

### Description of the internal quality control, the “self test” on HemoCue<sup>®</sup> systems

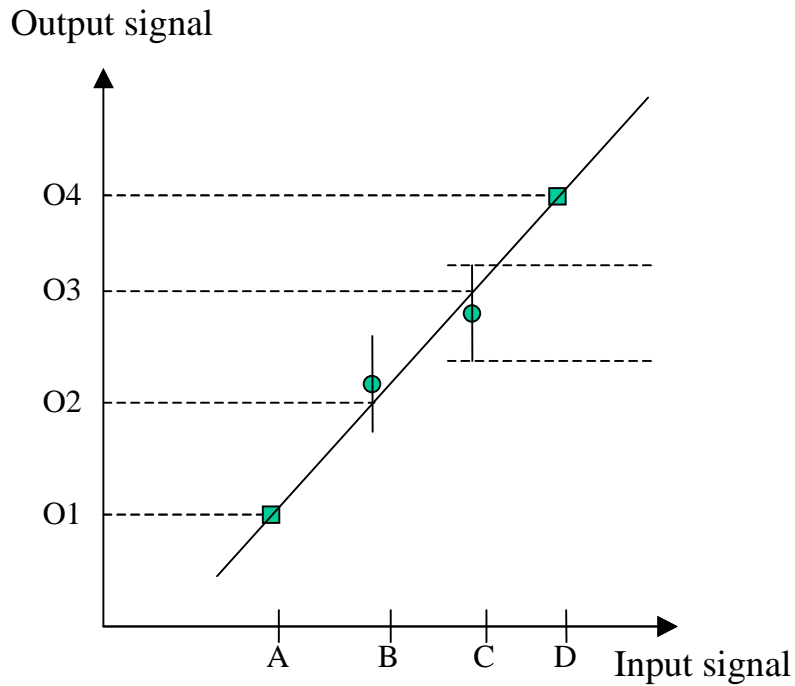
The HemoCue<sup>®</sup> 201, 201<sup>+</sup>, 201 RT, 201 DM and 301 systems all have an internal quality control, the “self test” that verifies that the optronic unit of the analyzer is working properly. The self test replaces the need for a control cuvette.

For Hb 201, 201<sup>+</sup>, 201 DM and 301 the following applies. The self test is performed automatically each time the analyzer is turned on. The word “SELFTEST” is displayed on the HemoCue<sup>®</sup> Glucose 201 system, the text “Please wait Selftesting...” is shown on the HemoCue<sup>®</sup> 201 DM Analyzer and an hourglass is displayed on the other systems during the duration of the self test. If the analyzer is connected to a power adapter and left on, the self test will be performed automatically every second hour, every eight hours for the HemoCue<sup>®</sup> 201 DM Analyzers.

For the HemoCue<sup>®</sup> Albumin 201 system the lid on the top of the analyzer should be closed **and no cuvette should be placed in the cuvette holder** for the analyzer to be able to perform the self test.

The analyzer is only able to perform the self test on the systems when the cuvette holder is in the loading position (outer position). If the cuvette holder is left in the measuring position (inner position) and the time limit for the self test is exceeded, the self test will be performed immediately after the cuvette holder is brought to the outer position. For the HemoCue<sup>®</sup> Albumin 201 system the lid on the top of the analyzer should be closed for the analyzer to be able to perform the self test.

The self test checks the linearity of the optronic unit by monitoring the current through the diodes and measuring the output on the detector.



**Figure 1:** Principle of the self test.

Figure 1 describes how the control is performed. Signals A and D, with respective output signals O1 and O4, are used as references. The expected linear output signals, O2 and O3 are calculated and compared to the true output signals. If the deviation is too large, the error code 930 is displayed on the HemoCue<sup>®</sup> Glucose 201 system and error code E30 on the other systems, and the program is interrupted. No further measurements can be made until the instrument is restarted and the requirements for linearity are fulfilled.