OXY-TEST 2000M

Software Manual

CE 1011

EN ISO 13485:2016

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1.   Introduction

The *OXY-TEST* measuring set consists of the following components:
1. *OXY-TEST 2000M* module;
2. fingertip sensor;
3. connecting cable (to connect the module to the USB port of the computer);
4. CD-ROM with the *OXY-TEST 2000M* software.

The *OXY-TEST* software is designed to perform pulse oximetry tests by means of an external measuring module. The software interface is shown in Fig. 2.

The *OXY-TEST 2000M* module (⇨ Fig. 1) measures, using a non-invasive method, percentage oxygenation of arterial haemoglobin (SpO2), heart rate (HR), and displays plethysmographic waves. The phenomenon of light absorption by blood flowing through pulsing arteries is used to determine oxygen saturation and heart rate. Measurement results are displayed digitally on the monitor screen. Time trends of HR and SpO2 values are also determined.
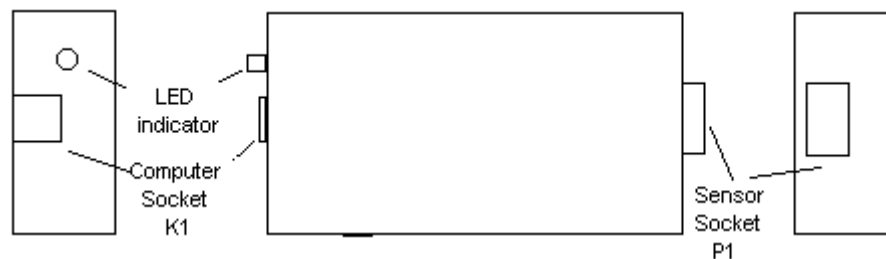
Fig. 1. OXY-TEST 2000M module - side view (LH), top view, side view (RH), front view

The module is equipped with three connectors.
1. K1 (⇨ Fig. 1) is a USB socket for PC connection. The socket should be connected to the USB socket of the PC.
2. P1 (⇨ Fig. 1) is a 9-pin Canon connector to connect the cable with a fingertip sensor.

1.1. Technical Data

SpO2 range	0%-100%
Heart rate range	30-300 bpm
SpO2 resolution	1%
SpO2 accuracy	2% - for SpO2 range from 70% to 100%
	3% - for SpO2 range from 70% to 95% (for newborns)
	2% - for SpO2 range from 70% to 100% (for earlobe sensors)
Heart rate resolution	1 bpm
Heart rate accuracy	3%
Response time	14 ms
Supply voltage	5 V (DC)
Power consumption	0.1 VA
Output type	USB

2. Installation

Correct installation of the *OXY-TEST 2000M* device is necessary to perform the test properly. Installation consists of the following steps:

1. Install the *OXY-TEST 2000M* software on the PC from the attached CD:
   - ➢ Run the *setup.bat* file in order to install the fonts required by the software;
   - ➢ Run the *setup.exe* file in order to start the *OXY-TEST 2000M* installer. Install the software.
2. Connect the cable between the K1 port of the module and the PC port.
3. Connect the fingertip sensor to the P1 port of the module. When power is supplied to the module, a red reflection must be visible on the sensor to confirm correct operation of the sensor.
4. Start the *OXY-TEST 2000M* software from the hard disk.
5. Perform the test according to the description given in Section 6.
6. If no plethysmographic wave and no SpO2 and HR values are displayed, the connections between the USB ports must be checked.
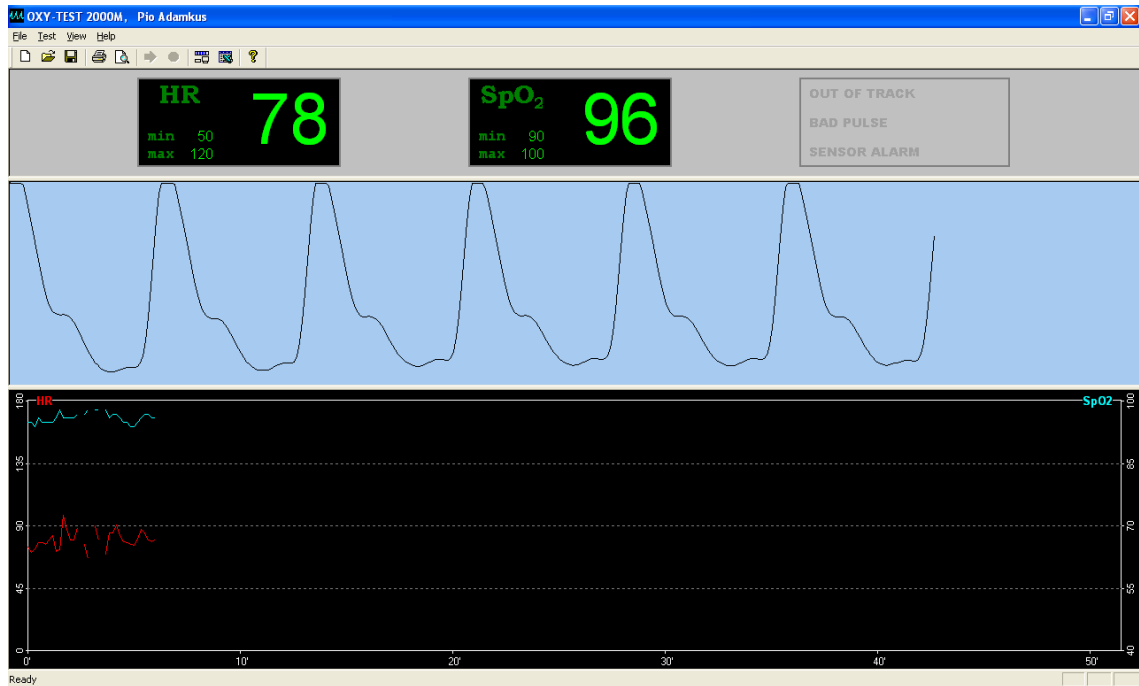
3. User Interface Description

Fig. 2. User interface

The user interface is shown in Fig. 2. It is divided into three basic parts by split bars. The split bars allow the user to modify the height of each part of the screen. Additionally, the interface contains the menu (⇨ Section 9), the toolbar (⇨ Section 10.1), and the status bar (⇨ Section 10.2).

The upper part of the screen contains windows dedicated to HR and SpO2 parameters, and the Test Status window. Parameter windows display their current values (large font) and threshold values (small font). When threshold values are exceeded, the current values change colour to red. The test status window displays alarms indicating incorrect test status (⇨ Section 6.2.1). The middle part of the screen displays the plethysmographic wave. The lower part of the screen displays trends of parameter values (⇨ Section 5.2.2). The HR trend is plotted in red (due to its association with heart), and the SpO2 trend is plotted in blue (due to its association with oxygen). The range of values for the time axis is set in the test options (⇨ Section 5.2.2).

4. Patient Data

Patient data are a collection of information necessary to identify a patient. No test can be performed without these data. Patient data can be entered in two ways:
1. By entering new patient data (⇨ Section 4.1).
2. By opening a file with former test results for an existing patient (⇨ Section 6.3).
After entering patient data, test results will be linked with these data. In order to examine another patient, his/her data must be entered first.

4.1. Entering New Data

New patient data are entered in the *Patient Data* dialog box (⇨ Fig. 3) accessible by selecting the *Patient Data* command (*File* menu). The dialog box contains fields in which the necessary information must be entered according to individual field labelling.
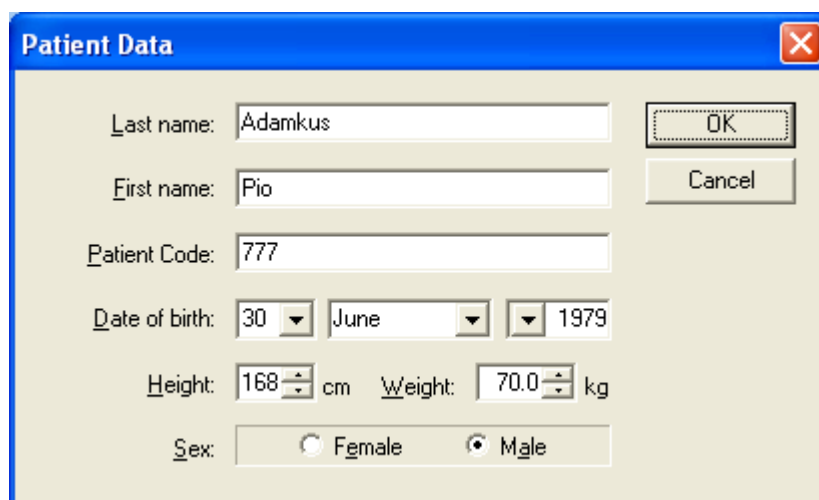

Fig. 3. *Patient Data* **dialog box**

4.2. Modifying Data

Patient data can be modified only prior to starting the test. After initiating the test, alteration of incorrectly entered and accepted data is not possible. In order to modify patient data, new test file must be opened (*File* menu, *New* command) and then incorrect data can be altered. The *Patient Data* dialog box, after opening a new test, contains data of the last examined patient. To modify these data, it is only necessary to correct wrong inputs, rather than re-enter all information.

Modification of patient data before initiating the test is possible through the *Patient Data* dialog box (⇨ Fig. 3), by selecting the *Patient Data* command (*File* menu). Modification of patient data is possible only after they have been previously entered (⇨ Section 4.1). All of the data can be modified.

4.3. Reviewing Data

Patient data can be reviewed by selecting the *Patient Data* command (*File* menu). These data can be modified prior to starting the test, ($\Rightarrow$ Section 4.2), but after the test is initiated, the data can be reviewed only.

5.   Test Options

Test options contain information necessary to run the test correctly. The options include parameters of data transmission between the pulse oximeter and the PC, and the parameters of the test itself. They are accessible by selecting the *Settings...* command from the *Test* menu.

5.1. Data Transmission Parameters

To ensure correct data transmission between the pulse oximeter and the PC, the number of computer port to which the pulse oximeter is connected must be determined first. This is done by selecting the *Settings...* command from the *Test* menu. A dialog box dedicated to data transmission parameters and test parameters will appear (⇨ Fig. 4). In this box, select the PC port to which the pulse oximeter is attached from the list shown in the *Port* field of the *Transmission parameters* group. The *Timeout* field is used to set the time needed to read out one sample from the device. This time should be extended in case of problems with data transmission. If the transmission takes place without problems, the time should be left unchanged. The optimum value of this parameter is 20 ms.
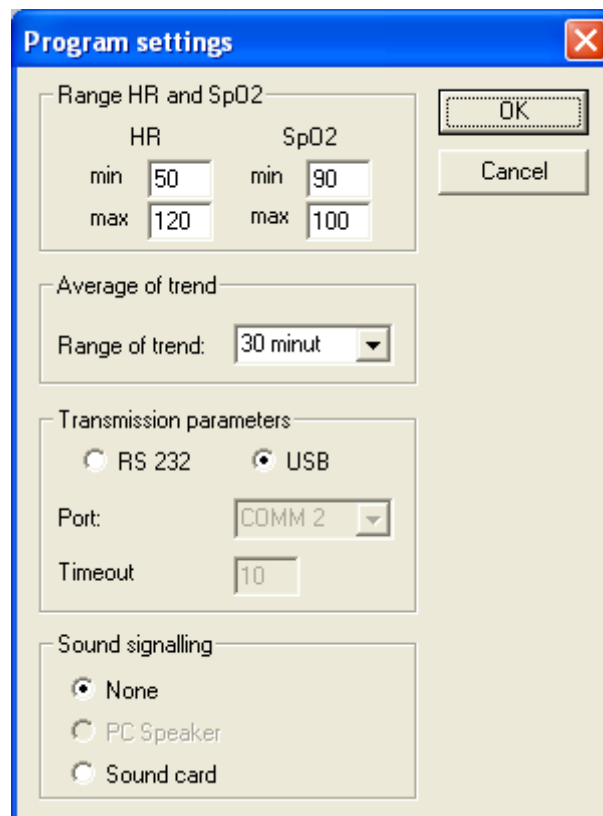
Fig. 4. Program settings

5.2. Test Parameters

5.2.1. HR and SpO2 Range

Test parameters are set in the same dialog box as data transmission parameters (⇨ Fig. 4). The dialog box is displayed by selecting the *Settings...* command from the *Test* menu. The minimum and maximum values of HR and SpO2 must be determined in the *Range HR* and *SpO2* groups of fields. If, during the test, the upper or lower threshold of the parameter value is exceeded, it is indicated by an appropriate sound alarm (continuous sound) and visual alarm (the values of SpO2 and HR are displayed in red). The threshold values are stored in the program, which means that after closing and opening the program again they are still valid.

5.2.2. Trend Averaging

The *Range of trend* field of the *Average of trend* group is used to define the time period applicable for trend display. *Trend* means time profiles of SpO2 and HR parameter values.

5.2.3. Sound Signals

By checking the *Sound signalling* field one can turn on sound signals representing heartbeats during the test (single "beeps"), and continuous sound alarm in case of exceeding any of HR or SpO2 threshold values.

6.   Test Execution

6.1.   Test Preparation

1. Check if the pulse oximeter module is connected to the serial port of the PC.
2. Connect the cable with the fingertip sensor to the module.
4. Make sure that the green lamp indicating module readiness is on, and that a red reflection is visible on the sensor, confirming correct operation of the sensor.
4. Start the *OXY-TEST 2000M* program.
5. Set test options (⇨ Section 5).
6. If required, change alarm threshold values of SpO2 and HR. These values are changed by selecting the *Settings...* command from the *Test* menu and correcting the minimum and maximum values for the SpO2 and HR parameters.
7. Attach the fingertip sensor to the patient's finger. Before attaching the sensor, make sure that the fingernails are not varnished and are not excessively long.
8. The set up of the measuring station should ensure that the sensor cable is not stretched and the lighting is not too strong. Blinking of fluorescent lamps may disturb the measurement.

6.2.   Performing the Test

1. Start the *OXY-TEST 2000M* program.
2. Input patient data.
3. Attached the finger clip to the patient's finger.
4. Set test options.
5. Initiate the test by clicking the *Start* button (the button with the green arrow pointing right).
6. Observe the plethysmographic wave signal, test status (displayed on the right-hand side of the SpO2 window), and the values of SpO2 and HR parameters. Wait until the signal is stabilized.
7. Test results are correct if none of the three status messages is on.
8. Exceeded threshold values of the HR and SpO2 parameters are indicated by their current values displayed in red and, if the *Sound Signals* field in the *Settings...* dialog box is checked (⇨ Section 5.2.3), by a continuous sound signal.
9. Finish the test by pressing the *Stop* button (the button with the red dot on it). Storing test results in a file is described in Section 6.5.
10. In order to perform a subsequent test, select the *New* command from the *File* menu. Patient data refer to the last patient. If the subsequent test is performed on a different patient, these data must be modified. The further steps are as described above, starting from point 3.

6.2.1.   Test Status

The *Test Status* field determines whether the test is performed correctly. Possible messages in this field are:

OUT OF TRACK Signal not stable ⇨ wait until the measurement conditions are stabilized, check if the fingertip sensor is attached, and ensure that the patient is not moving.

BAD PULSE Incorrect pulse ⇨ the patient is moving, the clip is attached incorrectly.

SENSOR ALARM No signal ⇨ the sensor is not connected or it is broken.

Change in the colour of the displayed value of SpO2 or HR to red indicates that the set threshold has been exceeded.

6.3. Reading Test Results from File

The program can open files of one type only (with *.otr extension), which contain test results in the form of a report. Section 6.5 describes how the report is structured. In order to open the desired file, select the *Open* command from the *File* menu. When the dialog box appears, select the file to be read. To make file selection easier, you can use a filter to define the extension of the desired file in the *File type* field.

6.3.1. Reviewing Test Results (Reports)

After opening the file with the test results (report), it will be not automatically visible in the program. In order to review the opened report, select the *Print Preview* command (*File* menu). The report can be also printed (⇨ Section 6.4).

6.4. Printing Test Results (Reports)

Test results can be printed when the test is finished (and, therefore, when the test report is prepared automatically), or after reading a ready-to-print test report from file (⇨ Section 6.3.1). In order to print a test report, select the *Print* command from the *File* menu, or click the printer icon on the toolbar. To preview the report, select the *Print Review* command, also from the *File* menu. The printout options can be modified by selecting the *Print Setup* command from the *File* menu.

6.5. Saving Test Results

In order to save test results (report), select the *Save As* command from the *File* menu. A dialog box will appear, asking for the name of the target file to which test results should be written. Standard file extensions *.otr will be used. The folder to which the file should be written can also be selected here. After entering the filename and confirming it, the report will be saved in the defined file and folder. If the test results are not saved, at an attempt to close the program the user will be reminded that the test results are not saved and will be allowed to save the test results before closing the program.

6.6. Exporting Data to an Excel Spreadsheet

In order to transfer the data to an Excel file, select the *Transmission do Excel'a* command from the *Test* menu, or press the ⬚ button on the taskbar. These options will be active only when a test is opened in the program. The file will be stored in the *C:\Mes\Pliki Excel z OXY-TEST* folder. The filename is structured as follows: *Name Last Name, Date, Time.txt*, where *Date* and *Time* are the date and hour of the test. The stored file is a text file where data are separated by tabs. This file must be imported into Excel as a text file (select „*Text file*" as file type when opening the document in Excel).
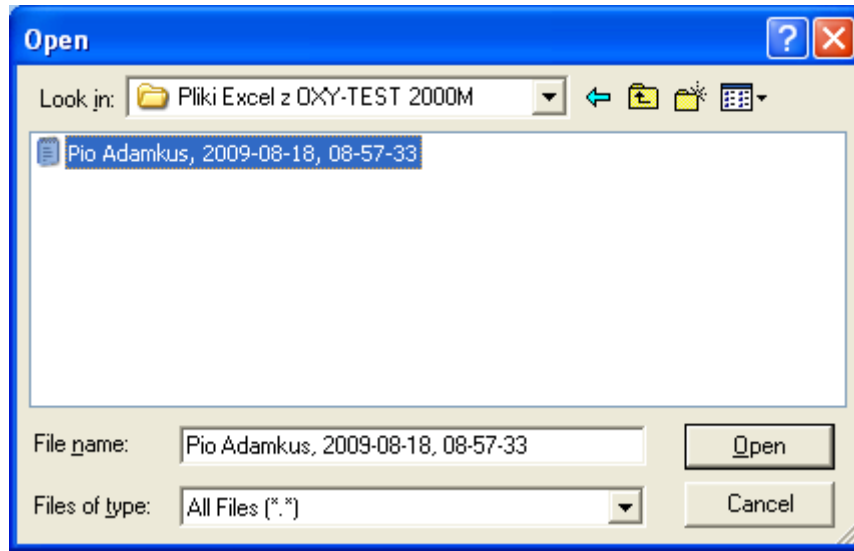

Fig. 5. Dialog box – opening text file

7.   Transmission of Data From the Oxy–Test 2000 Module

In order to transmit data from the *Oxy-Test 2000* module to the program, the *Oxy-Test 2000* module must be connected to the serial port of the PC. Next, select the *Read from Oxy Test 2000* command from the *Test* menu, or click the [icon] icon on the toolbar. A dialog box shown in Fig. 6 will appear:
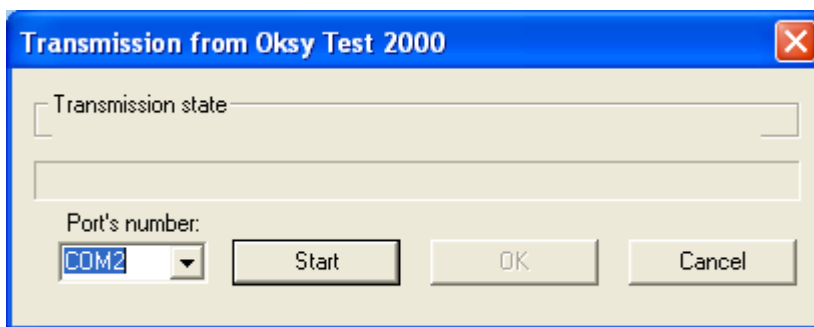
Fig. 6. *Transmission from Oxy Test 2000* **dialog box**

In the dialog box, select the number of the port to which the device is connected. This number is stored by the program, therefore it does need to be entered again after the program is started each time. Next, select the *Transmission to PC* command in the module and reply *Yes* to the *Czy transmitować?* question. When the module displays the *Oczekiwanie na komunikacje z PC* message (the device is waiting for the permission to transmit data), click the *Start* button in the dialog box. Data transmission will start and the progress bar will be shown. Completion of the transmission is indicated by the activated *OK* button, which must be pressed when the transmission is finished. If the data was transmitted correctly, a dialog box will appear, in which the information about the patient linked with the transmitted data must be entered (Section 4). **If the patient data are not entered now, data transmitted from the device will be lost!** If the transmission is not successful, the user will be alerted. Data transmitted in this way can be saved in a file like any other test results. A test report is also available and data can be exported to an Excel spreadsheet as well (Section 6.6).
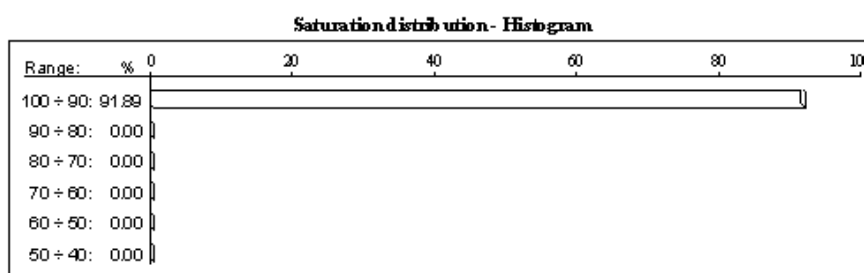
8. Test Report Configuration

Fig. 7. Test report layout

An example of a test report is shown in Fig. 7. At the top of the report, data of the examined patient are listed in the following order: first name and surname, date of birth, height, and weight. Next two lines show the date on which the test was conducted and test duration. Below these data, a table with the following test parameters is shown:

- *minimum value* – this is the minimum, correct value of the corresponding parameter (SpO2 or HR), which occurred during the test;
- *maximum value* – this is the maximum, correct value of the corresponding parameter (SpO2 or HR), which occurred during the test;
- *average value* – this is the average value of the corresponding parameter which occurred during the test;
- *initial average - first 30 minutes* – this is the average value of the corresponding parameters calculated for the first 30 minutes of the tests;
- *final average - final 30 minutes* – this is the average value of the corresponding parameters calculated for the last 30 minutes of the tests;

- *test quality indicator* – determines the percentage ratio of valid samples to all samples taken in the tests.

The following table contains episodes of desaturation for the SpO2 parameter, for the threshold value of 4%. An episode is defined as the period of time during which the value of SpO2 drops by more than 4% from the initial average. This table contains the following items:

- *number of episodes* – shows how many episodes occurred during the test;
- *total duration of episodes* – shows the total duration of all episodes;
- *percentage of test duration* – shows how much time (as a percentage of the total test duration) was taken by the episodes;
- *maximum desaturation time* – shows the duration of the longest episode;
- *percentage of test duration* – shows how much time (as a percentage of the total test duration) was taken by the longest episode;
- *start time of the longest desaturation period* – shows the time when the longest episode started;
- *minimum SpO2 level* – shows the minimum registered level of SpO2 during the episode.

Below the second table there is a histogram of the SpO2 parameter. The first column, "*range",* lists six value intervals for the parameter. The second column, "*%"* specifies the number of samples (as a percentage of all samples) with values within the corresponding interval. The right-hand side of that column displays horizontal bars whose lengths represent the values specified in the "*%"* column.

At the bottom of the report one can find trends of the HR and SpO2 parameter values. Trends are defined as time profiles of these parameters. The HR trend is plotted in red, and the SpO2 trend in blue. Values considered as incorrect (far from reasonable values) are not plotted; the plots show lack of continuity there. The left-hand Y-axis is the HR parameter axis, and the right-hand Y-axis is the SpO2 parameter axis. The X-axis is the time axis common to both parameters.

N O T E: If the test is shorter than 30 minutes, the report will not contain the initial and final averages, test quality indicator, episodes, and the histogram.

9.   Menu Commands

9.1.   *File* Menu

Patient data	⇨ Section 4
New	Starts a new test (⇨ Section 6.2)
Open...	⇨ Section 6.3
Save	⇨ Section 6.5
Save As...	Saves the test results under the indicated name
Print...	⇨ Section 6.4
Print Preview	⇨ Section 6.4
Print Setup...	⇨ Section 6.4
Last Files	Contains the list of recently opened files
Exit	Terminates the program

9.2.   *View* Menu

Toolbar	Displays or hides the toolbar.
Status line	Displays or hides the status line (⇨ Section 10.2).

9.3.   *Test* Menu

Start	Initiates a test routine (⇨ Section 6.2)
Stop	Terminates a test routine (⇨ Section 6.2)
Settings...	⇨ Section 5

9.4.   *Help* Menu

Settings...	Displays information about the program (version #, copyright, etc.)

10. Toolbar

10.1. Standard Toolbar

Fig. 8. Toolbar

The toolbar contains the following buttons:

	New	Starts a new test (⇨ Section 6.2)
	Open	⇨ Section 6.3
	Save	⇨ Section 6.5
	Print	⇨ Section 6.4
	Print Preview	⇨ Section 6.4
	Start	Initiates a test routine (⇨ Section 6.2)
	Stop	Terminates a test routine (⇨ Section 6.2)
	About…	Displays information about the program (version #, copyright, etc.)

10.2. Status Line

The status line is situated at the bottom edge of the main program window. Its position cannot be changed; however, the line can be hidden by selecting the *Status Line* command (*View* menu).

The status line displays descriptions of menu commands and toolbar buttons. In order to read the description, the mouse cursor must be placed over the button in question.

On the right-hand side of the status line there are three fields displaying the status of *CapsLock*, *NumLock* and *ScrollLock* keys.

Fig. 9. Status line