

Subject : No Equipment Calibration Requirement for FDC 4000i, NX500i NX600i and FDC7000i

Design Change Reason	Action	Time frame
<input type="checkbox"/> Specification/Function change <input type="checkbox"/> Pro-active improvement <input type="checkbox"/> Serviceability <input type="checkbox"/> Part Replacement <input type="checkbox"/> Corrective Action <input type="checkbox"/> Preventive Action <input type="checkbox"/> Regulatory Compliance <input checked="" type="checkbox"/> Other (information)	<input type="checkbox"/> Mandatory <input type="checkbox"/> Recommended <input type="checkbox"/> Not required () <input checked="" type="checkbox"/> Other (information only)	<input type="checkbox"/> Immediately <input type="checkbox"/> Next maintenance <input type="checkbox"/> Upon trouble situation <input type="checkbox"/> At your convenience <input checked="" type="checkbox"/> Not Applicable <input type="checkbox"/> Other ()

Date: 29/October/2014 Dept.: Medical Systems Business Div.

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Affected Products: FUJI DRI-CHEM analyzers FDC 4000i, NX500i NX600i and FDC700i

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To whom it may concern:

This document certifies that FUJI DRI-CHEM analyzers FDC4000i, NX500i and FDC7000i do not require equipment calibration.

The quality of these analyzers is guaranteed through the following principle.

FUJI DRI-CHEM analyzers are equipped with reference white and black plates. The functions of these plates are 1) to adjust the gain for all the interference filters before every measurement, and 2) to assure that the analyzer is working within the manufacturer's quality standard. 2) is conducted after gain adjustment, where the optical densities of reflectance for these plates measured in a constant interval, are checked. If the values exceed the threshold, the machine will indicate an error and the analyzer will not give a measurement result for this abnormal case.

The reference white and black plates are made from ceramic material which do not degrade over time, thus the quality of the analyzers can be confirmed over a long period of time.

- Special tools / Instruments : Yes No

- Supply of the articles : Yes No

If Yes, when :

Name / Code :

- Old parts after replaced : Yes No

- Report requirement after finished : Yes No