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COAGULOMETRU Helena C-Series

Caracteristici și specificații

- Platformă flexibilă cu 1, 2 sau 4 canale
- Analiză optică de înaltă performanță, fără cerință de agitare mecanică
- Detectare sensibilă cu volume mici de probă
- Măsurare optică de înaltă rezoluție, chiar și cu un volum de probă și reactiv de numai 75 µL
- Operare ușor de utilizat

Fluxul de lucru cu ecran tactil permite programarea simplă și pornirea automată

- Reglare optică automată

Asigură rezultate fiabile pe toate canalele atunci când calitatea probei variază

- Conectivitate puternică
- Urmărirea ID-ului pacientului și al probei cu scaner de coduri de bare opțional
- Construcție de înaltă calitate

Platformă analitică testată, proiectată și fabricată în UE

Display tactil colorat

Zona completă este preîncălzită la 37°C

1 x Poziție reactiv Ø24mm

2 x Poziție reactiv Ø22mm

(1 poziție pentru agitare pe Helena C-2 și Helena C-4)

2 x poziții de reactiv Ø13mm

10 x poziții de incubare cuvetă (x20 pe Helena C-2 și Helena C-4)

1 x poziții de măsurare a cuvei (x2 pentru Helena C-2, x4 pentru Helena C-4)

Operator Manual

Helena C-Series Family

Helena C-1 • Helena C-2 • Helena C-4

IVD

CE

For *In-Vitro* Diagnostic use

Instrumentation and reagents for human coagulation and haemostasis

Updates

Operator Manual Revision	Date of Issue	Amendments
Rev.1	2019-12	First edition
Rev. 2	2020-06	Minor updates throughout prior to the first distribution of the instrument.
Rev.3	2020-07	Correction to accessories listed on page 9.

Manufacturer

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Warranty

The Helena C-Series is warranted for a period of one year after delivery or first installation. It covers any defects in material, functionality or workmanship. The first installation must be registered online at www.c-series.com (see chapter “Registration”)

The warranty expires in case of failures caused by

- Accidents, neglected maintenance & service, abuse or misuse.
- Using unauthorised reagents, consumables or spare parts.
- Unauthorised service. Any repair or service must be performed by authorised persons.

List of figures

1. INTRODUCTION

This device left the factory in fault-free condition regarding its safety and engineering functionality. To maintain this condition and ensure risk-free operation, the operator must comply with the safety warnings and information in this Operator's Manual.

Use the Helena C-Series only in compliance with the instructions in this Operator's Manual. Otherwise, the manufacturer shall exclude the liability for any damages to the Helena C-Series, patients or operators.

1.1 SYMBOLS

The following standard symbols are used in this manual:

Symbol	Meaning	Explanation
Courier	**Info**	Key on keypad.
CAPS	**Info**	Screen message.
	**Read**	Indicates important information and tips.
⇨	**Info**	Describes reaction of the Helena C-Series to operator input.
	**Warning**	Risk of possible health damage or considerable damage to equipment, if warning is not heeded.
	**Danger**	Potential risk to operating personnel or equipment due to electric shock.
	**Biohazard**	Equipment can be potentially infectious due to the samples and reagents used.
	**Laser Radiation**	Avoid direct eye exposure.
	**WEEE**	Separate collection of electrical and electronic waste at the end of life, as required by European legislation

1.2 VIEWS OF THE DEVICE

FIGURE 1: TOP VIEW – HELENA C-1

Home Screen

Coloured Touch Display

Complete area is prewarmed to 37°C

1 x Reagent position Ø24mm
2 x Reagent position Ø22mm
(1 position will be stirred on Helena C-2 and Helena C-4)
2 x Reagent positions Ø13mm
10 x Cuvette incubation positions
(x20 on Helena C-2 and Helena C-4)
1 x Cuvette measurement positions
(x2 for Helena C-2, x4 for Helena C-4)

FIGURE 2: REAR VIEW

5V:	Power in
PC:	LIS or PC
SERVICE:	Software update
PRINTER:	Serial printer
BARCODE:	Handheld barcode scanner (serial)

FIGURE 3: SIDE VIEW

1.3 CONSUMABLES / ACCESSORIES

Helena C-Series products available

REF	Product	Description
C-1X	Helena C-1	1 x single channel semi-automated coagulation analyser with starter kit.
C-2X	Helena C-2	1 x two channel semi-automated coagulation analyser with starter kit.
C-4X	Helena C-4	1 x four channel semi-automated coagulation analyser with starter kit.
C-101V	Single Cuvettes (Voucher)	500 x single use cuvettes with activation card.
AC4302	Stir Bars	4x stirring magnets. Required to mix Thromboplastin L reagent for PT testing.
AC4300	Reagent Container (22.5mm)	100x plastic containers for holding reagent.
C-104	Reagent Tube (11.0mm)	100x plastic containers for holding reagent.
C-011	Reagent Adapter 22.5 – 24.2mm	1x Reagent adapter Ø 24.5 – 22.5 mm. Helps to place vials with different sizes.
C-013	Display Protection Foil	1x protection foil, to save glass from scratches. Kit includes, foil, clean tissues & remover tool.
C-02	TECAM Smart Software	A small local LIS and data management software package.
C-01	Thermal Printer	1x thermal printer, to print results, calibration data or system information. Supplied with UK power lead and C-015 interface cable.
C-016	Thermal Printer Paper	5 x rolls of paper for use with C-01
C-014	Barcode Scanner	1x external, handheld CCD-barcode reader. Reads 1D or QR codes for patient ID and cuvette vouchers.
2503600	Download cable	1x data cable for transfer of information between analyser and TECAM smart software.
C-015	Interface Cable	1 x Interface cable for Thermal Printer.

1.4 INTENDED USE

IVD

The Helena C-Series is designed to carry out blood coagulation tests such as PT, APTT, TT, Fibrinogen, single factor tests, chromogenic and immunoturbidometric tests (Antithrombin, D-dimer etc.) on human citrated plasma. The instrument must be used for the intended purposes and good technical condition maintained as described in this document. It is designed for use in a laboratory or clinical environment by trained operators. It is not intended for home use.

1.4.1 COMPARISON OF THE HELENA C-SERIES FAMILY

The Helena C-Series includes three different versions, Helena C-1, Helena C-2 and Helena C-4.

Helena C-Series	Helena C-1	Helena C-2	Helena C-4
			
Reagent and Optic block	prewarmed to 37°C		
Cuvette prewarm	10x	20x	20x
Reagent prewarm, 24mm	1x	1x	1x
Reagent prewarm, 22mm	2x	2x	2x
Microtubes prewarm	2x	2x	2x
Reagent stirrer	No	1x	1x
Printer, RS232	Yes		
Barcode Scanner, RS232	External handheld barcode scanner for 1D or QR labels To read patient-ID and vouchers.		
LIS, USB	Yes		
Firmware Update, USB	Yes		

Measurement			
Optic channels	1	2	4
Optic wavelength	405nm (UV)	405nm (UV)	405nm (UV)
Cuvette, total volume	Single, 75µL	Single, 75µL	Single, 75µL
Global Clotting Assays	PT+aPTT+Fib+TT	PT+aPTT+Fib+TT	PT+aPTT+Fib+TT
Special Clotting Assays	-	All factors, LA	All factors, LA
Chromogenic Assays	-	AT, PC	AT, PC
Latex enhanced Assays	D-Dimer	D-Dimer	D-Dimer

Software features			
Reagent Dual LOT manage two different lots for each test	No	Yes	Yes
Test Calibration LOT, expiry and up to 5 points for each test	Yes	Yes	Yes
Reagent Barcode Input LOT + Expiry	Yes	Yes	Yes
Patient Barcode Input patient ID by barcode scanner up to 16char	Yes	Yes	Yes
System Barcode Input voucher tickets by barcode scanner or smart device	Yes	Yes	Yes
Result Database save recent 100 results onboard	No	Yes	Yes
Double Determination Run patient twice and display mean value	No	Yes	Yes
Stopwatch function count up or down incubation time	1x	2x	4x
Result Identification Patient ID or sample ID or Auto ID	Yes	Yes	Yes
Real Time Clock	Yes	Yes	Yes
Change language EN, ESP, ITA, FR, DE, RO, PL, DA, NL, SR, ET, FI, HR, LV, LT, PT, SE, SK, SI, CS, HU	Yes	Yes	Yes
Start test at reagent addition No additional starter pipette required	Yes	Yes	Yes
Visualise Reaction Curve TECAM Software required	Yes	Yes	Yes
Link to LIS over USB or network/ASTM TECAM SMART Software required	Yes	Yes	Yes

1.4.2 TEST METHODS

The following tests are provided to detect defects of the human coagulation system, which can be bleeding or thrombosis and the monitoring of anti-coagulation drugs like Heparin or Warfarin.

Test	Name	Specimen	Method	Helena C-Series		
				Helena C-1	Helena C-2	Helena C-4
PT	Prothrombin Time	plasma	clot	Yes	Yes	Yes
APTT	Activated Partial Prothrombin Time	plasma	clot	Yes	Yes	Yes
FIB	Fibrinogen	plasma	clot	Yes	Yes	Yes
TT	Thrombin Time	plasma	clot	Yes	Yes	Yes
AT	Antithrombin	plasma	chromogen	No	Yes	Yes
DD	D-Dimer	plasma	immuno	Yes	Yes	Yes
Factors	Factors II, V, VII, VIII, IX, X, XI, XII	plasma	clot	No	Yes	Yes
PC	Protein C	plasma	chromogen	No	Yes	Yes
LA-S	Lupus Screen	plasma	clot	No	Yes	Yes
LA-C	Lupus Confirm	plasma	clot	No	Yes	Yes

1.4.3 SPECIMEN COLLECTION

Type:	Human citrated plasma
Collection:	Vein puncture, 1:10 mixed sodium citrate 3.2% (0.105M)
Centrifugation:	10min at 1500g
Storage:	Max 4h after collection at room temperature
Bilirubin:	< 50mg/dl
Haemoglobin:	< 9000mg/l
Triglyceride:	< 2500g/l

Always confirm specific specimen preparation and handling conditions for the test and reagent being used. This information can be found in the product specific IFU's or referenced in the Helena C-Series User Guide (HL-2-P-3429).

1.4.4 MEASUREMENT PRINCIPLE

The detection of plasma clotting is based on a photometric principle. No mechanical aids like mixing bars are required. Blood plasma is filled into a cuvette. Special reagents are added, which initiate the blood coagulation. The cuvette is transmitted by ultraviolet light during the coagulation process. When the sample starts to clot a change of light absorbance is measured. The time from measurement start, to change of light (turning point) is called clotting time and expressed in seconds [s].

The conversion of coagulation time into a specific test unit is one using a linear, hyperbolic, semi-logarithmic or double-logarithmic interpolation of the stored calibration points. The current mathematical model is printed out in "TEST SETUP." Values outside the calibration range are calculated by extrapolation and flagged as " * ".

Unit	Info	Decimal places	Maximum value
s	seconds	1	-
%	activity	1	250.0
U	units	0	29999
INR	Int. ratio	2	99.00
R	ratio	2	99.00
NR	polish ratio	0	250
mg/dl		0	999
g/l		2	99
IE/ml	Int. Units	2	99
mg/l		2	999
µg/ml		3	9.000
ng/ml		0	27500
µg/l		0	27500
IU/mL	Int. Units	2	99.00

R = clotting time / normal time
NR = 100 *(normal time/clotting time)
INR = Ratio ^{ISI} (International Normal Ratio)
IU/mL = IE/mL = International Units (1.00 IU/mL = 100 % activity)

1.4.5 CLOTTING METHOD (PT, APTT,..)

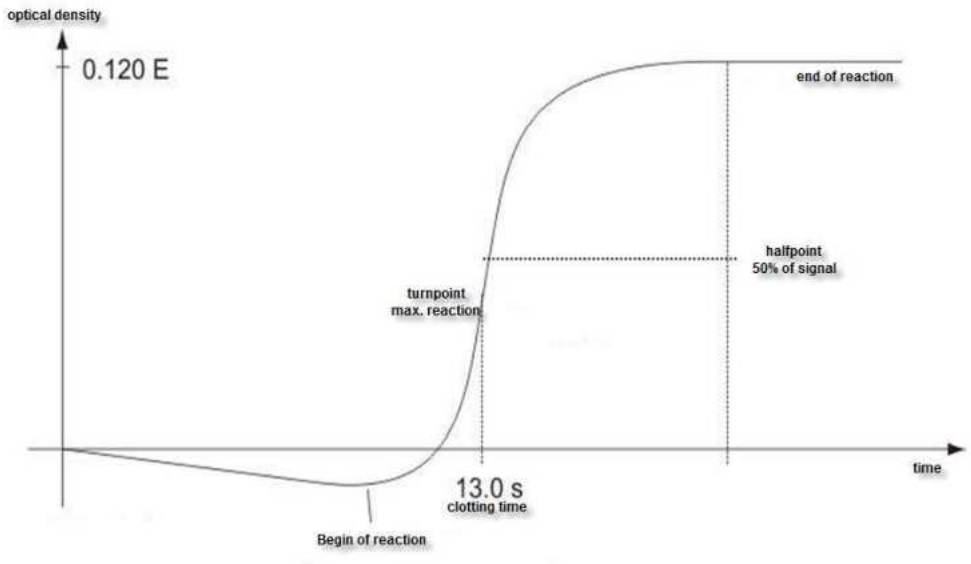


FIGURE 4: DETERMINATION OF TURNING POINT IN CLOTTING METHOD

The final reaction in the coagulation cascade is the transformation of fibrinogen into fibrin catalysed by thrombin. Fibrin formation increases turbidity of the sample, which is measured by the photometer and stored as the extinction. The result in seconds is the time from the start of the reaction to the time of half rate of change (50% point).

1.4.6 CHROMOGENIC METHOD (ANTITHROMBIN):

The change of optical signal is not caused by clot reaction, but by the release of colour particles (pNA) which causes a yellow colour. The change of colour is measured at 405nm and expressed as “dE/60sec” and proportional to the concentration or activity of analyte.

1.4.7 IMMUNOTURBIDOMETRIC METHOD (D-DIMER):

The change of light is caused by Antigen – Antibody reactions, which scatter the light. The antibodies are linked to latex particles to amplify the optical reaction. The change of light is proportional to the concentration of antigen, like D-Dimer and expressed as dE/120sec

1.5 SAFETY INFORMATION

1.5.1 SAFETY INFORMATION FOR OPERATION

Use only the cleaning and rinsing liquids approved by the manufacturer. Failure to do so could result in faulty measurements or malfunctions of the **Helena C-Series**. Prevent reagents from leaking into the Analyser. Failure to do so may result in damage to the instrument and result in expensive maintenance work!

Carry out control measurements at regular intervals to ensure that the analyser continues to function faultlessly.

If the instrument is used in a manner not specified by the manufacturer, the warranty could be affected!

Please read the Operation manual in its entirety prior to operation, in order to ensure a high level of performance and to avoid errors by user.

1.5.2 SAFETY INFORMATION FOR MATERIALS

Use only Helena Biosciences Europe approved and labelled material like cuvettes, spare parts or reagents for which the instrument is intended and validated for.

Consumables like cuvettes or yellow tips are intended as single-use items. Multiple use may result in false results due to contamination. Follow the guidance set out in the specific product IFU. Incorrect handling may result in false results.

Do not use materials after their date of expiry. Expired IVD reagents may cause false results.

Check correct function of manual pipette every year to ensure accurate results.

1.5.3 SAFETY INFORMATION REGARDING RISK OF HEALTH

Bleeding or Thrombosis

Diagnosis and medication of the human coagulation system based on false results may lead to critical bleeding or thrombosis. For risk reduction it is essential to follow the suggestions below.

Regarding risks:

Caused by faulty condition of the instrument, reagent or calibration data:

Perform a quality control before running a series of patient samples or after reconstitution of a vial or after test calibration to eliminate failure of the instrument, reagent or calibration data.

Caused by imprecise pipetting:

Validate your pipette every year and label it with the last date of validation.

Caused by false assignment of target values:

Run interlaboratory quality control standards.

Caused by purified water:

Use only high purified water to reconstitute controls or reagents. Check visually that the water is free of any particles.

Caused by expired reagent:

Do not use IVD reagents or other materials after their expiry date.

Infectious Material

Consider all surfaces and materials which might be in contact with plasma or other biological liquid as potentially contaminated with infectious material.

Avoid contact:

Wear medical infection grade protective gloves for all work involving potential contact with infectious material and use each pair of gloves only once. Use a hand disinfectant product, to disinfect your hands after completion of the work.

Dispose:

Dispose of infectious materials, such as cuvette waste and liquid waste, in accordance with local regulations.

Hygienic conditions**:**

The reagents intended for use with this instrument are for *in vitro* diagnostic use only – DO NOT INGEST. Wear appropriate personal protective equipment when handling all reagent components. Refer to the product safety declaration for each specific reagent being used and the link to appropriate hazard and precautionary statements where applicable. Any waste materials must be considered as potentially infectious. Direct contact must be avoided.

1.5.4 SAFETY INFORMATION FOR CLEANING, MAINTENANCE AND SERVICING

	**Authorized service only!** Carry out only the measures listed in this operator's manual for maintenance, repair and replacement. Improper manipulation of the device will void the manufacturer's liability obligations and may make service calls necessary, including payments which are not covered by warranty. Only authorized Customer Service personnel may carry out servicing. Only original replacement parts may be used. Before doing any servicing on the instrument, it is very important to thoroughly disinfect all possibly contaminated parts.
	**Cleaning and decontamination:** Before the instrument is removed from the laboratory for disposal or servicing, it must be decontaminated. The procedure is described in chapter "Cleaning and maintenance" and should be performed by authorised well-trained personnel only, observing all necessary safety precautions.
	**Cleaning certificate required!** Instruments to be returned must be accompanied by a decontamination certificate issued by the responsible laboratory manager. If a decontamination certificate is not supplied, the returning laboratory will be responsible for charges resulting from non-acceptance of the instrument.
	Regard all surfaces and materials which might be in contact with plasma or other biological liquid as potentially contaminated with infectious material.
	Avoid any direct contact with decontaminants or disinfections.

1.5.5 ELECTRICAL SAFETY

	**Precautions:** ▪ Avoid spilling liquids into the system. In case of spilled liquids disconnect the system from the power supply, then clean and dry all contaminated parts. ▪ Remove the power cord before opening the instrument. ▪ Do not touch any electronic parts during operation. ▪ Do not operate system without proper connection to grounding. ▪ Never intentionally interrupt protective ground contacts. ▪ Never remove housing elements, protective covers or secured structural elements, since doing so could expose parts carrying electric current. ▪ Make sure surfaces such as the floor and workbench are not moist while operating the device. ▪ Check electrical equipment regularly. Defective leads or socket must be replaced without delay.
	**Connection to power:** ▪ The instrument is in compliance with IEC 61010-1 / 61010-2-101 and classified as a portable instrument, class II. It does not require a safety connection to electrical earth. ▪ Ensure the operating voltage setting is correct before connecting the device to the mains power. Read chapter “installation” about electrical conditions. ▪ The power cord must be easily accessible during normal operation.
	**EMC Statement:** The **Helena C-Series** is suitable for use in clinical and industrial establishments. Tested according to standards IEC 61326-1:2013 and IEC 61326-2-6:2013. It is in compliance with the appropriate requirements of EN 55011 and EN 61000-4 -2,3,4,5,6,8.
	The maximum length of cables to external devices like printer, barcode or LIS must be less than 3m to keep compliance with EMC

1.5.6 RECYCLING OF THE INSTRUMENT

	The system must be decontaminated before being transported to an authorised disposer for electrical waste.
	The instrument must be recycled as required by guideline WEEE (2012/19/EU). As of the 19th February 2007, Helena Biosciences Europe products meet the European Union Waste Electrical and Electronic Equipment (WEEE) Directive. When supplied as B2B EEE the producer invokes regulation 12.2 and passes all WEEE obligations to the end user.

2. INSTALLATION OF THE HELENA C-SERIES

2.1 SCOPE OF DELIVERY

Contents of standard delivery package for Helena C-1, Helena C-2 and Helena C-4:

Contents	Qty
Helena C-Series Instrument	1
Power Supply Cable with EU, UK & US adaptors	1
Single Cuvettes (x100)	2
Reagent Containers, Ø22.5 mm (x5)	1
Reagent Tubes Ø11 mm (x5)	1
Display Protection Foil	1
Instrument ID Card	1
Instructions For Use statement	1

For items required but not provided see section 1.3.

2.2 CONDITIONS OF OPERATION

Ambient conditions:

Operating Temperature	15 to 30 °C
Humidity	< 70% rel. humidity
Elevation above NN sea level	< 3,000m
Free of dust	Grade 2
Impact resistance	According to IEC/EN 61010-1, 8.2.2
Not allowed	Vibrations, direct sun light and direct exposure to air conditioning.

Electrical conditions:

100-240 VAC, 47 - 63Hz, no earthing required (Class-2)

Electrostatic Discharge (ESD):

No special requirements for ESD protection (shoes etc.)

Storage conditions:

0 - 50°C, max. 12 months in original package.

Transport conditions:

No special conditions required. The general regulations for transport can be used.

Hygienic conditions:

Validate your hygienic management system according to international applied Good Laboratory Practice (GLP) or similar quality standard. Any waste material must be considered as potentially infectious. Direct contact must be avoided. Protective gloves during operation, service or cleaning are required.

Device environment:

No special requirements. Instruments are suitable for use in clinical and industrial establishments.

2.3 FIRST INSTALLATION

Inspect the packaging of the **Helena C-Series** instrument and accessories for any visible external damage. If the packaging is damaged, contact the transport company so that any damage to the device or accessories can be assessed.

The instrument is ready to use.

Once the instrument is installed go to www.c-series.com and complete the online Installation Check List.

First installation procedure:

1. Unpack and place instrument in conformity with conditions of operation (see previous chapter).
2. Install any accessory's (Protection foil, printer, barcode, Tecam – see next chapters)
3. Plug in power 5V.
4. Wait until green Status (approx. 15 min). The instrument is now ready to use.
5. Register instrument online for start of warranty period (see section 2.9).
6. Activate 500 cuvettes (see chapter-4 "ticket system").

	***Keep the original packaging material for transport.***

	maximum length of cables to external devices like printer, barcode or LIS must be less than 3m to keep compliance with EMC.

2.4 SWITCHING ON AND OFF

Switching on
Connect with power supply

Important Information:
The instrument requires approximately 15 minutes to heat up the optic block to 37°C. Afterwards it is ready for measurement, indicated by a green dot in the top right corner of the display. If the status symbol does not turn green, even after waiting for 25 minutes, press the status symbol to see the device status to identify the problem.

Switching off
The device supports no power switch. It must be disconnected from power. To do this, unplug the power adapter from the socket on the device first and then disconnect the power supply.

Standby
The system switches to standby after 2 minutes of idle operation. In standby mode, the display brightness is reduced to save display lifetime and reduce power consumption. The next touch anywhere on the display disables the standby mode.

Sleep
Open menu and touch the “sleep” button: ⏻

The menu bar is displayed on top of screen and only available if no measurement is ongoing. The power consumption during sleep is 0.2W.

Wakeup
To wake the device up from sleep, touch the display.

The system can be disconnected under any operational situations. There is no risk of system damage.

2.5 DISPLAY PROTECTION FOIL

Requirements:

Type:	Touch sensitive Protection foil, Ready to fix on display.
Size:	Same as Display (4,3")

Installation:

- Clean the display before attaching the protector foil. Removing any dirt or dust particles, first with a clean wet tissue and then a dry tissue.
- The protection foil consists of 2 pieces. 1 carrier foil and the protector itself. Don't touch the adhesive side of the protector with fingertips.
- Fix the protector smoothly on the display by pulling the carrier foil away. Do not bend the protection foil whilst applying. A plastic card covered in a soft cloth could help to apply the protection foil.
- Continue slowly pulling the carrier foil and smooth with the covered plastic card over the protector. Air bubbles can be brushed out from the inside to the outside.

2.6 EXTERNAL THERMAL PRINTER

Requirements:

Type:	Serial RS232 Printer
Power:	External supply, 24V 1.5A
Cable:	2 x Sub D9, female, straight, max length 3m
Interface:	RS232, 9600 Baud, 8, 1, No

Installation:

The printer is ready to plug in. No settings are required.

Do not plug power supply of printer (24V) to a Helena C-Series instrument. It will destroy the instrument! Double check before you plug-in.

2.7 EXTERNAL BARCODE SCANNER

Requirements:

Type:	Serial handheld scanner
Power:	5V DC over cable, PIN-9
Cable:	Included to scanner
Interface:	RS232 9600 Baud, 8, 1, No
Setting:	No handshake or protocol. Barcode must be finished with carriage return.

Installation:

The scanner is ready to plug in. no settings are required.

2.8 TECAM SMART

Requirements:

License:	TECAM SMART fingerprint and activation code.
Cable:	USB, type A to B, max 3m
Interface:	USB
Setting:	No handshake or protocol. Barcode must be finished with carriage return.

Installation:

a) Disconnect the device from PC.
b) Run setup.exe.
c) Confirm when asked to install the Helena C-Series instrument driver.
d) Connect device with PC.
e) Start TECAM

Further information available in chapter “7”.

2.9 REGISTRATION

The instrument must be registered online for warranty or service issues

1) Visit the C-Series website: www.c-series.com.

2) The site provides help and instructions. Follow the **Register** link.

3) Enter **SIN + PIN** of device.

   Both can be seen on the instrument label, instrument ID card or during start up or on info screen.

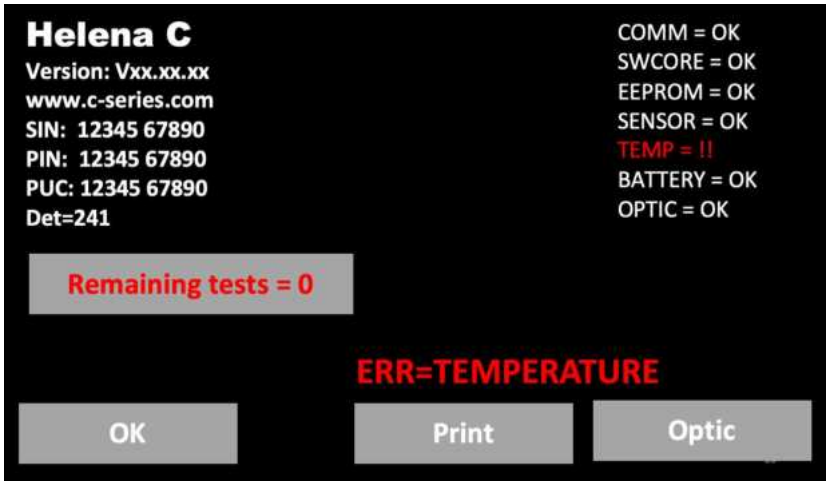


FIGURE 5: SYSTEM INFORMATION

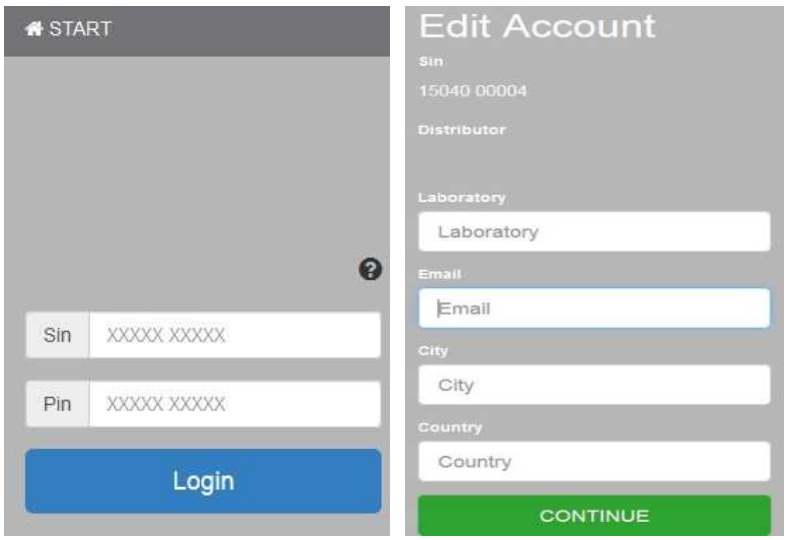


FIGURE 6: REGISTRATION OF HELENA C-SERIES

3. OPERATION OF THE HELENA C-SERIES

3.1 HOMESCREEN

After boot or home button following screen is displayed

FIGURE 7: HOMESCREEN HELENA C-SERIES

UI Element	Element Name	Use Function
(1)	Date & Time	Edit date
(2)	Current test	Change test
(3)	Stopwatch	Start/Reset stopwatch or countdown
(4)	Menu or Home	Open menu or return to main
(5)	Status Dot	Show device status/Open system information
(6)	Multistart	Activate all channels
(7)	Optic-Button	Channel-1 is idle. Touch to enter new PID and activate
	Active	Channel is active. Touch or add reagent to start
	Blinking green	Ongoing measurement. While green state it is allowed to touch, mix or move cuvette.
	Blinking orange	Ongoing measurement. Don't move nor touch cuvette. Touch button to stop measurement
	Current result	Touch to enter new PID

Other functionality:

[LIS]	Visible, if connected with LIS
Green LED	System is ready for measurement
Red LED	Indicate system problems. No measurement is possible.
37.0°C	Temperature on reagent block.
Greyed buttons	Use function is not possible during measurement.
Reduced brightness	Screensaver mode. Touch to reactivate.
Long touch	Repeat current function
Green Yellow Red	Green = Ready to measure, no problems Yellow = Ready to measure, minor problems Red = Not ready to measure, major problems

3.2 INPUT PATIENT IDENTIFICATION

Call: Home screen/Optic button

FIGURE 8: INPUT PATIENT ID

Button	UI Element	Use Function
Numeric keys	0-9, C, X	Change or delete PID.
Increment	-1 / +1	Increment PID. Use long touch feature for easy change.
Hi-Sense	Hi-Sense	Enable very high detection sensitivity. Useful for high diluted or lipemic samples or "+++" results.
Additional:		
Long touch	-	Press button > 2sec.
Sample barcode	-	Set PID to barcode.

3.3 TEST SELECTION

Call: Home screen/Test button

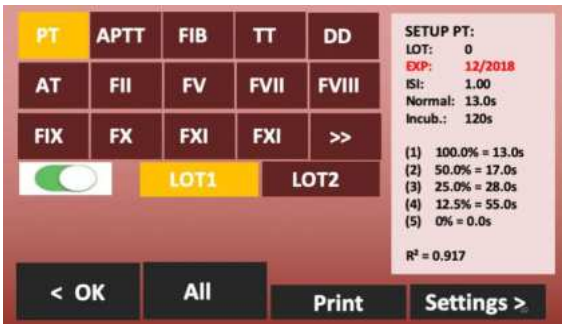


FIGURE 9: TEST SELECTION HELENA C-2/C-4.

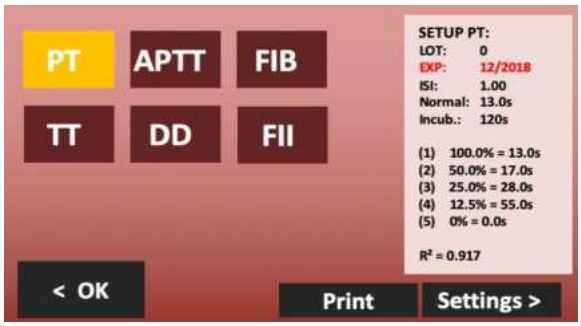


FIGURE 10: TEST SELECTION HELENA C-1.

Button	UI Element	Use Function
Test keys	PT – F12 >> <<	Select test. Change test table
On / Off	On / Off	Activate two LOTs per test (not available for Helena C-1).
LOT 1/2	LOT 1 / LOT 2	Load calibration of LOT 1 or LOT 2 from memory.
OK	< OK	Confirm test for current channel.
All	All	Confirm test for all channels.
Settings	Settings >	Change test calibration.
Print	Print	Print current test setup.
SETUP PT	Test Information Box	Calibration data of current lot and test. Red values indicate invalid data.

3.4 MEASUREMENT

FIGURE 11: SCREEN DURING MEASUREMENT

Button (7) during measurement	
PID	Patient identification number (max 16 numbers).
Result	PT = 12.5s, 115% 0,91 INR.
Flag	f = very low fibrinogen (weak clot). F = very high fibrinogen (strong clot). * = Result is out of calibration. X = double value deviate more than 15%.
Err	T = temperature not 36 - 38°C. E = reagent expired. S = light intensity too low.
mOD	Current optical absorbance. A change of value > 50mOD indicates an ongoing clot reaction.
Timer	Current time of measurement.
Grey blinking	Optic is ready for start of measurement
Green blinking	Measurement is started, but cuvette can be mixed or touched.
Orange blinking	Stop mixing and don't touch cuvette anymore

3.5 SYSTEM SETTINGS

Menu and functions depend on instrument version Helena C-1, Helena C-2, Helena C-4.
Call: Home screen/Menu button

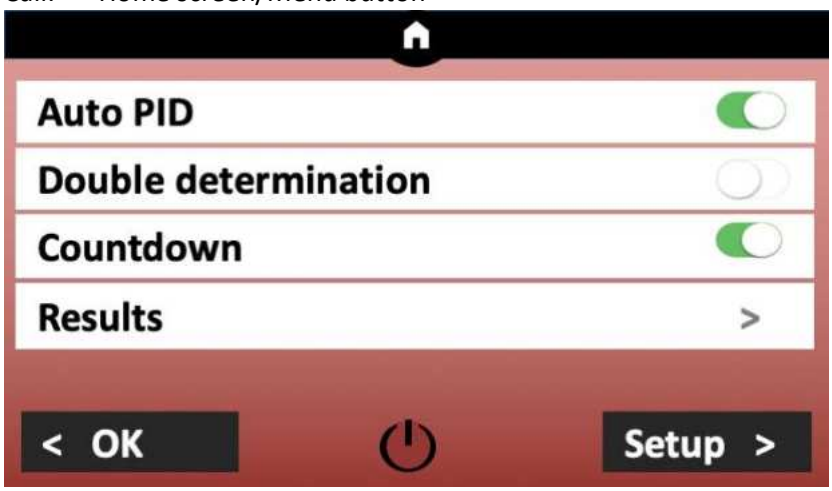


FIGURE 12: QUICKMENU HELENA C-SERIES

Button	Use Function
Auto PID	Enable/Disable the Auto PID feature.
Double determination (not visible for Helena C-1)	Enable/Disable Double determination
Countdown	Switch between Stopwatch and Countdown mode.
Results	Open the result history.
Setup	Open the system setup.
⏻	Put the device into sleep mode.
OK / 🏠	Return to the home screen.

Auto PID:
Using the Auto PID mode enables the user to let the device choose a consecutively numbered ID for every measurement. By setting the ID manually you set the start ID. Every new channel activation automatically sets the ID to the next higher number.

Auto PID mode must be enabled to use the Multistart feature!

Double determination:
When using double determination mode, the channels 1 / 2 (Helena C-2) respectively channels 1 / 2 and 3 / 4 (Helena C-4) are combined to perform a test using the same ID twice. Both results are combined by calculating the mean value.

Countdown:
Use the stopwatches in countdown mode. The period of countdown is defined by incubation time of test (see “test settings”). When Countdown mode is enabled, the stopwatches count down gives an alarm 5 seconds before zero.

Results:
Pressing the Results button opens the result history screen.

Setup:
Pressing the Setup button opens the system settings.

⏻:
Pressing the Sleep Button sends the device into the sleep mode. To wake the device up, touch anywhere on the screen.

OK Button / ⌂:
Pressing the OK or Home Button returns to the home screen.
Call: Home screen / Menu / Setup

FIGURE 13: SYSTEM SETTINGS HELENA C-2 AND HELENA C-4.

Setting/Buttons	Use Function
Date	Set system date, use long touch on "<" ">" to scroll through the values faster. Short touch on date change the format (EU / US) Long touch on date resets to default date.
Time	Set the system clock. Long Touch the time to reset to default.
Language	Select the system language DE/EN/ESP/ITA/FR/RO/PL/DA/NL/SR/ET/FI/HR/LV/LT/PT/SE/SK/SI/CS/HU.
Mixer (not available for Helena C-1)	Some reagents like PT sediment and need to be stirred. Select here the mixer intensity (Low/Normal/High). Insert vial and magnetic stirbar into middle position. Change speed until stirbar ensures proper mixing.
Temp	Correct the actual current temperature of the reagent block. Long touch the temperature value will reset to default. Detailed information can be read in chapter "Adjust temperature".
OK / ⌂	Return to the home screen.
Info	Open system information.
< / >	Increase or decrease value. Use long touch to scroll

3.6 TEST SETTINGS

Call: Home screen / Test button / Settings

FIGURE 14: TEST SETTING 1

Setting/Buttons	UI Element	Use Function
LOT	LOT Number field	Press the LOT text field to enter or change LOT number.
Expiry	Expiry date field	Press the expiry date value to select the field
Units	mg/dl 0-999 63 - 500	Press to change unit Result limited to unit range (min, max) Result limited to calibrated range
Incubation	Incubation time field	Press the incubation value to select the field.
Stop	Stop time field	Press the stop time value to select the field.
+ or -	+ or -	Change the value of the selected field.
Numeric keys	0 – 9 and C	Keys for LOT entry. C=Clear
OK	< OK	Save settings and exit screen.
ESC	ESC	Exit to test selection without saving.
Admin	Admin	Open advanced test settings. Only visible for administrator user.
Settings	Settings >	Open test calibration settings (Screen test settings 2)

LOT:
Enter the LOT of the used reagent for the selected test. If dual LOT is used, use the test selection screen to choose LOT 1 or LOT 2. Both LOT numbers have individual test settings.

Expiry:
Enter the expiry date of the reagent for the selected test (and LOT).

Units:
Value: Select the units used for the test results. The available unit is predefined for each test.
Range: Limit results to unit or calibration range. Results out of range are reported as “>Max” or “<Min”.

Incubation:
Required waiting time until adding final reagent and start measurement. The time is used for countdown.

Stop:
Some samples do not clot. After stop time the instrument stops measurement and reports "+++" (no clot detected)

Call: Home screen / Test button / Settings / Settings

FIGURE 15: TEST SETTING 2

Setting/Buttons	UI Element	Use Function
Calibration curve values	Value fields	Press a calibration value to select the field.
+ or -	+, -, ++, --	Change values in small or big steps. Use long touch to repeat change
Double/Half	0.5x 2x	Half or duplicate values
Delete	DEL	Delete the selected value.
Reset	Reset	Reset all values to default.
Calibrators	CAL	Shift all calibration points according to serial dilution (1:1 1:2 1:4 …)
OK	< OK	Save settings and exit screen.
ESC	ESC	Exit screen without saving.

Calibration curve:
Input of Calibration points. Minimum 2 points, maximum 5 points.

Normal:
Reference value for normal clotting time like for PT (MNPT). Only shown, if unit is selected.

ISI:
International Sensitivity Index of PT reagent. Value is available with the reagent.

R^2:
Linearity of calibration depending on mathematics

R^2<0.5	not linear	Y=LIN	linear interpolation
R^2<0.9	moderate linear	Y=1/X	reciprocal linear interpolation
R^2>0.9	high linear	Y=logXY	double logarithm interpolation

3.7 REVIEW RESULTS

The device automatically stores the most recent 100 results into its memory. The most recent result is shown first. If the result history exceeds the memory, then the oldest measurement result is overwritten.

Call: Home screen / Menu / Results

FIGURE 16: REVIEW RESULTS

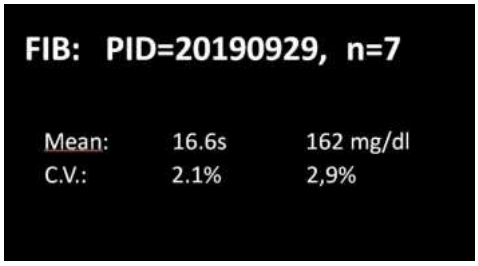
Setting/Buttons	Use Function
< >	Scroll the results.
Filter (on, off)	Scroll only current PID+Test
Print	Print the shown result.
QC  FIB: PID=20190929, n=7 Mean: 16.6s 162 mg/dl C.V.: 2.1% 2,9%	Print & display max. 14 values of current PID+Test including mean and C.V. value. QC REPORT 26.09.2019 System: Helena C-2 SIN: 01040 01234 Test: FIB PID: 20190929 --- 1 16.8s 1.59 g/L 2 17.1s 1.54 g/L 3 16.9s 1.57 g/L 4 16.2s 1.66 g/L 5 16.5s 1.63 g/L 6 16.4s 1.64 g/L 7 16.1s 1.68 g/L --- Mean: 16.6s 1.62 g/L C.V.: 2.1% 2.9%
Reset	Reset the result view to most recent result.
DEL	Delete current result
ESC	Exit screen.

FIGURE 17: QC REPORT

4. TICKET SYSTEM

1) Login to ticket system

Visit the general C-Series support site: www.c-series.com

Follow the **Register** link to the cuvette registration page.

Enter SIN and PIN of instrument! This information can be found on the instrument license plate (label on underside of instrument), Instrument ID card, or on info screen.

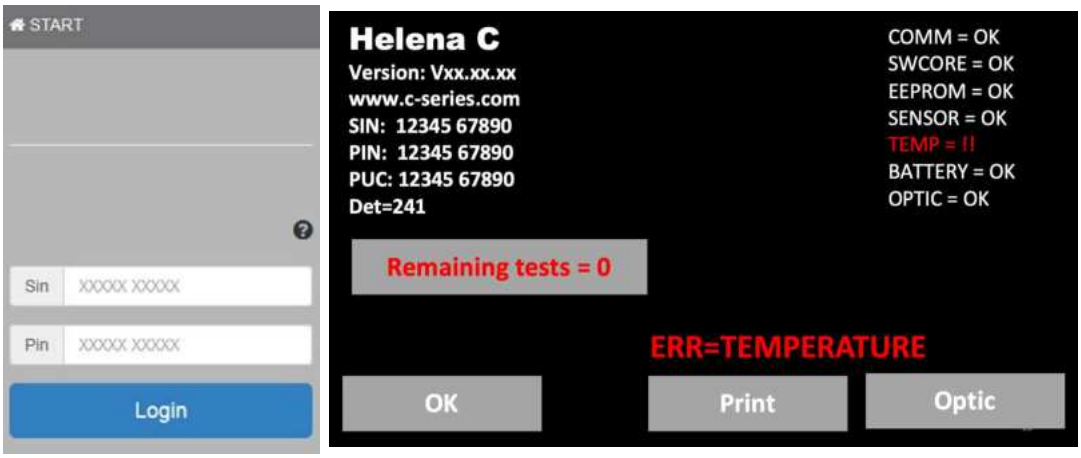
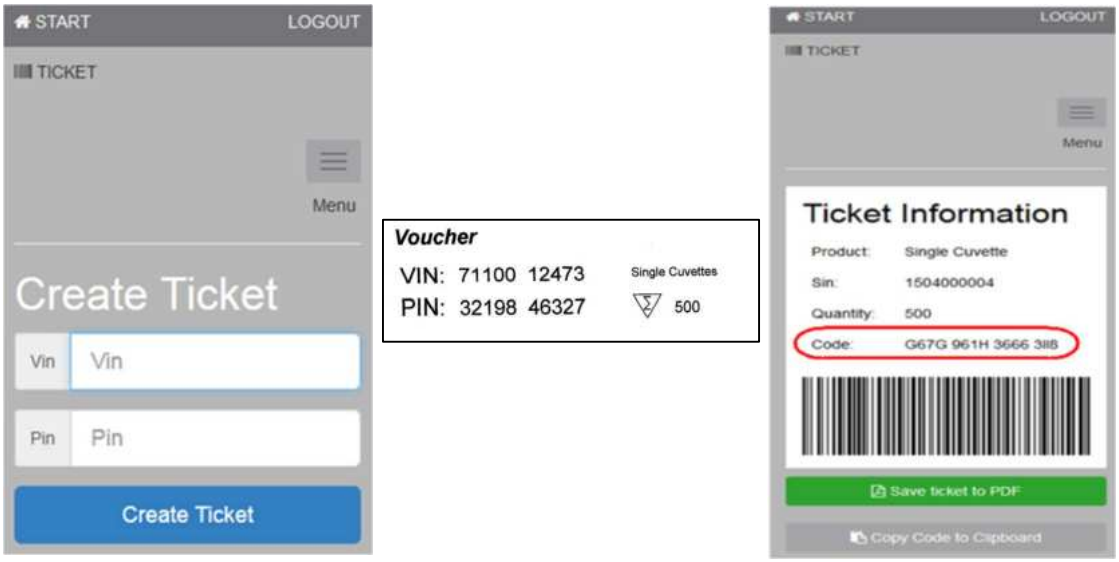


FIGURE 18: TICKET SYSTEM, LOGIN

2) Input Voucher



Enter VIN and PIN of voucher

Voucher is inside cuvette box

Transfer Ticket code to instrument

FIGURE 19: TICKET SYSTEM, VOUCHER

3) Transfer ticket code to instrument

Open info screen (touch blinking RED LED) and then “Remaining tests=0”. The code can be transferred by manual input, barcode scanner or TECAM SMART software.

FIGURE 20: TICKET SYSTEM, INPUT CODE

4) Using TECAM SMART software

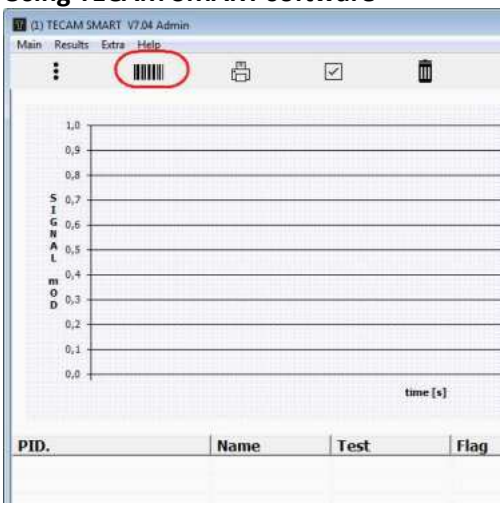


FIGURE 21: TICKET SYSTEM, TECAM SMART

a) Use your mobile device and scan QR code or “Get ticket”, if TECAM is connected to internet

b) Follow dialogue according to chapter (1)

c) Copy and Paste the code and “send” to instrument

5. SERVICE FUNCTIONS

Only for authorized and trained personnel. Unqualified modifications can cause problems and system errors!

5.1 SYSTEM INFORMATION

Call: Home screen / green or red LED

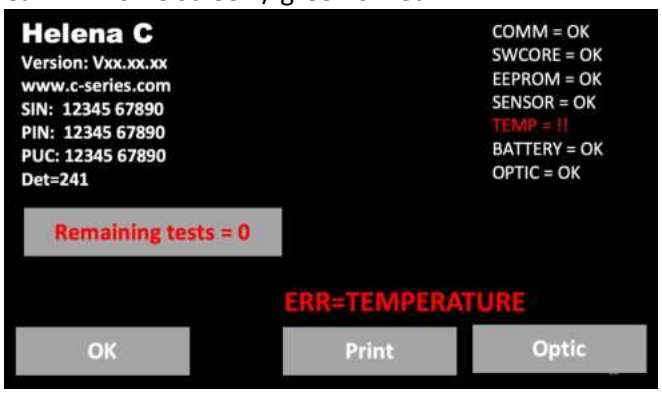


FIGURE 22: SYSTEM INFORMATION

UI Element	Element Name	Use Function
(1)	-	System version information
(2)	OK	Return to home screen
(3)	Remaining tests	Number of activated cuvettes. Touch to activate new cuvettes
(4)	Print	Print out of system information
(5)	ERR message	Show current error
(6)	Optic	Check optic system
(7)	-	System error information

System information

Version of software, URL link to register or use ticket system, system identity number (SIN), product identity number (PIN). SIN+PIN is required for login to ticket system.

Remaining tests=0:

The system will stop operation, activation of new cuvettes is required.

YELLOW warnings - Minor problems:

Reagent expired	Check expiry date of test
Remaining tests < 100	Activate cuvettes soon

RED warnings - System is not ready to measure:

COMM= communication to LIS	SWCORE = software memory overflow
EEPROM= EEPROM/memory error	SENSOR = temperature sensor
TEMP= temperature not 36-38°C	BATTERY = CR2032 on mainboard below 3V
OPTIC= optical system out of range	

5.2 OPTIC CHECK

Call: Home screen / green or red LED / Optic

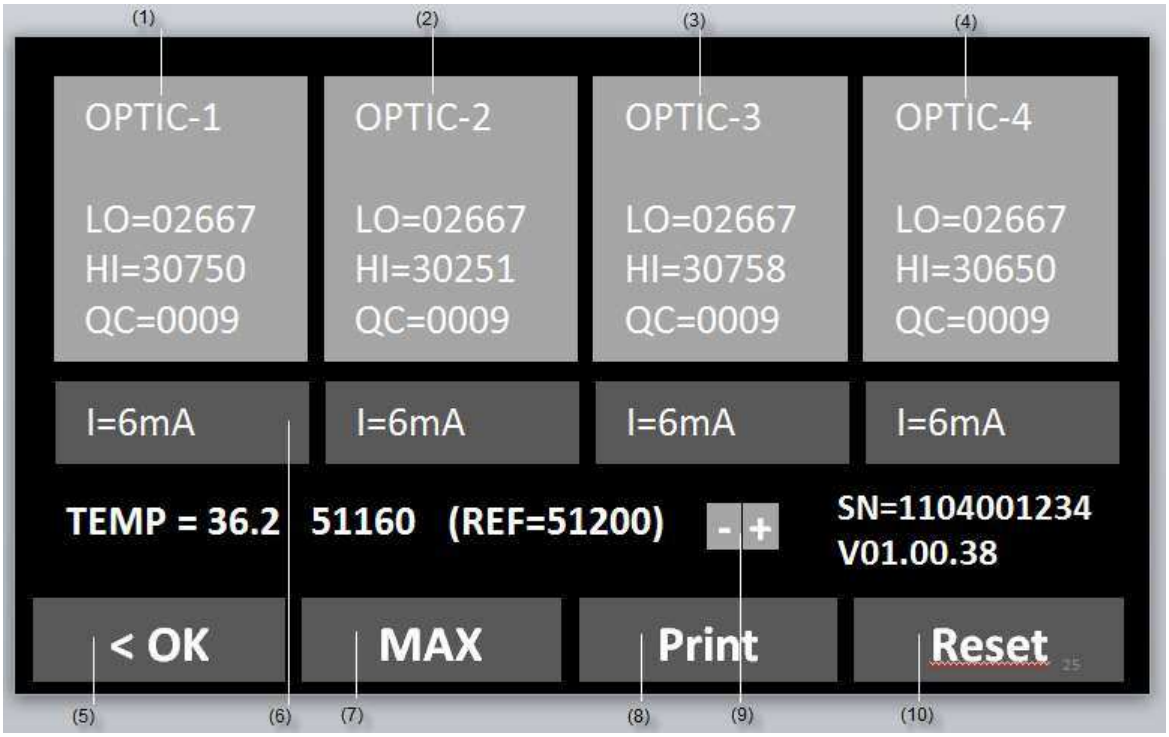


FIGURE 23: OPTIC CHECK

Button	Caption	Use Function
(1)-(4)	OPTIC xx	Reset QC value.
(5)	I=mA	Display and change intensity of LED.
(6)	OK	Return to home screen.
(7)	MAX	Set all LED to max. intensity (42mA).
(8)	Print	Print system report (see next chapter).
(9)	+ / -	Change temperature.
(10)	Reset	Reset all channels and re-calibrate optic .

Information on screen		Fault condition	Troubleshoot
LO	optic signal, when LED is off	> 2900	Replace optic board.
HI	optic signal, when LED is on	< 25000	Remove cuvette and touch "RESET".
QC	noise of optic signal	> 30	Touch button "OPTIC".
mA	power of LED (intensity)	not [3 - 12mA}	Remove cuvette and touch "RESET".
TMP	temperature in °C	not [36.0 - 38.0°C]	Wait 15min.
REF	signal of temperature sensor	not [48000 - 52000]	Adjust temperature or replace sensor.

5.3 SYSTEM REPORT

Call: Home screen / green or red LED / Print

```
SYSTEM REPORT

08.10.2019

System:      Helena C-4
Version:     Vxx.xx.xx
SIN :        01040 01234
PIN:         12345 67890

TEMP:        37.0°C
             50981  (target=51000)

Optic:
  Lo     Hi      mA     Qc
-------------------------------------------
1:2698  28822  5      1      OK
2:2698  29822  6      1      OK
3:2698  30822  7      1      OK
4:2698  29822  6      1      OK

PT=    123
aPTT=  102
FIB=   100
DD=    0
AT=    0

TOTAL  325
```

Date of report

name of system
software version
system identity number
product identity number

Temperature of optic and digital value of thermosensor.

Optical values
Lo= LED off
Hi= LED on
mA= LED power
Qc= noise of optic
OK= no fault
!!= fault condition

count of performed tests

Fault conditions are described in chapter “optic check”.

5.4 ADJUST TEMPERATURE

Call: Home screen / Menu / Temperature

1. Switch on device and wait approx. 15 minutes until system shows 37°C on screen.

2. Fill a reagent tube/vial with 2 mL water and place it in a reagent position. Place a calibrated digital thermometer in the reagent tube and let it warm-up for approx. 10 minutes.

3. Press menu
   Change the current system temperature to the value of the thermometer. Wait 10 minutes and repeat procedure.

   Typical problems:

Malfunction / Error	Possible cause	Measures
System heat not up to 37°C	Sensor calibration is out of range.	Reset to factory default as described in chapter “Hidden Function”.
System show 0.00°C	Sensor is out of range.	Ambient temperature must be 0 – 45°C.
	Sensor or optic LED board is defect.	Replace LED board.

5.5 OVERVIEW OF MAINBOARD

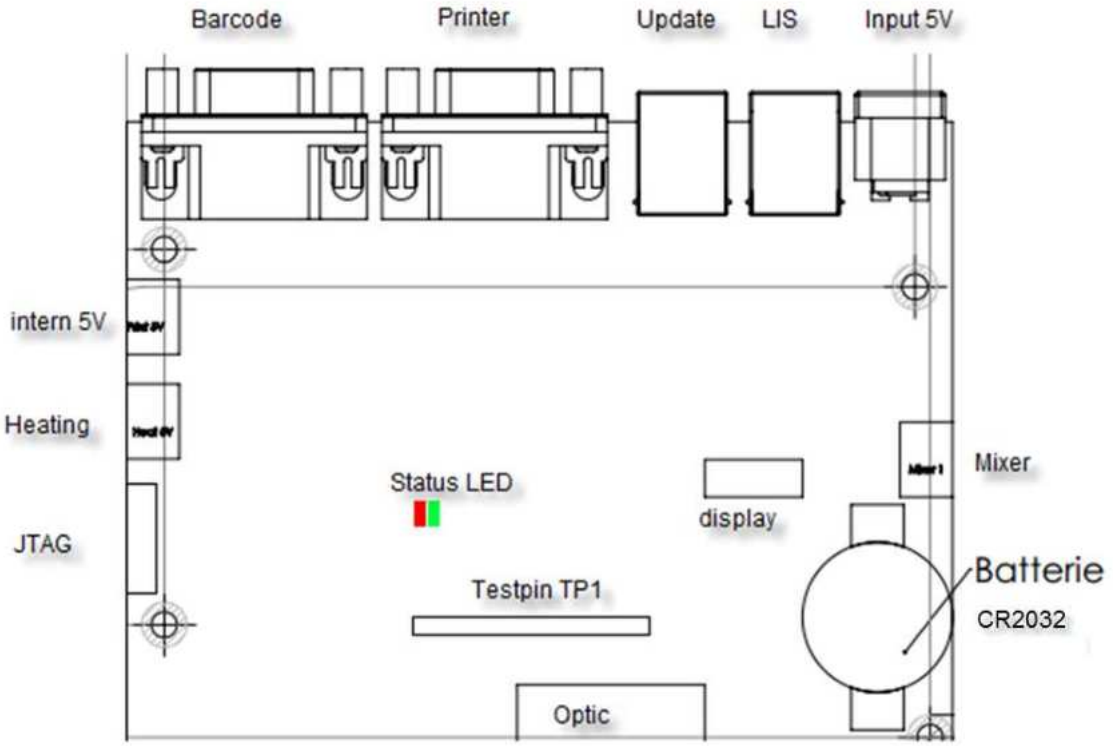


FIGURE 24: MAINBOARD

Testpin Function:

TP1 = Systick Interval, must toggle each 1ms
TP2 = indicate reading of SD24
TP3 = draw homescreen
TP4 = Write to EEprom
TP5 = Read from to EEprom
Other = not used

Status LED:

green, permanent	= everything OK	
red, permanent	= EEPROM error	defect optic unit and/or mainboard
green, blink	= Battery < 3.0V	battery expired
red, blink	= Temp sensor	Optic not connected

5.6 TYPICAL FAILURES

Malfunction / Error	Possible cause	Measures	By
System not ready	Multiple.	Open system info and check red errors.	User
Remaining tests = 0	No cuvette activated.	Create a ticket.	User
ERR=Comm	Mainboard defect.	Replacement.	Authorized service
ERR=SWCORE	Software failure or bug.	Update firmware.	User
ERR=Sensor	Temperature sensor defect.	Replacement of optic.	Authorized service
ERR=Temp	Temperature out of 36-38°C.	Wait 15 minutes.	User
ERR=Optic	Optic channel blocked or LED defect.	Remove cuvette from optic or clean optic or replace optic.	Authorized service
ERR=Battery	Battery low power.	Replacement.	Authorized service

False results	Possible cause	Measures
No or false clot detected.	True, patient anti coagulated or bleeding.	Remove cuvette and check with needle for clot.
	Reagent defect.	Check reagent visually for flakes or clots. Run control plasma to verify. Prepare new vial. Check diluent/water.
	Instrument missed clot.	Increase MAX time.
	Low fibrinogen or optical interference (lipemic, bilirubin, haemolytic).	Repeat but activate hi-sense option.
False result (INR, %, mg/dl, ...)	Method not correctly calibrated.	Check calibration data and correct LOT.

6. HIDDEN FUNCTIONS

6.1 RESET TO FACTORY DEFAULT

System factory reset procedure:

FIGURE 25: WELCOME SCREEN AND FACTORY DEFAULT

How to reset to factory default:

1. Press 3sec to spinner during boot up.
2. Select “OK” Switch on device and switch to home screen.
3. Confirm the reset.

⇨ ***Date, temperature and test calibration must be adjusted after a factory reset!!***

Default values:

- Temperature sensor = 51000
- Mixer = 1;
- Language = EN;
- Double determination = OFF;
- Auto PID = ON;
- Countdown = OFF;
- All results stored on board are deleted
- All test calibration data are reset to default

Test Calibration:

How to reset to factory input a PT calibration

1. Switch on device and switch to home screen.
2. Touch any test button.
3. Change test to ‘PT’ and touch ‘Setup’.
4. Enter LOT, Expiry and select units to ‘% +INR’.

7. WORKING WITH TECAM SMART

> ***This is an overview of TECAM. For additional information about installation and operation contact Helena Biosciences Europe Haemostasis Technical Support.***
> **TechSupport-HS@helena-biosciences.com**

TECAM software is a small local LIS and combines laboratory data management, quality control and research functions in one. It connects a Helena C-Series instrument to a larger LIS and manage results in its own local database. Flexible filters allow QC with Levey-Jennings graphs and Westgard analysis. Each result can be traced back to reagent lot and calibration.

Features	Smart
Receive result from analyser	The results can be reported and manage in a local database.
Receive calibration curve from analyser	Visualize and manage calibration data for all reagents and LOT.
Receive reaction curve	Visualize the optical reaction for research, result verification or failure analysis.
Patient information	Connect Patient-ID with name and other information.
LIS communication	Talk to LIS with ASTM-1394 standard protocol. Receive from LIS: Patient information. Send to LIS: Results.
Statistical analysis (QC)	Power filters allow quality Levey-Jennings graphs and Westgard analysis, for controls as well as for patients.
integrated TECMONI	This is a powerful research tool to visualize reaction curves in real time. It is a great tool for reagent development or adapting tests to an instrument.
Ticket system	Activation of cuvettes in its easiest way. Connect to ticket system, receive ticket and send to instrument.

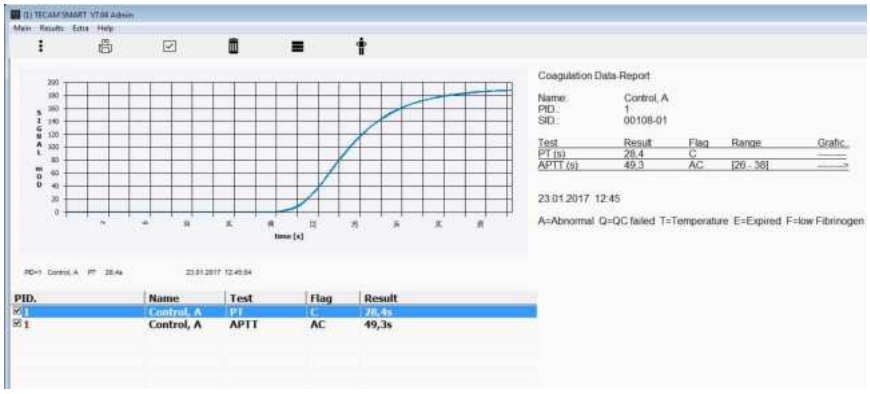


FIGURE 26: TECAM SMART

8. CLEANING AND MAINTENANCE

- Clean with a lint free cotton cloth or stick.
- Never put any liquid into the optic working area or onto touch display.
- Keep the device free of dust and moisture.
- If the device is soiled with liquids, remove the soiling with an absorbent cloth.
- If a liquid has accidentally been spilt or pipetted into a measurement channel, remove power immediately and clean the measurement channel with pipette and a lint-free cloth. Check the function of the optics in the menu SERVICE.

Regard all surfaces and materials, which might be in contact with plasma or other biological liquid as potentially contaminated with infectious material.

Avoid any direct contact with decontaminants or disinfectants.

8.1 CLEANING

- Use microfiber tissue only and no liquid to clean the screen.
- Clean and wipe up all spills around the working area with 5-10% diluted bleach detergent or water.

8.2 DECONTAMINATION

- Use 30% diluted bleach and commercial disinfectant.
- Decontaminate working area. Don’t apply liquid on display.

8.3 REGULAR MAINTENANCE

- No maintenance required.
- It is advised to perform a temperature check daily or before use.

9. APPENDIX

9.1 TECHNICAL DATA

Analyser	
Display	capacitive touch sensitive TFT 4.3'' 480x272
Measurement system	1-4 independent measurement channels wavelength of LED 405 nm
Cuvette	single channel cuvette for optical detection
Positions (prewarmed)	5 reagent positions at 36.5 – 37.5 °C 20 (10 for Helena C-1) cuvette positions at 36.5 – 37.5°C
Reaction volumes	Minimum total volume is 75 µl
Power supply	
Input Power	100 – 240VAC/ 50-60Hz/ 600-300mA
Output Power	5V DC, 5A
Battery (mainboard)	Lithium CR2032 3V
Power consumption	max. = 14W sleep < 0.5W
Dimensions	
Size (W x D x H)	225 x 150 x 90 mm
Weight	1.04 kg (without power supply)
Ambient conditions	
See chapter "Installation"	
Noise output	
Operating noise	max. 50 dBA
Interfaces	
RS232 (Barcode)	Sub-D9, female; 9600 Baud/8/1/N; Pin-9 powered with 5V DC. For external handheld barcode scanner, serial printers
RS232 (Printer)	Sub-D9 female; 9600 Baud/8/1/N; For serial printers
USB (Service, Firmware Update)	Type-B, female, 115200 Baud/8/1/N
USB (LIS)	Type-B, female, 115200 Baud/8/1/N; For LIS communication

Declaration of Conformity

HL-7- 0137 DC DOI 2013/10 (6)

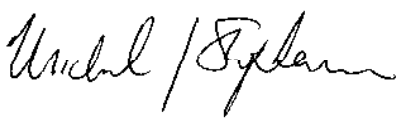
In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.*

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5186	Routine Control N	30590

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson Title: Managing Director

Signed:  Date: 31st October 2013

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United Kingdom

Declaration of Conformity

HL-7- 0138 DC DOI 2013/10 (6)

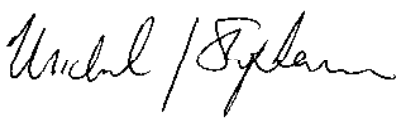
In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.*

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5187	Routine Control A	30590

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson Title: Managing Director

Signed:  Date: 31st October 2013

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Declaration of Conformity

HL-7- 0163 DC DOI 2014/05 (8)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.*

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5265	Thromboplastin LI	55983
5265H	Thromboplastin LI	55983
5267	Thromboplastin LI	55983
5269	Thromboplastin LI	55983

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson Title: Managing Director

Signed: Date: 07 May 2014

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Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

HL-7- 0511 DC DOI 2013/08 (3)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.*

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5376	Clauss Fibrinogen 100	55997
5376H	Clauss Fibrinogen 100	55997

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:

Date: 05 Aug 2013

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United Kingdom

Declaration of Conformity

HL-7- 0640DC DOI 2015/07 (1)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5504R	Calibration Plasma	55995

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson Title: Managing Director

Signed: Date: 30 Jul 2015

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United Kingdom

Declaration of Conformity

HL-7-DC-0814 Rev. 1

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5560	APTT Si L Minus	55981

I, the undersigned, declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: C.J. Sandercock Title: QA and Regulatory Affairs Officer

Signed: Date: 24 Nov 2020

Helena Biosciences Europe,
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EC REP
Prince Technologies B.V.
Waanderweg 62,
7812 HZ Emmen,
The Netherlands

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Helena Laboratories (UK) Ltd
trading as Helena Biosciences Europe
Queensway South
Team Valley Trading Estate
Gateshead
Tyne and Wear
NE11 0SD
United Kingdom

Holds Certificate Number: **MD 69326**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2002-10-25
Latest Revision Date: 2024-03-26

Effective Date: 2024-04-14
Expiry Date: 2027-04-13

...making excellence a habit.™

Certificate No: **MD 69326**

Location	Registered Activities
Helena Laboratories (UK) Ltd trading as Helena Biosciences Europe Sunderland Enterprise Park Colima Avenue Sunderland SR5 3XB United Kingdom	The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.
Helena Laboratories (UK) Ltd trading as Helena Biosciences Europe Queensway South Team Valley Trading Estate Gateshead Tyne and Wear NE11 0SD United Kingdom	The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.

Original Registration Date: 2002-10-25

Latest Revision Date: 2024-03-26

Effective Date: 2024-04-14

Expiry Date: 2027-04-13

Training certificate

helena
Biosciences Europe

This is to certify that

Sergiu Sorocovici

from

IM Global Biomarketing Group

has received training on the following:

Electrophoresis products: SAS-1/2,V8
Haemostasis products: C-series, AC-4, AggRAM and reagents
Service training: AC-4

Signed:

Helena Biosciences Europe (UK) • Helena Biosciences Europe (UK) • helena Biosciences Europe

Date: 31st October - 4th November 2011

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