Table of Contents

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Scope</td>
<td>2</td>
</tr>
<tr>
<td>2.</td>
<td>Objective</td>
<td>2</td>
</tr>
<tr>
<td>3.</td>
<td>Definitions</td>
<td>2</td>
</tr>
<tr>
<td>4.</td>
<td>Responsibility</td>
<td>3</td>
</tr>
<tr>
<td>5.</td>
<td>Procedure</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>5.1. Diagram of Clinitek Status® analyser</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>5.2. Set-up</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>5.3. Performing a Test</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>5.4. Quality Control</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td>5.5. Maintenance</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td>5.6. Troubleshooting</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>5.7. Flow Charts</td>
<td>16</td>
</tr>
<tr>
<td>6.</td>
<td>Precautions</td>
<td>29</td>
</tr>
<tr>
<td>7.</td>
<td>References</td>
<td>29</td>
</tr>
<tr>
<td>8.</td>
<td>Appendices</td>
<td>29</td>
</tr>
<tr>
<td>9.</td>
<td>Revision History</td>
<td>29</td>
</tr>
</tbody>
</table>

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Signature/Date: 12/10/2012

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1. Scope

This Standard Operating Procedure (SOP) applies to the staff and students using the Clinitek Status® Analyser in the Pharmacy Practice Resource Unit (PPRU) at the Pharmacy Department, University of Malta.

2. Objective

To describe the procedure for the setup, configuration, operation, recording and recalling of results, quality control, maintenance and troubleshooting of the Clinitek Status® Analyser.

3. Definitions

3.1. Clinitek Status® Analyser: A portable device used to analyse Siemens® urinalysis strips and Clinitest® immunoassay cassettes. It is used for the semi-quantitative detection of albumin, bilirubin, blood (occult), creatinine, glucose, ketones, leukocytes, nitrite, pH, protein, specific gravity and urobilinogen in urine samples. It is also used for the detection of human Chorionic Gonadotropin (hCG) in urine samples, when Clinitest® hCG Cassette Tests are used.

3.2. Full Test: A test which allows the user to enter an Operator ID, Patient Name and/or Patient ID prior to inserting a strip or cassette.

3.3. On/Off Button: A button located on the front of the device, which must be pressed for 2 seconds in order to switch the device on and off.

3.4. Quality Control Test: Performed each time a new reagent bottle is opened when using Siemens® branded urinalysis reagent strips. This test is also performed for immunoassay cassette testing when opening a new reagent box.

3.5. Quick Test: A test that does not require any operator or patient information. The test will be identified by a sequential test number when the results are displayed or printed.

3.6. Start-Up Wizard: A quick set-up procedure that is performed when the device is being used for the first time.

3.7. Results Format: An option which allows you to select the format in which you would like the results to be displayed and printed.
3.8. **Test Table:** A piece of apparatus that is required to hold the test table insert in place so as to be inserted just halfway into the analyser.

3.9. **Test Table Insert:** A piece of apparatus that is required to hold the test strip or cassette on the test table. One end is adapted to hold a reagent strip, while the other opposite end is adapted to hold an immunoassay cassette.

3.10. **White Calibration Bar:** A white strip found on test table from which reference readings are taken.

4. **Responsibility**

4.1. The members of the Department of Pharmacy (staff and students) are responsible for following this SOP.

4.2. The designated Laboratory Officer or Laboratory Assistant is responsible for ensuring that this SOP is followed.

5. **Procedure**

5.1 **Diagram of Clinitek Status® analyser**

![Diagram of Clinitek Status® analyser]

1 Clinitek Status® analyser
2 Test table
3 Test table insert
4 Power supply
5 Paper roll
5.2 Set-up

5.2.1. Installation

1.2.1.1 Place the device on a level work surface.
1.2.1.2 Plug the power cord into the power inlet socket of the device. Plug the other end of the power cord into an AC electrical wall outlet or remove the battery cover and insert six new AA batteries if device is to be operated via a battery supply and replace battery cover.

5.2.1. Test Strip Table Insertion for the First Time

5.2.2.1. Insert the test strip table into the device by holding it by the end opposite the white calibration bar and with the white bar facing up.
5.2.2.2. Push the test table into the device just over halfway through.

5.2.2. Loading Test Table Insert

5.2.2.1. Use either the side for a strip test or the other side for a cassette test.

5.2.4. Loading the Printer Paper or Label Roll

5.2.4.1. Pull up the tab to open printer cover.
5.2.4.2. Press the tab down and pull out to open paper roll compartment cover.
5.2.4.3. Lift paper holding arm into the open, upright position.
5.2.4.4. Place new paper roll into the printer paper compartment.
5.2.4.5. Feed paper up along wall and through printer. Approximately 10 cm of paper are to be passed through the printer.
5.2.4.6. Feed edge of paper through printer cover.
5.2.4.7. Push paper holding arm down into the closed position.
5.2.4.8. Close printer and paper roll covers.

5.2.5. Powering up the device

5.2.5.1. Press the on/off button located on the front of the device.
5.2.5.2. Wait until an automatic system diagnostic test is performed.
5.2.5.3. A quick set-up procedure (Start-Up Wizard) will follow to select basic functions of the device.
5.2.5.4. Check that no test strip or cassette is present on the test table.
5.2.6. Powering down the device

5.2.6.1. Press the on/off button. Wait for the Test table to retract into the analyser.
5.2.6.2. The test table will be pushed out and the analyser will switch off, if a strip or cassette is present on the test table.
5.2.6.3. Turn the analyser on, and then off (without a strip or cassette on the test table) to retract the test table into the analyser.
5.2.6.4. The door will close and the analyser will switch off if no strip or cassette is present on the test table.

5.3 Performing a Test

5.3.1 Choosing between a Full or Quick Urinalysis Strip Test

5.3.1.1 Press instrument setup.
5.3.1.2 Select [Operator and Patient Information].
5.3.1.3 Select [Full Test] or [Quick Test].
5.3.1.4 Press [Next].
5.3.1.5 Press [Done].
5.3.1.6 Press [Done] again on Settings Screen.

5.3.2 Performing a Urinalysis Strip Test

5.3.2.1 Press the on/off button to switch on the device.
5.3.2.2 Press Strip Test from the [Main Select] screen.
5.3.2.3 Wait for the [Prepare Test] screen to be displayed.
5.3.2.4 Check that the test table insert has the reagent strip holder facing upwards.
5.3.2.5 Take a test strip, urine sample and paper.
5.3.2.6 Dip the reagent strip into the urine sample, ensuring that all pads are wet.
5.3.2.7 Immediately remove the reagent strip from the urine sample.
5.3.2.8 Drag the edge of the reagent strip against the side of the sample container to remove any excess urine.
5.3.2.9 Blot the edge of the strip to the paper to remove excess urine.
5.3.2.10 Place the reagent strip in the channel of the table with the test pads facing up.
5.3.2.11 Slide the reagent strip to the end of the channel of the test table.
5.3.2.12 Wait for the test table and strip to be automatically pulled into the analyser.
5.3.2.13 Press the START button to start the test.
5.3.2.14 Wait for the eight second timer to be displayed for the following steps to be completed.
5.3.2.15 A timer will display the remaining time to analyse the strip results.
5.3.2.16 The [Printing] screen will be displayed until the print out is completed if the analyser is previously set up to automatically print the results.
5.3.2.17 The [Results] screen will appear if the analyser is not previously set up to automatically print the results.
5.3.2.18 Wait for the test table and strip to be automatically pushed out of the analyser.
5.3.2.19 Press More on the screen to view the remaining test results.
5.3.2.20 Press Print to print the results if the analyser has not been set up to automatically print the test results. (The results will automatically be sent to the connected PC if this option is set up in the analyser).
5.3.2.21 Remove and dispose of the used reagent strip.
5.3.2.22 Wipe the table insert, if necessary.
5.3.2.23 Press Done to complete the test and return to the main [Select] screen.
5.3.2.24 Press the on/off button to switch off the device.

5.3.3 Performing a Cassette Test

5.3.3.1 Press the on/off button to switch On the device.
5.3.3.2 Press Cassette Test from the main [Select] screen.
5.3.3.3 Press the Clinitest hCG cassette button.
5.3.3.4 Ensure that the test table insert is in the correct position for a cassette test.
5.3.3.5 Remove a test cassette from its foil package.
5.3.3.6 Draw a urine sample to the line marked on the pipette (approximately 0.2 mL).
5.3.3.7 Add the entire contents of the pipette into the sample well of the test cassette.
5.3.3.8 Wait for the test table and cassette to be automatically pulled into the analyser.
5.3.3.9 Place the cassette test on the test table.
5.3.3.10 Press the START button.
5.3.3.11 Wait for an eight second timer to be displayed for the following step to be completed.
5.3.3.12 A timer will display the time remaining in analysing the results.
5.3.3.13 The [Printing] screen will be displayed until the print out is completed if the analyser is previously set up to automatically print the results.

5.3.3.14 The [Results] screen will appear if the analyser is not previously set up to automatically print the results.

5.3.3.15 The first page of the test results are displayed on the screen and the test table and cassette are automatically pushed out of the analyser.

5.3.3.16 Press More on the screen to view the remaining test results.

5.3.3.17 Press Print to print results (The results will automatically be sent to the connected PC if this option is set up in the analyser) if the analyser has not been set up to automatically print the test results.

5.3.3.18 Remove and dispose of the used cassette.

5.3.3.19 Press Done to complete the test and return to the main [Select] screen. Press the on/off button for at least 2 seconds to switch Off the device.

5.3.4 Performing a Full Urinalysis Strip Test

5.3.4.1 Press the on/off button to switch On the device.

5.3.4.2 Press Strip Test to conduct urinalysis strip test.

5.3.4.3 Wait for the [Operator ID] screen to be displayed.

5.3.4.4 Choose between the Two options that are available under Operator ID i.e., Last Operator or Enter New Operator ID.

5.3.4.5 The last operator that entered his/her ID will be displayed on the screen if Last Operator option is enabled.

5.3.4.6 Press the Enter New Operator ID button to enter the information for a new operator if user is a new operator.

5.3.4.7 Use the keyboards to enter Operator ID using a maximum of thirteen characters.

5.3.4.8 Press Enter when finished entering the ID to move to the next screen.

5.3.4.9 Wait for the [Patient Information] screen to be displayed.

5.3.4.10 Choose between the two options that are available i.e. Recall Patient or Enter New Patient.

5.3.4.11 Press Recall Patient to look up previous patients.

5.3.4.12 A list of up to 200 patient results will appear on the screen if previous patient identification has been entered.

5.3.4.13 Press the Up and Down arrow buttons to scroll through the list of patients. The most recently performed test will be shown at the top.

5.3.4.14 Highlight the chosen patient.
5.3.4.15 Press *Select* button.
5.3.4.16 Press *Enter New Patient* button to enter the information for a new patient.
5.3.4.17 Use the keyboards to enter Patient Name using a maximum of 20 characters.
5.3.4.18 Press *Enter* when finished entering the patient’s name to proceed to the [*Patient Identification*] screen.
5.3.4.19 Use the keyboards to enter *Patient Identification* using a maximum of 13 characters.
5.3.4.20 Press *Enter* when finished entering the patient’s ID to proceed to the [*Prepare Test*] screen.
5.3.4.21 Insert a reagent strip in the test table facing upwards.
5.3.4.22 Get hold of test strip, urine sample and paper towel.
5.3.4.23 Dip the reagent strip into the urine sample, wetting all pads.
5.3.4.24 Immediately remove the strip from urine.
5.3.4.25 Drag edge of the strip against side of the sample container.
5.3.4.26 Blot edge of the strip to the paper towel to remove any excess urine.
5.3.4.27 Place reagent strip in the channel of the table with the test pads facing up.
5.3.4.28 Slide strip to end of the channel.
5.3.4.29 When the 8 second countdown finishes, the test table and strip will automatically be pulled into the analyser.
5.3.4.30 Press *START* button.
5.3.4.31 Wait for the eight second timer to be displayed for the following steps to be completed.
5.3.4.32 A timer will display the time remaining in analysing the results.
5.3.4.33 A [*Select Appearance*] screen will be displayed while the strip is being analysed.
5.3.4.34 Visualise the urine sample and select the appropriate colour and clarity.
5.3.4.35 Press the *Yellow and Clear* button if the urine sample is yellow and clear.
5.3.4.36 Press the *Other* button if the urine sample is not yellow and clear.
5.3.4.37 Choose the appropriate colour by touching the circle button that corresponds to the correct description. If the *Other* button is selected,
5.3.4.38 Select clarity by touching the circle that corresponds to the correct description.
5.3.4.39 Press *Next*.
5.3.4.40 the time remaining for the completion of strip analysis is indicated by a time indicator on the [*Select Appearance*] screen.
5.3.4.41 After colour and clarity have been selected the next screens displayed are either.
5.3.4.42 Analysing – if the strip is still being analysed.
5.3.4.43 Results – if the strip has been analysed completely.
5.3.4.44 A [Printing] screen will be displayed until the print out is completed if Automatic results printing has been set up.
5.3.4.45 The [Results] screen will appear if Automatic results printing has not been set up.
5.3.4.46 Wait for the first page of the test results to be displayed and the test table and strip to be automatically pushed out of the analyser.
5.3.4.47 Press More on the screen to view the remaining test results.
5.3.4.48 Press Print to print results if the analyser has not been set up to automatically print the test results.
5.3.4.49 Results will automatically be sent to the connected PC if this option is set up in the analyser.
5.3.4.50 Remove and dispose of the used urinalysis strip in a biohazard container.
5.3.4.51 Wipe the table insert, if necessary.
5.3.4.52 Press Done to complete the test and return to the main [Select] screen.
5.3.4.53 Press the on/off button to switch Off the device.

5.3.5 Performing a Full Urinalysis cassette Test (for Pregnancy)

5.3.5.1 Press the on/off button to switch on the device.
5.3.5.2 Press Cassette test to conduct hCG pregnancy test.
5.3.5.3 Wait for the [Operator ID] screen to appear.
5.3.5.4 Choose between the two options available under Operator ID i.e. Last Operator or Enter New Operator ID.
5.3.5.5 The last operator that entered his/her ID will be displayed on the screen if Last Operator option is enabled.
5.3.5.6 Press Enter New operator ID to enter the information for a new operator if New Operator
5.3.5.7 Wait for the [Enter Operator ID] screen to be displayed.
5.3.5.8 Use the keyboards to enter Operator ID using a maximum of thirteen characters.
5.3.5.9 Press Enter when finished entering the ID to move to the next screen.
5.3.5.10 Wait for the [Patient Information] screen to be displayed.
5.3.5.11 Choose between the two options available under Patient Information i.e. Recall Patient or Enter New Patient.
5.3.5.12 Press Recall Patient to look up previous patients.
5.3.5.13 A list of up to 200 patient results will appear on the screen if previous patient identification has been entered.
5.3.5.14 Press the Up or Down arrow buttons to scroll through the list of patients.
5.3.5.15 The most recently performed test will be shown at the top.
5.3.5.16 Highlight the desired patient.
5.3.5.17 Select the Select button displayed on touch screen.
5.3.5.18 To enter the information for a new patient, press [Enter New Patient] button.
5.3.5.19 Wait for the [Enter Patient Name] screen to be displayed.
5.3.5.20 Use the keyboards to enter Patient Name using a maximum of 20 characters.
5.3.5.21 Press Enter when finished entering the patient’s name to proceed to the next screen.
5.3.5.22 Wait for the [Patient Identification] screen to be displayed.
5.3.5.23 Use the keyboards to enter Patient Identification using a maximum of 13 characters.
5.3.5.24 Press Enter when patient’s ID has been entered.
5.3.5.25 Wait for the [Prepare Test] screen to be displayed.
5.3.5.26 Insert the reagent strip in test table insert facing upwards.
5.3.5.27 Get hold of a test strip, urine sample and paper towel.
5.3.5.28 Draw the urine sample to the line marked on the pipette (approximately 0.2 mL).
5.3.5.29 Add entire contents of the pipette into the sample well of the test cassette.
5.3.5.30 At the end of the 8 second countdown, test table and cassette will automatically be pulled into the analyser.
5.3.5.31 Press START button.
5.3.5.32 An eight second timer is displayed showing how much time is left to complete the following steps.
5.3.5.33 A timer will display the time remaining in analysing the results.
5.3.5.34 The [Printing] screen will be displayed until the print out is completed if Automatic results printing has been set up.
5.3.5.35 The [Results] screen will appear if Automatic results printing has not been set up.
5.3.5.36 The first page of the test results are displayed on the screen and the test table and cassette are automatically pushed out of the analyser.
5.3.5.37 Press More on the screen To view the remaining test results
5.3.5.38 Press Print to print results if the analyser has not been set up to automatically print the test results.
5.3.5.39 Results will automatically be sent to the connected PC if this option is set up in the analyser.
5.3.5.40 Remove and disposed of the used cassette.
5.3.5.41 Press *Done* to complete the test and return to main [*Select*] screen.
5.3.5.42 Press *on/off* button.

5.3.6 Performing a Urine Test for Microalbumin

5.3.6.1 See section 5.3.4

5.3.7 Recall Results

5.3.7.1 Press *Recall Results* from the main [*Select*] screen.
5.3.7.2 Wait for the test results to be displayed in chronological order. (The most recent test result is displayed at the top of the screen).
5.3.7.3 Use the up and down arrow keys to scroll through the list of patient tests.
5.3.7.4 Highlight the desired patient.
5.3.7.5 Press the *Select* button to view patient result details.
5.3.7.6 Press the *Print* button, if you would like to print the results.
5.3.7.7 Press *Done*, to return to the [*Select Text Results*] screen.
5.3.7.8 Press *Exit*, to return to the main [*Select*] screen.
5.3.7.9 Press the *Send all data* button, in order to send all results to the connected computer.

5.4 Quality Control

5.4.1 Quality Control Testing

5.4.1.1 Perform a quality control test with each new reagent bottle opened.
5.4.1.2 Verify if the results of the quality control test performed are positive, see Section 8 of the Clinitek® Status Analyser Manual, which contains Summary tables of the results from the waiver studies and physician office studies.

5.5 Maintenance

5.5.1 Cleaning of test table insert

5.5.1.1 Remove test table insert and thoroughly clean by rinsing both of its sides under running water.
5.5.1.2. Dry and re-insert test table insert.

5.5.2. Cleaning of test table

5.5.2.1. Slowly pull out the test table.
5.5.2.2. Lift the test table insert from the test table.
5.5.2.3. Drain the drip tray if necessary.
5.5.2.4. Wet a cotton-tipped stick with water and carefully clean test table (except for white calibration bar).
5.5.2.5. Dry the test table thoroughly (except for the white calibration bar) with a soft cloth or lint-free tissue.
5.5.2.6. Reinsert the test table into the device by holding the table at the end opposite the white calibration bar, with the white calibration bar facing upwards.
5.5.2.7. Push the test table firmly but slowly, just over halfway into the device.
5.5.2.8. Replace the test table insert.

5.5.3 Disinfecting the test table and test table insert

5.5.3.1 Wipe with an alcohol swab and air dry.

5.5.4 Cleaning the White Calibration Bar

5.5.4.1. Remove the insert from the test table.
5.5.4.2. Remove the test table by pulling it slowly out of the device.
5.5.4.3. Check the white calibration bar on the test table for dirt or discolouration.
5.5.4.4. If the calibration bar is dirty or discoloured, wipe and clean it with a new cotton-dipped stick or lint-free cloth wetted with distilled water.
5.5.4.5. Leave the calibration bar to air dry.
5.5.4.6. Inspect the surface for dust, scratches or any other foreign material.
5.5.4.7. Obtain a new test table if the calibration bar cannot be cleaned or is still marked.
5.5.4.8. Reinsert the test table by holding the table at the end opposite the white calibration bar, with the calibration bar facing upwards.
5.5.5 Cleaning the Outside of the Analyser

5.5.5.1. Press the on/off button, to turn Off the device.
5.5.5.2. Wipe the outside (including the display) with a damp (not wet) cloth and a mild detergent.

5.6 Troubleshooting

<table>
<thead>
<tr>
<th>Display Message</th>
<th>Cause/s</th>
<th>Solution/s</th>
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<tbody>
<tr>
<td>E01</td>
<td>Low battery power</td>
<td>- Replace batteries</td>
</tr>
<tr>
<td>“E10” or “E48”</td>
<td>Loss of test results</td>
<td>- Press the on/off button</td>
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<tr>
<td></td>
<td></td>
<td>- Switch the device on again, by re-pressing the button</td>
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<tr>
<td></td>
<td></td>
<td>- Repeat the test</td>
</tr>
<tr>
<td>E11</td>
<td>Failure of test table</td>
<td>- Ensure test table is in place</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Slightly move test table in or out of the analyser to re position the test table</td>
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<tr>
<td></td>
<td></td>
<td>- If error is still present, with the analyser powered on, unplug the power cord from rear of the device and plug back in</td>
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<tr>
<td></td>
<td></td>
<td>- Press the grey power button to turn the device on</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- If the error remains, contact local supplier</td>
</tr>
<tr>
<td>E23</td>
<td>Low battery power</td>
<td>- Replace batteries</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Press Error Report selection area to view the instructions on display</td>
</tr>
<tr>
<td>E24</td>
<td>No printer paper</td>
<td>- Replace printer paper</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Press Error Report selection area, to view the instructions on display</td>
</tr>
<tr>
<td>E25, E64 or E65</td>
<td>Failure of automatic calibration</td>
<td>- Clean calibration strip.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- If the error persists, contact local supplier</td>
</tr>
<tr>
<td>E27</td>
<td>Set up failure</td>
<td>- Press on/off button to switch off the device</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Press the on/off button again to switch on the device</td>
</tr>
<tr>
<td>E28</td>
<td>Printer error</td>
<td>- Lift printer cover and push paper holding arm back into position</td>
</tr>
<tr>
<td>Code</td>
<td>Issue Description</td>
<td>Resolution</td>
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</table>
| E50  | Incorrect strip type | - Ensure that correct strip type selected in *Instrument Set Up* is being used  
- If correct type of strip is being used, check the instrument operation by running another test using: a) a yellow and clear sample, or b) Chek-Stix<sup>®</sup> |
| E52  | Invalid barcode | - Repeat test using a Siemens® cassette |
| E53  | Strip Test selected but cassette detected | - Repeat test using the Cassette Test routine |
| E54  | Cassette test selected | - Repeat test using the Strip Test routine |
| E56  | Incorrect test table size | - Repeat test using the correct test table |
| E57  | Missing strip or cassette | - Repeat test ensuring that strip or cassette is positioned on the test table |
| E58  | Misplaced strip | - Repeat test ensuring that strip is correctly positioned on test table  
- If error persists and you are testing a urine dip strip, examine test table insert to ensure that the white calibration bar is present and not damaged.  
- If this white line is damaged or missing contact local supplier |
| E59  | Inverted strip positioned on the test table | - Repeat test to ensure that strip is correctly positioned on test table |
| E60  | Tilted strip | - Repeat test ensuring that the strip is correctly positioned on the test table |
| E61  | Dry strip | - Repeat test ensuring that the strip has been in contact with the sample |
| E63  | Failure to find end of strip | - Repeat the test ensuring that the strip is correctly positioned on the test table |
| E67 or E68 | Insufficient sample | - A sample flow issue with the cassette test may have been detected.  
- One or more of the test indicator
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<td>E02</td>
<td>Failure of calibration data</td>
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<tr>
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<td>E12</td>
<td>Failure of LED</td>
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<td>E20</td>
<td>Failure of clock</td>
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<td>E62</td>
<td>Light Ingress</td>
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<td>E03, E04, E05, E06, E07, E08, E21, E22, E90, E91, E92 or E93</td>
<td>Failure of computer software</td>
</tr>
</tbody>
</table>
5.7 Flow Charts

5.7.1. Set-Up – powering up, start up wizard

Start

Press on/off button

Start-up wizard will be displayed if it is the first time the instrument is turned on

Choose one of the following settings:
- Language
- Date and time
- Preferred test sequence (e.g. Quick Test or Full Test)
- Type of urinalysis strip
- Results format

After selecting your choice, the analyser displays a Confirmation screen

Ensure that no strip or cassette is present on the test table and that the table and insert are clean before turning off the instrument

Press on/off button

If a strip or cassette is present on the test table, the test table will be pushed out and the analyser will switch off

To retract the test table into the analyser, turn the analyser on, and then off (without a strip or cassette on the test table)

End
5.7.2. Operation

5.7.2.1. Quick or Full Urinalysis Strip Test

Start

Press on/off button

Yes

Carry out a Full Urinalysis Strip Test

No

Select The Preferred Test Sequence choosing Full Test

Press Strip Test from the Main Select screen

Select The Preferred Test Sequence choosing Quick Test

Press Strip Test from the Main Select screen

[Operator ID] screen will appear. Two options are available under Operator ID: Last Operator or Enter New Operator ID

Yes

Need to select the Last Operator

No

1

2

3
The last operator that entered his/her ID will be displayed on the screen. Press the Last Operator button to proceed.

If you are a new operator, press the Enter New Operator ID button to enter the information for a new operator.

Use the displayed keyboards to enter Operator ID using a maximum of thirteen characters.

Press Enter.

Need to select Recall Patient

Press the up and down arrow buttons to scroll through the list of patient then highlight the chosen patient.

Insert reagent strip in test table insert facing upwards

Have a test strip, urine sample and paper towel ready.
4. Dip the reagent strip into the urine sample, wetting all pads.

Immediately remove the strip from urine.

Drag edge of the strip against side of the sample container.

Blot edge of the strip to the paper towel to remove excess urine.

Place reagent strip in channel of the table with the test pads facing up.

Slide strip to end of the channel.

Press START button.

At the end of the 8 second countdown, test table and strip will automatically be pulled into the device.

While the strip is being analysed, a [Select Appearance] screen will be displayed.

The urine sample must be visually observed and the appropriate colour and clarity must be selected.

Select the appropriate corresponding colour and clarity then press Next.
Press More to view the remaining results

If not set up to print automatically, touch Print to print results

Remove and dispose of the used urinalysis strip and wipe test table insert, if necessary

Press Done to complete test and return to main [Select] screen

Press on/off button

End
5.7.2.2. Quick or Full Urinalysis Cassette Test

Start

Press on/off button

Yes

Carry out a Full Urinalysis Cassette Test

No

Select The Preferred Test Sequence choosing Full Test

Select The Preferred Test Sequence choosing Quick Test

Press Cassette Test from the Main Select screen

Press Cassette Test from the Main Select screen

[Operator ID] screen will appear. Two options are available under Operator ID: Last Operator or Enter New Operator ID

Need to select the Last Operator

The last operator that entered his/her ID will be displayed on the screen. Touch the Last Operator button to proceed

If you are a new operator, touch the Enter New Operator ID button to enter the information for a new operator

Use the displayed keyboards to enter Operator ID using a maximum of 13 characters

1

2

3
1. Press Enter

2. Need to select Recall Patient
   - Yes: Press the up and down arrow buttons to scroll through the list of patients and highlight the chosen patient.
   - No: Press Enter New Patient button.

3. Enter Patient Name, then press Enter. Enter the patient's ID number, then press Enter.

4. Draw the urine sample to the line marked on the pipette (approximately 0.2 mL).
   - Press START button. You have 8 seconds to complete the following steps:

5. Add entire contents of the pipette into the sample well of the test cassette. At the end of the 8 second countdown, the test table and cassette will automatically be pulled into the analyser.

6. The first page of the test results is displayed on the screen and the test table and cassette are automatically pushed out of the analyser.

7. Press More on the screen to view the remaining test results.
If not set up to print automatically, press Print to print results

The results will automatically be sent to the connected PC if this option is set up in the analyser

Remove and dispose of the used cassette

Press Done to complete the test

Press on/off button

End
5.7.3 Quality Control

Start

Perform a quality control test including negative and positive controls with each new reagent bottle opened

Yes

Need to perform a quality control test for Urinalysis Strips

Yes

Water should NOT be used as a negative control. Contact your Siemens® Healthcare representative for more information on performing QC testing

No

Refer to the quality control product insert for expected values for each analyte

No

Need to perform a quality control test for Urinalysis Cassettes

Refer to the Clinitek hCG cassette test package insert for appropriate quality control material

End
5.7.4 Maintenance

Start

Remove insert and clean by rinsing both sides of the table insert under running water

Yes

Need to routinely clean test table insert

No

Dry and replace insert

Remove the test table by pulling it out slowly. Lift the test table insert from the test table, drain the drip tray if necessary

Yes

Need to periodically clean test table insert

No

Wet a cotton-tipped stick with water and carefully clean test table (except for white calibration bar)

Dry the test table (except for the white calibration bar) with a soft cloth or lint-free tissue

Reinsert the test table into the analyser by holding the table at the end opposite the white calibration bar, with the white calibration bar facing upwards

Push the test table into the analyser

Replace the test table insert when required

1
1

Need to disinfect the test table and insert

Yes

Use Isopropyl alcohol (70%-80%) swabs and air dry

Do not use swabs on the white calibration bar

No

Remove the insert from test table after pulling out the test table from the analyser

Check the white calibration bar on the test table for dirt or discolouration

2
**UNIVERSITY OF MALTA**
**FACULTY OF MEDICINE & SURGERY**
**PHARMACY DEPARTMENT**

**STANDARD OPERATING PROCEDURE**

**CLINITEK STATUS® ANALYSER**

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<tbody>
<tr>
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<td>2 years from approval</td>
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</tbody>
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**2**

**The white calibration bar is clean and not marked**

- **Yes**
  - Replace the table into the analyser by holding the table at the end opposite the white calibration bar, with the calibration bar facing upwards
  - Replace the test table insert

- **No**
  - Wipe and clean it with a new cotton-dipped stick or lint-free cloth wetted with distilled water
  - Leave the calibration bar to air dry
  - Inspect the surface for dust, scratches or any other foreign material
  - The calibration bar is clean and not marked

  - **Yes**
    - Reinsert the test table by holding the table at the end opposite the white calibration bar, with the calibration bar facing upwards
  - **No**
    - Obtain a new test table

---
Press the on/off button to turn the analyser off

Wipe the outside (including the display) with a damp cloth and a mild detergent

Need to clean the outside of the analyser

Yes

No

Remove the test table from the analyser

Place the analyser on its side and remove the battery cover by pressing down on the tab and pulling out

Remove current batteries

Place 6 new AA-size batteries into the analyser

Replace the battery cover

End
6. Precautions

6.1. The device should be used at a temperature between 22°C and 26°C (72°F and 79°F).
6.2. Do not place the device near windows, ovens, hot plates, or radiators.
6.3. Do not remove the Check Cassette from its foil packaging. The Check Cassette should be available if the need to call local supplier for assistance with a device error arises.
6.4. Store cassette in the pocket located inside the back cover of the Operator’s Manual.
6.5. Push the test table half-way
6.6. into the analyser, but just half way, as the test table may become jammed.
6.7. Ensure that the test table and test table insert are clean before turning off the instrument.
6.8. Avoid touching the white calibration bar.
6.9. Do not use any solvents apart from distilled water to clean the white calibration bar.
6.10. Do not use anything hard or pointed to press the screen as this may cause damage.

7. References


8. Appendices

N/A

9. Revision History

<table>
<thead>
<tr>
<th>Version Number</th>
<th>Amendments/ Reasons for change</th>
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<tr>
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Page 29 of 29