Công ty TNHH Roche Việt Nam

Tầng 27, Tòa nhà Pearl Plaza, 561A Điện Biên Phủ,

Phường 25, Quận Bình Thạnh, Tp. Hồ Chí Minh

Kính gửi: **Sở Y Tế Thành phố Hồ Chí Minh**

Sản phẩm trang thiết bị y tế thuộc loại A:

- Tên trang thiết bị y tế: IVD là giá đựng ống pha loãng mẫu
- Chủng loại: CPC / t 411 Dilution rack
- Mã sản phẩm: 06311296001

Được sử dụng để đựng ống pha loãng mẫu trên máy phân tích đông máu tự động cobas t 411 và chủ sở hữu trang thiết bị y tế không ban hành hướng dẫn sử dụng riêng cho sản phẩm này.

Công ty chúng tôi xin được phép nộp hướng dẫn vận hành tiếng Anh của máy **cobas** t 411 cho các mục tài liệu sau đây của sản phẩm:

- Tài liệu kỹ thuật mô tả chức năng, thông số kỹ thuật của trang thiết bị y tế do chủ sở hữu trang thiết bị y tế ban hành
- Tài liệu hướng dẫn sử dụng bằng tiếng Anh do chủ sở hữu trang thiết bị y tế ban hành.

Rất mong Sở Y Tế chấp thuận.

Xin chân thành cảm ơn.

Công ty TNHH Roche Việt Nam

(Đã ký)

M.S.D.N: 0310805269 - C.T.T.N.H.H - CÔNG TY TRÁCH NHIỆM HỮU HẠN ROCHE VIỆT NAM - Q. BÌNH THẠNH - T.P HỒ CHÍ MINH

Trương Thị Tố Hoa
Trưởng phòng Đăng ký,
Đối ngoại và Quản lý Chất lượng

Cobas t 411

Short Instrument Operation

	Manufactured in: *Kommanditgesellschaft Behnk Elektronik GmbH & Co.* *Hans-Bockler-Ring 27, 22851 Norderstedt, Germany*
	*Manufactured for:* *Kommanditgesellschaft Behnk Elektronik GmbH & Co.* *Hans-Bockler-Ring 27, 22851 Norderstedt, Germany*

** This document is a translation and an excerpt of the English version of the operator manual (OM) in Vietnamese*
** A point (period/stop) is always used in this Short Instrument Instruction as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.*

Contents

I. **Intended use** (p.7 OM)

The cobas t 411 coagulation analyzer is a fully automated blood plasma analysis system intended for in vitro determination of coagulation. It performs optical clotting time detection, using chronometric, chromogenic, and immuno-turbid metric measurement methods. It is designed for 24h/day operation.

II. **System overview** (p.15-31)

Overview of the analyzer

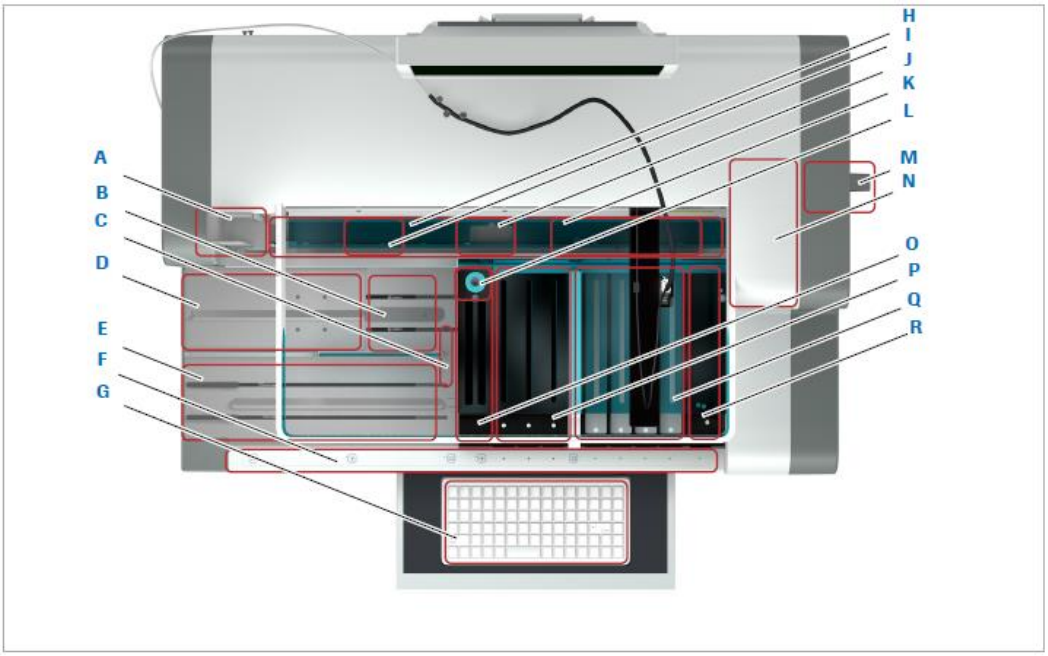
Measuring principle

The analyzer performs optical clotting time detection, using chronometric, chromogenic, and immuno-turbidimetric measurement methods.

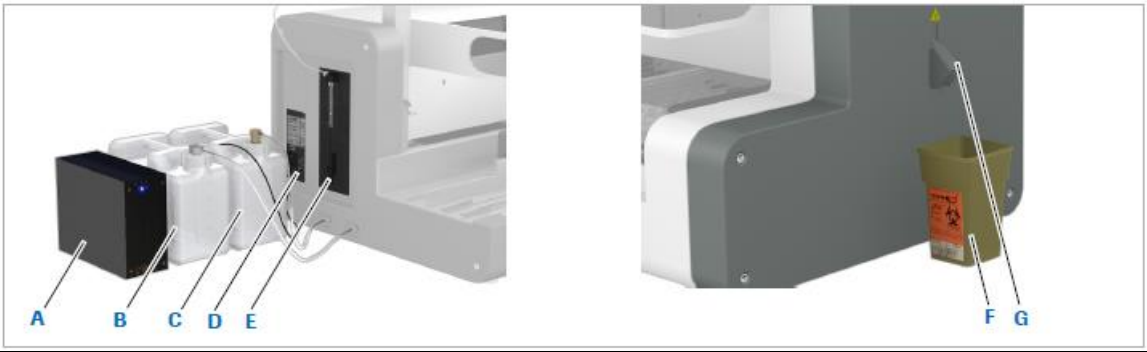
Measuring principle

1. The analyzer pipets sample and reagents.
2. Incubation ensures that all reaction components in the cuvettes are at the correct temperature.
3. When the cuvette bar enters the photometer unit, it is tilted by 90°. Sample and reagents are combined and actively mixed.
4. The photometer measures light absorbance and time:
   - For clotting tests, it measures the change in turbidity.
   - For chromogenic tests, including immuno- turbidimetric measurements, it measures the kinetic reaction.

Analyzer overview



A Cuvette bar compartment	H Cuvette conveyor
B Sample pipetting area	I Waiting position
C Barcode reader for samples	J Pipetting station
D Output buffer	K Incubation positions
E Input buffer	L Rinse station
F Button bar	M Waste chute with cover
G Keyboard	N Photometer unit
	O Dilution area
	P Left reagent area
	Q Right reagent area
	R Barcode reading slot



A Control unit	F Solid waste container
B Water container	G Waste chute with cover
C Liquid waste container	
D Connectors, power switches, and fuses	
E Syringe	

III.Warnings and precautions (p.6 in cobas t 411 coagulation analyzer- Safety Manual-Version 3.0)

General attention

To avoid serious or fatal injury, read this publication thoroughly before you use the analyzer.

- Pay particular attention to all safety precautions.
- Always follow the instructions in this publication.
- Do not use the instrument in a way that is not described in this publication.
- Keep this publication in a safe place to ensure that it is not damaged and remains available for use.

This publication must always be easily accessible

Safety precautions (p.8-30 in cobas t 411 coagulation analyzer- Safety Manual-Version 3.0)

To avoid serious or fatal injury, read and comply with the following safety precautions.

About operator qualification

Insufficient knowledge and skills

As an operator, ensure that you know the relevant safety precaution guidelines and standards and the information and procedures contained in these instructions.

- Do not carry out operation and maintenance unless Roche Diagnostics has trained you to do so.
- Leave maintenance, installation, or service that is not described to trained Roche Service representatives.
- Carefully follow the procedures specified in the instructions for operation and maintenance.
- Follow good laboratory practices, especially when you work with biohazardous material.

About safe and proper use of the system

Missing personal protective equipment

Working without personal protective equipment means danger to life or health.

- Wear appropriate personal protective equipment, including, but not limited to, the following items:
  - Eye protection with side shields
  - Fluid-resistant laboratory coat
  - Approved lab gloves
  - Face shield if there is a chance of splashing or splattering
- Follow good laboratory practices and regularly change lab gloves to minimize the risk of infection and contamination (especially after contact with waste or sample material).

Exposure to chemicals

- Avoid exposure to chemicals.

Exposure to infectious waste

Failure to place an appropriate solid waste container below the waste chute can lead to exposure to infectious waste material.

- Always place a solid waste container below the waste chute during operation.
- Follow good laboratory practices and regularly change lab gloves to minimize the risk of

infection and contamination (especially after contact with waste or sample material).

Regular cleaning
To prevent inaccurate results and unsafe operation of the system:
- Regularly clean and/or decontaminate the instrument as required. Follow good laboratory practices for cleaning and decontamination.
- Ensure that the laboratory is regularly cleaned and is maintained in an orderly manner.

Approved cleaning solutions
- Use only approved cleaning solutions for cleaning.

Errors in installation
Only trained Roche Service representatives may install the system.
- Leave installation to trained Roche Service representatives.

Exchange or removal of parts
Unauthorized exchange or removal of system parts can damage the system or stop it from functioning correctly.
- Do not exchange or remove any part of the instrument.
- Leave replacement of instrument parts to trained Roche Service representatives.

Unsuitable environmental conditions Operation outside of the specified ranges may lead to incorrect results or malfunction of the system.
- Use the system indoors only, and avoid heat and humidity outside of the specified range.
- Make sure that the system's ventilation openings always remain unobstructed.
- To maintain the environmental conditions of the system, perform maintenance in accordance with the specified intervals.
- Keep the operating instructions undamaged and available for use. Operating instructions must be easily accessible for all users.

For the allowable environmental conditions, see the Operator’s Manual.

Non-approved spare parts
Use of non-approved spare parts or devices may result in malfunction of the system and may render the warranty null and void.
- Use only spare parts and devices approved by Roche Diagnostics.

Non-specified third-party software
Installation of third-party software is not approved by Roche Diagnostics and may result in malfunction.
- Do not install third-party software.

Non-specified consumables
Use of non-specified consumables can lead to incorrect results.
- Do not use consumables that are not intended for use with the analyzer.

For a list of supported materials, see the Operator’s Manual.

IV. Contraindicated: *Not applicable*

V. Adverse effects: *Not applicable*

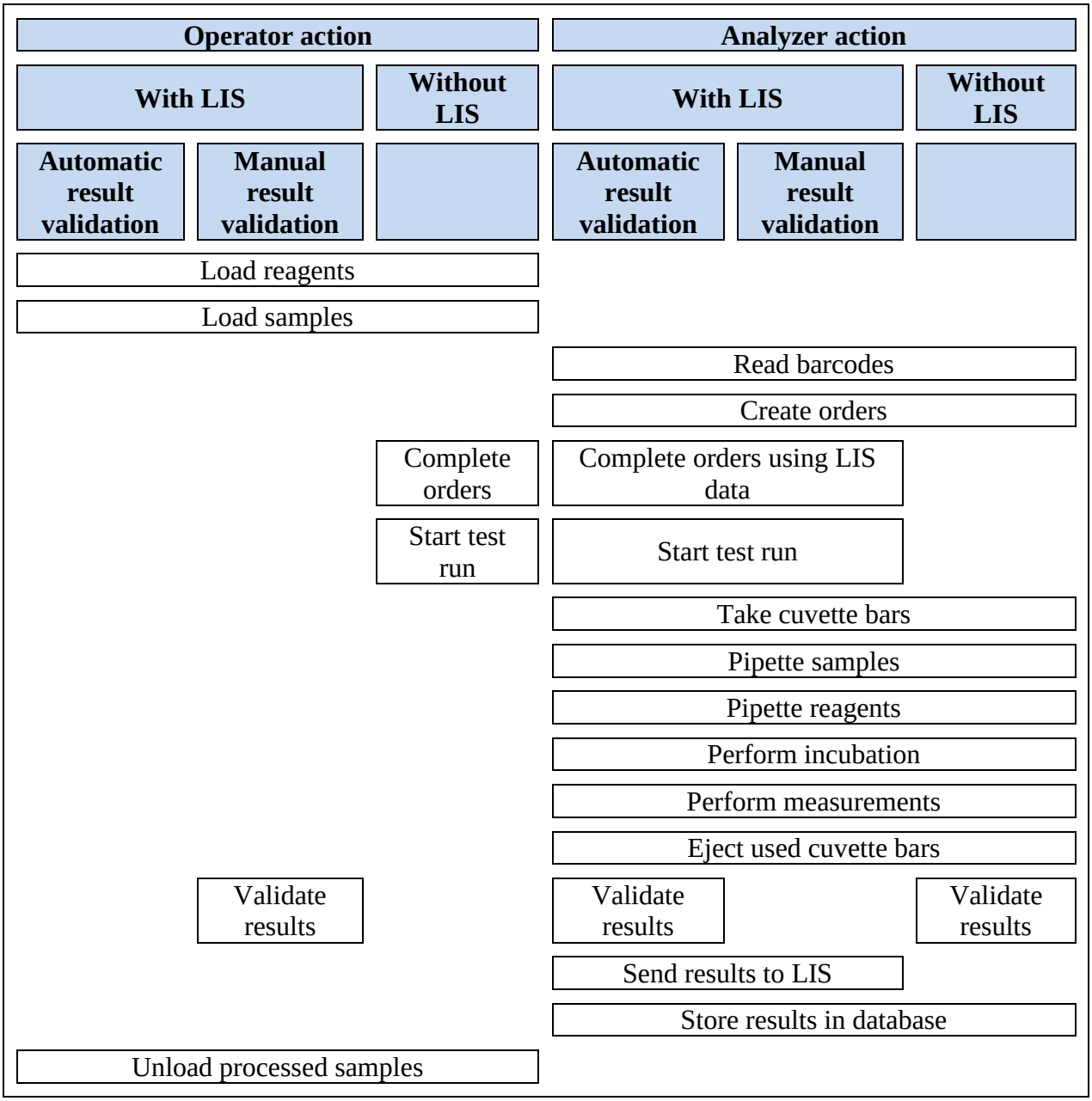
VI. Specifications and conditions of use to maintain the safety and efficacy of the medical device (brochure p.2)

Sample management	Sample carrier	5 position rack
	On-board sample capacity	100 samples
	Cap-piercing	yes
	Handling of STAT	dedicated, always available STAT port
	Sample identification	positive, via internal barcode reader
	Sample loading/unloading	integrated concept w/off board storage unit included
Reagent management	Reagent loading	racks of 6, 8 or 10 positions
	Vial positions on board (reagent, calibrators, controls, aux. reagents)	70 vials
	Reagent vial identification	positive, via built in reading station
	Reagent cooling	15 °C
	SW guided reagent management	yes
	Reagent usage optimization	tilted racks minimize dead volume
Cuvettes	Type of cuvette	4-cuvette-rack
	Cuvette capacity on board	240 cuvettes
Software	Operating software	Linux
	QC program	incl. Levy-Jennings
	LIS connection	RS232
Analytical	Measurement channels	4
	Detection system	opto-mechanical
	Wavelengths	405 nm / 620 nm
	Clotting- / chromogenic / immunological tests	yes / yes / yes
	Automatic rerun testing	yes
	Reflex testing	yes
	Throughput in tests/hour	140 tests (PT)
	Automatic pre-dilution	yes
	Automatic level detection	yes
Environmental	Max. instrument dimensions (WxHxD in cm / model type)	95 x 47 x 62 (benchtop)
	Max. maintenance duration in minutes (daily / weekly)	5 / 15

VII. Instruction for use (p. 46)

The workflow depends on whether the analyzer is connected to an LIS, and if so, whether you work with manual result validation or not. The standard setup is with LIS and without manual result validation.

The figure below shows the actions of the operator and of the analyzer for the three different setups.



VIII. Reference

1. **cobas®** t 411 coagulation analyzer_Operator's Manual, V 3.0, page 7
2. **cobas®** t 411 coagulation analyzer_Operator's Manual, V 3.0, page 15-31
3. **cobas®** t 411 coagulation analyzer_Safety Manual, V 3.0, page 6-30
4. **cobas®** t 411 coagulation analyzer_Technical Spectification, V 3.0, page 2
5. **cobas®** t 411 coagulation analyzer_Operator's Manual, V 3.0, page 46

IX. Additional information

Additionnal information of instruction for use, conditions and time for warranty, technical documents serving the repair and maintenance of the product: Please refer to technical support 1800599991

The import license holder, warranty and importation:
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