

CALIBRATION CERTIFICATE

DIAGNOSTICNAME COSMOSDIAGNOSTIC

ASSRESS #503, SMV ARCADE ANDRAHALLI

MAIN ROAD BANGALOREKARNATAKA

ANALYSER ICUBIO (iMagic - M7)

DEPARTMENT BIOCHEMISTRY DEPT.

DATE APRIL18,2021

This is to certify that the above mentioned analyzer was calibrated by the following procedure as per manufacturer *s recommendations.

- 1. Analyser Rotor Init position check
- 2. Check Abs sensitivity100%
- 3. Check Init Position Accuracy
- 4. Check Pump Motor condition
- 5. Air/watercalibration

All the checks and calibration were done and system is being used under recommended conditions Next calibration is due on April18, 2022

Euro Diagnostic Systems Pvt. Ltd.

Gopi SL Technical Specialist Bangalore

Euro Diagnostic Systems Pvt. Ltd.

36/37; Millenium House', M.K. Srinivasan Nagar Main Road, Rajiv Gandhi Salai, Perungudi, Chennai-600 096. Tamil nadu, INDIA Phone: 044-2496 0541, Fax: 044-2496 2825, email: eurods@vsnl.net, WWW.eurodiagnostics.in

Date: 10/07/2021 Place: Bangalore

Certificate of Training

This is to certify that

Mr./Ms./Mrs.Praveen kumar

Of <u>Cosmos clinics and diagnostic</u>, located at #503, SMV Arcade, Andrahalli main raod, Syndicate bank layout, Bengaluru, Karnataka 560091 has undergone training on the operation and user maintenance of the Fully Automated Chemistry Analyzer iCubio iMagic- M7.

For Euro Diagnostic Systems Pvt Ltd

Authorized Signatory



Euro Diagnostic Systems Pvt. Ltd.

36/37, Millenium House', M.K. Srinivasan Nagar Main Road, Rajiv Gandhi Salai, Perungudi, Chennai-600 096. Tamil nadu, INDIA Phone: 044-2496 0541, Fax: 044-2496 2825, email: eurods@vsnl.net, WWW.eurodiagnostics.in

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Of <u>Cosmos clinics and diagnostic</u>, located at #503, SMV Arcade, <u>Andrahalli main raod</u>, <u>Syndicate bank layout</u>, <u>Bengaluru</u>, <u>Karnataka 560091</u> has undergone training on the operation and user maintenance of the <u>Fully Automated Chemistry Analyzer</u> iCubio iMagic- M7.

For Euro Diagnostic Systems Pvt Ltd

Authorized Signatory

Hospital/Lab Name: PHOENIX DIAGNOSTICS

Address: BASAVESHWARANAGAR

Ph. No.: 08043757868 Email ID:

Model: Magne NOT Instrument: The Auto

ANALYSER

Serial No.: 31167417 Challan No.:

Instrument Delivery date: 29 10 12018

Instrument Installation Date: 29/11/2018

WARRANTY: YEAR

(Warranty starts either from the date of delivery or installation of Instrument whichever is earlier).

Contact Person:

SINO	NAME	DESIGNATION	PHONE/MOBILE NO.	EMAIL ID
1 0	m Nigupon	na		
_				

Site Output Voltage: 250v

(Kindly check the recommended power supply voltage or voltage mentioned backside of the Instrument)

Power Source: DIRECT / UPS / CVT

(UPS/CVT to be provided by customer. Voltage fluctuation should be constant and maximum 5VAC fluctuation is allowable)

Site Earthing Voltage:

(Earthing voltage should be 0VAC, otherwise suggest customer to maintain the same)

Line/Neutral: Line/Earth: Earth/Neutral: (leakage voltage should be 0VAC)

Absorbance Test/ OD of Distilled Water in each Flow cell Mode: (Flow Cell should be filled with D/W) "Range of Abs in each filter"

Filter	340 nm	405 nm	450 nm	505 nm	546 nm	576 nm	630 nm	Remarks	
AD Value	46512	LGLAC	47512	GILAU	46316	LEGIL	46716	cslac)
Off Set	,								

Tests Performed:

TEST	NAME	RESULT	REPEAT NO	REMARKS
l	GLU	105	10	
2	CHOL	75	10	
3	UREA	49	10	Goco
4	ALB	5	10	
5	TAZ	6	10	
6	CREA	(10	

Persons' Trained: UDAY

Customer Feedback:

Engineer's Remark: Instrument is ward find

Gum

Service Engineer

Abbinand T

Seal & Signature of the Customer

NOTE: Please fill the form in Capital Letters only.

IMP: Please note that in case of non-compliance of above points, report shall not be accepted at H.O



Technical Service Report

CUSTOMED NAME	
ADDRESS I CO3 CHY Archard A Charge has file	DATE 18 02 202/
Arcara, Amarchall Main Hood	India service n AMC
CUSTOMER NAME: COS MO Colore holdic ADDRESS: I SO2 SMV Arcard, American Moura Hood TEL.NO: Synidicate Bayant Ban-91	CHARGEABLE CALL P.M.VISIT
VOLTAGE: Line/Neutral 234.V, Line /Earth: 2 BO.V, Earth/Neutral:	CHARGEABLE CALL P.M.VISIT COURTESY CALL APPLICATION
POWER SOURCE: DIRECT / LIPS / CVT	OOS) COURTESY CALL APPLICATION
POWER SOURCE: DIRECT / UPS / CVT INSTRUMENT! Fully Andomated Analy Zer.	
MODEL:	WORK CARRIED OUT AT
MODEL: SERIAL NO: PROBLEM REPORTED:	SITE SERVICE CENTRE
The second secon	
PARAMETERS (Synergy Bio 1904C)	
T: 0 Pump Speed : 0	ARAMETERS (AutoLab Star Plus/ Versa)
Pump Speed : O	ump Calibration:
Gain Cal: O Pump Cal: 6 50	00 ul (800-1200 ul)
FILTER STATUS:	
Filters in nm 340 405	
ain A/D Valu	
A/D Value (for Star Plus & Versa) 48500 4/2410	
(for Star Plus & Versa) 48500 464.10 Abs of D/Water 0.00 0 0 0	
0.00	
Instrument Status:	
Outer Body: Ok Display: Ok Key Pad: O Pump I Aspiration Button: Ok Tubing Set: Ok Flow Cell: Ok Interna	1
Aspiration Button: Tubing Set: OF Flow Cell: 8 / Internal	Motor: • Printer: • A
Remarks on the defective part / parts if any:	al Connectors: of Software: of
SERVICE DETAILS	
FOLLOWING PARTS HAVE BEEN REPLACED (if changed) PART NO. DESCRIPTION OTV	TO BE FILLED IN BY CUSTOMER
	- SOUTOWIEK
S62 128 Lamp Land Replaced	
USED FROM COMPANY'S STOCK CUSTOMER'S STOCK	PREVENTIVE MAINTENANCE/
SERVICE CHARGE / SPARE PARTS' CHARGE DETAILS:	SERVICE WORK CARRIED OUT SATISFACTORILY
, STANGE DETAILS:	JATISI ACTORILY
न्स्टceived with thanks the sum of Rs (Rupees	FAULT RECIFIED & INSTRUMENT
vide cash/Cheque No	IS WORKING SATISFACTORILY
as the service charge/ spare parts' charge for servicing the above	
mentioned instrument.	3.7
NOTE:	
Parts replaced are chargeable once warranty Period is over.	
 Consumables like Printer Head, Lamp, tubings, paper rolls, glass parts etc. are not covered by warranty and hence are chargeable. 	
of the customer is not under AMC, customer needs to pay service charge to the engineer for any sort of	DATE: CUSTOMER
	SIGNETURE WITH SEAL
NGINEER' REMARKS Howeville mailtense dans	7271
Last to see charles . E Checked	OFFICE USE
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NGINEERS' SIGNATURE & NAME:	CHECKED BY:
NGINEERS SIGNATURE & NAME: Shelhadory	



Technical Service Report

CUSTOMER NAME:	0 - 00-	6	51	/_		
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ADDRESS:# 503	Y NO M	"LCO of &	Anobrahali	i Mai	du roo	A, India Aervice n AMC
TEL.NO:	Indicate	Bark	layout	Bou	1.91,	CHARGEABLE CALL P.M.VISIT
VOLTAGE: Line/Neutr	ral:230.V, Lin	ie /Earth:230	V, Earth/Neutra	l: OV(sho	ould not >0	COURTESY CALL APPLICATION
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INSTRUMENT:	Lulle duto	miles a	Irelysee.			WORK CARRIED OUT AT
	young					SITE SERVICE CENTRE
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PARAMETERS (Synerg	y Bio 1904C)	***************************************			Р	ARAMETERS (AutoLab Star Plus/ Versa)
	: OK Pu	ump Speed :	OK			
Pump: OK Fron	t Board: OK	Gain	Cal: Ok F	Pump Cal: (. 18	ump Calibration: 00 ul (800-1200 ul)
FILTER STATUS:						
Filters in nm	340	405				
ainقب	. 1					
A/D Value	48512	46420				
(for Star Plus & Versa)	1705	10.1				
Abs of D/Water						
Instrument Status:						
Outer Body: OK	Display	- 0 W	V - D-J	. 17	2	
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Remarks on the defect		if any	of Flow Cell.	OK 1	Intern	al Connectors: OK Software: ok
110	ive part / parts	il dily.	SERVICE D	DETAILS !	reginery	Charged Completely.
FOLLOWING PARTS HA	AVE BEEN REPL/	ACED (if chang		/LIAILS -	<u> </u>	TO BE FILLED IN BY CUSTOMER
PART NO.	DESCRIPTIO		QTY	PRICE		TO BE FILLED IN BY COSTOWIER
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as mentioned instrument		.narge/ spare	parts' charge to	r servicing	the abov	e
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Parts replaced are charges	able once warrants	Pariod is over				
• Consumables like Printer F			ss parts etc. are not co	wered by warr	ranty and	20.06.202 Leebone
hence are chargeable.						DATE: CUSTOMER
 If the customer is not und service, 	er AMC, customer	needs to pay ser	vice charge to the eng	ineer for any	sort of	SIGNETURE WITH SEAL
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Technical Service Report

CUSTOMER NAME: (Phoen	ix Dia	gnushics				DATE		20
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TEL.NO:				002					APPLICATION
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Outer Body:	Display	<i>y</i> :	Key Pad:		Pu	ımp Mo	otor:	Printer	
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NOTE: • Parts replaced are charges	able once warrant	y Period is over						. 7	7
Consumables like Printer F			ass parts etc. are r	not covered by wa	arranty ar	nd		`	
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ENGINEER' REMARKS					^				
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ENGINEERS' SIGNATUR	RE & NAME:	ny							

Euro Diagnostic Systems Pvt. Ltd.



COSMOS CLINICS AND DIAGNOSTICS #503, SMV Arcade, Andrahalli Main Road, Syndicate Bank Layout, Bengaluru- 560091

Title	Daily Bio-chemistry QC Log -Normal	QC Log -Normal	
Document Type	Format	Document Number	CCD.LAB.FR.
Prepared By	PRAVEEN	Checked by / Approved by	TANVEER BANU / DR Nirupama .S
QC LOT No.	26482	Issue MONTH	Taby

SIGN	CALCIUM	D Bill	TBill	Creatinine	HDL	Uric Acid	GGT	ALP	SGPT	SGOT	Albumin	T.protein	Triglyceride	Cholesterol	Urea	Glucose		Test Name
	10.6-13.0	0.40- 1.20	3.50-5.30	3.85-6.85	24.8-28.4	8.80-11.8	118-198	358-508	84-130	107-207		3.7-5.3	72- 108	87-125	32.9-60.9	267-335		Range
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COSMOS

COSMOS CLINICS AND DIAGNOSTICS #503, SMV Arcade, Andrahalli Main Road, Syndicate Bank Layout, Bengaluru- 560091

Title	Daily Bio-chemistry QC Log -Normal	ry QC Log -Normal	
Document Type	Format	Document Number	CCD.LAB.FR. \
Prepared By	PRAVEEN	Checked by / Approved by	TANVEER BANU / DR Nirupama . S
QC LOT No.	26482	Issue MONTH	1:18

SIGN	CALCIUM	D Bill	T Bill	Creatinine	HDL	Uric Acid	GGT	ALP	SGPT	SGOT	Albumin	T.protein	Triglyceride	Cholesterol	Urea	Glucose		Test Name
	10.6-13.0	0.40- 1.20	3.50-5.30	3.85-6.85	24.8-28.4	8.80-11.8	118-198	358-508	84-130	107-207		3.7-5.3	72- 108	87-125	32.9-60.9	267-335		Range
	11.8	0.80	4.40	5.35	26.6	10.3	158	433	107	157	Approximately in the same and t	4.5	90.0	106	46.9	301		Mean
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#503, SMV Arcade, Andrahalli Main Road, Syndicate Bank Layout, Bengaluru-560091

COSMOS

Title QC LOT No. Prepared By Document Type Daily Bio-chemistry QC Log -Normal PRAVEEN 26482 Format Checked by / Approved by Document Number Issue MONTH TANVEER BANU / DR Nirupama .S CCD.LAB.FR. 14

SIGN	CALCIUM	D Bill	T Bill	Creatinine	HDL	Uric Acid	GGT	ALP	SGPT	SGOT	Albumin	T.protein	Triglyceride	Cholesterol	Urea	Glucose		Test Name
	10.6-13.0	0.40- 1.20	3.50-5.30	3.85-6.85	24.8-28.4	8.80-11.8	118-198	358-508	84-130	107-207	-	3.7-5.3	72- 108	87-125	32.9-60.9	267-335		Range
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COSMOS CLINICS AND DIAGNOSTICS #503, SMV Arcade, Andrahalli Main Road, Syndicate Bank Layout, Bengaluru- 560091

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COSMOS CLINICS AND DIAGNOSTICS #503, SMV Arcade, Andrahalli Main Road, Syndicate Bank Layout, Bengaluru- 560091

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litle	Daily Dio-Circumst	Daily bio-chemish of regulation	COD I AB EB
Document Type	Format	Document Number	CCD.LAB.FR.
Document type			TANKEED BANKEY DO NICHOSON S
Prepared By	PRAVEEN	Checked by / Approved by	IAMVEEN DANO / UN MI upania .5
OC LOT NO	26482	Issue MONTH	
QC LOT No.	70407		X

	SIGN	CALCIUM	D Bill	T Bill	Creatinine	HDL	Uric Acid	GGT	ALP	SGPT	SGOT	Albumin	T.protein	Triglyceride	Cholesterol	Urea	Glucose		Test Name
	ž	10.6-13.0	0.40- 1.20	3.50-5.30	3.85-6.85	24.8-28.4	8.80-11.8	118-198	358-508	84-130	107-207		3.7-5.3	72- 108	87-125	32.9-60.9	267-335		Range
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COSMOS CLINICS AND DIAGNOSTICS #503, SMV Arcade, Andrahalli Main Road, Syndicate Bank Layout, Bengaluru- 560091

Title	Daily Bio-chemistry QC Log -Normal	QC Log -Normal	
Document Type	Format	Document Number	CCD.LAB.FR.
Prepared By	PRAVEEN	Checked by / Approved by	TANVEER BANU / DR Nirupama .S
QC LOT No.	26482	Issue MONTH	

SIGN	CALCIUM	D Bill	TBill	Creatinine	→ HDI	Uric Acid	GGT	ALP	SGPT	SGOT	Albumin	T.protein	Triglyceride	Cholesterol	y Urea	Glucose		Test Name
outbe	10.6-13.0	0.40- 1.20	3.50-5.30	3.85-6.85	24.8-28.4	8.80-11.8	118-198	358-508	84-130	107-207		3.7-5.3	72- 108	87-125	32.9-60.9	267-335		Range
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Daily Bio-chemistry QC Log -Normal PRAVEEN Format Checked by / Approved by #503, SMV Arcade, Andrahalli Main Road, Syndicate Bank Layout, Bengaluru- 560091 Document Number TANVEER BANU / DR Nirupama .S CCD.LAB.FR.

Title

COSMOS

QC LOT No. Prepared By Document Type

26482

Issue MONTH

SIGN	CALCIUM	D Bill	T Bill	Creatinine	HDL	Uric Acid	GGT	ALP	SGPT	SGOT	Albumin	T.protein	Triglyceride	Cholesterol	Urea	Glucose		Test Name
	10.6-13.0	0.40- 1.20	3.50-5.30	3.85-6.85	24.8-28.4	8.80-11.8	118-198	358-508	84-130	107-207		3.7-5.3	72- 108	87-125	32.9-60.9	267-335		Range
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5			BIO-CHE	MISTRY (IQBIO	BIO-CHEMISTRY (IQBIO) Maintenance Log		
Document Type	Format		Document Number	er	CCD.LAB.FR.015		
Prepared By	Mamatha		Checked by /		Tanveer Banu / Dr.Nirupama.S		
Revision No.	0		Issue Date				
Daily maintenance	1 2 3 4	5 6 7 8	9 10 11 12	13 14 15 16	17 18 19 20 21 22 23 24 25 26	27 28 29 30	31
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Document Tyne	Format	Document Number	er	CCD.LAB.FR.015	
Prepared By	Mamatha	Checked by / Approved by		Tanveer Banu / Dr.Nirupama.S	
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Title		BIO-CHEMISTRY (IQBIO) Mainter	Maintenance Log
Document Type	Format	Document Number	CCD.LAB.FR.015
Prepared By	Mamatha	Checked by /	Tanveer Banu /
Revision No		Approved by	Dr.Nirupama.S
Revision No.	_	Issue Date	

	Operator's initials	Clean the processing center	Perform subsystem cleaning	Clean the key board and key board cover	Clean the touchscreen monitor	Clean the sample supply system	Clean the sample supply system	Clean the tip disposal chute/cup retainer		Clean the samples metering probosics	Weekly-date/initial boxes	Reagent packs and SRpacks	Verify inventory and load:	Inspect: Universal sample trays	Clean the signal reagent probe assembly	Remove outdated and empty: Reagent pack and SRpacks	Solid waste container	Daily maintenance
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CCD.LAB.FR.015	Document Number	Format	Document Type
	BIO-CHEMISTRY (IQBIO) Maintenance Log		Title
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iCubio iMagic- M7 Chemistry Analyzer

Installation Qualification

Chemistry Analyzer – iCubio iMagic- M7

For

Phoenix Diagnostics

Sri Sai Vaibhav Complex, New MIG-115, KHB Colony, 2nd Stage,
80Feet Road, Basaveshwaranagar
Bengaluru, Karnataka 560079

Chemistry Analyzer - iMagic- M7

Installation Qualification for Chemistry Analyzer – iMagic- M7

Product : Chemistry Analyzer

Special Tools : Standard Field Engineer's Tool Kit

Reference : CHEMISTRY Analyzer User's Manual

Prepared by : Technical Service Team

Facility : Chennai

Location : Chennai

Purpose

This section provides detailed installation protocol for the Chemistry Analyzer. You must follow the installation steps correctly to ensure proper installation, operation and service.

Scope

To be performed during new installation and relocation

INTRODUCTION:

- Chemistry Analyzer is an automated In-Vitro Diagnostic Equipment for research purpose and can be used in laboratory
- Chemistry Analyzer is a kind of semi-automatic optic-electric color comparator

Accessories for CHEMISTRY Analyzer

Standard Accessories

- Power wire
- Power adaptor
- Waste tube
- Print paper
- Reaction Cuvettes
- Reagent Bottles
- Personal Computer

Preparing for Installation

Pre Site Survey

The pre site survey is conducted by the Field Engineer to qualify and prepare a customer site before installation of an CHEMISTRY Analyzer. The CHEMISTRY Analyzer pre site survey is provided as an attachment to this document.

- 1. Complete the survey with the assistance of the Laboratory personnel
- 2. Indicate any abnormalities on the form
- 3. Indicate any un resolved issues
- 4. When all unresolved issues are closed, sign the appropriate section on the Approval sheet so that the Analyzer can be installed.

Installation Procedure

SAFETY NOTES



Follow the Operator's Manual!

Precise knowledge and attention to these operating instructions is required. Use On-line UPS with at least 45-60 minutes power backup.



DANGER! Danger of fatal electric shock!

Do not open the power adaptor. There are no elements inside which require servicing or maintenance. Never use a mechanically damaged power adaptor (or) plug – live connections might be exposed. The power adaptor plug is not insulated against fluid ingress. Never let liquids come into contact with it. Check that the mains voltage and frequency printed on the power adaptor plug type label match your mains socket and whether the shape and configuration of the plug contacts are compatible for the connection.



Keep The Analyzer Away From Liquids!

The Analyzer is not insulated against fluid ingress. Take care that no liquids enters the analyzer. There is no Protection provided for the same.

IQ/ Chemistry Analyzer – iMagic-M7

36/37, 'Millenium House', M.K. Srinivasan Nagar Main Road, Rajiv Gandhi Salai, Perungudi, Chennai-600 096. Tamil nadu, INDIA Phone: 044-2496 0541, Fax: 044-2496 2825, email: eurods@vsnl.net, WWW.eurodiagnostics.in

Operating Condition:

Temperature: 15 °C to 35 °C & Relative Humidity: 75%



WARNING! Never Open The Analyzer!

Maintenance and Repairs can only be carried out by us or by our Authorized Service Agent, using original spare parts that will maintain the high quality of the Analyzer.

Make your contribution to a clean environment!

Electrical and electronic device may contain endangering substances which have potential influence on the environment and human health. Old electrical and electronic equipment may not be disposed of under any circumstances in the unsorted domestic garbage.

Symbols used on the Shipper Carton

Symbols	Description
*	Keep Away from Sunlight
	Fragile, Handle with Care
Ť	Keep Dry
<u>11</u>	This way up
2	Do Not Pile Up More than 2
*	Handle With Care



Euro Diagnostic Systems Pvt. Ltd.

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64	Manufacturer		
IVD	In-Vitro Diagnostic <i>Equipment</i>		

Selecting a location for CHEMISTRY Analyzer

- Installation should be planned in a dust free area.
- Keep the analyzer on a stable and horizontal flat surface.
- Keep adequate space on all the sides of the analyzer, to ensure proper air circulation.
- Keep the analyzer away from centrifuge; oscillating agitators or other vibrating machines. CHEMISTRY is very sensitive to vibrations which can cause a false increase of results.
- Keep the analyzer away from electromagnetic devices that produce magnetic field.
- Keep the analyzer away from extreme changes of temperature; direct sunlight and humidity.

Optimum Environmental Conditions:-

Temperature: 15 °C to 35 °CRelative Humidity: 75%

Adaptor Power requirements:-

• Type: Switching Power Supply

Adaptor Input Voltage: AC100/240V±10% 50/60±1 Hz

Symbols used on the Analyzer

Symbols	Description
\triangle	Before Operating the CHEMISTRY Analyzer Please Read the Operator's Manual, Caution



Euro Diagnostic Systems Pvt. Ltd.

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	Disposal and Recycling
IVD	In-Vitro Diagnostic
س	Manufactured Year
27	Manufacturer

Connections

Attach the cables in the following order:

- Connect the Computer (PC) to the USB socket, if you intend to use the Data Management Software (DMS).
- Connect the power Cable provided to the power socket on the back of the analyzer.
- Plug the power Cable into the main power outlet and put ON the power switch on the rear of the analyzer. The display will show the software version
- Note: It is recommended that the analyzer be plugged into a power surge protector for additional protection from power surges and fluctuations.

Dis-Connections

- Switch OFF the power switch on the rear of the analyzer.
- To disconnect the analyzer, unplug the power adaptor from the wall outlet / on-line UPS.
- If required Unplug the Power Cable from main supply and disconnect the cable, connector & other accessories.
- It is not necessary to routinely disconnect the Analyzer when it is not in use.

WARNING! Note: Turn off the main power before removing or reinstalling any connectors on the analyzer.

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It is prohibited to use power supply with high-power equipment together, and it's better to equip with voltage-regulated power supply.

In areas with unstable voltage, use UPS to ensure the normal working of the analyzer.

• User Qualification: Only appropriately trained operators are qualified to operate the analyzer.

Note: Power cords and electrical outlets vary in appearance by region and country

Safety measures

- Environmental conditions: The analyzer is approved for indoor use only.
- Temperature: 15 °C to 35 °C, Relative Humidity: 75%
- Electrical Safety: As in all electrical equipments, the power supply is a potential source of danger.

WARNING! Never carry out maintenance on the equipment when it is under

Electrical tension.

- Until the analyzer remains closed as supplied, the operator is protected against electric shock.
- The analyzer is powered by low voltage and thus does not present the same dangers of the equipment's powered by an electrical line.
- The analyzer has a voltage elevator circuit, so it can provoke electrical shocks, but it is not dangerous for the trained personnel dedicated to the service assistance.
- Disconnect the power supply when the operator intervenes on the Analyzer's internal parts.
- Do not open or move the analyzer with the mechanical parts in movement.
- Read the instructions carefully before testing with the analyzer.
- Mechanical Safety: Do not open the analyzer without disconnecting it from the mains.
- Do not make contact with the mechanical parts in movement.
- The safety rules also apply even for the technically qualified service staff/operator while intervening on the analyzer.

Reagents: QC Reagents if in use follow the safety as well as the operating instructions of the manufacturers.

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Biological Safety: Liquid waste is potentially biologically



Hazardous: Always wear gloves if handling those materials.

Consult the laboratory protocol for handling bio-hazardous materials.

Unpacking & Installation

- Carefully unpack the Analyzer, removing it from its plastic bag.
- Keep the original boxes and packaging material until being assured that nothing is missing, that the unit has no (internal) transport damage and are working properly.
- It is recommended to securely keep the original packing and packaging material for further use. It can be used to transport the analyzer from one location to another and even for transportation for a service issue.

Re-Packing Instructions

- The Analyzer contains delicate electrical components and needs to be properly packed in the original packing & packaging material before shipping. Please contact us with any questions or to obtain the correct packaging materials.
- Unplug the Analyzer. Remove the cables, connectors and other accessories.
- Place the Analyzers in the thermo Cole packing and further in the shipper carton securely.
- Place all the Standard Accessories in the designated place along with the Analyzer.
- Always ship the Analyzers and components as "FRAGILE"!

Maintenance

- The electronic; electrical and mechanical component parts are simple & inside the analyzer and do not require special maintenance.
- The most sensitive part is the flow cell, please clean it every day after testing, do not leave reaction liquid in flow cell overnight.

Customer Responsibilities

The safety of the unit and of the operator cannot be guaranteed if the following conditions are not satisfied:

- The mains should be "compatible" with the voltage and current specifications indicated on the nameplate placed on the rear of the unit. It is also advisable to periodically check the efficiency of the electric system.
- The mains should be equipped with a ground connection, as per current law requirements.
- It is recommended that the analyzer be plugged into a power surge protector for additional protection from power surges and fluctuations.
- Before connecting or disconnecting the external device, Analyzer should be switched off.
- Before connecting the unit with external devices (power input, LPT, etc.,) check that these are compatible with the technical specifications set.
- Individual safety means (gloves, disinfectant solution, etc.,) must always be made available.
- Operators should be familiar with the procedures, prohibitions and warning described in this manual, in addition with safety regulations applicable in the workplace.

Limited Warranty

- CHEMISTRY Analyzer is warranted to be free from defects in materials and workmanship under normal use and service, for a period of one year.
- The warranty is extended only to the original purchaser.
- The warranty shall not apply to any product or parts which have been damaged on account of improper installation without a online UPS and a CVT, improper connections, misuse, neglect, accident or abnormal conditions of operation.
- Any attempt to tamper with the product as evidenced by disruption of warranty sticker and/or unauthorised repair/modification of the product shall render this warranty null and void.
- If CHEMISTRY Analyzer is used in ways other than as specified in this User's Manual, the protection provided by the Analyzer may be impaired.

6/37, Millenium House, M.R.Srinivasan Nagar Main Road, Rajiv Gandhi Salai, Perungudi, Chennal-600 096. Tamii nadu, TNDIA Phone: 044-2496 0541, Fax: 044-2496 2825, email: eurods@vsnl.net,WWW.eurodiagnostics.in

Installation Checklist

S. No	Activity	Remarks (to be filled in by Field Engineer)
1	Un packing the instrument	
2	Checking Contents	
3	Installation & Repacking	
4	Installation of Instrument a. Locating instrument b. Checking Power Supply c. Optional Accessories	
5	Verification of Analyzer Level Surface	
6	Switch On a. Start Up sequence (Please record any abnormalities)	

Installation Qualification Report

Equipment Name : iMagic- M7

Equipment Serial No : 31187417

Software Version (if valid) : 6.4

Date of Installation / Relocation : 29/10/2018

Observation : Installation Requirements found to be satisfactory.

This is to certify that the iMagic-M7 CHEMISTRY Analyzer bearing Sr. No: is successfully installed and commissioned at **Phoenix Diagnostics**, **Sri Sai Vaibhav Complex**, **New MIG-115**, **KHB Colony**, **2**nd **Stage**, **80Feet Road**, **Basaveshwaranagar**, **Bengaluru**, **Karnataka-560079**.

The installation/relocation protocol has been successfully completed as per the standard procedure and the instrument was found to be functioning satisfactorily. The instrument is ready for operational qualifications and further validations.

Performed by	
Name	Abhinand T
Designation	Service Engineer
Signature and Date	
Reviewed by	
Name	Sheshadri S
Designation	Business Development Manager
Signature and Date	
Approved by	
Name	
Designation	
Signature and Date	

iCubio iMagic- M7 Chemistry Analyzer

Operational Qualification

Chemistry Analyzer – iCubio iMagic- M7

For

Phoenix Diagnostics

Sri Sai Vaibhav Complex, New MIG-115, KHB Colony, 2nd Stage,
80Feet Road, Basaveshwaranagar
Bengaluru, Karnataka 560079

iMagic M7 Chemistry Analyzer

Operational Qualification for Autolab Versa Chemistry Analyzer

Product : iMagic M7 Chemistry Analyzer

Special Tools : Standard Field Engineer's Tool Kit

Reference : iMagic M7 Chemistry Analyzer User's Manual

Prepared by : Technical Service Team

Facility : Chennai

Location : Chennai

Purpose

This section provides detailed operational protocol for the Chemistry Analyzer. You must follow the installation steps correctly to ensure proper installation, operation and service.

Scope

To be performed during new installation, Modification and relocation

Powering up the system

Adaptor Power requirements:-

• Type: Switching Power Supply

It is prohibited to use power supply with high-power equipment's together, and it's better to equip with voltage-regulated power Supply.

- In areas with unstable voltage, use UPS to ensure the normal working of the analyzer.
- User Qualification: Only appropriately trained operators are qualified to operate the analyzer.

Note: Power cords and electrical outlets vary in appearance by region and country



Temperature: 15 °C to 35 °CRelative Humidity: 75%

Connections

Attach the cables in the following order:

- Connect the Computer (PC) to the socket marked RS 232, if you intend to use the Data Management Software (DMS).
- Connect the power Cable provided to the power socket on the back of the analyzer.
- Plug the power Cable into the main power outlet and put ON the power switch on the rear of the analyzer. The display will show the software version and the printer self-check by printing some characters like "Testing Report" before motor initiation begins.
- Note: It is recommended that the analyzer be plugged into a power surge protector for additional protection from power surges and fluctuations.

Dis-Connections

- Switch OFF the power switch on the rear of the analyzer.
- To disconnect the analyzer, unplug the power adaptor from the wall outlet / on-line UPS.
- If required Unplug the Power adaptor from main supply and disconnect the cable, connector & other accessories.
- It is not necessary to routinely disconnect the Analyzer when it is not in use.

WARNING! Note: Turn off the main power before removing or reinstalling any connectors on the analyzer.

SETTING UP AN ANALYZER & Selecting a location for Chemistry Analyzer

- Installation should be planned in a dust free area.
- Keep the analyzer on a stable and horizontal flat surface.
- Keep adequate space on all the sides of the analyzer, to ensure proper air circulation.
- Keep the analyzer away from centrifuge; oscillating agitators or other vibrating machines.
- Keep the analyzer away from electromagnetic devices that produce magnetic field.
- Keep the analyzer away from extreme changes of temperature; direct sunlight and humidity.
- Connect the power supply of the Chemistry Analyzer through an online UPS.

Performing instrument Calibrations

The analyzer is pre-set, no configuration is necessary after switching ON.

Verifying Performance / Operating Procedure

- Connect the power supply through an online UPS.
- Connect a computer to the RS 232 port of the analyzer if you intend to you a Data Management Software (DMS) if required.
 (Refer the separate instruction sheet for installation of DMS on the PC given in the CD
 - supplied along with the Analyzer.)
- Switch ON the analyzer.
- Go to water blank, reagent blank, standard, QC, sample menu to do the tests.

Quality Control Tests for Labs

In order to make sure the correctness of the test result, the quality control sample should be tested on machine to verify the machine status.

Operator Training

The operator training is conducted in two parts one for operating the instrument effectively, including principles of operation and performance of samples / controls.

The second part of training covers basic trouble shooting procedures which help to maintain and handle common errors. This training will be conducted by the Technical team.

For basic trouble shooting please refer User's Manual.

NOTE:

 For safety reasons it is advisable to <u>read carefully</u> the recommendations and instructions contained in this manual before installing and using the unit

•

- The User's Manual should be kept together with the analyzer for consultation when necessary.
- If Chemistry Analyzer is sold or transferred, make sure that the User's
 Manual is supplied along with the unit so that the new user receives all the
 necessary information regarding its functions and safety instructions. It is
 also suggested to store the original primary and secondary packing and
 packaging material received by you at the time of purchase of the unit so
 that the new user receives all the same which helps in shifting and transfer
 the unit safely.

Technical Assistance Requests:

If technical assistance is required, contact the name supplier at the address indicated on the invoice at the time of delivery of the unit; otherwise contact the local Engineer or Technician suggested by the Supplier.

S. No	Activity	Observations & Remarks
1.	Powering up the system	Passed
2.	Checking Errors	Passed
3.	Procedures	
	a. Sampling	Working Fine
	b. Recording results	Working Fine
4.	Errors List	Working Fine
5.	Operator Training	Working Fine

Operational Qualification Report

Equipment Name : iMagic M7

Equipment Serial No : 31187417

Equipment ID No : NA

Software Version (if valid) : 6.2

Date of Installation / Relocation : 29/10/2018

Observation :

Deviation and Acceptance :

Conclusion

With reference to the Operational Procedure and the studies carried out in the laboratory, Chemistry Analyzer meets all criteria outlined for Operational Qualification.

Exceptional conditions, have been successfully addressed.

The Analyzer is ready for Performance Qualification.

Performed by	
Name	Abhinand T
Designation	Service Engineer
Signature and Date	
Reviewed by	
Name	Sheshadri S
Designation	Business Development Manager
Signature and Date	
Approved by	
Name	
Designation	
Signature and Date	

iCubio- iMagic- M7 Chemistry Analyzer

Performance Qualification

Chemistry Analyzer – iCubio iMagic- M7

For

Phoenix Diagnostics

Sri Sai Vaibhav Complex, New MIG-115, KHB Colony, 2nd Stage,
80Feet Road, Basaveshwaranagar
Bengaluru, Karnataka 560079

Chemistry Analyzer - iMagic M7

Performance Qualification for Autolab VERSA Chemistry Analyzer

Product : Chemistry Analyzer – iMagic M7

Special Tools : Standard Field Engineer's Tool Kit

Reference : Chemistry Analyzer iMagic M7 User's Manual

Prepared by : Technical Service Team

Facility : Chennai

Location : Chennai

Purpose

To determine that the Chemistry Analyzer performs as intended by repeatedly running the instrument on its intended schedules and recording all relevant information and data. Results must demonstrate that performance consistently meets pre-determined specifications under normal conditions.

Scope

To be performed after the Installation and Operational Qualification have been completed and approved. To be performed after installation, modification or relocation and for re – validation at appropriate intervals

Materials, Equipment, Documents

Laboratory's SOPs for normal operation of the instrument under test.

Quality control Material

Accuracy: The test parameter should fall within the manufacturer specified reference range.

Precision: The test parameter should be within the manufacturer specified reference range.

Quality Control Tests for Labs

- Good Laboratory Practices is to test every day at least one control (1 normal and 1 abnormal) to check if the analyzer is working correctly.
- This control stimulates the behavior of normal and abnormal human serum so can be used to test the analyzer's performances.
- Controls must be tested exactly as normal patient's specimen and results should be recorded on Quality Control Charts.
- Each laboratory can establish its own acceptability ranges if needed.

Automated Chemistry testing solution

Chemistry Analyzer is an automated In-Vitro Diagnostic Equipment for research purpose and can be used in laboratory for Clinical determination of biochemical component according to the color change caused by the reaction between serum & reagent.

Chemistry Analyzer can constantly and simultaneously.

Technical Specifications for Chemistry Analyzer

Analysis method	1 point end, 2 point end (Sample blank), Kinetics, Fixed-time.
Optics	7 filters, 340, 405, 450, 505, 546, 578, 630. 2 more for optional
Lamp house	Long-life Tungsten Halogen Lamp(6V 10W), Auto- Sleep Function
Sample Position	20+2 positions, up to 71
Sample and reagent Probe	One Independent Probe with stirring function
Temperature	25, 30, 37°C and Room temperature. By means of Peltier elements
Reagent position	50 Positions, Refrigerated Reagent tray
Cuvette Specification	Optical diameter is 5.8mm
Photometric range	0.0000-3.0000 Abs
Operating system	Windows XP/7/8
Interface	Standard RS 232 with Multi Language
Interface	4 USB Host; 1 USB Slave; 1 Ethernet port USB ports(host) for Keyboard, Mouse, Printer, disk, Bar code reader etc. USB ports(slave) for PC connection(support PC software control function)
Operational Environment	Temperature: 10°C~37°C; Humidity: ≤85%
Power requirement	Wide power supply AC100-240V, 50/60Hz
Dimension	500mmx440mmx470mm
Weight	40Kg

Performance Qualification Report

Equipment Name : iMagic M7

Equipment Serial No : 31187417

Equipment ID No : 31187417

Software Version (if valid) : 6.4

Date of Installation / Relocation : 29/10/2018

Observation :

Deviation and Acceptance :

Conclusion

With reference to the studies carried out in the Laboratory, it is determined that the analyzer meets all performance criteria and has passed Performance Qualification.

The Analyzer is ready for Specific Use.

Performed by	

Euro Diagnostic Systems Pvt. Ltd.

36/37, 'Millenium House', M.K. Srinivasan Nagar Main Road, Rajiv Gandhi Salai, Perungudi, Chennai-600 096. Tamil nadu, INDIA Phone: 044-2496 0541, Fax: 044-2496 2825, email: eurods@vsnl.net, WWW.eurodiagnostics.in

Name	Mr. Abhinand T
Designation	Service Engineer
Signature and Date	
Reviewed by	
Name	Sheshadri S
Designation	Business Development Manger
Signature and Date	
Approved by	
Name	
Designation	
Signature and Date	



Preventive Maintenance Report (PM Visit)

CUSTOMER NAME	E: Cos	MOS	DIAG	116.870		Date : O	8 08	2021	
Address: Door No # 503 Street Analychall Main Road							PM Visit Number (Ex : Int Visit or 2 nd Visit)		
. SMY Annalminia Baran language 560091									
State Kennertakor Landmark Syndicate Bank Laugant						☐ WARRANTY			
Contact No 9945670868Email Labo CosmoSoliagnosin									
Voltage: Line / Neutral 20V, Line/Earth 230V, Earth/Neutral:OV (Should not>005) Power Source: Direct / UPS / CVT									
Instrument: I Magic M7						WORK CARRIED OUT AT			
SERIAL NO: 3 1 1 8 7 4 1 7 SERVICE CENTRE									
a la a consponent adjoe formin									
PARAMETERS CALIBRATION 09/08/2003						PARAMETERS: 950ml			
T: OK A: OK Pump Speed: OK						Pump Calibration :			
Pump : OK Front Board : OK Gain Cal : OK Pump Cal : OK						500 ul (800-1200 ul)			
FILTER STATUS :									
Filters in nm	340	405	505	546	578	600	630		
Gain	15	OK	OK	ok	OK	OK	ok		
A/D Value	20	OK	OK	ok	OK	ak	OR		
Abs of D/Water	10	OK	OK	OK	OK	OK	OK		
Instrument Status: Outer Body: Ok Display: Ok Key Pad: Ok Pump Motor: Ok Printer Ok Aspiration Button: Ok Tubing Set: Ok Remarks on the defective part / parts if any: Ok									
ENGINEER'S REMARKS Calibration Completed						Note: Very Important			
Calibration Period 08/08/21 to 08/08/20						Seal & Signature of the Customer			
CUSTOMER'S FEEDBACK									
ENGINEER'S SIGNATURE & NAME: Nikhilk Gan									

Euro - A division of Peerless Biotech Pvt Ltd.

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