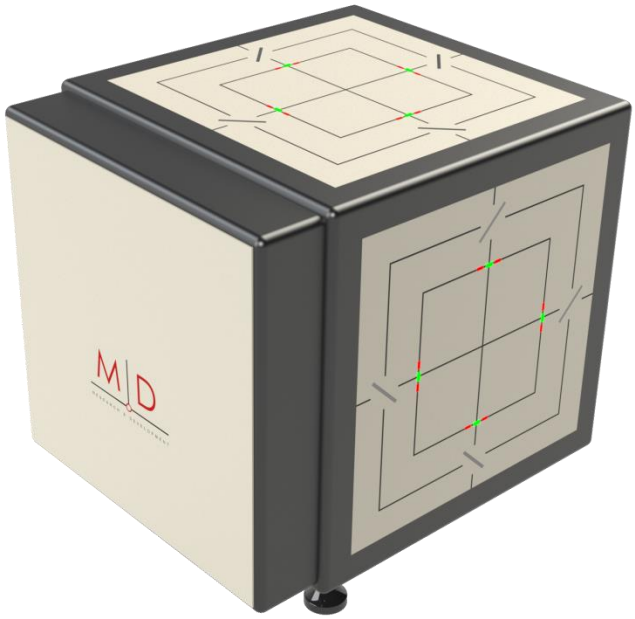

D-Cube Smart QA System User Guide

Version 1.0

13/01/2019

Document No: 1

Mail: info@mdarge.com

Document Title	D-Cube Smart QA System User Guide
Summary	This document provides the latest version information on using the D-Cube Smart QA System v1.1.
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Please follow http://mdarge.com/ where you can find more information about the latest version of the D-Cube Smart QA System and software.

CONTENTS

Section I: General Features of the Device and Software

I. 1. Introduction

One Device for Necessary LINAC Daily QA Tests: Fast, Accurate and Sensitive

The D-Cube has been developed to perform QA tests of Medical Linacs quickly and precisely. It has the feature of completing the tests without the need of electricity with the battery inside. In addition, with the indicator lamps on the D-Cube, basic tests can be performed quickly without using the software.

The D-Cube device automatically makes the necessary angle and position corrections. Therefore, it eliminates the possible user dependent uncertainties. There are light photodiodes placed on the measurement array with special geometry.

It is easy to detect the possible deviations during test with the real time measurements. For instance, during rotational gantry test it is possible to detect the deviation length and its angle.

Key Features

✓ Patented design and measurement method

✓ User independent measurement

✓ Automatic isocenter detection

✓ Real-time measurements – view data instantly

✓ Export PDF reports

✓ Absolute Measurement: Since the D-Cube checks each parameter separately during the test, it can easily find the actual deviation source. D-Cube never assumes.

✓ Automatic Laser Alignment: All laser sources can be aligned according to the isocenter automatically.

✓ Smart QA: Thanks to the combination of different measurement results, more than 30,000 different treatment points are controlled from approximately 30 measurements.

This User Manual provides the necessary information to use the D-Cube v1.1 software effectively.

I. 2. Overview

- Patented design and measurement method
- User Independent Measurement
- Automatic isocenter detection
- Simultaneous measurements - view data instantly
- Report PDF
- Absolute Measurement: During the test, the D-Cube checks each parameter separately therefore it can easily find the source of deviation.
- Smart QA: Thanks to the combination of different measurement results, more than 30,000 different treatment points can be checked from approximately 30 measurements.

I. 2. A. Warning & Cautions

Warnings and Cautions warn the users of dangerous situations that may occur if the instructions in the manual are not followed. Warnings are situations that can harm the user. Cautions can cause damage to the device and internal electronics.

Warning:

The correct use of this device depends on careful reading of all instructions and labels.

Warning:

MD R&D product is designed for use with Medical LICENSE devices available at the time of its launch. MD R&D does not provide liability and/or warranty for future usage, reliability, safety or ability issues ad to developments, updates or changes to these products or systems. It is the customer's or user's responsibility to determine whether the MD R&D product can be used correctly with these products or systems.

Caution:

This device should never be sunk into any liquid, brushed with an abrasive cleaner or placed where liquid can be poured on it.

Caution:

Do not drop, replace, or disassemble this device.

Contact qualified persons for the entire service.

Caution:

Do not expose the electronic part of the D-Cube to the primary radiation.

Caution:

When making the first calibration measurement, make sure that the appropriate Linac is selected to add new data.

Caution:

It is recommended to avoid screwing the serial cable into the unit and instead to put the connection firmly in place.

Caution:

Contact MD R&D for additional information.

I. 3. Installation and Use of the System

I. 3. A. Hardware Connection

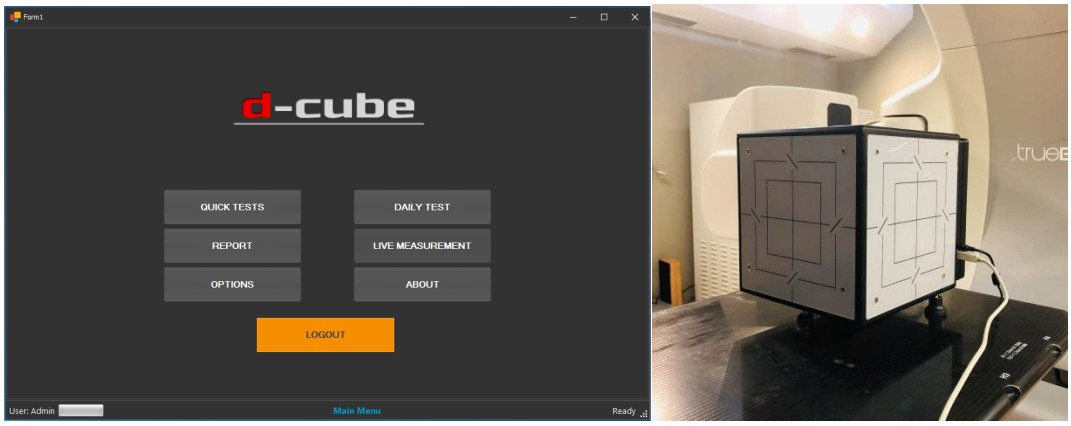


Figure 1: Hardware Connection

The D-Cube hardware works after the connection cables are connected. If all connections are correct and the D-Cube hardware is switched on from the power button, if the D-Cube v1.1 software still cannot automatically find the hardware, you can

provide the connection from the D-Cube v1.1 software help menu, following the hardware connection instructions.

I. 3. B. Shutdown

To shut down the system, save unsaved files. After closing the software, unplug the system components.

I. 4. Positioning of D-Cube

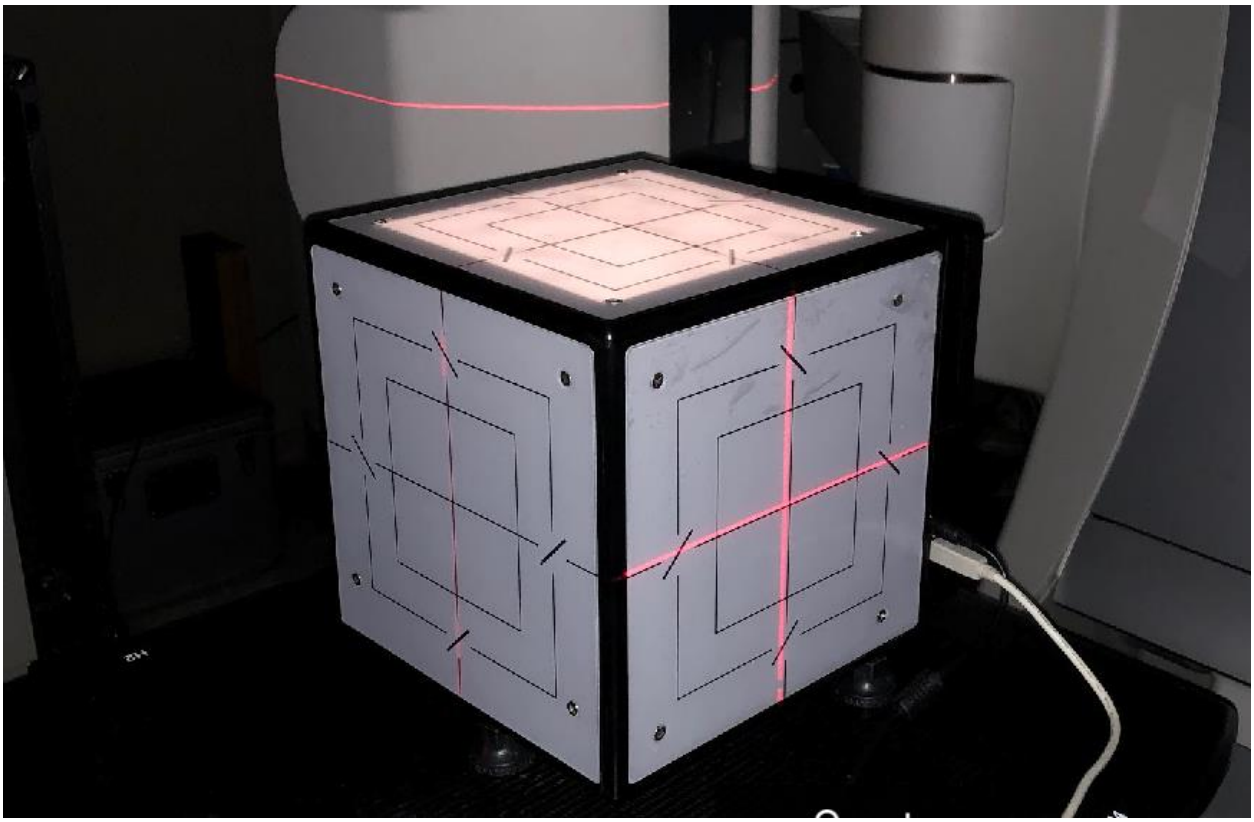


Figure 2: D-Cube Positioning

The D-Cube device should be placed as all the lasers and cross hair should be placed on the sensors. Laser projection and cross-hair lines do not need to be perfectly overlapped with sensor center.

I. 5. Measurement

Hardware	
Dimensions: (cm) Height Width Length	 27 23 23
Connection Cables: Power Supply Data Cable Connection Protocol	 5V - DC USB RS232
Material:	Delrin
Photodiode Detectors for Geometric Measurement: Detector Type Detector Range (mm) Number of Detectors in Each Array Spectral wavelength range (nm)	 Si Photodiode Array 1.58 16 340-1100
MV /kV Detector: Sphere Pins Radius (mm)	 1.5

Figure 3: Hardware Information

I. 6. Hardware Reference

I. 6. A. Photodiode Arrays

Above the photodiode arrays, there is a 1mm PMMA (so as not to cover the sensor active area), a transparent surface with a thickness of 0.5mm to protect external factors. Sensors placed with a special geometry to detect cross-hair & laser projection position with 0.1mm precision, although the diode size is 1.6mm x 1.6mm*.

* Sensitivity may change depending on ambient light.

I. 7. Maintenance and Support

I. 7. A. Repair

There are no components in D-Cube that can be maintained by the user. If there is a problem with the device, contact MD R&D. If the device cannot be calibrated to match a known standard value, please contact MD R&D.

I. 7. B. Maintenance

Periodically examine cables and parts for damage. If there is any mechanical or electrical deterioration or suspicious situation, contact MD R&D. If the D-Cube measuring panel or case is damaged, contact MD R&D.

I. 7. C. Cleaning

If necessary, the outer surfaces can be cleaned with a moist swab, moistened with water and light cleaning solution. Do not allow any liquid to flow on any surface or into any space. Do not sink into any liquid. Do not use solvents or abrasive cleaning agents.

I. 7. D. Storage and Transportation

Store and carry the D-Cube in the protective bag. Place in a closed, protected environment where the device will not be exposed to radiation.

I. 7. E. MD R&D Support

• Send a support request using email

Send your support request to the following e-mail address.

info@mdarge.com

Bölüm II: Installation of the Software and Setting Up The Necessary Settings on First Use

II. 1. Login Screen and Settings

When the software's working window is displayed for the first time. At this stage, you need to click on the "Login" button without making any changes to the Username and Password sections.

Figure 6: Login Screen

At the first time of operation, the software will login to the program with a user with full authority. At this stage, click on the "Options" button first. After the process, the software's settings – user settings screen will be opened.

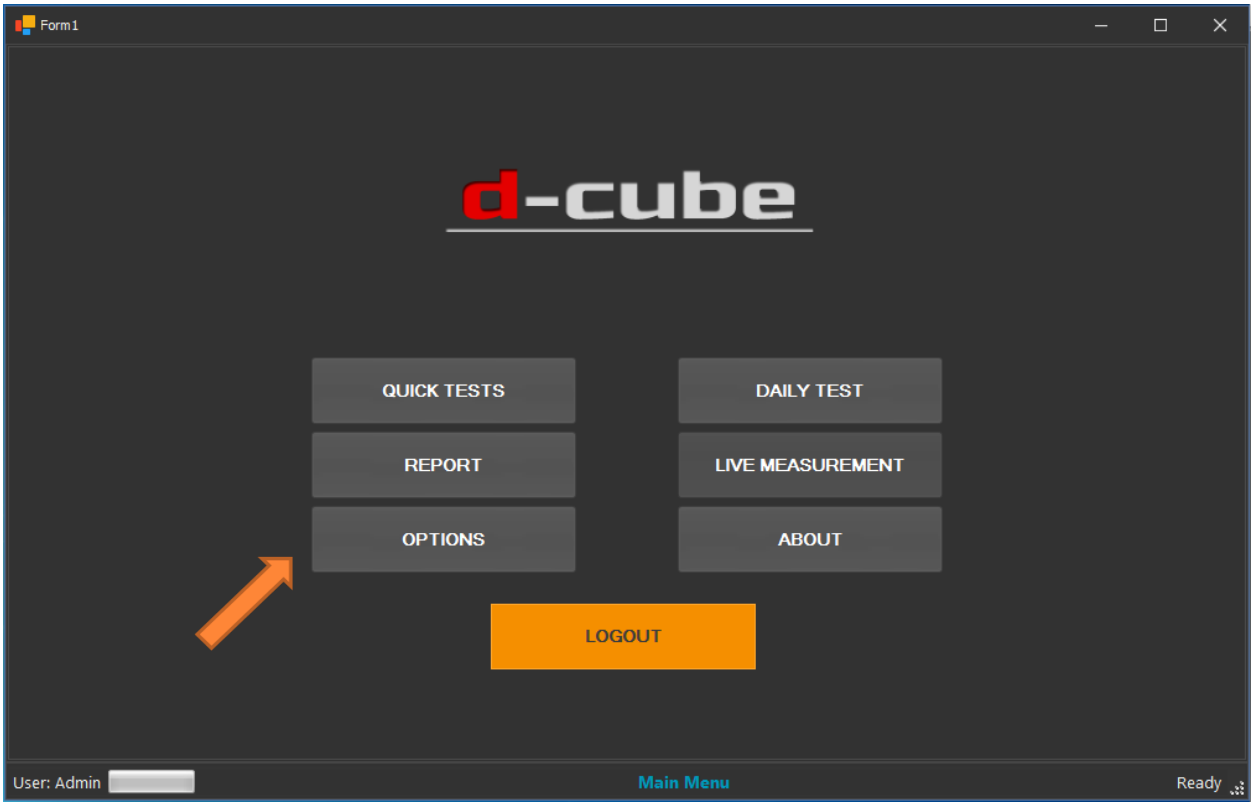


Figure 7: Menu Screen

II. 2. A. User Settings

The user settings window is as follows. There are predefined users on the form located on the left side. Users you identify with will also be able to be added and deleted here.

As a user with full authority during the first run, you can add and authorize users at this stage.

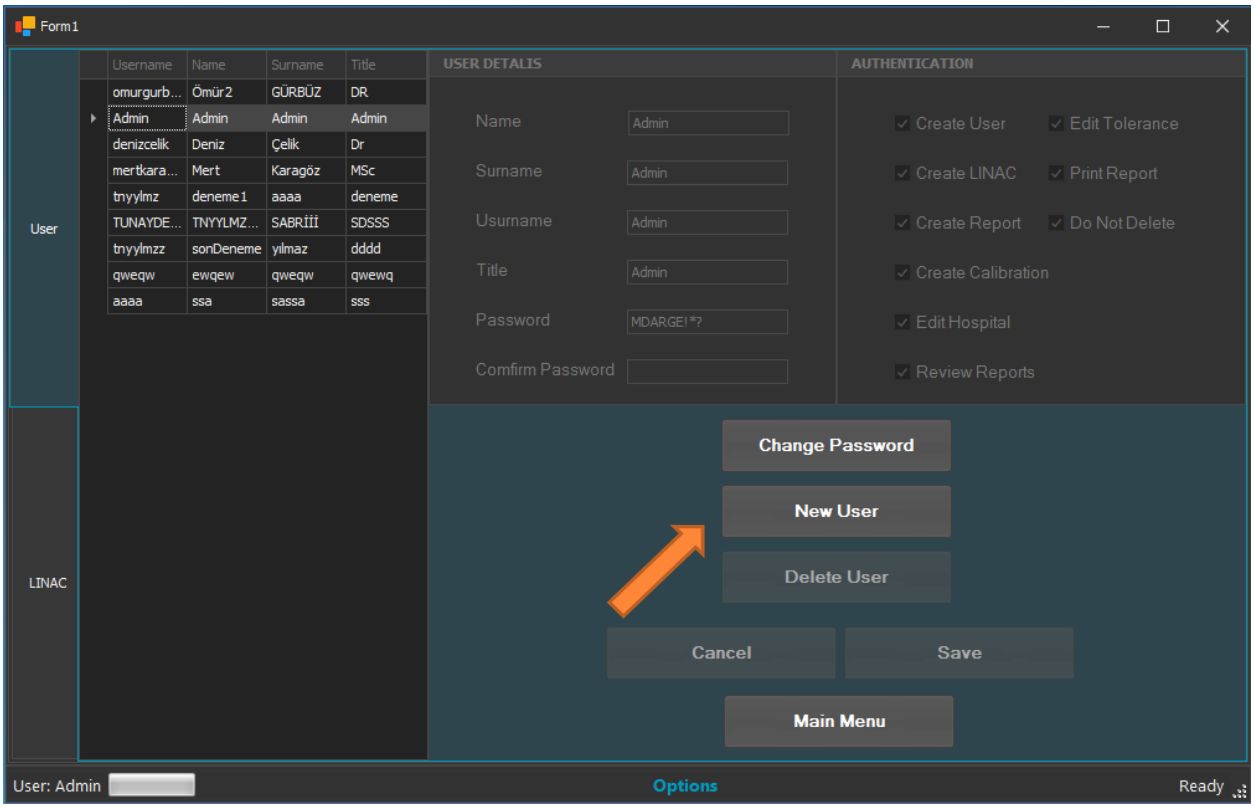


Figure 8: User Settings

To add a user, you need to click the "New User" button.

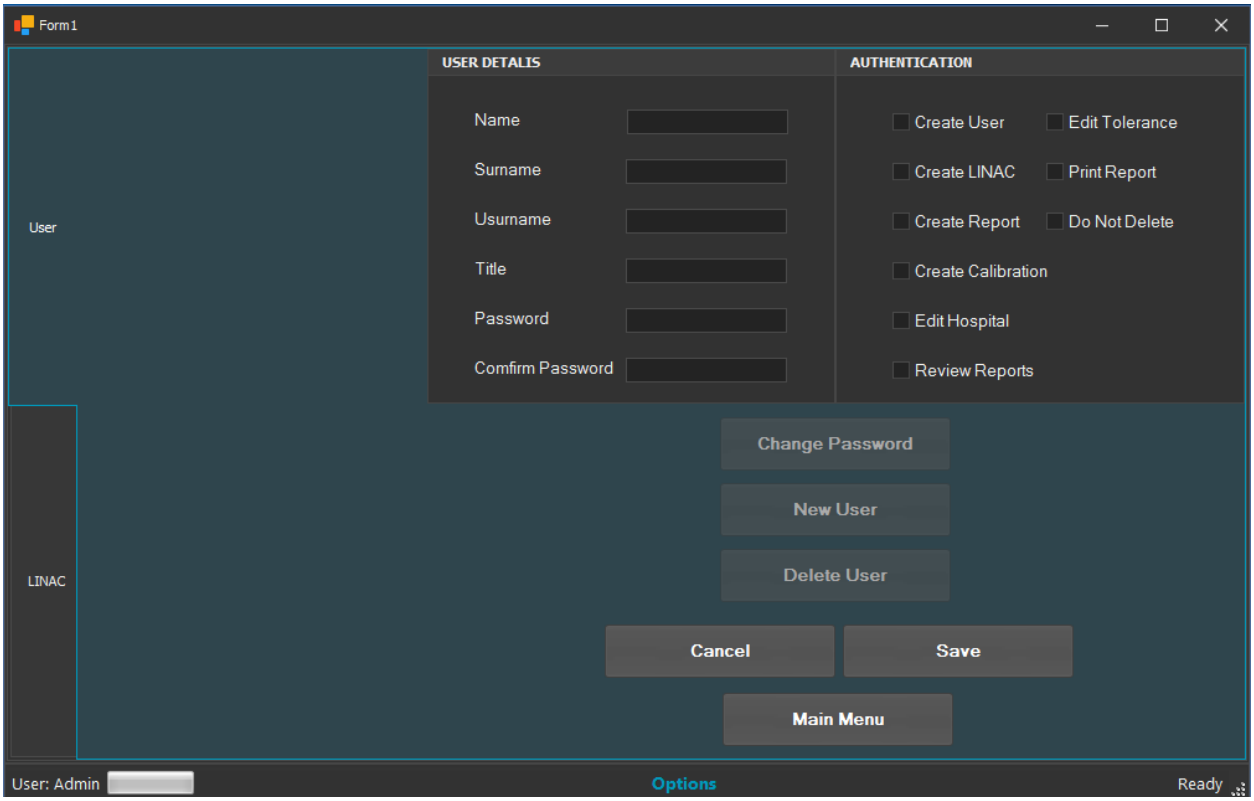


Figure 9: New User Addition

- **<u>Authentication</u>**
  - ***Create User:*** Allows the user to create a new user in the program and edit registered users who do not have the "Do Not Delete" right.
  - ***Create LINAC:*** Allows the user to create a new Linac where the D-Cube device will be used and tested, and to detail its features. In addition, the user can edit this registered Linac.
  - ***Create Report:*** Allows the user to create report from QA tests.
  - ***Edit Calibration:*** Allows the user to edit calibration parameters such as beam data creation and recorded beam data deletions.
  - ***Edit Hospital:*** Allows the user to edit hospital information.

- ***Review Reports:*** Allows the user to view reports generated as a result of QA tests.
- ***Edit Tolerance:*** Allows the user to set different tolerance values for different treatment methods (IMRT, SBRT, etc.)
- ***Print Report:*** Allows the user to print the report
- ***Do Not Delete:*** If this section is selected, the created user will not be deleted or rearranged under any circumstances. A warning window will also open indicating this situation and waiting for your approval. You can continue by clicking on the "Yes" button stating that you have approved it.

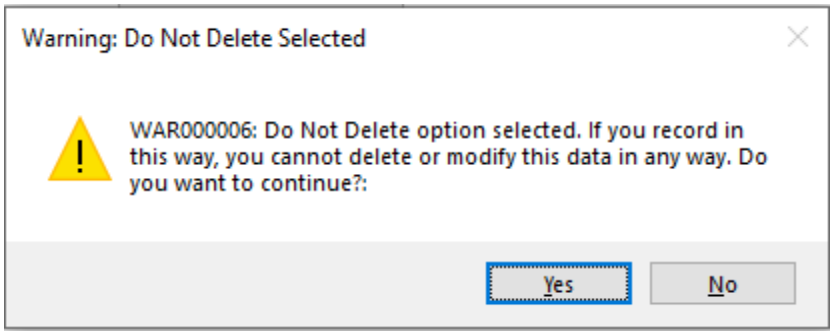


Figure 10: Warning Message (Do not delete)

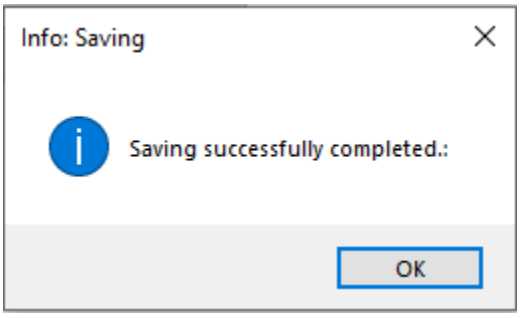


Figure 11: Warning Message (Saving)

II. 2. B. Linac Settings

In order to reach the Linac settings window – you need to click on the LINAC panel in the left corner on the user settings window.

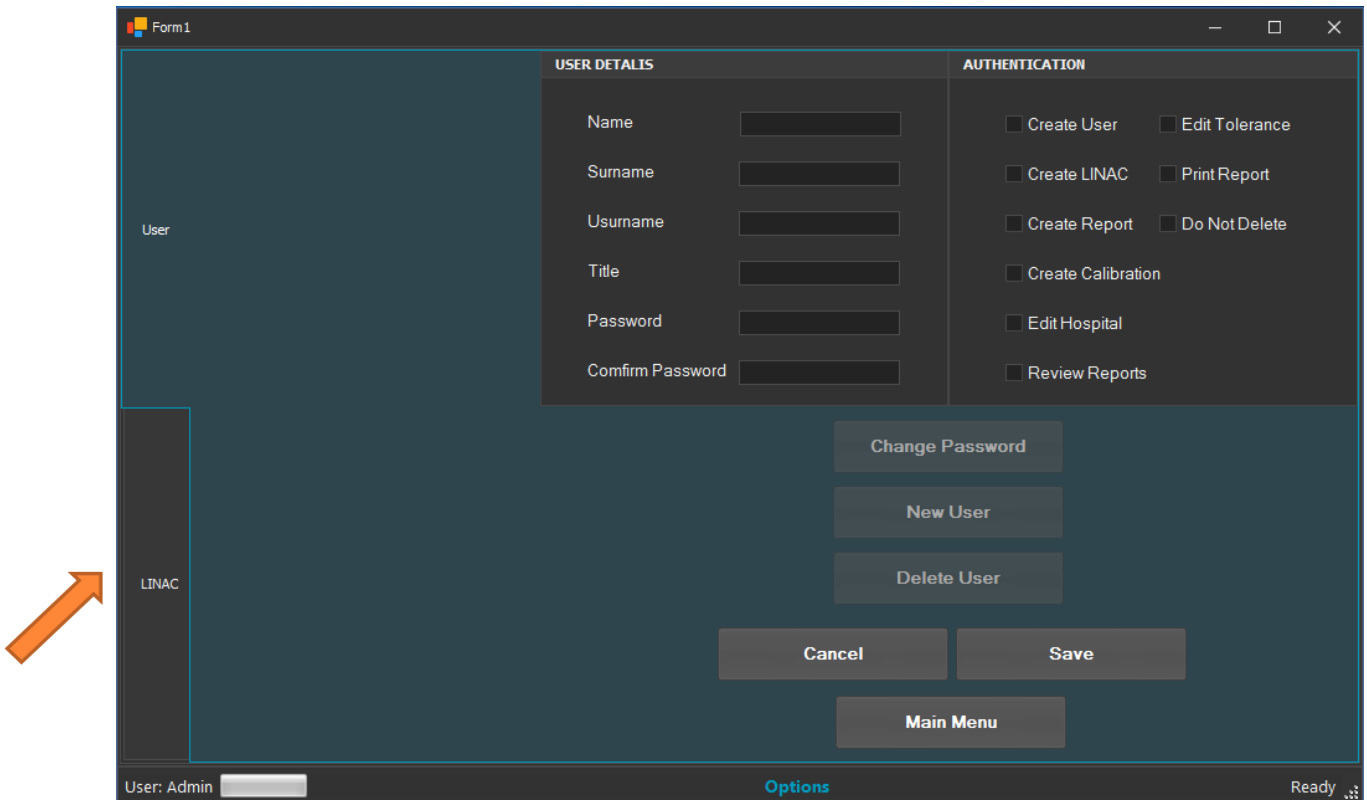


Figure 12: Linac Settings Display

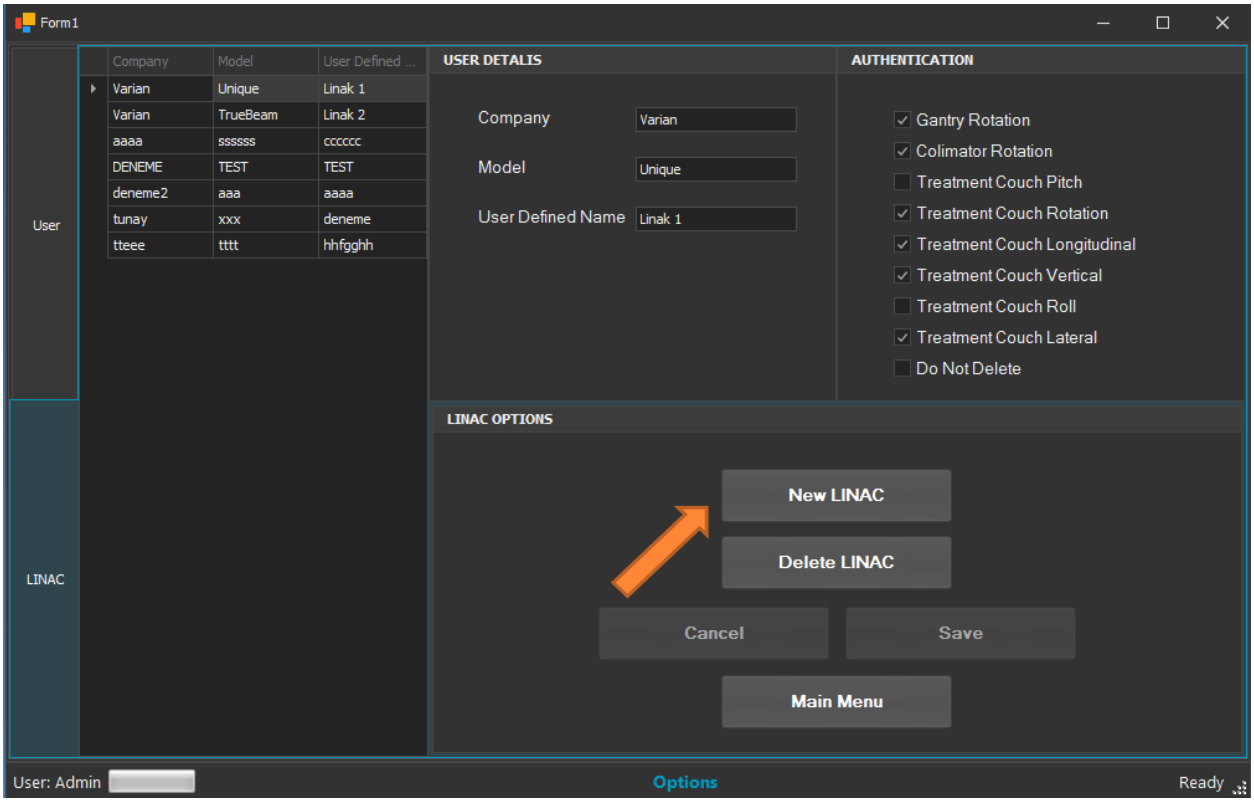


Figure 13: New Linac Creation

The "New LINAC" button should be clicked to create a new Linac and tests.

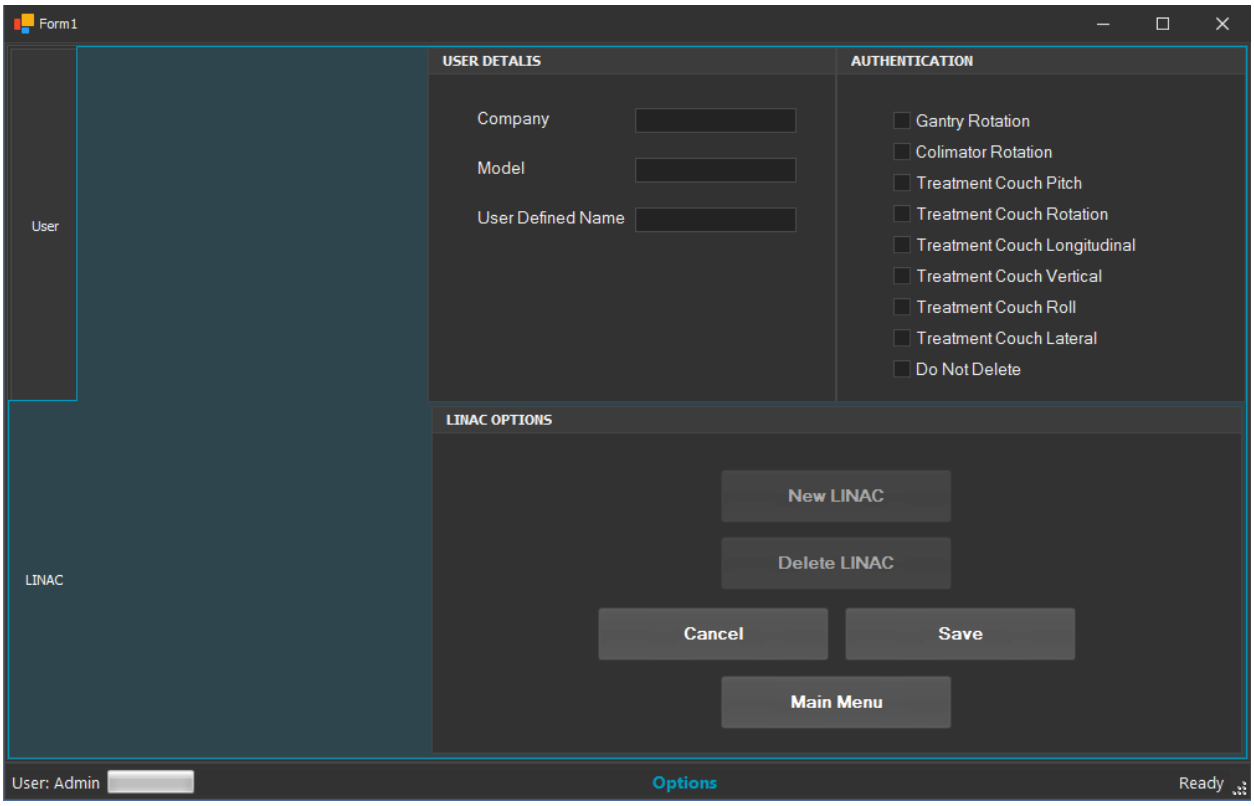


Figure 14: New Linac Features

- **<u>LINAC Details</u>**:
  - ***Company:*** Indicates the device belongs.
  - ***Model:*** Indicates the model of the device
  - ***User Defined Name:*** Indicates the user-defined name to be shown in the program.

- **<u>Axis</u>**:
  - ***Gantry Rotation***
  - ***Collimator Rotation***
  - ***Treatment Couch Pitch***
  - ***Treatment Couch Rotation***
  - ***Treatment Couch Longitudinal***

- ***Treatment Couch Vertical***
- ***Treatment Couch Lateral***
- ***Treatment Couch Roll***

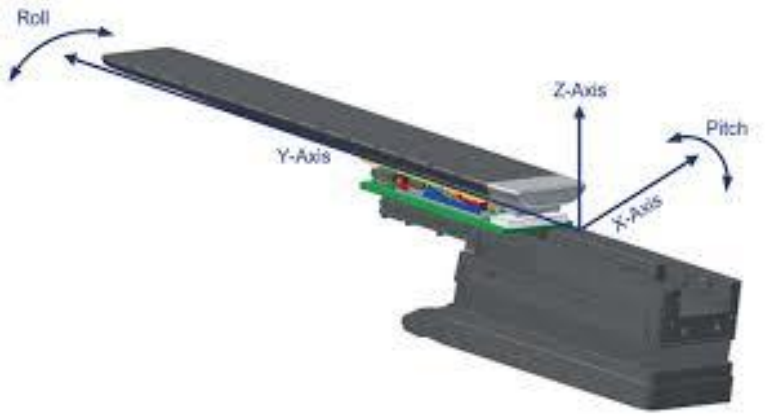


Figure 15: Treatment Couch Rotation Axes

- ***Do Not Delete:*** If this section is selected, the created device will not be deleted or rearranged under any circumstances. A warning window will also open indicating this situation and waiting for your approval. You can continue by clicking on the "Yes" button.

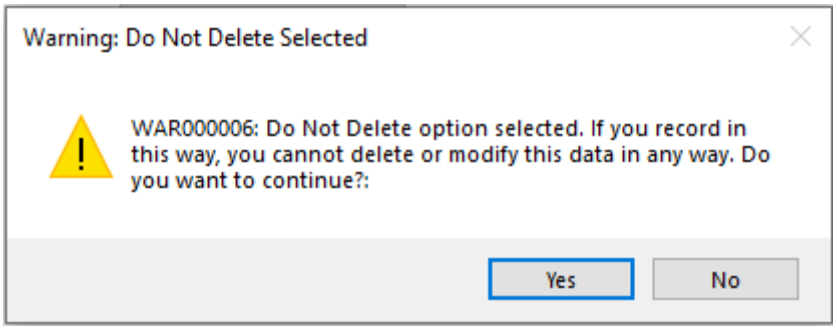


Figure 16: Warning Message (Do Not Delete)

After creating the Linac, you need to click the "SAVE" button to create a Linac device by saving the changes, and the "Cancel" button to cancel this operation.

The created device is given in the same way as the information window indicating that it was successfully registered. You can continue by clicking on the "OK" button. If you encounter any error windows at this stage, please refer to section IV of this guide.

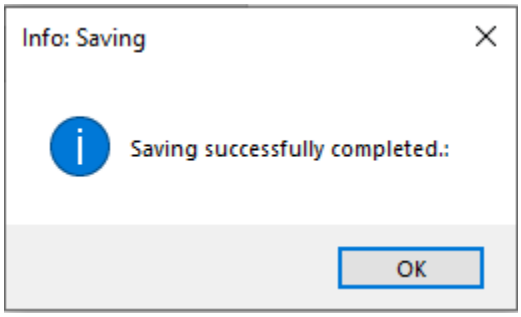


Figure 17: Warning Message (Saving)

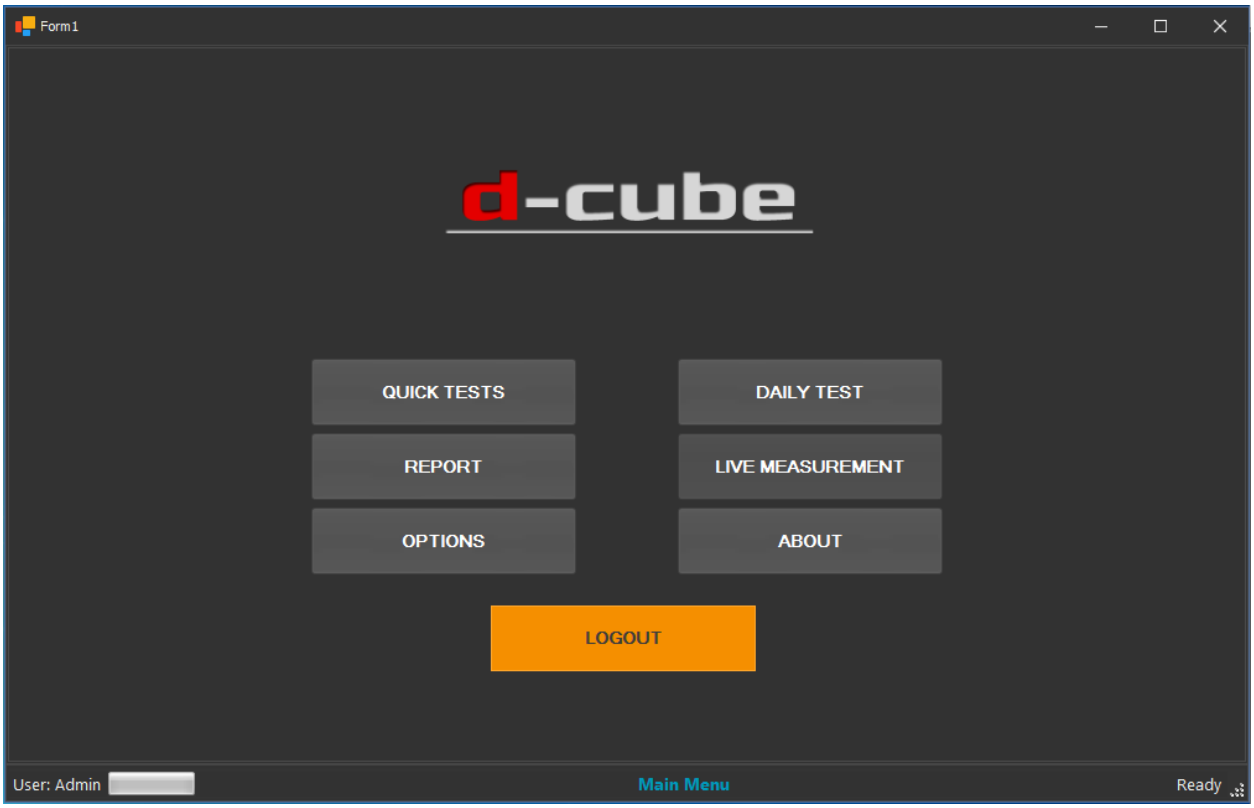
II. 3. To Do Before Linac QA Tests

Before starting the software, make sure that the hardware and the D-cube connection is made properly and the device is positioned on the couch where the tests will take place.

At this stage, if you want to check the measurement on D-Cube surfaces instantaneously, you can move to the "Live Measurement" section via the main menu.

Bölüm III: Software

III. 1. Main Menu



Şekil 1: Main Menu

- ***Quick Tests***
- ***Daily Test***
- ***Report***
- ***Live Measurement***
- ***Options***
- ***About***
- ***Logout***

Not: In order to perform some of the operations mentioned in this section, the user who is signed in to the program must be authorized for that selections. If you attempt to perform an operation that is not within your authority, at least one of the steps mentioned below will keep the intermediate face element required for you to continue the process passive or not created at all. In order to carry out the selection, the program must be entered with a user who is authorized.

III. 2. Quick Tests

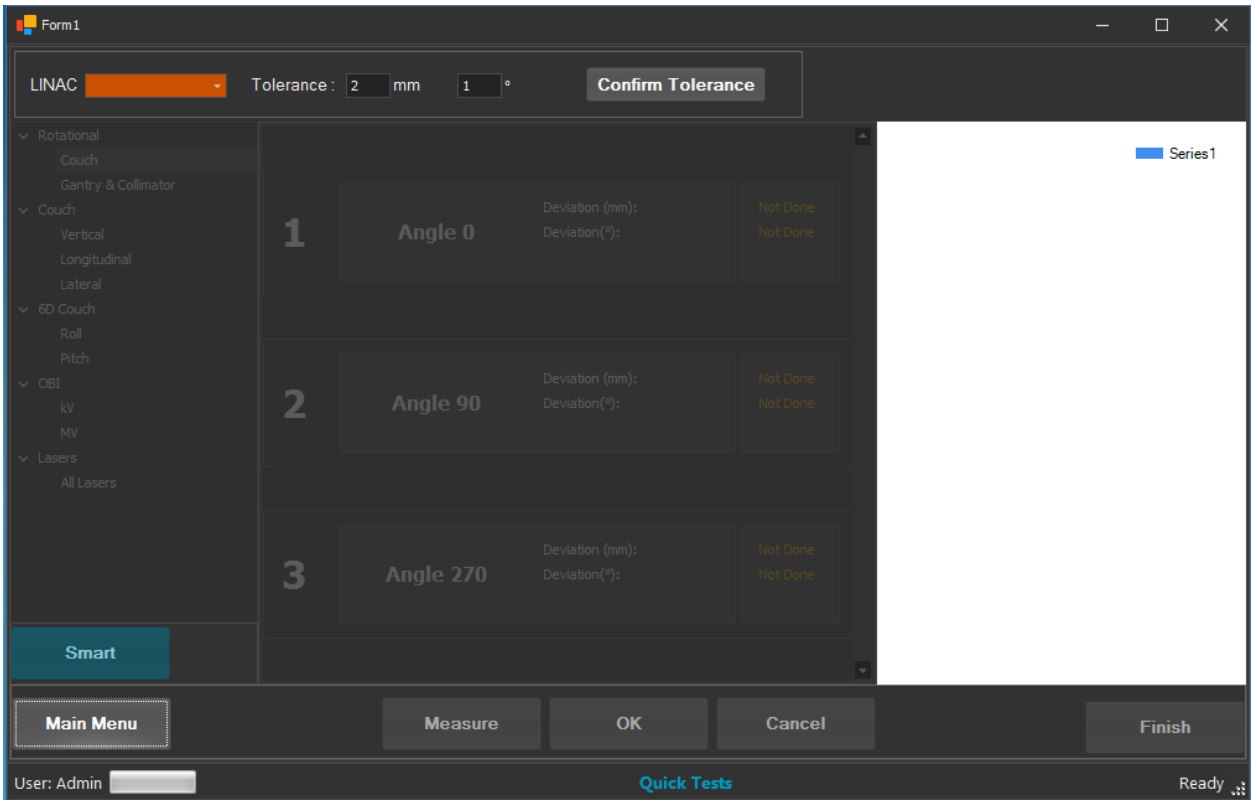


Figure 22: Quick Tests

In the left part of the Quick Tests screen, you can select Linac position tests, OBI tests and laser tests.

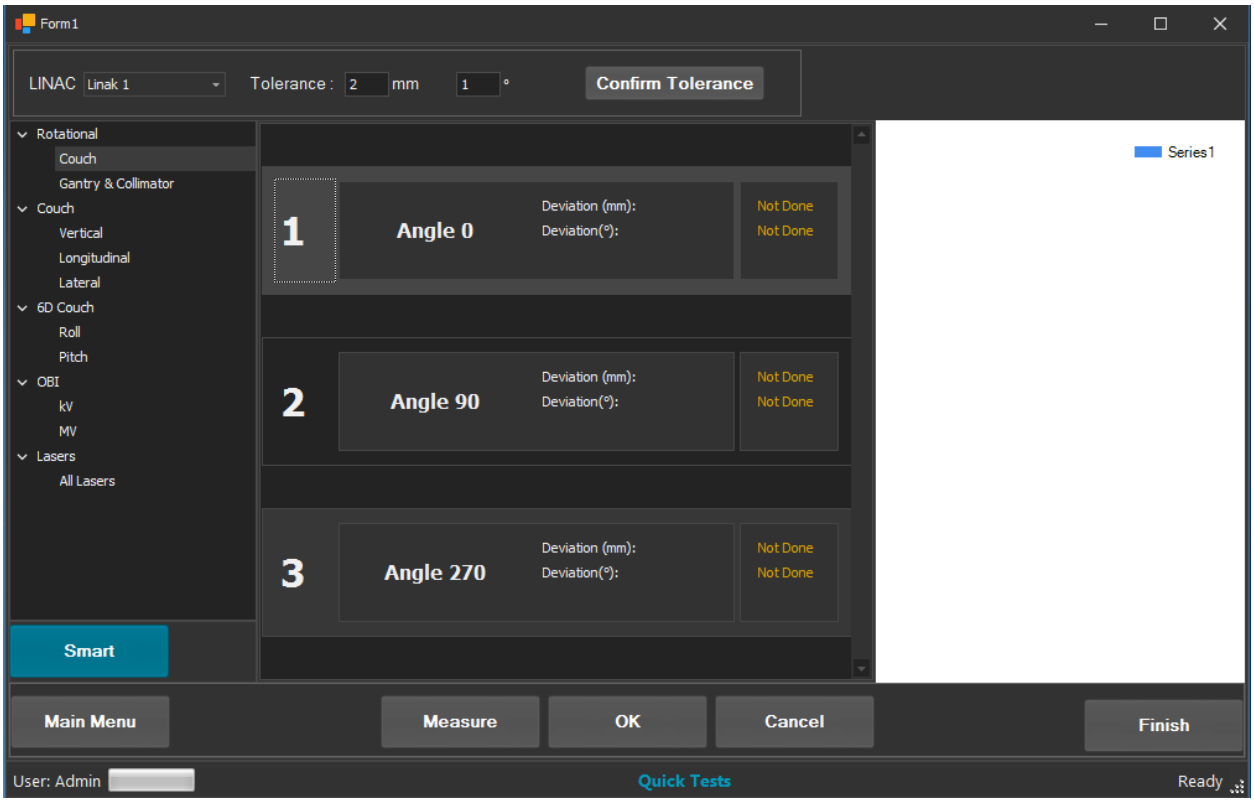


Figure 23: Quick Tests Selection

After the parameter selection, you can perform the process by clicking the "Measure" button and view the results simultaneously. You can re-select each test you want to measure and repeat the process by clicking the "Measure" button again. You can view the results in the result table and observe whether the test has been successfully done (Passed) within the tolerance limits.

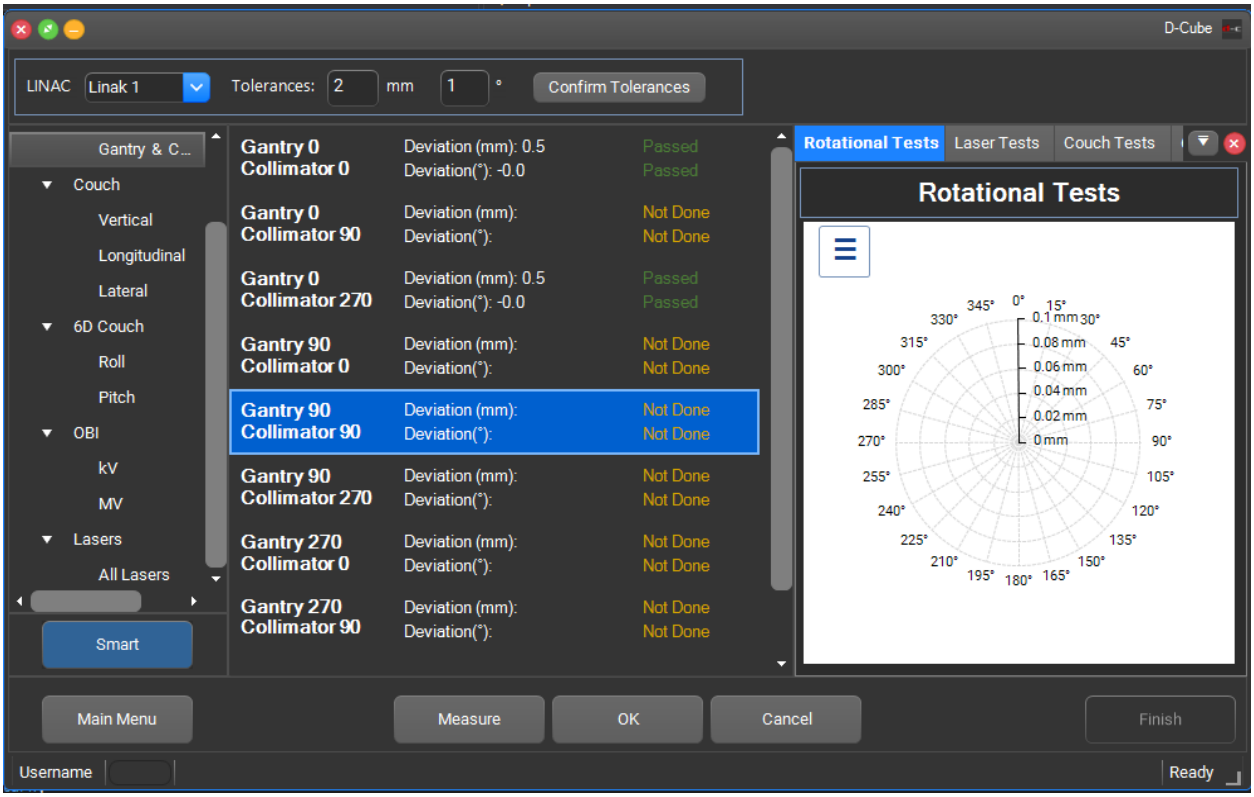


Figure 24: Quick Tests Results

After the test you need to click the "OK" button to record the results or click the "Cancel" button not to save the results. For completing and saving the quick tests section click the "Finish" button or cancel all tests and move to the main menu with the "Main Menu" button.

III. 3. Daily Tests

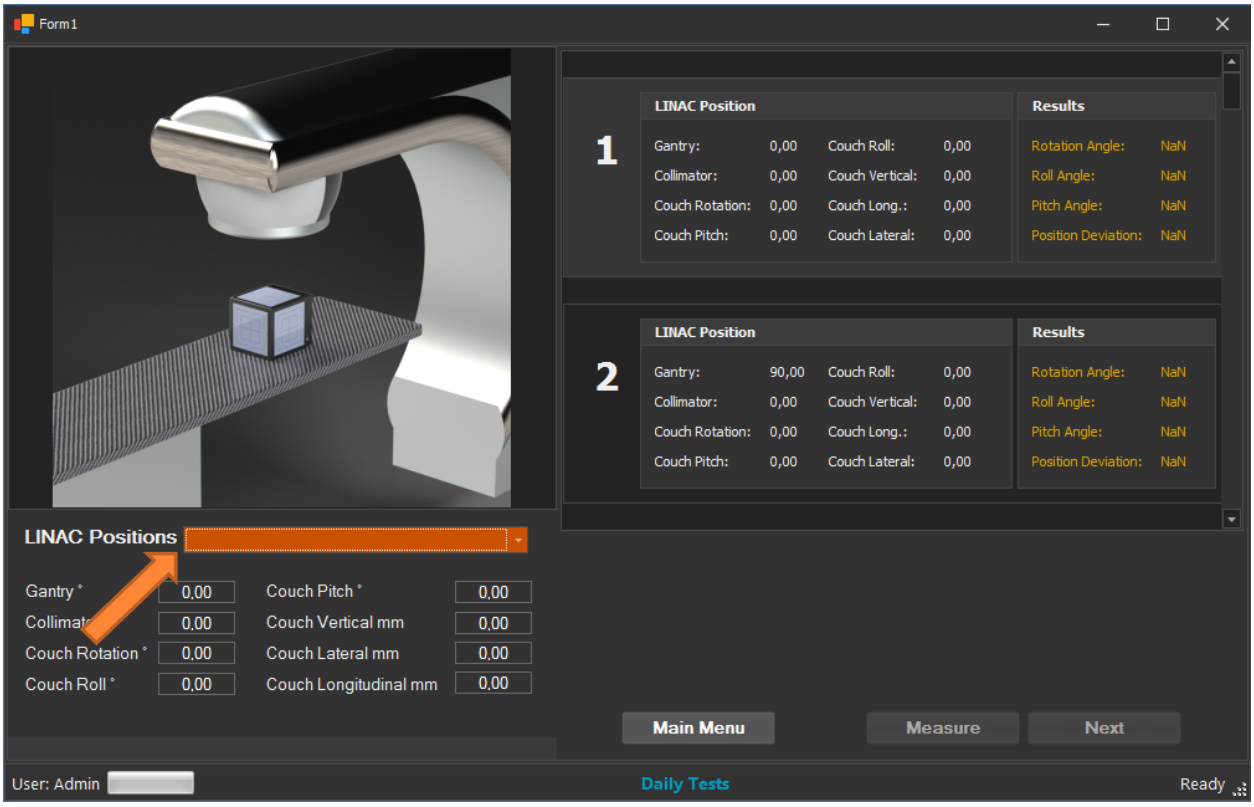


Figure 25: Daily Tests Set-Up

First of all, you need to select a registered Linac. After that, the "Measure" button will be activated.

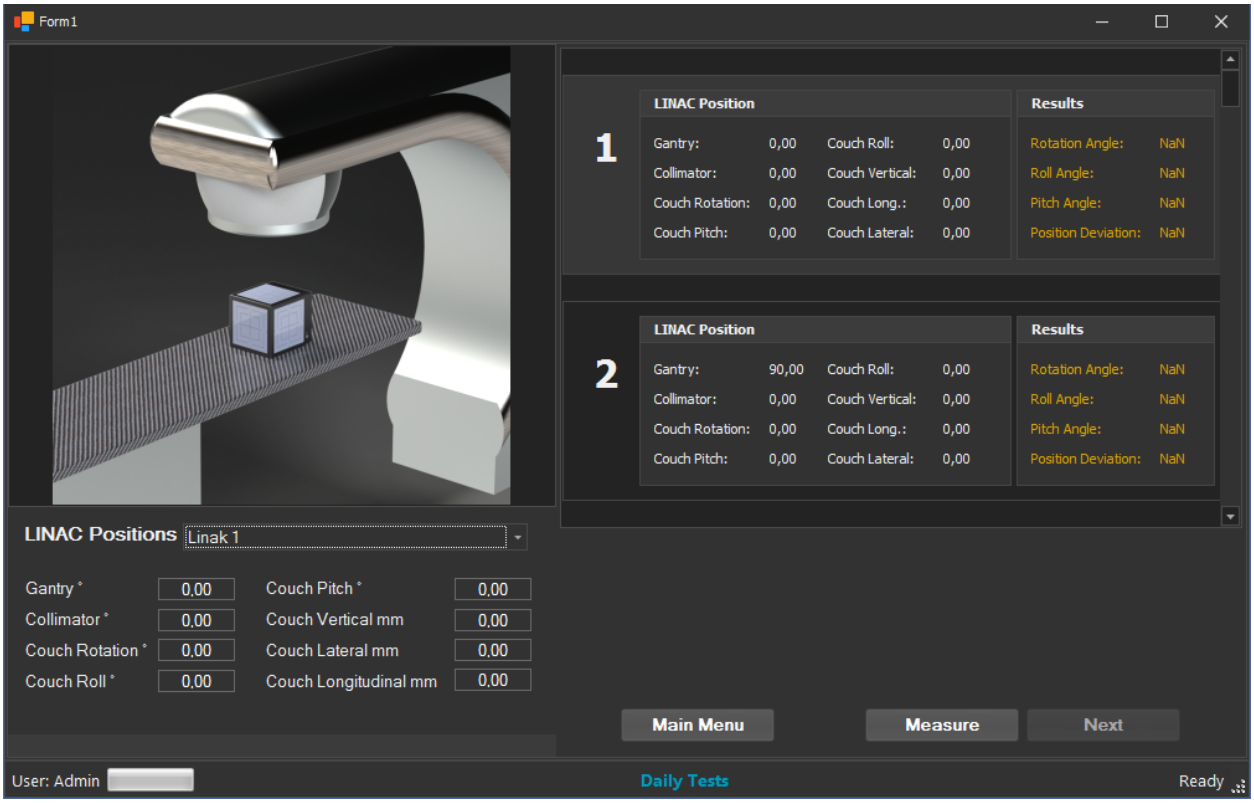


Figure 26: Daily Tests Measurement

Make sure that the Linac is located in the correct position. After that, you need to click on the "Measure" button to perform the measurement. At this stage, an information or warning window will occur in the lower-right section of the program to see if the measurement has been completed correctly. If the measurement is completed correctly, the "Next" button will be activated. You need to click on the "Next" button to move on to the next measurement step. If you want to re-measure the current step before moving to the next step, you can use the "Measure" button again.

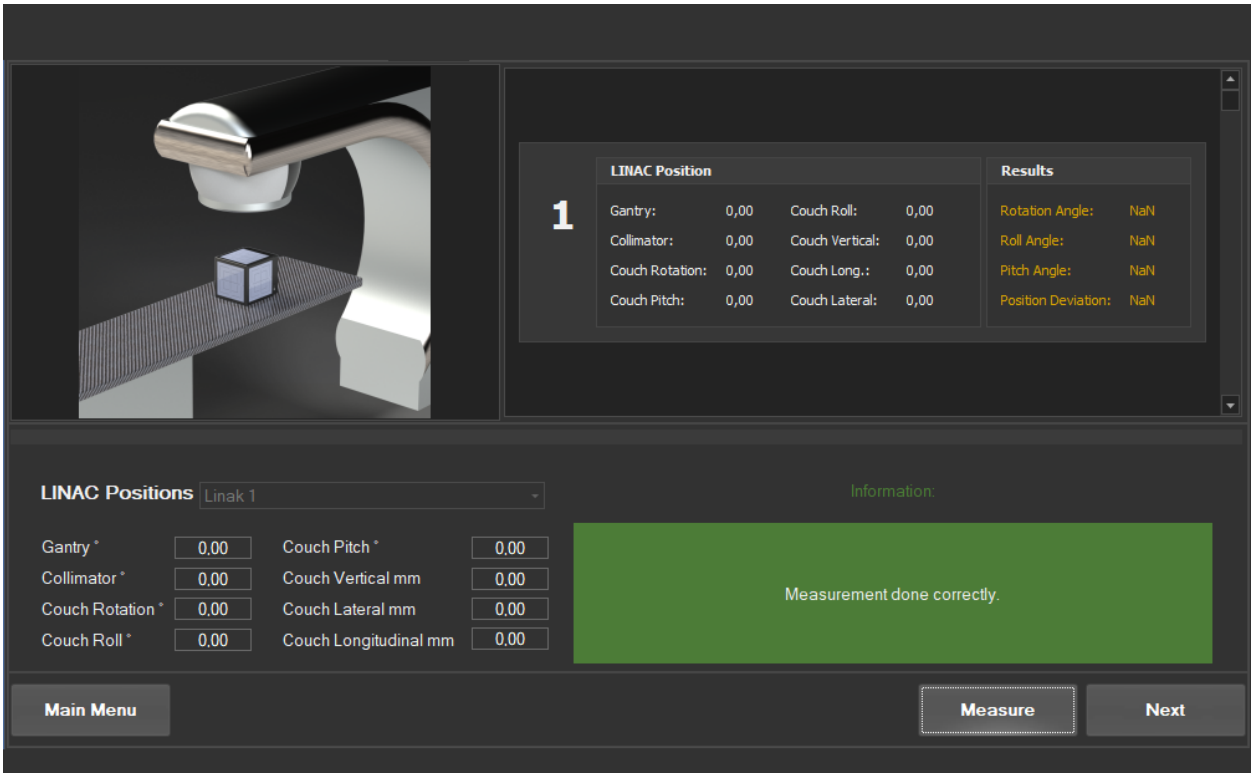


Figure 27: Daily Tests Result Display

If an error occurs, the warning window will provide information. Accordingly, you can repeat the current step with the "Measure" button. And the "Next" button will not be activated until the measurement is completed correctly.

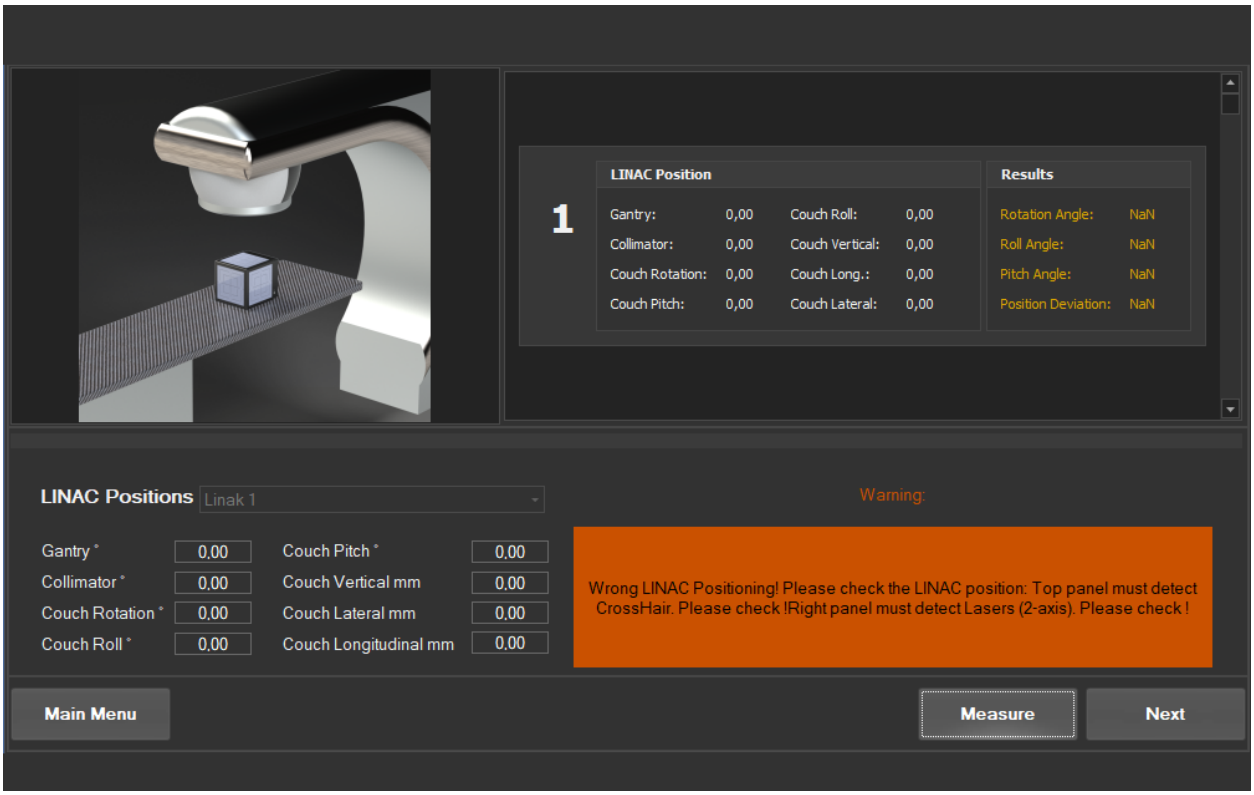


Figure 28: Daily Tests Warning Display

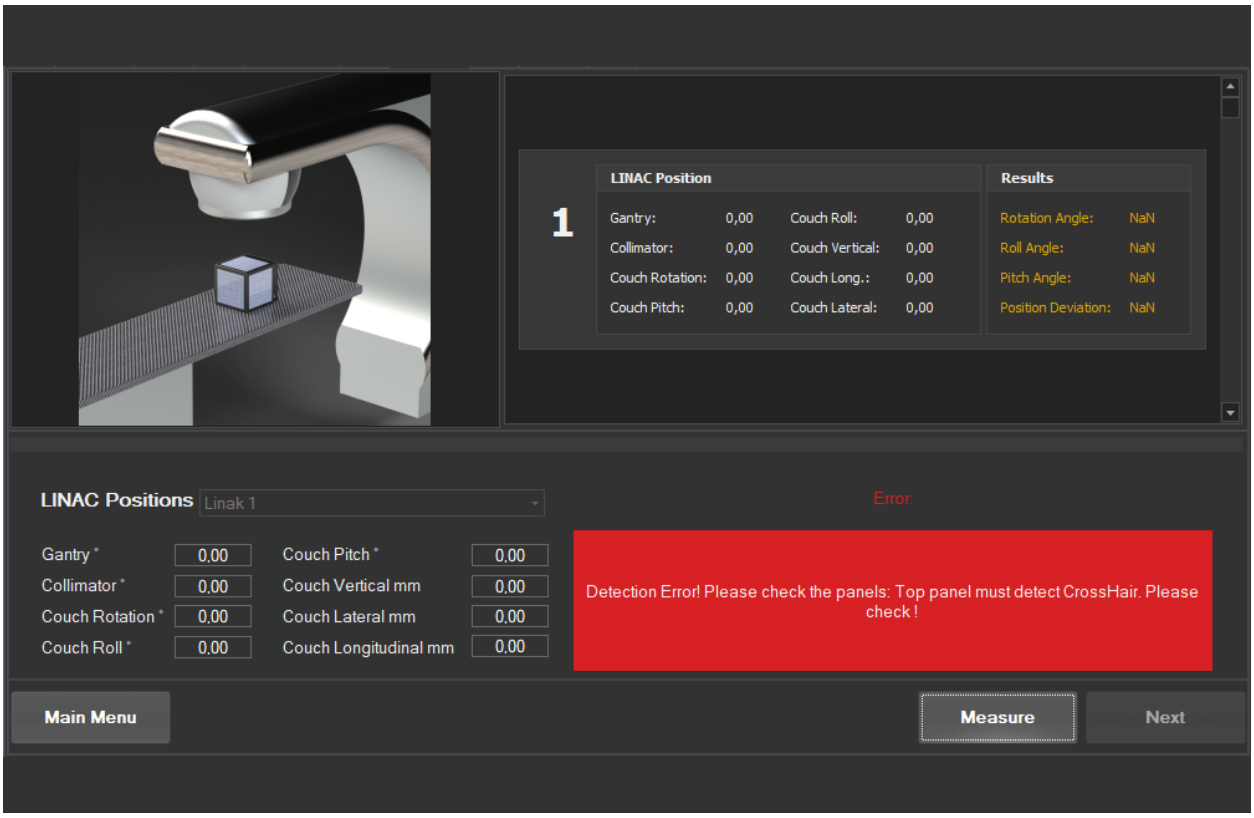


Figure 29: Daily Tests Error Display

The Linac position values are given at the bottom left of the measurement screen. If the values are shown in green, the position is same as the previous measurement position. If the values are shown in orange, the position is different from the previous measurement position.

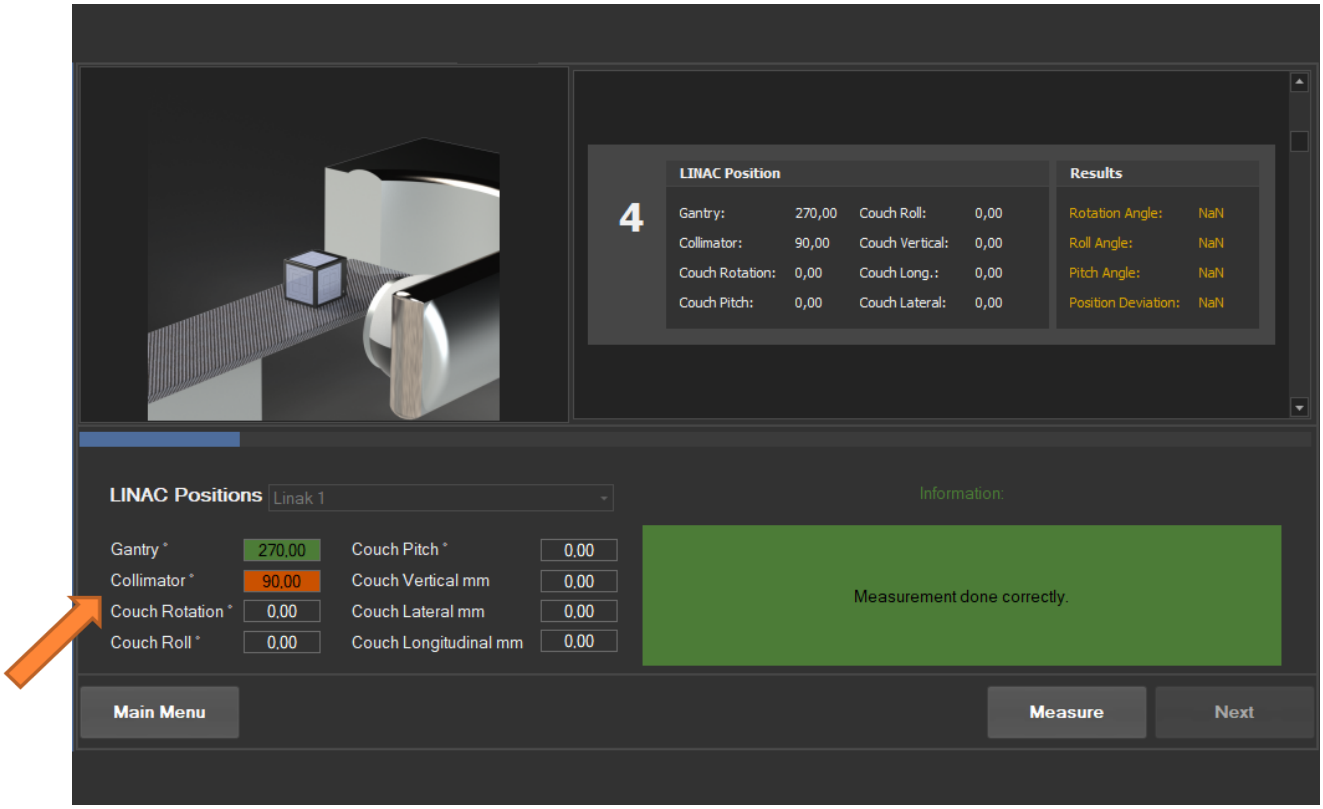


Figure 30: Linac Positions

When the Daily Test is completed, the "Next" button will turn into the "Finish" button. By clicking that button, you can complete the "Daily Test" measurements and reach the report screen.

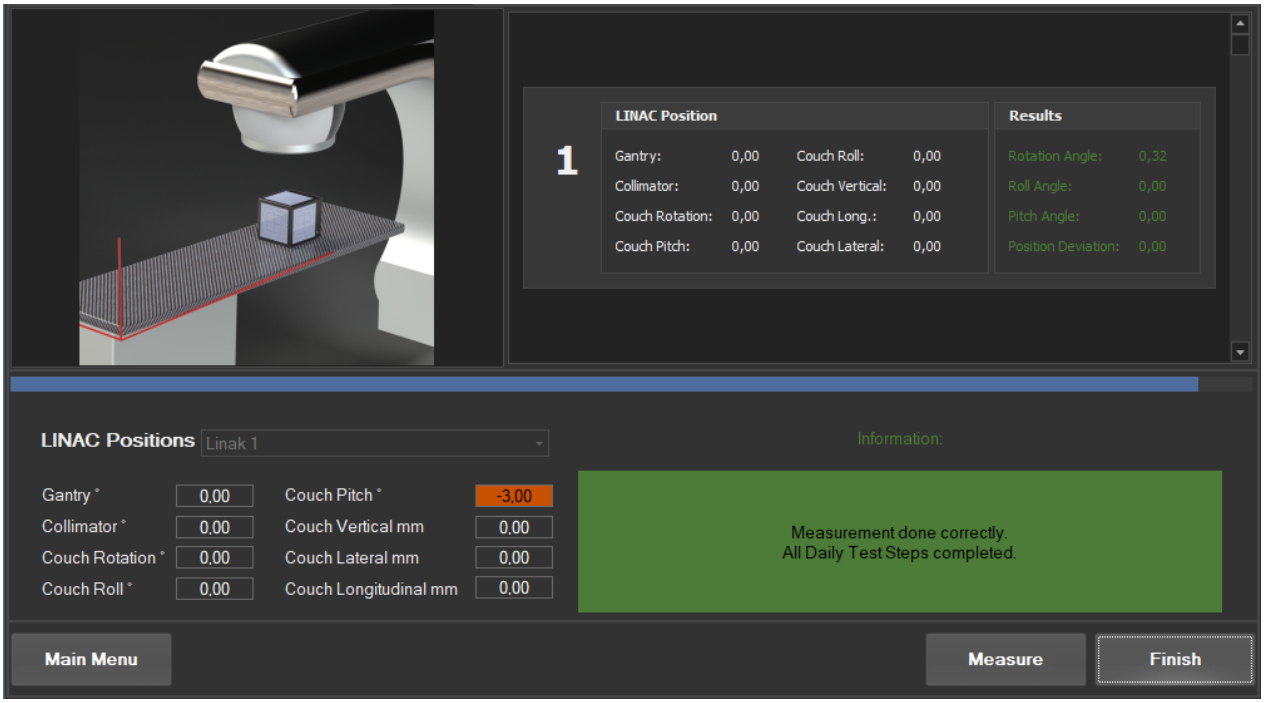


Figure 31: Completing Daily Tests

III. 4. Report

In this section, you can view the current and previous reports.

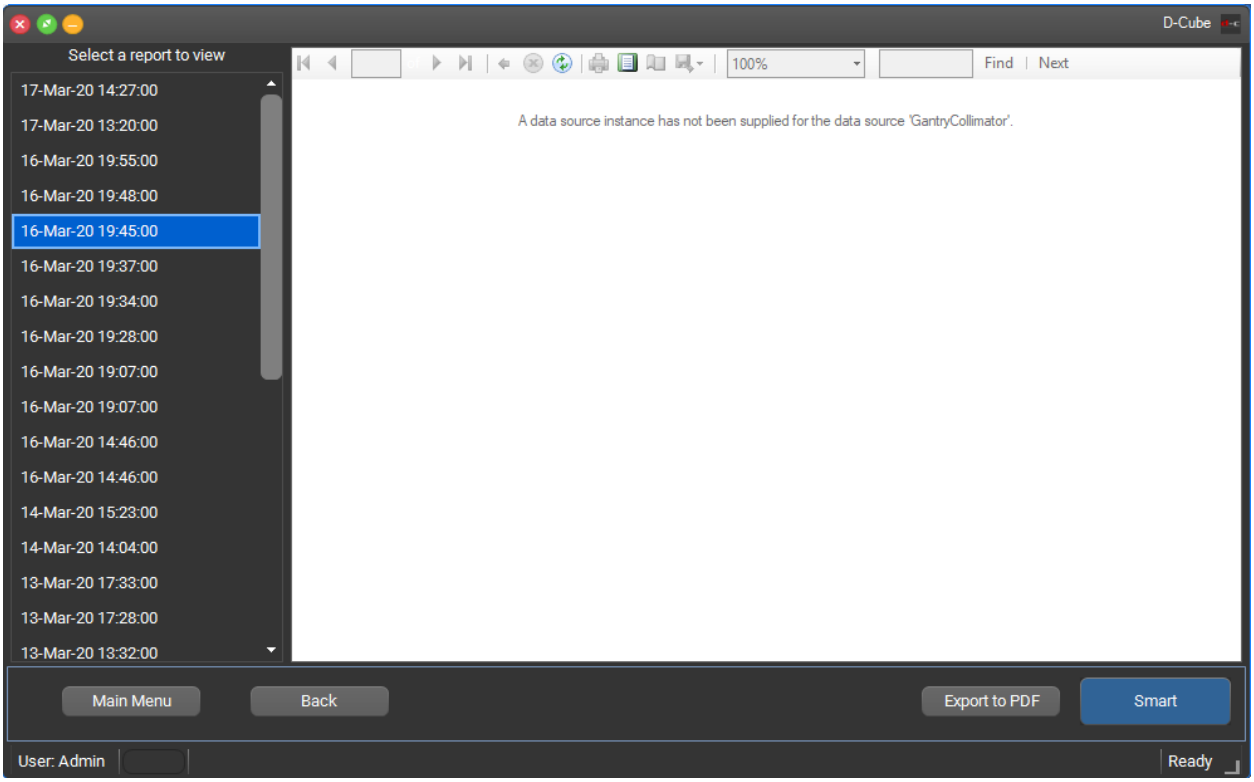


Figure 32: Report Screen

You can view the report results by selecting by date from the list on the left side of the screen. The "Export to PDF" button exports the selected report result as a PDF file. You can reach the Smart Test results screen with the "Smart" button.

III. 5. Live Measurement

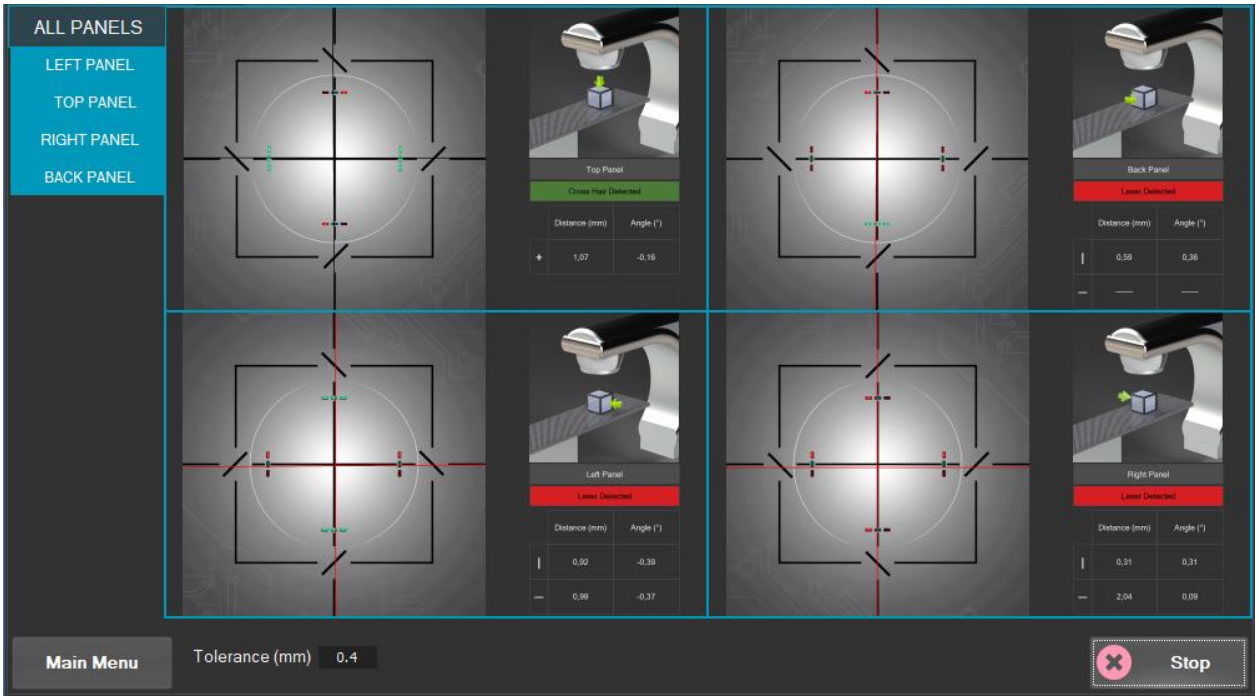


Figure 33: Live Measurement

You can change the tolerance value of the measurements. If the measurement is within this tolerance level, all LED indicator color will be green. Similarly, if there is no laser or cross-hair is projected on the sensors, all the LED indicator colors will be red. And, if the measurement is not within the tolerance level, a single LED indicator color will be red and the others will be black.

If laser is detected, the lines will be red and if cross-hair is detected the lines will be black.

III. 6. Options

In this section, you can create and authorize a new user, edit existing user info, delete a registered user.

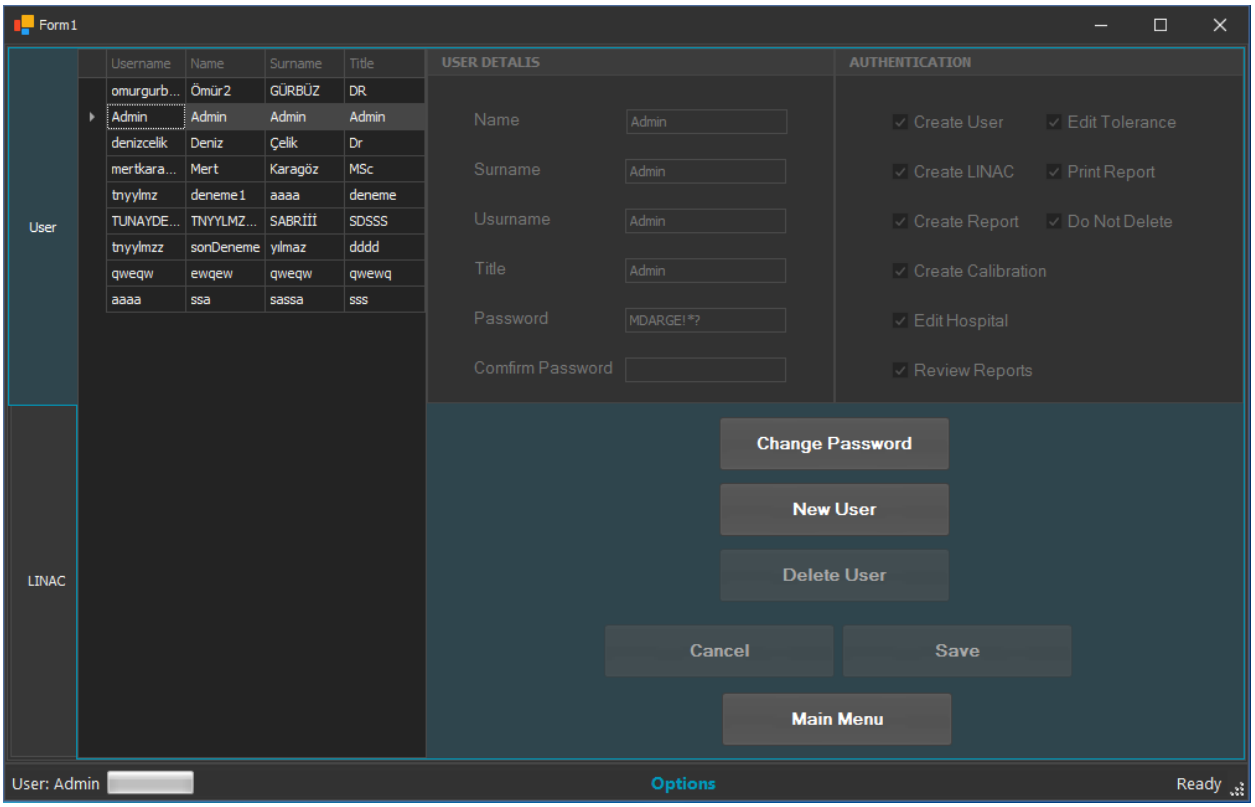


Figure 34: User Settings

III. 7. About

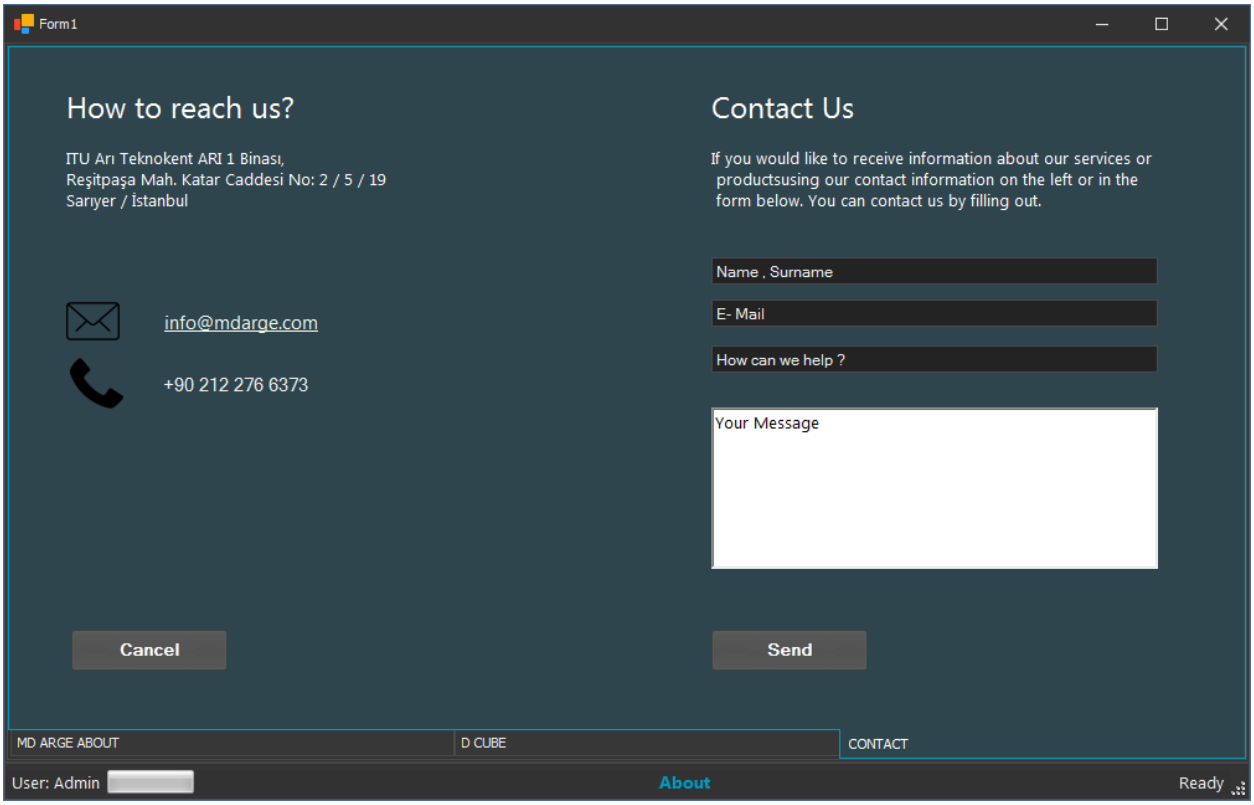


Figure 35: About – Contact

You can find the detailed information about D-Cube v1.1 program and support in the "About" section. You can use the e-mail address on the screen to get support or information about the software.

Annex I: Error List

- **ERR000001:** Wrong username or password.

Make sure that the username and password are typed correctly.

- **ERR000002:** You are not authorized.

Please log in with an authorized user for this section.

- **ERR000003:** An error occurred while opening the user interface.

There was a problem when loading the section.

- **ERR000006:** Please enter a valid name for the Personal Test Option.

You did not enter the test option name in the appropriate format.

- **ERR000007:** The name of the Personal Test Package you entered has been used before. Please enter a different name.

- **ERR000008:** To create a Personal Test Package, please select the tests first.

- **ERR000009:** Please enter a valid reference depth value.

- **ERR000010:** Please enter one of the depths with dose values as a reference value in the following list.

- **ERR000011:** The beam data name you entered has been used before. Please select a different name.

- **ERR000012:** There is an error in the Setup values you entered. Please enter the correct Setup values.