# 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 displayed on the digital display.

## 2 Installation

### 2.1 Unpacking and 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 Site preparation prior to operation

Physical environment required for proper functioning:

| | |
|---|---|
| **Power Suppler Voltage** | 5V |
| **Power Suppler Current** | 1.5Amp (Max) |

| | |
|---|---|
| **Storage & Operating Temperature** | 15°C to 30°C |
| **Operating Humidity** | 30% to 60%, non-condensing |
| **Altitude** | up to 2000m |
| **Computer Operating System** (Optional for UTS Desktop Software) | Windows 7 or later* |

*Contact Clinical Design for information on other operating systems

### 2.3 Starting up prior to operation

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

The UTS Digital Analyser™ contains internal batteries that are shipped partially charge and must be fully charged before first use. It is recommended to keep the analyser on charge for at least 24 hours prior to first use to ensure the unit is ready for operation.

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 optimum charging performance it is recommended to only use the USB power adaptor supplied with the analyser.

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

## 3 Operating procedure

### 3.1 Battery Status

The UTS Digital Analyser™ can be used either:
- Standalone, operating from its internal batteries
- Permanently connected to a USB charger

If the device is used standalone, it must be recharged daily before first use.

The UTS Digital Analyser™ monitors its battery levels and will prevent operation if there is insufficient charge available. Operation is prevented if the battery state is in the critical or fault state. Charge status is indicated on the analyser's display screen according to the following states:

Elements of the icons may flash; this indicates the batteries are currently being charged.

| Battery State | 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 Analyser from operation |  |

### 3.2 Device Procedure

Ensure the UTS Digital Analyser™ has sufficient charge before running a test and only proceed with the following procedure once you are ready to run the test immediately.

Step 1. Lift 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.
Step 2. A 'Processing' status and progress bar will be displayed on the screen once the analysis has started.

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

Step 3. Once the test analysis period has elapsed, a set of results will be displayed on the display screen.
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 specimen.**

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.

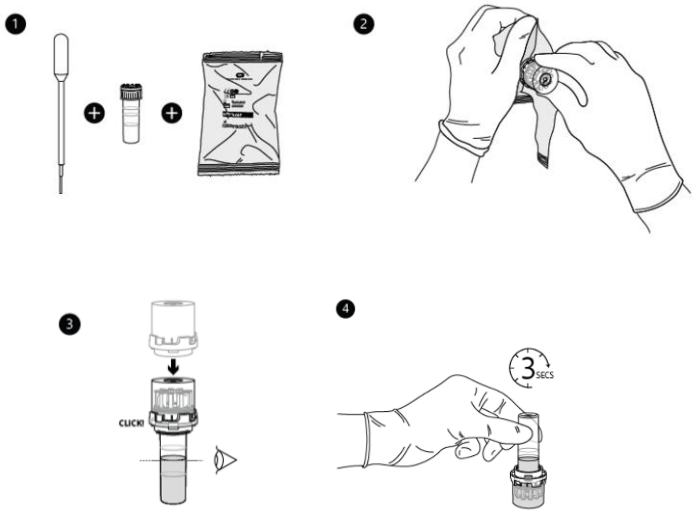
Step 6. Dispose of the UTS-10 Cap™ and UTS Tube 5ml™ according to local policy.

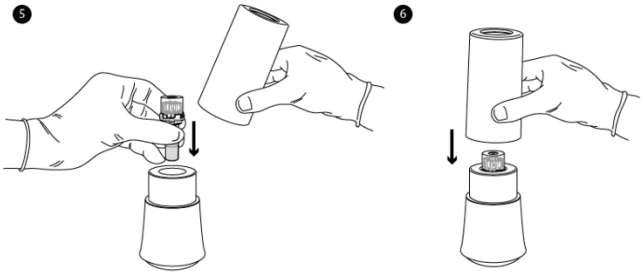
Refer to Section 12 for System faults.

### 3.3 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 the 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 cap aligns with bottom of the lid
Step 4. Once the UTS-10 Cap™ is connected to the tube 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 and dropping the UTS-10 Cap™ and UTS Tube 5ml™ into the bottom and replacing 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 Control Procedure

Use a wet QC control solution in line with local/ national requirements to verify that the UTS Digital Analyser™ is performing.

### 4.2 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 during each analysis using the reference pad on the UTS-10 Cap™ as a colour reference.

## 5 Storage and Transport

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

For transport, it is recommended to place the analyser into its original packaging prior to transporting.



Urine Testing System

CE UKCA IVD

## 6 Warnings and Precautions

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

- **Important:** The urine specimen must be allowed to equilibrate to room temperature before testing - Failure to do so may invalidate the results.
- 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 analyser, the tube should be filled and closed using the provided lid and the UTS-10 Cap™ attached prior to placing into the analyser.
- Please ensure that an appropriate amount of sample is used for testing. Ensure that the UTS Tube 5ml™ has been filled up to the middle line indicated on the tube. Too much or too little sample 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, when handling specimens to protect themselves against hazardous agents.

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

**NOTE: Any serious incident that has occurred in relation to this device should be reported by the user to the manufacturer and the competent authority of the country/ Member State in which the user and/or the patient is established.**

## 7 Specimen Collection and Handling

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

Firmware updates can be applied using the UTS Desktop Software. Consult with your local IT services if you require an update to be applied.

### 8.2 Charging

The USB Power Adaptor and USB Lead enable the UTS Digital Analyser™ to be powered from a mains socket. Although the UTS Digital Analyser™ is designed to operate with any USB power adapter or USB host device such as a Personal Computer (PC), for optimum charging performance it is recommended to only use the USB power adaptor supplied with the analyser.

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 Cleaning wipes (e.g. Clinell Universal Wipes or equivalent)

Do not submerge the UTS Digital Analyser™ Bottom.

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

Please contact your local or regional distributor to order more UTS-10 Cap's, UTS Tube 5ml™'s 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 Manufacturer

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## 12 Troubleshooting and Support

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

The following messages may be seen on the display screen when the 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. |
| Empty Chamber | No UTS-10 Cap™ is detected in the UTS Digital Analyser™ Bottom |
| Faulty Cap | One or more reagent pads on the UTS-10 Cap™ were found to be out of specification during the analysis. Repeat the test using a new UTS-10 Cap™ and specimen. |
| 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 specimen. |
| Incorrect Top | An incorrect Top has been fitted to a Bottom. When a Top is not used with the paired Bottom, this message will be displayed on the screen. |
| Invalid Analysis | The Top is pre-programmed to enforce a reasonable timeframe when interrupting an active analysis to replace a specimen. This message will be displayed on the screen when the Top has been refitted onto the Bottom with insufficient time to have replaced the specimen. |
| Replace Sample | The Top is pre-programmed to enforce a reasonable timeframe in between replacing specimens after a completed analysis. This message will be displayed on the screen when the Top has been refitted onto the Bottom when it detects insufficient time to have replaced the specimen. |
| Calibration Error | The calibration required to normalise the image of the current test sample is too great, this is due to either a faulty UTS-10 Cap™ or UTS Digital Analyser™. |

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

## 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.

**Copyright Notice**

## 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.<br>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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uts™ Urine Testing System

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