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PROFLO-U

Model – Max

SKU – PSSKU/0291

Proflo-U® Analyzer

Urine Analyzer

Model - Max SKU - PSSKU/0291

Users Manual (Ver 2.01.03)

Prantae Solutions Pvt. Ltd. S-3/35, Mancheswar Industrial Estate, Bhubaneswar, Odisha 751010

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Declaration

Proflo-U analyzer has been specially designed for Proflo-U uALB and Proflo-U uCRE test. The device is a miniaturized spectrophotometer/nephlometry that measures fluorescence and absorbance to estimate the albumin and creatinine from urine. The concentration is determined through the standard curve derived from a physiologically healthy urine matrix. Variability may appear in the measured value due to biological variabilities in urine samples such as high turbidity or fluorogenic components, etc.

Dear Valued Customer,

Your health matters to us the most With Proflo-U® platform, you're taking a significant step towards better health and wellness We're excited to be part of your journey.

Sincerely, The Proflo-U Team

Rapid Reliable Revolutionary

WARRANTY

Prantae Solutions warrants solely to the Buyer that the Proflo-U analyzer will be free from defects in materials and workmanship, when given normal, proper and intended usage, and will perform in accordance with Prantae Solutions' specifications for a period of twenty four months from the date of delivery.

At its expense, Prantae Solutions agrees to repair, or replace with a new or reconditioned unit, any Proflo-U analyzer which is under warranty and not performing substantially in accordance with applicable product specifications, provided that the Buyer has given Prantae Solutions notifications of such warranty claim within the warranty period. If Prantae Solutions is unable after reasonable efforts to repair or replace the Proflo-U analyzer not performing substantially in accordance with applicable product specifications, the Buyer's sole remedy shall be the refund of an amount not to exceed the actual purchase price paid by the Buyer for the Proflo-U analyzer. All repairs will be done during normal working hours. All replaced parts shall become Prantae Solutions' property. Prantae Solutions shall require the Buyer to ship the Proflo-U analyzer to Pranate Solutions' Manufacturing address, for warranty service to be performed.

Notwithstanding the foregoing, Prantae Solutions shall have no obligation to make repairs, replacements or corrections which result, in whole or in part, from (i) an act of God or other unforeseen catastrophe, (ii) any error, omission or negligence of the Buyer, (iii) improper or unauthorized use of the Proflo-U uACR, (iv) operating errors or the disregard of warnings and pre-cautions described in this Proflo-U analyzer User Manual;

(v) repairs performed to the Proflo-U analyzer by any person other than an authorized Prantae Solutions service representative; (vi) use of the Proflo-U analyzer in a manner for which it has not been designed, (vii) causes external damage to the Proflo-U analyzer such as, but not limited to, physical damage or electric power surges, (viii) use of the Proflo-U analyzer in combination with equipment, components or software not supplied and/or specified in this ifu by Prantae Solutions Pvt Ltd. (ix) battery damage due improper charging or due to use of faulty/non-specific charger shall not be covered.

EXCEPT AS STATED IN THIS SECTION OF THE USER MANUAL, PRANTAE SOLUTIONS DISCLAIMS ALL WARRANTIES, WHETHER EXPRESS OR IMPLIED, WRITTEN OR ORAL, WITH RESPECT TO THE PROFLO-U ANALYZER, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. PRANTAE SOLUTIONS' MAXIMUM LIABILITY ARISING OUT OF THE SALE OF THE PROFLO-U ANALYZER OR ITS USE, WHETHER BASED UPON WARRANTY, CONTRACT, TORT OR OTHERWISE, SHALL NOT EXCEED THE ACTUAL PURCHASE PRICE PAID BY THE BUYER FOR THE PROFLO-U ANALYZER. IN NO EVENT SHALL PRANTAE SOLUTIONS AS BE LIABLE FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING, BUT NOT LIMITED TO, LOSS OF PROFITS, LOSS OF DATA OR LOSS OF USE DAMAGES, ARISING HERE UNDER OR FROM THE SALE OF THE PROFLO-U ANALYZER.

THIS WARRANTY MAY NOT BE TRANSFERRED BY THE BUYER. *2 years of warranty on device and 1 year of warranty on battery

The acknowledgement of claims shall be reported to your Technical Care Specialist at support@prantae.com

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Introduction

The Proflo-U analyzer is an urine analyzer specifically designed for use with Proflo-U uALB & uCRE cartridges. It measures urine albumin and urine creatinine in human urine samples and calculates the Urine Albumin to Creatinine Ratio (uACR). It provides clinical grade accuracy in a simple and quick test that can be deployed for Point of Care Testing (PoCT).

Always conduct both albumin and creatinine test from the same urine sample. uACR values are better indicator than individual values.

For more information regarding urine albumin and creatinine test refer to the respective IVD kit product insert.

#Only for Humans urine samples, Not recommended for other body fluid or animal urine samples.

How to Contact Prantae

Address : Prantae Solutions Pvt Ltd. S-3/35, Mancheswar Industrial Estate, Bhubaneswar, Odisha 751010

Email : support@prantae.com website : www.proflou.com



What is Inside the Box?



Proflo-U analyzer features





Light indications for different functionalities of Proflo-U analyzer



Red

A **RED** light on the device indicates while testing refers it is switched ON.

During charging, it means the charging process is ON.



Green

A **GREEN** light on the device indicates it is connected/ paired to the Proflo-U App.

During charging, it means the device is fully charged.

Blue

A **BLUE** light indicates that the device is conducting the test.

Adding Calibration ID

#for more information refer to page no.- 11



Enter the Calibration ID found at the back of Proflo-U analyzer box and press the 'CALIBRATE' button (calibration ID is specific to the analyzer, please ensure to enter right calibration ID to get best results.)



#This page will be depreciated from the android application version 2.3.0+, device will be auto callibrated from here onwards.

#The App may be subjected to upgradation that may result in change in ui/ux.



How to use pipette



inside the cartridge, press the plunger completely)

(Release the plunger gently while the pipette tip is submerged in the urine sample)

Specifications of Proflo-U analyzer

Parameters Measured	Urine Albumin, Creatinine Urine Albumin to Creatinine Ratio (uACR)	
Sample Type	Midstream Urine	
Test Method	Fluorescence and Absorbance	
Sample Volume	100uL	
Test Time	25 sec for Albumin 2 min for Creatinine	
Accuracy	Clinical grade accuracy	
Operating Temperature	RT (5°C to 50°C)	
Humidity Range	<80% RH	
Power Source	Rechargeable Battery (Li-ion)	
Data management	HIPAA compliant	

Battery Life	~100 uALB tests and ~100 uCRE per charge
Report	Stores up to 1,00,000 results on the mobile device
Connectivity	Bluetooth (5.2)
Device Dimensions	92 mm x 77 mm x 77 mm (L x W x H)
Device Weight	~200 grams
Display	No (Result on the smartphone with Proflo-U app)
Regulatory Compliance	ISO 13485:2016, CDSCO
Storage Temperature	20°C to 30°C
Albumin detection range	20 - 1200 mg/L
Creatinine detection range	0.25 - 3.5 g/L



Scan the QR code to download Proflo-U App



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Proflo-U App: Sign up Process





After the installation is complete, sign up using your phone number. Then press next.

Add a password and wait for the OTP. Enter the OTP to complete the sign-up process.





Proflo-U Calibration

Proflo-U App: Calibration



Profile setup

Proflo-U App: Profile setup



Click on the Profile button to add different profiles.



Add all the necessary information.





You can add more profiles by pressing the Add button.

Proflo-U App: Pairing and Connecting



Proflo-U Pairing and Connecting



Enable all the permissions required

Now the Proflo-U analyzer is connected to the app, and you can measure your albumin and creatinine values.



Albumin Test User Guide



Scan QR to Watch Guide in Video Format Inside the Proflo-U uALB Test Kit Sachet, you will find a cartridge and a pipette tip.

QR code is on top of the sachet.

Always hold the cartridge from the top and ensure no fingerprints in the area where liquid is present Always conduct both albumin and creatinine test from the same urine sample. uACR values are better indicator than individual values.



QR Code (Should be scanned to conduct the test) Cartridge(Disposable, single use only) Pipette Tip (Disposable, single use only) Material required for the test but not provided with the analyzer pack

- 1. Sterile/ fresh urine container
- 2. Android/iOS/windows device
- 3. Urine sample

- 4. Gloves
- 5. Charger adapter & Cable
- 6. uALB Cartridges

Always use fresh urine sample. Old sample and/or improperly stored samples may show erroneous results

Press the power button on the analyzer to turn on the device. Device switched 'ON' status will be indicated with RED light.







Tap on 'Connect' button in the app to pair the device. Once connected/paired , the light indicator will turn **GREEN**.

3

To perform the test, tap on 'Take a Test' button on the app and scan the QR or enter the code provided on the test kit sachet.

#The QR code on each sachet is specific to its test. Please scan the QR code on the sachet that belongs to the test cartridge you are using or enter the code mentioned on the sachet.





4

Open the sachet labeled Red Cap uALB Cartridge (Cartridge -1) and follow the steps as guided by the app, which are also shown below for reference:

Proflo-U Albumin Test User Guide

Now add Urine in Red Cap UALB Cartridge (Cartridge -1) pipette and tip provided with the Device. f.

(Correct way of using pipette and tip explained in page no. – 06 and backside of the test kit sachet)

h.

g. Shake gently for mixing (Avoid shaking too hard to prevent froth formation.)

5

Open the sachet labeled Blue Cap uALB Cartridge (Cartridge -2) and follow the steps as guided by the app, which are also shown below for reference:

Proflo-U Albumin Test User Guide

Now add Urine in Blue Cap uALB Cartridge (Cartridge -2) pipette and tip provided with the Device.

(Correct way of using pipette and tip explained in page no. - 06 and backside of the test kit sachet)

Proflo-U Albumin Test User Guide

Profip·L

How Profio-U can keep you healthy

Don't have Profin-07 Get it now

AXML

80

NA

E Tree Report

Carter.

5

NA

Contrary Support

Tap on 'Next'

#Cartridge cover should always be put over the test cartridge in analyzer while performing the test else may get erroneous result

6

k.

After completing the test, the app will analyse the data and display the result.

Results should be interpreted by the professional healthcare practitioners.

#For more information refer Proflo-U[®] uALB test kit product insert.

Inside the Proflo-U uCRE test kit sachet, you will find a cartridge and a pipette tip.

QR code on top of the sachet.

Always hold the cartridge from the top and ensure no fingerprints in the area where liquid is present Always conduct both albumin and creatinine test from the same urine sample. uACR values are better indicator than individual values.

QR Code (Should be scanned to conduct the test)

25

Cartridge (Disposable, single use only) Pipette Tip (Disposable, single use only) Material required for the test but not provided with the analyzer pack

- 1. Sterile/ fresh urine container
- 2. Android/iOS/windows device
- 3. Urine sample

- 4. Gloves
- 5. Charger adapter & Cable
- 6. uCRE Cartridges

Always use fresh urine sample. Old sample and/or improperly stored samples may show erroneous results

Tap on 'Connect' button

Tap on 'Connect' button in the app to pair the device. Once connected/paired , the light indicator will turn **GREEN**.

3

To perform the test, tap on 'Take a Test' button on the app and scan the QR or enter the code provided on the test kit sachet.

#The QR code on each sachet is specific to its test. Please scan the QR code on the sachet that belongs to the test cartridge you are using or enter the code mentioned on the sachet.

4

Follow the steps as guided by the app, which are also shown below for reference:

Add urine within 10 sec

Add urine within 10 sec timer range. After 10 sec next step will start automatically.

(Correct way of using pipette and tip explained in page no.- 06 and backside of the test kit sachet)

f.

Shake gently for mixing

(Avoid shaking too hard to prevent froth formation.)

Proflo-U Creatinine Test User Guide

#Cartridge cover should always be put over the test cartridge in analyzer while performing the test else may get erroneous result

5

After completing the test, the app will analyse the data and display the results.

Results should be interpreted by the professional healthcare practitioners.

#For more information refer Proflo-U uCRE kit product insert.

Proflo-U Result Annotation

You have to conduct both albumin and creatinine test to get uACR value.

Tap on "Measure uACR" button to get the uACR value

Tap on 'Measure uACR'

Result annotation

Tests	Default unit	Optional units
Proflo-U uALB	mg/L	mg/L, g/L, mg/dL, g/dL
Proflo-U uCRE	g/L	mg/L, g/L, mg/dL, g/dL
Proflo-U uACR	mg/g	

Maintenance

Warning

To prevent possible electrical shock, fire, or personal injury, have our company's approved technician repair the product.

Caution

To avoid damage to the product, do not keep the device on or near wet surface and high intensity light source.

How to Charge the Device

Use C-type cable and good quality of adapter from reputated brand to charge the device. During charging phase the red light indicator refers to charging status and green light indicator refers to fully charged.

How to Clean the Product

Outer suface of the device can be carefully wiped with a moist cotton clothes. The cloth may be moistened with water.

Once in a year or in case of liquid spillage. Use mild soap water on a cotton swabs and carefully clean the Sample Chamber. Ensure not to leave any fabric or fiber residue inside the sample chamber.

Storing the Device

Temperature:

Store the device in a cool, dry place. Avoid exposure to extreme temperatures, both hot and cold. Always store the device with device cap.

Humidity:

Keep the device away from areas with high humidity to prevent internal damage.

Battery Care

Charging:

- It is recommended to charge the device fully before first use.
- Use any commercially available C-type charger with a power rating 5V @0.5A (compatible with majority of the smart phone chargers).
- Avoid overcharging; unplug the device once fully charged(full charging is indicated by change of switch light from red to green).

If the device is not in used for an extended period, store it with a partially charged battery and recharge it every 2 months.

Software Updates

Regular Updates:

Check for software updates regularly. Install updates promptly to ensure the device operates with the latest features and security patches.

Handling and Usage

Gentle Handling:

- Handle the device with care to avoid drops and impacts.
- Avoid placing heavy objects on the device.

Proper Use:

- Follow the instructions for use carefully.
- Do not attempt to disassemble or repair the device yourself.

Calibration

Device comes with factory calibration, Calibration ID on the Proflo-U analyzer box corresponds to the same.

In case calibration desired at the user end can be facilitated, please contact customer support (support@prantae.com)

Troubleshooting Common Issues

Inconsistent Results:

- Ensure the device is clean and properly calibrated.
- Sample should be collected in a fresh urine container.
- Sample should be properly stored and should not be kept for more than 2 hrs at 'room temperature'.
- Ensure the test procedure has been properly followed.
- Avoid shaking the cartridge too hard to prevent froth formation.
- Re-test with a new test kit to verify results.

Device Not Powering On:

- Charge the device for atleast 30 mins and check.
- Ensure the power button is functioning correctly.

Software Malfunctions:

- Restart the device to resolve minor software glitches.
- Install any pending software updates.
- Press the reset button with the reset pin provided.

Physical Damage:

- Inspect the device for visible damage.

Contact customer support (support@prantae.com) for repairs or replacements if necessary.

Table 1: Symbols

Symbol	Meaning	Symbol	Meaning	
IVD	In vitro diagnostic medical device	13485:2016	ISO 13485 : 2016 complaint	
	Read Instruction		Product and waste must be treated at a	
	Keep away from moisture and rain		specialized treatment facility for re-use, recycling and recovery.	
	Keep away from direct sunlight	Œ	CE complaint	
	The affixed label indicates that you must not discard this electrical/electronic product in domestic household waste. Do not dispose of this product as unsorted municipal waste. Go to Prantae website for recycling information.			
CDSCO	Central Drugs Standard Control Organisation Registered			

Take Care of Whole Family with **Proflo-U®** Analyzer

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