

Detecting amplifier

Real-Time PCR System

TC 9443 - 007 - 46482062 -2004

TECHNICAL PASSPORT

JTOK 170604.00



“DNA-Technology” research-and-production close corporation
Moscow, 2004

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1. General information

A fluorescent PCR cycler (named hereinafter as a “device”) is a special-purpose device allowing to register a fluorescence of a reaction mixture in the tubes immediately during a carrying out of a polymerase chain reaction (PCR).

2. Function

This device is intended for a registration of PCR results at the use of test systems based on the principles of the fluorescent detection.

This device is intended to be used in laboratories of research and public health organizations.

3. Technical parameters

3.1. The device provides a registration of PCR results for the samples containing fluorescent labels with the maximum emission equal to 520 nm (first channel) and 570 nm (second channel).

3.2. A thermoblock is meant for 32 standard 200 µl PCR-tubes (8 x 4).

3.3. A threshold of sensitivity of the device for the solutions of standard fluorophores is not less than 0,001 picomoles/µl (first channel) and 0,001 picomoles/µl (second channel).

3.4. A calibration equation (the dependence of a fluorescence intensity on a concentration of the fluorophore) is linear within a range of a standard fluorophore concentration up to 0,2 picomoles/µl.

3.5 Temperature range of a thermoblock _____ 4...99° C.

3.6. Time of a working mode achievement _____ no more than 5 min.

3.7. Discontinuity of a temperature adjustment _____ 0.1° C

3.8. Unevenness of a thermoblock temperature _____ no more than 0.3°C

3.9. The device provides a continuous work for 8 hours.

4. Delivery set

1. PCR cycler _____	1
2. USB A-B interface cable _____	1
3. CD with the software and documentation _____	1
4. DNA detection kit (PCR technique)* _____	1
5. Three-wire power cord _____	1
6. Technical passport _____	1
7. Cardboard package _____	1

* - is delivered by request

5. Design of the device and its working principles

5.1. The design of a thermoblock provides 32 sockets for 200 µl tubes made on two matrixes (16 tubes in each matrix).

5.2. Execution unit of a thermoblock _____ Peltier element

5.3 Excitation source _____ LED

5.4. Detector _____ CCD-array

5.5. To work with the device it is necessary to install a software delivered with the device. The software is intended for Windows 98, Windows ME, Windows 2k/XP.

The device consists of the following elements:

- matrixes with the tube sockets;
- fast-cyclic thermostat with Peltier elements as the active elements;
- two optical blocks;
- microprocessor control modules;
- LCD indicator.

The function of the device is a registration of a fluorescence arising in a reaction mixture from the lighting of the sample by the excitation source immediately during a PCR process.

6. General operating rules

To put the device into operation it is necessary to do the following sequence of operations:

- 1) Unpack the device; if the device remained at the low temperatures for a long time, then it should be kept for 1 hour at the room temperature (+18-25°C);
- 2) Place the device on the position suitable for a work;
- 3) Connect the device to the idle USB port of a computer;
- 4) Connect the device to the electrical supply (220 V, 50 Hz).

The device contains some precision mechanical elements, so it is necessary to avoid any strokes during the carriage shifts. A transportation of the device should be carried out only with the blocked carriage.

7. Safety measures

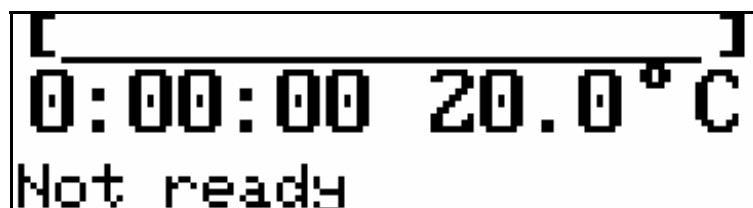
Avoid an ingress of moisture into the device. Do not open a case of the device.

8. Operating rules

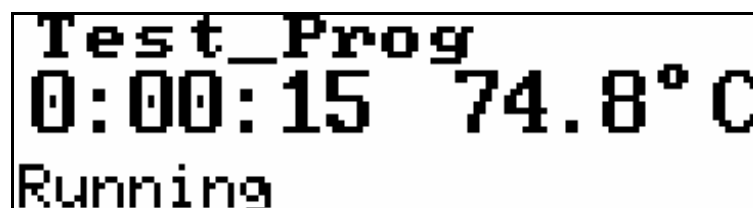
8.1 General notes

LCD indicator displays 3 lines containing the following information:

- name of a program
- current temperature and the rest of time
- device's state (**Not ready** – the device is heating, up to 5 min, **Running** – the program is running, **Restarted<n:m>** - the program is restarted at the “n” cycle, where there were fulfilled “m” repetitions, **Device failure** – power supply malfunction; can appear at the switching off the device) Pict. 1 – Pict. 4.



Pict. 1.



Pict 2.



Test_Prog
0:12:17 72.3° C
Restarted <2:3>

Pict. 3.



Test_Prog
0:12:17 83.5° C
Device failure

Pict. 4.

In a case of the power supply failure the device stores an information about its state and later restores an interrupted program. So there is no need to keep the device in a cooling state if this is already not necessary.

8.2 Beginning of a work

Arrangement conditions

- Environmental temperature - 15...30 °C
- PC with installed Windows 98 SE or Windows XP
- idle USB port

Arrangement order

- Unpack the device
- Connect a power cord to the appropriate power socket of the device
- Attach the device to a computer by a USB cable
- Attach a power cord to a ground plug socket
- Turn on a computer and wait for a loading of the operation system
- Turn on the device (the switch is located at the back panel). The indicator should begin to shine and it should display a temperature equal to 20.0 °C.
- Windows system should detect a new device. It is necessary to define a driver's location ("Drivers" folder on the CD with the software)
- Run Setup program from the CD. The software will be installed. The preparation of the complex to the work is completed.

Adjustment.

- Run the program
- Check and correct, if necessarily, the coordinates of light spots. To do this you should choose a Settings/Image Review menu-item, then choose a channel (for example, FAM), choose an exposure type (40 FAM, 80 HEX), then place scintillating samples into a thermoblock and press the "Review" button. Look at the image. Contours indicating the boundaries of a

measuring area should be located at the edges of spots. If no, then choose “Settings” menu in the “Review” window and change coordinates of the corner tube sockets. The same operations should be fulfilled for the second channel.

- Check the cleanness of the tube sockets. An absence of bright spots during a fulfillment of the previous operation testifies the sockets are clean.
- Set an exposure of optical measurements. Choose Settings/Exposure menu-item, choose a channel and set the required exposure (select by an experience). In the presence of the source of fluorescence it is possible to make test measurements by a pressing of the “Apply” button. The same operations should be fulfilled for the second channel.

Carrying out of PCR

- Input of a temperature program: load it from the CD by a choosing of File/Amplification Program/Open or create it in an Amplification Program Editor field.
- Now the program can process data with the one optical measurement in a cycle.
- Save the program by a choosing of File/Amplification Program/ Save.
- Run the program in the device by a choosing of File/RT322 Device/Run a Program in the Device... You will be offered to choose a file to save the results of optical measurements. An LCD indicator should display the name of program, remaining time and the modelled temperature of the tube.
- Current data of the execution of a temperature rule and optical measurements are in the “Optical measurements” directory.

Analysis of results.

- Load analyzed data from the file on the disc (or load the data of current measurements).
- Adjust an area of a base line calculation (initial and final cycles), if necessary.
- The final result (the relative initial concentration in the analyzed sample) can be obtained by the threshold or analytical methods.
- For the threshold method it is necessary to choose a threshold (moving a threshold line by a mouse or changing a numerical value of the threshold in a spin-box). During this action it is better to switch to a logarithmic scale.
- Obtained relative concentrations are shown in the right column. By default all concentrations are calculated at the moment of the data loading relatively the socket with the minimal concentration.
- An operator can define any other socket (separately for FAM and HEX channels) to be a basis for a calculation of relative concentrations. To do this you should position a mouse cursor on a designation of the desired socket (A1, C5, ...), press the right mouse button and choose “Basic value for a relative concentration” in a pop-up menu.

- Measured Ct values (for the chosen threshold) can be seen in the right column if you mark off the “Cycle number” in the “Show” directory.
- To set the scale of the obtained relative concentrations you can set an expected amplification efficiency in the “Settings” directory (mark “Set an amplification efficiency” and set the value in a range from 0 to 100%.
- For an analytical method it is necessary to set a validation level for the basic data in the “Analytical method” directory.
- You can see CP and E values calculated by the analytical method if you mark off “Cycle number” and “Amplification efficiency” in the “Show” directory.

9. Information about a content of precious metals

The device does not contain any precious metals.

10. Storage and transportation

The device can be stored within 12 months in a manufacturer’s package at the following conditions: ambient temperature within a range from +5 to +40°C, relative humidity – up to 80% (at +25°C).

The stowage should be free of the dust, acid or alkaline vapors, aggressive gases or other noxious gases causing a corrosion.

11. Packing certificate

A fluorescent detecting PCR cycler, works number _____, manufactured by “DNA-Technology” research-and-production close corporation is packed in accordance with requirements of “Technical requirements” № 9452-005-46482062-2002.

Packing date _____

The packing was made by _____ (signature)

A packed device was accepted by _____ (signature)

Stamp

Note. This form should be filled in the organization that has made a packing.

12. Acceptance certificate

A fluorescent detecting PCR cycler, works number _____, manufactured by “DNA-Technology” research-and-production close corporation has passed the hand-over test. It satisfies the “Technical requirements” № _____ and is considered to be ready for service.

Date on “ _____ ” “ _____ ” 200 _____

Stamp

Signature of a responsible person _____

13. Warranty

The manufacturer guarantees a compliance of the fluorescent detecting PCR cyclers to the Technical Requirements № 9452-005-46482062-2002 on the assumption of an observance of Operating instructions listed in this technical passport.

Warranty life time for the detector is 24 months from a date of purchase.

The warranty repair will be carried out only at a presentation of the technical passport of the device with the duly completed reclamation list.

WARRANTY CLAIM № 1 completed by a manufacturer
For a warranty repair (servicing) of a fluorescent detecting PCR cycler
 manufactured
 (works number) (date)
 Manufacturer's Inspection Department representative
 (Stamp of Inspection Department)
 Sale stamp «DNA-Technology» research-and-production close corporation, Moscow
 (company name)
 “.....”.....200..... Stamp of a company.....
 (date) (personal signature)
 Owner and his address

 (personal signature)

WARRANTY CLAIM № 2 completed by a manufacturer
For a warranty repair (servicing) of a fluorescent detecting PCR cycler
 manufactured
 (works number) (date)
 Manufacturer's Inspection Department representative
 (Stamp of Inspection Department)
 Sale stamp «DNA-Technology» research-and-production close corporation, Moscow
 (company name)
 “.....”.....200..... Stamp of a company.....
 (date) (personal signature)
 Owner and his address

 (personal signature)

WARRANTY CLAIM № 3 completed by a manufacturer
For a warranty repair (servicing) of a fluorescent detecting PCR cycler
 manufactured
 (works number) (date)
 Manufacturer's Inspection Department representative
 (Stamp of Inspection Department)
 Sale stamp «DNA-Technology» research-and-production close corporation, Moscow
 (company name)
 “.....”.....200..... Stamp of a company.....
 (date) (personal signature)
 Owner and his address

 (personal signature)

Completed by a repair service

Underside of the WARRANTY CLAIM № 1

Works number of the device

Contents of the repair

.....
.....
.....

Date of repair

(day, month, year)

Repairman Owner

(signature, stamp)

(signature)

Completed by a repair service

Underside of the WARRANTY CLAIM № 2

Works number of the device

Contents of the repair

.....
.....
.....

Date of repair

(day, month, year)

Repairman Owner

(signature, stamp)

(signature)

Completed by a repair service

Underside of the WARRANTY CLAIM № 3

Works number of the device

Contents of the repair

.....
.....
.....

Date of repair

(day, month, year)

Repairman Owner

(signature, stamp)

(signature)

Reclamation list

Detailed failure description

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