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:
**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.

<table>
<thead>
<tr>
<th>Bio-QC-Grad</th>
<th>Limitation</th>
<th>Additional Limitation</th>
</tr>
</thead>
<tbody>
<tr>
<td>BA</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>BB</td>
<td>1 value out ±2SD</td>
<td>-</td>
</tr>
<tr>
<td>BC</td>
<td>1 value out ±3SD</td>
<td>-</td>
</tr>
<tr>
<td>BD</td>
<td>≥4 values out of ±1SD</td>
<td>only consecutive values on same side of mean</td>
</tr>
<tr>
<td></td>
<td>≥2 values out of ±2SD</td>
<td>only consecutive values on same side of mean</td>
</tr>
<tr>
<td></td>
<td>≥1 values out ±3SD</td>
<td>-</td>
</tr>
<tr>
<td>BF</td>
<td>&lt;20 baseline values</td>
<td>-</td>
</tr>
</tbody>
</table>

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

Proceed accordingly for FVC, FEV1, FEV6, VC In.