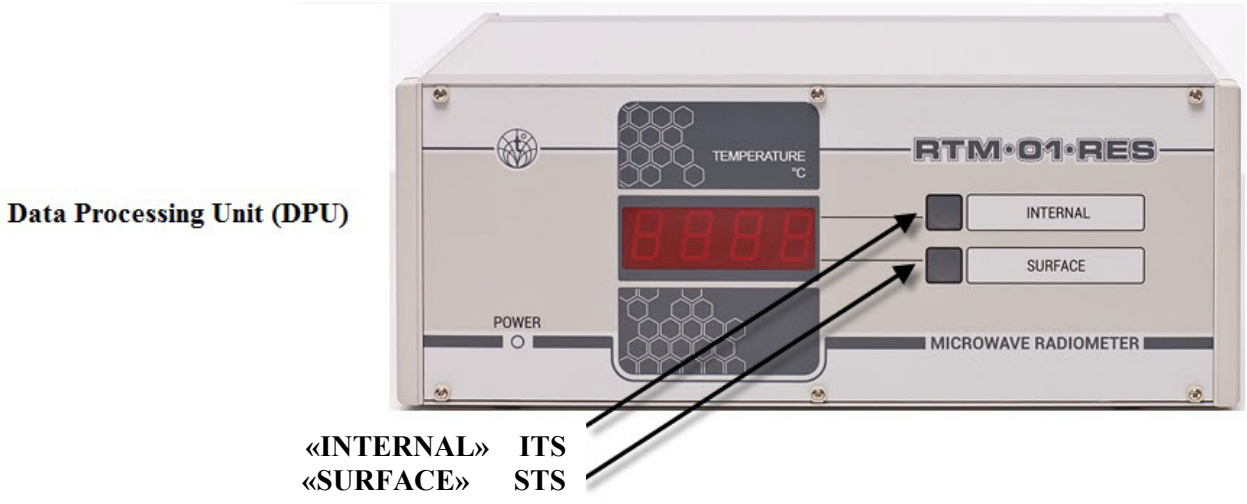


Fig.1 Data Processing Unit (DPU)

Fig.2 **Internal Temperature Sensor with antenna-applicator (ITS)**

Fig.3 **Surface Temperature Sensor (STS)**

5.2. According to physics laws, any object above zero emits radiation at all frequencies, and in particular, at microwave (MW) frequencies and at infrared frequencies (IR).

This feature of heated body is used for measuring averaged internal tissue temperature and detecting thermal abnormalities of internal tissues (higher or lower temperature of internal tissues).

At microwaves frequencies the noise power received by the antenna contacted an evenly heated absorbing object is:

$$P=kTB,$$

where:

k – Boltzmann's constant

B – System bandwidth (Hz),

T – Temperature of the biologic object

Therefore the power noise received by antenna is proportional to the tissue temperature.

When the object temperature is 309 K, i.e. 36°C the noise power received by the antenna is $3x10^{-13}$ Watt. This value corresponds with the noise generated by the antenna. Special methods are applied for receiving and processing signals.

Bio-objects that are usually examined consist of several layers (e.g. skin – fat – muscle). The radiation power passes through all parts of tissues with different loses and different temperatures, so the temperature measured by the antenna is not equal to the physical temperature of the ex-

amined organ, but depends on the temperature of other body parts and losses in these parts. Also the antenna does not match the measured object absolutely. This can lead to errors, but they are eliminated by the circuitry method.

The device is a modulated null-radiometer with a slipping circuit for compensating reflection between the biological object and the antenna.

The ITS measures simultaneously the signal at microwave frequency band and at infrared frequency band.

The measurement in IR frequency band allows to get the information about the skin temperature in the same point in which we measure the internal temperature. This is used for breast diagnosis.

The functional scheme is illustrated in ***Fig.4***. When the temperature is measured, the antenna contacts the patient's skin at the projection of the examined organ. The antenna receives microwave radiation and IR radiation from the examined organ.

Functional Diagram of RTM-01-RES

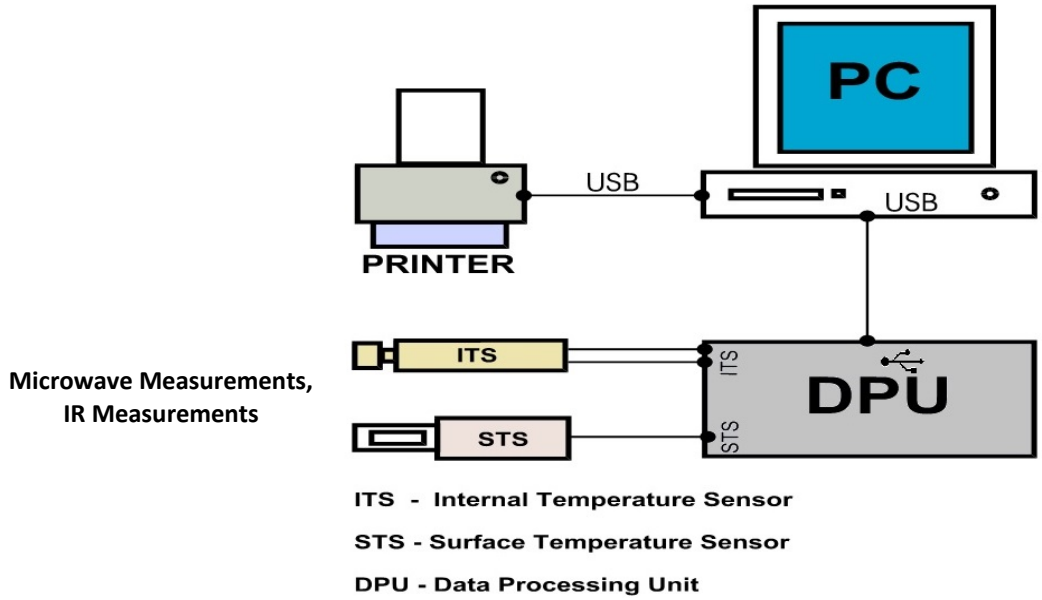


Fig.4

The both signals amplified in the Internal Temperature Sensor (ITS) is transmitted to the DPU (data processing unit), where it is processed.

Besides the two frequency band ITS additional Surface Temperature Sensor (STS) may be used for measurement the surface temperature. The voltage from the Surface Temperature Sensor (STS) is transmitted to the DPU too. The surface temperature sensor is non-contact infrared receiver.

The buttons located on the front panel of the data processing unit switches the modes of measurement. The internal and skin temperature values are displayed on the 3-digit temperature indicator as degrees Celsius with discreteness of 0.1.

Data Processing Unit (DPU) produces serial digital signals for interfacing with PC.

6. Safety measures

6.1. The Radiometer RTM-01-RES complies with the requirements of the national standards GOST R 50276.0-92 class 1, type B and International standards and norms Directive 93/42/EEC, IEC 60601-1:2005-12 3rd ed., class IIa, type BF.

6.2. The safety measures for Radiometer RTM-01-RES are similar to the general safety measures for any electronic device.

6.3. The Radiometer RTM-01-RES is grounded by contacting solder pads that are in the two-pin plug.

6.4. Devices connected to the Radiometer RTM-01-RES (PC, printer) must comply with the requirements of the national standards GOST R 50276.0-92 class 1, type B.

6.5. When PC is used, a processing unit, a monitor and a printer must be located at 1.5 m distance and more from the patient.

6.6. The radiometer and the PC must be connected to tripolar separated sockets.

6.7. To avoid the risk of electric shock, this device must be connected to the mains with protective earthing.

6.8. To avoid the risk of electric shock, STS sensor must be checked for completeness before each using.

7. Set up

7.1. The Radiometer RTM-01-RES must be used indoors and all climatic requirements defined in the “User manual” must be met.

7.2. The Radiometer RTM-01-RES is transported in the pasteboard box. The device must be unpacked indoors at room temperature.

7.3. Open the box and take off the polyethylene cover from the units.

7.4. Check to make sure that all items indicated in paragraph 4 are delivered.

7.5 Connection DPU with PC.

Fig.5

Before connection DPU with PC shut down computer.

Connect the “Cable for DPU - PC connection” with the “USB” socket on the Back Panel of the DPU as is illustrated on the **Fig.5** on the one hand and the “USB” socket of the Computer on the other hand.

7.6 Connection ITS with DPU

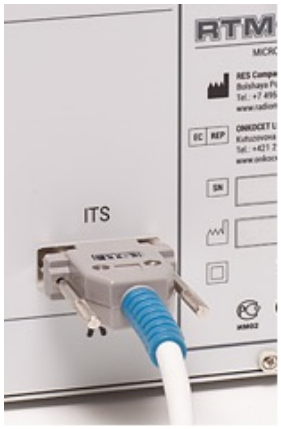


Fig.6

Connect ITS-plug with the DPU as is illustrated on the **Fig. 6** and tighten up the ITS-plug by screws.

7.7 Connection STS with DPU

Fig.7

Connect STS-plug with the DPU as is illustrated on the **Fig. 7** and tighten up the STS-plug by screws.

7.8 Connect power cord (mains cable)

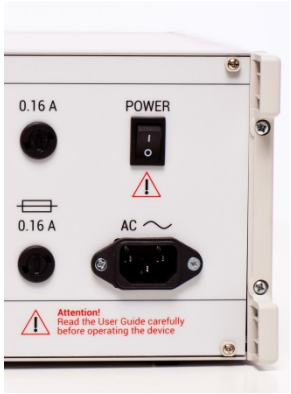


Fig.9

Connect power cord (mains cable) to inlet filter as illustrated on the Fig. 8

7.9 Rear View of the Data Processing Unit (DPU)

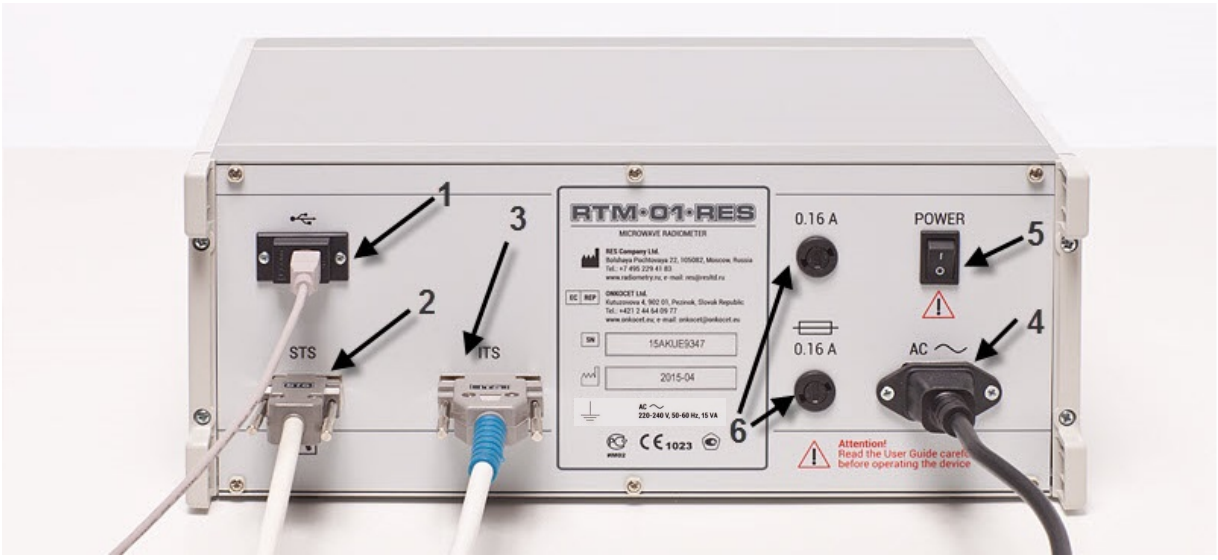


Fig.9

1 - Plug of Cable for DPU - PC connection
2 - Plug of STS
3 - Plug of ITS
4 - From mains
5 - Power On / Off
6 - Fuses (F160mAL, 250V)

7.10 Turn on the DPU of Radiometer RTM-01-RES by button «POWER». The Radiometer RTM-01-RES is ready after 30 minutes.

7.11 Switch STS to surface temperature mode (infrared band): press the **SURFACE** button on the front panel of the DPU (***Fig.1***). The below temperature indicator will be on.

7.12 Connect the STS to the skin of the palm near foundation of the thumb. Displayed temperature will be 30…35°C.

7.13 Switch ITS to the internal temperature mode (microwave band): press once the **INTERNAL** button on the front panel of the DPU (***Fig.1***). The indicator that is above will be on.

7.14 Connect the ITS to the skin with the right or left neck side at the 5-cm high from the collarbone. Displayed temperature should be about 32…36°C.

7.15 Switch ITS to the surface temperature mode (infrared band): press again the **INTERNAL** button on the front panel of the DPU (***Fig.1***). The indicator that is above and the indicator that is below will be on.

7.16 Connect the ITS to the skin with the right or left neck side at the 5-cm high from the collarbone. Displayed temperature should be about 30…35°C.

7.17 Turn on the PC and install the RTM-Diagnosis software. Now the device is ready to use.

8. Measurement procedure

8.1. Start the RTM-Diagnosis and choose organ which you wish to examine and follow to the RTM-Diagnosis User Manual.

8.2. For measuring the internal temperature press the **«INTERNAL»** button and put the antenna on the body at the examined point. Substances for improving antenna contact with the skin are not required. The entire antenna surface must contact the skin.

8.3. Wait for the appearance of GREEN colour “Traffic Light” to be displayed on the computer screen and then press the **«ENTER»** button on the ITS. The setting time is not more than 2 seconds.

8.4. The skin temperature is measured by the Surface Temperature Sensor (STS). Switch the**«SURFACE»** button on. The sensor must be perpendicular to the body surface. When the examined spot is less than 5 mm it is required to use a short nozzle. For the examined spot, which is more than 10mm but less than 18 mm it is required to use a long nozzle.

8.5. Wait for the appearance of GREEN colour “Traffic light” to be displayed on the computer screen and then press the **«ENTER»** button on the STS. The setting time is not more than 2 seconds.

9. Warnings and safety notices

9.1. Modification of this equipment is not allowed. Hazards can result from unauthorized modification!

9.2. It is forbidden to use RTM-01-RES with flammable anesthetics.

9.3. It is forbidden to use RTM-01-RES in conjunction with flammable agents.

9.4. It is forbidden to use RTM-01-RES when the operating staff is under the influence of alcohol, and medicines negatively affecting performance and attention.

9.5. It is forbidden to use the device and its parts when any device component is damaged, especially when the cover of the sensor is missing or is damaged.

9.6. It is forbidden to touch any metal materials or parts inside the sensors.

9.7. To avoid the risk of electric shock, this device must be connected to the mains with protective earthing.

10. Maintenance

10.1. Maintenance shall be carried out in order to prevent device malfunction.

10.2. Read “Safety Measures” section of User Manual before carrying out maintenance.

10.3. The following are the maintenance types:

Day-to-day service performed by trained personnel according to section 7 herein;

Annual service to be performed by authorized technical service once a year.

10.4. The device must **always** be repaired by authorized technical service. On request, the manufacturer will provide circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist SERVICE PERSONNEL to repair parts designated by the MANUFACTURER as repairable by SERVICE PERSONNEL.

11. Troubleshooting guide

11.1. Possible problems are the following:

Problem	*Possible cause*	*What to do*
1. No power	1. The AC power cord is not properly connected to an AC outlet or DPU's socket. 2. One of the fuses of the DPU is burnt.	1. Re-insert plug into the mains socket or DPU's socket and switch on the DPU again. 2. Replace a fuse.
2. When the internal temperature sensor (ITS) is checked in accordance with section 7, the temperature displayed on the temperature indicator is less than 30°C or more than 38°C.	The internal temperature sensor is not connected to DPU properly.	Reconnect the 15-pin plug and BNC-plug of the internal temperature sensor (ITS).
3. When the internal temperature sensor is directed to the environment the temperature displayed on the temperature indicator is more than 40°C	There is powerful external interference.	Eliminate the source of interference.

11.2. When other problems occur, contact your supplier.

11.3. Before calling for service:

- Try to solve the problem yourself (see "Troubleshooting Guide").
- Start again program and make sure the error is repeated.
- If the device fault persists, call service.

Please provide the following information:

- The nature of the problem.
- Serial number of the device.

12. Packing and transporting

12.1. For delivery the radiometer is packed into a polyethylene film and box.

12.2. The documentation is covered by paraffined paper, packed into polyethylene film and put into the box with the device.

12.3. The radiometer can be transported by any flight transport excluding non-heated airplane sections, climatic conditions must correspond to the national standard GOST 15150-69, group 5.

13. Storage

13.1. For short term the radiometer must be stored indoors at 10 to 35°C temperatures and relative humidity must be 80 per cent at temperature of 25°C.

13.2. For long term the radiometer must be stored at a warehouse of a manufacturer or customer in accordance with the storage conditions of the national standards GOST 15150-69.

14. Service & Warranty

14.1. The manufacturer guarantees that the Radiometer RTM-01-RES corresponds to indicated specifications when all conditions and use, technical service, transporting and storing requirements indicated in the device documents are met.

14.2. Subject to all matters set out below, manufacturer warrants:

- The Radiometer RTM-01-RES for twenty four (24) months.
- All components and accessories for twenty four (24) months.

14.3. The warranty period is 24 months and begins once the Radiometer RTM-01-RES is set to be used but not longer than one month from the date of purchase.

14.4. This warranty applies only where the purchaser:

- Immediately notifies supplier or manufacturer of the alleged defect;
- Returns the Radiometer RTM-01-RES to the supplier; and
- Presents the relevant sales docket and this warranty document to the dealer to confirm the date of purchase.

14.5. Except for this warranty, manufacturer gives no warranties of any kind whatsoever (whether express or implied), in relation to the product, and all warranties of whatsoever kind relating to the product are, to the extent permissible by statute, hereby excluded.

14.6. To the extent permissible by statute, manufacturer disclaims any liability of whatsoever nature in respect of any claim or demand for loss or damage which arises out of:

- Accidental damage or normal wear of the equipment or equipment's components;
- Any cost relating to damage resulting from wear and tear;
- Blown fuses, loss or damage caused by electrical surges, power surges or power spikes;
- Loss or damage due to theft, fire, flood, rain, water, lightning, storms or force majeure
- Damage as a result of incorrect usage;
- Evidence of unauthorised repairs
- Any cost relating to damage caused by misuse, negligence or failure to maintain the equipment in a proper working order as per clauses (d) through (f);
- Installation, adjustment or use not in accordance with this operational manual;
- Attempted or complete modification or repairs to the product carried out by an unauthorised person to carry out such modification or repairs;
- Faulty or unsuitable connection which the product is fixed;
- Radio (including citizen band transmission) or any electrical interference;
- Damage causes by insects;
- Loss or damage to any property whatsoever or any loss or expense whatsoever resulting or arising there from or any consequential loss;
- Any cost or expense arising due to manufacturer recall of any product;
- Any cost or expense due to negligence of the approved service provider.

14.7. If the radiometer is damaged as a result of incorrect usage of the device, the repairs carried out will attract a fee to the customer.

14.8. This warranty is void if equipment is not returned in original or suitably secure packaging.

14.9. This warranty is only applicable for repairs to the equipment carried out within Australia.

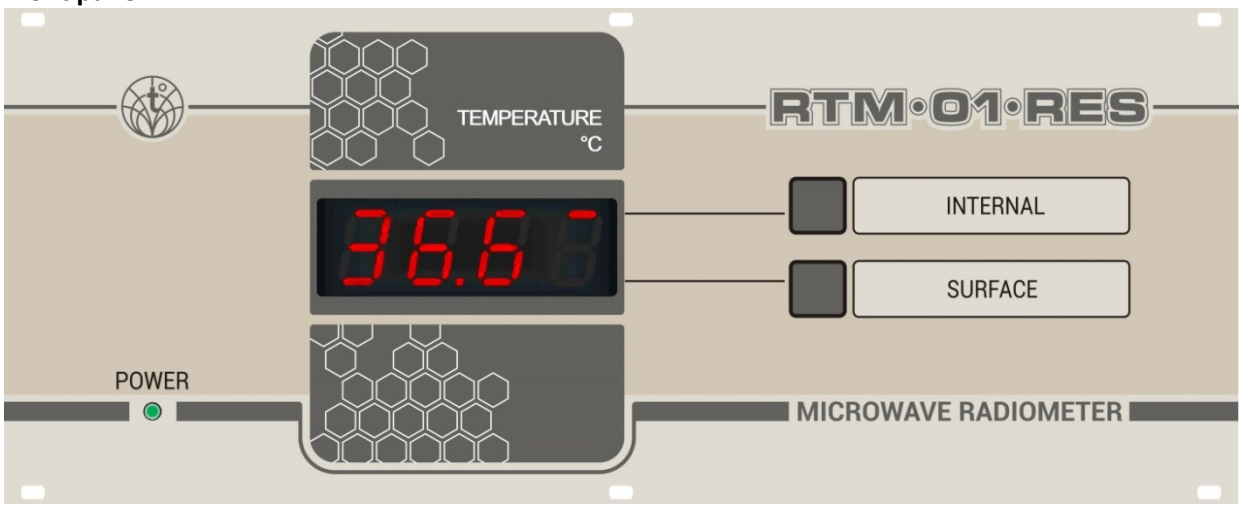
14.10. This warranty is not transferable.

14.11. In case of need of warranty servicing, please contact:

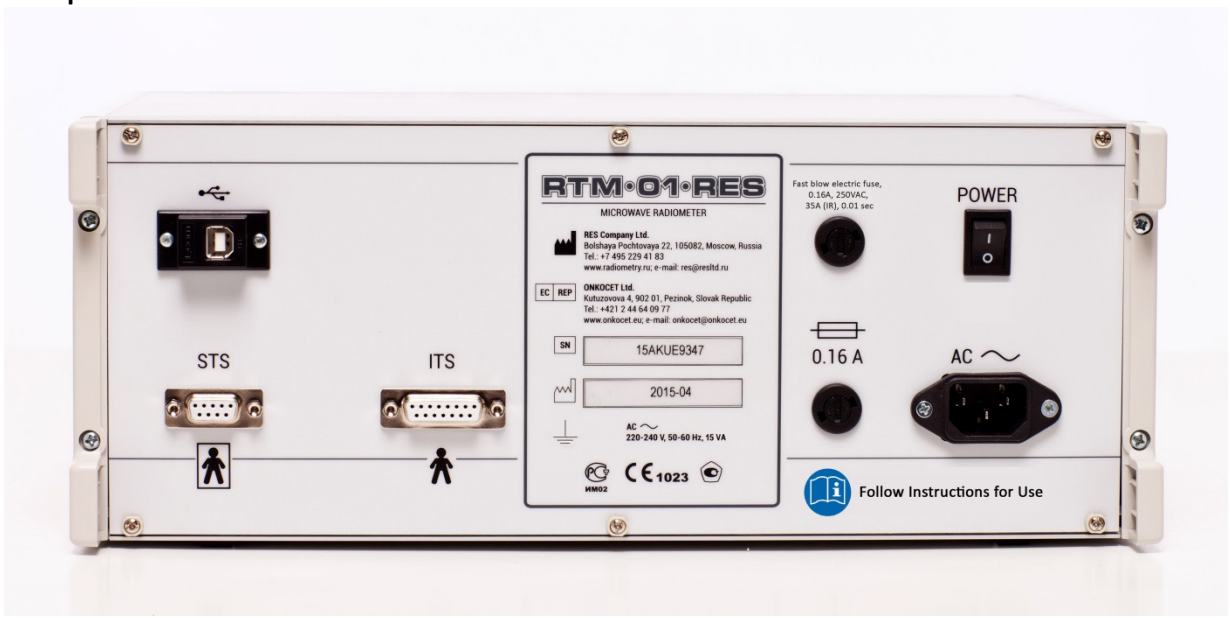
- the official supplier from whom you purchased RTM-01-RES;
- manufacturer: RES Company, Ltd. , Russia, tel.: +74952294183, res@resltd.ru
- representative of the manufacturer of the Radiometer RTM-01-RES in the EU: ONKOCET Ltd., Slovakia, tel. + 421 2 44 64 09 77, mail: onkocet@onkocet.eu

15. Labelling

Front panel



Rear panel



	Follow Instructions for Use IEC 60878 Safety 01[b]		**Alternating current** IEC 60417-5032
	General mandatory action sign ISO 7010-M001		**Manufacturer** ISO 15233
	General prohibition sign ISO 7010-P001		**Date of manufacture** ISO 15233
	General warning sign ISO 7010-W001	EC REP	**Authorised representative in the Euro-pean Community** ISO 15233
	Type B applied part IEC 60417-5840	SN	**Serial number** ISO 15233
	Type BF applied part IEC 60417-5333	CE	**CE marking** ISO 15233
	Earth (ground) IEC 60417-5017		**Fuse** IEC 60417
	Earth (ground) ISO 7000		**Adress of producer:** RES Company, Ltd. 22, Bolshaya Pochtovaya, Moscow, 105082, Russia, tel.: +7 495 229 41 83; res@resltd.ru

16. Acceptance protocol

The Radiometer RTM-01-RES, Serial No _____ complies with the technical requirements and is serviceable.

Warranty period is 24 months; it begins once the device is set to be used.

Production date "_____" _____ 201 _.

_____ _____
(Signature) (Surname)

The Radiometer RTM-01-RES, Serial No _____ is packaged by RES Company Ltd. in accordance with technical requirements.

Packaging Date: "_____" _____ 20__.

Packer _____ _____
(Signature) (Surname)

RES Company, Ltd.
22, Bolshaya Pochtovaya, Moscow, 105082, Russia
tel.: +7 495 229 41 83
email: res@resltd.ru

WARRANTY CERTIFICATE

For repair (replacement) of Medical device - Radiometer RTM-01-RES within the warranty term

Number and production date_____

Purchase _____

(Date, signature and stamp of seller)

set in operation _____

(Date, signature)

accepted for warranty _____

(Date, signature)

RES Company, Ltd.
22, Bolshaya Pochtovaya, Moscow, 105082, Russia
tel.: +7 495 229 41 83
email: res@resltd.ru

17. Packaging, storage, handling and transportation

The radiometer is packed into a polyethylene film and box for delivery.

The documentation is covered by paraffined paper, packed into polyethylene film and put into the box with the device.

The radiometer can be transported by any flight transport excluding non-heated airplane sections, climatic conditions must correspond to the national standard GOST 15150. Vehicles used to transport medical devices should be properly designed and equipped to ensure protection from different environmental and weather conditions in which it operates. The use of vehicles with defects that could affect the quality of the medical devices should be avoided.

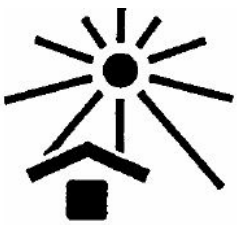
For short term the radiometer must be stored indoors at 10…35°C temperature and relative humidity must be lower than 80% at temperature of 25°C.

For long term the device must be stored at a warehouse of a manufacturer or customer in accordance with store conditions of the national standards GOST 15.150.

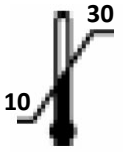
Labelling on the outside package:

Keep dry

This way up



Keep away from sunlight



Temperature limitation

18. DISPOSAL

DISPOSAL OF PACKAGING - packaging components (cardboard, plastics etc.) are all classified as solid waste and can be therefore easily disposed of with the use of recycling processes.

Before disposal is always advisable that you check the validity of the relevant provisions in the place of installation.

PLEASE MAKE proper disposal!

PRODUCT DISPOSAL – RTM-01-RES is made of various materials. Most of them (plastic, metal, electric conductors, etc.) may be handed over in recycling sites and can be recycled. However, other components (electric plates, etc.) may contain hazardous substances. Therefore the following components should be submitted in the respective centers or the European representative of the producer, where the qualified ensure their disposal.

Before disposal is always advisable that you check the validity of the relevant provisions of the disposal site.

PLEASE MAKE proper disposal!

CE **1023**

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