



Abbott Healthcare Pvt. Ltd.
Floor 13-19, Godrej BKC, Plot C-68
G Block, Bandra Kurla Complex
Near MCA Club, Bandra East
Mumbai - 400051. India

Registered Office:
4, Corporate Park, Sion
Trombay Road, Mumbai
- 400071. India

T : +91 22 3816 2000 / 1010
F : +91 22 3816 2400 / 2401
Email : webmaster@abbott.co.in
Site : www.abbottdiagnostics.com
CIN : U24200MH1997PTC104834

Installation & Calibration Certificate

This is to inform that the Abbott Architect i1000sr fully automated immunology Analyzer bearing the serial number S/N: I1SR65336 Installed at Medical Trust Hospital , has been installed & Hardware Calibration performed on 24.11.2021 . The result are within the acceptable limit.

The Preventive Maintenance and Hardware Calibration due is on 23THNov 2022.

For Abbott Healthcare Pvt Ltd.

A handwritten signature in black ink, appearing to read 'Vignesh Ganesan'.

VIGNESH GANESAN

(Technical Service specialist)

INSTALLATION REPORT

REPORT NO.: 24112021



ABBOTT HEALTHCARE (P) LTD
DIAGNOSTICS DIVISION

Abbott Healthcare Pvt. Ltd.
Floor 13-19, Godrej BKC, Plot C-68
G Block, Bandra Kurla Complex Near MCA Club, Bandra East Mumbai -
400051. India

Medical Trust Hospital	MODEL:	Architect i1000Sr
	SERIAL NUMBER:	I1SR65336

WORK STARTED DATE: 23-11-21 TIME: 9:00am	WORK ENDED DATE: 24-11-21 TIME: 5:00pm	INSTALLATION REQUIREMENT CHECK UPS/REQUIRED VOLTAGE: 230V EARTHING VOLTAGE: 0.30v SPACE AVAILABILITY AS PER SPECS: YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> ROOM TEMP AS PER SPECS : YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>
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HARDWARE CALIBRATIONS / SETTINGS CARRIED OUT: YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>	ACCESSORIES RECEIVED All Received
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CUSTOMER TRAINING CARRIED OUT ON : NA	ASSAY CALIBRATED TSH
Carried out HW & SW installation , Calibrated the system , performed Biological Standardization, Found results to be within limits	

CUSTOMER REMARK	COMMENT:
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CUSTOMER SIGN :	F.S.E'S NAME: Arun Kuriakose
DATE : 24/11/2021	SIGN: DATE: 24-11-21





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INSTALLATION / OPERATIONAL/PERFORMANCE QUALIFICATION

Document No.:

IQ/OQ/PQ/ ABBOTT ARCHITECT i1000SR


Revision No.:

01

Equipment ID:

i1SR65336

Installation Qualification

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Purpose: To have complete certification on Installation Qualification for Architect i1000SR

Scope & Criteria.

- Customer details.
- Pre Installation Requirement
- Power & Computer Details.
- Setup Procedure
- Data Sheet
- Enclosures:
 - A .Installation Report .

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i1SR65336

Revision No.:

01

Customer Information

Company / Institute : Medical Trust Hospital

Department : Biochemistry

Manufacturer : Abbott Laboratories ,IL Park ,USA

Instrument Details

SI No	Model Name	Serial Number	Remark
1	Architect i1000SR	i1SR65336	Checked


1.Power Requirement

- 3 KVA UPS with 30 Min Back up.
- 12Amps Main Socket 2 Nos .
- 6 Amps Socket 1 Nos

2.1 Power requirement: 220 – 240 V

Connect the instrument only to an electricity supply system with protective earth.

Voltage	Required	Actual	Checked By
A/C Supply	PH: to Neutral: 220 – 240 V	215 V	Arun Kuriakose
	PH: to Earth: 220 – 240 V	215 V	Arun Kuriakose
	Neutral to Earth: 0 - 2 V	1.6 V	Arun Kuriakose

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2.2 Environmental requirement

The instrument should have required
Ambient temperature: 15 Deg to 35 Deg


Comments: Checked Found ok

1.Place Requirement

	Height	Width	Depth
System	68 Cm	81 Cm	60 cm

Comments:

Performed by	Signature	Date
Arun Kuriakose Technical Service Specialist		24/11/2021
Reviewed by	Signature	Date
Medical Trust Hospital		

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4.0 Installation Setup Protocol

Introduction

This Chapter contains the necessary information for installing the instruments. The installation procedure involves unpacking, environmental requirements, power requirement and interfacing.


4.1 Procedure:

- a. Visually inspect the container for damage, before opening it.
- b. Visually inspect the instrument for loose, bent or broken parts. Report any damage immediately.
- c. Compare the instruments serial number, attached on the rear panel of the instrument, against the serial number of the instrument on the delivery (shipping) note.
- d. Check the instrument accessories against the delivery (delivery) shipping note.
- e. Open the Transportation Lock.

4.2 Installation of instrument

The following procedure details the necessary steps to be followed when installing the instrument



- a. Place the instrument into the required position Ensure that the distance between the back panel of the instrument and the wall is at least 30 cm.
- b. Install the RV Hopper
- c. Install all the Pipettor Probe
- d. Ensure that the main power switch in the back panel of the instrument is in the off position.


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- e. Insert the power cable into the main socket in the back panel.
- f. Install the Key board ,Monitor and the SCC (system Control Centre) with necessary cables
- g. Power on the SCC

4.3 Installation of Software

- a. The “Architect Software V 9.50 “ software using the following procedure.
- b. Insert Base Configuration CD into the CD ROM drive.
- c. Boot the system from the CD .
- d. Follow the software installation procedure to complete the Base Configuration Installation
- e. Insert the “Architect Software V 9.50 “ to the CD ROM
- f. Follow the Software installation procedure to complete the installation
- g. Verify the software installation .

Performed by	Signature	Date
Arun Kuriakose Technical Service Specialist		24/11/2021
Medical Trust Hospital	Signature	Date
		


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4.4. Starting the "Architect i1000 SR "

<u>Instrument Information:</u>	<u>Status</u>
1. Instrument Basic Checked	Checked
2. Communication Checked	Checked

<u>Instrument</u>	<u>Status</u>
1. Power On Instrument	Done
2. Initialize Instrument	Done
3. Basic Start up	Done

<u>RSH (Re Test Sample Handler)Calibration</u>	<u>Status</u>
1. Calibrated the RSH	Done
2. Pipettor Calibration	Done
3. Performed the bar code Calibration	Done

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- Enclosures:

- a. Installation Report

The Technician confirms that the installation of the instrument has been performed in accordance with the installation qualification Approval by the lab Manager or Responsible person is required

Comments:

Performed by	Signature	Date
Arun Kuriakose Technical Service Specialist		24/11/2021
Medical Trust Hospital	Signature	Date
		



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Equipment ID:

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Operational Qualification

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Purpose: To have complete certification on Operational Qualification for Architect i1000SR

Scope & Criteria.

- Start up Procedure
- Instrument Calibration Check

Startup Procedure

1. Power on the Main Power Switch
2. Switch on the CPU and wait until the Snap shot screen appear in the screen as "OFFLINE "
3. Switch on the Instrument and wait till the screen changes from "OFFLINE " to "STOPPED"
4. Select the RSH module and Module 1 and give startup
5. Wait until the snap short changes to "READY" then bring the system to "Running "Mode
6. Load the Reagents and then the samples to perform the test.

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Comments: Checked the startup procedure and found ok

Scope : To check the instrument calibration performance.

1.Wash Cup Pre-alignment

To set the pipettor probe position at the wash cup required for flushing the system. This procedure is used during i1000SR installation.

Commend : Passed

2. Pipettor Calibration

Pipettor probe positioning is set for all positions required for aspirating and dispensing specimens and reagents during processing. Probe straightness is determined.

Commend : Passed


3. Carrier Transport Calibration

To align the carrier transport to the reagent carousel latch actuator and a sample carrier to the load/unload area.

Commend : Passed

4.WZ Aspiration Test

Wash zone aspiration is tested during this procedure. The wash zone dispenses and aspirates buffer from 14 RVs. The operator is instructed to remove the RVs and determine if the RV is half full of buffer. Wash zone aspiration is tested during this procedure. The wash zone dispenses and aspirates buffer from 14 RVs. The operator is instructed to remove the RVs and determine if the RV is half full of buffer.

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Commend : Passed

5.1022 Optics Background

Three background readings are taken during this procedure. One with no RV in position, the second with an empty RV and the third with Pre-Trigger solution in the RV.
 Normalization and linearity parameters are not used during this procedure. Raw counts must be between 3 RLU - 500 RLU.

Commend : Passed

6.Optics Verification


To verify the optics CMIA reader is working as expected. Normalization and linearity factors are verified by taking five reads from the three levels of optics normalization solution and comparing the reads to the standard. The three reads taken are 376, 1,504, and 94,000 attomoles. Background levels are also verified.

Comments : Passed

7.Residual Volume

Fifteen numbered and weighed RVs are loaded by the user during this procedure. Wash Buffer is dispensed into then aspirated out of the RVs. After aspiration the user removes and reweighs the RVs to determine residual volume. The difference between the weights for each RV is determined. This average difference should be <9 µL (mg) and a S.D. <2 µL (mg).



Commend : Passed


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8. Visual inspection: (No special tools required)


The fluid remaining in the RVs may be used as a qualitative visual indication of Wash Zone function. The final RV should have approximately 2 drops in the bottom and no evidence of splashing in the RV.

Commend : Passed

Performed by	Signature	Date
Arun Kuriakose Technical Service Specialist		24/11/2021
Medical Trust Hospital	Signature  Dr. Deepa	24/11/2021

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Instrument Verification Test

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Purpose: To have complete certification on Instrument Verification Test for Architect i1000SR



1.Scope: To Calibrate TSH Assay and Check for Precision and


1. Ordered the TSH Assay from the order list
2. Ran the Assays and the calibration got passed and RLU value are within the limits

Comments: Assays Passed


2. Scope: To check Precision of the instrument with TSH Assay

Comments: Precision are with in the manufacture limits

Performed by	Signature	Date
Arun Kuriakose Technical Service Specialist		24-11-2021
Medical Trust Hospital	Signature 	Date 24/11/2021

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Performance Qualification

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Purpose: To have complete certification on Performance Qualification for Architect i1000SR

Performance qualification validates the test procedure performed on the new instrument.
Performance qualification not only validates instrument performance but also test procedure.

All in-house protocols are validated for performance qualification of instrument and method.

1.Scope: To Calibrate HIV, Anti-HCV, HBsAgQ2 Assay.

- 1) Ordered the HIV, Anti-HCV, HBsAgQ2 Assay from the order list.
- 2) Ran the Assays and the calibration got passed and RLU value are within the limits.
- 3) IQC performed and recovery found satisfactory.

Comments: Assays Passed /Failed.

2. Scope: To check Precision of the instrument with HIV, Anti-HCV, HBsAgQ2 Assay


- 1) Run Precision and the Result are attached along with the PQ.

Comments: Precision study: Passed / Failed

3.Scope: To perform the carry over study for HIV, Anti-HCV, HBsAgQ2 Assay

- 1) Carryover study performed, and the Result are attached along with the PQ

Comments: Carryover study: Passed / Failed

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4. Scope: To perform the Method Comparison study for HIV, Anti-HCV, HBsAgQ2 Assay

- 1) Method comparison study study performed, and the Result are attached along with the PQ

Comments: Method Comparison: [✓] Passed / Failed

Performed by	Signature	Date
Jithin Preetha Lead-Technical Application Specialist	<i>JITHIN PREETHA</i>	<i>04/12/2021</i>
Medical Trust Hospital, Cochin Microbiology Department	<i>[Signature]</i>	<i>4/12/21</i>

Procedure Report

Procedure: 1109 Wash Cup Pre-alignment

Procedure version: 6

Date: 24.11.2021

Module no.: 1

Time: 11:57:12

Serial no.: i1SR65336

Status: Completed

Operator ID: FSE

Results:

Target	Theta
Wash Cup	-1175

Procedure Report

Procedure: 1110 Pipettor Calibration

Procedure version: 13

Module no.: 1

Serial no.: i1SR65336

Operator ID: FSE

Date: 24.11.2021

Time: 12:05:40

Status: Completed

Results:

Target	Theta	Z
Wash Cup	-1155	91
Probe at carousel	11201	11682
Probe at sample aspiration	-2176	
Carrier position	2860	
Outer carousel position	29065	
Middle carousel position	29308	
Inner carousel position	29970	

Procedure Report

Procedure: 1114 Carrier Transport Calibration

Procedure version: 13

Module no.: 0

Serial no.: RSH65336

Operator ID: FSE

Date: 24.11.2021

Time: 11:56:16

Status: Completed

Results:

Position	Result
Latch actuator position	-6787
Z at IA load platform	7791
Theta at aspiration	86
X at bottle rotator	4686
Z at bottle rotator	2436

Procedure Report

Procedure: 3240 Bar Code Calibration

Procedure version: 2

Module no.: 0

Serial no.: RSH65336

Operator ID: FSE

Date: 24.11.2021

Time: 12:07:05

Status: Completed

Results:

Calibrated Bar Code Position:

3999

Calibration completed

Procedure Report

Procedure: 3540 Temperature Status

Procedure version: 3

Module no.: 1

Serial no.: i1SR65336

Operator ID: FSE

Date: 24.11.2021

Time: 12:40:29

Status: Completed

Results:

TEMPERATURE ZONE	TEMPERATURE RANGE	TEMP	STATUS
Process Path Zone 1	36.4 <---> 37.6	36.9 deg. C	OK
Process Path Zone 2	36.4 <---> 37.6	36.9 deg. C	OK
Process Path Zone 3	36.4 <---> 37.6	36.9 deg. C	OK
Trigger & Pre-trigger	32.0 <---> 37.6	35.9 deg. C	OK
Wash zone	34.0 <---> 36.5	35.9 deg. C	OK
Reagent cooler	2.0 <---> 12.0	10.1 deg. C	OK
Reagent cover heater	34.0 <---> 44.5	32.9 deg. C	Low
Ambient	0.0 <---> 0.0	26.5 deg. C	Current Reading

All temperatures are in degrees Celsius.

Procedure completed.

Cal Curve Details Report

Operator ID: FSE

System serial number: 85728

Assay name: TSH	Assay number: 241
Reagent lot: 30353UD00	Expiration date: 28.12.2022
Serial no.: 45312	

Cal status: Active	Module / Serial no.: 1 / i1SR65336
Cal date: 24.11.2021	Cal time: 13:50
Cal type: Adjust	Operator ID: FSE
Calibrator lot: 30022UD00	
Lot expiration: 15.08.2022	

Cal ID	Cal 1 ratio: 2.009	Cal 2 ratio: 1.039	
	Mean RLU	Rep. 1 RLU	Rep. 2 RLU
Cal 1	229.0	273	185
Cal 2	1876216.0	1851033	1901399

Concentration uIU/mL	Ref. Cal RLU	Fit curve RLU
0.0000	114	229.0
0.5000	42500	44145.5
2.0000	160162	168722.2
10.0000	698691	718325.1
40.0000	1805899	1886620.1
100.0000	2703947	2810140.0

Results List Report

Operator ID: FSE

Released

System serial number: 85728

C / P	Module	SID	Name	Assay	Result	Flags	Code	Date / Time
G269/1	1	PRECISION		TSH	25.8652 uIU/mL		R	24.11.2021 13:52
G269/1	1	PRECISION		TSH	29.0221 uIU/mL		R	24.11.2021 13:51

Reagent Status Report

Operator ID: ADMIN

System serial number: 85728

M / P	Assay	Cal status	Reagent lot	Remaining tests	Reagent status	Exp. date	Stability	Carrier Status
1 / 9	HBsAgQ2	Active	32331FN00	41	OK	14.08.2022	28	
1 / 17	_HIV Ag/Ab	Active	30410BE00	43	OK	27.03.2022	28	
1 / 25	anti-HCVII	Active	31377BE00	46	OK	19.07.2022	28	

Cal Curve Details Report

Operator ID: ADMIN

System serial number: 85728

Assay name: **HBsAgQ2**

Assay number: 628

Reagent lot: 32331FN00

Expiration date: 14.08.2022

Serial no.: 01081

Cal status: Active

Module / Serial no.: 1 / i1SR65336

Cal date: 02.12.2021

Cal time: 14:24

Cal type: Index 2 pt

Operator ID: ADMIN

Calibrator lot: 30057FN00

Lot expiration: 22.06.2022

Cal ID	Mean RLU	Rep. 1 RLU	Rep. 2 RLU	Rep. 3 RLU
Cal 1	9373.3	9333	9642	9145
Cal 2	130.7	133	124	135

Cal Curve Details Report

Operator ID: ADMIN

System serial number: 85728

Assay name: **anti-HCVII**

Assay number: 607

Reagent lot: 31377BE00

Expiration date: 19.07.2022

Serial no.: 10372

Cal status: Active

Module / Serial no.: 1 / i1SR65336

Cal date: 02.12.2021

Cal time: 14:12

Cal type: Index 1 pt

Operator ID: ADMIN

Calibrator lot: 30564BE00

Lot expiration: 11.06.2022

Cal ID	Mean RLU	Rep. 1 RLU	Rep. 2 RLU	Rep. 3 RLU
Cal 1	115333.3	114676	116784	114540

Cal Curve Details Report

Operator ID: ADMIN

System serial number: 85728

Assay name: **_HIV Ag/Ab**

Assay number: 639

Reagent lot: 30410BE00

Expiration date: 27.03.2022

Serial no.: 08820

Cal status: Active

Module / Serial no.: 1 / i1SR65336

Cal date: 02.12.2021

Cal time: 14:28

Cal type: Index 1 pt

Operator ID: ADMIN

Calibrator lot: 29273BE00

Lot expiration: 18.03.2022

Cal ID	Mean RLU	Rep. 1 RLU	Rep. 2 RLU	Rep. 3 RLU
Cal 1	4556.0	4760	4726	4182

QC Results List Report

Operator ID: ADMIN

Released

System serial number: 85728

C / P	Module	SID	Control name	Assay	Result	Flags	Code	Date / Time
G269/4	1	_HIV Ag/AbPOS 3	_HIV Ag/Ab - POS 3	_HIV Ag/Ab	3.40 S/CO			02.12.2021 14:51
G269/3	1	_HIV Ag/AbPOS 2	_HIV Ag/Ab - POS 2	_HIV Ag/Ab	5.05 S/CO			02.12.2021 14:50
G269/2	1	_HIV Ag/AbPOS 1	_HIV Ag/Ab - POS 1	_HIV Ag/Ab	6.22 S/CO			02.12.2021 14:50
G269/1	1	_HIV Ag/AbNEG	_HIV Ag/Ab - NEG	_HIV Ag/Ab	0.08 S/CO			02.12.2021 14:48
G261/2	1	HBsAgQ2POS	HBsAgQ2 - POS	HBsAgQ2	3.31 S/CO			02.12.2021 14:46
G261/1	1	HBsAgQ2NEG	HBsAgQ2 - NEG	HBsAgQ2	0.21 S/CO			02.12.2021 14:45
G263/2	1	anti-HCVIIPPOS	anti-HCVII - POS	anti-HCVII	4.64 S/CO			02.12.2021 14:42
G263/1	1	anti-HCVIINEG	anti-HCVII - NEG	anti-HCVII	0.08 S/CO			02.12.2021 14:41