cobas h 232 POC system

Facilitate your clinical decisions with rapid results

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Facilitate your clinical decisions with rapid results

Thanks to its small, portable design, the **cobas h** 232 POC system can be easily deployed near the point of patient care where space is tight, be it at the bedside, in triage bays or a designated lab area. The instrument is intended to be used in emergency care settings or CCU for patients presenting with acute chest pain, dyspnea and other symptoms suggestive of acute cardiovascular diseases. Studies have proven the effectiveness of cardiac marker testing with the **cobas h** 232 POC system in physician office settings, in particular where the use of NT-proBNP is supporting the diagnosis and assessment of heart failure.[10] The system can also be used in pre-hospital settings like ambulances or helicopters.

The cobas h 232 POC system fits to:

- **Emergency department**
- **Intensive care unit**
- **Physician's office**
- **Patient's home visits by a physician**
- **Ambulance**
- **Outpatient settings**
- **Remote emergencies**

Examples of expertise in action

- **Troponin T in chest pain** – the 'Gold Standard' biomarker whose detection is a strong indicator of myocardial damage[5]
- **Myoglobin/CK-MB in chest pain** – two biomarkers with diagnostic potential (re-infarction) early after the onset of symptoms[5]
- **NT-proBNP in dyspnea** – now widely used, this biomarker can improve the diagnostic accuracy of acute heart failure in patients presenting with ambiguous or confusing symptoms[5]
- **D-dimer in venous thromboembolism** – a reliable and sensitive biomarker for the exclusion of PE or DVT diagnosis in symptomatic outpatients[2]

"The next decade will undoubtedly see a vibrant co-evolution of cardiac biomarkers and POC testing as the vanguard of cardiac diagnostics"

McDonnell, B., et al., Clinical Biochemistry 2009[5]

"Vein to Brain" in less than 15 minutes

Simple three step testing for rapid results

Insert strip

Apply sample

Read the result

Using the **cobas h** 232 POC system a blood sample can be analyzed on the spot and accurate results will be delivered in only 15 minutes.

The National Academy of Clinical Biochemistry guidelines recommend:

- *"the laboratory should perform cardiac marker testing with a turnaround time (TAT) of 60 minutes, optimally 30 minutes or less. The TAT is defined as the time from blood collection to the reporting of results."* [6]

- *"Institutions that cannot consistently deliver cardiac TATs of one hour or less should implement POC testing devices."* [6]

Point of Care (POC) improves turnaround time

Comparison of POC and central laboratory turnaround times (TAT) in cardiac markers
The overall gain in time from POC testing compared with central laboratory measurements was 65 minutes (range 34-135 minutes).[7]

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cobas h 232 POC system realizes POC benefits

- Enables fast patient stratification
- Accelerates moving patients to the right place
- Ensures valuable resources are focused on those patients who need it the most
- Cost-effective due to improvements in workflow[8,9]

cobas h 232 POC system is easy to use

- No sample preparation
- Automatic calibration
- No complicated setup procedures: intuitive, icon-based interface
- Maintenance-free

cobas h 232 POC system is highly versatile

- Lightweight, compact and portable: the instrument can be moved once the test strip has fully absorbed the sample
- Stand alone or connected to IT system
- Configurable software for individual needs
- Easy handling thanks to intuitive user guidance

cobas h 232 POC system is reliable

- Roche CARDIAC assays are validated by clinical studies and comparable to Roche laboratory methods (allowing seamless follow-up testing)[1-4]
- Use of patient and user ID allows to properly document test results

Enhanced expert analysis and expertise

Rapid results delivered by the cobas h 232 POC system can augment the decision process and clarify next steps

- Helps to rule in and to identify the critically ill patient
- Enables prioritization of those patients for whom early intervention is critical
- Confirmatory diagnosis avoids unnecessary referral to ICU
- Gives comfort to your patients and the family members by reassurance

The capabilities of the cobas h 232 POC system can be further enhanced when connected to the comprehensive cobas IT 1000 data management system

- Additional functions e.g. remote set up, patient and operator lists
- Electronic storage of test results in central patient record
- Controlled access to **cobas h** 232 POC system only for trained and certified operators supports quality results and avoids unmonitored overuse
- Connection to other data management solutions and the HIS/LIS

References

1. Zugck, C. et al. (2006). Multicentre evaluation of a new Point of Care test for the determination of NT-proBNP in whole blood. *Clin Chem Lab Med; 44(10):* 1269-1277.
2. Dempfle, C.E. et al. on behalf of the CARDIM study group. (2006). Sensitivity and specificity of a quantitative Point of Care D-dimer assay using heparinized whole blood, in patients with clinically suspected deep vein thrombosis. *Thromb Haemost; 95:* 79-83.
3. Derhaschnig, U. et al. for the CARMYT Multicentre Study Group. (2004). Diagnostic efficiency of a Point of Care system for quantitative determination of troponin T and myoglobin in the coronary care unit. *Point of Care; 3(4):* 162-164.
4. Bertsch, Th. et al. (2010). Multicentre evaluation of a new Point-of-Care System for the determination of Cardiac and Thromboembolic Markers. *Clin: Lab 56 (1-2):* 37-49.
5. McDonnell, B. et al. (2009). Cardiac biomarkers and the case for Point of Care testing. *Clinical Biochemistry; 42:* 549-561
6. Nichols, J.H. (2006). National Academy of Clinical Biochemistry Laboratory Medicine Practice Guidelines: evidence based practice for point of care testing. *Washington, DC: AACC Press.*
7. Gaze, D. et al. (2004). The Use of a quantitative Point of Care system greatly reduces the turnaround time of cardiac marker determination. *Point of Care; 3(4):* 156-158.
8. Collinson, P.O. et al. (2004). A prospective randomized controlled trial of Point of Care testing on the coronary care unit. *Ann Clin Biochem; 41:* 397-404
9. Apple, F.S. et al. (2006). Decreasing patient charges following implementation of Point of Care cardiac troponin monitoring in acute coronary syndrome patients in a community hospital cardiology unit. *Clinica Chimica Acta; 370:* 191-195.
10. Tomonaga, Y. et al. (2011). Diagnostic accuracy of point-of-care testing for acute coronary syndromes, heart failure and thromboembolic events in primary care: a cluster-randomised controlled trial. *BMC Family Practice 2011,* 12:12.

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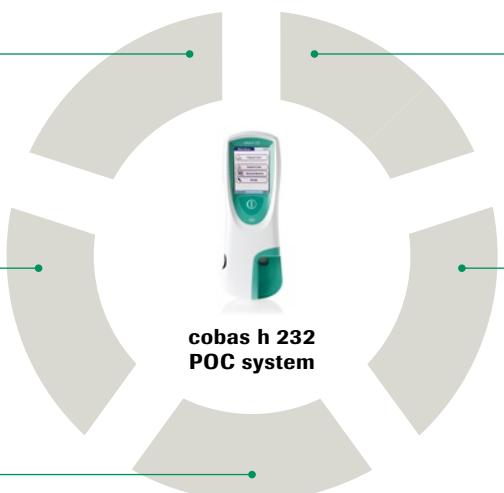
Improved features of the cobas h 232 POC system

New software release

New features at a glance



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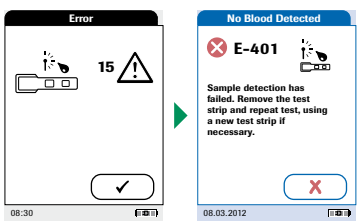
Improved features of the cobas h 232 POC system

New software release

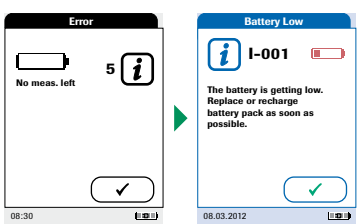
New dialog function



Old version *New version*

Improved error message display:

- Error reference number
- Clear error description
- Suggested steps to correct the error

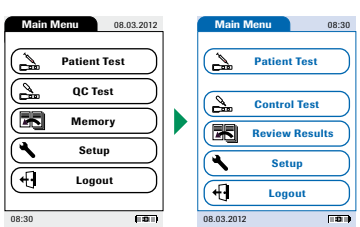


Old version *New version*

Improved information display:

- Reference number of information message
- Clear information message
- Suggested next steps

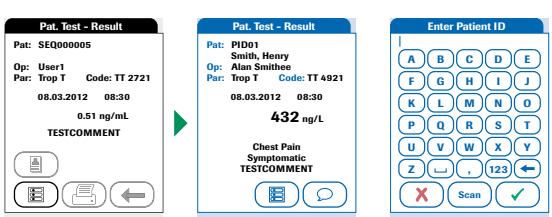
Improved usability of certain functionality



Old version *New version*

Improved main menu:

- Increased space between “Patient Test” button and others ensures quicker test access
- New position of time and date display matches POC standard

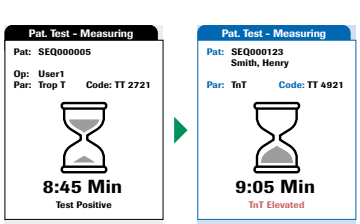


Old version *New version*

Improved “Patient Test – Result” window:

- Bigger font size emphasizes the most important information
- Up to three independent comments can be added by typing or selecting from a pre-stored list
- New “Scan” button allows reactivation of the scanner when entering operator or patient ID – no need to restart test if batch is not scanned within 10 seconds

Early warning of TnT elevation

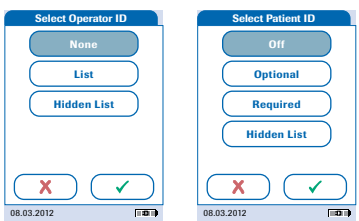


Old version *New version*

Improved early TnT alert functionality:

- Changed threshold from 100ng/L to 50ng/L when this limit is reached during the measurement
- Changed display from “TnT Positive” to “TnT Elevated”

New features with cobas IT 1000 – Hidden List



New version

Operator ID “Hidden List”:

- Operator verification before instrument use – especially useful if operators are not required to use a password
- Added security offered by the combination of password and “Hidden List”

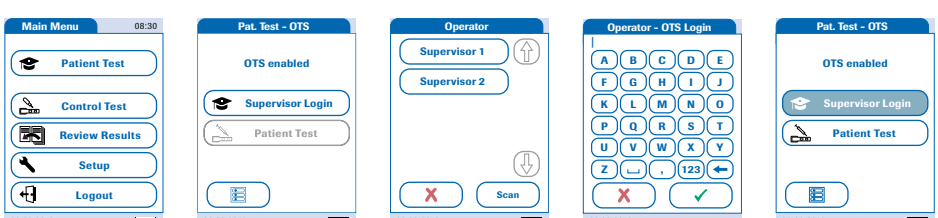
Patient ID “Hidden List”:

- Prevents test assignment to a random patient
- Entry of patient ID required before test start
- Patient ID matched against patients on the “Hidden List”

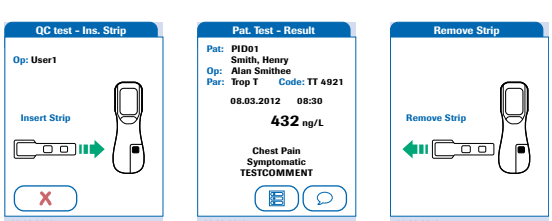
New features with cobas IT 1000 – OTS (observed test sequence) supported with cobas IT 1000 V2.01

- Enables (re)certification of an operator
- Allows storage of patient test results only after supervisor approval

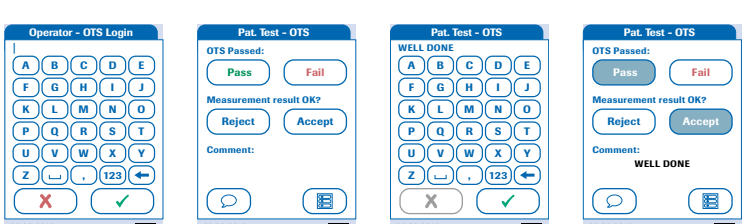
Step 1: Patient tests marked with “trainee operator” symbol require OTS



Step 2: A designated supervisor observes every step



Step 3: Supervisor’s approval is granted only when the operator passes the OTS



New version

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Restandardized Roche CARDIAC T Quantitative

For consistency between lab and Point of Care

Restandardized Roche CARDIAC T Quantitative – standardized against Elecsys cTnT-hs

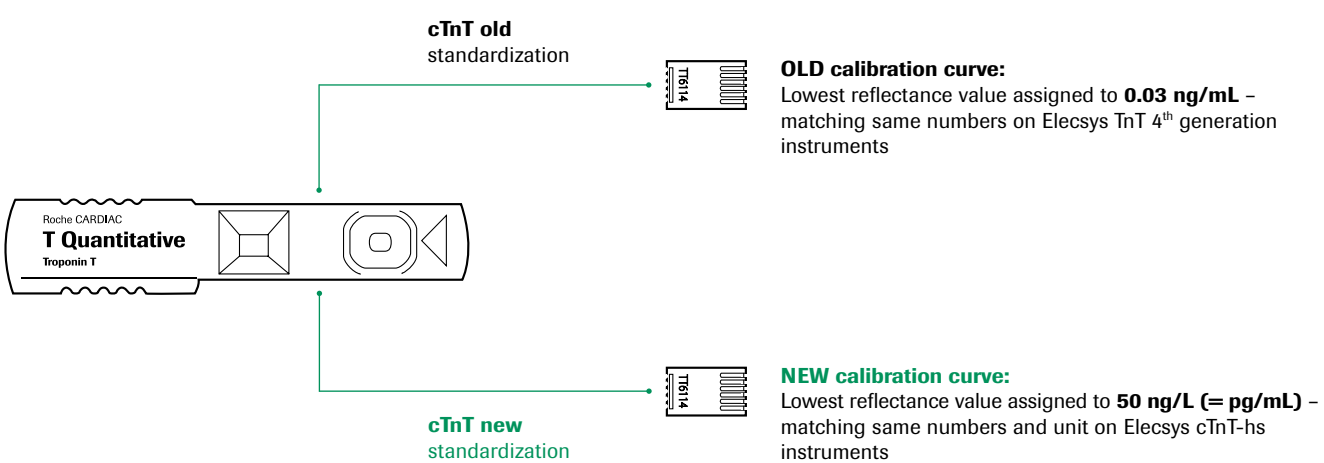
Same test strip (unchanged)

- cTnT from blood reacts with antibodies on the strip and being localized on the capturing line
- Signal intensity (of the capturing line) is being quantified by the **cobas h** 232 POC system as reflectance value (raw unit of the instrument, not displayed to the user)
- For the same sample the reflectance value remains the same before and after the re-standardization
- Strip does not contain standardization information
- Strip test does not change clinical performance, sensitivity and stability

Different code chip (changed)

- Standardized against Elecsys cTnT-hs
- Chip contains standardization information and new calibration curve
- cTnT concentration is being calculated by the **cobas h** 232 POC system based on calibration curve from code chip and measured reflectance value
- One reflectance value can get different concentration values and units assigned, depending on the lot-specific calibration curve

Restandardized Roche CARDIAC T Quantitative – the units change from ng/mL to ng/L (= pg/mL) to be consistent with Elecsys cTnT-hs



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Restandardized Roche CARDIAC T Quantitative

For consistency between lab and Point of Care

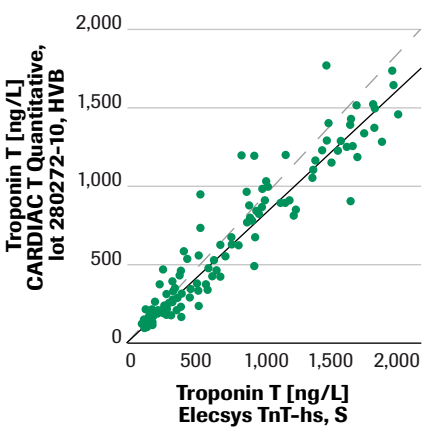
Restandardized Roche CARDIAC T Quantitative – comparable reported results with Elecsys cTnT-hs*

TnT value measured on cobas h 232 POC system with the Roche CARDIAC T Quantitative test standardized against Elecsys cTnT 4th gen. STAT (ng/mL)	TnT value measured on cobas h 232 POC system with the Roche CARDIAC T Quantitative test standardized against Elecsys cTnT-hs (ng/L)	TnT value displayed on cobas h 232 POC system with the Roche CARDIAC T Quantitative test standardized against Elecsys cTnT-hs (ng/L)
0.03 0.05 0.08	51 70 97	Trop T 50 - 100 ng/L
0.10	116	Trop T 116 ng/L
0.25	242	Trop T 242 ng/L
2.0	1,748	Trop T 1,748 ng/L
2.5	2,245	Trop T > 2,000 ng/L

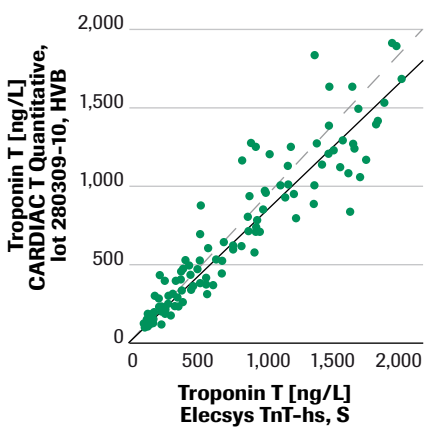
** Data on file*

Restandardized Roche CARDIAC T Quantitative – consistent results between lab and Point of Care

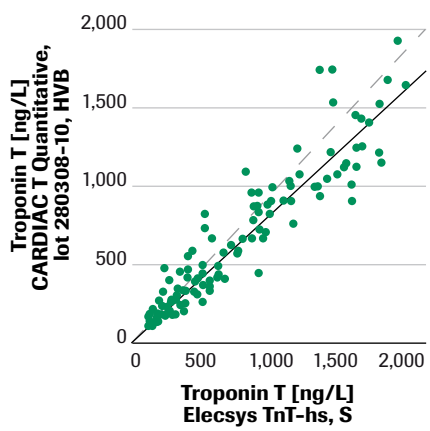
The figures below show method comparisons between 3 lots of Roche CARDIAC T Quantitative and Roche Elecsys TnT-hs: results of 5 sites based upon 148 - 159 evaluable pairs of values.[1]



P/B Regression
*Y = 0.88 * X + 2.3*
N = 154 r = 0.96



P/B Regression
*Y = 0.89 * X + 4.0*
N = 157 r = 0.95



P/B Regression
*Y = 0.86 * X + 15.7*
N = 159 r = 0.95

The results demonstrate the reliability of the calibration of the assay and the good concordance with the laboratory reference.

References

1 Roche Diagnostics/Roche Professional Diagnostics, Performance Evaluation New Calibration Roche CARDIAC T Quantitative – CIM RD001256, unpublished data, Jan. 2012.

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cobas h 232 POC system
Product specifications

Item Material order no	Dimensions (mm)	Screen	Power supply	Connectivity
cobas h 232 POC system 04 901 126 190	L 275 W 102 D 55	Touch screen 78x58 mm	Input: 100-240 Volt/50-60Hz/400mA Output: 7.5 Volt/1.7A CE/TÜV/VDE-GS/UL label	Infrared data port enables data transfer to optional Handheld Base Unit or printer with serial infrared port
cobas h 232 POC system with integr. barcode scanner 04 901 142 190	L 275 W 102 D 55	Touch screen 78x58 mm	Input: 100-240 Volt/50-60Hz/400mA Output: 7.5 Volt/1.7A CE/TÜV/VDE-GS/UL label	Infrared data port enables data transfer to optional Handheld Base Unit or printer with serial infrared port

Parameter Test strip Material order no	Reaction time	Measuring range	Clinical utility	Cut-off / Reference range
Troponin T Roche CARDIAC T Quantitative 04 877 772 190	12 mins	50-2000 ng/L (quantitative range 100-2000 ng/L)	Diagnosis of acute coronary syndrome and myocardial infarction	< 50 ng/L – AMI not likely, but possible 50-100 ng/L – AMI possible; initiate treatment accordingly (re-test) > 100 ng/L – AMI (very) likely; initiate treatment accordingly
CK-MB Roche CARDIAC CK-MB 04 877 900 190	12 mins	1.0-40 ng/mL	Diagnosis of acute coronary syndrome and myocardial infarction, assessment of re-infarction	Female 4 ng/mL* Male 7 ng/mL*
Myoglobin Roche CARDIAC M 04 877 799 190	8 mins	30-700 ng/mL	Early marker of myocardial damage to assist in diagnosis of acute coronary syndrome and myocardial infarction	Female 7 ng/mL - 64 ng/mL Male 16 ng/mL - 76 ng/mL
D-dimer Roche CARDIAC D-Dimer 04 877 802 190	8 mins	0.1-4.0 µg/mL	Exclusion of deep vein thrombosis and pulmonary embolism	0.5 µg/mL
NT-proBNP Roche CARDIAC proBNP+ 05 533 643 190	12 mins	60-9000 pg/mL	Aid in diagnosis of patients with suspected heart failure, in monitoring of patients with compensated left ventricular dysfunction and in risk stratification of patients with acute coronary syndromes	Exclusion of non-acute heart failure < 125 pg/mL Exclusion of acute heart failure < 300 pg/mL Consideration of age-stratified cut-points for diagnosis (= CHF likely considering confounding factors) Patient age — NT-proBNP value < 50 — > 450 pg/mL 50-75 — > 900 pg/mL > 75 — > 1800 pg/mL

* *At the 99th percentile of a reference population*

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Quality Controls Material order no	Utility
Roche CARDIAC Control Troponin T 04 890 515 190	Control set for use with Roche CARDIAC T Quantitative (control set for 2 x 6 quality control checks, level 1/2, and code chip)
Roche CARDIAC Control CK-MB 04 890 426 190	Control set for use with Roche CARDIAC CK-MB (control set for 2 x 6 quality control checks, level 1/2, and code chip)
Roche CARDIAC Control Myoglobin 04 890 469 190	Control set for use with Roche CARDIAC M (control set for 2 x 6 quality control checks, level 1/2, and code chip)
Roche CARDIAC Control D-Dimer 04 890 523 190	Control set for use with Roche CARDIAC D-Dimer (control set for 2 x 6 quality control checks, level 1/2, and code chip)
Roche CARDIAC Control proBNP 04 890 493 190	Control set for use with Roche CARDIAC proBNP^{+} (control set for 2 x 6 quality control checks, level 1/2, and code chip)
Roche CARDIAC IQC 04 880 668 190	Reusable control strips to verify the function of the **cobas h** 232 POC system

Accessories Material order no	Utility
Roche CARDIAC Pipettes 11 622 889 190	Dosing device for sample transfer from primary sampling tube, labelled to show required sample volume
Handheld Battery Pack 04 805 640 001	Rechargeable battery pack for up to 18 measurements

Options Material order no	Utility
Handheld Base Unit/Connectivity Interfaces 04 805 658 001	Battery pack recharging. Data interface. Connectivity: USB and Ethernet port
IT Data Management	Interface to **cobas IT** 1000 data management solution POCT1A – protocol for interfacing to **cobas IT** 1000 data management solution or third party systems as well as LIS/HIS

*The **cobas h** 232 POC system features easy-to-use on-board data management. Through connectivity, results can be made available throughout your site. With a Point of Care data management system, data administration, control over QC and instrument configuration is enabled from a remote point e.g. the laboratory.*

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