

TRENDS in INNOVATIVE BIOTECHNOLOGY ORGANIZATION







MYCOLOR TK 504

MYCOLOR TK 336

MYCOLOR TK 120

and

MYCOLOR TK SOFTWARE

INSTRUCTIONS FOR USE



Introduction

MYCOLOR TK is an automated computerized incubator-reader device developed for rapid mycobacterial culture with TK Media.

TK Media detects early, the growth of tuberculosis bacilli, based on color change. It enables the detection of growth of tubercle bacilli in average 2 weeks compared to 4 weeks required in classical culture media like Löwenstein-Jensen. The medium, which turns from red to yellow with the growth of mycobacteria, turns green in the case of the growth of non-mycobacterial microorganisms, allowing the contamination to be differentiated from true mycobacterial growth. **TK SYSTEM** enables the detection of susceptibility to antituberculosis drugs in a short period of time with drug-containing media and also differentiate tuberculosis from non-tuberculosis mycobacteria.

MYCOLOR TK has the ability to show the growth in **TK Media** as a growth curve, and to differentiate between *Mycobacterium tuberculosis* (MTB) and non-tuberculous mycobacteria (NTM) or other microorganisms that cause contamination, by evaluating the growth curves. **MYCOLOR TK** also performs susceptibility determination to antituberculosis drugs automatically.

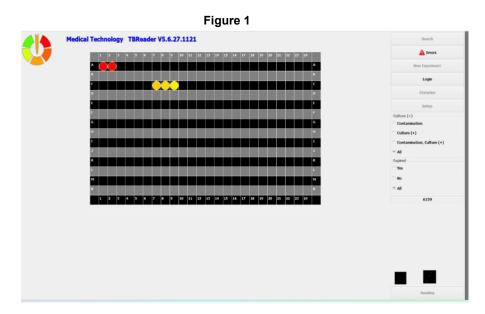
MYCOLOR TK

Main screen

The Main Screen of **MYCOLOR TK** displays the color status of the tubes in the device, as identified in the last reading. By clicking on the buttons on the right of the screen, you can view all tubes, only those with positive (Growth (+)), Contamination, Contamination and Growth (+) or only those with expired (Expired) tubes. To view all tubes again, click on the "All" button. (Figure: 1)

You must log in from the "User Login Screen" with your personal username and password in order to see more features or detailed examination of the culture tubes on the main screen, (See "User Settings" below to add a new user.)

After logging in, users can use features such as "Search", "New Experiment", "Statistics", "Settings" and "Experiment Status" within the program, which will be explained in detail below, in line with the authorization given to the user. When you hover over a tube with the cursor on the "Main Screen", brief information about that tube is displayed. For detailed information, you need to enter the "Experiment Status Screen".



User Login Screen

Each user of the program is given a username and password in order to prevent unauthorized use of the features specified in the program and to take regular records.

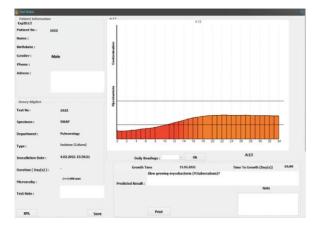
The user presses the "User Login" button from the main screen and reaches the "User Login Screen". After typing the given "Username" and "password", the user clicks the "OK" button and access to the home screen and authorizations are reached.

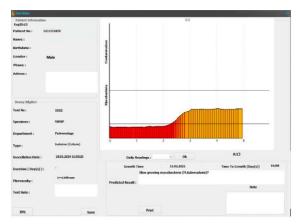
Experiment Status Screen

The "Experiment Status Screen" of **MYCOLOR TK** is a feature that you can access directly from the "Home Screen" in the program. To access this screen, simply click on the tube you want to view from the tubes on the "Main Screen". Another way to find the experiment of the patient you want is to access it with the "Search" button.

Patient Information is located at the top left of the screen. Experiment information is displayed in the lower left part. This section also shows the experiment starting date and the elapsed time. The screen has a graph showing the status of the experiment and tubes. This graph changes according to the type of experiment. Time to detect growth, total time after culture and the probable result for the experiment is located just below the graph. (Figure: 2-3) You can enter the microscopy results for that experiment at the bottom of the graph. To do this, select the desired microscopy result and press the "Save" button. You can also write any necessary information about the sample, that might be required later, into the "Test note" box.

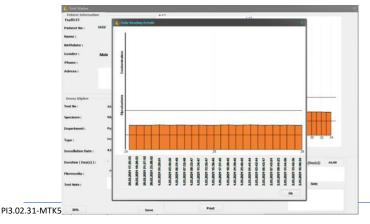
Figure 2 Figure 3

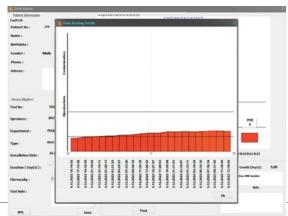




In culture (Isolation) experiments, reading details for a day on the graph can be accessed by double-clicking on the desired day. (Figure: 4) In Susceptibility testing and typing experiments, all growth in different tubes is shown as bar-graph. When the bar of the tube whose growth details are desired to be visualized is double-clicked, the graph of the daily readings is displayed as a different window. (Figure: 5)

Figure 4 Figure 5







Experiment result can be changed before termination in "Culture" and "Typing" experiments. In order to terminate the experiment, the tube or tubes in the device must be removed and the "End" button must be clicked on this screen. When confirmation is made from the checkbox that appears, the experiment is completely terminated, and this experiment can only be accessed from the search section. Printouts can be taken from the system for terminated or ongoing experiments. You can get a printout from the screen that appears, with the "Print" button at the bottom right.

Search

The purpose of the "Search Screen" is to enable users to access the experiments that have been completed or are still in progress on the system.

When the search criteria are entered correctly, the desired record can easily be found by pressing the "Search" button. When the desired record is selected and clicked with the right button, a menu opens that allows you to go to the "Experiment Status Screen". With this menu, information about a new or old experiment can be easily accessed.

New Experiment

MYCOLOR TK is a system that allows you to perform four different experiments:

- Culture / Isolation (Recommended)
- Typing
- Susceptibility testing
- Susceptibility testing and typing (Recommended)

In order to perform an experiment on a patient's sample via the program, several steps need to be taken. The first step is to click on the "New Test" button on the Home Screen. First, the patient's information needs to be filled in or, if the patient has been previously registered, the patient needs to be found and selected using the surname and first name. It is mandatory to enter the "Patient No", "Name", "Surname", and "Gender" information when entering the patient. If given, the "Test No" needs to be entered, the department the sample was sent needs to be selected, the type of test needs to be selected, the type of sample needs to be selected, and an experiment note needs to be entered if desired. (Figure: 6)

Figure 6



When the experiment type is selected, the following tube order automatically appears in the "Tube name" section in the upper right corner of the screen, depending on the experiment type.

Culture / Isolation:

"TK MEDIUM/ TK SLC"

Typing:

"TK MEDIUM/ TK SLC", "TK PNB"

Susceptibility testing:

"TK MEDIUM/TK SLC", "TK INH", "TK RIF", "TK STR", "TK EMB"

Susceptibility testing and typing (Recommended)

"TK MEDIUM/TK SLC", "TK INH", "TK RIF", "TK STR", "TK EMB" and "TK PNB" tubes. (Figure: 7)

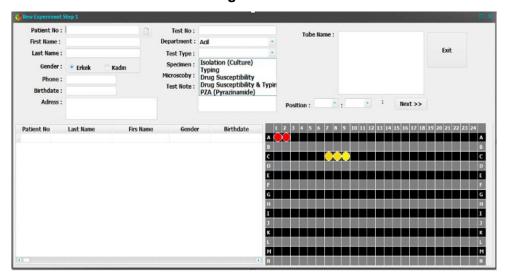


Figure 7

At the last stage, the tube is placed in the first empty space marked "green" by the program, or in the space you choose by clicking anywhere on the main page on the right side of the screen that you see available. In the same way, the tube is placed in the device where it was selected in the program. If using solid medium, the medium surface should face upward at this time.

By clicking the Continue button, the experiment is entered into the system. The program returns to the first step for a new entry.

Statistics

With the MYCOLOR TK program, the statistics of the test results in a certain date range can be obtained and printed, based on the gender, the type of sample studied, the department from which the sample came from, the age range of the patients and the microscopy results on the tests performed in the system.

After the desired features are selected, statistics are created with the "Search" button. The results are displayed in tabular form and in graphical form according to the selected chart type. The results can be printed by clicking the "Print" button at the bottom right.

Settings

When MYCOLOR TK is first installed, there are some settings that need to be made before starting to use it. These settings are accessed by clicking the "Settings" button from the Main Screen and selecting from the menu that opens.

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If these settings are examined in the order of menu the following settings will be viewed:

- **1- Parameter Settings:** Limited to the technical service and installers. In this part, the necessary settings are made for the operation of the system and the calibration of the device.
- **2- Position Settings**: Limited to the technical service. In this part, the settings related to the internal functioning of the device are located.
- **3- User Settings: MYCOLOR TK** includes a user management section to determine who will do the operations that can be done on the system and to prevent unauthorized access. From this section, new users can be added, information can be changed, or users can be deleted. To add a new user, click the "New" button at the bottom. Confirm by entering "Username" and "Password" on the screen that opens. In order to change a user's information or delete a user, select the desired user in the user list. Right-click to open a menu with "Change" and "Delete" commands. To add a new user, necessary authorizations must be given in the authorizations section. In terms of security, it has been considered that it would be appropriate for only one person to add and authorize users.
- **4- Authorizations:** It is the section where the operations that can be done in the program are determined for the users added from the "User Settings" section. Select from the top section the user who will be authorized or whose authorization will be deleted. The previous authorizations of the selected user will be displayed as selected. The desired authorizations are selected and saved by clicking the "Save" button.
- **5- Language Settings**: **MYCOLOR TK** program can be used in any desired language. A new language can be added, a desired language can be deleted, or its contents can be changed from the "Language Settings" section of the program, which is installed in English and Turkish as a standard. The language used in the program cannot be deleted. It is possible to switch between installed languages from the "Language Selection" section at the bottom left of the screen. A new language can be added by typing the name of the language to be added in the space at the bottom right and clicking the "Add" button. For the newly added language, the translations of the English equivalents in the desired language are written in the areas counter to them, and finally, the "Save" button is clicked to save the changes made in this section.
- **6- Departments:** To keep track from which department the samples are coming, you can add the name of a new department to the records by using the "New" button from the Departments section. The name of an existing department can be changed, or it can be deleted completely. Please note that there should be no experiment on the device for that department before deleting a department. Changing and deleting operations are done by selecting the desired record on the list and clicking on the desired function from the menu that opens with the right button.
- **7- Samples:** In order to use sample types in the system during the experiment entry, they must be added to the samples section in advance. While a new sample type can be entered with the "New" button, the list can be changed and deleted from the menu opened with the right button. A sample type that is used cannot be deleted.
- **8- Tubes:** This section can be used to change only the names and barcode numbers of the tubes used in the system. Sorting or deleting operations cannot be performed.
- 9- Test Types: The names of the test types can be changed as desired.
- **10- Microscopy:** While a culture experiment is in progress, microscopy information of the experiment can be entered from the experiment status screen. The content of this information is added, changed or deleted from the microscopy section.
- 11- Genders: The information in this section can only be changed as content.
- **12- Results:** This is the part where content of the experiment results, which can be selected when typing or culture type experiments are terminated, can be changed. Information cannot be sorted or deleted.
- **13- Age Groups:** In this section you can add, change and delete the information showing the age ranges used in the preparation of statistical data.
- **14- Report Title:** This is the part where report title that has the information about department and hospital can be changed for printer outputs and reports.



15- Information:

- **a. User Records:** It is the part of the database that the operations made by the users are kept, where you can control the operations according to a certain date, username or transaction.
- b. Tests: This is the part that allows correcting minor mistakes that can be made while entering data.
- **c. Patients:** This part allows correcting wrongly recorded name, surname, address information, phone number when entering patients into the system.
- 16- Data Base Setting: It is used by the technical service.
- 17- Camera Settings: It is used by the technical service.
- 18- Reading-Correction Screen: It is used by the technical service.

Errors

In case of any error due to test conditions, the button flashes red. When the button is clicked, there is a message stating the error description and the position of the faulty tube in the device.

Product Catalog No: MTK504, MTK336, MTK120