CLINICALDESIGN

User Manual

UTS Digital Analyser™
1 Unit

Table of Contents:

1. Introduction

This manual provides detailed instructions and procedures that must be followed for the safe and correct operation of the UTS Digital Analyser™.

For *in vitro* diagnostic use by a Healthcare Professional only.

1.1 Intended purpose

The UTS Digital Analyser™ is a semi-automated *in vitro* diagnostic reflectance photometry device, designed to support the performance of the UTS-10 Cap™ that detects specific urine analytes by presenting the results as digital results. The UTS Digital Analyser™ is a closed system that can be used as a USB connected or battery-operated device.

The UTS Digital Analyser™ is intended for use by healthcare professionals in a near-patient setting.

1.2 Theory of Operation

The UTS Digital Analyser™ contains electronic systems in both its Bottom and Top units and uses an optical sensor and regulated light source within the Top to capture an image of the UTS-10 Cap™ at specific intervals.

These images are analysed by the UTS Digital Analyser™ to determine the colour change of each reagent pad and categorise the level of reaction into predefined categories according to the concentration of analyte present in the specimen. The results for each reagent pad will be shown on the display.

2 Installation

This User Manual must be read and understood completely before initiating operation.

2.1 Contents

Contents:
- 1 x UTS Digital Analyser™
- 1 x USB Lead
- 1 x USB Power Adaptor

Once the UTS Digital Analyser™ has been removed from the packaging, inspect the Analyser for any visible damage, ensuring the paired Top and Bottom are sealed with a sticker. Do not use the UTS Digital Analyser™ if any damage is observed and contact your local distributor to report.

2.2 Initial Set up

The UTS Digital Analyser™ is shipped in a special low power mode. Before first use, it must be connected to the USB charger or a computer for activation. **It is recommended to charge the device for at least 24 hours prior to first use** to ensure it is fully prepared for operation.

Upon activation, the UTS Digital Analyser™ will briefly display the battery charge status, that indicates the UTS Digital Analyser™ is active and ready for its first charge and subsequent use.

The UTS Digital Analyser™ is supplied with a USB power adaptor and USB lead. The USB lead connects the UTS Digital Analyser™ via a socket in the Bottom unit, to either the supplied USB power adaptor or a PC (personal computer).

The UTS Digital Analyser™ is designed to operate from any USB power source, for optimal charging performance, it is recommended to use only the supplied USB power adaptor supplied with the Analyser.

Refer to Section 3.1 for the Battery Status and associated charge levels.

2.3 Site Preparation prior to Operation

Physical environment required for proper functioning:

Power Supply Voltage	5V
Power Supply Current	1.5Amp (Max)
Operating Temperature	15°C to 30°C
Operating Humidity	30% to 60%, non-condensing
Altitude	up to 2000m

3 Operating procedure

3.1 Battery Status

The UTS Digital Analyser™ is designed to operate using internal batteries without the need for a wired connection. The battery charge level is displayed during each analysis and should be monitored regularly. To ensure continuous availability, the device should be recharged daily.

When the battery charge reaches a 'Critical' level (25% or less), the device will prevent an analysis from starting. The display will first show the battery status and then go blank. Full operation will resume once the battery has been sufficiently recharged.

Charge status is indicated on the UTS Digital Analyser™ display according to the following states:

Battery Status	Charge Levels/ Description	Display Icon
Full	Bottom: >89% **and** Top: >89%	
Good	Bottom: 50 - 89% **and** Top: 50- 89%	
Low	Bottom: <50% **and** Top: <50%	
Critical	Bottom: <25% **or** Top: <25%	
Battery fault	Battery Fault detected. Remove UTS Digital Analyser™ from operation	

3.2 Device Procedure

Important: Ensure the Initial Set up (Section 2.2) has be followed completely before performing the first test.

It is important to ensure that a newly prepared UTS-10 Cap™ and UTS Tube 5ml™ is used for each new analysis. The same UTS-10 Cap™ and UTS Tube 5ml™ must never be analysed twice as the results may be incorrect.

During operation - It is recommended to keep the UTS Digital Analyser™ connected to a USB power source (included) to ensure the batteries remain fully charged and the device is always available for operation.

To start a new analysis, follow the following procedure below once you are ready to run the test:

Step 1. Remove the UTS Digital Analyser™ Top and insert the UTS-10 Cap™ and UTS Tube 5ml™ into the Bottom, then immediately replace the UTS Digital Analyser™ Top to start the analysis. The analysis will begin automatically.

Step 2. A 'Processing' status and progress bar will be displayed on the display once the analysis has started. A complete analysis takes approximately 90 seconds, and the progress bar will advance to indicate the status of the current analysis.

NOTE: Do not lift the UTS Digital Analyser™ Top until the analysis has been completed. If the UTS Digital Analyser™ Top is lifted during the analysis, the test will be invalidated and will need to be repeated using a new UTS-10 Cap™ and UTS Tube 5ml™.

Step 3. Once the test analysis period has elapsed, a set of results will be shown on the display.

Step 4. Record the test results before lifting the UTS Digital Analyser™ Top.

NOTE: Do not lift the UTS Digital Analyser™ Top before the results are recorded. The results will be lost, and the test will need to be repeated using a new UTS-10 Cap™ and UTS Tube 5ml™.

Step 5. Lift the UTS Digital Analyser™ Top to remove the UTS-10 Cap™ and UTS Tube 5ml™, then immediately replace the UTS Digital Analyser™ Top.
Step 6. Dispose of the UTS-10 Cap™ and UTS Tube 5ml™ according to local policy.

Refer to Section 11 Troubleshooting and Support.

3.3 UTS Digital Analyser™ Displays and Functions

Following analysis, one of the following options will be shown on the display:

Displays	Display Description
Test Results	Once the UTS Digital Analyser™ successfully completes an analysis, the results are automatically presented on the display. The set of results is shown across four sequential screens. This process will be repeated for 8 cycles (200 seconds) before the UTS Digital Analyser™ goes into sleep mode to conserve power. **Important:** Once the UTS Digital Analyser™ goes into sleep mode, the results are deleted and cannot be recovered. Ensure they are reviewed and noted while active on the display. At the end of each screen cycle, a QR Code is displayed for optional connectivity.
Empty Chamber	At the start of each analysis, the UTS Digital Analyser™ automatically confirms that a specimen is present in the chamber. If none is found, the UTS Digital Analyser™ will indicate "Empty Chamber" on the display. After a short period, the UTS Digital Analyser™ will go into sleep mode until the next analysis.
Faulty Cap	At the start of each analysis, the UTS Digital Analyser™ performs an internal check. If this check fails, the UTS Digital Analyser™ will terminate the analysis and indicate "Faulty Cap" on the display. If this occurs, the UTS-10 Cap™ and UTS Tube 5ml™ must be disregarded, and a new UTS-10 Cap™ and UTS Tube 5ml™ must be prepared.

Sleep Mode

- The UTS Digital Analyser™ will go into sleep mode after each analysis to conserve power. When in sleep mode it's display will appear blank.
- The UTS Digital Analyser™ will automatically wake and begin a new analysis when the Top is removed and replaced by the user.

Alarm - Top Missing

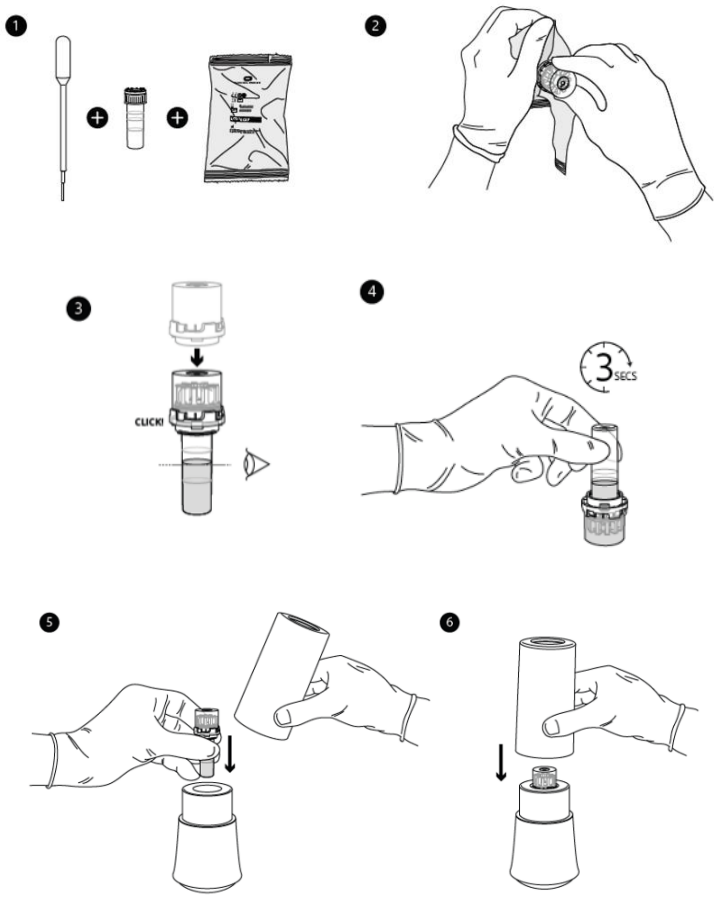
- If the Top is removed from the Bottom and not replaced within 30 seconds, an alarm will sound periodically to alert the user to prompt replacement. The alarm will silence as soon as the Top is replaced onto the UTS Digital Analyser™.

This function is important to ensure the Top is fitted to the Bottom to prevent accidental damage to sensor components within the Top.

3.4 Overview of Test Procedure Using All UTS™ Devices in Combination

The UTS Digital Analyser™ is intended to be used in combination with the UTS-10 Cap™ and UTS Tube 5ml™ to perform a test. The UTS-10 Cap™ and UTS Tub 5ml™ are sold separately.

Step 1. Prepare the specimen for testing by using a Transfer Pipette, UTS Tube 5ml™, and UTS-10 Cap™.
Step 2. Tear open the blister packaging and remove the UTS-10 Cap™.
Step 3. Place the UTS-10 Cap™ onto the top of the lid of the UTS Tube 5ml™ specimen and press the UTS-10 Cap™ firmly down onto the lid of the UTS Tube 5ml™ specimen until the UTS-10 Cap™ aligns with the bottom of the lid.
Step 4. Once the UTS-10 Cap™ is connected to the UTS Tube 5ml™ lid, invert for 3 seconds and ensure that all the reagent pads are fully soaked. Reinvert the UTS-10 Cap™ and UTS Tube 5ml™ to the upright position.
Step 5. The UTS-10 Cap™ and UTS Tube 5ml™ should then be immediately inserted into the UTS™ Digital Analyser™ by lifting the UTS™ Digital Analyser™ Top, dropping the UTS-10 Cap™ and UTS Tube 5ml™ into the Bottom.
Step 6. Replace the UTS™ Digital Analyser™ Top to start the analysis.



The following devices/ consumables are not provided with the UTS Digital Analyser™.

Devices required to perform a test:

1 x UTS-10 Cap™
1 x UTS Tube 5ml™

Consumables (i.e. Transfer Pipette, PPE/ gloves) - Please follow applicable internal procedures in accordance with relevant local or national regulations.

4 Control and Calibration

4.1 Calibration

The UTS Digital Analyser™ does not require any calibration activities to be carried out by the user.

The UTS Digital Analyser™ will perform an automated calibration before the start of every analysis, using the reference point on the UTS-10 Cap™ to ensure accurate analysis.

4.2 Quality Control (QC) Procedure

To perform a wet QC, please use KOVA® Control solution **only**.

Positive: Use the UTS-10 Cap™ and UTS Tube 5ml™ in accordance with the IFU and use KOVA® Liqua-Trol with Microscopics Level I Abnormal Control solution instead of a urine specimen.

Using KOVA® Liqua-Trol with Microscopics Level I Abnormal Control solution, a **PASS** should display the following results:

Reagent	Normal Urinalysis Control Pass	Abnormal Urinalysis Control Pass
Leukocytes	Neg	Trace / + / ++ / +++
Nitrites	Neg	Trace / Pos
Blood	Neg	Trace / + / ++ / +++ / NH10 / NH80
Glucose	Neg	Trace / Pos
Ketones	Neg	+/- / + / ++ / +++ / ++++
Protein	Neg	Trace / + / ++ / +++ /++++
SG	1.000 - 1.030	1.010 – 1.030
pH	5, 6, 6.5, 7	7, 7.5, 8, 8.5
Bilirubin	Neg	Neg / + / ++ / +++
Urobilinogen	Norm	2 / 4 / 8

Negative: Use the UTS-10 Cap™ and UTS Tube 5ml™ in accordance with the IFU and use KOVA® Liqua-Trol with Microscopics Level II Normal with hCG Control solution instead of a urine specimen.

NOTE: If the initial QC test fails, remove the UTS Digital Analyser™ from operation and contact your local distributor.

5 Storage

Store in a clean and dry area.
The UTS Digital Analyser™ is intended for indoor use only.

6 Warnings and Precautions

For *in vitro* diagnostic use by a Healthcare Professional only.
Indoor use only.

The User Manual must be read and understood completely before performing the test.

- **Important:** The urine specimen must be allowed to equilibrate to room temperature before testing - Failure to do so may invalidate the results.
- It is important to ensure that a newly prepared UTS-10 Cap™ and UTS Tube 5ml™ is used for each new analysis. The same UTS-10 Cap™ and UTS Tube 5ml™ must never be analysed twice.

uts™ Urine Testing System

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- It is recommended that the UTS Digital Analyser™ is charged for 24 hours before first use to ensure all internal batteries are fully charged.
- The User Manual must be read and understood completely before performing the test.
- For optimum charging performance it is recommended to only use the USB Power Adaptor supplied with the UTS Digital Analyser™.
- The UTS Digital Analyser™ should be checked for visible damage before every use. Do not use the UTS Digital Analyser™ if there are any visible signs of damage to the device.
- A UTS Digital Analyser™ displaying the battery fault icon should be removed from operation and reported to your local or regional distributor.
- The Analyser should only be used with the UTS-10 Cap™ (UTSCA01) and UTS Tube 5ml™ (UTSTT02) – each device is sold separately.
- The UTS Tube 5ml™ should not be filled whilst in the UTS Digital Analyser™, the UTS Tube 5ml™ should be filled and closed using the provided lid and the UTS-10 Cap™ attached prior to placing into the UTS Digital Analyser™.
- Please ensure that an appropriate amount of specimen is used for testing. Ensure that the UTS Tube 5ml™ has been filled up to the middle line indicated on the UTS Tube 5ml™.
  Too much or too little specimen size may lead to invalid or no results.
- Handle all specimens as if they contain infectious agents
- Observe established precautions against handling of urine specimens throughout testing and follow the local or national standard procedures for proper disposal of specimens.
- Users are responsible for wearing appropriate personal protective equipment (PPE) such as gloves according to local policy, when handling specimens to protect themselves against hazardous agents.

Please comply with applicable internal procedures in accordance with local or national regulations.

7 Specimen Collection and Handling

The UTS Digital Analyser™ should be used with a urine specimen only.

Refer to the Instructions for Use (IFU) for the UTS Tube 5ml™ **- Product Name and Code: UTS Tube 5ml™ (UTSTT02)** for the procedure for specimen collection and handling.

8 Maintenance

8.1 Updating Firmware

Clinical Design Technologies Ltd will determine when an update to the UTS Digital Anlsyer™ firmware is required.

8.2 Charging

It is recommended to keep the UTS Digital Analyser™ on charge for at least 24 hours prior to first use to ensure the unit is ready for operation.

The USB Power Adaptor and USB Lead enable the UTS Digital Analyser™ to be powered from a mains socket. For optimum charging performance it is recommended to only use the USB power adaptor supplied with the Analyser. Alternatively, the UTS Digital Analyser™ can also be powered from a Personal Computer (PC) via USB.

Refer to Section 3.1 for the Battery Status and associated charge Levels

8.3 Cleaning

The UTS Digital Analyser™ is intended for indoor use only and should be kept dry and free from dust/ dirt.

8.3.1 UTS Digital Analyser™ Top

The camera opening within the UTS Digital Analyser™ Top should only be cleaned using a lint free cloth.

The use of cleaning agents or rigid cleaning utensils should not be used as this may result in damage to the optical components leading to a deterioration of the performance of the UTS Digital Analyser™.

8.3.2 UTS Digital Analyser™ Bottom

Clean using only Universal Disinfectant Cleaning Wipes (e.g. Clinell Universal Wipes or equivalent).

Do not submerge the UTS Digital Analyser™ Bottom into any liquid.

9 Ordering more UTS-10 Cap™ and UTS Tube 5ml™

Please contact your local or regional distributor to order more UTS-10 Cap™, UTS Tube 5ml™ and Transfer Pipettes.

10 Disposal

The UTS Digital Analyser™ contains Lithium-Ion re-chargeable batteries, therefore must be disposed of in accordance with local and national regulations.

Waste Electrical and Electronic Equipment (WEEE)

11 Troubleshooting and Support

The UTS Digital Analyser™ includes monitoring of its internal systems and will indicate faults to the user on its display.

The following messages may be seen on the display when the UTS Digital Analyser™ detects a fault:

System Faults	Fault Description
Camera Fault	An error has occurred when attempting to retrieve image data from the optical system. The error indicates a system fault.
Calibration Error	The calibration required to normalise the image of the current test specimen is too great. This is due to either a faulty UTS-10 Cap™ or UTS Digital Analyser™.
Invalid Analysis	If the UTS Digital Analyser™ Top is lifted off or partially removed during an analysis, this message will be displayed to indicate that the current analysis has been invalidated as insufficient time has elapsed for the user to have replaced the UTS-10 Cap™ and UTS Tube 5ml™ with a new specimen. To ensure accurate results, a new UTS-10 Cap™ and UTS Tube 5ml™ must be used for every analysis.
Analysis Cancelled	The UTS Digital Analyser™ has cancelled its current analysis. This can occur if an internal system fault is detected. Repeat the test using a new UTS-10 Cap™ and UTS Tube 5ml™.
Wrong Top. Have: xxxxxxxx, expecting yyyyyyyy.	The UTS Digital Analyser™ Top and Bottom are paired together and cannot be interchanged with other units. If an incorrect Top is fitted onto a Bottom the UTS Digital Analyser™ will not perform an analysis. To continue operation, the correct Top must be found and fitted to the Bottom.
Empty Chamber	At the start of each analysis, the UTS Digital Analyser™ automatically confirms that a specimen is present in the chamber. If none is found, the UTS Digital Analyser™ will indicate "Empty Chamber" on the display. After a short period, the UTS Digital Analyser™ will go into sleep mode until the next analysis.
Replace Sample	To ensure accurate results, a new UTS-10 Cap™ and UTS Tube 5ml™ must be used for every analysis. An automatic check is carried out by the UTS Digital Analyser™ once the Top is replaced. This check ensures that sufficient time has elapsed for the user to have removed the previous UTS-10 Cap™ and UTS Tube 5ml™ and replaced them with a new UTS-10 Cap™ and UTS Tube 5ml™. If the UTS Digital Analyser™ determines that the Top was not removed for long enough, it assumes that the UTS-10 Cap™ and UTS Tube 5ml™ have not been replaced and rejects the analysis.
Faulty Cap	At the start of each analysis, the UTS Digital Analyser™ performs an internal check. If this check fails, the UTS Digital Analyser™ will terminate the analysis and indicate "Faulty Cap" on the display. If this occurs, the UTS-10 Cap™ and UTS Tube 5ml™ must be disregarded, and a new UTS-10 Cap™ and UTS Tube 5ml™ must be prepared.

If any faults persist, the UTS Digital Analyser™ should be removed from operation, and your local/regional distributor should be contacted for assistance.

NOTE: Any serious incident that has occurred in relation to this device should be reported by the user to the manufacturer (quality@clinical.design) and the Competent Authority of the country/ Member State in which the user and/or the patient is established.

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12 Manufacturer

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13 Copyright Notice and Policy Statement

Policy Statement

The information in this User Manual was correct at the time of printing. However, Clinical Design Technologies Ltd continues to improve products and reserves the right to change specifications, equipment, and maintenance procedures at any time without notice.

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14 Symbols

SYMBOL	DEFINITION
SN	Serial Number
IVD	*In Vitro* Diagnostic Medical Device
REF	Part Number / Catalogue Number
UDI	Unique Device Identifier
	Upper and Lower Temperature Limits
	Near Patient Testing
	Manufacturer and Address Details. Includes Date of Manufacture (CCYY-MM)
	Please consult IFU
	Waste Electrical and Electronic Equipment (WEEE)
	Do not use if package is damaged
CE	CE Mark for European Conformity
EC REP	EU Authorized Representative
	EU Importer

EC REP

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2595 AM The Hague
The Netherlands

UDI **506069102DANN**

REF **UTSDA01**

uts™ Urine Testing System

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