FUJIFILM

INSTALLATION QUALIFICATION

OPERATIONAL QUALIFICATION

&

PERFORMANCE QUALIFICATION

For the Instrument FUJI DRI CHEMISTRY ANALYZER

Model: FDC NX 500i

Serial No.: 56952923

FUJIFILM INDIA PRIVATE LIMITED

Registered Office: Unit No. 504 & 505, 5th Floor, 349 Business Point, Western Express Highway, Andheri (East), Mumbai – 400069, Telephone: +91-22-42364000 Fax: +91-22-42364001.
Corporate Office: Unitech Cyber Park, Unit No. 801-807, 8th Floor, Tower C, Sector 39, Gurugram -122001, Haryana
Telephone : +91-124-4325500, Fax : +91-124-4325555, Website : www.fujifilm.com, Email : contact@fujifilm.com
CIN: U24233DL2007PTC171054.

FUJIFILM

VALIDATION REPORT

Equipment Name : Biochemistry Analyzer

Equipment Make : Fuji DRI-CHEM

Equipment Model No. : FDC NX 500i

Equipment Serial No. : **56952923**

Manufacturer : FUJIFILM

Supplier : Fujifilm India Pvt. Ltd

Contact Name & Address : Fujifilm India Pvt. Ltd

Unitech Cyber Park,

8th Floor, Unit No.801-807,

Tower C, Sector – 39,

Gurugram, Haryana-122001.

FUJIFILM INDIA PRIVATE LIMITED

Registered Office: Unit No. 504 & 505, 5th Floor, 349 Business Point, Western Express Highway, Andheri (East), Mumbai – 400069, Telephone: +91-22-42364000 Fax: +91-22-42364001.
Corporate Office: Unitech Cyber Park, Unit No. 801-807, 8th Floor, Tower C, Sector 39, Gurugram -122001, Haryana
Telephone : +91-124-4325500, Fax : +91-124-4325555, Website : www.fujifilm.com, Email : contact@fujifilm.com
CIN: U24233DL2007PTC171054.

FUJIFILM

I. Approval of IQ/OQ Procedure

Both Disha CRL (Clinical Reference Laboratory), Mumbai and Fujifilm India Pvt. Ltd. are jointly responsible for the Installation of FDC NX 500i Serial No. 56952923 in the Biochemistry Laboratory.

Validation Team From Vendor

Name : **Mr. Navin Bhatia**

Designation : Service Engineer

Signature :

Date : **31/05/2016**

Company : Unique Diagnostics (FFIN Authorized Channel Partner)

Validation Team From Clinical Lab

Name : Ms. Mohammad Neyazudin

Designation : Technical Supervisor

Signature :

Date : **31/05/2016**

Department : Biochemistry Laboratory, Disha CRL

Customer Authorization

Name : Dr.Santosh Wanave

Designation : Pathologist (MD Path)

Signature :

Date : **31/05/2016**

Company : Disha CRL

FUJIFILM

II. Instructions

1. This document is to be completed at the time the system is shifted to its current location (Clinical Laboratory) and setup for operation.

2. An authorized (Company) representative will check the entire system and enter specific data related to installation, operation and performance qualification.

3. Employees of (Customer) Clincial Laboratory will verify each result and sign the results. The member of Validation will carry this out.

4. All deviation from the normal specification to include any problems with installations will be noted under COMMENTS.

5. A Competent Authority (Customer) will supervise the the entire procedure and procvide the necessary Authorization of the procedure.

FUJIFILM INDIA PRIVATE LIMITED

Registered Office: Unit No. 504 & 505, 5th Floor, 349 Business Point, Western Express Highway, Andheri (East), Mumbai – 400069, Telephone: +91-22-42364000 Fax: +91-22-42364001.
Corporate Office: Unitech Cyber Park, Unit No. 801-807, 8th Floor, Tower C, Sector 39, Gurugram -122001, Haryana
Telephone : +91-124-4325500, Fax : +91-124-4325555, Website : www.fujifilm.com, Email : contact@fujifilm.com
CIN: U24233DL2007PTC171054.

FUJIFILM

III. Scope

This Installation Qualification Protocol is performed on the Fuji Dri Chem FDC NX 500i vide Serial No.56952923 located at Biochemistry Laboratory of Disha CRL (Clinical Reference Laboratory), Mumbai

This Protocol defines the documentation that is used to evaluate the instrument installtaion in accordance with the manufacturer's specification and intended use.

Successful completion of this protocol verifies that this instrument has been installed, operated in accordance with the intended usage.

Installation checks are performed to verify that the instrument has been installed with proper connection and utilities.

Operational qualifications will evaluate that the instrument have operational features available for the successful operation of instrument in accordance with the manufacturer's specifications.

Performance qualifiaction will verify the actual functioning or performance of instrument.

IV. Certificate of Purchase Order Compliance

I certify to the best of my knowledge. The instrument Fuji Dri Chem FDC NX 500i vide Serial No 56952923 installed on 31/05/2016 is in compliance with the specification of the purchase order.

FUJIFILM INDIA PRIVATE LIMITED

Registered Office: Unit No. 504 & 505, 5th Floor, 349 Business Point, Western Express Highway, Andheri (East), Mumbai – 400069, Telephone: +91-22-42364000 Fax: +91-22-42364001.
Corporate Office: Unitech Cyber Park, Unit No. 801-807, 8th Floor, Tower C, Sector 39, Gurugram -122001, Haryana
Telephone : +91-124-4325500, Fax : +91-124-4325555, Website : www.fujifilm.com, Email : contact@fujifilm.com
CIN: U24233DL2007PTC171054.

FUJIFILM

V. Equipment Description

Sr. No.	Instrument Identification		Verified by	Date
1	Equipment Name	**Fuji Dri Chem**	Navin Bhatia	31 May'2016
2	Model	**FDC NX 500i**	Navin Bhatia	31 May'2016
3	Equipment ID.	**---**	Navin Bhatia	31 May'2016
4	Serial No.	**56952923**	Navin Bhatia	31 May'2016
5	Power, Voltage Limit	**200VA, 100 – 240 V**	Navin Bhatia	31 May'2016
6	Electromagnetic Compatibility	**Class A (Confers to Part 15 of the FCC Rules)**	Navin Bhatia	31 May'2016

VI. Utilities

Sr. No.	Instrument Identification		Verified by	Date
1	Environemnt Condition		Navin Bhatia	31 May'2016
	Free from Dust, electrical & Magnetic Interference	**Yes**	Navin Bhatia	31 May'2016
	Temperature	**15 -32^{0}C**	Navin Bhatia	31 May'2016
	Humidity (RH)	**30 to 80%**	Navin Bhatia	31 May'2016
	Illumination (no vapor condensation)	**<6000 lux**	Navin Bhatia	31 May'2016
If Instrument is to be used with the sample barcode reader illumination should be below 3,000 cd/m^2 (lux)				
2	Adequate Space for Installation	**At least 10 cm on the back and both the sides.**	Navin Bhatia	31 May'2016
3	Electrical Outlets			31 May'2016

FUJIFILM INDIA PRIVATE LIMITED

Registered Office: Unit No. 504 & 505, 5th Floor, 349 Business Point, Western Express Highway, Andheri (East), Mumbai – 400069, Telephone: +91-22-42364000 Fax: +91-22-42364001.
Corporate Office: Unitech Cyber Park, Unit No. 801-807, 8th Floor, Tower C, Sector 39, Gurugram -122001, Haryana
Telephone : +91-124-4325500, Fax : +91-124-4325555, Website : www.fujifilm.com, Email : contact@fujifilm.com
CIN: U24233DL2007PTC171054.

	Actual Voltage on site	**240V**	Navin Bhatia	31 May'2016
	Grounding	**<2V**	Navin Bhatia	31 May'2016
	Connected through UPS	**Yes**	Navin Bhatia	31 May'2016
	Stabilizer	---N/A---		

VII. The Instrument Has Been Checked For The Following

Sr. No.	Verification		Verified by	Date
1	Instrument is identified	**Yes**	Navin Bhatia	31 May'2016
2	Manufacturer's specification are included	**Yes**	Navin Bhatia	31 May'2016
3	Accessories/Consumables are listed	**Yes**	Navin Bhatia	31 May'2016
4	Equipment Manual from the Manufacturer	**Yes**	Navin Bhatia	31 May'2016
5	Manufacturer certificate of compliance is attached	**Yes**	Navin Bhatia	31 May'2016

VIII. Accessories / Consumables

The following accessories were supplied with the instrument. Check "Verified by" in case they are found to be in order. Separate list included.

Sr. No.	Description	Qty.	Verified by	Date
1	Accessory Box	1	Navin Bhatia	31 May'2016

IX. List of Manuals and Certificates

Supplier provides the following with the instrument

FUJIFILM INDIA PRIVATE LIMITED

Registered Office: Unit No. 504 & 505, 5th Floor, 349 Business Point, Western Express Highway, Andheri (East), Mumbai – 400069, Telephone: +91-22-42364000 Fax: +91-22-42364001.
Corporate Office: Unitech Cyber Park, Unit No. 801-807, 8th Floor, Tower C, Sector 39, Gurugram -122001, Haryana Telephone : +91-124-4325500, Fax : +91-124-4325555, Website : www.fujifilm.com, Email : contact@fujifilm.com
CIN: U24233DL2007PTC171054.

Sr. No.	Description	Qty.
1	Instruction Manual	Available
2	Purchase order	Available
3	Calibration Certificate	Available
4	Instrument / Kit approval certificate	Available
5	Training Records	Available
6	Certificate of Authorization / Training of engineer	Available

X. Maintenance

The instrument listed within this document will be placed under the control of purchasing institution with respect to proper maintenance procedures as detailed in the operator's manual.

The Maintenance procedures will be filled separately.

A trained analyst using the manuals provided with the instrumentation can perform simple maintenance. Upon expiration of the warranty period vendor will offer several level of maintenance agreements and performance testing services to assist you in maintaining GLP / GMP compliance.

Contacting your local representative and requesting the additional service agreement can supply additional information.

XI. Installation Procedure

a) Installation of Incubator Chamber

Follow the instructions mentioned in the quick installation guide.

b) Installation of Instrument

Follow the instructions mentioned in the installation guide.

FUJIFILM INDIA PRIVATE LIMITED

Registered Office: Unit No. 504 & 505, 5th Floor, 349 Business Point, Western Express Highway, Andheri (East), Mumbai – 400069, Telephone: +91-22-42364000 Fax: +91-22-42364001.
Corporate Office: Unitech Cyber Park, Unit No. 801-807, 8th Floor, Tower C, Sector 39, Gurugram -122001, Haryana
Telephone : +91-124-4325500, Fax : +91-124-4325555, Website : www.fujifilm.com, Email : contact@fujifilm.com
CIN: U24233DL2007PTC171054.

FUJIFILM

XII. Operational Qualification

Following features / functions are available in the instrument as per manufacturer's specification and verified for ex. Self-Test. Quality Control, Test Assay, CRP Calibration and Maintenance Checks.

Sr. No.	Description	Test Purpose	Verified by	Date
1	On Board Diluent Test	System Performance	Navin Bhatia	31 May'2016
2	Maintenance	Daily, weekly & Monthly	Navin Bhatia	31 May'2016
3	Test Assay	Biochemistry	Navin Bhatia	31 May'2016
4	Audit Trail	Yes	Navin Bhatia	31 May'2016
5	Interfacing Facility	Bi-Directional	Navin Bhatia	31 May'2016

XIII. Performance Qualification

Performance qualification validates the test procedure performed on the new instrument.

Performance qualification not only validates instrument performance but also test procedure.

Following are the steps required to validate your instrument and method.

1. Run QC inter day run to check the accuracy of parameters on Fuji Dri Chem.
2. Run known sample 10 times to check the precision of parameters.

FUJIFILM INDIA PRIVATE LIMITED

Registered Office: Unit No. 504 & 505, 5th Floor, 349 Business Point, Western Express Highway, Andheri (East), Mumbai – 400069, Telephone: +91-22-42364000 Fax: +91-22-42364001.
Corporate Office: Unitech Cyber Park, Unit No. 801-807, 8th Floor, Tower C, Sector 39, Gurugram -122001, Haryana
Telephone : +91-124-4325500, Fax : +91-124-4325555, Website : www.fujifilm.com, Email : contact@fujifilm.com
CIN: U24233DL2007PTC171054.

FUJIFILM

Accuracy Data:

Para	Range	QC	29-Dec	31-Dec	01-Jan	02-Jan	03-Jan	04-Jan	05-Jan	06-Jan	07-Jan	09-Jan	10-Jan	11-Jan	12-Jan	13-Jan	14-Jan	15-Jan	Mean	SD	CV%
Na	145 - 157	1	150	152	151	148	149	146	150	151	152	153	150	152	148	150	148	149	149.94	1.88	1.25
	127 - 137	2	130	129	131	132	132	134	133	130	129	129	131	130	128	130	131	133	130.75	1.69	1.29
K	3.60 - 4.40	1	4.2	4.1	3.9	3.7	3.7	3.9	4	4.1	4.2	4.1	4.2	4.3	4.1	3.9	3.7	3.9	4.00	0.19	4.83
	5.60 - 6.60	2	6.1	6	5.8	5.7	5.7	5.9	6.1	6.2	6.4	6.5	6.4	6.2	6.1	5.9	6	6.2	6.08	0.24	3.96
CL	95 - 109	1	100	98	99	101	102	99	97	96	98	99	101	103	104	106	104	105	100.75	3.00	2.98
	83 - 96	2	84	83	85	86	88	91	90	89	89	87	88	87	86	88	90	93	87.75	2.62	2.99
Creat	3.80 - 4.80	2	4.1	4	4	3.9	4.2	4.1	4.3	4.5	4.4	4.6	4.7	4.6	4.5	4.3	4.2	4	4.28	0.25	5.89
BUN	13.3 - 17.2	1	16.1	15.9	15.8	15.5	14	13.9	14.2	15.1	15.5	15.7	16.2	16.5	14.2	14.7	16.2	15.7	15.33	0.86	5.63
	41 - 49.5	2	48.3	46.9	47.4	44.3	45.9	42.1	48.1	48.5	46.1	47.9	48.1	42	44.1	45.6	46.5	47.6	46.21	2.11	4.56
GPT	69 - 88	2	84	85	81	80	82	78	87	78	79	80	84	85	86	85	84	83	82.56	2.90	3.51
TP	4.50 - 5.70	1	5.3	5.2	4.99	5.3	5.23	5.02	4.76	5.67	4.91	5.15	5.2	5.39	5.23	5.2	5.3	5.15	5.19	0.21	4.00
	2.90 - 3.90	2	3.4	3.5	3.42	3.5	3.49	3.52	3.59	3.4	3.48	3.5	3.4	3.56	3.48	3	3.45	3.4	3.44	0.13	3.82
ALB	> 6.00	1	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6.00	0.00	0.00
	3.40 - 4.60	2	4.2	4	4.23	4.45	4.2	4.32	4.29	4.35	4.39	4.28	4.2	4.25	4.26	4.3	4.25	4.3	4.27	0.10	2.33
ALKP	120 - 184	1	169	176	160	165	162	158	161	152	155	159	160	152	153	159	160	157	159.88	6.24	3.90
	685 - 894	2	746	784	750	752	769	749	770	776	749	756	751	752	748	760	761	770	758.94	###	1.52
IP	3.0 - 4.0	1	3.8	3.6	3.6	3.7	3.8	3.6	3.6	3.6	3.7	3.8	3.6	3.6	3.8	3.6	3.6	3.5	3.66	0.10	2.64
	6.60 - 8.40	2	8.2	8	7.92	8.1	8.2	8.3	8.1	7.99	7.95	7.88	8.2	8	8.1	7.95	8	7.93	8.05	0.12	1.53
GGT	45 - 66	1	62	55.9	55.4	54	53.8	55	55.9	55	54.9	54.2	54	55.2	54.9	55.3	55.8	55	55.39	1.88	3.40
	147 - 194	2	195	170	177	172	173	-	172	172	175	172	173	172	175	174	177	172	174.73	5.95	3.40
Ca	8.2 - 10.8	1	9.7	-	9	9.2	9.1	8.9	8.8	8.9	9	9	9.1	8.9	9	8.8	9.3	8	8.98	0.35	3.93
	11.4 - 14.5	2	14.4	-	14	13.9	14.1	14	14.2	14.1	14	14.3	14.5	14.2	14.1	14.2	14	13.9	14.13	0.18	1.24
TBIL	0.60 - 1.20	1	1	0.92	0.93	0.92	1	1.1	1.09	1.05	0.9	1.1	0.91	0.92	0.9	0.98	0.98	0.98	0.98	0.07	7.34
	2.7 - 4.3	2	3.7	-	3.6	3.5	3.5	3.6	3.7	3.8	3.9	3.8	3.8	3.7	3.6	3.7	3.5	3.6	3.67	0.12	3.37
TC	213 - 263	1	242	240	241	235	234	240	238	23	24	23	24	24	24	24	23	23	239.	2.27	0.

FUJIFILM INDIA PRIVATE LIMITED

Registered Office: Unit No. 504 & 505, 5th Floor, 349 Business Point, Western Express Highway, Andheri (East), Mumbai – 400069, Telephone: +91-22-42364000 Fax: +91-22-42364001.
Corporate Office: Unitech Cyber Park, Unit No. 801-807, 8th Floor, Tower C, Sector 39, Gurugram -122001, Haryana
Telephone : +91-124-4325500, Fax : +91-124-4325555, Website : www.fujifilm.com, Email : contact@fujifilm.com
CIN: U24233DL2007PTC171054.

HO	87 - 111	2	99	98	95	97	96	95	98	97	95	98	96	99	98	95	96	98	25 96.88	1.45	95 1.50
GLU	63 - 82 223 - 269	1 2	77 250	77 246	75 251	74 249	75 248	76 250	74 245	75 244	76 250	75 250	77 249	78 251	75 250	74 248	73 250	72 248	75.19 248.69	1.60 2.09	2.13 0.84
AMY	64 - 89 279 - 349	1 2	79 300	78 310	77 311	77 315	78 312	79 314	76 310	75 302	74 305	73 320	75 316	76 319	80 310	79 315	77 314	78 312	76.94 311.56	1.98 5.53	2.58 1.77
LIP	30 - 62 71 - 103	1 2	44 81	45 84	45 85	46 84	45 83	47 86	48 87	46 85	49 84	45 86	44 87	43 82	44 84	45 85	47 86	48 87	45.69 84.75	1.70 1.77	3.72 2.09

Conclusion:

Accuracy was checked by running L1 & L2 controls for 15 days. CV% was all found with in 5% (acceptable limit).

Performance Qualification of Fuji Dri Chem Analyser NX 500i installed at Disha CRL (Clinical Reference Laboratory), was completed successfully. QC Check results show parameter within acceptable range.

QC Results - Pass

Certificate of Training

1. Technician Training

This certifies that the technicians listed below have received basic user training for the system described.

Sr. No.	Training Program	Initials	Date
1	Instrument Setup	Trushi Sonavaria	02 Jun'2016
2	System Operation	Trushi Sonavaria	02 Jun'2016
3	Basic Troubleshooting	Trushi Sonavaria	02 Jun'2018

FUJIFILM INDIA PRIVATE LIMITED

Registered Office: Unit No. 504 & 505, 5th Floor, 349 Business Point, Western Express Highway, Andheri (East), Mumbai – 400069, Telephone: +91-22-42364000 Fax: +91-22-42364001.
Corporate Office: Unitech Cyber Park, Unit No. 801-807, 8th Floor, Tower C, Sector 39, Gurugram -122001, Haryana Telephone : +91-124-4325500, Fax : +91-124-4325555, Website : www.fujifilm.com, Email : contact@fujifilm.com
CIN: U24233DL2007PTC171054.

FUJIFILM

Training Given by : Trushi Sonavaria

Training Attended by :

1. Mohammad Neyazudin
2. Khan Gulzar Mohammad Israr
3. Shaiyad Ali
4. Khan Somaiya Jamaluddin
5. Zalte Komal Laxman
6. Dhamane Akanksha Anant
7. Dr. Sushant Chavan
8. Pragati Hankar

Validation Procedure Performed by FFIN

Name : **Ms. Trushi Sonavaria**

Designation : Application Specialist

Signature :

Date : **18/01/2019**

Company : Fujifilm India Pvt. Ltd.

Validation Team From Clinical Lab

Name : Mr. Mohammad Neyazudin

Designation : Technical Supervisor

Signature :

Date : **18/01/2019**

Department : Biochemistry Laboratory, Disha CRL

FUJIFILM INDIA PRIVATE LIMITED

Registered Office: Unit No. 504 & 505, 5th Floor, 349 Business Point, Western Express Highway, Andheri (East), Mumbai – 400069, Telephone: +91-22-42364000 Fax: +91-22-42364001.
Corporate Office: Unitech Cyber Park, Unit No. 801-807, 8th Floor, Tower C, Sector 39, Gurugram -122001, Haryana Telephone : +91-124-4325500, Fax : +91-124-4325555, Website : www.fujifilm.com, Email : contact@fujifilm.com
CIN: U24233DL2007PTC171054.

FUJIFILM

Customer Authorization

Name : Dr. Santosh Wanave

Designation : (MD Path) Pathologist

Signature :

Date : **18/01/2019**

Company : Disha CRL

FUJIFILM INDIA PRIVATE LIMITED

Registered Office: Unit No. 504 & 505, 5th Floor, 349 Business Point, Western Express Highway, Andheri (East), Mumbai – 400069, Telephone: +91-22-42364000 Fax: +91-22-42364001.

Corporate Office: Unitech Cyber Park, Unit No. 801-807, 8th Floor, Tower C, Sector 39, Gurugram -122001, Haryana Telephone : +91-124-4325500, Fax : +91-124-4325555, Website : www.fujifilm.com, Email : contact@fujifilm.com

CIN: U24233DL2007PTC171054.

FUJIFILM

Corporate Office :
FUJIFILM INDIA PRIVATE LIMITED
Vatika Business Park, 7th Floor,
Block - One, Sohna Road, Sector - 49,
Gurgaon Haryana - 122 001.

TOLL FREE No. 1800-103-3854

128395

CUSTOMER NAME	DISHA CRL CLINICAL LAB — CONTACT PERSON Mr./Mrs. SAMTOO!
ADDRESS :	71, SIDDHIVINAYAK BLD OPP. KEMPAS — Phone 022 - 24127777
CITY	PAREL MUMBAI — STATE MAHARASHTRA.
REGION :	☐ NORTH ☑ WEST ☐ EAST ☐ SOUTH
☐ FIELD SERVICE REPORT	☑ INSTALLATION REPORT
MEDICAL :	PROBLEM DESCRIPTION & ERROR CODE :
COMPLAINT DATE	
COMPLAINT NUMBER	
START DATE / TIME	31/05/16 10:30
END DATE / TIME	31/01/16 3:00
	ACTION TAKEN : INSTALLATION DONE AS PER STANDARD PROCEDURE
ENGINEER NAME :	UMESH TAPARE
DEALERS NAME :	UNIQUE DIAGNOSTICS
EQUIPMENT TYPE	FUJI DRY CHEM.
MODEL NO.	NX (100)
SR. NO.	56912913
SOFT VERSION	V 1.0 - P09.
CONSOLE VERSION	
WORKSTATION :	
CONNECTED	JOB STATUS ☐ MACHINE UNDER OBSERVATION ☑ COMPLETED ☐ INCOMPLETE
	REASON FOR INCOMPLETION :
	JOB STATUS ☐ MACHINE UNDER OBSERVATION ☑ COMPLETED ☐ INCOMPLETE
	REASON FOR INCOMPLETION :

☐ PARTS USED / REQUIDED

	PART NUMBER	DESCRIPTION	QTY.

CUSTOMER SIGNATURE

ENGINEER SIGNATURE

CUSTOMER REMARKS

FUJIFILM ECN information

2021/04/15

Subject : No Equipment Calibration Requirement for FDC NX600, NX500 and NX700

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

Date: 15 - April - 2021 Dept.: Medical Systems Business Div.

Originator: M.Jumawid Edited by: M. Jumawid Approved by: Y. Kashi

Affected Products: FUJI DRI-CHEM analyzers FDC NX600, NX500 and NX700

To whom it may concern:

This document certifies that FUJI DRI-CHEM analyzers FDC NX600, NX500 and NX700 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