1. **PURPOSE AND SCOPE**

The purpose of this document is to describe the procedure for performing a cardiac Troponin T (TnT) test using the Radiometer AQT90 FLEX analyser. The Radiometer AQT90 FLEX analyser can be used by healthcare professionals for measuring major cardiac blood markers. This document will be focusing on Troponin T, and further information on the other parameters can be found on their website.

2. **HAZARDS**

**Patient Samples**

All patient samples should be treated as potentially infectious and handled appropriately. Standard precautions should be employed. Gloves should be worn when processing samples, performing maintenance and troubleshooting procedures.

3. **CLINICAL SIGNIFICANCE**

Acute Coronary Syndrome (ACS) is a term used to describe a group of conditions resulting from insufficient blood flow to the heart muscle. These conditions range from atypical chest discomfort and non specific electrocardiographic changes to a large ST-segment elevation, myocardial infarction and cardiogenic shock. Symptoms can include chest pain including tightness and heaviness in the chest, discomfort in the arms and upper body, shortness of breath and other constitutional symptoms including sweating, nausea and light-headedness.

Diagnosis of ACS is based on a complete medical history, physical examination, electrocardiogram to evaluate the electrical activity of the heart and blood tests to evaluate the presence of biological markers resulting from cardiac cell injury.

Troponin T & I are members of a group of cardiac regulatory proteins which function to regulate the calcium mediated interaction of muscle filaments actin and myosin resulting in contraction and relaxation of striated muscle. Troponin T is almost exclusive to the myocardium, with small amounts expressed in skeletal muscle not detectable in current Troponin T assays. Insufficient blood flow and oxygen supply to the heart muscle causes necrosis of the myocardium and subsequent release of Troponin T & I into the bloodstream.

Troponin T in the bloodstream rises to detectable levels after 4-6 hours, peaks at 10-12 hours and can be detected for up to 14 days post infarction. Troponin I is released from necrotic cardiac myocytes into the bloodstream within hours (~4-8 hours) after the onset of chest pain. The peak TnI concentration is generally reached in 12-48 hours. Troponin I serum levels
can remain elevated for up to 4–7 days.\textsuperscript{5}

The diagnostic utility of Troponin T & I to detect myocardial necrosis and to enable risk stratification in patients with ACS is well established.\textsuperscript{5,8} Furthermore, the use of Troponin T as a prognostic indicator for recurrence of ischaemic events and death in ACS patients is increasing.\textsuperscript{5,9}

Results from PoCT devices measuring Troponin T & I should always be used in conjunction with clinical presentation, history and other diagnostic information.

4. \textbf{TEST PRINCIPLE}

All the reagents are provided in a dry, stable form within an assay test cup. In the assay process, the sample and the assay solution are automatically added to the cup containing the assay-specific reagents. During the incubation period, the tracer and capture antibodies form sandwich complexes with the Troponin T present in the sample. After the incubation, the assay cup is washed with the assay solution and dried. The signal from the tracer antibody is then measured by means of time-resolved fluorometry (TRF), directly from the dry surface of the assay cup. The concentration of the analyte in the blood is directly proportional to the measured signal. The measured signal is converted to a concentration using the calibration curve stored in the memory of the instrument.

4.1 \textbf{Interference}

No significant interference (< 20\%) was observed at the following concentrations for all analytes:

<table>
<thead>
<tr>
<th>Acetaminophen 12 mg/L</th>
<th>Indomethacin 16 mg/L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetylsalicylic acid 200 mg/L</td>
<td>Isosorbide dinitrate 4 mg/L</td>
</tr>
<tr>
<td>Allopurinol 240 mg/L</td>
<td>Lisinopril 16 mg/L</td>
</tr>
<tr>
<td>Amiodarone 20 mg/L</td>
<td>Lovastatin 16 mg/L</td>
</tr>
<tr>
<td>Ampicillin 200 mg/L</td>
<td>L-thyroxine 46 mg/L</td>
</tr>
<tr>
<td>Ascorbic acid 24 mg/L</td>
<td>Metyldopa 100 mg/L</td>
</tr>
<tr>
<td>Amlodipine Besylate 4 mg/L</td>
<td>Milrinone lactate 2.4 mg/L</td>
</tr>
<tr>
<td>Atenolol 40 mg/L</td>
<td>Nicotine 1.6 mg/L</td>
</tr>
<tr>
<td>Atorvastatin 32 mg/L</td>
<td>Nicotinic acid 4. Ng/L</td>
</tr>
<tr>
<td>Biotin 0.05 mg/L</td>
<td>Nifedipine 36 mg/L</td>
</tr>
<tr>
<td>Caffeine 30 mg/L</td>
<td>Nystatin 7 mg/L</td>
</tr>
<tr>
<td>Captopril 40 mg/L</td>
<td>Nitrofurantoin 40 mg/L</td>
</tr>
<tr>
<td>Chloramphenicol 50 mg/L</td>
<td>Nitroglycerin 0.16 mg/L</td>
</tr>
<tr>
<td>Clopidogrel Bisulfate 30 mg/L</td>
<td>Oxytetracycline 100 mg/L</td>
</tr>
<tr>
<td>Creatinine 110 mg/L</td>
<td>Phenytoin 40 mg/L</td>
</tr>
<tr>
<td>Cyclosporine 40 mg/L</td>
<td>Probenecid 200 mg/L</td>
</tr>
<tr>
<td>Diclofenac 60 mg/L</td>
<td>Procainamide 20 mg/L</td>
</tr>
<tr>
<td>Digoxin 0.040 mg/L</td>
<td>Propranolol 64 mg/L</td>
</tr>
<tr>
<td>Diltiazem 120 mg/L</td>
<td>Quinidine 20 mg/L</td>
</tr>
<tr>
<td>Dipyridamole 30 mg/L</td>
<td>Simvastatin 32 mg/L</td>
</tr>
<tr>
<td>Dopamine 130 mg/L</td>
<td>Spironolactone 40 mg/L</td>
</tr>
</tbody>
</table>
Enalapril Maleate 16 mg/L
Erythromycin 100 mg/L
Furosemide 16 mg/L
Heparin 8 IU/mL
Hydralazine 20 mg/L
Hydrochlorothiazide 20 mg/L
Sulfamethoxazole 320 mg/L
Theophylline 40 mg/L
Trimethoprim 64 mg/L
Verapamil 96 mg/L
Warfarin 4 mg/L

• No hook effect was found when TnT concentrations up to 100,000 ng/L were measured.
• Carry over from a sample with high TnT value (100,000 ng/L) to an adjacent negative sample was determined to be < 100 ppm
• To minimize any potential interferences from HAMA (human anti-mouse antibodies), mouse IgG was added as a blocker substance.

Important! It is possible that other substances and/or factors not listed above may interfere with the test and cause false results.

4.2 Accuracy

This product fulfills the requirements of the EU Directives. The AQT90 FLEX TnT assay (y) was compared to the commercially available cardiac troponin T assay TnT for the Roche Elecsys 2010 system (x) using lithium-heparin plasma samples in the range of 0-25 µg/L (with the AQT90 FLEX TnT assay). The correlation (Passing-Bablok) was found to be: y = 0.980x – 0.0004; R² = 0.9928 (n = 214).

4.3 Precision

Within-day and total imprecision was determined by analysing plasma pools over 20 days, twice a day, 2 replicates per run.

<table>
<thead>
<tr>
<th>Sample</th>
<th>Mean µg/L</th>
<th>SD µg/L</th>
<th>% CV</th>
<th>Sample</th>
<th>Mean µg/L</th>
<th>SD µg/L</th>
<th>% CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plasma pool 1</td>
<td>0.027</td>
<td>0.0023</td>
<td>8.5</td>
<td>Plasma pool 1</td>
<td>0.027</td>
<td>0.0026</td>
<td>9.6</td>
</tr>
<tr>
<td>Plasma pool 2</td>
<td>0.21</td>
<td>0.0073</td>
<td>3.5</td>
<td>Plasma pool 2</td>
<td>0.21</td>
<td>0.0116</td>
<td>5.6</td>
</tr>
<tr>
<td>Plasma pool 3</td>
<td>12.0</td>
<td>0.343</td>
<td>2.9</td>
<td>Plasma pool 3</td>
<td>12.0</td>
<td>0.644</td>
<td>5.4</td>
</tr>
</tbody>
</table>

5. INSTRUMENT
# Product specifications

## 5.1 Operating Conditions and Technical Data

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Temperature range</strong></td>
<td>15° – 32°C</td>
</tr>
<tr>
<td><strong>Relative humidity</strong></td>
<td>20 - 80% (non-condensing)</td>
</tr>
<tr>
<td><strong>Maximum altitude</strong></td>
<td>2000m</td>
</tr>
<tr>
<td><strong>Position</strong></td>
<td>Place analyser on a level, vibration-free surface with ample working space in front and on the sides for cooling; with easy access to the main power off switch</td>
</tr>
<tr>
<td><strong>Measuring range</strong></td>
<td>10 - 25,000 ng/L</td>
</tr>
<tr>
<td><strong>Sample size</strong></td>
<td>2 mL</td>
</tr>
<tr>
<td><strong>Test time</strong></td>
<td>Approx. 12 minutes</td>
</tr>
<tr>
<td><strong>Memory</strong></td>
<td>2000 patient test results, 1000 calibration tests, 99 LQC setup solutions</td>
</tr>
<tr>
<td><strong>Barcode scanner</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Interface</strong></td>
<td>RS232, 9-pin subD connector. 5V is available at pin 9 for supply of external barcode reader; 3 USB 2.0 ports; Ethernet RJ45 connector, 10/100Mbit/sec; Keyboard/mouse port; external VGA screen port.</td>
</tr>
<tr>
<td><strong>Battery operation</strong></td>
<td>No</td>
</tr>
<tr>
<td><strong>Mains connection</strong></td>
<td>Yes – 100 - 240 V ± 10%; 50/60Hz ± 5%</td>
</tr>
<tr>
<td><strong>Number of tests with battery</strong></td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Safety class</strong></td>
<td>Class A</td>
</tr>
<tr>
<td><strong>Automatic power-off</strong></td>
<td>No – normally analyser is kept permanently switched on</td>
</tr>
<tr>
<td><strong>Dimensions</strong></td>
<td>450 x 460 x 480 mm</td>
</tr>
<tr>
<td><strong>Weight</strong></td>
<td>35 kg</td>
</tr>
</tbody>
</table>

## 5.2 Storage and transport conditions

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Temperature range</strong></td>
<td>-20° to +60°C</td>
</tr>
<tr>
<td><strong>Meter (In original container)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Relative humidity</strong></td>
<td>20 - 80% (non-condensing)</td>
</tr>
</tbody>
</table>
6. SPECIMEN REQUIREMENTS

6.1 Sample Material
Venous or arterial whole blood collected in EDTA or lithium-heparin tubes or plasma specimens are acceptable. Blood collection tubes containing gels or other additives are not recommended. Samples are stable for 3 hours at 22 - 25°C. Do not freeze whole blood samples.

Venepuncture (see suitable anticoagulants above)
• Skin surface must be cleaned with an alcohol swab and dried well prior to collection to ensure there are no substances on the skin surface
• Mix the sample immediately after collection by gently inverting the tube several times to dissolve the anticoagulant.
• Samples should be tested as soon as possible after their collection
• Do not collect sample from the same arm receiving an infusion solution
• The minimum sample volume is 2 mL (independent of the number of AQT90 FLEX tests required).

7. CARTRIDGES/REAGENTS

7.1 Storage and handling
• Each Test Cartridge contains 16 analyte-specific assay cups, thus can run 16 tests.
• The TnT test cartridges should be stored unopened at 2° - 8°C, until the expiry date.
• The test cartridge pouch should only be opened just before the cartridge is inserted into the analyser.
• The TnT Test Cartridge is stable for up to 10 days onboard the analyser
• The TnT CAL cartridges should be stored unopened at 2° - 8°C, until the expiry date.
• The TnT CAL Cartridge is stable for up to 1 day onboard the analyser
• The Blank Cartridge (for system cleaning) should be stored unopened at room temperature for up to 12 months.
• The Blank Cartridge is stable for up to 12 months onboard the analyser
• The Reagent Pack contains assay buffer for up to 200 tests and closed receptacles to contain discarded cups and liquid waste. The same Reagent Pack is used for all assays.

NOTE: A number of activities, i.e. needle clean and startup will reduce the buffer and thus the number of tests.
• Store the unused Reagent Pack at 2-32 °C until the expiration date stated on the label.
• The Reagent Pack is stable for up to 25 days once inserted into the analyser.
• During transport, the Reagent Pack can be kept at up to 40 °C for a maximum of 2 weeks
• Cleaning Solution Tubes should be stored refrigerated at 2° - 8°C, up to 4 months and for single use only.

NOTE: Do not use any cartridge that has not been kept according to...
storage specifications or that has been damaged or taken out of its protective pouch.

7.2 Storing information about test cartridges
Test cartridges have a barcode on one side, which contains the lot-specific information for that cartridge. Test Cartridges with a new lot number can only be used after a successful calibration adjustment procedure has been performed using a CAL Cartridge with the same lot number.

8. CALIBRATION

Calibration of the AQT90 FLEX TnT assay is comparable to calibration of the TnT assay for the Roche Elecsys 2010 system. The assay has been factory-calibrated. Factory-calibration data is provided in the form of a barcode in parameter-specific Test Kits or CAL Cartridge boxes.

8.1 Calibration Adjustment procedure
The calibration adjustment process adjusts the factory-defined calibration data to the specific instrument used and thus it determines the accuracy with which the analyser measures its parameters. A calibration adjustment procedure must be performed:

• Every time a parameter-specific test cartridge with a new lot number is used
  NOTE: If not performed, the analyser will request it as soon as it detects the Test Cartridge.
• As often as stated in relevant regulations.

To perform a calibration adjustment measurement
• Press ‘Analysers status’ then ‘Consumables’,
• In the Reagent Pack table, check that the Cup capacity is at least 16, if <16, replace the Reagent Pack
• Find the CAL Cartridge in the Test Kit box with the new lot number.
• Open the pouch and inspect the CAL cartridge to make sure that it has not been damaged
• In the "Consumables" part of the Analyser status screen, press ‘Insert/Replace’ then ‘Insert/replace cartridge’
• The cartridge inlet door opens and with its barcode facing downwards, load the CAL Cartridge into the cartridge inlet
• Scan the barcode from the "TnT Factory-defined Calibration Data" sheet provided in the Test Kit box.
• Data stored in the barcode is read into the analyser and shown on the screen and press ‘Accept’ then press ‘Start Calibration’
• The main screen appears with a pop-up message indicating that the calibration adjustment procedure will start automatically in 10 seconds and press ‘OK’.
• The Main screen showing a link to the calibration adjustment procedure appears.
• Press the document icon to view the calibration adjustment measurement details
• The result is shown as soon as it becomes available and the procedure takes approx. 48 minutes to complete
• When the procedure is completed, remove the CAL cartridge from the analyser by pressing ‘Analyser status’, ‘Consumables’, ‘Insert/Replace’ and then ‘Insert/replace cartridge’.
• The cartridge inlet door opens and removes the CAL cartridge from the cartridge inlet and dispose of in the bio hazardous waste.

9. QUALITY CONTROL

9.1 Quality control material (perform as per your organisation protocol)

Accurately testing known levels of Troponin T ensures that the system and your technique used in testing give accurate results on patient tests. The control solutions have defined (known) values. The results for these solutions must first fall within a certain acceptable range in order to allow valid patient testing.

A quality control test should be performed every time a new shipment of test cartridges are received, when a new lot number of test cartridges are used, after a calibration adjustment procedure has been performed if the clinical picture does not correlate with the patient test results, after major maintenance, and at a minimum of once a month.

Enrolling in an External Quality Assurance Program is encouraged to objectively compare results with other users using the same method of testing. If an External Quality Assurance Program is not available, monthly lab comparison is encouraged.

System check
The analyser has an automatic built-in QC Check, and the analyser can also perform a system check on demand, which includes all environmental checks and process checks that can be performed without a sample.

To perform a system check
• Press ‘Menu’ then ‘Analyser status’
• Press ‘QC’
• Press ‘Start system check’
• When the check is complete, the results are automatically stored in the system-check log.

Control solutions
The liquid quality control (LQC) solutions has three levels:
• LQC TnT-CHECK level 1 (TnT1)
• LQC TnT-CHECK level 2 (TnT2)
• LQC TnT-CHECK level 3 (TnT3)

Each control level contains 6 tubes. Store the control solutions below
-18°C. The control solutions are stable up to the stated expiration date, when stored unused below -18°C. Once thawed, the control solutions are stable for 3 days if stored unused at 2-8°C; or stable for maximum of 1 hour if stored unused at room temperature. Do not refreeze solutions.

9.2 Setup for a liquid quality control solution

- Before a liquid QC (LQC) can be performed with any QC solution, a LQC must be created for it.
- The LQC setups are parameter specific and lot number specific
- Every time the lot number of a particular type of LQC solution changes, a new LQC setup needs to be created.

Setup for a Radiometer LQC solution

- Press ‘Menu’ > ‘Utilities’ > ‘Setup’ > ‘LQC Setup’ > ‘LQC’
- Select an unused number in the position column
  **NOTE:** ‘Position’ is the number that tells the analyser where to store setup data for the LQC solution. Only one setup can be created for a LQC solution with a specific Solution name and Lot no.
- Scan the 2 barcodes on the slip of paper in the LQC kit
- The data stored in the barcodes is stored in the selected position
  **NOTE:** If a ‘used’ position was selected, it will delete all statistical data for the LQC configured in the selected position.
- To assign the LQC solution name, press ‘Edit setup’ and enter the name in the ‘LQC name’ text box.

Setup for a Non-Radiometer LQC solution

- Press ‘Menu’ > ‘Utilities’ > ‘Setup’ > ‘LQC Setup’ > ‘LQC’
- Select an unused number in the ‘Position’ column
  **NOTE:** ‘Position’ is the number that tells the analyser where to store setup data for the LQC solution. Only one setup can be created for a LQC solution with a specific Solution name and Lot no.
- Press the ‘Add Non-R-’ button and select the same position as in the previous step
  **NOTE:** If a ‘used’ position was selected, it will delete all statistical data for the LQC configured in the selected position.
- To assign the QC solution name, press ‘Edit setup’ and enter the name in the ‘LQC name’ text box.
- In the ‘expiry date’ text box, enter the expiry date of the QC solution
- To enter the limits for the control ranges for a specific parameter, select the relevant parameter, press ‘Edit (2)’ and enter the relevant values in the ‘Assigned’ textboxes

9.3 Running a Radiometer control solution

Preparing the control solution

- Remove the LCQ solution from the freezer and let it thaw at room temperature (a maximum of 30 minutes) and use immediately.
  **NOTE:** Do not refreeze solution.
Inserting the Radiometer LQC sample
• With the analyser turned on, press ‘Introduce sample’ and the sample inlet doors open.
• Place your LQC sample tube in the sample inlet with its barcode facing downwards.
• The LQC identification screen appears showing all the data associated with the LQC sample.
• Press ‘Accept’ and the Pre-selected LQC tests screen appears showing the parameter(s) that are included in the setup created for this LQC solution.
• Press ‘Start’ to begin the analysis.

Results
• In the main screen, press the ‘document’ icon for the LQC to view the measurements in progress.
• The LQC result screen appears. Results are shown as soon as they become available.
  **NOTE:** A progress bar is shown alongside each parameter with an estimate of how long (in minutes:seconds) each test will take to complete.
• To print the results of the completed LQC tests, press the ‘Print’ button and then press ‘Close’
• As soon as the last test in the LQC measurement is complete, the link to the LQC measurement is removed from the main screen. LQC results are stored and can be viewed in the LQC log.
Remove the LQC tube

- When the analyser mode changes to either "Ready", "Ready for sample registration" or "Ready for sample registration and cartridge replacement mode", press ‘Menu’, then ‘Remove tube’.
- The inlet doors open and remove the tube from the inlet and dispose of it in the biohazardous waste
- Press ‘OK’ and the inlet doors close.

9.4 Running a non-Radiometer control solution

Preparing the control solution

- Prepare the quality control solution as described in the insert enclosed with the control solution.

Preparing an LQC sample tube

- Determine the volume of LQC solution you require (One parameter: 400 µL; Two parameters: 450 µL; Three parameters: 500 µL; Four parameters: 550 µL; Five parameters: 600 µL)
- Remove the opal plastic cap from the outer tube and then remove the rubber septum from the inner tube.
- Use a pipette to transfer the relevant volume of LQC solution into the inner tube.
- Replace the rubber septum on the inner tube and place the opal plastic cap over the outer tube and press it down until it clicks into place.
- The tube is now ready for use in a LQC test procedure

Inserting the non-Radiometer LQC sample

- With the analyser turned on, press ‘Introduce sample’ and the sample inlet doors open.
- Place your LQC sample tube in the sample inlet

NOTE: If a tube is sitting in the inlet, remove it and place your sample tube
in the inlet.

- Press ‘LQC ID’ and the LQC identification screen appears
- Select the LQC ID setup created for the Non-Radiometer LQC solution

**NOTE:** The analyser counts every LQC measurement it makes and attaches a unique number to each measurement. The LQC number is displayed at the top center of the screen.

- Press ‘Accept’ and the Pre-selected LQC tests screen appears, showing the parameter(s) that are included in the setup created for this LQC solution.
- Press ‘Start’ to begin the analysis and the main screen appears showing the link to the measurements

### Results

- In the main screen, press the ‘document’ icon for the LQC to view the measurements in progress.
- The LQC result screen appears. Results are shown as soon as they become available.

**NOTE:** A progress bar is shown alongside each parameter with an estimate of how long (in minutes:seconds) each test will take to complete.

- To print the results of the completed LQC tests, press the ‘Print’ button and then press ‘Close’
- As soon as the last test in the LQC measurement is complete, the link to the LQC measurement is removed from the main screen. LQC results are stored and can be viewed in the LQC log.
Remove the LQC tube

- When the analyser mode changes to either "Ready", "Ready for sample registration" or "Ready for sample registration and cartridge replacement mode", press 'Menu', then 'Remove tube'.
- The inlet doors open and remove the tube from the inlet and dispose of it in the bio hazardous waste.
- Press 'OK' and the inlet doors close.

10. TEST PROCEDURE

Measurements cannot be performed if the Reagent Pack is full. Check for messages relating to the Reagent Pack cup capacity at least once a day.

10.1 Performing the Test

- If prompted, log on by entering your Operator ID and password.
- Touch the 'Introduce Sample' button on the screen.
- The doors to the sample port will open automatically.
- Make sure the cap on the sample tube is firmly in place, and with the cap-side upwards, gently place the sample tube in the bottom of the tube holder and press the upper part of the tube until it clicks in place between the tabs. Use only 5 mL size vacutainers.
NOTE: The analyser requires a minimum sample volume of 2 mL, irrespective of the number of tests to be run on it.

- Enter the patient details in the patient identification fields using the touch screen and/or scan barcode in the required field(s)
  
  NOTE: You must enter data in all mandatory fields before you can continue; however the sample tube type will be entered during the following steps

- Touch the ‘Accept’ button on the screen to verify patient details

- Select the tube type by touching the screen – EDTA purple cap, lithium heparin green cap.

- Select the required tests i.e. TnT
  
  NOTE: A maximum of 5 tests can be selected.

  ![Image of the analyser interface]

- Press the ‘Start’ button
  
  NOTE: Do not remove or replace a tube immediately after you have pressed ‘Start’

- The sample inlet doors close and the analyser rotates the sample to mix it thoroughly before aspirating for measurement.
  
  NOTE: No new measurements can be started until the operating mode of the analyser changes to ‘Ready’, ‘Ready for sample registration’ or ‘Ready for sample registration and cartridge replacement’.

- It takes 2 minutes for the analyser to aspirate a sample and start a test, so if the analysis included only one test, you will be able to start analysis of a new sample 2 minutes after the start of the analysis.

Results

- A results link appears on the main screen with the estimated time to completion. When the measurement is completed, the ‘Time to result’ field will be empty

- The patient results will automatically print out once complete (first result after 10-20 minutes (test dependent), each subsequent test 2 minutes thereafter). Time to completion is displayed on the screen.
Remove a sample tube
- Press ‘Menu’, then ‘Remove tube.
- The inlet doors open and remove the tube from the inlet
- Press ‘OK’ and the inlet doors close.

11. RESULTS

11.1 Measuring Range
The measuring range is 10 - 25,000 ng/L.

11.2 Interpretation of results

<table>
<thead>
<tr>
<th>Troponin T Concentration</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Below 50 ng/L</td>
<td>Acute myocardial infarction not likely, but still possible; in context of clinical assessment repeat the test (e.g. after 3–6 h) to detect rising Troponin T levels.</td>
</tr>
<tr>
<td>Between 50 ng/L and 100 ng/L</td>
<td>Acute myocardial infarction possible, repeat the test to detect rising Troponin T levels in context of clinical assessment according to guidelines; search for differential diagnosis and other causes of Troponin T elevation.</td>
</tr>
<tr>
<td>Between 100 ng/L and 2000 ng/L</td>
<td>Acute myocardial infarction likely; consider differential diagnosis for other causes of Troponin T elevation.</td>
</tr>
<tr>
<td>Above 2000 ng/L</td>
<td>Acute myocardial infarction very likely; consider differential diagnosis for other causes of Troponin T elevation.</td>
</tr>
</tbody>
</table>

11.3 Transferring Data to a printer or computer
- Results can be printed from the in-built printer once the test is complete
- Data can also be transferred to the computer/LIS/HIS/local database

12. MAINTENANCE

- The color of the traffic-light signal in the ‘Consumables’/‘Maintenance’/‘System messages’ buttons in the Analyser status screen will change color when these require attention.
- Do not open the cover of the instrument if blood is spilled inside the
analyser. Call your Radiometer representative and have a service technician clean the instrument.

- Clean the analyser covers and outer case with a soft lint-free cloth moistened with soapy water or a mild detergent
- Clean the touch screen by gently wiping it with either a dry or a soft lint-free cloth lightly dampened with a 70% isopropanol solution. Do not use an aerosol or liquid cleaner to clean the touch screen of the analyser.

12.1 Viewing the status of consumables

- Either press ‘Menu’ then ‘Analyser status’ or press ‘Analyser status’ on the main screen.
- Press ‘Consumables’ to view information about the cartridges and Reagent Pack

For the Reagent Pack you can view:
- “Reagent Pack lot info” – lot number of the pack
- “Installation date” – the date the pack was installed in the analyser
- “On-board expiry date” – after this date the Reagent Pack will not be used
- “Cup capacity” – after every measurement the used cups are disposed in the reagent pack. The number in the column tells you how many more cups can still be disposed of in the pack
- Press “Detailed inventory”

For the cartridges you can view:
- Parameter
- Remaining tests
- Lot information
- On-board expiry date (a cartridge cannot be used after this date)
- Type (Test or CAL Cartridge)
- Status (Valid or invalid)
- Calibrated (whether the cartridge has been calibrated, or not).

12.2 Replacing a Reagent Pack

- Press ‘Analyser Status’ on the main screen
- Press ‘Consumables’ then ‘Insert/Replace’, then ‘Replace Reagent Pack’.
- Pull out the old Reagent Pack that has been ejected and dispose of it in the biohazardous waste

- Remove the top label on the new Reagent Pack to expose the biohazard symbol and slide the pack into the reagent pack slot on the analyser
- The analyser reads the information on the pack and displays its lot number, on-board stability date and the cup capacity.
- Press Accept.

NOTE: If the Accept and Cancel buttons do not appear on the screen,
press Eject on the Replace Reagent Pack screen and re-insert the Reagent Pack

- The analyser flushes out the old buffer from the tubes and circulates buffer from the new Reagent Pack. During this process, which takes approximately 2 minutes, measurements cannot be performed.

12.3 Replacing a Test Cartridge

- The analyser knows the expiry date for each inserted cartridge. It also knows how many used cups each cartridge contains. If the cartridge wheel is full (maximum 15 cartridges) during an insert/replace cartridge procedure it will eject a cartridge before a new one can be inserted in the following order: a cartridge that contains no cups (a used-up or empty cartridge); then an expired cartridge.
- Press Analyser status on the main screen.
- Press ‘Consumables’ then ‘Insert/Replace’, then ‘Insert/replace cartridge’.
- Wait for the analyser to locate a free slot or eject a used or expired cartridge
- The cartridge will be ejected, and dispose of it in the bio hazardous waste

**NOTE**: An ejected cartridge can be re-used on the same analyser if its expiry date is not exceeded and it still contains unused cups
- Insert a new cartridge with its barcode facing downwards
- A barcode reader in the analyser reads the barcode on the new cartridge and displays the cartridge information
- The analyser keeps a check on the test cartridge’s expiry date
- Press ‘Accept’ to accept the new cartridge and the cartridge inlet closes
- Press ‘Close’ and it returns to the main screen

12.4 Replacing/removing a specific test cartridge
• This procedure must be followed if you need to remove a specific cartridge, or the analyser contains its maximum number of cartridges (15) and none of them are empty, and none of them have exceeded their expiry date:
  • Press ‘Analys er status’ on the main screen. The Analyser status screen appears.
  • Press ‘Consumables’ then ‘Detailed inventory’ to see a list of all the cartridges in the analyser.
  • Select the desired cartridge and press ‘Insert/replace cartridge’. The selected cartridge is ejected.
  • Remove the ejected cartridge and dispose of it as bio hazardous waste.
  • Insert a new cartridge with its barcode facing downwards.
  • A barcode reader in the analyser reads the barcode on the new cartridge and displays the cartridge information.
  • Press ‘Accept’ to accept the new cartridge and the cartridge inlet closes.

12.5 Replacing Printer Paper
• Press the release button to release the printer cover and remove any leftover paper from the printer.
  NOTE: To prepare the new roll, tear off and discard approximately the first 25 cm of paper and cut the leading edge of the paper straight.
• Place the new roll in the printer so that the paper unreels from underneath the roll and the thermal side of the paper is on the outside of the roll.
• Extend the leading edge of the paper beyond the lip of the printer cover. The paper will feed through the printer automatically once the internal sensor detects the edge of the paper.
• Realign if required.
• Close and press the two ends of the printer cover until it locks itself.

12.6 System Clean
• System clean is a procedure that cleans the sample-handling section of the liquid-transport system of the analyser and should be performed every 200 test episodes (available with software version 8.3 onwards).
  • Press ‘Introduce sample’.
  • Place the Cleaning Solution Tube in the inlet with its cap-side upwards, and its barcode facing downwards until it “clicks” in place between the tabs.
  NOTE: The Cleaning Solution Tubes contains approx. 5% hypochlorite w/v and for single use only.
• The analyser checks that it has the materials it needs to perform a system-cleaning procedure. If it does not, a pop-up window appears to tell you what you need to do before the procedure can be performed.
  NOTE: The system clean needs a Blank Cartridge containing at least one empty cup and no reagents; and enough buffer in the Reagent Pack (the Reagent Pack Cup capacity must ≥2).
  • Press ‘Accept’.
  • The ‘Time to result’ is shown in the link that appears on the Main screen, and the cleaning cycle takes approx. 6.5 minutes to complete.
  ALTERNATIVELY: You can also start a system clean procedure as follows: Press ‘Menu’, ‘Analys er status’, ‘Maintenance’, ‘Maintenance...’.
details' and then press the ‘System clean' button. The analyser will check that it has the materials it needs for the procedure, before prompting you to insert a Cleaning Solution Tube

• The Solution Cleaning Tube should be removed and discarded immediately after use.

13. REFERENCES

This method has been adapted from the Radiometer Operator’s Manual, Reference Manual, reagent pack, test cartridges and control solution package inserts.


