

DLCO Bio-Calcheck EasyOne Pro

General:

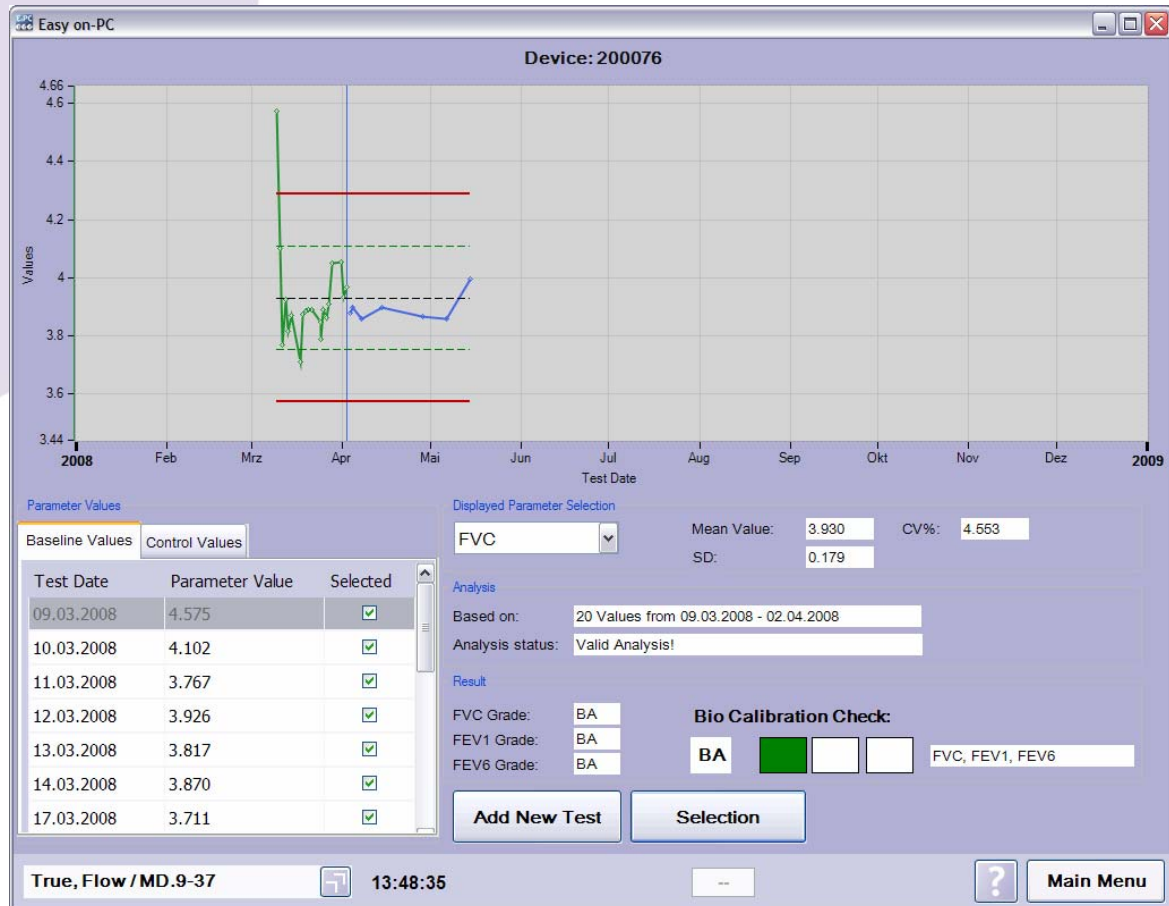
A Bio-Cal-Check tests the performance of the equipment and operational reliability without using a calibration tool like for example a syringe. A Biological Standard subject (BioCal Subject, usually 1 or more operators) performs a series of tests which are observed and statistically controlled whether they are within an expected range. Usually a Lewy Jennings plot with SD

The data is collected on individual healthy, non smoking BioCal Subjects.

Main Screen BioCal-Check:

The screenshot shows the 'Easy on-PC' software interface. The window title is 'Easy on-PC'. The interface is divided into several sections:

- Device Selection:** A table with columns 'Serial Number' and 'DeviceType'. It contains two rows: (200220, SPIROSON_AS) and (200065, SPIROSON_AS).
- BioCal Subject Selection:** A table with columns 'Patient ID', 'Last Name', and 'First Name'. It contains one row: (001, Björnsson, Olaf). Below this table is an 'Add New BioCal Subject' button.
- Parameter Values:** A section with two tabs: 'Baseline Values' (selected) and 'Control Values'. Below the tabs is a table with columns 'Test Date', 'Parameter Value', and 'Selected'.
- Displayed Parameter Selection:** A dropdown menu showing 'FVC'. To its right are input fields for 'Mean Value: 0.0', 'SD: 0.0', and 'CV%: 0.0'.
- Analysis:** A section with 'Based on:' and 'Analysis status:' labels and corresponding input fields.
- Result:** A section with 'FVC Grade:', 'FEV1 Grade:', and 'FEV6 Grade:' labels and checkboxes.
- Bio Calibration Check:** A section with a color-coded status bar (white, white, yellow, white) and an input field.
- Buttons:** 'Add New Test' and 'Graph' buttons are located at the bottom center.
- Status Bar:** At the bottom left, there is a time display '13:25:26'. At the bottom right, there is a '?' icon and a 'Main Menu' button.



Procedure: Open BioCal-Check and Add New Test

1. Start application
2. Open menu **Utilities**
3. Open menu **Check Calibration**
4. Open menu **Biological Calibration Check** (Main Screen BioCal-Check is opened)
5. *Device Selection:* Select device according to serial number (check label on sensor)
6. *BioCal Subject Selection:* Select subject which performs the BioCal-Check test. If the subject is not in the list, press **Add New BioCal Subject** and select or add new subject. Afterwards return to BioCal-Check menu.
 - a. *Recommendation:* **Set Patient ID** to 'Bio-1, Bio-2, ...'
7. Press **Add New Test**
8. Perform Test (Test selection: DLCO, (or TLCO,) VA, others as applicable)
 - a. *Recommendation:* Try to blow a **QC-Grade 'A'** test
 - b. *Recommendation:* Perform only one BioCal-Check test a day
9. Press **Finish Test**
10. The result is shown in the **Analysis** section and the **Result** section.

Functionalities to Review Data:

1. To show the trend graph press the *Graph* button
2. To select another review parameter change selection in **Displayed Parameter Selection** section
3. The *Parameter Values* section is divided into 2 Tab-Sheets: *Baseline Values* (used to calculate warning levels) and *Control Values* (controlled values for BioCal-Check QC-Grade calculation)
4. To deselect a Test (*Baseline* and *Control Values*) remove the mark in the *Parameter Values* section of the according test. A deselected test is not used anymore for calculations. This means also that by deselecting a *Baseline Value*, the first *Control Value* is moved to the *Baseline Values* because a minimum number (20) of Baseline Test is required for valid analysis.

Specifications BioCal-Check QC-Grade:

For each parameter as selected, an individual BioCal-Check QC-Grade is calculated. Additionally the lowest grade of all parameters is reported.

Bio-QC-Grad	Limitation	Additional Limitation
BA	-	-
BB	1 value out \pm 2SD	-
BC	1 value out \pm 3SD	-
BD	\geq 4 values out of \pm 1SD	only consecutive values on same side of mean
	\geq 2 values out of \pm 2SD	only consecutive values on same side of mean
	\geq 1 values out \pm 3SD	-
	\geq 10 values, consecutive on same side of mean	-
BF	< 20 baseline values	-

- Bio-Cal-Check ok
- Warning: repeat Bio-Cal-Check
- Out of control: Contact Service
- Out of control: Contact Service

Spirometry:

Proceed accordingly for FVC, FEV1, FEV6, VC_{In}