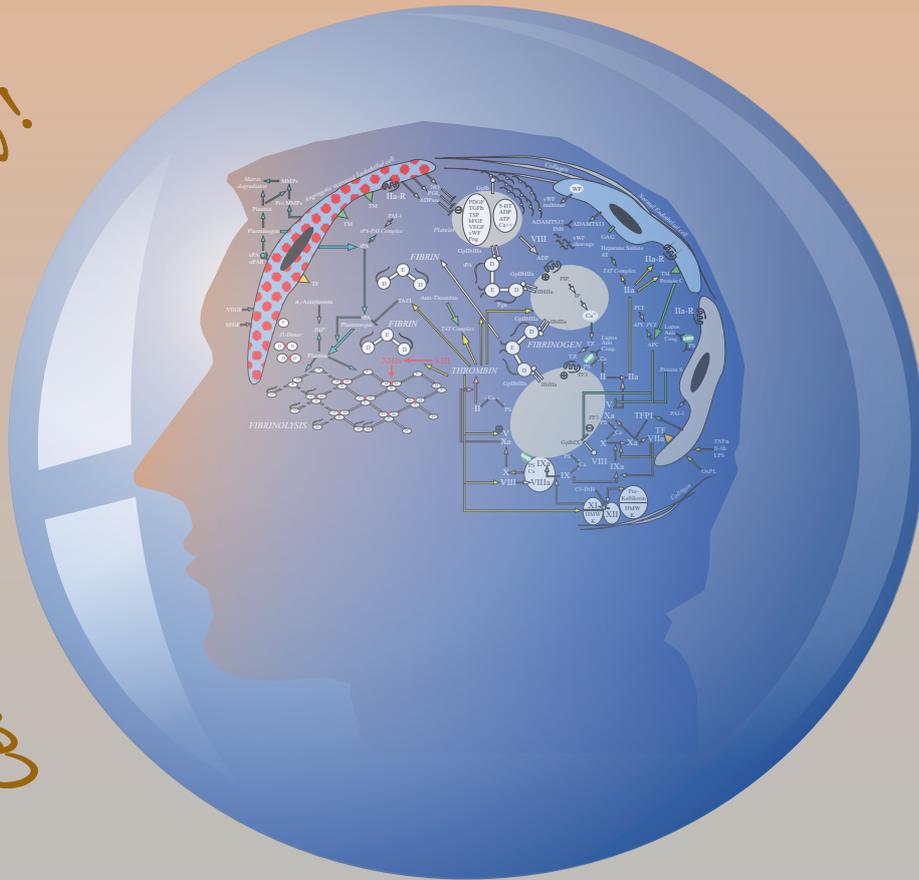


Ceveron on your mind!



ceveron[®]m
User Manual

USER MANUAL
Semi - Automated Blood Coagulation Analyzer
Ceveron m series
Ceveron m1; Ceveron m2; Ceveron m4
SW Version: 1.04.52

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REF:3052600RUO-002

CONTENTS OF THIS MANUAL

To use this instrument and its functions to its full extent, please read this manual carefully and use the instrument as described.

RECEIVING INSTRUCTIONS

The Ceveron m series instrument has been thoroughly tested before shipment, and has been packaged carefully to prevent damage from shipping and handling. Follow these guidelines when the system arrives:

- Perform a visual inspection of the outside for any kind of possible shipping damage. Document any sign of damage on the bill of lading, regardless of how insignificant it may appear. This is for your protection!

WARRANTY INFORMATION

The Ceveron m series instruments are warranted for a period of one year after delivery or first installation. It covers any defects in material, functionality or workmanship. First installation must be registered online at www.technoclone-reg.com.

This warranty does not cover any defect, malfunction, or damage due to:

1. Accident, neglect or willful mistreatment of the product.
2. Failure to use, operate, service, or maintain the product in accordance with this manual.
3. Failure to use the appropriate reagents or chemicals specified for the product.

IMPORTANT

- It is prohibited to reproduce parts or all of the contents of this manual without permission.
- The display screens shown in this manual may differ slightly from the actual displays.
- As a result of product improvements, details described in this manual may differ slightly from the actual product.
- Specimen names and doctor names are entered for information and illustration purposes only, and do not imply real specific persons.

HAZARD AND PRECAUTIONS

The cautions and safety regulations in this instruction manual correspond to international classification.



Danger

Warns of a risk of injury or of a risk to life (for example, by electrical shock).



Caution

Warns of a risk of injury or of the instrument being severely damaged.

The following caution and safety regulations must be observed at all times:



All blood and plasma samples and products have to be regarded as potentially infectious. They have to be handled with appropriate care and in compliance with the biosafety regulations in force. They must be disposed of in the same way as hospital waste.



Warns of a risk of the eyes being severely damaged.



LED Light Radiation

Avoid direct eye exposure.

The optional available CCD barcode scanner is assigned to EN 55022:2010 class B, EN 62471:2008.



Danger

1. Electrical safety

Never knowingly interrupt the earthing contacts. There is the risk of an electrical shock if:

- the protective conductor is interrupted within or outside the device, and
- the grounding contact has been disconnected from the mainline.

Never remove protective guards or secured components since you could expose live parts in this way.

Electrical connection contacts (plugs, sockets etc.) can be electrically live.

Even after the device has been switched off, components (e.g. capacitors) can be under voltage as the result of an electrical charge.

All current-carrying parts are sources of danger for an electrical shock.

Surfaces (floors, work tables, etc.) have to be dry when you are working with the device. Do not use the device on a moist base.

Avoid spilling liquids into system. In case of spilled liquids disconnect the system from power, then clean and dry all contaminated parts.

Check electrical equipment regularly. Defective leads or socket must be replaced without delay.

Instrument is in compliance with IEC 61010-1 / 61010-2 and classified as portable instrument, class II. It does not require a safety connection to electrical earth.

Make sure to use only the power supply which was delivered together with the instrument.

The power cord always has to be easily accessible during normal operation.

The Ceveron m series instrument is suitable for use in domestic and industrial establishments. It was tested according to standards IEC 61326-1:2013 and IEC 61326-2-6:2013, It is in compliance with the requirements

Emission: EN 55011, Class B, Group 1

Immunity: EN 6100-4 -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



Caution

2. Fire and explosion hazards	Do not place any fire or hazardous explosive material in the proximity of the analyzer. Electrical sparks could cause fire or explosions.
3. Samples	Risk of infection: Avoid any direct contact with samples which are potentially infectious or which may generate other risks to the human body. If samples material is spilled onto the analyzer, wipe it off immediately.
4. Reagents	Observe the suggestion in the package insert for a correct use of the reagents.
5. Waste solution	Dispose of waste solution in compliance with legal provisions.
6. Accuracy and precision of the measurement results	In order to ensure a flawless operation of the analyzer, measure control samples and watch the function of the instrument and the used pipettes closely. Wrong results of measurements may result in an incorrect diagnosis and thus to a risk for the specimen.
7. Restrictions for samples and reagents	For cuvettes, reagent container and reagent tubes, no guarantee can be provided for any resistance against organic solvent. For this reason, do not use any organic solvents unless such solvents are expressly authorized.
8. Operator qualification	<i>The analyzer should be operated by trained personnel only.</i>
9. Cleaning and Decontamination	Before the instrument is removed from the laboratory, it must be decontaminated. The procedure is described in chapter "Cleaning and Decontamination" and should be performed by authorized well-trained personnel only, observing all necessary safety precautions

Frequently used abbreviations

TC.....Technoclon

LIS.....Laboratory Information System

QC.....Quality Control

ASTM....American Society for Testing Materials

LED.....Light-Emitting Diode

INR.....International Normalized Ratio

ISI.....International Sensitivity Index

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Ceveron is a registered trademark of Technoclon Herstellung von Diagnostika und Arzneimitteln GmbH.

Other product names used in this operator's manual are trademarks of the respective companies.

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1. Introduction

1.1. Intended use

The Ceveron m series systems are semi-automated instruments for analyzing research use only coagulation tests including clotting, chromogenic and turbidimetric methods. Analysis is performed in human plasma or whole blood, depending on the specific device model. The devices are intended for professional use by qualified personnel in laboratories or clinical environments.

1.2. General description

The Ceveron m series includes three different versions: Ceveron m1, Ceveron m2 and Ceveron m4

Ceveron m series	m1	m2	m4
			
Reagent and optic block temperature	37 °C		
Cuvette prewarm positions	10	20	20
Reagent prewarm positions, 24mm	1	1	1
Reagent prewarm positions, 22mm	2	2	2
Microtubes prewarm positions	2	2	2
Reagent stirrer	No	Yes	Yes
Printer, RS232	Yes, external		
Barcode Scanner, RS232	Yes, external		
LIS, USB	Yes		
Firmware Update, USB	Yes		

Measurement			
Optic Channels	1	2	4
Optic Wavelength	620nm (RED)	405nm (UV)	405nm (UV)
Cuvette, Total Volume	Single, 75µL	Single, 75µL	Single, 75µL
Global Clotting Assays*	PT Owren+ PT+aPTT+Fib +TT	PT+aPTT+Fib +TT	PT+aPTT+Fib+ TT

Chromogenic Assays*	-	AT	AT
Latex enhanced Assays*	-	-	-
Whole Blood Testing	Yes	No	No

*Actual status when launching the instrument. More parameters are in development and validation process.

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 date; or positive LOT detection	Yes	Yes	Yes
Specimen barcode Input specimen ID by barcode scanner up to 16 characters	Yes	Yes	Yes
System barcode Input voucher tickets by barcode scanner directly from display of smart device	Yes	Yes	Yes
Result database save recent 100 results on board	No	Yes	Yes
Double determination Run specimen twice and display mean value	No	Yes	Yes
Stopwatch / Timer function incubation time	1x	2x	4x
Result identification Specimen ID, sample ID or auto ID	Yes	Yes	Yes
Real time clock	Yes	Yes	Yes
Multiple languages	Yes	Yes	Yes
Start test automatically after reagent pipetting	Yes	Yes	Yes
Visualize reaction curve Ceveron DAT software required	Yes	Yes	Yes
Link to LIS using USB or network/ASTM Ceveron DAT Software required	Yes	Yes	Yes

1.3. Test Methods

Following parameters are available on Ceveron m series instruments.

Test	Name	Specimen	Method	Ceveron m		
				m1	m2	m4
PTB	PT Owren	blood	clotting	Yes	No	No
PT	TECHNOPLASTIN HIS	plasma	clotting	Yes	Yes	Yes
APTT	Siron LS	plasma	clotting	Yes	Yes	Yes
FIB	Fibrinogen	plasma	clotting	Yes	Yes	Yes
TT	Thrombin Time	plasma	clotting	Yes	Yes	Yes
AT	Antithrombin	plasma	chromogen	No	Yes	Yes

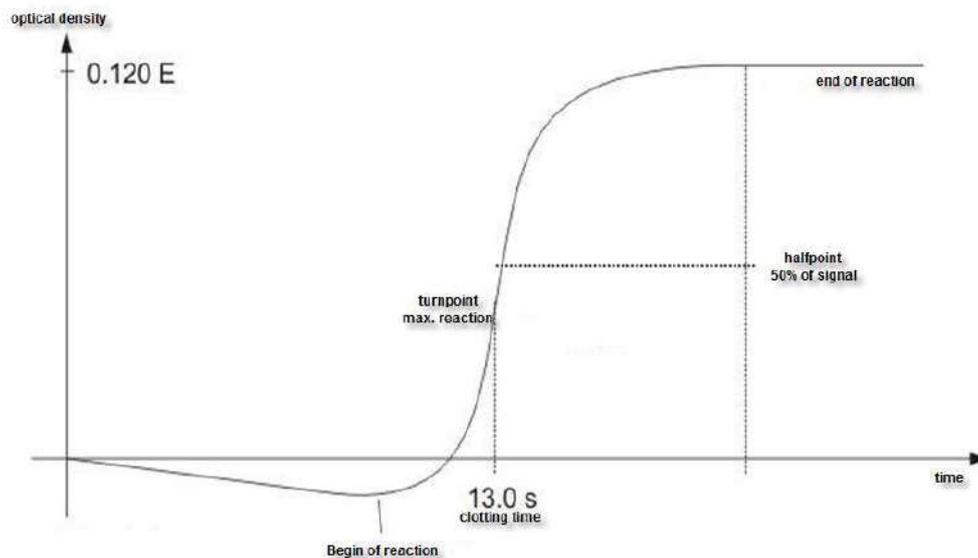
1.3. Principle of measurement

The detection of plasma clotting is based on a photometric principle. Citrated plasma is pipetted into a cuvette. Reagents are added, which initiate the coagulation. The cuvette is transmitted by light during the reaction. When the sample starts clotting 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 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	International normalized ratio	2	99.00
R	ratio	2	99.00
NR	normalized ratio	0	250
mg/dL		0	999
g/l		2	99
IE/mL	Int. Units / milliliter	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 Normalized Ratio)
 IU/mL = IE/mL = International Units (1.00 IU/mL = 100 % activity)

1.3.1. Clotting method:



The optical clot detection is based on the change of the optical density caused by the formation from fibrinogen to fibrin.

Fibrin formation results in an increasing of the turbidity in the sample, which is detected by the photometer and stored as the extinction. The result in seconds is the time from the start of the reaction to the turnpoint.

1.3.2. Chromogenic method:

Chromogenic reactions can be direct or indirect proportional. On direct proportional reactions the substrate reacts directly with the analyte. On indirect proportional reactions the analyte is binding complexes with known amounts of enzymes. Unbound enzyme reacts with substrate. Due to the reaction para nitro aniline is released. The change of color is measured at 405nm and expressed as "dE/60sec".

1.3.3. Immunospectrometric method:

The change of light is caused by Antigen – Antibody reactions, which change the optical density. 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.

1.4. Structure of this manual

To ensure an optimal operation of the Ceveron m series analyzer, please read this instruction manual carefully before you start working with the instrument.

This instruction manual contains 9 chapters:

- 1. Introduction**
- 2. System description / Installation**
- 3. Software description and Operation**
- 4. Maintenance**
- 5. Consumables and accessories**
- 6. Errors**
- 7. Disposal**
- 8. Barcode guideline**
- 9. Reagent LOT Management**
- 10. Technical data**

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2 System description / Installation

2.1. Overview



Home screen

Coloured Touch Display

Complete area is pre warmed to 37°C

1 x Reagent position Ø24mm
1 x Reagent position Ø22mm
1 x Reagent position Ø22mm, stirred

2 x Reagent positions Ø13mm

20 x Cuvette incubation positions

1/2/4 x Cuvette measurement positions
(depending on Ceveron m version)



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

2.2. Consumables

Single cuvettes	Box of 500 pieces including a activation voucher
Reagent adapter Ø 24,5 → 22,5 mm	Reducer to place smaller reagent vials on the Ceveron m
Reagent vials Ø 11 mm	Required to pre warm on the instrument

2.3. Conditions of operation

Ambient conditions:

Operating temperature	15 to 30 °C
Humidity	< 70 % rel. humidity
Elevation above NN sea level	< 3,000 m
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 condition.

Electrical conditions:

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

Electrostatic Discharge (ESD):

No special requirements for ESD protection (shoes etc.)

Storage conditions:

0 – 50 °C

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 is suitable for or use in domestic and industrial establishments.

2.4. First Installation

Inspect the packaging of the Ceveron m 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 and don't need a specific procedure.

2.4.1. First installation procedure

1. Unpack and place instrument in conformity with conditions of operation
2. Install accessory
3. Plug in power 5V
4. Wait until green Status (approximately 10 to 15 minutes). The instrument is now ready to use.
5. Register instrument online to start the warranty period.
6. Activate 500 cuvettes using ticket system



Keep the original packaging material for purposes of later transport.



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

2.4.1.1. Contents of standard delivery package

- 1 Pc Ceveron m instrument
- 1 Pc Power Supply (EU/US)
- 2x100 Pcs Single cuvettes
- 5 Pcs Reagent tubes, Ø11mm
- 1 Pc Operation Manual (not on picture)
- 1 Pc Instrument ID-Card



2.4.1.2. Optional available

- External Thermal Printer
- External Barcode scanner
- Ceveron DAT Software

2.4.1.3. System registration

The instrument must be registered online for warranty or service issues

- 1) Open www.technoclone-reg.com, or scan QR Code of the ID card using your smartphone.
- 2) Enter **SIN + PIN** of device

Both can be seen on instrument license label (on the backside of your instrument), during startup or on the info screen (touch green or red LED on home screen)



Follow the instructions on the website and enter all required information.



ceveron m4
05040 00902

Edit Account

sin
05040 00902

Distributor
Technoclone, Austria

Laboratory

Email

City

Country

CONTINUE

Content Chapter 3:

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3. Software description

3.1. Switching ON and OFF

Switching on

Connect with power supply

Important Information:

The instrument requires about 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 has 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

Open menu and touch the standby button .

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

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

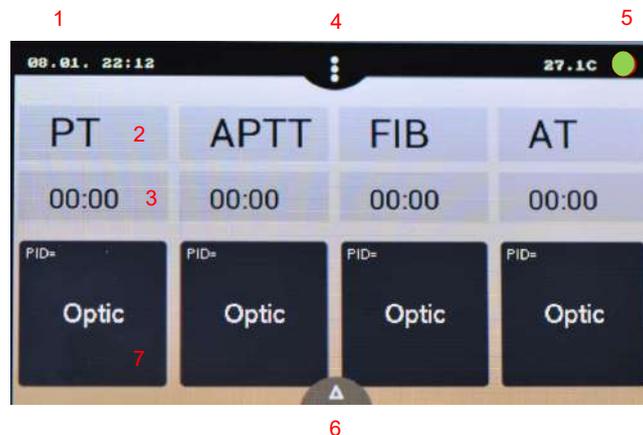
Wake up

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

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

3.2. Operation of the Ceveron m

3.2.1. Home screen



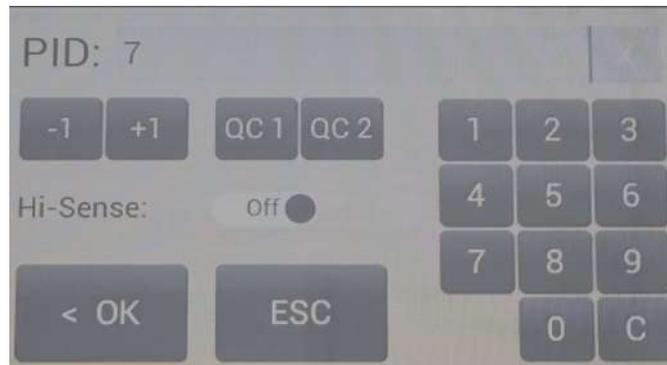
UI Element	Element Name	Use Function
(1)	Date & Time	Edit date
(2)	Current test	Change test
(3)	Stopwatch	Start/Reset stopwatch or countdown
(4)	Menu or Home	Open menu or return to main
(5)	Status Dot	Show device status/Open system information
(6)	Multistart	Activate all channels
(7)	Optic-Button	Channel-1 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
Grayed buttons	During measurement function is not possible
Reduced brightness	Screensaver mode. Touch to reactivate
Long touch	Repeat current function
Green	Ready to measure, no problems
Yellow	Ready to measure, minor problems
Red	Not ready to measure, major problems

3.2.2. Input Specimen identification

3.2.2.1 Home screen → Optic button



Button	UI Element	Use Function
Numeric keys	0-9, C, X	Change or delete Specimen identification number; max 16 numbers
Increment	-1 / +1	Increment PID. Use long touch feature for easy change
QC1 / QC2	QC1 / QC2	Set PID to 'QC1' or 'QC2'. Useful for quality control and statistics.
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	-	Input PID by barcode.

3.3. Test selection

3.3.1. Home screen → Test button

Test selection Ceveron m2/m4:



Test selection Ceveron m1:



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 Ceveron m1)
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
Scan reagent barcode	-	Select current test and lot A long beep indicates an invalid barcode or LOT
SETUP PT	Test Information Box	Calibration data of current lot and test Red values indicate invalid data

About reagent barcode:

The barcode on reagent label can be used to switch to correct Test and LOT. Before use of barcode, the test LOT + Calibration must be entered in calibration menu (see chapter test setting)

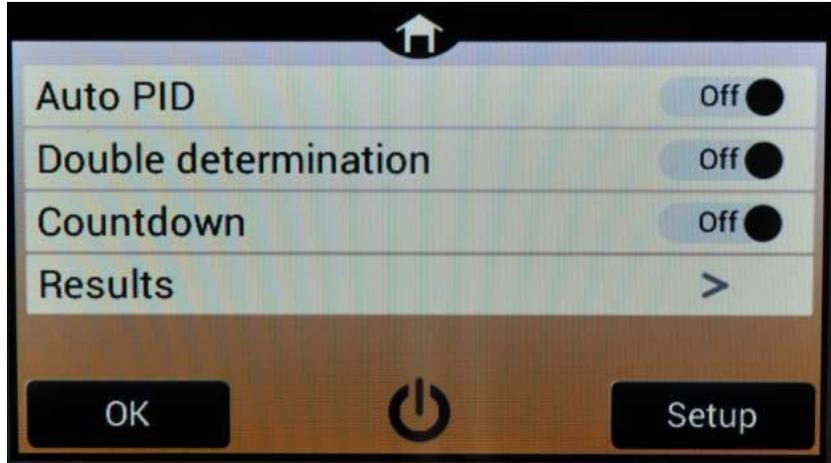
3.4. Measurement



Button (7) during measurement	
PID	Specimen identification number
Result	PT = 12.5s, 115% 0,91 INR.
Flag	f = low change of absorbance (very low fibrinogen) F = high change of absorbance (very high fibrinogen) * = Result is out of calibration curve X = double value deviate more than 15 %
Err	T = temperatue not within range (36 – 38 °C) E = reagent expired S = light intensity too low
mOD	Current optical absorbance. A change of value > 50 mOD 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 do not touch cuvette anymore

3.5. System settings

3.5.1. Home screen → Menu button



Button	Use Function
Auto PID	Enable/Disable the Auto PID feature
Double determination (not visible for Ceveron M1)	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 standby 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 multi start feature!

Double determination:

When using double determination mode, the channels 1 / 2 (Ceveron m2) respectively channels 1 / 2 and 3 / 4 (Ceveron m4) 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 give alarm 5sec before zero.

Results:

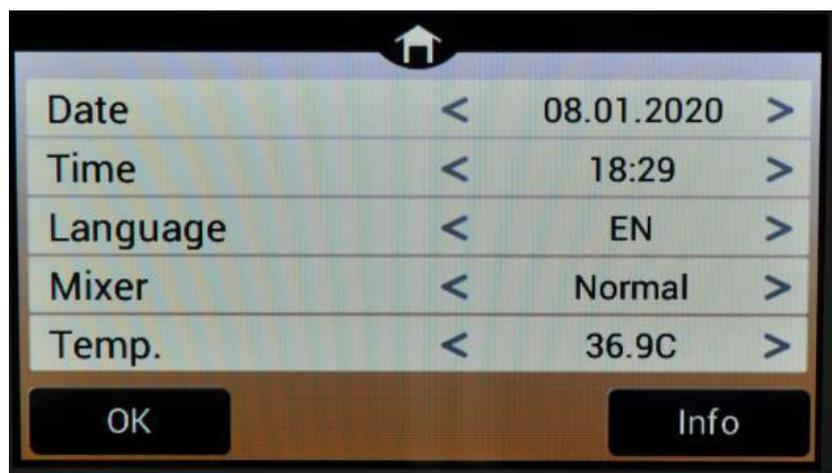
Pressing the Results button opens the result history screen.

Setup:

Pressing the Setup button opens the system settings 

: Pressing the standby button sends the device into the standby mode. To reactivate the device, touch the screen.

OK Button /  : Pressing the OK or Home Button returns to the home screen.

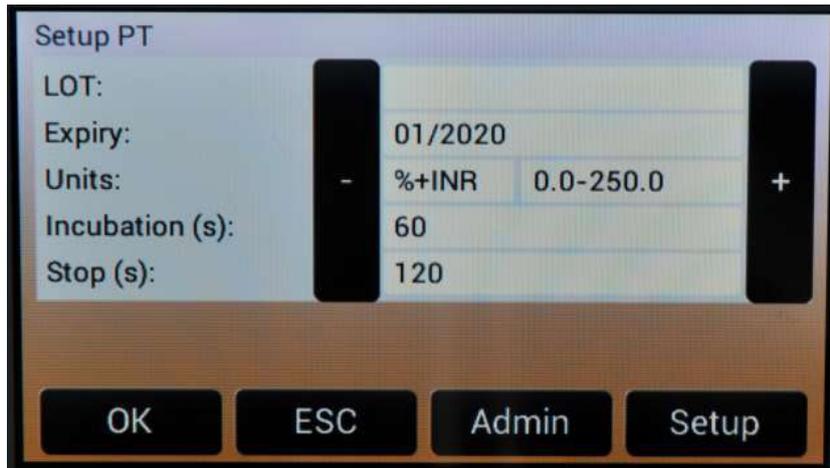
3.5.2. Home screen → Menu → Setup

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 reset to default date
Time	Set the system clock. Touch long to reset the time to default
Language	Select the system language DE/EN/ESP/ITA/FR/RO/PL more are optional
Mixer (not visible for Ceveron m1)	Some reagents need to be stirred The mixer intensity (Low/Normal/High) can be selected. Insert vial and magnetic stir bar into middle position. Change speed until stir bar 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
< / >	In or decrement value. Use long touch to scroll

3.6. Test Settings

3.6.1. Home screen → Test button → Settings



Setting/Buttons	UI Element	Use Function
LOT	LOT Number	Press the LOT text field to enter or change LOT number.
Expiry	Expiry date	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
In/Decrement	+ 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)
Barcode:	LOT barcode entry	Scan reagent barcode to input LOT and expiry date

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”.

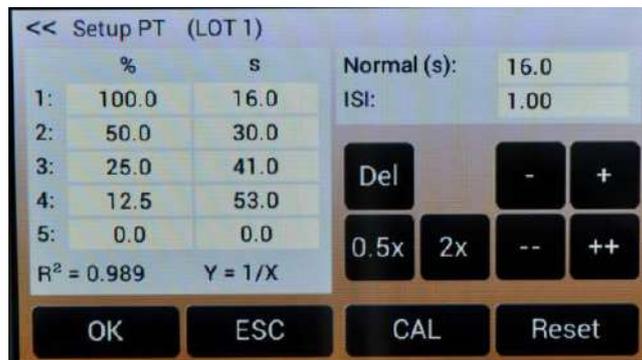
Incubation:

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 reading and reports “+++” (no clot detect)

3.6.2. Home screen → Test button → Settings → Settings



Setting/Buttons	UI Element	Use Function
Calibration curve values	Value fields	Press a calibration value to select the field
Increment Decrement	+, -, ++, --	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 (PT; MNPT). Only shown, if unit is selected.

ISI:

International sensitivity index of PT reagent. Value is stated on reagent label.

R²:

Linearity of calibration depending on mathematic

R²<0.5	not linear	Y=LIN	linear interpolation
R²<0.9	moderate linear	Y=1/X	recim2cal linear interpolation
R²>0.9	high linear	Y=logXY	double logarithm interpolation

3.7. Review results

The device holds automatically the recent 120 QC and 60 specimen results into EEPROM memory. The most recent result is shown first. If the result history exceeds the memory, then the oldest measurement result is overwritten.

3.7.1. Home screen → Menu → Results



Setting/Buttons	Use Function																																																						
< >	Scroll the results																																																						
QC (on, off)	On = Scroll quality control results (QC1/QC2) Off = Scroll Specimen results																																																						
Print	Print the shown result																																																						
Statistics	Print & display QC report of max. 14 values of current PID + Test including mean and C.V. value.																																																						
<div data-bbox="225 1153 703 1413" data-label="Image"> </div>	<div data-bbox="748 1153 1118 1796" data-label="Table"> <table border="1"> <thead> <tr> <th colspan="3">QC REPORT</th> </tr> <tr> <th colspan="3">26.09.2019</th> </tr> </thead> <tbody> <tr> <td>System:</td> <td colspan="2">Ceveron X</td> </tr> <tr> <td>SIN :</td> <td colspan="2">01040 01234</td> </tr> <tr> <td>Test:</td> <td colspan="2">FIB</td> </tr> <tr> <td>PID:</td> <td colspan="2">20190929</td> </tr> <tr> <td colspan="3">-----</td> </tr> <tr> <td>1</td> <td>16.8s</td> <td>159 mg/dl</td> </tr> <tr> <td>2</td> <td>17.1s</td> <td>154 mg/dl</td> </tr> <tr> <td>3</td> <td>16.9s</td> <td>157 mg/dl</td> </tr> <tr> <td>4</td> <td>16.2s</td> <td>166 mg/dl</td> </tr> <tr> <td>5</td> <td>16.5s</td> <td>163 mg/dl</td> </tr> <tr> <td>6</td> <td>16.4s</td> <td>164 mg/dl</td> </tr> <tr> <td>7</td> <td>16.1s</td> <td>168 mg/dl</td> </tr> <tr> <td colspan="3">-----</td> </tr> <tr> <td>-</td> <td colspan="2"></td> </tr> <tr> <td>Mean:</td> <td>16.6s</td> <td>162 mg/dl</td> </tr> <tr> <td>C.V. :</td> <td>2.1%</td> <td>2.9%</td> </tr> </tbody> </table> </div>	QC REPORT			26.09.2019			System:	Ceveron X		SIN :	01040 01234		Test:	FIB		PID:	20190929		-----			1	16.8s	159 mg/dl	2	17.1s	154 mg/dl	3	16.9s	157 mg/dl	4	16.2s	166 mg/dl	5	16.5s	163 mg/dl	6	16.4s	164 mg/dl	7	16.1s	168 mg/dl	-----			-			Mean:	16.6s	162 mg/dl	C.V. :	2.1%	2.9%
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Mean:	16.6s	162 mg/dl																																																					
C.V. :	2.1%	2.9%																																																					
DEL	Delete current result																																																						
ESC	Exit screen																																																						

3.8. Basis coagulation tests

This section describes only rudimental how to run PT and aPTT on Ceveron m instruments. The correct procedure may be different for specific reagents. Always follow the procedure in the test definitions, which are available at your local distributor or www.technoclone.com.

Test definitions are available for:

- Antithrombin
- aPTT (Siron LS, Dapttin)
- Fibrinogen Clauss
- PT Owren capillary
- PT (Technoplastin HIS)

Others are in development and validation status.

3.8.1. Quick guide: PT determination

How to run a PT sample:

1. Switch on instrument and wait for green state (approx. 15 minutes until 37°C)
2. Reconstitute PT reagent and wait 30 minutes before next step
3. Change test to "PT" by pressing on the current test
4. Place empty cuvettes into optic
5. Pipette 25 µL sample into cuvette
6. Press "00:00" to start the stopwatch and wait 30 seconds
7. Press "OPTIC" and enter PID
8. Add 50 µL of PT reagent, when "Active" is blinking – the measurement will start automatically when adding the reagent
9. Wait for result or touch optic button to abort measurement

Multi-Activation (not for Ceveron m1):

1. Open menu and set Auto PID = On
2. Place empty cuvettes into each channel and pipette 25µL of sample to each cuvette
3. Press button multistart
4. Add 50µL PT in to each cuvette from left to right.

How to calibrate a PT using AK Calibrant set

1. Reconstitute calibrators and wait for 30 minutes
2. Calibrators
 - a. AK Calibrant A
 - b. AK Calibrant B
 - c. AK Calibrant C
 - d. AK Calibrant D
3. Pipette 25 µL calibrator into cuvette
4. Press "00:00" to start the stopwatch and wait 30 seconds
5. Press "OPTIC" and enter PID
6. Add 50 µL of PT reagent, when "Active" is blinking – the measurement will start automatically when adding the reagent
7. Wait for result or touch optic button to abort measurement

8. Enter PT settings and enter
 - a. Correct LOT number
 - b. Set UNITS to "INR + %"
 - c. Input normal time (= 100% result) + ISI (see vial)
 - d. Input % of calibration

3.8.2. Quick guide of aPTT determination

How to run an aPTT measurement:

1. Switch on instrument and wait for green state (approx. 15 minutes until 37 °C)
2. Change test to "aPTT" by pressing on the current test
3. Place CaCl₂ into instrument and let incubate for at least 5 minutes
4. Place empty cuvette into optic or pre-incubation
5. Pipette 25 µL of sample into cuvette
6. Pipette 25 µL of cold aPTT reagent into cuvette
7. Press "00:00" to start the stopwatch and wait 180 seconds
8. Short before the end of incubation press "OPTIC" and enter a PID
9. Add 25 µL CaCl₂, when "Active" is blinking – the measurement will start automatically
10. Wait for result or touch optic button to abort measurement

3.9. Ticket system

1) Log in to ticket system

Please log in on our website www.technoclone-reg.com to unlock your cuvettes voucher.



The screenshot shows the login interface of the Technoclone website. At the top left, there is a 'START' button and the Technoclone logo. Below the logo, there are two input fields: 'Sin' and 'Pin', both containing placeholder text 'XXXXX XXXXX'. A blue 'Login' button is positioned below the input fields. A help icon (?) is visible in the top right corner of the form area.

Enter SIN and PIN of your instrument! This information can be found on instrument license label (Type label) or on info screen.

2) Input voucher information

The voucher information is outside of the cuvette box. Enter the VIN and PIN number to create your ticket.



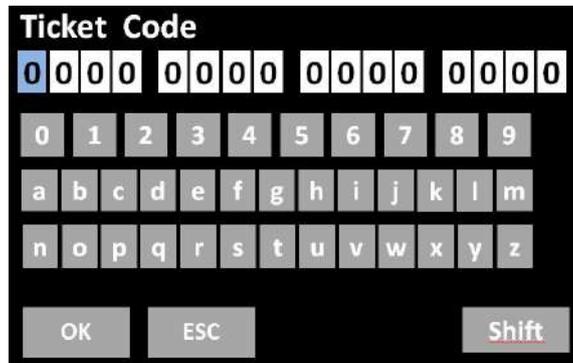
This is another screenshot of the Technoclone login page, identical to the one above. It shows the 'START' button, the Technoclone logo, and the 'Sin' and 'Pin' input fields with placeholder text 'XXXXX XXXXX'. A blue 'Login' button is at the bottom. A help icon (?) is in the top right corner.

The ticket includes a ticket information code, which has to be entered on your Ceveron m instrument.



3) Transfer ticket code to Ceveron m

Open info screen (touch blinking red LED) and then “Remaining tests=0”. The code can be transferred manually, barcode scanner or using CEVERON DAT software.

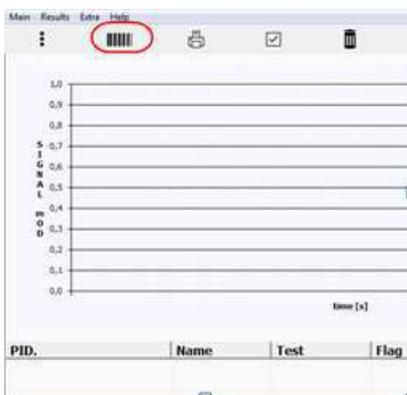


4) Using Ceveron DAT software

To generate a ticket code using Ceveron DAT software you have following options:

- Use your mobile device and scan QR code of your instrument ID card
- Click “Get ticket”, if Ceveron DAT is connected to internet

Follow dialogue according to chapter (1) and copy / paste the generated code. Send the code to your Ceveron m instrument



Content Chapter 4:

4. Maintenance and Cleaning	2
4.1. Regular maintenance	2
4.2. Cleaning	2
4.3. Decontamination	2

4. Maintenance and Cleaning

- Clean your Ceveron m with a lint free cotton cloth or stick.
- Never pour any liquid into optic, working area or on the touch screen display.
- Keep the device free of dust and moisture.
- If the device is soiled with liquids, remove the liquid 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.



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



Avoid any direct contact with decontaminants or disinfections.

4.1. Regular maintenance

- No maintenance required

4.2. 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.

4.3. Decontamination

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

Content Chapter 5:

- 5. Consumables and Accessories..... 2
 - 5.1 Consumables..... 2
 - 5.2. Accessories..... 2
 - 5.2.1. Ceveron DAT Software 2

5. Consumables and Accessories

5.1 Consumables

REF	Product
9830030	Cuvettes for Ceveron m; 500 pcs
9830032	Reagent container 22.5 mm diameter; 100 pcs
9830033	Reagent tubes 11 mm diameter; 100 pcs

All consumables have to be stored between 0...50 °C and are ready to use.

The reagent container can be covered with the **cap with hole** to avoid reagent evaporation while in use on the Ceveron m!

Never close the reagent container with the cap without hole while being placed on the instrument!

5.2. Accessories

REF	Product
9830034	External thermal printer
9830035	Thermal printer paper, 5 rolls
9830031	External barcode scanner
9830040	Ceveron DAT Software

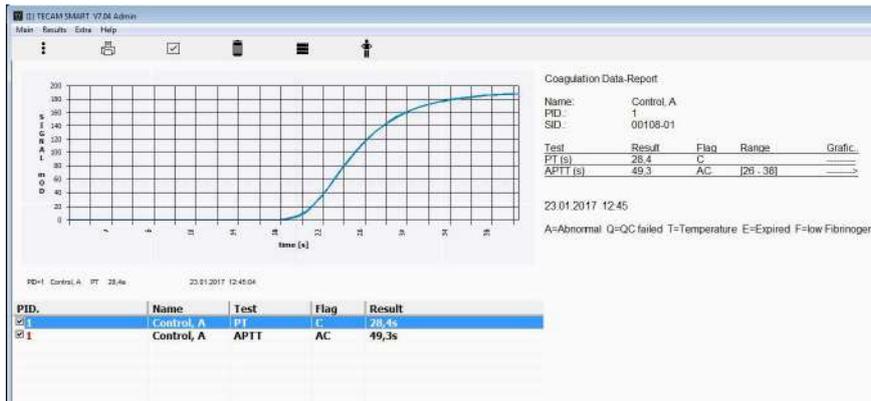
The thermal printer paper has to be stored between 0...25 °C. Direct sunlight has to be avoided.

All other accessories have to be stored between 0...50 °C.

5.2.1. Ceveron DAT Software

Ceveron DAT software is a middleware and combines laboratory data management, quality control and research purpose. It connects the Ceveron m instruments to the LIS and manages results in an own local database. Flexible filters allow QC with Levey-Jennings graph and Westgard analysis. Each result can be traced back to the used reagent lot and calibration.

Features	Smart
Receive result from analyzer	The results can be reported and manage in a local database
Receive calibration curve from analyzer	Visualize and manage calibration data for all reagents and LOTs
Receive reaction curve	Visualize the optical reaction for research, result verification or failure analysis
Specimen information	Connect Specimen - ID with name and other information
LIS communication	Communication to LIS with standard ASTM-1394 protocol Receives Specimen information, and sends results to LIS
Statistical analyze (QC)	Power filters allow quality Levey - Jennings graph and Westgard analysis for controls as well as for Specimens
Mirror print	Instead of portable thermo printer, use Ceveron DAT for print outs
Ticket system	Activation of cuvette in its easiest way. Connect to ticket system, receive ticket and send to instrument



For ordering consumables and accessories contact your local distributor or Technoclone at sales@technoclone.com.

Content Chapter 6:

6. Errors 2

6. Errors

Malfunction / Error	Possible cause	Measures	By
System not ready	various	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	Temp sensor defect	Replacement of optic	Authorized service
ERR=Temp	Temperature out of 36-38 °C	Wait 15 min	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	Replacement	Authorized service

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

Content Chapter 7:

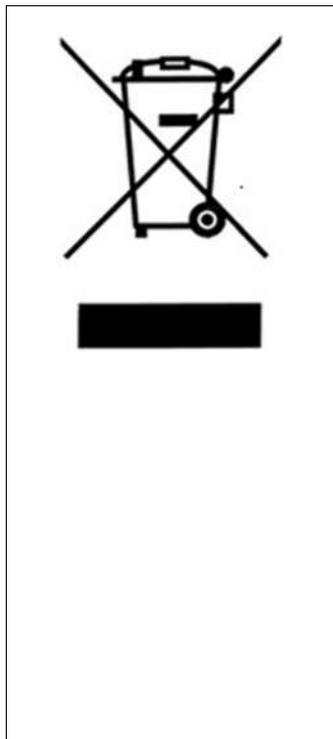
7. Disposal 2

7. Disposal

Prior to disposal, please ensure and document, that a decontamination procedure was performed according to the instructions in this manual. Please see the respective chapter under maintenance.

Information on disposal for users of waste electrical & electronic equipment

This symbol on the products and / or accompanying documents means that used electrical and electronic products should not be mixed with general household waste.



Disposing of this product correctly will help to save valuable resources and prevent any potential negative effects on human health and the environment which could otherwise arise from inappropriate waste handling. Please contact your local authority for further details of your nearest designated collection point.

Penalties may be applicable for incorrect disposal of this waste, in accordance with national legislation.

For business users in the European Union

If you wish to discard Ceveron m series instrument, please contact Technoclone, your dealer or supplier for further information. Technoclone will take back the instrument and will dispose according WEEE regulations.

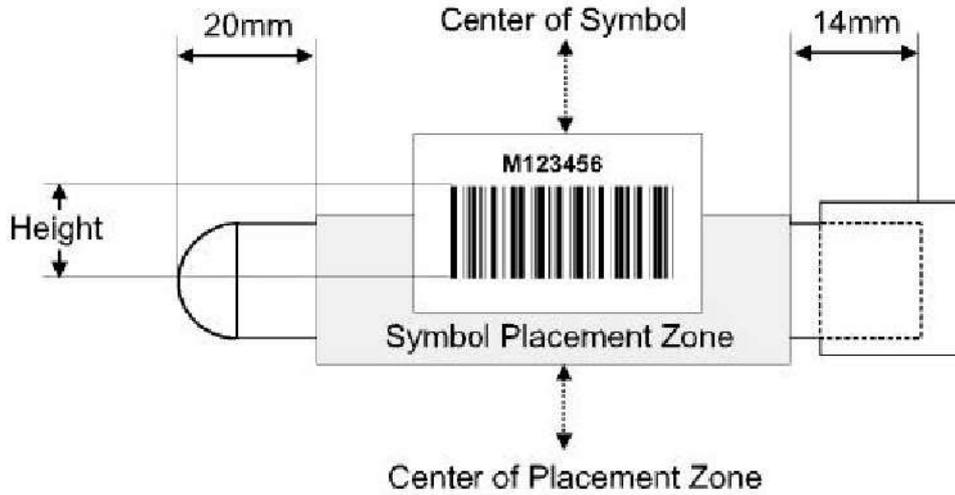
Information on disposal in other countries outside the European Union

This symbol is only valid in the European Union. If you wish to discard this product, please contact your local authorities or dealer and ask for the correct method of disposal.

Content Chapter 8:

8. Barcode guideline 2

8. Barcode guideline



Specification of label:

- Label length: 50 – 70 mm
- Label height: 20 - 30 mm
- Barcode length: 40 – 60 mm
- Barcode height: 10 - 20 mm
- Quiet zone: >5 mm
- Resolution/module: 5 -20 mils (0.2 – 0.5mm)
- Ratio: min. 1:2, 5 to 1:3 (two dimensional codes)
- Quality: Level A or B according to ANSI X3.192 -1990

Accepted codes:

- Code 128: 3 – 16 characters, use checksum without show
- EAN 128: 3 – 13 characters, use checksum without show
- Code 39: 4 – 13 characters, no checksum
- Code 93: 4 – 13 characters, no checksum
- 2/5 interleaved: 8 - 12 characters, no checksum

Content Chapter 9:

9. Reagent LOT management 2

9. Reagent LOT management

Ceveron m series instruments accept only numeric LOT numbers. Therefore Technoclone suggests transition of the alphanumeric LOT numbers to numeric as described:

Global clotting tests:

TECHNOPLASTIN HIS: 11

E.g.: 6T99 on reagent vial → 1199 on Ceveron m

TECHNOCLOT PT Plus: 12

E.g.: 6C99 on reagent vial → 1299 on Ceveron m

TECHNOCLOT PT Owren manual: 13

E.g.: 6M99 on reagent vial → 1399 on Ceveron m

DAPTTIN TC: 14

E.g.: 6V99 on reagent vial → 1499 on Ceveron m

SIRON LS: 15

E.g.: 6S99 on reagent vial → 1599 on Ceveron m

Fibrinogen Reagent: 16

E.g.: 6E99 on reagent vial → 1699 on Ceveron m

Thrombin Reagent: 17

E.g.: 6D99 on reagent vial → 1799 on Ceveron m

Special clotting tests

TECHNOCLOT DTI: 21

E.g.: 6X99 on reagent vial → 2199 on Ceveron m

Chromogenic tests:

TECHNOCHROM anti Xa: 31

E.g.: 0899 on reagent vial → 3199 on Ceveron m

TECHNOCHROM AT: 32

E.g.: 6W99 on reagent vial → 3299 on Ceveron m

Content Chapter 10:

10. Technical data 2

10. Technical data

Analyzer	
Display	capacitive touch sensitive TFT 4.3" 480x272
Measurement system	1-4 independent measurement channels wavelength of LED 405 nm (Ceveron m2; m4) or 620 nm (Ceveron m1)
Cuvette	single channel cuvette for optical detection
Positions (pre warmed)	5 reagent positions at 36.5 – 37.5 °C 20 cuvette positions at 36.5 – 37.5 °C
Reaction volumes	Minimum total volume is 75 µl
Barcode scanner	
CCD Scanner	max. power = 120 mA pulse period = 330 /s wavelength = 617 nm best distance = 80 -120 mm
Class B EN 55022:2010, EN 62471:2008	
Accepted codec	EAN (8,13, 128), Code (39,93,128), Codabar, Interleaved 2 of 5
Power supply	
Nominal Input Voltage	100 – 240 VAC, 47-63 Hz
Maximal Input Current	0.7 A rms
Output Power	5V DC, 3.3 A
Battery (mainboard)	Lithium CR2032 3 V
Power consumption	max. = 14 W sleep < 0.5 W
Dimensions	
Size (W x D x H)	225 x 150 x 90 mm
Weight	1.04 kg (without power supply)
Ambient conditions	
See chapter System description / 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

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