

DOCUREADER 2 PRO

URINE CHEMISTRY ANALYZER

INSTALLATION
QUALIFICATION

For

Heer Clinical Laboratory ,
1st floor National plaza,
Opp.- Himason Circle,
Near Railway Station,
Surat, Gujarat - 395003

IQ #:

Marketed by:

Suyog Diagnostics Pvt. Ltd.

B- 53, Indus house, 5 floor, opp.monginis factory,
Off New link road, Andheri (w)
MUMBAI - 400 053

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I. Approval of the IQ procedure

Both Heer Clinical Laboratory Surat and Suyog Diagnostics Pvt. Ltd. are jointly responsible for the installation of the Urine Chemistry Analyzer manufactured by 77 ELEKTRONIKA, Hungary. Model: DOCUREADER 2 PRO, Sr. No. UD202002312 as per the attached protocol.

Protocol Performed By : Suyog Diagnostics Pvt. Ltd. Representative

Name : Mr Harshil Mistry
Title : INSTALLATION QUALIFICATION
Company : Suyog Diagnostics Pvt. Ltd.

Signature

Harshil

Customer Authorizations:

Name : Dr. Anil Shah
Title : INSTALLATION QUALIFICATION
Site : Heer Clinical Laboratory Surat
Signature :
Date : 06-09-2022

Anil Shah

II. Instructions

1. This document is to be completed at the time the system is installed at its current location and set up for operation.
2. An authorized Suyog Diagnostics representative will check the system and enter the specific data as outlined in the appropriate Installation Qualification. Each result will be noted and dated. Employees of (customer) Heer Clinical Laboratory Surat will verify each result and sign in the last page. The members of the validation team will carry this out.
3. ALL deviations from normal specification to include any problems with installation will be noted under **COMMENTS**. All resolution to such problems will also be noted in the **COMMENTS** section. Additional space is provided at the end of this protocol for the same.
4. This document contains proprietary information and is in no way to be copied, photographed or duplicated in any way without expressed written authorization by the Manager Instrumentation at Suyog Diagnostics Pvt. Ltd. , B- 53, Indus House, 5th Floor, Opp. Monginis Factory, Off. New Link Road, Andheri (west), Mumbai – 400 053.

III. Scope

This Installation Qualification protocol will be performed on the Urine Sediment Analyzer manufactured by 77 ELEKTRONIKA, Hungary. Model: DOCUREADER 2 PRO, Sr. No. UD202002312 in Heer Clinical Laboratory Surat. This will define the documentation that will be used to evaluate the instruments installation in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrument identified has been installed in accordance with the intended usage.

Installation checks will be performed to verify that the Instrument has been installed with proper connections and utilities.

Trained, knowledgeable personnel will perform qualification studies.

Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All documents will be initialed and dated.

IV. Ancillary Information.

a. Certification of Purchase Order Compliance

I certify to the best of my knowledge, the instrument installed on 06-09-2022, was placed in compliance with the specifications of the agreement.

Verified By:  _____

Date: 06-09-2022

b. Utilities

Sr · N o	Utility	Verified by	Date
1.	Environmental condition as per requirement: (permissible range of temperature 15 – 32 °C, air conditioning facility, non exposure to direct sunlight, dry place)	Yes	06-09-2022
2.	Size and weight of Main Unit W:190 mm D:236 mm, H:77mm Weight:1.5 kg	Yes	
3	Power Source Requirements 100W max Voltage & Tolerance : 100- 240 VAC Frequency & Tolerance : 50/60 Hz ± 2Hz	Yes	

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c. The instrument has been verified for the following

Sr. No.	Verification	Verified by	Date
1.	Instruments identified	Yes	06-09-2022
2.	Manufacturer' s specifications are included	Yes	
3.	Accessories list attached & verified	Yes	
4.	Equipment manual from the manufacturer is documented(CD)	Yes	
5.	Unpacking & installation process.	Yes	

V. Installation Qualification

A. Equipment Description

The Docureader 2 pro is a semi- automated urine chemistry analyzer providing 11 chemical parameters, Blood, Glucose, Nitrite, Specific gravity, Bilirubin, Protein, Urobilinogen, Leucocytes, ketones, pH, Ascorbic acid

Instrument Identification		Verified by	Date
Equipment Name :	Semi Automated urine Chemistry Analyzer		06-09-2022
Model :	Docureader 2 pro		
Manufacturer :	77 ELEKTRONIKA (Hungary)		
Marketed by :	Suyog Diagnostics Pvt. Ltd.		
Serial Number :	UD202002312		
Size (in mm) :	Main unit: 190mm L ,236mm D , 77mm H		

Power :	100- 230 VAC		
Power consumption :	100W		

Accessories/Consumables

The Docureader 2 pro systems consists of the following unit

Description	Quantity	Verified by	Date
Main unit	1		06- 09- 2022
Power cord	2		
Operator Manual English(CD)	1		
Data Cable	1		

1.0 Main unit

C. List of Manuals, Certificates:

Suyog provides the following with the instrument.

Operator' s Manual (CD)

D. Change Control Procedure

The instrument will not be altered, enhanced, modified or substituted for another system until a formal Change Control Authorization is approved from Suyog Diagnostics Private Limited and Heer ClinicalLaboratory Surat.

E. Maintenance

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

A trained analyst using the manuals provided with the instrumentation can perform simple maintenance. Upon expiration of the warranty period Suyog offers Annual Maintenance Agreement 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.

VI Installation Procedure

1. Unpack the instrument main unit.
2. Install the instrument on a working table able to bear 1.5 kg of the instrument.
3. Provide enough space on the right & left side to reach the power supply switch located on the backside of the instrument.
4. Avoid connection to the mains through plug adapters.
5. After all the checks, install display unit and then switch ON the instrument.
6. Verify if the initialization procedure gets completed without any error.
7. Any possible anomaly must be signaled on the installation and testing.
8. The initialization gets completed successfully once the screen displays Main Menu, if the initialization of the instrument gets completed then the instrument is ready for loading samples.

All the above have been installed correctly and are working satisfactorily: Yes

VII. COMMENTS:

The instrument has been installed as per the installation procedure.

VIII. System Certification

Study data has determined that the system described in this document has been installed as per the procedure described in this protocol and in the specified environment, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for specified usage.

Customer Authorizations:

Name : Dr. Anil Shah
Title : INSTALLATION QUALIFICATION
Site : Heera clinical Laboratory .



Signature :

Date : 06-09-2022

DOCUREADER 2 PRO

URINE CHEMISTRY ANALYZER

**OPERATIONAL
QUALIFICATION**

For

**Heer Clinical Laboratory
1st floor, National plaza,
Opp.Himson circle,
Near Railway Station,
Surat, Gujarat 395003.**

OQ#:

Marketed by:

Suyog Diagnostics Pvt. Ltd.

**B- 53, Indus house, 5 floor, Opp.monginis factory,
Off New link road, Andheri (w)
MUMBAI - 400 053**

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I. Approval of the OQ procedure

Both Heer Clinical Laboratory and Suyog Diagnostics Pvt. Ltd. are jointly responsible for the operational qualification of the Urine Sediment Analyzer manufactured by 77 ELEKTRONIKA , Hungary. Model: DOCUREADER 2 PRO, Sr. No. UD202002312as per the attached protocol.

Protocol Performed By : Suyog Representative

Name : Harshil Mistry
Title : OPERATIONAL QUALIFICATION
Company : Suyog Diagnostics Pvt. Ltd.

Signature : 

Validation Team :

Name : Dr. Anil Shah
Department : Heer Clinical Laboratory

Signature : 

II. Instructions.

1. An authorized Suyog Diagnostics representative will check each module and enter the specific data as outlined in the Operational Qualification. Each result will be noted and dated.
2. Employees of (*customer*) Heer Clinical Laboratory Surat will verify each result and sign in the last page. The members of the validation team will carry this out.
3. ALL deviations from the acceptance criteria detailed in this document will be noted in the COMMENTS section at the end of the OQ protocol. All resolution to such problems will also be noted in the COMMENTS section, and must be resolved prior to issuance of a SYSTEM CERTIFICATION. These will be an additional cost to the purchasing institution (customer). However this additional cost will be waived when this test is conducted at time of initial operational check of new instruments.
4. Any test data, which does not meet the specified acceptance criteria, will be submitted to the appropriate laboratory personnel for solution. All steps taken subsequently will be documented.
5. This document contains proprietary information and is in no way to be copied, photographed or duplicated in any way without expressed written authorization by

the Instrumentation Manager at Suyog Diagnostics Pvt. Ltd ,B- 53,Indus house,5
Floor,Opp.Monginis factory ,off. New link road, Andheri (w), Mumbai- 400053.

III. Scope

This Operational Qualification protocol will be performed on the Urine Sediment Analyzer manufactured by 77 ELEKTRONIKA, Hungary. Model:DOCUREADER 2 PRO Sr.No: UD202002312 , Heer Clinical Laboratory Surat. This will define the documentation that will be used to **evaluate the instruments installation in accordance with the manufacturer' s specifications and intended use.** Successful completion of this protocol will verify that the instrument identified has been installed in accordance with the intended usage. Trained, knowledgeable personnel will perform qualification studies.

Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All documents will be initialed and dated.

IV. Operational Qualification

A. Instrument Identification

Verified & Date

- | | | |
|------------------|------------------|------------|
| 1. Model Name | DOCUREADER 2 PRO | 06-09-2022 |
| 2. Serial Number | UD202002312 | 06-09-2022 |

B. Following is a list of tests to be performed and verified:

Test No.	Test Name	Test Purpose	Verified
1	AUTOMATIC INITIALISATION	Instrument Ready Status	YES
2	SAMPLE RUN	To check instrument functioning.& result confirmation, chemistry test parameters	YES

C. operational Testing

Test 1

Test Name: Automatic initialization
Purpose: To check instrument ready status.
Method: Switch On the instrument ,after 5 min instrument checks Completed and instrument is ready for loading of samples.

Test 2

Test Name: Sample run
Purpose: To check the instrument functioning
Method: Chemistry load strip dipped in urine,excess urine to be absorbed on tissue or absorbent paper .
 autostart. Results displayed on the screen in 1min.

D. Operational procedure

A. Certificate of Training

1. Technician Training

This certifies that the staff members listed below have received basic user training in the following categories for the system described in this Installation Qualification. Certificates annexed.

Mr. Harshil Mistry who is certified by Suyog Diagnostics Pvt. Ltd has

conducted the training.

Sr. No.	Training program	Initials	Date
1.	Instrument Setup		06-09-2022
2.	System Operation		06-09-2022

B. Operator Training

The users responsible for the operation of this instrument will be trained in the proper usage of the system. Training will focus on the basic operation and maintenance of the system. The training of the operators will be documented and the training records will be filed as indicated below:

Sr. No.	Operators	Location	Initials	Date
1	Bhavisha Patel	Heer Clinical Laboratory Surat	B.J. Patil	06-09-2022
2	Axita Parekh		A.B. Parekh	
3	Pooja Rathod		Pooja	
4				

COMMENTS : Basic operations and maintenance training completed.

V. System Certification

Study data has determined that the system described in this document either meets all criteria outline in this Operational Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for specified usage.

Report Performed By: Suyog Diagnostics Pvt . Ltd Representative

Name : Harshil Mistry
Title : OPERATIONAL QUALIFICATION
Company : Suyog Diagnostics Pvt. Ltd



Customer Authorizations:

Name : Dr. Anil Shah
Title : OPERATIONAL QUALIFICATION.
Site : Heer Clinical Laboratory .



Signature:

Date:06-09-2022

DOCUREADER 2 PRO

URINE CHEMISTRY ANALYZER

**PERFORMANCE
QUALIFICATION**

For

**Heer Clinical Laboratory,
1st floor, National Plaza,
Opp- Himson circle,
Near Railway Station,
Surat, Gujarat 395003**

PQ#:

Marketed by:

Suyog Diagnostics Pvt. Ltd.

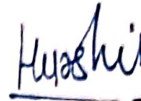
**B- 53, Indus house, 5 floor, Opp.Monginis Factory,
Off New link road, Andheri (w)
MUMBAI - 400 053**

I. Approval of the PQ procedure

Both Heer Clinical Laboratory, Surat and Suyog Diagnostics Pvt. Ltd. are jointly responsible for the performance qualification of the Urine Chemistry Analyzer manufactured by 77 ELEKTRONIKA , Hungary. Model: DOCUREADER 2 PROI, Sr. No. UD202002312 as per the attached protocol.

Protocol Performed By : Suyog diagnostics Pvt. Ltd. Representative

Name : Mr. Harshil Mistry
Title : PERFORMANCE QUALIFICATION
Company : Suyog Diagnostics Pvt. Ltd.



Validation Team :

Name : Dr. Anil Shah
Department : Heer Clinical Laboratory, Surat

Department :



II. Instructions

An authorized Suyog Diagnostics Pvt. Ltd. representative will check for the performance of the instrument and enter the specific data as outlined in the Performance Qualification. Each result will be noted and dated.

Performance checks on a regular basis described in the Further Performance Checks will be the responsibility of Dr Anil Shah Pathology laboratory personnel.

Employees of Heer Clinical Laboratory, Surat and Suyog Diagnostics Pvt. Ltd., will verify each result and sign in the last page. The members of the validation team will carry this out.

ALL deviations from the acceptance criteria detailed in this document will be noted in the COMMENTS section at the end of each PQ protocol. All resolution to such problems will also be noted in the COMMENTS section, and must be resolved prior to issuance of a SYSTEM CERTIFICATION.

Any test data that does not meet the specified acceptance criteria will be submitted to the appropriate laboratory personnel for solution. All steps taken subsequently will be documented.

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III. Scope

This Performance Qualification protocol will be performed on the Urine Chemistry Analyzer manufactured by 77 ELEKTRONIKA, Hungary. Model: DOCUREADER 2 PRO, Sr. No.UD202002312 in Heer Clinical Laboratory, Surat and Suyog Diagnostics Pvt. Ltd., This will define the documentation that will be used to evaluate the instruments installation in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrument identified has been installed in accordance with the intended usage. Trained, knowledgeable personnel will perform qualification studies.

Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All documents will be initialed and dated.

IV. Performance Qualification

A. Instrument Identification

- | | |
|--------------------|------------------|
| 1. Model Name : | DOCUREADER 2 PRO |
| 2. Serial Number : | UD202002312 |

B. Following is a list of tests to be performed and verified:

Performance Testing

Test 1

- | | |
|-------------|---|
| Test Name : | Correlation Test |
| Purpose : | To verify samples by both existing method & new automation |
| Method : | a) Run 30 samples on Docureader 2 pro and reference Method in existence.
b) Note down the results and tabulate.
c) Document the findings. (Data attached) |

V. Comments: Successful completion of performance qualification.

VI. System Certification

Study data has determined that the system described in this document either meets all criteria outline in this Performance Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for specified usage.

Protocol Performed By : Suyog Representative

Name : Mr. Harshil Mistry
Title : PERFORMANCE QUALIFICATION
Company : Suyog Diagnostics Pvt. Ltd.

Harshil

Customer Authorizations:

Name : Dr. Anil Shah
Title : PERFORMANCE QUALIFICATION
Site : Heer Clinical Laboratory, Surat

Signature:



Date: 06-09-2022

CHEMISTRY ANALYZER

SI

ID	Method	billirubin	UBG	Ketone	ASC	Glucose	protein	Blood	Ph	litrite	leucocy	RBC
712	strumen	-	normal	-	-	normal	-	-	6.5	-	-	-
	manual	-	-	-	-	-	-	-	-	-	-	-
718	strumen	-	normal	-	-	normal	-	++ 50	5.0	-	+	-
	manual	-	-	-	-	-	-	-	-	-	++	-
122	strumen	-	normal	-	-	normal	-	-	7.0	-	1-3	-
	manual	-	-	-	-	-	-	-	-	-	-	-
744	strumen	-	normal	-	-	normal	-	-	7.0	-	-	-
	manual	-	-	-	-	-	-	-	-	-	-	-
693	strumen	-	normal	-	-	normal	-	-	5.5	-	-	-
	manual	-	-	-	-	-	-	-	-	-	-	-
695	strumen	-	normal	-	-	++++	+	300 +++	-	+	+++	++++
	manual	-	-	-	-	+++	+	10-20	-	-	100-150	40-60
769	strumen	-	normal	-	-	normal	-	300 +++	5.0	-	+	+++
	manual	-	-	-	-	-	-	10-20	-	-	-	40-60
766	strumen	-	normal	-	-	normal	+++	-	6.5	-	-	-
	manual	-	-	-	-	-	+++	-	-	-	-	-
778	strumen	-	normal	-	-	normal	-	-	5.5	-	-	-
	manual	-	-	-	-	-	-	-	-	-	-	-
733	strumen	-	normal	-	-	normal	-	-	5.0	-	-	-
	manual	-	-	-	-	-	-	-	-	-	-	-
776	strumen	(+)	normal	-	-	normal	+	-	5.5	-	-	-
	manual	-	-	-	-	-	+	-	-	-	-	-
780	strumen	-	normal	-	-	normal	-	+	5.0	-	-	+
	manual	-	-	-	-	-	-	1-2	-	-	-	4-8
781	strumen	-	normal	-	-	normal	-	+	5.0	-	-	+
	manual	-	-	-	-	-	-	-	-	-	-	5-10
787	strumen	-	normal	-	-	normal	+	+++	6.5	-	+++	-
	manual	-	-	-	-	-	+	5-10	-	-	20-40	-
789	strumen	-	normal	-	-	normal	-	+	5.0	-	-	-
	manual	-	-	-	-	-	-	-	-	-	-	4-8
802	strumen	+	normal	(+)	-	normal	+	+	5.5	+	+++	+
	manual	+	-	-	-	-	(+)	4-8	-	-	40-60	5-6
808	strumen	-	normal	-	-	normal	-	+	5	-	-	-
	manual	-	-	-	-	-	-	-	-	-	-	-
126	strumen	-	normal	-	-	normal	-	+	7	-	-	-
	manual	-	-	-	-	-	-	-	-	-	-	-
128	strumen	-	normal	-	-	normal	-	-	5	-	-	-
	manual	-	-	-	-	-	-	-	-	-	-	-
130	strumen	-	normal	-	-	normal	-	-	5	-	-	-
	manual	-	-	-	-	-	-	-	-	-	-	-
131	strumen	-	normal	-	-	normal	-	-	5.5	-	-	-
	manual	-	-	-	-	-	-	-	-	-	-	-
135	strumen	-	normal	(+)	-	normal	+	++	5.5	-	+++	+
	manual	-	-	(+)	-	-	+	-	-	-	-	20-40
136	strumen	-	normal	-	-	normal	-	-	5	-	-	-

Date: 2022-09-06 10:48
Sample ID: QC000066
Solution: L2 (8775220231231)
Device S/N: UD202002312
Operator ID: autologin
Strip LOT: 2065/0624

PASSED

Bil +++
Ubg +++
Ket +
Asc neg
Glu ++++
Pro +
Ery +++
pH 6.5
Nit +
Leu ++
SG 1.015

Reproducibility Results.

Date: 2022-09-06 09:36
Sample ID: QC000065
Solution: L2 (8775220231231)
Device S/N: UD202002312
Operator ID: autologin
Strip LOT: 2065/0624

PASSED

Bil +++
Ubg +++
Ket +
Asc neg
Glu ++++
Pro +
Ery +++
pH 6.5
Nit +
Leu +++
SG 1.015

Date: 2022-09-06 10:16
Sample ID: 52311127
Device S/N: UD202002312
Operator ID: autologin
Strip LOT: 2065/0624

Bil neg
Ubg norm
Ket neg
Asc neg
Glu norm
* Pro +
* Ery +++
pH 6.5
Nit neg
* Leu +++
SG 1.020

Date: 2022-09-06 10:19
Sample ID: 52311127
Device S/N: UD202002312
Operator ID: autologin
Strip LOT: 2065/0624

Bil neg
Ubg norm
Ket neg
Asc neg
Glu norm
* Pro +
* Ery +++
pH 6.5
Nit neg
* Leu +++
SG 1.020

Date: 2022-09-06 10:18
Sample ID: 52311127
Device S/N: UD202002312
Operator ID: autologin
Strip LOT: 2065/0624

Bil neg
Ubg norm
Ket neg
Asc neg
Glu norm
* Pro +
* Ery +++
pH 6.5
Nit neg
* Leu +++
SG 1.020

Date: 2022-09-06 10:14
Sample ID: 52311127
Device S/N: UD202002312
Operator ID: autologin
Strip LOT: 2065/0624

Bil neg
Ubg norm
Ket neg
Asc neg
Glu norm
* Pro +
* Ery +++
pH 6.5
Nit neg
* Leu +++
SG 1.020

Date: 2022-09-06 10:21
Sample ID: 52311127
Device S/N: UD202002312
Operator ID: autologin
Strip LOT: 2065/0624

Bil neg
Ubg norm
Ket neg
Asc neg
Glu norm
* Pro +
* Ery +++
pH 6.5
Nit neg
* Leu +++
SG 1.020