OPERATION MANUAL

MEDICAL MINICENTRIFUGE-VORTEX

DTspin

TS 32.50.50-003-96301278-2024

“DNA-Technology R&P”, LLC

Protvino

Contents

READ THIS MANUAL CAREFULLY BEFORE PROCEEDING TO WORK!

General safety

Improper use or mishandling of the appliance may invalidate the warranty and pose a health hazard.

After transport or storage in humid and cold conditions, dry the device for at least 2 hours at room temperature between 18 °C and 25 °C before connecting it to the mains supply.

WARNING! The device design does not provide for unauthorized repair work! The interior of the device does not contain any user-serviceable components.

WARNING! The device's power cord has a European plug with a third grounding pin. Before plugging in the device, please make sure that your outlet provides the necessary grounding. Do not plug the device into an outlet without a grounding conductor.

The power cord supplied with the device must be used to connect to the power outlet. Modification or damage to the power cord may result in electric shock, short circuit or fire due to overheating. The power cord should not be bent, squeezed or modified, nor should it come into contact with any heat source.

Before plugging in the device, make sure that the plug-in cord is intact.

The device must be connected only to electrical networks with the voltage values specified in this manual. If liquid gets inside the device, disconnect it from the mains and contact the service department.

CAUTION, DANGER OF ELECTRICAL SHOCK! Replacement of the fuses installed inside the device enclosure to protect against overloading of the electrical circuits of the device must be performed at the manufacturing company.

Do not operate the device when the humidity in the room exceeds 80%. Condensation may cause damage to the electronic components of the device.

The device must be protected against shocks and drops. Do not allow any liquids or objects to get inside the chassis of the device. This may result in damage to the device.

Careless device handling may result in injuries!

Do not touch the surface of the spinning rotor, wait until the rotor stops spinning completely.

When using the device, it is necessary to comply with the requirements of health and safety regulations established in the user's organization.

«DNA-Technology R&P» LLC. is not liable for any injury or damage to health resulting from improper use of the device, self-repair and modification of the device.

"DNA-Technology R&P", LLC is not responsible for the use of the device as a medical device in clinical diagnostic laboratories and medical institutions.

1. Intended use

Purpose: the device is intended for shaking and spinning the contents of tubes/strips by means of a shaker attachment (vortex), as well as for low-speed centrifuging of the contents of tubes/strips by means of centrifuge rotors as an aid in clinical laboratory for in vitro diagnostics.

Functional purpose: auxiliary means in clinical laboratory diagnostics in vitro.

Type of tests sample: biological liquids and solutions.

Indications for use: shaking and spinning, low-speed centrifuging of test samples in tubes and strips.

Contraindications for use: if the device is used within its intended purpose and in strict compliance with the operating documentation, it has no contraindications and foreseeable side effects.

Potential users: qualified personnel trained in laboratory techniques and procedures work in a clinical laboratory diagnostician: doctor of a clinical laboratory diagnostician, medical laboratory assistant.

Device application area: clinical diagnostic laboratories of medical institutions.

In terms of electrical safety, the shaker belongs to products with basic insulation, overvoltage category II, pollution degree 2 according to IEC 61010-1.

Multiplicity of use: for multiple use according to the intended purpose.

Sterility: the device is supplied non-sterile and is not subject to sterilization.

2. Technical parameters

No.	Name	Value
1	50/60 Hz AC mains voltage, V	230 ± 10%
2	Maximum power consumption, W	55 ± 10%
3	Rated power, W	14–17
4	Overall dimensions of the product, mm width depth height	 121 ± 1 179 ± 1 120 ± 3
5	Weight of the product (net) without a set of spare parts and accessories, kg	0.88 ± 5%
6	Continuous operation time, min	30
7	Touch panel, mm length width	 92 ± 1 42 ± 1
8	Constant rotation speed, rpm	2,820±150
9	Relative centrifugal force (RCF), max (50 Hz)	645 x g
10	Time of acceleration to maximum rotor speed, s	≤ 1
11	Rotor full stop time, s	≤ 5
12	Eccentric amplitude, mm	4
13	Noise sound power level at the operator’s workplace, dBA	≤ 70
14	Timer setting, s	3, 5, 10 or indefinitely
15	Protection class	IP30

3. Package contents

No	Name	Quantity, pcs.
1	DTspin medical minicentrifuge-vortex 	1
2	Rotor R1 for 12 0.5 mL microtubes and 12 0.2 mL microtubes 	1
3	Rotor R2 for 12 1.5/2.0 mL microtubes 	1
4	Rotor R3 for 6 1.5/2.0 mL microtubes, 6 0.5 mL microtubes, and 6 0.2 mL microtubes 	1

5	Rotor R4 for 6 8x0.2 mL strips and 6 2.0/1.5 mL microtubes 	1
6	Shaker attachment (vortex) 	1
7	Power cable (three-wire) 	1
8	Operation manual	1
9	Device certificate	1

4. Marking

Device marking is performed in accordance with IEC 61010-1 and contains the following information printed on the label (nameplate) of the device:

- name and/or trademark of the manufacturing enterprise;
- name of the device;
- serial number of the device;
- month and year of manufacturing;
- designation of technical specifications for products (TS);
- mains voltage;
- AC mains frequency range;
- maximum power consumption of the device;
- manufacturer's address;
- symbol "Refer to the instructions for use";
- IP symbol "Degree of protection provided by the shell".

Note - it is allowed to apply market signs and barcoding to the label.

The label is located on the bottom panel of the device.

Example of label is presented in Figure 1.

Fig.1. Label example

The front panel of the device contains the following information:

- trademark of the manufacturer;
- short name of the device "DTspin".

The upper panel of the device contains a label: Caution, danger! Do not touch the rotor with your hands during acceleration, operation or stopping.

The back panel of the device contains:

- marking of the mains switch;
- marking of the mains power connector;
- symbol "Caution! Electrical voltage".

Rotors have marking and comply with IEC 61010-2-020:

- manufacturer name;
- batch number;
- nominal rotation speed;
- the volume of the microtubes/strips to be installed.

Symbols are printed on labels.

The packaging for transportation bears the warning manipulation signs “Fragile, handle with care”, “Keep dry”, “Top”, “Stacking limit”, “Temperature limit”, as well as:

- trademark or the name of manufacturer;
- manufacturer’s address and contacts;
- name of the device;
- device technical specifications (TS);
- serial number of the device;
- date of manufacture (year and month of packaging);
- net weight;
- gross weight;
- ambient parameters during transport and storage.

An example of transportation container marking is shown in Figure 2.

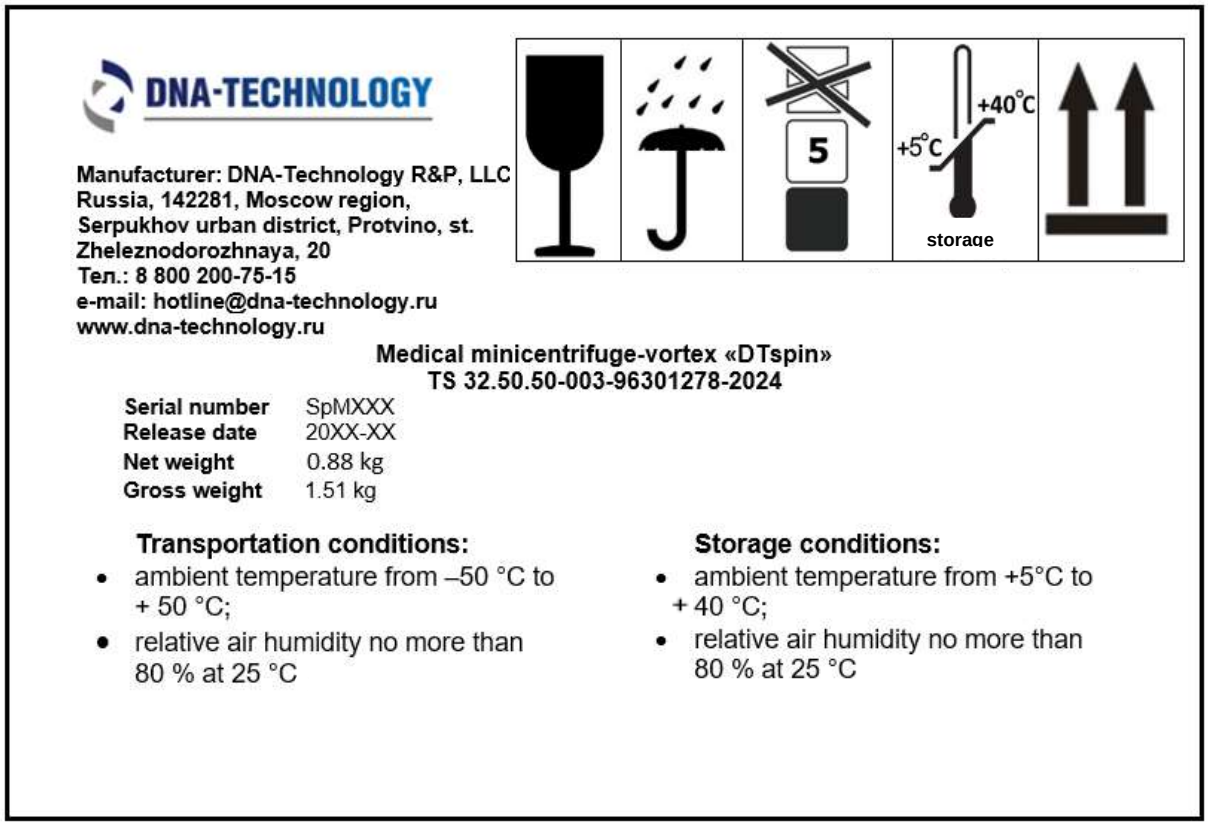


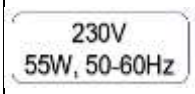
Fig.2. Transportation container marking

The marking of the components included in the delivery set of the device is indicated on the label attached to the ziplock bag and contains the following information:

- trademark or the name of manufacturer;
- name of the device;
- device technical specifications (TS);
- name of components;
- number of components.

Symbols that are used for marking are listed in Table 1.

Table 1 – Marking symbols

	Medical product for in vitro diagnostic		Fragile, handle with care
	Serial number		Keep dry
	Consult instructions for use		Mains power input connector designation
	Date of manufacture		Caution, danger! Do not touch the rotor with your hands during acceleration, operation or stopping
	Manufacturer		Caution! Electrical voltage
	Temperature limit		On (source)
	Stacking limit		Off (source)
	Top		Alternating current
		IP30	Degree of protection provided by the shell

5. Device design and operation

5.1 Design

The device consists of a case with mounted control elements and a motor shaft (Fig. 3).

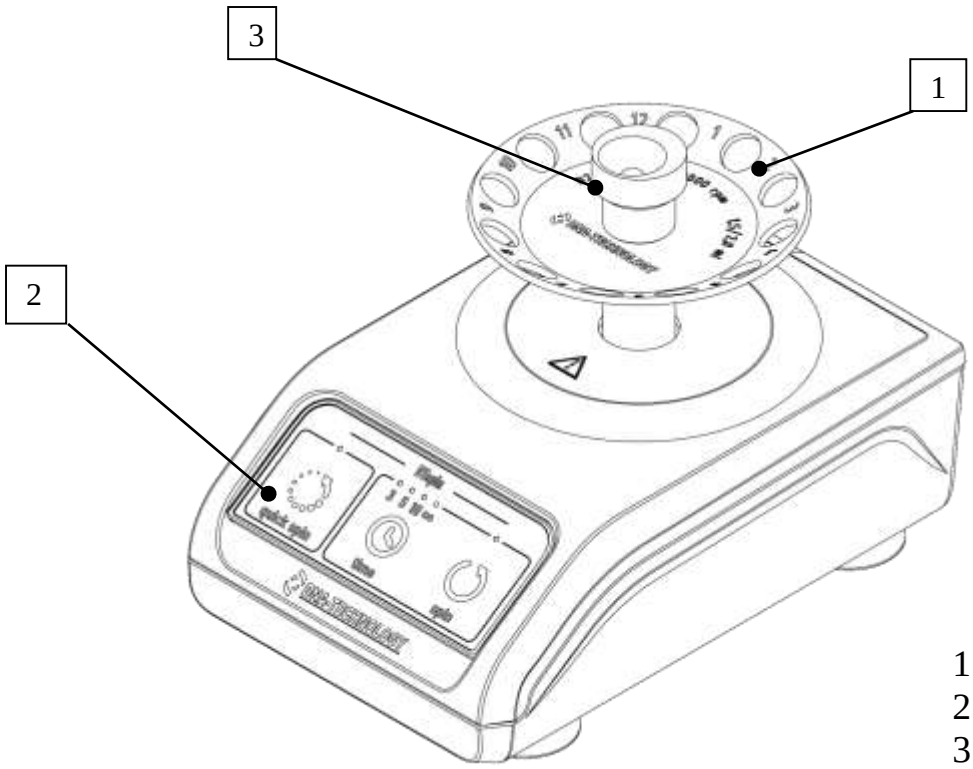
Fig. 3 Exterior of the device

The main design elements of the device are shown in Figures 4, 5.

Test tubes with samples are placed in the rotor seats (1).

Frontal touch panel (2) contains buttons for controlling the device and displaying the current operating mode.

The shaker attachment (vortex) (3) with threaded connection holds the rotor to the device.

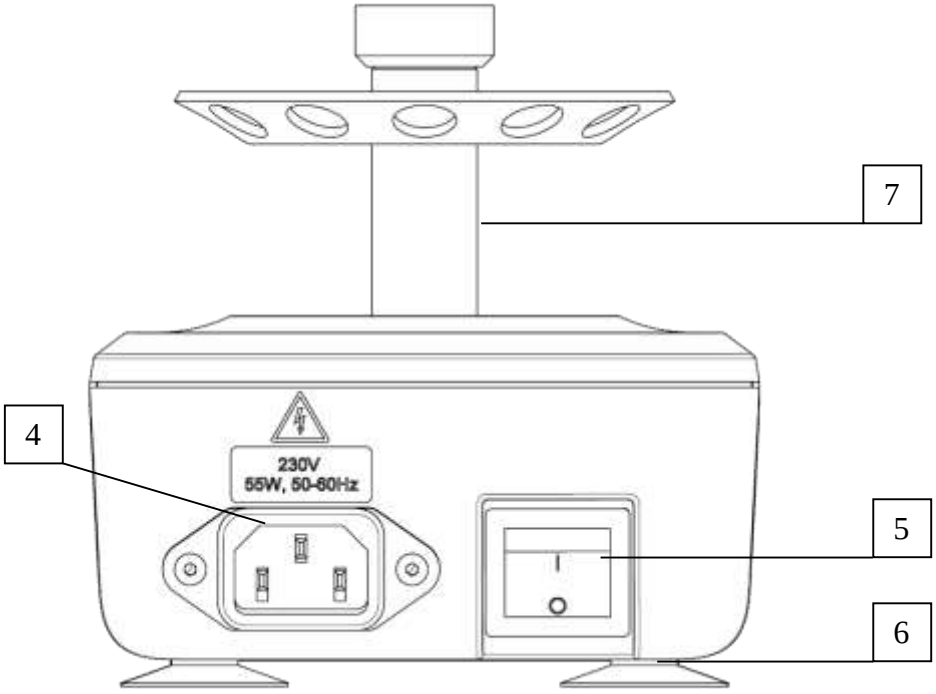


1. Rotor
2. Touch panel
3. Shaker attachment (vortex)

Fig.4 Design elements of the device

On the back (rear) side of the device (Fig. 5) there is a power cord connector (4) with a plug for connecting the device to the mains and a key switch (5) for switching the device on/off.

On the bottom of the device there are suction feet (6), which ensure a secure grip of the product on the work surface.



4. Power cord connector
5. Key switch
6. Suction feet
7. Shaft

Fig.5 Back side of the device

5.2 Functioning

When the device is switched on, the electric motor starts to rotate the shaft (7) with the shaker attachment (vortex) (3) and the rotor (1) with tubes installed in it. The shaker attachment (vortex) is used to shake or stir the contents of the tubes, and the centrifuge rotors are used to centrifuge the contents of the tubes/strips at low speed.

Shaft rotation is provided by an asynchronous two-pole electric motor.

Centrifugation, shaking or stirring of the contents of the tube(s) is controlled by the user or the built-in microprocessor and is regulated by a timer on the front panel of the device.

The user has the possibility to set the rotation time of 3, 5, 10 seconds or unlimited time. Braking of the shaker drive shaft is carried out automatically.

6. General operating instruction

6.1 Requirements for premises

The product is designed to operate in the following ambient conditions:

— inside,
— at temperature in the premise from 10 °C to 35 °C,
— at relative humidity in the premise no more than of 80% at 25 °C.

6.2 Preparation to work

Carefully unpack the product and inspect it for external damage. Keep the original packaging for possible transportation or storage. Check that all components are present according to the package contents (section 3 of this manual). Carefully inspect the product for any damage sustained during shipment. Such damage is not covered by the warranty. The warranty does not apply to devices transported not in their original packaging.

Note: Clean the suction feet regularly for better adhesion to the work surface.

After a long stay in the cold, the device should be held for at least 2 hours without plugging it in, so that the device case warms up to room temperature.

6.3 Device installation

Place the device on a flat, hard, horizontal surface in a convenient location, at least 30 cm away from flammable or heating materials and allow at least 2 cm of space around the device for ventilation.

Connect the product with the mains cable to a 230 V, 50/60 Hz power supply and position it so that it is easily accessible to the socket and the cable.

6.4 Installation/replacement of the rotor

WARNING! Inspect the rotor for signs of wear. Replace if necessary.

To install/replace the rotor, hold the shaft with one hand and unscrew the shaker attachment (vortex) (Fig. 4 and 5) counterclockwise.

Install/replace the rotor and screw in the shaker attachment (vortex) as far as it will go.

The rotors are made of aluminum and are autoclavable.

6.5 Biological safety

Without the use of a biological containment system, the device is not a biologically safe system according to EN 61010-2-20 and cannot be used for centrifugation of hazardous materials contaminated with toxic, radioactive substances or pathogenic microorganisms.

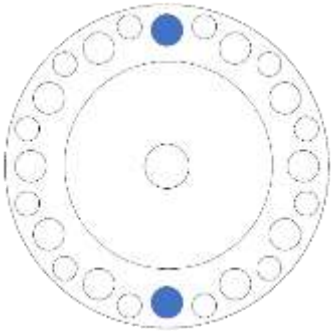
The user is responsible for the disposal of hazardous materials spilled on or inside the device.

7. Useful tips

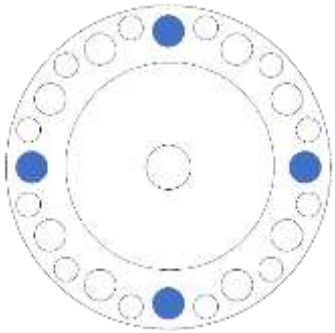
If the rotor is not fully loaded, place the tubes symmetrically in the rotor as far as possible to avoid strong vibrations of the device (see scheme 1). If an odd number of tubes are used, if necessary, place an additional filled tube with an equal volume of liquid in the rotor.

Do not fill the tubes installed in the rotor.

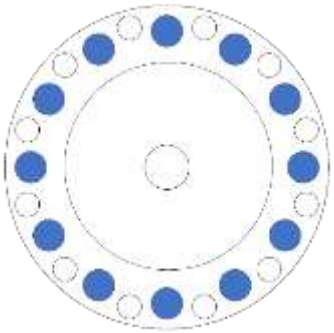
If the device is used intermittently throughout the day, it is best to leave it on throughout the day.



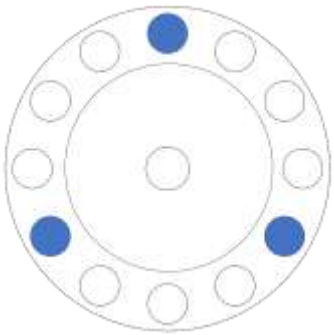
2 tubes



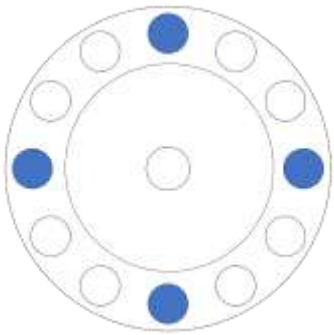
4 tubes



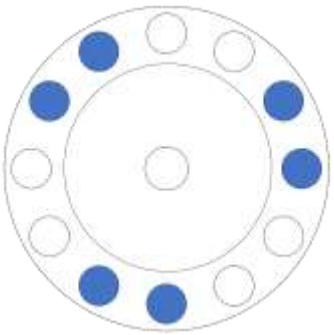
12 tubes



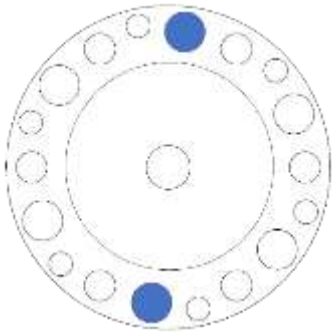
3 tubes



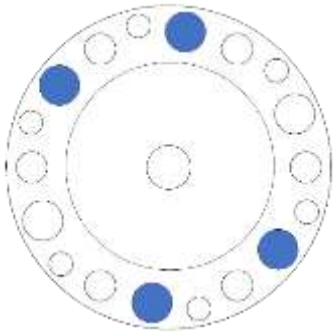
4 tubes



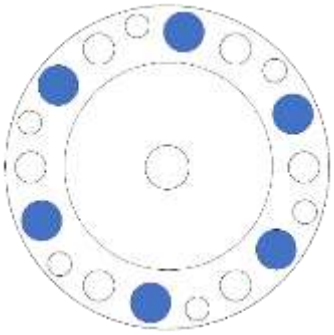
6 tubes



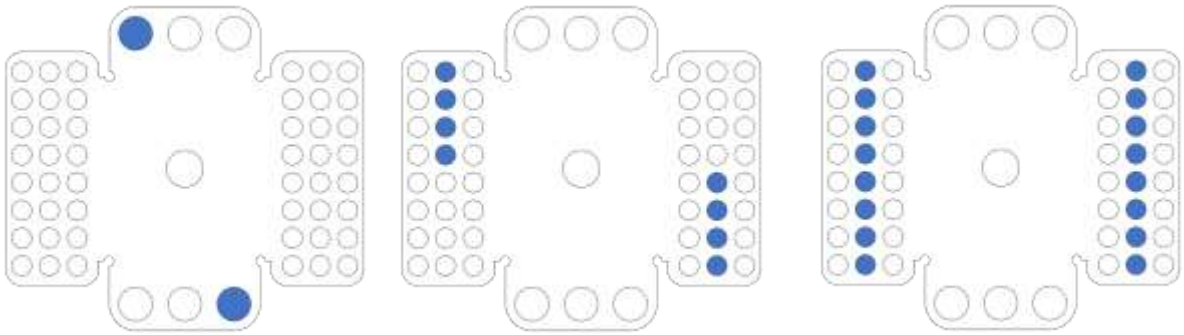
2 tubes



4 tubes



6 tubes



2 tubes 8 tubes 16 tubes

Scheme 1. Symmetric placement of tubes in the rotor

8. Device operation

The device is switched on with a key switch on the back side of the device (see Fig. 5). To switch on the device, press the | until the clicking position; to switch off, press the ◯.

The user interface of the device includes a touch screen (dimensions: 92±1(W)×42±1(H) mm) which displays the service information about the device's current status. The touch screen allows to control the device by touching the desired fields ("buttons") on the screen.

8.1. Description of controls and starting the spinning

After the device is switched on, the timer indicators light up.

Fig. 6.1. Front panel indicators and backlighting

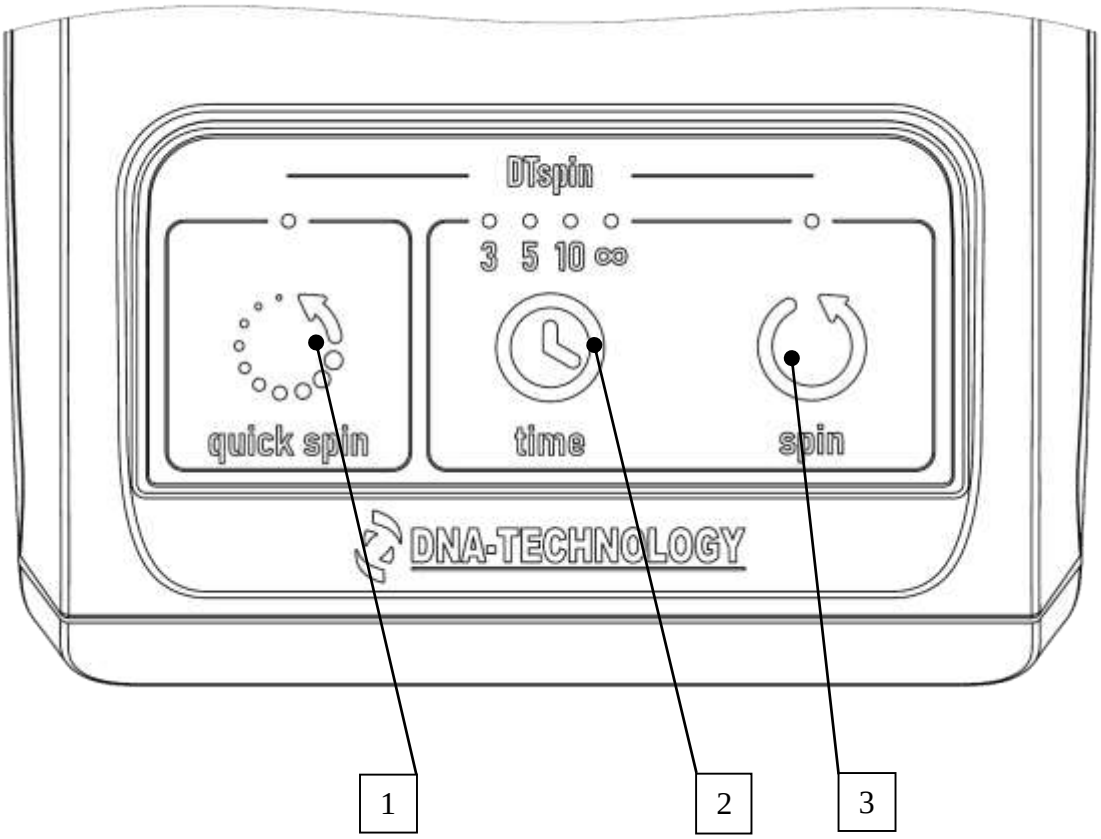


Fig. 6.2. Front panel

1 — Button to enable/disable the pulse rotation mode. Touch the button to start rotation and keep your finger on the button to continue rotation. Remove your finger from the button to stop. The indicator above the button is lit while the rotor is rotating.

2 — Timer button. LEDs and inscriptions above the button indicate the set timer time. When switching on, the timer is set in position ∞ (unlimited rotation time). Pressing the timer button switches the timer mode sequentially from left to right: 3 sec, 5 sec, 10 sec, unlimited rotation time.

Press the “Start” button (3) to start rotation in the selected mode. If the unlimited rotation time mode is selected, press the “Start” button (3) again to stop the rotation.

WARNING! Do not stand or leave hazardous materials less than 30 mm from the edges of the device during centrifugation.

WARNING! Do not centrifuge flammable or chemically active substances. If such liquids come into contact with the rotor of the product, immediately wipe all contaminated parts with a damp cloth moistened with soap solution.

8.2. Shaking

To stir the test tube using the shaker attachment (vortex) it is necessary, holding the test tube by the upper part (near the lid) to place the cone-shaped part

of the test tube vertically or with a slight inclination into the eccentric recess, at a given time interval.

8.3. Low-speed centrifugation

Install the required centrifuge rotor according to section 6.4 of this manual.

Place the required number of microtubes/strips into the selected rotor according to section 7 of this manual.

Using the touch screen display, set the time required for stirring/low-speed centrifugation and perform the stirring/low-speed centrifugation of the contents of the tube(s)/strips.

9. Maintenance and repair

WARNING! The device is a technically complex device. Failure to comply with this requirement will invalidate the appliance warranty.

9.1. General provisions

All types of device repair, including the replacement of fuses installed inside the device case to protect against overloading of electrical circuits of the product, must be performed at the manufacturer's facility.

Product maintenance is aimed at keeping the product in working order and maximizing its service life.

Maintenance must be performed by qualified personnel who studied this manual carefully.

The device is designed for minimal maintenance during normal laboratory use.

It is necessary to protect the device from mechanical impact, as well as from contact of any liquids with the device body, except for liquids used for daily maintenance of the device.

9.2. Daily maintenance of the device

— inspection of the device to make sure that there are no damages on its surface, checking the condition (integrity) of the power cord, reliability of its connection to the device;

— inspection of the working surface of the table (and under the device) for foreign small objects (pieces of paper, swabs, etc.);

— cleaning of working surfaces of the device and rotor holes with a cotton swab soaked in 96% ethyl or 100% isopropyl alcohol;

— disinfection of external and working surfaces of the device by wiping them with a cloth soaked in 1% chloramine B solution or 3% hydrogen peroxide solution with 0.5% detergent or in accordance with the requirements of the sanitary rules in force in the user's institution.

WARNING! When working with cotton swabs and cloth napkins, it is necessary to avoid dripping from them.

9.3. Intermittent works

Intermittent device maintenance works must be performed in order established in the user's organization (institution).

9.4. Disinfection recommendations

The outer surfaces of the device are resistant to repeated treatment with disinfectants.

Use only chemicals authorized in accordance with the established procedure as local requirements.

WARNING! All operations must be performed in protective powder-free gloves.

9.5. Troubleshooting

Possible fault	Possible cause	Actions for elimination
After switching on the device, the signal LEDs on the touchscreen display do not light up	No mains voltage	Check for voltage, check the socket for proper operation
	Bad contact or break in the power cable	Check the contact between the power cable and the power supply
	The touch screen display is defective	Contact Customer service department of “DNA-Technology, LLC”
The touch display is turned on but does not respond to touch	The touch screen display is defective	Contact Customer service department of “DNA-Technology, LLC”
Rotor does not rotate	The electric motor is defective	Contact Customer service department of “DNA-Technology, LLC”

10. Requirements for device disinfection and decontamination before maintenance and repair

Before sending the device for repair and service, it is necessary to fulfill the requirement to disinfect and decontamination the device (ANNEX 1).

It is the responsibility of the user to ensure that the device is used correctly and that it is properly disinfected before it is sent to the manufacturer for service and repair.

11. Transportation

The device must be transported by all types of roofed transport in accordance with rules of cargo shipment effective for this type of transport.

Transport conditions of the device must be at a temperature from -50°C to +50°C at relative humidity of 80% at +25°C.

The device in the manufacturer's packaging should be stored in warehouses (heated and ventilated warehouses, air-conditioned warehouses located in any macroclimatic areas) at temperatures from 5°C to 40°C and relative humidity of 80% at 25°C.

The room where the device is stored or operated must be free of dust, vapors of acids and alkalis, aggressive gases and other harmful substances causing corrosion of metal parts or destruction of electrical insulation.

12. Environmental protection and disposal

The product must be pre-disinfected and autoclaved before disposal.

The product after use and disinfection belongs to class A (epidemiologically safe wastes).

The destruction of devices must be carried out by licensed organizations at specially equipped sites, landfills and premises.

The minicentrifuge-vortex is not a source of biological hazard. The laboratory-user profile determines the condition of the device in conditions of work with biological hazard and, if necessary, requires the installation of warning signs “Biological hazard”.

13. Information on the content of precious metals

The device does not contain precious metals.

14. Manufacturer's warranty

The manufacturer guarantees the proper operation of the DTspin medical minicentrifuge-vortex under the operating, transport and storage conditions described in this manual.

The warranty period of the device is 24 months from the date of sale to the customer. Warranty repair is performed only upon presenting the certificate for this device with a filled complaint sheet.

During the warranty period, the manufacturer undertakes to eliminate defects of the device free of charge by repairing it or replacing it with a similar one, provided that the defect was caused by the manufacturer's fault.

Fulfillment by the manufacturer of warranty obligations to repair the defective device leads to an increase in the warranty period for the time of repair of the equipment.

The warranty period under the storage conditions (section 11) is 60 months from the date of manufacture.

Under no circumstances shall the manufacturer and seller be liable for any damages, including loss of data, loss of profits, or other incidental, consequential, or indirect damages resulting from improper installation, maintenance, or operation, or from device failure or temporary inoperability.

The manufacturer is not responsible for defects and malfunctions of the device resulting from

— improper transport, storage, operation, or improper installation;

— improper handling, improper use of this device, or failure to follow operation manual;

— repair or reconstruction of the device by persons not authorized by the manufacturer, as well as breach of warranty seals;

— acts of God (fire, flood, earthquake, etc.) or the influence of random external factors (voltage surges in the mains, etc.);

— ingression of foreign objects, substances, liquids, insects, etc.

The warranty does not apply to devices with external defects (obvious mechanical damage, cracks, chips on the case and inside the device, broken contacts of connectors), and/or in the case of traces of mechanical damage of components on the boards.

15. EMC declaration

DTspin medical minicentrifuge-vortex meets the interference immunity and electromagnetic emission requirements given in EN 61326-1.

DTspin medical minicentrifuge-vortex is designed for use in the electromagnetic environment described below:

— DTspin medical minicentrifuge-vortex is constructed and tested in accordance with CISPR 11 requirements and is suitable for use in all spaces, including domestic spaces and spaces directly connected to the public low-voltage mains supplying buildings used for household purposes.

— The floors of the room should be made of wood, concrete or ceramic tiles. If the floors are covered with synthetic material, the relative humidity should be at least 30 %.

— The quality of the mains power supply must meet typical conditions of use in commercial facilities or hospitals.

— Industrial frequency magnetic fields should be at a level appropriate for typical use in commercial facilities or hospitals.

— Do not use the device in the proximity of sources of strong electromagnetic radiation, which may interfere with its normal operation.

Notes:

1 The manufacturer is responsible for providing the consumer or customer with information about the electromagnetic compatibility of the equipment.

2 The customer is responsible for maintaining an electromagnetic environment for the equipment that ensures compatibility in which the equipment is intended to function.

16. List of applied standards

1. IEC 61010-1 :2010 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements

2. IEC 61010-2-020:2006 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-020: Particular requirements for laboratory centrifuges

3. EN 61326-1 :2012 Electrical equipment for measurement, control and laboratory use. EMC requirements. Part 1. General requirements

4. CISPR 11:2015 Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement

ANNEX 1

Device decontamination certificate

1	Name of the device	
2	Manufacturing number	
3	Name of the owner organization	
4	Address of the owner organization	
5	Full name and signature of the person responsible for disinfection	

WARNING: *All the table graphs must be filled.*

1. Has the equipment been in contact with material contaminated or suspected to be contaminated with pathogenicity group I-IV microorganisms, including:	□ Yes	□ No
Blood components and preparations	□ Yes	□ No
material suspected of infection with microorganisms of pathogenicity groups III-IV	□ Yes	□ No
Including hepatitis B, S and HIV viruses	□ Yes	□ No
material suspected of infection with microorganisms of pathogenicity groups I-II	□ Yes	□ No
2. Has the equipment been in contact with toxic, carcinogenic or radioactive substances?	□ Yes	□ No
If so, specify types and quantities:		
3. The following reagent kits were used (list the names of the kits with the manufacturer): _____ _____ _____		
4. The following decontamination methods were used to prepare the equipment for the manufacturer's site:		

By sending the above equipment for work, we assume full responsibility for its biological, chemical and radiological decontamination, disinfection and cleaning as well as packaging.
We agree that in case of damage to the equipment during transport due to poor quality packaging, "DNA-Technology R&P", LLC assumes obligations to carry out maintenance/repair work only after written agreement with the Customer.

Customer:

_____
Organization name

_____
Signature, full name of the head of organization

Cut line

Manufacturer: DNA-Technology, Research & Production, LLC

20 Zheleznodorozhnaya Street, Protvino,
Moscow Region, Russia, 142281
Phone/fax: +7(4967) 31-06-70
E-mail: protvino@dna-technology.ru
https://dna-technology.com/

Customer support:

Phone: 8 800 200-75-15 (free for Russia)
E-mail: hotline@dna-technology.ru
Feedback form see on DNA-Technology's website
https://dna-technology.com/service_warranty

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