Operation Manual

DTprime

Real-Time PCR instrument

PART I

Operating Procedure

TS 9443-004-96301278-2010

CE

Safety Regulations

READ THIS MANUAL CAREFULLY BEFORE YOU START WORKING!

General safety regulations

If you encounter the  "Caution, Danger!" sign, contact your supervisor.

Before using the DTprime Real-Time PCR instrument (hereinafter referred to as the instrument), it is necessary to read this manual and pay special attention to the safety regulations. In order to avoid injuries and failure of the instrument and the equipment used with it, it is necessary to observe the following safety rules.

Improper use or misuse of the instrument may impair the protection provided by the equipment and may pose a health hazard.

Do not operate the unit if the humidity in the room exceeds 80 %. Condensation can lead to damage to the electronics of the instrument.

The device must be protected from shocks and falls.

The instrument should be stored and transported only in an upright position.

After transportation or storage in humid and cold conditions, before connecting to the power grid, the instrument must be kept in the room at a temperature of 18 °C to 25 °C for at least 3 hours.

Avoid all liquids or objects getting inside the unit. Doing so may cause the instrument to malfunction.

"DNA-Technology Research & Production", LLC is not responsible for any injuries or damage to health caused by improper use of the instrument or its independent repair and modification.

Electrical safety regulations

Before plugging in the instrument, ensure that the instrument is earthed by checking the protective earth in the socket to which the instrument will be connected and that the mains cable is intact. Do not plug the instument into an outlet without an earthing conductor. To connect to the mains it is necessary to use the mains cable included with the instrument.

Connect the instrument to the mains with voltage indicated on the nameplate of the device. If liquids get inside the instrument, disconnect it from the mains immediately and contact Customer Services.

 **Caution, danger of electric shock!** The fuses must be replaced during operation by a qualified person, using protective equipment and observing electrical safety standards and regulations. Fuses must only be replaced when the equipment is de-energized. The equipment is considered de-energized only when the mains cable is disconnected from the mains socket as well as when the computer-to-computer communication cable is disconnected from the USB 2.0 port of the instrument.

During operation

Do not expose the instrument to heat or direct sunlight or other strong light sources.

Maintenance

Do not open the instrument yourself! The interior of the instrument does not contain any user-serviceable components.
The instrument should only be serviced by specially trained qualified personnel.

 **Warning!** Parameters of settings of motor controllers, calibration parameters of optical and temperature units of instruments cannot be changed by the user. Calibration of the specified parameters of the instruments is performed by the manufacturer in accordance with the internal quality control regulations. If necessary, the instrument calibration data is provided by the service department of "DNA-Technology Research & Production", LLC. Adjustment of adjustable parameters should be performed according to the operation manual.

Safety precautions for use

The instrument corresponds to the following safety standards: EN 61326-1:2013, EN 61326-2-6:2020, EN 61010-1:2010, EN 61010-2-101:2017.

Operation of the instrument is considered safe under the following conditions:

- indoors;
- at altitudes up to 2.000 m;
- at temperatures from 5 °C to 35 °C;
- at maximum relative humidity 80 % for temperatures up to 31 °C; with linear decrease of relative humidity to 50 % for temperature no more than 35 °C
- at line voltage from 100 to 240 V, frequency 50-60 Hz.

The IP code for the instrument is IP20.
The instrument is a medical equipment for in vitro diagnostics (IVD) and is intended for research of DNA samples with application of PCR method and detection of accumulated product in real time (real-time PCR); it has no direct biological hazard.

Environmental impact

Decommissioning for repair or disposal: The instrument poses no direct biological hazard under normal operating conditions.

The instrument must be disposed of in accordance with the laws in force in the country of use. The instrument does not contain any materials that pose a direct threat to the environment.

Note

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user.

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1 Description and operation

1.1 Purpose and modifications

The instrument is intended for DNA samples analysis using the PCR method and real-time detection of the accumulated product (real-time PCR).

Field of application: clinical laboratory in vitro diagnostics.

Functional purpose: auxiliary in vitro diagnostics.

Type of sample to be analyzed: nucleic acids extracted from biomaterials, depending on the test specific reagent kits used.

Potential user: qualified personnel trained in molecular diagnostic techniques and clinical diagnostic laboratory rules.

The instrument is available in the following modifications:

4M1, 4M3, 4M6, 5M1, 5M3, 5M6, 4X1, 5X1.

Modification of the device is defined by the following structure XXX, where:

- the first X is a digit (4 or 5) and indicates the number of optical detection channels;
- the second X is a symbol (M or X) and is the format of the thermoblock M – 96 wells of 200 µl, X – 384 wells of 45 µl;
- The third X is a number (1, 3 or 6) and indicates the the structure of the thermoblock (1 – monoblock, 3 or 6 – number of sections).

The DTmaster service program is used to control the instrument.

The instrument can perform the set amplification program autonomously.

Preparation, initialization of experiments and subsequent analysis of the obtained data is performed by the user on the computer using the installed software included in the delivery set.

All data from the last assay are recorded in the instrument's own memory and can be read even after a power failure (power outage) during amplification. A failure of the operating system of the host computer, or a computer shutdown, also does not cause the amplification program to stop.

The instrument is not bound to specific test systems and is an **open system**.

1.2 Technical specifications

Technical specifications of the instrument are presented in Table 1.

Table 1 – Technical specifications

Characteristic	Value
Thermoblock format (modification M)	96 0.2 mL tubes (12x8)
Thermoblock format (modification X)	384-well microplate
Tube type (modification M)	200 µl PCR tubes (separate, in 8-tube strips)
Tube type (modification X)	45 µl 384-well microplate
Reaction mixture volume (modification M), µl	10 - 100 (10 - 50 is recommended)
Reaction mixture volume (modification X), µl	5 - 30
Temperature control range of the thermoblock, °C	0 - 100
Discreteness of temperature setting, °C	0,1
Accuracy of temperature maintenance, up to, °C	±0,2
Temperature irregularity of the thermoblock, up to, °C	0,3
Average speed of heating of the thermoblock in the temperature range from 0°C to 100°C (modification M), °C /sec Maximum heating rate of the thermoblock in the temperature range from 0°C to 100°C (modification M), in °C /s	3,3 3,5
Average rate of thermoblock cooling in the temperature range from 100 °C to 55 °C (modification M), °C /s Maximum cooling rate of the thermoblock in the temperature range from 100 °C to 55 °C (modification M), °C /s	2,1 2,5
Average rate of thermoblock heating in the temperature range from 0 °C to 100 °C (modification X), °C /s Maximum speed of thermoblock heating in the temperature range from 0 °C to 100 °C (modification X), °C /s	2,1 2,5
Average rate of thermoblock cooling in the temperature range from 100 °C to 55 °C (modification X), °C /s Maximum cooling rate of the thermoblock in the temperature range from 100 °C to 55 °C (modification X), °C /s	1,0 1,5
Hot lid temperature, °C	105±1
Actuating device of thermoblock	Peltier elements
Excitation source	LED

Detector	CCD
Number of optical channels	4 (modifications 4M1, 4M3, 4M6, 4X1), 5 (modifications 5M1, 5M3, 5M6, 5X1)
Excitation/detection wave lengths, nm	470/515, 530/560, 580/620, 630/660, 687/731*
Sensitivity threshold of each channel for standard fluorophore solutions, mol	0,05·10-12
Interface with computer	USB 2.0 High-speed
Power Consumption, up to, W	550
Supply voltage, V	100-240
Mains frequency, Hz	50 - 60
Dimensions, WxHxV, mm	210x540x540
Time of preparation after switching on, up to, min	5
Weight, kg	27
* Upon agreement with the customer, the spectral characteristics of the channels can be changed within the range from 450 to 750 nm	

Warning! For consistent results, tubes with a cone angle of 17º20' should be used.

1.3 Package contents

The instrument package contents is presented in Table 2.

Table 2 – Set

Name	Manufacturer	Number, pcs.
Detection thermal cycler	“DNA-Technology Research & Production”, LLC	1
Operation manual (in two parts)	“DNA-Technology Research & Production”, LLC	1
PC communication cable, USB 2.0 type	China	1
Mains cable (3-wire)	Taiwan	1
Safety fuses (10A, 5x20mm, 250V)	Siba, Germany	2
Software distribution package (DTmaster,v.1.1 and higher)	“DNA-Technology Research & Production”, LLC	1
PC with software preinstalled*	Any brand, any manufacturer that meets the safety and EMC requirements (confirmed by the technical regulations of the Customs Union), see section 1.4 for characteristics	1

* On customer’s request

Notes

1 The manufacturer reserves the right to make changes and additions to the list of additional devices and consumables as further developments occur.

2 If the customer uses additional devices and consumables that are not provided for in the table above, the manufacturer is not responsible for the quality and reliability of the device operation.

1.4 PC requirements

The instrument operates under the control of a personal computer of any brand and any manufacturer that meets the safety and electromagnetic compatibility requirements (confirmed by the technical regulations of the Customs Union), which have the following minimum requirements:

- Intel or AMD processor with a clock frequency of at least 1 GHz;
- Memory capacity of at least: 1 Gb for 32 bit system or 2 Gb for 64 bit system;
- at least 512 Mb of free disk space;
- minimum screen resolution of 1024x768 pixels;
- Windows 7, Windows 8, Windows 10 operating system;
- availability of free ports in the computer that comply with the USB 2.0 standard.

1.5 Connection possibilities

One computer can control several simultaneously connected devices of DT series manufactured by «DNA-Technology Research & Production», LLC (the number of instruments depends on the characteristics of the computer). In this case the instruments must be connected to the computer by USB communication cable.

1.6 Design and principle of operation

The instrument is a specialized device that combines the functions of a precision programmable thermocycler and an optical system that makes it possible to record the fluorescence of the reaction mixture in test tubes directly during PCR.

1.6.1 Design of the instrument

The instrument design is a supporting frame on which the following units are mounted:

- the instrument design is a supporting frame on which the following units are mounted:
- a heat block (thermoblock) with a moving and positioning device;
- optoblock, consisting of fluorescence excitation sources based on LEDs and detector based on a camera with CCD;
- an optotract unit for transporting the light beams;
- the carriage that ensures the movement of the heat block on it;
- a heat cover unit that prevents the spontaneous opening of the caps of the test tubes, possible contamination of the product with the products of amplification, condensation of liquid on the caps inside the test tubes;
- a horizontal drive to move the carriage horizontally to load and unload tubes into the heat block matrix;
- a vertical drive that provides vertical movement of the carriage to press the tubes to the heat block matrix;
- electronics modules with power supply units.

Bearing frame is structurally closed by decorative and side panels. On the side panels and in the bottom of the instrument there are ventilation slots.

On the front of the device there are (Figure 1):

- LCD screen;
- push-button control panel;
- hot lid front panel;
- thermal unit front panel.

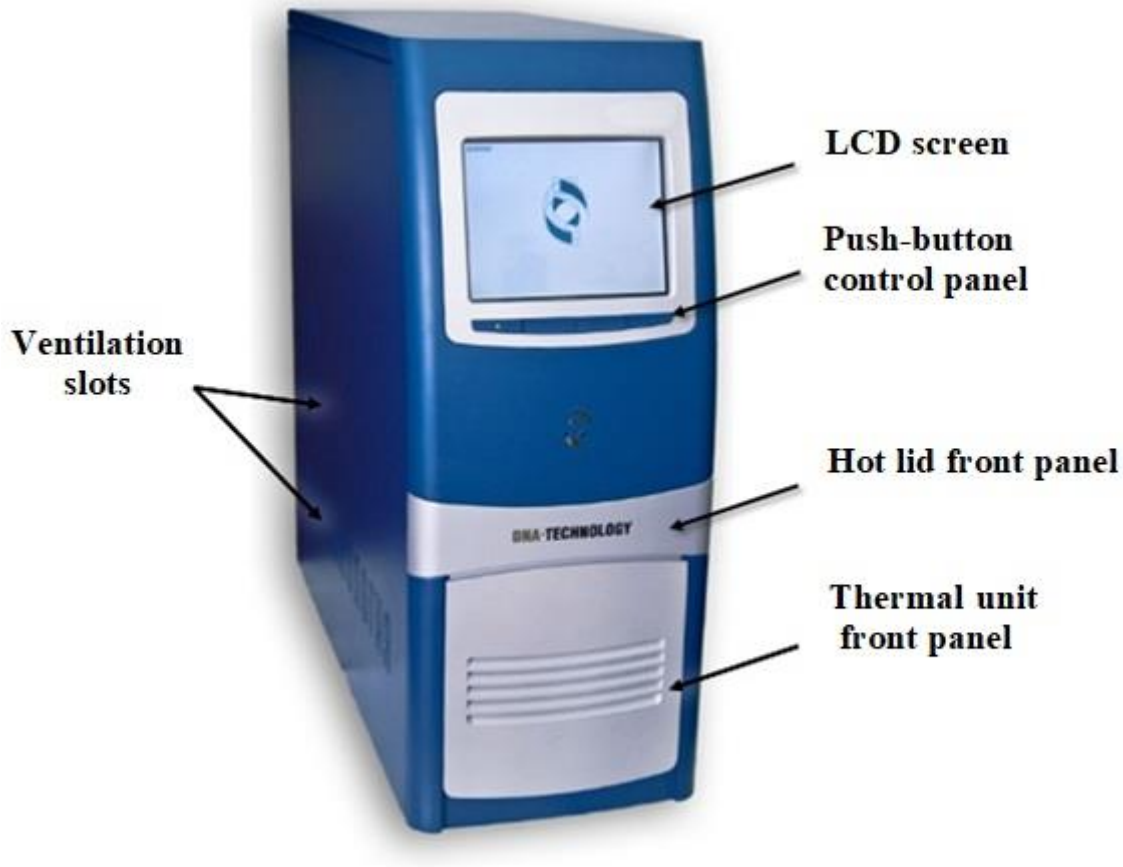


Figure 1 – Location of controls and displays

The rear panel of the instrument (Figure 2) contains:

- power switch;
- fuses;
- power connector socket;
- USB 2.0 High-speed connector socket for connecting the instrument with a PC.

Figure 2 – Connector layout on the rear panel

Functionally, three main systems can be distinguished in the instrument:

- the high-speed thermal management system;
- optical system;
- control and display system.

1.6.2 High-speed thermal management system

The high-speed thermal management system includes a thermoblock, a thermoblock movement and positioning unit, and a hot lid unit.

The heat block (thermoblock) provides thermocycling of test tubes according to the law set by the amplification program with minimal deviations from this law. Test tubes are placed in a matrix, which is a cellular structure with stiffening ribs. Six thermoelectric Peltier elements are used in the device for cooling and heating the matrix. Each element has its own temperature sensor and temperature controller, which allows to set the necessary temperature gradients across the matrix.

The movement and positioning unit of the thermoblock is designed to provide comfortable access to the tubes for their replacement.

Hot lid unit is designed to provide a reliable thermal contact between the tubes and matrix and maintain the temperature of tube caps at 105±1 ºC, which is necessary to avoid the formation of condensation on the tube caps, which can lead to significant distortions in the measurement of light flux. The design of the lid provides variable clamping force of the tubes to the matrix, which depends on the number of installed tubes. During a PCR program, the hot lid moves vertically from bottom to top. The moment the tubes touch the surface of the hot lid is monitored by a special sensor and the electronic system calculates the necessary clamping force. The drive system moves the heat block vertically by the value that provides the necessary clamping force of the tubes to the surface of the hot lid.

1.6.3 Optical system

The optical system of the instrument consists of the optical unit and the light beam transport unit.

The optical unit is a system of lenses, mirrors and filters, providing the alignment of the light flux of several projectors on one optical axis and its separation from the light flux entering the CCD. The light sources are powerful LEDs.

The light beam transport unit ensures the transfer of the light flux from the illuminators of the optical unit to the tubes and the fluorescence light flux from the tubes to the CCD located in the optical unit.

The light beam transport unit is a rectangular box. At the corners of the box there are rectangular mirrors, which ensure the passage of light in the right direction.

The system of light locks design provides complete isolation of the optical path from the outside light.

1.6.4 Control and display system

The control and indication system includes a push-button panel for manual control of the thermoblock drive and an LCD monitor for indication of the amplification program progress.

The OSD button displays information about the functions of the other buttons of the panel in the given operating mode of the instrument.

Button for controlling the thermoblock drive (second from the left) is used to start the following operations:

- pulling out the thermoblock from the device body to insert tubes into the wells of its matrix before performing PCR;
- precise positioning of the thermoblock and optics in the working position in order to avoid penetration of extraneous light into the optical path and securely clamp the tubes to the matrix.

A liquid crystal display (Figure 3) is designed to display a text description of the amplification program and indication of the process of its execution and displays the following information:

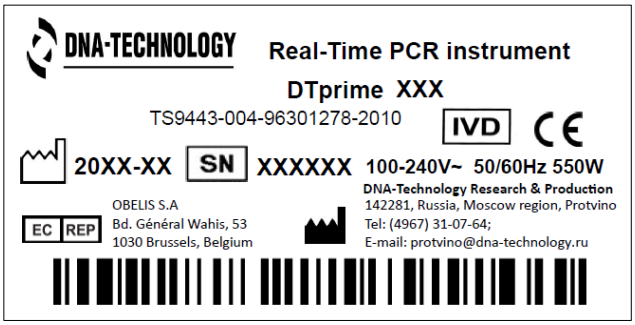
- operator's name;
- date of start of the amplification program;
- protocol number;
- name of the amplification program;
- Instrument serial number;
- number of measurements performed;
- start time of the amplification program;
- status of the instrument at the end of the amplification program;
- current temperature of the reaction mixture;
- time remaining before completion of the amplification program;
- text description of the amplification program;
- fluorescence measurement channels involved;
- optical measurements indicator;

– indicator of the execution of the amplification program.

Figure 3 – Liquid crystal display

1.7 Labelling

Instrument labelling is made according to the requirements of EN ISO 18113-1:2011, EN ISO 18113-3:2011, EN 61010-1:2010, EN 61010-2-101:2017.
Example of label (namebody) placed on the instrument body:



Shipping crates (or boxes) are marked with warning handling signs: “Fragile, Handle with Care”, “Top”, “Protect from Moisture”, “Stack Prohibited”, and:

– trademark or name of the manufacturer;

– name of the instrument;

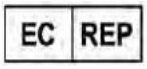
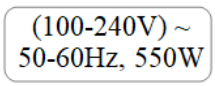
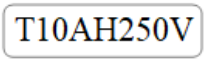
– year and month of packing;

– net weight;

– gross weight;

– environmental parameters during transportation and storage.

Labelling symbols:

	In vitro diagnostic medical device
	Temperature limit
	Fragile, handle with care
	Upright
	Keep dry
	Do not stack
	Date of manufacture
	Manufacturer
	Caution! High voltage
	Caution
	Serial number
	Medical devices comply with the requirements of the European Directive
	Authorized representative to the European Community
	Mains voltage, mains frequency and maximum power consumption of the device
	Name of mains fuses
	Connector designation
UDI	DTprime 4M1 Basic UDI-DI: **4660014360505** DTprime 4M3 Basic UDI-DI: **4660014362370** DTprime 4M6 Basic UDI-DI: **4660014362387**

	DTprime 5M1 Basic UDI-DI: **4660014360499** DTprime 5M3 Basic UDI-DI: **4660014362417** DTprime 5M6 Basic UDI-DI: **4660014362424** DTprime 4X1 Basic UDI-DI: **4660014362363** DTprime 5X1 Basic UDI-DI: **4660014362400**

2 Preparing the instrument for use

2.1 Unpacking the appliance

The instrument is delivered in the manufacturer's shipping package, which is a cardboard box with polyethylene foam inserts.

The instrument is placed in a non-woven bag before being packed in the box.

Warning! In addition to the thermal cycler, the box contains the following components (see section 1.3).

 **Warning! Heavy!** The instrument must be delivered to the place of installation in the manufacturer's package by two people.

To remove the instrument from the box do the following:

- prepare a working place for the device on the table;
- Place the box with the device near the table and open the lid;
- Remove the accessories included in the delivery, as well as the upper foam inserts from the box;
- check the availability of accessories, according to the delivery kit (see item 1.3);
- taking precautionary measures, two people lifting by transportation straps and holding by the base, take out the device from the box and put it on the table;
- Remove the instrument from the bag and examine it for any external damage.

If the instrument or any accessories are damaged or missing, please contact the "DNA-Technology" representative in your region.

2.2 Carrying the instrument

The instrument in operation can be carried by two people over short distances within the building with the packaging removed or on a mobile table (cart) with installation on a previously prepared workplace, taking the necessary precautions.

If it is necessary to carry the instrument over long distances or transport it by vehicle, it is necessary to place it in the manufacturer's packing

Warning! The withdrawable thermoblock must always be in the locked position when transporting the instrument. Locking is done by issuing a command to close the thermoblock. If this is not the case (e.g. if the instrument is defective), please consult the manufacturer's representative.

2.3 Installing and connecting the instrument

Warning! The instrument contains precision mechanical components. To avoid displacement of the optical system, jolts and shocks should be avoided during operation and handling. The unit may only be transported with the thermoblock locked-in position (closed).

Warning! When deciding where to place the instruments, make sure there is a minimum distance of 14 cm between the front of the instrument and the edge of the table and that there is a clearance of at least 12 cm to the right, left and rear of the instrument.

The instrument must be installed in a convenient location with adequate ventilation to prevent condensation and free access to the thermoblock and power switch.

Switching the instrument on and off is done with the power switch located on the back of the unit.

To de-energize the instrument completely, you must be able to access the back of the instrument and the power outlet to disconnect the power cord and the USB 2.0 cable from the computer.

The instrument does not need additional devices that stabilize the mains voltage. If you need to connect the instrument to uninterruptible power supply devices, take into account that the latter should provide, in addition to other consumers, an output power of at least 550 W to power the instrument.

Before you plug in the device, make sure there is a protective earth in the socket the device will be connected to. First connect the supplied power cord to the appliance. Then, making sure that the mains power switch is in the Off position, plug the mains plug into the socket.

Connect the instrument to the computer using the supplied USB 2.0 communication cable.

Switch on the unit with the mains power switch – position On, then the start window will appear on the monitor of the instrument.

Warning! It is important that the unit and the control computer are properly grounded at the sockets to which they are connected. If this condition is not met, the instrument may malfunction.

2.4 Software

The DTmaster software and the device driver must be installed on the user's computer in order to control the device.

Note – The installation files are supplied on a USB flash drive and can also be obtained from the Internet.

Instructions for installing the driver for DT series detector thermal cyclers are included on the USB flash drive along with the installation files.

For the software installation procedure, see Part II of the operation manual.

The software installation should be carried out only if the instrument is purchased separately from the computer. If a computer was delivered with the instrument, the software is already installed on it.

Warning! If you purchase the instrument separately from the computer, the installation disk with the Windows operating system is not supplied.

3 Operating the instrument

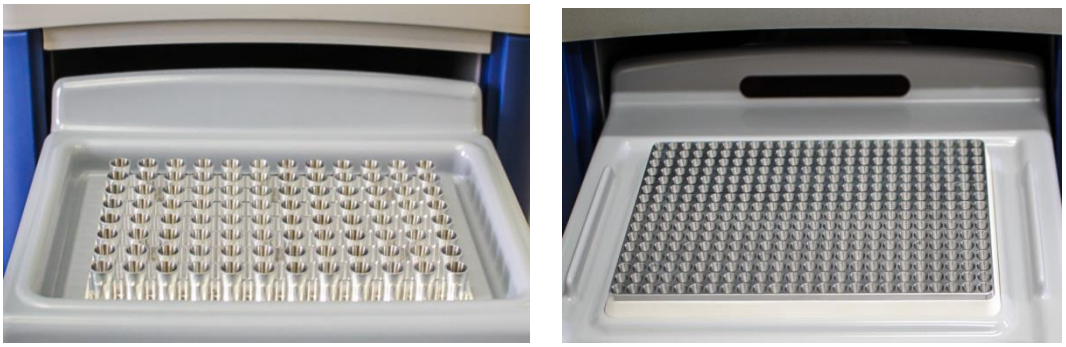
3.1 Preparing the instrument for PCR

Checking the readiness of the instrument for PCR is performed automatically each time the instrument is switched on.

Before the first run of the instrument, the geometrical settings of the optical unit are checked, the cleanliness of the wells is checked, and the height of the tubes is adjusted.

3.2 Inserting tubes into the instrument

To install the tubes into the instrument, do the following:



a b

Figure 4 – Appearance of the thermoblock matrix in the extended position

(a – modification **M**, b – modification **X**)

Step 1. Open the thermoblock by pressing the **Open thermoblock** button in the control program window of the instrument or the thermoblock manual control button on the instrument and wait until the thermoblock locks in the extended position.

Note – it is recommended to clean the thermoblock wells before turning on the device for the first time (see section 4.2).

Step 2. Set up the tubes in the wells of the thermoblock according to the completed PCR protocol.

Step 3. Close the thermoblock by pressing the **Close thermoblock** button in the instrument control window or the manual button on the thermoblock drive and wait until the thermoblock is in the locked position.

Warning! At least 8 test tubes should be installed to prevent deformation of the test tubes. If the number of working tubes is smaller, it is recommended to add empty tubes of the same height.

Caution! The instrument provides automatic loading and unloading of test samples from the thermoblock in the operating position. The command to move (open or close) the thermoblock comes from the user. It is forbidden to perform any manipulations with the thermoblock during its moving, as this may damage the moving mechanisms. If the thermoblock is obstructed in the process of closing, the thermoblock automatically enters the opening mode. To ensure the safety of the user, in case of a mechanical obstacle during the movement of the thermoblock, the decorative front panel of the thermoblock is designed to be hinged.

3.3 Starting the amplification program

Step 1. After making sure the instrument is turned on and communicating with the computer, run the instrument control software on the user's computer.

Step 2. Create (edit) a measurement protocol and amplification program, and enter parameters for the upcoming run.

For the procedure for creating (editing) the protocol and amplification program, see Part II of the operation manual.

Step 3. Install the tubes into the thermoblock.

Step 4. Run the created amplification program from the user computer. After the program is complete, the results are viewed in the instrument control software.

When the amplification program is complete, the instrument goes into standby mode. If a subsequent “Store” or “Sleep” mode was specified when the program was created, the instrument will automatically switch to the specified mode after the amplification program is completed.

Warning! The thermoblock matrix and hot lid unit can be heated up to 100 ºC and 105 ºC respectively during operation. The thermoblock matrix and hot lid unit are not accessible to the user during the PCR program (run mode). Once the instrument has completed the amplification program, do not remove the tubes from the thermoblock until the program message is displayed on the user computer.

4 Maintenance and repair

4.1 General information

Do not open the device yourself! The interior of the unit does not contain any user-serviceable components.

Warning! The settings of the motor controllers, the calibration parameters of the optical and temperature units of the instrument cannot be changed by the user. The calibration of these instruments is done by the manufacturer in accordance with the internal quality control regulations. Data on calibration of the abovementioned devices are provided by the technical support service of "DNA-Technology Research & Production", LLC, if necessary. Adjustment of adjustable parameters should be performed according to the operation manual.

The instrument is a technically complex device. Scheduled service maintenance and repair of the device is performed by specialists of the manufacturer's service department.

Maintenance of the DTprime detection thermal cycler by the users is aimed at keeping the instrument in operating condition and ensuring its maximum service life

 **Caution, danger of electric shock!** Fuses must be replaced only when the equipment is de-energized. The equipment is considered de-energized only when the mains cable is disconnected from the mains socket, and when the computer communication cable is disconnected from the USB port of the instrument.

When replacing it is necessary to use fuses T10AH250V with parameters (10 A, 250 V slow-blow with high breaking capacity) 5x20 mm in size.

It is necessary to protect the instrument from mechanical influences, from getting any liquids on the case of the instrument.

In order to keep the thermostat wells and optical system components clean, the thermoblock of the instrument must always be in the fixed (closed) position (except for the periods of inserting and removing sample tubes).

Warning! To avoid failure of the optical system, no substances (heat-resistant pastes, oils, etc.) should be used to improve the contact between the tube and the well of the thermoblock.

4.2 Routine maintenance

Routine maintenance of the instrument should be performed by qualified personnel who have studied this manual in detail.

The instrument is designed for minimal routine maintenance during normal laboratory operation.

The following steps should be performed by service personnel at the specified intervals:

1.2.1 External inspection of the device for damage on the surface of the device. Condition (integrity) of the power cord, reliability of its connection to the device.

Frequency of action: before starting work.

1.2.2 Remove dust and dirt from the surface of the device, using disinfectant solutions, in accordance with the requirements mandatory for use in the facility of the user.

Frequency of action: before starting work.

1.2.3 Cleaning of the thermoblock wells to eliminate possible contamination with nucleic acid amplification products shall be performed using disinfectant solutions according to the standards and regulations applicable in the user facility. The thermoblock wells are cleaned with a cotton swab wrapped around a wooden rod and moistened with, for example, 70 % ethanol.

Frequency of action: every 20 runs of the device.

After cleaning, the image of the thermoblock for all channels should be viewed. If there are bright spots in the wells of the thermoblock in any of the fluorescence registration ranges, additional cleaning of the wells of the thermoblock is necessary.

Note – To check the cleanliness of the thermoblock wells, see Part II of the operation manual.

Warning! It is strictly prohibited to use metal objects (tweezers, paper clips, wire etc.) as a cotton swab!

Warning! When cleaning the wells and the surface of the thermoblock matrix do not allow liquids to get into the gap around the edges of the thermoblock matrix and between the sections of the matrix in the sectional modification!

4.3 Requirement for disinfecting the instruments prior to maintenance and repair

It is the responsibility of the user to decontaminate the instrument before servicing or repairing it.

Before sending the instrument for repair or maintenance, the instrument must be decontaminated and a “Statement of Work” must be filled out (see Appendix A). Disinfect the instrument according to section 4.2.3.

4.4 Possible faults and measures to remedy them

Possible faults with indication of further user actions are presented in Table 3.

Table 3 – Possible faults and recommended user actions

Fault description	Possible reason	User actions
There is no information on the monitor after turning on the device	No mains voltage	Check availability of voltage, serviceability of the socket
	Bad contact or open circuit in power cable	Check contact of the power cable and the device, replace with the similar (10 A, 250 V, 3x0,75 mm) cable, replace the fuses T10AH250V (10 A, 250 V), which are included in the delivery. Failed fuses can only be replaced once!
"No device" status appears in the "Device list" software window	Bad contact or wire breakage in the cable for PC connection	Check the instrument PC connection cable
	Device driver not installed	Install the instrument driver (see section 2.4)
	Windows system failure	Restart the computer
After 10 - 15 minutes of warm-up the instrument does not go into standby mode. The instrument serial number appears in the software status bar against a yellow background.	Instrument malfunctioned	Contact the supplier of the device
During the execution of the amplification program the instrument's serial number appears in the software status bar against a red background	Instrument connection with the computer is broken	Restore the connection between the instrument and PC, then the software will detect the instrument and count the missed data without interrupting the amplification program. If this message appears continuously, stop the application and start it again

5 Storage and transport

The instrument should be stored in a closed room with natural ventilation at a temperature from 5 °C to 40 °C and relative humidity up to 80 % at 25 °C. In case of long-term storage without use, the instrument should be stored in the manufacturer's package.

The rooms where the instrument is stored or operated should be free of dust, acid and alkaline vapors, aggressive gases and other harmful substances that cause corrosion of metal parts and destruction of electrical insulation.

When transporting the instrument must be protected from dust and atmospheric precipitation. **It is not allowed to tilt the instrument.** Before transportation, the unit must be fixed to ensure a stable position, exclude displacements and shocks.

The instrument can be transported by all types of transport in the manufacturer's package in compliance with the requirements of the handling marks applied on the surface of the package for transportation. During transportation the instruments must be at temperatures from minus 50 °C to plus 50 °C and relative humidity of up to 80 % at 6 °C.

Warning! The instrument contains precision mechanical components. To prevent their damage during handling and transportation, the requirements of the handling marks on the packaging for transportation must be strictly observed.

Warning! The unit may only be transported with the thermoblock in the locked (closed) position.

Warning! When transporting the instrument, it is guaranteed that its technical characteristics (section 1.2), including those determined during certification of the amplifier as a test equipment, remain intact.

6 Instrument disposal

Disposal of medical devices must be carried out in accordance with the classification, rules of collection, use, disinfection, storage, transportation, accounting, and disposal of medical waste established by the authorized federal executive body.
Disposal of the instrument must be carried out by organizations having the appropriate license, at specially equipped places in accordance with the requirements stipulated by the current federal laws, and with observance of mandatory requirements for environmental protection in accordance with the local regulations.

7 EMC declaration

The instrument complies with the interference immunity and electromagnetic emission requirements given in EN 61326-1:2013, EN 61326-2-6:2021.

The instrument is designed for use in the electromagnetic environment described below:

- The appliance is designed and tested in accordance with CISPR 11 suitable for use in all areas, including domestic premises and areas directly connected to the public low-voltage power supply network supplying buildings intended for domestic purposes.
- Mains power quality should be that of a typical commercial or hospital environment.
- Commercial frequency magnetic fields should be at a level appropriate for typical commercial or hospital environments.
- The instrument uses radio frequency energy exclusively for its internal function. The level of radio emission is very low and does not disrupt the operation of nearby electronic equipment.
- Do not use the device near sources of strong electromagnetic radiation that may impair 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.

8 System liability

The manufacturer guarantees proper operation of the DTprime Real-Time PCR instrument and its compliance with TS 9443-004-96301278-2010 when observing the rules of operation set forth in this manual.

The warranty period of the device and accessories is **24 months** from the date of sale to the consumer. Warranty repair is performed only on presentation of the coupon for this device with a filled complaint sheet.
The average calendar service life of the device is at least **5 years** from the date of operation.
At the end of the average service life of the instrument, the user is recommended to contact the manufacturer's service department to obtain a conclusion on further operation of the instrument.
The warranty shelf life of the device is **12 months** from the date of manufacture if the storage conditions are observed (heated storage with the room temperature from 5 °C to 40 °C).
During the warranty period, the manufacturer undertakes to eliminate the defects of the instrument by repairing it or replacing it with a similar one free of charge, provided that the manufacturer is responsible for the defect.
Fulfillment by the manufacturer of warranty obligations on repair of the failed equipment entails extension of the warranty period for the time of repair of the equipment.
The manufacturer is not responsible for compatibility of specialized software with any hardware or software supplied by other manufacturers, unless otherwise specified.
In no event shall the manufacturer and seller be liable for any damages, including loss of data, loss of profit, or other incidental, consequential, or indirect damages resulting from improper installation, maintenance, or operation by the user, or from failure or temporary inoperability of the instrument.
The manufacturer shall not be liable for defects and malfunctions of the instrument resulting from:

- non-compliance with the rules of transportation, storage conditions, operation or improper installation;

- improper operation, improper use of the instrument for other purposes, non-compliance with the requirements set forth in the operating manual;

- repair or modification of the equipment by persons unauthorized by the manufacturer, as well as violation of warranty seals;

- acts of God (fire, flooding, earthquake, etc.) or the influence of random external factors (voltage surges in the electrical network, etc.);

- the warranty does not apply to the instrument if foreign objects, substances, liquids, insects, etc. get inside the device.

The warranty does not apply to devices with external defects (obvious mechanical damage, cracks, chips on the case and inside the instrument, broken contacts of connectors), to instruments with open or damaged seals on the screws fixing the side panels of the case.

9 Model Packaging certificate

Date of packaging «…….»…….20…

Performed the packaging _____ (signature)

Received the instrument after packaging_____ (signature)

Place seal

Note – The form is filled out at the company that made the package.

10 Model Certificate of acceptance

Device has passed the acceptance tests, complies with

TS 9443-004-96301278-2010 and recognized suitable for operation.

Date of manufacture «…….»…….20…

Place seal

Responsible for acceptance _____ (signature)

11 Model warranty service coupons

Warranty Card No. 1 ***filled out by manufacturer***

For warranty repair (maintenance)

A representative of the manufacturer's Quality Department ……..……

(seal of the QD)

Sales note _____

(name of the enterprise)

"…….".…….20… Seal of the enterprise

(date) (personal signature)

Owner and his address……(personal signature)

……

Warranty Card No. 2 ***filled out by manufacturer***

For warranty repair (maintenance)

A representative of the manufacturer's Quality Department ……..……

(seal of the QD)

Sales note _____

(name of the enterprise)

"…….".…….20… Seal of the enterprise

(date) (personal signature)

Owner and his address……(personal signature)

Back of the Warranty Card No. 1 ***filled out by repair facility***

Repair procedure

……..……..

……...……

……...

……...

……

Repair date……..
(DD.MM.YYYY)

Specialist…….Owner……....
……(signature, seal) (signature)

……...

Back of the Warranty Card No. 2 ***filled out by repair facility***

Repair procedure

……..……..

……...……

……...

……...

……

Repair date……..
(DD.MM.YYYY)

Specialist…….Owner……....
……(signature, seal) (signature)

12 List of claims and instrument disinfection procedure

Serial number of instrument: _____

Detailed description of the defect: _____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

Means used for disinfection: _____
_____
_____
_____

Procedure of instrument disinfection: _____
_____
_____
_____
_____
_____
_____
_____

Full name: _____

Position: _____

Company: _____

Signature: _____

Date: _____

Appendix A

Disinfection certificate

***Attention*: It is necessary to answer all questions in the table.**

1. Has the instrument operated with material contaminated or suspected of being infected with microorganisms of I-IV pathogenicity groups, including:	☐ Yes	☐ No
components and blood substances	☐ Yes	☐ No
samples suspected of being infected with microorganisms of III-IV pathogenicity groups	☐ Yes	☐ No
including hepatitis B and C viruses, HIV	☐ Yes	☐ No
samples suspected of being infected with microorganisms of I-II pathogenicity groups	☐ Yes	☐ No
2. Has the instrument operated with toxic, carcinogenic or radioactive substances?	☐ Yes	☐ No
If yes, please indicate types and quantities:		
3. the following kits were used with the instrument (list the names of the kits with the manufacturer's indication): _____ _____ _____ _____ _____ _____ _____ _____ _____ _____		
4. the following decontamination methods were used prior to sending the instrument to repair a manufacturer production site:		

Company _____ takes full responsibility for the biological, chemical and radiological decontamination, disinfection and cleaning, as well as packaging of the instrument serial number _____. We agree that in case if the instrument is damaged during transportation due to poor-quality packaging, DNA-Technology R&P LLC assumes obligations to carry out maintenance / repair procedures after written agreement with the Customer only.

Customer:

_____
Company name

_____
Signature

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Phone/fax: +7(4967) 31-06-70
E-mail: protvino@dna-technology.ru
http://www.dna-technology.ru

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Chertanovo Severnoye, Varshavskoe shosse, 125Zh,
building 5, floor 1, office 12
Phone/fax: +7(495) 640-17-71
E-mail: info@dna-technology.com

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Feedback form see on DNA-Technology's website
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