

Operation Manual

DTprime II
Real-Time PCR instrument
Operating Procedure

TS 26.51.53-001-96301278-2022

“DNA-Technology Research&Production”, LLC
Protvino



Safety Information

READ THIS MANUAL CAREFULLY BEFORE USING THE INSTRUMENT!

General safety

Before using the **Real-Time PCR instrument DTprime II** (hereafter referred to as the “instrument”), please read this manual carefully and pay particular attention to the safety information. To avoid accidents, as well as breakdown of the instrument and equipment used therewith, observe the safety rules given below.

Do not operate the instrument if humidity exceeds 80 % in the room. Condensate formation may result in a short circuit in the instrument electronics.

The instrument should be saved from shocks and falls.

The instrument must be stored and transported only in a vertical position.

After transport or storage in humid and /or cold conditions, dry out the instrument for at least 3 hours in a room temperature from 15 °C to 31 °C in the shipping package.

If the instrument is switched on while drying, the internal protection may be compromised.

Avoid getting any liquids or objects inside the instrument case. Doing so may result in damage to the instrument. Ingress protection IP20.

Electrical safety



Before connecting the instrument to the mains, ensure that it is earthed by checking that there is a protective earth connection in the socket to which the instrument is to be connected and that the mains cable is intact. Do not plug the instrument into an outlet without a grounding conductor. The mains cable supplied with the instrument must be used to connect it to the mains power supply.

The instrument must be connected to the mains with the voltage specified on the nameplate of the instrument.

Do not replace the mains cable with an incorrectly rated cable.

If liquid gets inside the instrument, disconnect it from the mains immediately and call for service.



Caution! Danger of electrical shock! Replacement of fuses during operation of the instrument should be carried out by a qualified technician, using protective equipment and observing electrical safety rules and regulations. Fuses should only be replaced when the instrument is de-energized. The instrument is de-energized only when the mains cable is disconnected from the mains socket and the communication cable is disconnected from the instrument.

During operation

The instrument does not generate noise that may cause danger. The sound power level of the device noise does not exceed 70 dBA.

Do not expose the instrument to heat and sunlight or bright light from other intensive light sources.



Warning, hot surface! The heat block panel can be heated to high temperatures. Be careful when operating the instrument and avoid burns.

Do not open the instrument yourself! There are no user-serviceable components inside the instrument.

There is no need for regular optical calibration of the instrument during operation.

Operational safety

The instrument corresponds to the following safety standards: EN 61326-1:2021, EN 61326-2-6:2020, EN 61010-1:2010/A1:2019, EN 61010-2-101:2018.

If the instrument is used improperly or not as intended, the protection of the instrument may be impaired. The instrument should only be serviced by specially trained, qualified personnel.

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

The instrument does not come into contact with patients. Disposable gloves and protective clothing should be worn when working with the instrument. Protect your eyes when handling samples. Gloves should be changed as soon as they become visibly contaminated. At the end of work wash hands thoroughly.

Environmental effect

Decommissioning for repair or disposal: the instrument does not pose a biological hazard under normal operating conditions. The instrument must be disposed of in accordance with local regulations. 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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Marking symbols
















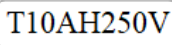
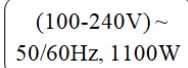


	Medical device for <i>in vitro</i> diagnostics
	Medical devices comply with the requirements of the European Directive
	Authorized representative to the European Community
	Serial number
	Temperature range
	Fragile, handle with care
	Top
	Keep dry
	Stacking is forbidden
	Date of manufacture
	Manufacturer
	Warning! Electrical voltage
	Warning, hot surface
	USB connector
	Ethernet connector
	Mains fuse
	Mains power input connector
	On (source)
	Off (source)
UDI-DI	DTprime II 4M1 4660014366453, DTprime II 4X1 4660014366460, DTprime II 4M3 4660014366477, DTprime II 4M6 4660014366484, DTprime II 5M1 4660014366491, DTprime II 5X1 4660014366507, DTprime II 5M3 4660014366514, DTprime II 5M6 4660014366521, DTprime II 6M1 4660014366538, DTprime II 6X1 4660014366545, DTprime II 6M3 4660014366552, DTprime II 6M6 4660014366569

Table of contents

1	Main instrument information	7
1.1	Purpose and versions	7
1.2	Delivery set	9
1.2.1	Instrument components	10
1.2.2	Necessary equipment not provided in the delivery set	11
1.3	Technical parameters	12
1.4	Operating conditions	14
1.5	PC requirements	14
2	Instrument design and principle of operation	14
3	Preparation for operation	17
3.1	Unpacking the instrument	17
3.1.1	Carrying the instrument	17
3.2	Installing and connecting the instrument	17
3.3	Checking the readiness of the instrument for the assay	18
3.4	DTmaster software	18
3.4.1	Instrument driver installation	18
4	Controlling the instrument	19
4.1	DTprime_2 start window interface	19
4.2	Setting the network connection	21
4.2.1	Static IP addressing	21
4.2.2	Dynamic (DHCP) addressing	22
4.2.3	Checking the network availability of the instrument	23
4.2.4	Connecting the instrument to the cloud task server	24
4.3	Uploading a protocol to the instrument	25
4.4	Viewing information about the selected protocol	26
4.5	Last run function	27
4.6	Installing the samples into the heat block	27
4.7	Running the protocol	27
4.8	Viewing the protocol execution in real time	27
4.9	Saved protocols archive	29
4.10	Viewing assay results	30
4.11	Saving the protocol	32
4.12	Settings	32
4.12.1	Adjustment of technical parameters of the instrument	32
4.12.1.1	Checking geometric settings of the optical block	32
4.12.1.2	Measuring tube height	33
4.12.2	Connection to PC	34
4.12.3	Instrument network settings	34
4.12.4	Instrument diagnostics	35
4.12.5	Software update	35
4.13	Turning off the instrument	36
5	Maintenance and repair	37
5.1	General	37
5.2	Possible failures and their elimination	38
5.3	Contacting customer support	39
6	Requirements for periodic cleaning and disinfection of the instrument	39
6.1	Requirement for disinfection of instruments before maintenance and repairs	40
7	Storage and transport	40
8	Disposal	40
9	EMC declaration	41
10	Warranties	42
	Annex A. Sample work request	43

1 Main instrument information

1.1 Purpose and versions

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

Indications for use: The instrument can be used in laboratories of medical institutions and clinical laboratories to detect nucleic acids of infectious pathogens and mutations.

Functional purpose: Instrument for *in vitro* diagnostics.

Scope: clinical laboratory *in vitro* diagnostics.

Types of test samples: Nucleic acids extracted from biomaterials, depending on the test-specific reagent kits used.

Potential users: Personnel qualified in molecular diagnostics and trained to work in diagnostic laboratory: lab doctor, lab assistant (medical lab technician).

This medical instrument is intended for professional use only.

There are no contradictions for use of the instrument.

The following versions of Real-time PCR instrument DTprime II are produced:

DTprime II 4M1, DTprime II 4M3, DTprime II 4M6, DTprime II 5M1, DTprime II 5M3, DTprime II 5M6, DTprime II 6M1, DTprime II 6M3, DTprime II 6M6, DTprime II 4X1, DTprime II 5X1, DTprime II 6X1.

The instrument version is designated by three symbols:

- number (from 4 to 6) – designates the number of optical detection channels;
- letter (M or X) – heat block format M – 96 wells for 200 µL tubes, X – 384 wells for microplates with 45 µL wells;
- number (1, 3 or 6) – heat block structure (1 – single block, 3 or 6 – number of sections).

Example: DTprime II 5M1, where number 5 designates the number of optical detection channels, letter M designates the heat block format (96 wells), and number 1 designates the heat block structure (single block).

DTprime_2 software has been developed and integrated into the instrument for autonomous operation. DTprime_2 software functions: viewing of downloaded protocols; control of the heat block; starting and stopping the amplification program; viewing of optical measurements; deletion, saving of performed protocols; instrument diagnostics.

DTmaster software was developed to control the instrument from a control PC. DTmaster software functions are: creation of assay protocols; creation and editing of tests; creation, start and control of amplification program execution; analysis of optical measurement data; generation of assay report; instrument control; interaction with laboratory information system (LIS).

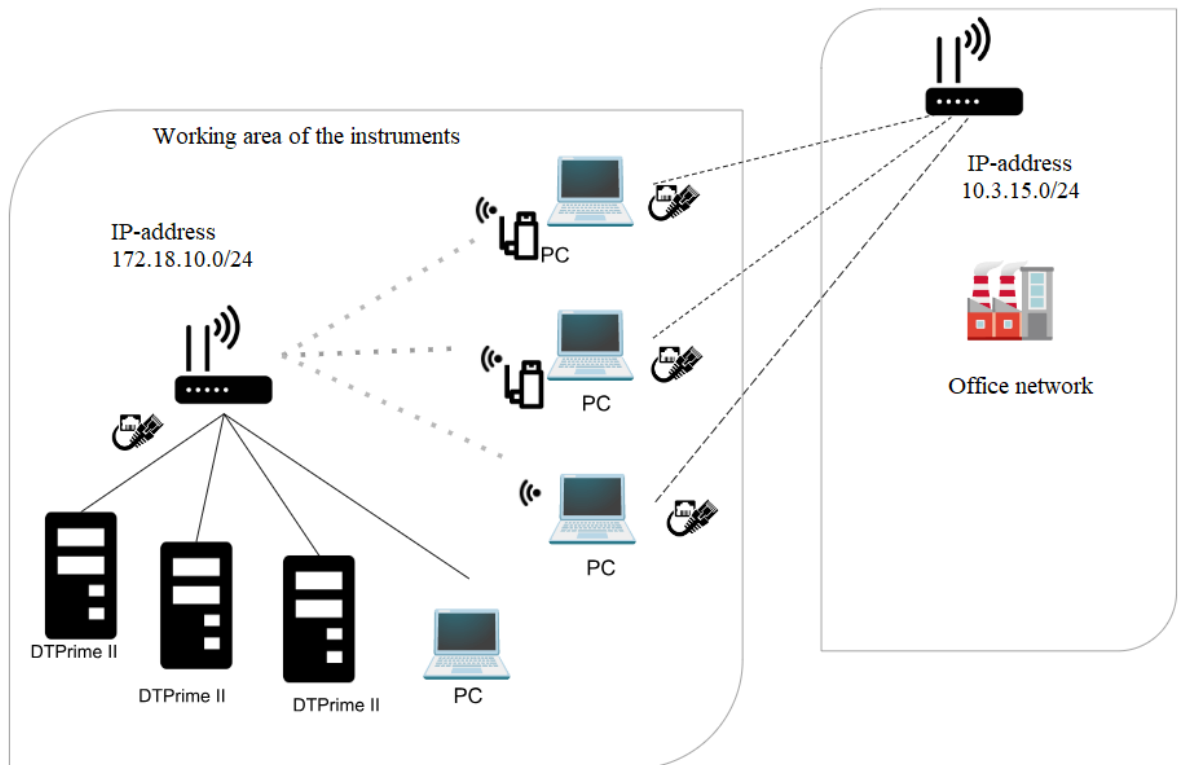
Built-in full-fledged operating system allows the user to organize remote access via local network and the Internet.

The instrument is protected against short-term mains voltage failures (automatic resumption of amplification program execution after the mains voltage is restored). When communication with the control computer is interrupted, the instrument operates in stand-alone mode.

One computer can control several simultaneously connected DT instruments manufactured by DNA-Technology Research&Production, LLC (the number of instruments

depends on the characteristics of the computer). The instruments must be connected to the network via Fast Ethernet (10/100 Mbpc) interface or to the computer via USB cable.

Sometimes it may be necessary to organize a local network of instruments and workstations of laboratory/diagnostic departments without overlapping with the existing office network. As a solution to this problem, it is suggested to use a separate Wi-Fi router and wireless USB adapters at workstations (see Scheme 1):



Scheme 1 – Organizing local instrument network and workspace

1.2 Delivery set

Name	Quantity, pcs.
1 DTprime II Real-time PCR instrument	1
2 Ethernet cable	1
3 PC connection cable USB 2.0	1
4 Network cable (three-wire)	1
5 Fuses (10 A, 5x20 mm, 250 V)	2
6 DTmaster software version 1.2 or higher on a USB flash drive	1
7 Operation manual. Operating procedure. DTprime II Real-time PCR instrument	1
8 User guide. DTmaster software	1
9 Certificate	1

Note – If the customer uses additional equipment and consumables not provided in the above table, the manufacturer is not responsible for the quality and reliability of the instrument operation.

1.2.1 Instrument components

Name	Description
1 Ethernet cable	<p>The Ethernet cable is used to connect the instrument to the Internet.</p> <p>Characteristics according to the manufacturer's specification:</p> <p>Patch-cord UTR 5e cat. "NK-SC5EUTR-RD-2.0" with RJ-45 connectors, 26AWG/0,4 mm</p> <p>Cable: cat5e UTR 26AWG</p> <p>Shell: PVC, cable diameter 5,5 mm</p> <p>Filler cap: PVC</p> <p>Plug: RJ-45: polycarbonate, cat5e,8p8c</p> <p>Category: 5e</p> <p>Design: unshielded, UTR</p> <p>Connector format: RJ45/8p8c</p> <p>Cable diameter: 5,5 mm; Length: 2,0 m</p> <p>Manufacturer: China</p> <p>or similar according to the specified characteristics</p> <p>Supplier: Internet Solutions LLC, Russia</p>
2 PC connection cable USB 2.0	<p>Computer cable, USB 2.0 type, is designed to connect the instrument with the user's computer</p> <p>Characteristics according to the manufacturer's specification:</p> <p>Dimensions, mm: 1800x5x5</p> <p>Cable outer shell: PVC (polyvinyl chloride).</p> <p>Conductor material: Copper</p> <p>Connector 1: USB 2.0 Type-A</p> <p>Connector 1: Plug</p> <p>Connector 2: USB 2.0 Type-B</p> <p>Connector type 2: Plug</p> <p>Rated current, A: 1</p> <p>Max load, W: 12</p> <p>Manufacturer: China</p> <p>or similar according to the specified characteristics</p> <p>Supplier: Bion LLC, Russia</p>
3 Network cable (three-wire)	<p>The mains cable (three-wire) is used to supply power from the mains to the product.</p> <p>Specifications according to the manufacturer's specifications:</p> <p>Plug: molded PVC 45P, black 16 A, 250 V</p> <p>Plug: molded PVC 45P, black</p> <p>Terminal: 2x4 mm</p> <p>Wire: H05 W-F 3G 0,75 mm² GTSA-3,OD6,8 mm</p> <p>Manufacturer: China</p> <p>or similar according to the specified characteristics</p> <p>Supplier: LLC "Mitsar", Russia</p>

<p>4 Fuses (10 A, 5x20 mm, 250 V)</p>	<p>Fuses (10 A, 5x20 mm, 250 V) are designed to protect the instrument against overload. Characteristics according to the manufacturer's specification: Fuse type: cylindrical, ceramic. Rated current: 10 A Rated voltage: AC250V Dimensions, mm: 5x20 Maximum breaking capacity: 1500 AC 250V Manufacturer: Germany or similar, according to the specified characteristics Supplier: Tok Elektroniks LLC, Russia</p>
<p>5 DTmaster software on a USB flash drive</p>	<p>DTmaster software version: 1.2. It is possible to equip the instrument with a later version of DTmaster software.</p> <p>Note – DTmaster software versions are numbered by four consecutive numbers separated by dots, where: the first number is a major version, the basic version, which changes only with a radical change in the set of functional requirements; the second number is the main version of the service pack, which includes improvements and changes in functionality within the current functional requirements</p>

1.2.2 Necessary equipment not provided in the delivery set

- single 0.2 mL PCR tubes (transparent, white or matte with caps)
- 0.2 mL PCR tubes in strips of 8 (transparent, white or matte with caps). The size between tube axes in the strip is 9 ± 0.01 mm.
- PCR microplates, transparent, white or matte with 0.2 mL wells.
- The caps must be optically transparent. The tube material is propylene.

1.3 Technical parameters

Parameter	Value
Heat block temperature control range, °C	0 – 100
Discreteness of the heat block temperature setting, °C	0.1
Precision of heat block temperature maintenance, °C	± 0.2
Temperature variability across the heat block, °C, up to	0.3
Maximum (average) heating rate of the heat block in the temperature range from 50 °C to 100 °C: – for heat block M – for heat block X	5.0 (4.0) 5.0 (4.0)
Maximum (average) cooling rate of the heat block in the temperature range from 100 °C to 50 °C: – for heat block M – for heat block X	3.6 (2.5) 3.6 (2.5)
Maximum temperature difference when creating a gradient temperature field for heat block M, °C	10
Direction of the temperature field gradient	Horizontal, vertical
Maximum measurement time of one channel, sec	10

The instrument provides PCR and registration of results by channels, including Real-time, in which fluorescent tags have absorption maxima in the range from 450 to 697 nm and emission maxima in the range from 500 to 746 nm.

Operating ranges of excitation wavelengths by channels:

Parameter	Channel					
	FAM	HEX	ROX	Cy5	Cy5,5	FRET
Excitation operating wavelength, nm	450-470	520-540	565-595	620-640	677-697	450-470

Operating ranges of detection wavelengths by channels:

Parameter	Channel					
	FAM	HEX	ROX	Cy5	Cy5,5	FRET
Detection operating wavelength, nm	500-530	550-570	605-635	650-670	716-746	605-635

Main parameters:

Parameter	Value
Supply voltage, V	100-240
Power supply frequency, Hz	50/60
Power consumption, up to, W	1100
Dimensions, WxHxH, mm	210 ⁺¹ x 538 ⁺² x 540 ⁺²
Weight, kg	28.4 ± 5 %
Type of reagent reservoirs (heat block M)	<ul style="list-style-type: none"> – 96 200 µL PCR tubes; – 200 µL PCR tubes in strips of 8; – 96-well PCR plate with 200 µL wells;
Type of reagent reservoirs (heat block X)	384-well microplate with 45 µL wells
Permissible range of PCR-mix volume in tubes (heat block M), µL	10 –100 (preferably 10 – 50)
Permissible range of PCR-mix volume in tubes (heat block X), µL	5 – 20

Maximum DTprime_2 software loading time calculated from the moment the instrument is switched on to the opening of the software interface must be up to 30 sec.

Maximum DTmaster software loading time calculated from file startup to software interface opening must be up to 30 sec. The maximum time to get to the operating mode with the instrument must be up to 5 min.

1.4 Operating conditions

The instrument must be operated in strict compliance with the operating manual.

The instrument is intended for indoor use under the following conditions:

- temperature during operation from 10 °C to 35 °C;
- relative humidity for temperature 25 °C must be up to 80 %;
- altitude must be up to a maximum of 2000 meters;
- at supply voltage 100-240 V, frequency 50/60 Hz.

Note – Recommended indoor temperature during operation of the instrument is from 15 °C to 31 °C.

1.5 PC requirements

Minimum software and hardware requirements for the control PC:

PC parameters	Requirements
Processor	Intel Core i3 2100 / AMD Ryzen 3 1200 and higher
Random-access memory	At least 4 Gb
Disk space	At least 64 Gb
Monitor	Resolution 1024x768 pixels
Operating system	Windows 10, 11
Ports	USB 2.0 High-Speed, Ethernet

2 Instrument design and principle of operation

The instrument is a specialized equipment combining the functions of a precision programmable thermal cycler and an optical system that allows real-time recording of fluorescence of the PCR-mix in tubes.

CV repeatability value calculated by signal level difference in fluorescence channels does not exceed 8 %, CV reproducibility value calculated by signal level difference in fluorescence channels does not exceed 12 %, relative standard deviation CV by signal values does not exceed 8 %.

The construction of the instrument is a supporting frame on which the following assemblies are mounted:

- heat block heated and cooled by thermoelectric Peltier elements;
- optical unit consisting of fluorescence excitation sources on the basis of LEDs and detector on the basis of active-pixel sensor;
- optical tract unit for light beam transportation;
- carriage to accommodate the following components:
 - heat block;
 - built-in barcode scanner (for heat block X);
- heat cover unit preventing spontaneous opening of tube caps, possible contamination of the instrument with amplification products, condensation of liquid on the caps inside the tubes;
- horizontal drive providing carriage movement in the horizontal plane for loading and unloading tubes into the heat block matrix;

- vertical drive that provides vertical movement of the carriage to ensure that the tubes are pressed against the heat cover;
- built-in computer with at least 2 GB of disk space;
- electronics modules;
- power supplies.

The supporting frame is structurally closed with decorative and side panels.

The front panel of the instrument contains:

- color touch panel (liquid crystal color touch screen monitor, 7-inch screen);
- push-button control panel;
- USB 2.0 (type A) connector for USB flash drive connection.

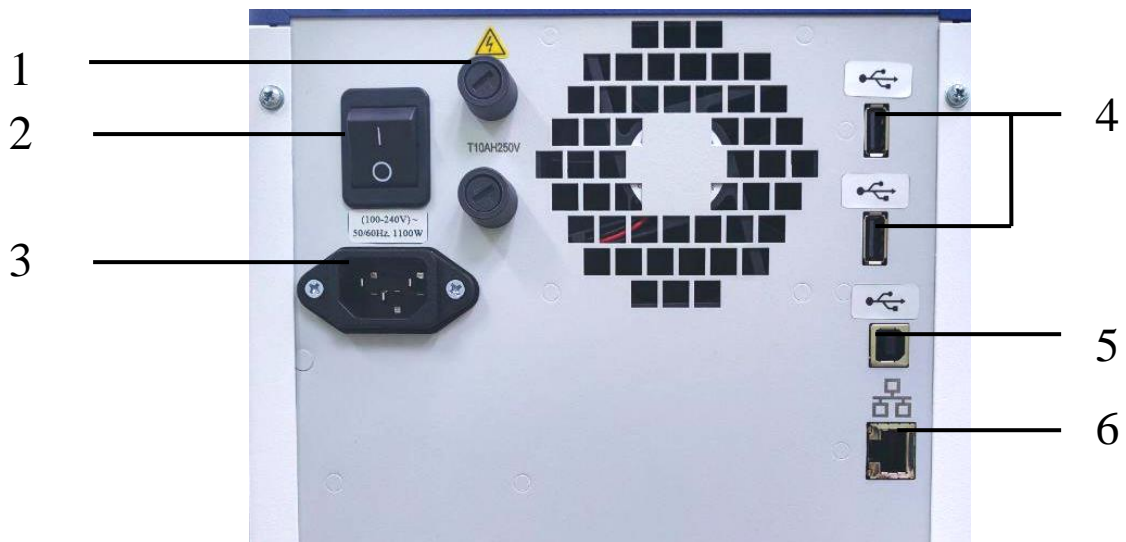
The rear panel of the instrument contains:

- mains switch;
- fuses;
- mains power connector socket;
- Ethernet connector socket for connecting the instrument to a local area network;
- two USB 2.0 (type A) sockets for connecting a USB flash drive;
- USB 2.0 (type B) socket for connecting to a computer.

The front view and rear panel of the instrument are shown in Figures 1 and 2.



Figure 1 – DTprime II, front view



1 – fuses, 2 – mains switch, 3 – mains power connector socket, 4 – USB 2.0 (type A) socket, 5 – USB 2.0 (type B) socket, 6 – Ethernet socket

Figure 2.1 – DTprime II, rear panel

Example of marking tag (nameplate) placed on the rear panel of the instrument:

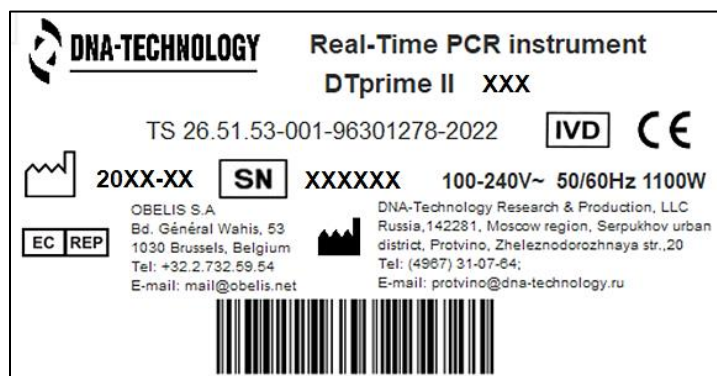


Figure 2.2 – DTprime II, nameplate

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

- A high-speed thermal management system comprising a heat block, a heat block handling and positioning unit, and a heat cover module;
- Optical system comprising an optical block and an optical tract unit for light beam transportation.

Optical block is a system of lenses, mirrors and light filters, which provides combining the light flux of several spotlights on one optical axis and separating it from the light flux entering the matrix. Light sources are high-power LEDs.

Optical tract unit for light beam transportation provides transmission of light flux from optical unit projectors to tubes and fluorescence light flux from tubes to a matrix located in the optical unit.

- Control and display system including touch screen monitor and push button control panel.

The touch screen monitor provides access to view, run and save protocols. The monitor is sensitive to hand (including gloved hands) and stylus touch.

There are five control buttons on the instrument panel, whose functions change depending on the DTprime_2 firmware dialog box.

3 Preparation for operation

3.1 Unpacking the instrument

The instrument is supplied in the manufacturer's delivery package, which is a cardboard box with polyethylene foam inserts designed to protect the instrument from mechanical damage during transportation and storage.

Before packing into a box, the instrument is placed in a primary packaging (bag) made of non-woven material with grab handles.

Delivery of the instrument to the place of installation must be carried out by two persons in the manufacturer's packaging.

To remove the instrument from the box, proceed as follows:

- prepare a working place for the instrument on the table;
- place the instrument box next to the table and open the lid;
- remove the components included in the delivery set and the upper polyethylene foam inserts from the box;
- check that the components are present according to the delivery set (see section 1.2);
- taking precautions, two persons lifting the instrument by the gripping handles and holding it by the base, remove it from the box and place it on the table;
- remove the instrument from the bag and inspect it for external damage.

If the instrument or any accessories are damaged or missing, please contact the representative office of DNA-Technology in your region (the list of regional representatives is available on the official website of the company www.dna-technology.com).

3.1.1 Carrying the instrument

The instrument can be carried during operation over short distances within the building by two people, placing the instrument in a primary package (bag) made of non-woven material with gripping handles 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 transport, it is necessary to place the instrument in the transport packaging of the manufacturer.

Warning! *When transporting the unit, the retractable heat block must always be in the locked position. This is secured by giving a command to close the heat block. If this is not the case (e.g. if the unit is defective), please consult the manufacturer's representative.*

3.2 Installing and connecting the instrument

Warning! *The instrument contains precision mechanical components. In order to avoid displacement of the optical system, shocks and impacts should be avoided when operating and moving the instrument. The instrument may only be transported with the heat block in the locked position (closed).*

Warning! *When choosing a place for installation of the instrument, consider that there must be a free space of at least 18 cm in front of the front panel of the instrument. Otherwise, the front panel of the heat block may be damaged by foreign objects that are located or appear in the area of its movement.*

Make sure that the working environment of the instrument is free of electromagnetic interference, vibration and high-frequency electrical equipment (see section 9).

The user can install and connect the instrument without the manufacturer's representative by following the instructions in the operating manual.

The instrument must be installed in a convenient place with sufficient ventilation to prevent condensation and free access to the heat block and to the rear panel, where the power switch and connectors for connecting the instrument are located. To connect the instrument it is necessary to provide access to a power socket. For normal operation of the instrument it is necessary to provide at least 12 cm of free space on the right, left and back of the instrument.

The power consumed by the instrument from the mains during operation does not exceed 1,100 W.

The instrument does not need additional devices that stabilize the mains voltage. If it is necessary to connect the instrument to uninterruptible power supply devices, it should be considered that the latter should provide, in addition to other consumers, an output power of at least 1,100 W to power the instrument.

Warning! *It is essential that the sockets to which the instrument and the control PC are connected have a reliable earth connection. Failure to do so may result in damage to the instrument.*

Connect the mains power connecting cable from the delivery set to the instrument.

Make sure the mains power switch is in the “O” (Off) position.

Connect the instrument to 100-240 V, 50/60 Hz mains power supply.

Warning! *Using the wrong power supply can damage systems.*

Depending on the intended operating mode, connect the instrument to the USB and/or Ethernet port of the control PC using the supplied communication cable.

Turn on the instrument using the mains power switch, position “I” (On). After loading, the DTprime_2 firmware splash screen will be displayed on the instrument monitor.

3.3 Checking the readiness of the instrument for the assay

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

Warning! *Before the first PCR run, the following settings should be configured to eliminate the possibility of obtaining unreliable results:*

- *check of geometrical settings of the instrument optical block;*
- *checking the cleanliness of the heat block wells;*
- *tube height adjustment.*

For a description of the procedures, see section 4.12 of this manual and «User guide. DTmaster software».

3.4 DTmaster software

To operate the instrument on the control PC, the DTmaster software supplied with the instrument must be installed. The installation procedure is described in detail in the «User guide. DTmaster software».

3.4.1 Instrument driver installation

If the instrument is connected to a PC with a USB cable, before installing DTmaster you must also install a driver to allow the PC to communicate with the instrument. The distribution kit can be downloaded from the official company website www.dna-technology.com.

When connecting the instrument to a computer via Ethernet network, driver installation is not required.

4 Controlling the instrument

The instrument can be controlled in the following modes:

1) with an Ethernet connection

In this mode, the device is controlled by the built-in DTprime_2 software via a touchscreen monitor. The instrument must be connected to the Ethernet port of the control PC or to the router to connect to the DTmaster software or cloud storage. Configure the network connection in section 4.2 of the manual.

2) with USB connection

In this mode, the instrument is controlled by the control PC using the DTmaster software. The instrument must be connected to the USB port of the control PC.

With a USB connection, the functionality of the instrument is limited. The control buttons on the display "Start", "Open block", "Close block" and the tab "Temperature graph" are active. The tab "Graphs of changes in the fluorescence level" is not available for viewing on the "Launch" and "Archive" pages.

3) Autonomous mode

In this mode, the instrument is controlled by the built-in DTprime_2 software via a touchscreen monitor without using a control computer. The protocols are downloaded from a USB flash drive (the device must have the Ethernet mode set, see 4.12.2 of the manual).

4.1 DTprime_2 start window interface

The DTprime_2 Start window will open immediately after loading (Fig. 3).

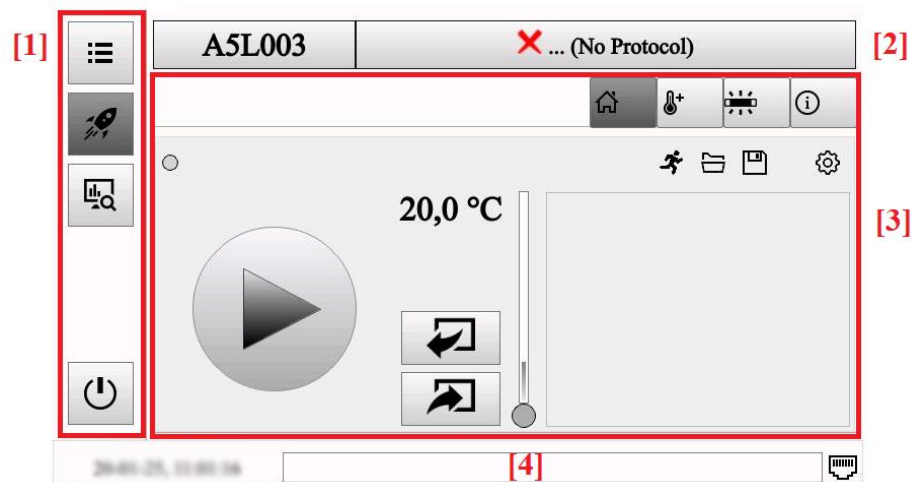









Fig 3 – DTprime_2 Start window interface

DTprime_2 Start window interface includes:








- [1] – buttons for switching between interface pages;
- [2] – field with the instrument serial number and protocol name;
- [3] – window workspace;
- [4] – field with the current operation progress bar, icons about the instrument status:
🔌 - server connection, 📶 - connection type (Ethernet/USB), ⚙️ - running the protocol.

Interface pages:

Page buttons	Symbol	Purpose
Protocol		Uploading the protocol to the instrument
Run		Running the assay protocol. Viewing protocol execution in real time
Archive		Viewing previously saved assay protocols
Turn off		Turning off / restarting the instrument. Switching to sleep mode

The working area of the window contains control buttons, a temperature shelf passage indicator with the current temperature, tabs for viewing the protocol execution in real-time mode    (see section 4.8).

Control buttons:

Name	Symbol	Purpose
Start		Running the protocol
Open block		Open the heat block
Close block		Close the heat block
Last run		Last run
Open		Loading the protocol
Save		Saving the completed protocol
Settings		Setting the instrument operation





Note – When the instrument is connected to the control computer via USB, the instrument functionality is limited: the control buttons “Start”, “Open block”, “Close block” are active.

4.2 Setting the network connection

Warning! To set up a network connection, contact your system administrator.

Make sure the Ethernet cable is plugged into the Ethernet port on the back of the appliance and the free part of the cable is plugged into the router.

To control the network interface settings, first of all, you need to switch the instrument from USB operation mode to Ethernet connection mode.

Press the **Settings**  button on the Start window of the instrument (Fig. 3); in the Settings menu press the Connection tab  (1) on the upper panel and select the **Ethernet**  (2) connection type. Then press the Instrument network Settings tab  (3) on the upper panel to select the instrument network connection mode (Fig. 4).

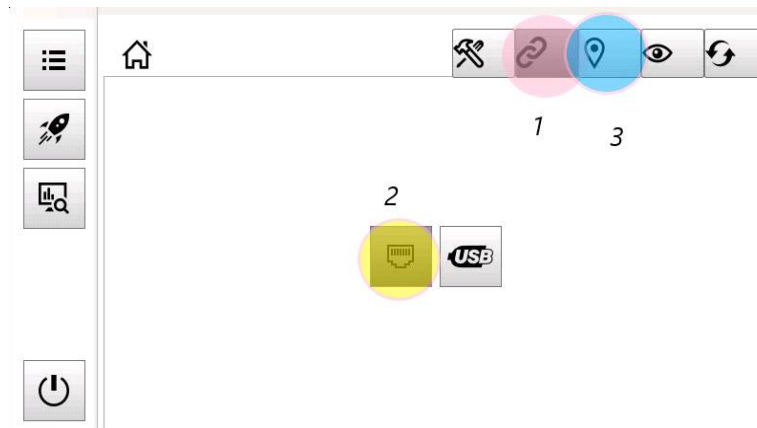


Figure 4 – Connection tab

Options for connecting the device to an Ethernet network

The instrument can be connected to your network either with static addressing or in dynamically allocated IP address (DHCP) mode (Fig. 5; 6), depending on your current network usage policy.

The Instrument network Settings tab  contains information about the network MAC address. Provide these parameters to your network administrator for correct registration of the instrument in your local network.

4.2.1 Static IP addressing

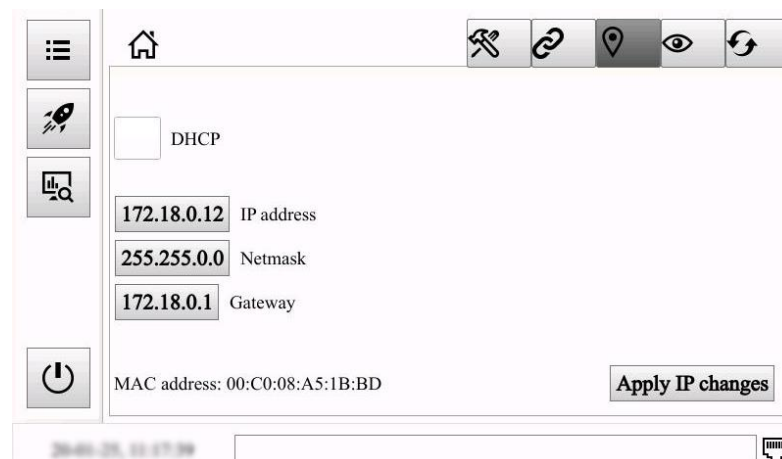



Figure 5 – The instrument is in static IP addressing mode

Connection options with static addressing:

- When connecting the instrument directly to a PC with an Ethernet cable.


Before connecting, contact your network administrator to obtain a free IP address on your network and information about the network mask and gateway. Enter these data in the Instrument network Settings tab  in the appropriate input fields with the **DHCP** box unchecked (Fig. 5);

- When connecting the instrument to a PC directly without using a router.

Use IP addresses on the PC and on the instrument from the same subnet (for example: PC – **172.18.0.3**, instrument – **172.18.0.12**). All fields must be set on this tab.

Information on the instrument's network address and installed software version is shown on the instrument monitor splash screen at instrument startup or in standby mode (to switch to this window, press once the rightmost button on the instrument control panel button bar).

4.2.2 Dynamic (DHCP) addressing

With dynamic addressing, the instrument will obtain an IP address on your network automatically when the Ethernet cable is connected to the router (or network outlet) and the address will be displayed automatically in the Instrument network Settings tab . Check the **DHCP** box (Fig. 6).

For the changes to take effect, press the **Apply** button, after which the instrument will be rebooted.

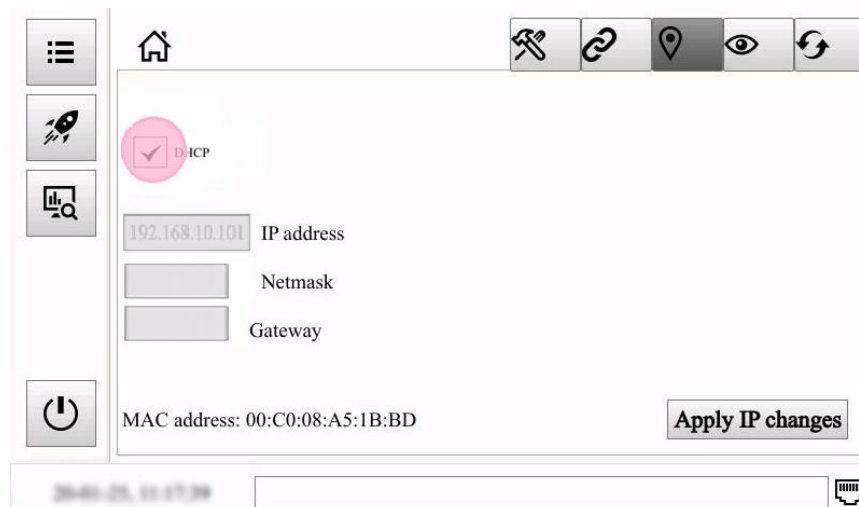


Figure 6 – The instrument is in dynamic IP addressing mode (DHCP)

4.2.3 Checking the network availability of the instrument

You can verify the correctness of the instrument connection in the Ethernet network by opening a page in the WEB-browser of the computer with the received (or assigned) IP-address, for example: <http://172.18.0.12/rt>, where 172.18.0.12 is the instrument IP address (Fig. 7).

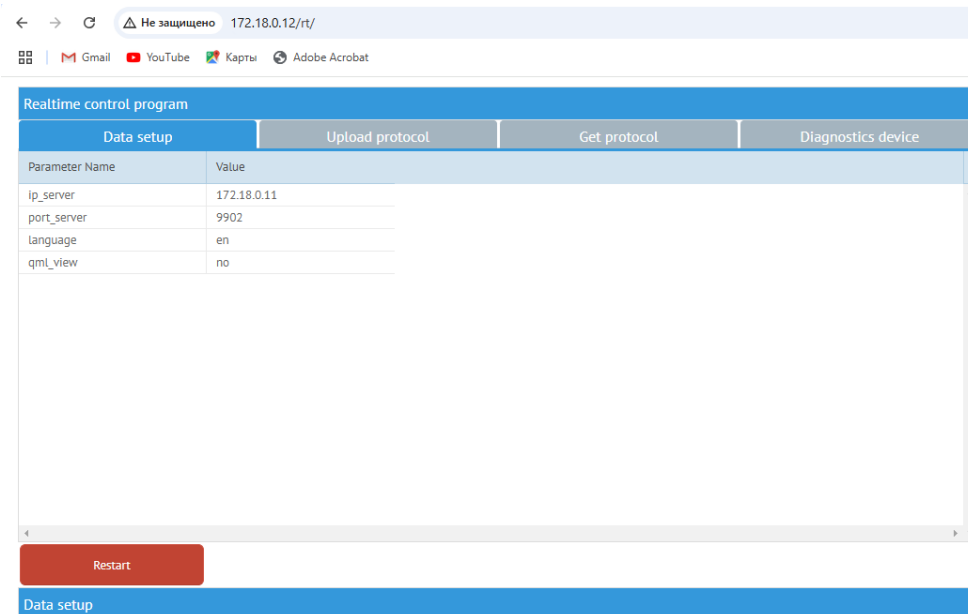


Figure 7 – Instrument WEB page


You can check the applied address in the Instrument network Settings tab  or on the instrument splash screen (Fig. 8).



Figure 8 – The Splash screen of the instrument

4.2.4 Connecting the instrument to the cloud task server

Required data: after connecting the instrument to the office's local network, you can also connect it to the cloud infrastructure. This will allow you to receive tasks for execution on the instrument, send ready-made data for analysis to a PC, monitor tasks, etc.

Enter the cloud server address in the «**ip_server**» field on the settings WEB page (Fig. 7) and click **Restart**.

The cloud server address: If DTmaster software with an additional package LIS was installed on one of the PCs in the office's local network, then the cloud server address corresponds to the IP address of this PC.

Help: Open the Task Manager with **Ctrl+Alt+Delete** and by clicking "Start Task Manager", go to the "Performance" tab and on it to the Ethernet section (Fig. 9). Your IPv4 address will be visible in this window.

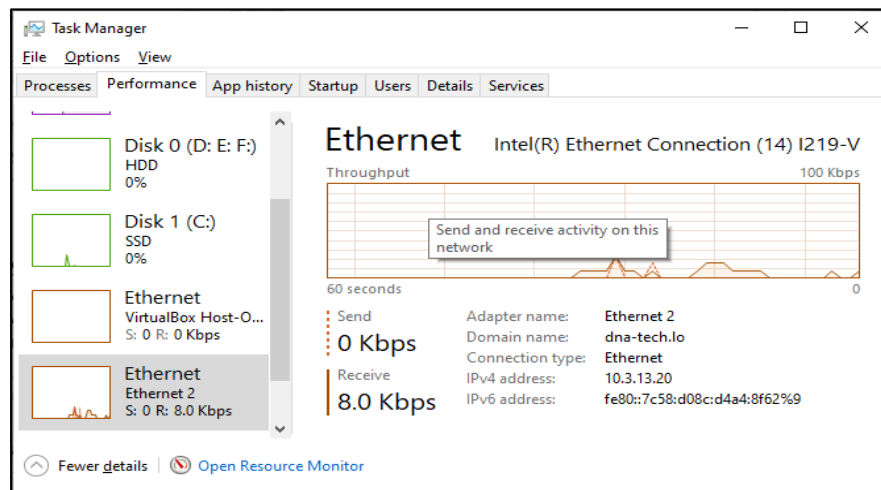


Figure 9 – The active IPv4 address of your PC

The status of the cloud server running on your PC will be displayed on the "Services" tab, in the "DNA-Tech. WebSocket service" and in "DTWebSocketServiceDropper", "DTWebSocketServiceStorage" – they correspond to the service components of the cloud system (Fig. 10).

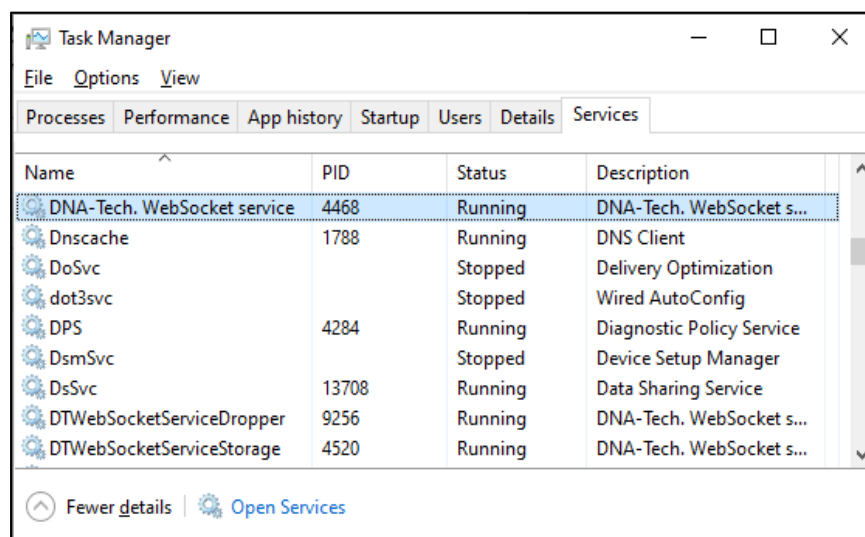


Figure 10 – Cloud System Services

After entering the address of the cloud server on the WEB page and accepting the instrument of this configuration, the cloud icon will appear on the instrument screen and the ability to receive tasks from the cloud storage list will become available (Fig. 11).

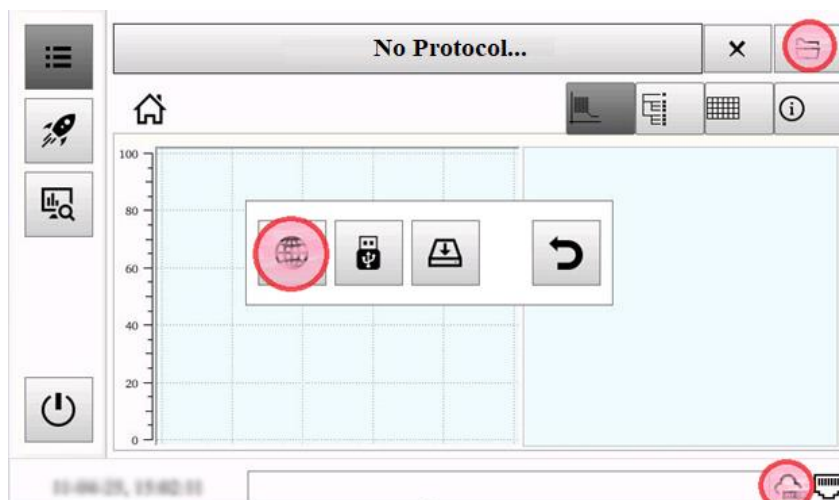



Figure 11 – The instrument is part of a cloud task server

Uploading and launch the protocol see the sections 4.3, 4.7. The completed optical measurements will be automatically sent to cloud storage and will be available for analysis on DTmaster on the PC. The DTmaster must be connected to this cloud server.

4.3 Uploading a protocol to the instrument

In Ethernet mode, downloading the protocol in *.rt format is possible in several ways:

1. In the Start window workspace, click the button **Open**  (Fig. 12):

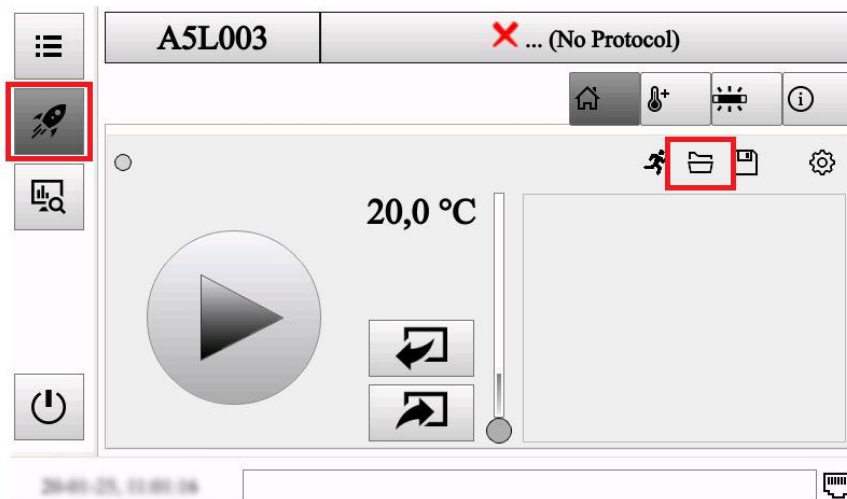







Figure 12 – Uploading a protocol in the Start window


Select the protocol location in the dialog box that opens:

-  - Web (remote server/PC)
-  - USB device;
-  - Internal disk.

To exit the menu, click the button **Back** .

To upload a protocol from a remote server/PC, select **Web** . Use is only possible if an Ethernet connection is available.

To upload a protocol from a USB device, select **USB** . The protocol file must be located in the root directory of the USB device. Use is possible in the absence of an Ethernet connection.

If the protocol has been previously uploaded by the user to the instrument, it will be available for selection in the list of uploads from the internal disk. To view the list, press the button **Internal disk** .

After selecting the file press **Apply**.

2. To upload the protocol from the Protocol page , press **Open**  (Fig. 13). Select the location of the protocol and click **Apply**.

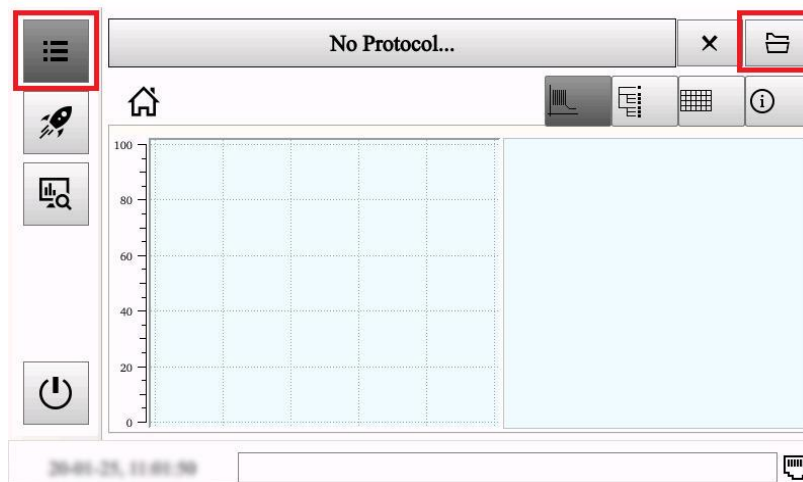


Figure 13 – Protocol page

To delete the protocol data, press **Delete** . Protocol data will be deleted from the working area window.

4.4 Viewing information about the selected protocol

You can view information about the selected protocol by switching the following tabs on the “Protocol” page:



- Protocol

The tab displays temperature graph and data on amplification conditions: temperature and duration of temperature shelves, number of cycles, presence of optical measurements.



- Samples/Tubes/Channels

The tab contains information about the planned tests and the samples used.



- Tube layout


The tab contains a color scheme of the tube layout.




- Information

The tab contains general information about the protocol.


4.5 Last run function

This function allows you to open the last executed protocol on the instrument. To do this, press **Last run**  on the Start window. The data will be displayed in the working area of the window.

4.6 Installing the samples into the heat block

Step 1. To install sample tubes into the instrument, press the **Open block**  control button in the Start window and wait for the block to lock in the extended position.

Step 2. Place the sample tubes into the heat block matrix according to the completed assay protocol.

Step 3. Press the **Close block**  control button and wait for the block to lock in the working position.

Note - The heat block can also be controlled from the push-button panel of the instrument.

Warning! *A minimum of 16 tubes should be placed to prevent deformation. If the number of test tubes is smaller, it is recommended to add empty tubes of the same height.*

Warning! *The instrument provides automatic loading and unloading of test samples from the heat block in the working position. The command to move (open or close) the heat block comes from the user. It is forbidden to make any manipulations with the heat block while moving it, as it may cause damage to the moving mechanisms. To ensure the safety of the user, in case of a mechanical obstacle in the process of movement of the block, the decorative front panel of the block is made hinged.*

Warning! *Do not remove the samples from the heat block until the program is completed.*

4.7 Running the protocol

To start the selected protocol, click the **Start** button in the Start window. The assay will start according to the amplification program.

The **Start** button after starting the assay changes to **PAUSE / STOP** buttons for pause / stop, respectively.

Warning! *We strongly recommend that you do not stop program execution until it is complete.*

4.8 Viewing the protocol execution in real time

To view the protocol execution, use the Start window and the tabs on the working area of the window.

The Start window displays the following protocol execution parameters (Fig. 14):

program execution time [1], temperature shelf passage indicator with the current temperature [2], number of the cycle being executed and total number of program cycles set [3], sequence of program blocks [4].

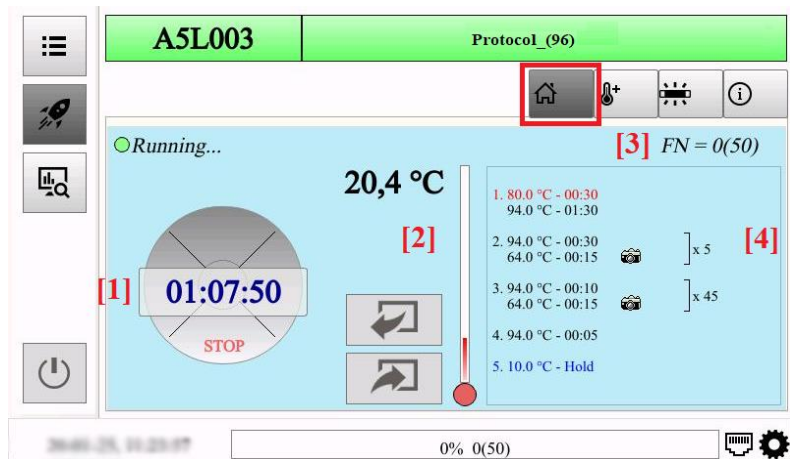


Figure 14 – Controlled parameters of protocol execution

 - **Temperature graph**

This tab displays a real-time graph of the heat block temperature change with the current temperature in real time (Fig. 15).

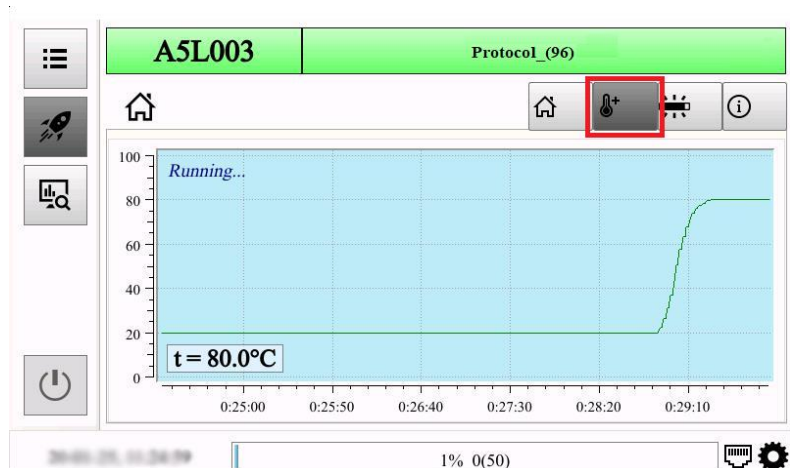


Figure 15 – Temperature graph tab

 - **Fluorescence level change graph**

This tab displays real-time graphs of fluorescence level changes during the amplification program (Fig. 16).

The tab is not available when the instrument is connected to a computer via USB connection.



Figure 16 – Fluorescence level change graph tab

 - Information

This tab contains general information about the instrument (Fig. 17).

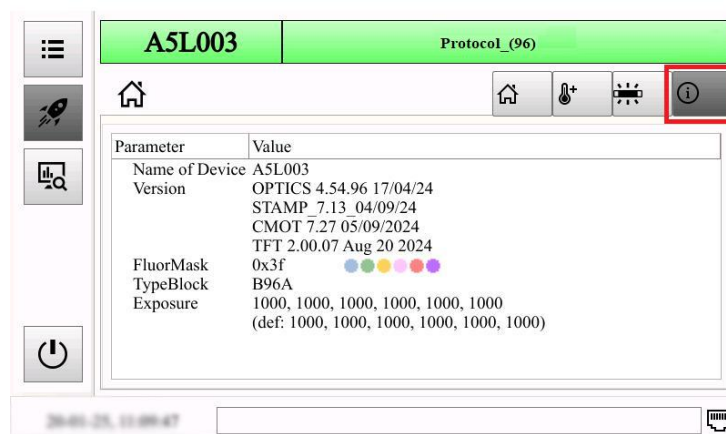









Figure 17 – Information tab


4.9 Saved protocols archive


You can view previously saved protocols on the Archive page . To upload the protocol to view the results of the assay, press the button **Open**  (Fig. 18). Select the location of the protocol:

-  - Web (remote server/PC);
-  - USB device;
-  - Internal disk.

To exit the menu, press **Back** .

To upload a protocol from a remote server/PC, select **Web** . Use is only possible if an Ethernet connection is available.

To upload a protocol from a USB device, select **USB** . The protocol file must be located in the root directory of the USB device.

If the protocol was previously run on this instrument, it will be available for selection in the internal disk upload list. To view the list, press the **Internal disk** .

Press **Apply**.

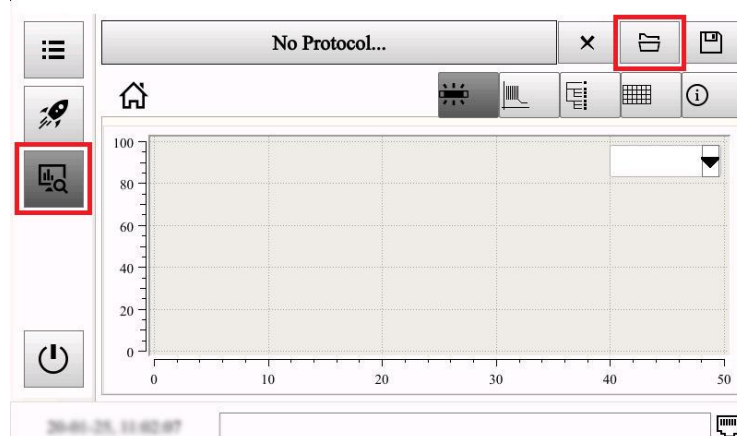


Figure 18 – Archive page

To delete the protocol data, press **Delete** . The protocol data will be deleted from the working area.

4.10 Viewing assay results

You can view the results of assays of the selected protocol by switching the following tabs on the Archive page:



- Fluorescence level change graph

The tab displays graphs of fluorescence level changes during the performed amplification program (Fig. 19).

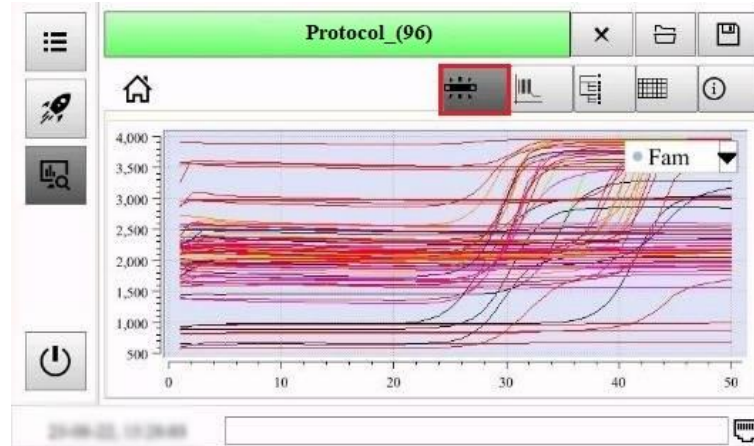


Figure 19 – Fluorescence level change graph tab



- Program

The tab displays the temperature graph and data on amplification conditions (temperature and duration of temperature shelves, number of cycles, presence of optical measurements) (Fig. 20).

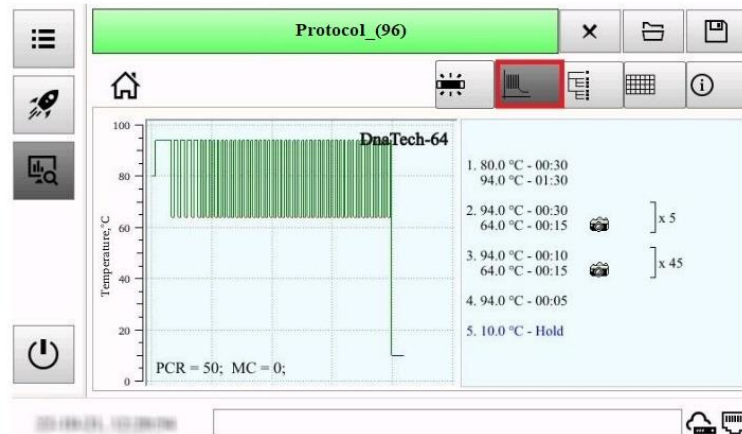


Figure 20 – Program tab

 - **Samples/Tubes/Channels.**

The tab contains general information about the samples and the tests performed on them (Fig. 21).

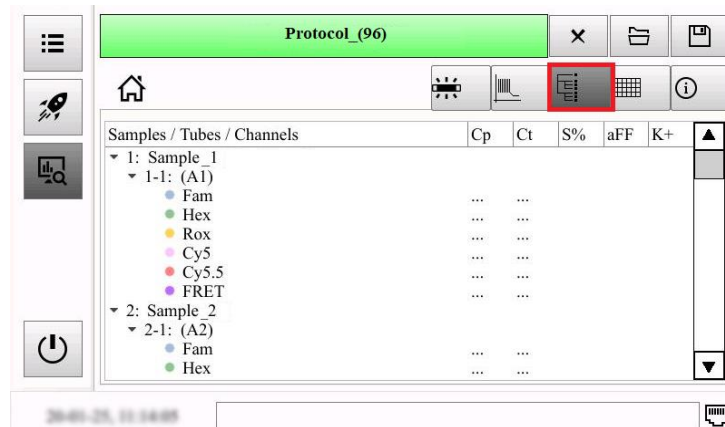


Figure 21 – Samples/Tubes/Channels tab

 - **Tube layout.**

The tab contains tube layout color scheme (Fig. 22).

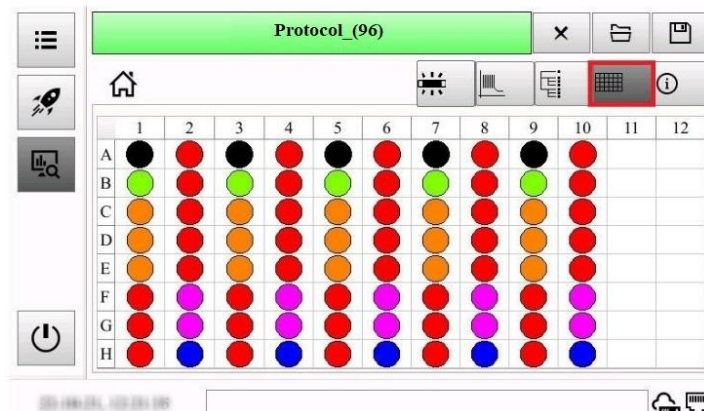


Figure 22 – Tube layout tab

 - **Information.**

The tab contains general information about the instrument and the executed protocol (Fig. 23).

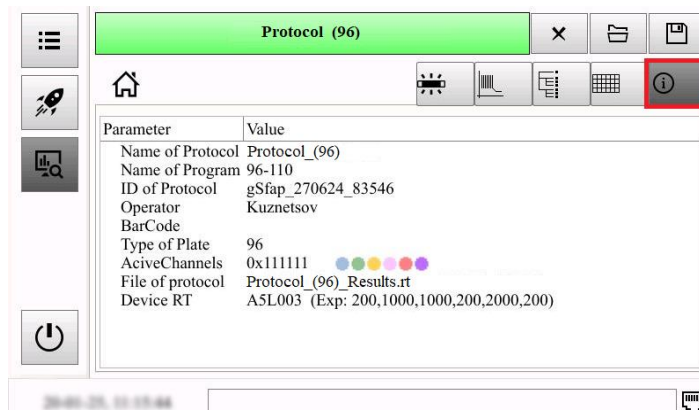





Figure 23 – Information tab

4.11 Saving the protocol


After the examination is completed, the measurements performed are automatically saved on the local disk of the instrument.

To save the protocol with the obtained results to an external device, click the **Save** button  located in the working area of the Start window and on the toolbar on the Archive page. Select a place to save the protocol by pressing the **Web** button  or the **USB** button  and press the **Save** button. The protocol will be saved in *.rt format in the root directory of the selected location.


If you do not want to save the assay protocol, click the **Cancel** button.

4.12 Settings

Press the **Settings** button  in the Start window to go to the instrument settings. This menu provides access to viewing and changing the following instrument settings:

 - Adjustment of technical parameters of the instrument (check of geometrical settings of the optical unit, measurement of test tube height);


 - Connection to PC;

 - Instrument network settings;


 - Instrument diagnostics;

 - Software update.

4.12.1 Adjustment of technical parameters of the instrument

The Adjustment of technical parameters of the instrument  tab contains the following tabs:



 - Check geometric settings of the optical block;

 - Measure tube height.

Note – The “Check geometric settings of the optical block” and “Measure tube height” tabs are not available when the instrument is connected to a USB control computer.

4.12.1.1 Checking geometric settings of the optical block

When turning on the instrument for the first time after transportation or any movement, it is recommended to check the geometric settings of the optical block.

To check, press  button in the Adjustment of technical parameters of the instrument tab  (Fig. 24).

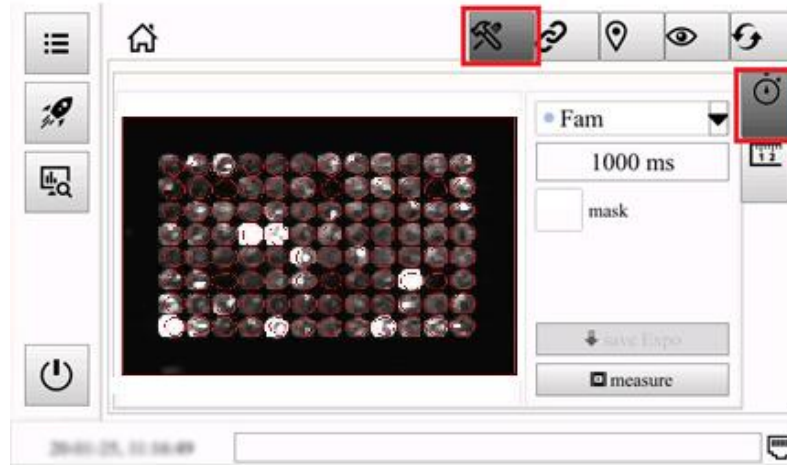


Figure 24 – Adjustment of technical parameters of the instrument tab



In the opened window select the measurement channel, set the required measurement exposure value, set the **Mask** selection flag and click the **Measure** button. Analyze the obtained image.

If the data obtained indicates that the mask settings need to be corrected, it is recommended to connect to the instrument via the control PC and make the correction using DTmaster «User guide. DTmaster software».

4.12.1.2 Measuring tube height

Measurement of tube height is recommended when changing to a different type of tubes or strips, or when there is doubt about the quality of the “hot lead” clamping of tubes.

When measuring tube height, arrange at least 24 tubes or 3 strips evenly across the matrix.

To measure tube height, press **Measure**  in the Adjustment of technical parameters of the instrument tab  (Fig. 25).

In the window that opens, click on the **Measure tube height** button. After measuring, we recommend saving the changed settings.

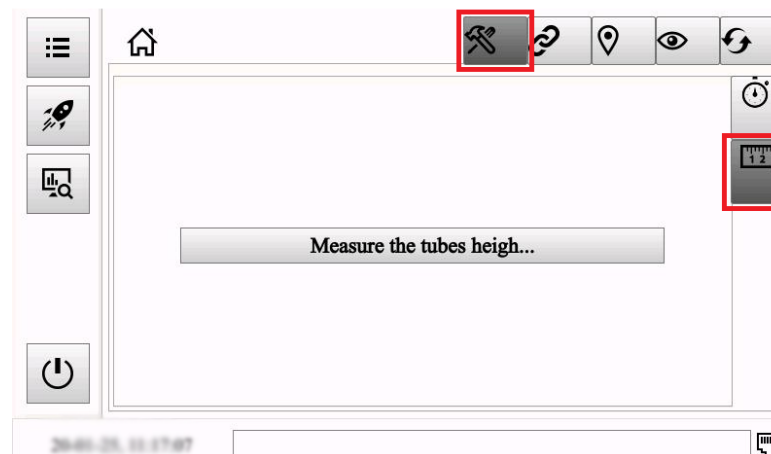



Figure 25 – Measuring tube height tab

4.12.2 Connection to PC

The type of connection between the instrument and the PC is selected in the Connection tab  (Fig. 26).

When connecting to the instrument via an Ethernet connection, press the **Ethernet**  button.

When connecting to the instrument via a USB connection, press the **USB**  button.



Figure 26 – Connection to PC tab

4.12.3 Instrument network settings



Network settings of the instrument can be changed in the Instrument network settings tab  (Fig. 27)



Figure 27 – Instrument network settings tab

4.12.4 Instrument diagnostics

To go to this menu, press the button  (Fig. 28). The instrument automatically performs self-diagnostics by displaying on the monitor the information of the built-in PC communication with the instrument's microcontrollers.

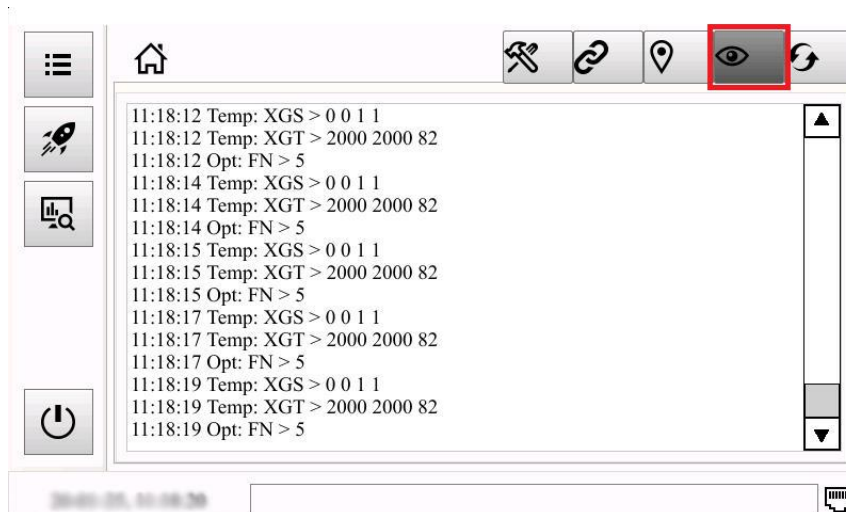


Figure 28 – Instrument diagnostics tab

4.12.5 Software update

The software update is performed from a USB device with the update loaded in it. After inserting the device into the instrument USB port, press the buttons **Update soft / Updating the software code of microcontrollers** (Fig. 29).

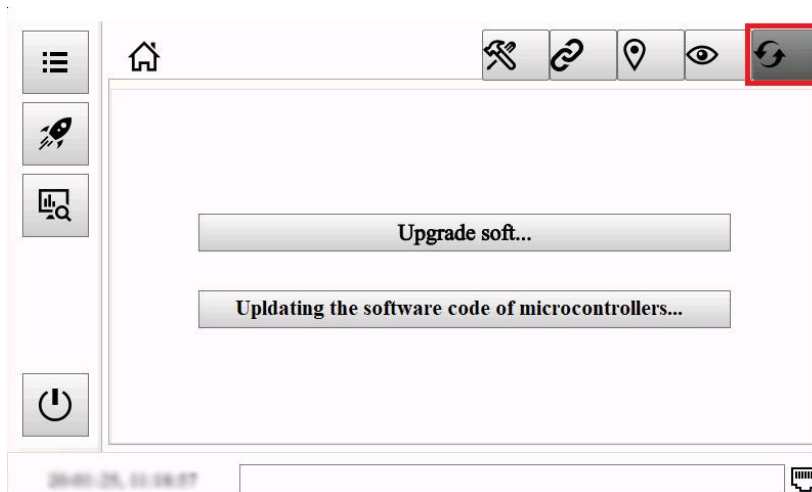



Figure 29 – Software update tab

4.13 Turning off the instrument

To end the instrument operation, press the **Turn off**  button. In the dialog box, select further actions from the listed options:



- turn off;



- restart;



- sleeping mode;



- exit the dialog box.

You can also turn off the instrument from the instrument control panel.

Press the rightmost button on the control panel to switch the instrument to the following modes:

- standby mode (press the button once; to exit, press the button again);
- power saving mode (hold down the button for 2 sec.; to exit, press any button on the control panel again);
- shut down the instrument (hold the button for 5 sec.). Next, press the shutdown button on the back of the instrument.

Warning! *Wait until the screen is completely off before turning off the power supply by pressing the mains switch on the back of the instrument.*

5 Maintenance and repair

5.1 General

Do not open the instrument yourself! The insides of the instrument do not contain any self-serviceable components.

Warning! Parameters of settings of motor controllers, calibration parameters of optical and temperature units of the instruments cannot be changed by the user. Calibration of these instruments is performed by the manufacturer in accordance with the internal quality control regulations. If necessary, data on calibration of the above instruments are provided by the technical support service of “DNA-Technology Research&Production”, LLC. Adjustment of regulated parameters should be carried out in accordance with the operation manual.

The instrument is a technically complex equipment. Technical maintenance and repair of the instrument is performed by the manufacturer’s service specialists.

Maintenance of the instrument by users during operation is aimed at keeping the instrument in working condition, ensuring its cleanliness and performing disinfection operations.



Warning, danger of electric shock! Fuses should only be replaced when the equipment is de-energized. The equipment is de-energized only when the mains cable is disconnected from the power socket and the PC communication cable is disconnected from the instrument.

When replacing, fuses with parameters 10 A, 250 V, 5x20 mm must be used.

To maintain the cleanliness of the wells and optical system elements, the instrument's heat block should always be in a fixed (closed) position (except for the periods of insertion and removal of tubes with samples).

Warning! To avoid failure of the optical system of the instrument, it is forbidden to use any substances (heat-resistant pastes, oils, etc.) to improve the contact of the test tube with the well of the heat block.

5.2 Possible failures and their elimination

Failure description	Possible causes	User's actions
No information on the LCD monitor after the instrument is turned on	No power in the mains	Check for voltage, check the socket for proper operation
	Monitor's malfunction	Contact the instrument supplier
	Bad connection or break in the mains cable	Check the contact between the mains cable and the instrument, replace it with a similar cable (16 A, 250 V, 3G 0.75 mm ²), replace the fuses (10 A, 250 V, 5x20 mm) included in the delivery set. Replacement of failed fuses is only allowed once!
The status "No instrument" appears in the "Instrument list" window of DTmaster software	Connection to the instrument has not been made	Follow the operation manual
	Bad connection or break in the PC connection cable	Check the instrument and PC connection cable
	Instrument driver has not been installed	Install the instrument driver
	Windows failure	Reload the computer
After 10 - 15 minutes of heating up the instrument does not enter the ready mode. In the status bar of the DTmaster software the instrument serial number appears on a yellow background	Instrument's malfunction	Contact the instrument supplier
While the amplification program is running, the instrument serial number appears on a red background in the status bar of DTmaster software	Connection between the instrument and the PC is interrupted	Reconnect the instrument to the computer, after which the DTmaster software will detect the instrument and count the missing data without interrupting the amplification program. If this message keeps appearing, stop the application and start it again

5.3 Contacting customer support

If you have any questions or require further clarification, please contact customer support:

8 800 200-75-15 (the call is charged)

E-mail: hotline@dna-technology.ru

6 Requirements for periodic cleaning and disinfection of the instrument

Periodic cleaning and disinfection of the instrument should be carried out by qualified personnel who have studied this manual in detail.

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

The following actions must be performed by maintenance personnel at the specified intervals:

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

Frequency of actions: before starting work.

2. Removal of dust and dirt from the surface of the instrument, using disinfectant solutions, in accordance with the requirements mandatory for use in the user's institution.

Frequency of actions: before starting work.

3. Cleaning of the wells of the heat block to eliminate their possible contamination by nucleic acid amplification products should be carried out with a cotton swab twisted on a wooden rod and moistened with disinfectant solution according to the norms and rules mandatory in the user's institution.

Frequency of actions: every 20 operating runs of the instrument (but at least once a week).

After cleaning it is necessary to review the image of the heat block for all channels. If there are bright spots in the wells of the heat block in any of the ranges of fluorescence registration, it is necessary to perform additional cleaning of the wells (see DTmaster User Guide).

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

When cleaning the wells and the surface of the heat block matrix, do not allow liquids to get into the gap along the edges of the heat block matrix and between the matrix sections in case of its sectional design!

Do not use abrasive or corrosive detergents or concentrated alkaline solutions. These agents can scratch the surface and damage the heat block, resulting in poor temperature control accuracy.

6.1 Requirement for disinfection of instruments before maintenance and repairs

It is the responsibility of the user to decontaminate the instrument before maintenance or repair work is performed.

Before sending the instrument for repair or maintenance, disinfect the instrument and fill out the “Work Order” (see Annex A).

Before using the instrument for the first time and after each use thereafter, disinfect the external surfaces of the instrument by wiping them twice with a calico or gauze cloth soaked in a disinfectant solution approved for use in medical practice for plastic and metal products, observing the interval between wipes. Information on the preparation and use of disinfectant is given in the product manufacturer’s instructions.

7 Storage and transport

The instrument should be stored packed in a closed room with natural ventilation at temperatures from 5 °C to 40 °C and relative humidity of up to 80 % at 25 °C. In case of prolonged storage without use, the instrument should be stored in the manufacturer’s packaging.

The premises where the instrument 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 and destruction of electrical insulation.

When transporting the instrument, it must be protected from dust and atmospheric precipitation. **It is not allowed to roll the instrument.** Before transportation, the instrument must be secured to ensure stable position, avoid displacements and shocks.

The instrument can be transported by all types of transport in the manufacturer's transport package in compliance with the requirements of the handling marks on the surface of the transport package. Conditions of transportation of the instrument: temperature from minus 50 °C to 50 °C and relative humidity of up to 80 % at 6 °C.

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

Warning! The instrument may only be transported with the heat block in the locked (closed) position.

Warning! During transportation the device is guaranteed to retain the technical characteristics listed in p.1.3, including those determined during certification of the thermal cyclers as a test equipment.

8 Disposal

Medical devices are disposed of in accordance with the classification, rules of collection, use, neutralization, disposal, placement, storage, transportation, accounting and recycling of medical waste established by the authorized federal executive authority.

The disposal of the products is carried out by organizations having the appropriate license at specially equipped sites, landfills and premises in accordance with the requirements stipulated by the existing Federal Laws and in compliance with mandatory requirements for environmental protection in accordance with local regulations.

9 EMC declaration

The instrument complies with the immunity and electromagnetic emission requirements of EN 61326-2-6:2020.

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

- The instrument is designed and tested in accordance with the requirements of CISPR 11 suitable for use in all premises, including domestic premises and premises directly connected to the public low-voltage power supply network supplying buildings intended for domestic purposes.
- The electromagnetic environment must be evaluated before operation.
- Using this instrument at low relative humidity, especially when there are synthetic materials (synthetic clothing, carpets, etc.) in the vicinity, may cause erroneous results due to the effects of electrical discharges.
- The floors of the room should be made of wood, concrete or ceramic tiles.
- The quality of the mains power supply should be suitable for typical use in commercial establishments or hospitals.
- Magnetic fields of industrial frequency should be at levels appropriate for typical use in commercial establishments or hospitals.
- The instrument uses radio frequency energy exclusively for its internal function. The RF emission level is very low and does not lead to malfunctions of nearby electronic equipment.
- Do not use this instrument near sources of strong electromagnetic radiation (e.g., unshielded intentional radio frequency sources), as they may interfere with its normal function.

Notes

- 1 The manufacturer is responsible for providing the consumer or customer with information on the electromagnetic compatibility of the equipment.
- 2 The user is responsible for maintaining an electromagnetic environment for the equipment that ensures compatibility, whereby the equipment must function in accordance with its intended use.

10 Warranties

The manufacturer guarantees correct operation of the Real-Time PCR instrument DTprime II and its compliance with TS 26.51.53-001-96301278-2022 in case of observance of the operation rules stated in this manual.

The warranty period for the instrument and accessories is **24 months** from the date of sale to the consumer. Warranty repair is performed only upon presentation of the warranty card for this device with a completed claim sheet.

The average calendar service life of the instrument is not less than 5 years from the moment of its 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 an opinion on further operation of the instrument.

Guaranteed shelf life under storage conditions (heated storage with room temperature from 5 °C to 40 °C) of the product **12 months**.

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

When performing repair works of the instrument, the manufacturer provides the user with a replacement instrument (if necessary).

Fulfillment of warranty obligations by the manufacturer for repair of the failed equipment entails extension of the warranty period for the time of repair of the equipment.

The manufacturer shall not be responsible for the compatibility of the specialized software with any hardware or software supplied by other manufacturers, unless otherwise specified.

In no event shall the manufacturer or seller be liable for any damages whatsoever, including loss of data, loss of profits, or other incidental, consequential, or indirect damages, resulting from improper installation, maintenance, or operation by the user, or from failure or temporary inoperability to operate the product.

The manufacturer is not liable for defects and malfunctions of the instrument, which have occurred as a result of:

- non-compliance with transportation, storage, operation or incorrect installation regulations;
- incorrect actions, use of the instrument not for its intended purpose, non-compliance with the requirements set forth in the operating instructions;
- repair or modification of the equipment design by persons not authorized by the manufacturer, as well as in case of breach of warranty seals;
- force majeure (fire, flood, earthquake, etc.) or the influence of random external factors (voltage surges in the power grid, etc.);
- if foreign objects, substances, liquids, insects, etc. get inside the instrument

The warranty does not cover instruments with external defects (obvious mechanical damage, cracks, chips on the case and inside the device, broken connector pins).

Warranty repairs can only be carried out upon presentation of the warranty card for this instrument with a completed claim sheet.

Annex A. Sample work request

To Service Dept. of "DNA-Technology Research&Production", LLC:
8 (800) 200-75-15, fax: 8 (495) 640-17-71,
hotline@dna-technology.ru, service@dna-technology.ru

To Director General of
"DNA-Technology Research&Production", LLC
V. Y. Dmitrovskiy

Work request

We hereby request you to conduct the following works:

- maintenance
 repair

of the following equipment manufactured by "DNA-Technology Research&Production", LLC

1 Organization information:

Location: _____
TIN _____ TRRC _____
PSRN _____
Operating account _____
Correspondent account _____
BIK _____
Ph. _____
Head full name _____

2 Contact person:

1. Last name _____ Name _____ Middle name _____
Position _____ Phone number _____
E-mail _____

3 Equipment information:

Equipment _____
Manufacturing number _____
Commissioned « ____ » _____ 20__

4 Equipment state description:

- ❖ PC connection: yes; no; other _____
- ❖ Instrument ready signal: yes; no; other _____
- ❖ Heat block movement: yes; no; other _____
- ❖ Hot lid movement: yes; no; other _____
- ❖ Instrument case ventilator: functional; non-functional; other _____
- ❖ Instrument display: functional; non-functional; other _____
- ❖ Instrument control buttons: functional; non-functional; other _____

If the answers to the above questions do not fully reflect the condition of the equipment, describe it:

5 Provision of a replacement instrument

The text of the replacement instrument contract can be found on the company's website www.dna-technology.com in the "Technical Support" section.

The terms and conditions of provision, operation and return of the replacement instrument are familiarized with and agreed to.

Please provide a replacement instrument for the duration of the work Yes No

6 Equipment decontamination certificate

WARNING: Please fill in every column of the table.

1. Has the equipment been in contact with material contaminated or suspected to be contaminated with pathogenicity group I-IV microorganisms, including:	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Blood components and preparations	<input type="checkbox"/> Yes	<input type="checkbox"/> No
material suspected of infection with microorganisms of pathogenicity groups III-IV	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Including HBV, HCV, HIV	<input type="checkbox"/> Yes	<input type="checkbox"/> No
material suspected of infection with microorganisms of pathogenicity groups I-II	<input type="checkbox"/> Yes	<input type="checkbox"/> No
2. Has the equipment been in contact with toxic, carcinogenic or radioactive substances?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
If so, indicate 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 deactivation, disinfection and cleaning, as well as packaging.

We agree that in case of equipment damage during transportation due to poor quality packaging, "DNA-Technology Research&Production", LLC assumes obligations to carry out maintenance/repair works only after written agreement with the Customer.

Customer:

 Organization

 Head of organization full name and signature

Place seal

Manufacturer: DNA-Technology Research & Production, LLC
20 Zheleznodorozhnaya Street, Protvino, Serpukhov urban district,
Moscow Region, Russia, 142281
Phone/fax: +7(4967) 31-06-70
E-mail: protvino@dna-technology.ru
<https://www.dna-technology.ru>

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

Service department:

Phone: +7(4967) 31-14-67, +7(4967) 31-06-71 (ex. 3126)
E-mail: service@dna-technology.ru

Hotline for CIS and foreign countries:

Phone: +7(495) 640-16-93

Authorized representative in the EU:

OBELIS S.A
Registered address:
General Wahis Boulevard, 53
B-1030 Brussels,
Belgium
Tel: +32.2,732.59.54
Fax: +32.2,732.60.03
E-mail: mail@obelis.net
<http://www.obelis.net>