

IQ-02-12



Installation Qualification

Instrument Type: Blood Cell Counter	Manufacture Name: ERMA Japan INC
Model Name: ERMA PCE 210	Supplier Name: AGD Biomedicals (P) LTD

Operational Verification Report

Instrument Type: Blood Cell Counter	Name of the Customer: Care Hospital, Bareilly
Serial Number: 29210	Model Number: ERMA PCE 210
Date of Installation: 11.03.2011	Date of receipt: 10.03.2011

Power Check:

Power Supply:	220 V AC
Earth Voltage	OK

Physical Check of the equipment

Check for damage	Checked	No damage found
Visual & functional inspection	Checked	OK
No damage on internal assembly	Checked	No damage found

System configuration equipment

Positioning of the equipment – flat stable surface	Checked	Found OK
Adequate space around the equipment	Checked	Found OK
Interference to other equipment	Checked	No Interference

Result:

Installed the ERMA PCE 210 satisfactorily and is ready for operational verification

Installed by: Mr Harivansh Yadav	Checked by: <i>Dr. Anika God.</i>
Signature: <i>Harivansh</i>	Signature: <i>Dr. Anika God.</i>
Date: 11.03.2011	Date: 11/03/2011

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ISO : 9001 : 2015
ISO : 13485 : 2016



Performance Qualification

Instrument Type: Blood Cell Counter	Manufacture Name: ERMA Japan INC
Model Name: ERMA PCE 210	Supplier Name: AGD Biomedicals (P) LTD
Installed On: 11.03.2011	Sales & Service Engineer: Mr Harivansh Yadav

Performance Verification Report

Name of the Hospital: Care Hospital, Bareilly	Instrument Type: Blood Cell Counter
Model Number: ERMA PCE 210	Serial Number: 29210
Date of receipt: 10.03.2011	Date of Installation: 11.03.2011

Performance Check:

Background Check	OK
Pressure Check	OK
HGB Unit Check	OK
Syringe Movement Check	OK
Printer Check	OK



Result:

The performance verification of ERMA PCE 210 has been completed satisfactorily and Instrument is ready to be placed in service.

Performance Check done in presence of:	HOD: Signature: Date:
Performance check: <i>OK</i> Performed by: <i>Mr. Harivansh Yadav</i>	Checked by:
Date: <i>11/03/2011</i>	Date:

Installation, Operational and Performance Qualification Certificate

The equipment ERMA PCE 210 Serial No 29210 is installed and commissioned. The operational and performance verification is done and observations are:

- All system components are working in normal condition
- All tests were carried out in accordance with qualification protocol and standard operating procedure.
- The performance of the ERMA PCE 210 is as per the acceptance criteria.