

# **C-1** Single-channel coagulometer

**helena**  
Biosciences Europe

Operator's Manual



Operation Manual  
for  
**Helena C-1**  
Software: C1.20a



For *In-Vitro* Diagnostic use



Instrumentation and Reagents for Coagulation / Hemostasis





Revision 13  
Issue Feb-2009

Document No: HL-2-1819P 2009/03(2)

- Warning** This manual is valid for firmware **Helena C-1, Software Revision C1.20a**. The manual may differ slightly from the actual product as a result of product improvements.
- Please read the Operation manual in its entirety prior to operation. In order to ensure a high level of performance, all warnings and references to technical safety in this Operation Manual must be followed. Repairs to the instrument may only be carried out by trained personal, and replacement parts must comply with instrument specifications.
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- Warranty** **Helena Biosciences Europe** guarantees that the instrument will be delivered in a fault free condition. Any damages resulting from accidents, improper use, using non-recommended material or negligence of maintenance are excluded from the warranty. Warranty will be void, if unauthorized persons perform any service on the instrument
- Service** Repairs to the instrument may only be carried out by trained personnel, and replacement parts must comply with instrument specifications. Please contact the local distributor of **Helena Biosciences Europe**, if service is required.

## Symbols

The following standard symbols are used in this manual:

Symbol	Meaning	Explanation
	Advice	Indicates important information and tips.
	Warning!	Risk of possible health damage or considerable damage to equipment if warning is not heeded.
	Biohazard!	Equipment can be potentially infectious due to the samples and reagents used.
	Danger!	Potential risk to operating personnel or equipment due to electric shock.

## The HELENA C-1

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Sub-Distributor:



Sub-Distributor's stamp / address / label

## Software History

- 1.04 - first release
- 1.08 - dead time for PT/TT/FaE = 5sec (former 7sec)
  - dead time for PTT/FaI = 10sec (former 7sec)
  - dead time FIB = 4.5sec (former 5sec)
- 1.09 - auto-amplification of optic improved to avoid optic-failure messages
- 1.10 - Complete new measurement control system implemented. The basic timer interruption is controlled by the crystal clock instead of the controller clock to isolate the measurement from temperature.
  - Optic check in the service menu added. By pressing key "menu" the optic will start to calibrate. The value should be between 10000 – 14000 (empty channel required). By pressing key "UP/DOWN" the amplification can be changed manually.
  - Automatic start of optic. After the optic is set to "active" the measurement will start automatically when the optic signal change (i.e. adding reagent). At very clear reagents (e.g. Fibrinogen) the "Autostart" requires a very quick pipeting technique.
  - COAC-correction introduced for each test.
  - New test D-Dimer adapted
- 1.11 - Input of calibration data improved. The value is changed by 10er increments firstly. By changing the direction the value is changed by 1er increments.
  - Algorithms for all tests equalized to Helena C-2
  - Change of auto-amplification of optic improved to avoid optic-failure messages
- 1.12 - Special Software, only for 400nm optic block.
  - Test FA-I and FA-E reduced to one test FAC (to save memory)
  - Implementation of 2 new test ECAH and ECAT
- 1.13 - Tests on board: PT, PTT, TT, FAC, DD
  - Implementation of 3 point calibration curve for PT (100%, 50%; 25%), if 50% and 25% are set to 0 (zero) – no calculation of %-activity is done
  - Data transmission protocol changed ("M1 NR TEST SEC mOD % INR Unit"), separated with "TAB" and finished with "LF" (example: "M1 5 PT 12.5 0 100 1.00 0")
- 1.18 (requires 400nm optic block)
  - Introduction of chromogenic methods
  - New Tests on board: AT3, PC (or ECAH , ECAT for some countries)
  - Double determination including meanvalue display and print
  - PT-% will be calculated with double log mathematic to enhance linearity
  - Instruments reboots on last used test
  - Automatic optic start can be adjusted or switched off
  - D-Dimer test can be adapted to different reagent providers
  - Interface supports TECAM SMART protocol to use LIS features
- 1.19 - Improved analog digital conversion to reduce signal noise ratios
  - Autostart deactivated if optic signal is below 350 digits
  - DD default: 3200-150mE, 1600-80mE, 200-20mE, OD\_corr=180 , COAG\_corr=240
- 1.20 - Optic check during Power Up.
  - Service pack for AD conversion , especially required for D-Dimer testing

## TABLE OF CONTENTS

<b>1</b>	<b>SAFETY INFORMATION</b> .....	<b>7</b>
<b>2</b>	<b>GENERAL DESCRIPTION</b> .....	<b>8</b>
<b>3</b>	<b>INTENDED PURPOSE</b> .....	<b>12</b>
<b>4</b>	<b>INSTALLATION</b> .....	<b>13</b>
4.1	EQUIPMENT.....	14
4.2	OVERVIEW.....	15
4.3	TECHNICAL DATA .....	16
4.4	SAFETY STANDARD APPROVALS .....	17
<b>5</b>	<b>THEORY OF OPERATION</b> .....	<b>18</b>
5.1	TURBIDITY METHOD (CLOTTING METHOD) .....	19
5.2	CHROMOGENIC ASSAY (KINETIC) .....	20
5.3	IMMUNOTURBIDIMETRIC ASSAY (IMMUNO) .....	21
<b>6</b>	<b>OPERATION INSTRUCTION</b> .....	<b>22</b>
6.1	WARM UP .....	22
6.2	TEST SELECTION .....	23
6.3	STOPWATCH .....	23
6.4	CALIBRATION .....	24
6.5	MEASUREMENT .....	25
6.6	DOUBLE DETERMINATION.....	26
<b>7</b>	<b>PT – DETERMINATION</b> .....	<b>27</b>
<b>8</b>	<b>APTT – DETERMINATION</b> .....	<b>29</b>
<b>9</b>	<b>FIB – DETERMINATION</b> .....	<b>31</b>
<b>10</b>	<b>TT – DETERMINATION</b> .....	<b>33</b>
<b>11</b>	<b>EXTRINSIC FACTOR DETERMINATION</b> .....	<b>35</b>
<b>12</b>	<b>INTRINSIC FACTOR DETERMINATION</b> .....	<b>37</b>
<b>13</b>	<b>D-DIMER DETERMINATION</b> .....	<b>39</b>
<b>14</b>	<b>SERVICE</b> .....	<b>41</b>
14.1	DEFAULT VALUES .....	42
14.2	TEMPERATURE ADJUSTMENT .....	43
14.3	RESULT CORRECTION .....	44
14.4	OPTIC CHECK .....	45
14.5	AUTOSTART TRIGGER.....	45
14.6	INTERFACE RS 232 .....	46
14.7	LIS WITH TECAM SMART .....	47
<b>15</b>	<b>TROUBLESHOOTING GUIDE</b> .....	<b>50</b>
<b>16</b>	<b>INSTRUMENT, CONSUMABLES, SPARE PARTS</b> .....	<b>52</b>
<b>17</b>	<b>TECHNICAL DRAWING (3D-EXPLOSION)</b> .....	<b>53</b>

## TABLE OF FIGURES

Figure 1	Front panel.....	15
Figure 2	Detection principle.....	18
Figure 3	The turbidity method .....	19
Figure 4	The chromogenic method .....	20
Figure 5	Latex agglutination .....	21
Figure 6	Relationship of light absorbance and concentration of D-dimer.....	21
Figure 7	Result management of Tecam Smart.....	47
Figure 8	Database of Tecam Smart .....	48
Figure 9	Statistics with Tecam Smart.....	48
Figure 10	Result report with Tecam Smart .....	49
Figure 11	3D explosion drawing.....	53

## 1 Safety information



### **Recommend materials**

Use only original disposables.  
Use only manufacturer approved material.



### **Avoid contact**

Never touch moving parts.



### **Do quality control**

Carry out control measurement runs at regular intervals to ensure that the analyzer continues to function faultlessly.



### **Waste cuvettes**

The cuvettes are intended as single-use items only.



### **Infectious Material**

Avoid direct contact with samples and sample residues in the used cuvettes.

Infectious material such as cuvette waste and liquid waste must be disposed of in compliance with local regulations governing infectious materials.

Wear medical infection grade protective gloves for all cleaning and maintenance work involving potential contact with infectious liquids and use each pair of gloves once only.

Use a hand disinfectant product, e.g. Sterilium<sup>®</sup>, to disinfect your hands after completion of the work.



### **Environmental condition**

Temperature must be 18 – 25°C  
Humidity must be below 80%  
Avoid any vibrations or impacts to analyzer  
Do not use analyser if explosive or inflammable gas is around.



### **Electrical Safety**

Make sure the operating voltage setting is correct before connecting the device to the power mains.  
Use only shockproof (grounded) electrical sockets.  
Use only shockproof extension leads in perfect condition. Defective leads must be replaced without delay.  
Never intentionally interrupt protective ground contacts.  
Never remove housing elements, protective covers or secured structural elements, since so doing could expose parts carrying electric current.  
Make sure surfaces such as the floor and workbench are not moist while work is being done on the device.



## 2 GENERAL DESCRIPTION

Haemostasis is the biochemical process which protects the body from loss of blood after vascular damage. Haemostasis occurs in three phases:

**Vessel contraction** and **Platelet Aggregation** stop bleeding immediately (within seconds) and trigger the coagulation cascade.

The **coagulation cascade** is a chain reaction in which inactive enzymes are converted to their active form. The cascade ends with fibrinogen conversion to fibrin catalyzed by activated Thrombin. In the presence of activated factor XIIIa the fibrin is cross-linked and clotted to an insoluble thrombus (fibrin-clot). The bleeding is finally stopped.

To prevent the body from unnecessary thrombotic events, the coagulation cascade has to be controlled very sensitively. This is done by the **fibrinolytic system**. Inhibitors are able to invert the activation of factors and so regulate coagulation. The basic inhibitors are Antithrombin and Protein C. The fibrinolytic system is also responsible for lysing the fibrin-clot. After clot-lysing the vessel injury is completely healed.

All factors and inhibitors are balanced very carefully. In case of imbalance or any dysfunction, severe vascular diseases can and will appear. Dysfunction of the complex Haemostasis system is one of the most common diseases, which is very often deadly (~ 1 in 1000). Examples are deep vein thrombosis (DVT) or pulmonary embolism (PE).

The **Helena C-1** is a single-channel optical coagulometer to determine the basic parameters of the second stage of Hemostasis (coagulation cascade) in human citrated plasma. It is designed for in-vitro coagulation testing in the clinical laboratory. Clotting assays with fibrin formation as the endpoint may be run on the instrument, as well as immunoturbidimetric tests (e.g. quantitative D-Dimer) or chromogenic tests (eg. Antithrombin , Protein C).

The following tests and features are available on the instrument:

### **PT (Prothrombin Time).**

The PT is expressed in seconds (100 ms sampling rate) and automatically normalized into INR (International Normalized Ratio). A normal PT-value (100%) and the Thromboplastin ISI - value (International Sensitivity Index) can be stored on board. Additionally the result can be converted into %-Activity, when the 100% value and the 25% value are stored in the memory.

### **APTT (Activated Partial Prothrombin Time).**

The APTT is expressed in seconds and automatically normalized into Ratio. The normal APTT-value can be stored on board.

### **TT (Thrombin Time).**

The TT is expressed in seconds and automatically normalized into Ratio. The normal TT-value can be stored on board.

### **FIB (Fibrinogen).**

The FIB is expressed in seconds and automatically converted into mg/dL concentration in plasma. A calibration curve is necessary to obtain the results in mg/dL. Three calibration points can be stored on board.

### **FAC (Factors)**

The coagulation factors are expressed in seconds and automatically converted into activity % in plasma. A calibration curve is necessary to obtain the results in %. Three calibration points can be stored on board.

### **DD (D-Dimer)**

The D-Dimer is measured immunoturbidimetricly and expressed in milli optical density per minutes (mOD/min) and converted into ng/mL concentration in plasma. A calibration curve is necessary to obtain the results in ng/mL. Three calibration points can be stored on board.

### **AT3 (Antithrombin)**

The AT3 tests are measured chromogenically and expressed in milli optical density per minute (mOD) and converted into % plasma activity. Up to three calibration points can be stored on board.

### **PC (Protein C)**

The Protein C tests are measured chromogenically and expressed in milli optical density per minutes (mOD) and converted into % plasma activity. Up to three calibration points can be stored on board.

**FEATURES:**

All tests are performed with a quarter of the regular volumes. The micro cuvette can be run with a minimum of 75 µl → i.e. 25 µl sample + 50 µl Thromboplastin for PT.

The **Helena C-1** supports an unidirectional RS232 interface (fixed setting at 2400, 8, 1, No). All results are printed automatically, if the interface is set to print mode. The RS 232 can also be set to LIS mode. Then the results, including their reaction curves, are sent in TECAM SMART format to the PC. TECAM SMART is an easy to use coagulation data management system which fulfills LIS demands (laboratory information system).

The Helena C-1 has an incubation area for 6 samples and 2 reagent positions. The instrument needs 5 min to warm up to 37.0°C. A green signal light indicates the correct incubation temperature has been reached.

- Coagulation analyser for clotting, chromogenic and immunoturbidimetric assays.
- Highly reliable, longlifespan and nearly service free system
- Autosense optics to eliminate interferences such as Bilirubin and Haemoglobin
- Approved clotting algorithm for all kind of samples and reagents. If there is a clot - it will be detected.
- Automatic start at reagent addition
- Cost-effective determination by micro volumes (total 75 µL)
- Calibrations are programmable with up to 3 calibration points
- Calculation of % activity, INR, Ratio, g/L, ng/mL
- Stop-watch function onboard
- Support of double determination (mean result)
- Print-outs for result, calibration, service and system
- Optional external thermal printer
- Optional RS232 communication for data research
- Linkable to Laboratory Information Systems
- Small dimension and weight - fits on every desktop

## Declaration of Conformity

EC Declaration of Conformity  
Déclaration de conformité CE  
EG-Konformitätserklärung



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herewith declares that: / *déclare ci-après que:* / erklärt hiermit dass:

Instrument type / *Type d'appareil* / Gerätemodell

*Helena C-1*

REF

C-1

- is in conformity with the provisions of the Directive 98/79/EC on in vitro diagnostic medical devices, and the Directive 80/181/EEC
- *est conforme aux dispositions de la Directive 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro, et de la Directive 80/181CEE*
- konform ist mit den Bestimmungen der Richtlinie 98/79/EG über In-vitro-Diagnostika und der Richtlinie 80/181/EWG

and furthermore declares that: / *et déclare par ailleurs que:* / und erklärt ausserdem dass:

- the standards EN 60601-1, EN 60601-1-2, DIN EN ISO 14971:3/2001, DIN EN 1041:4/98 have been applied.
- *les normes EN 60601-1, EN 60601-1-2, DIN EN ISO 14971:3/2001, DIN EN 1041:4/98 ont été appliquées.*
- die Normen EN 60601-1, EN 60601-1-2, DIN EN ISO 14971:3/2001, DIN EN 1041:4/98 angewendet wurden.

This certificate is valid for all instrument produced of this type.

Ce certificat est valable pour tous les appareils produits de ce type.

Dieses Zertifikat ist für alle produzierten Geräte dieses Modells gültig.

### 3 Intended purpose

The **Helena C-1** is designed to carry out coagulometric tests such as PT, PTT, TT, fibrinogen, single factor tests, chromogenic and immunoturbidimetric tests (e.g. Antithrombin-III, D-dimer etc.).

The Helena C-1 must be operated by a specialist trained in clinical laboratory techniques who has also received instruction and training in the instruments' operation and has read and understood this Operator's Manual

Use only citrated plasma for test analysis runs: Mix 9 parts venous blood with 1 part 3.2% (0.105M) sodium citrate and centrifuge the mixture at 1500g for approx. 10 minutes. Plasma must be used within 4h.



Do not use plasma with more than 25mg/dL Bilirubin concentration  
Do not use plasma with more than 1000mg/L Haemoglobin concentration



As there is no known test that can offer complete assurance that products derived from human blood will not transmit Hepatitis, AIDS, or other infectious diseases, appropriate precautions should be taken by the instrument operator. In case of plasma spill on the instrument, clean with a paper towel soaked in 10% bleach.

## 4 INSTALLATION

No special precautions are necessary when starting up the **Helena C-1**. However, the following is recommended:

- Place on a level surface in an area free from excessive temperature fluctuations
- Avoid vibration during measurement
- Protect the instrument from direct sunlight, moisture and dust
- Check that the voltage and frequency data on the identification plate on the instrument agree with the local power rating before starting the instrument for the first time



The instrument is connected to the power supply by the mains cable supplied. If obvious damage has occurred during shipping, **do not use**. Contact your local distributor for replacement or repair.



**Note:** When the printer is connected to the *Helena C-1*, both the printer and the instrument must be turned on. The printer interface must be set to serial, 2400 Baud, 8 Databit, 1 Stopbit, no parity.

## 4.1 Equipment

### Standard delivery package

- 1 Pc **Helena C-1**
- 1 Pc Power Supply
- 1 Pc Printer Cable
- 25 Pcs Single cuvettes
- 5 Pcs Reagent tubes
- 2 Pcs Reagent adaptors
- 1 Pc Warranty card
- 1 Pc CD: Manual, Service and Application Notes

- Accessories: (see section 16.0)

## 4.2 Overview

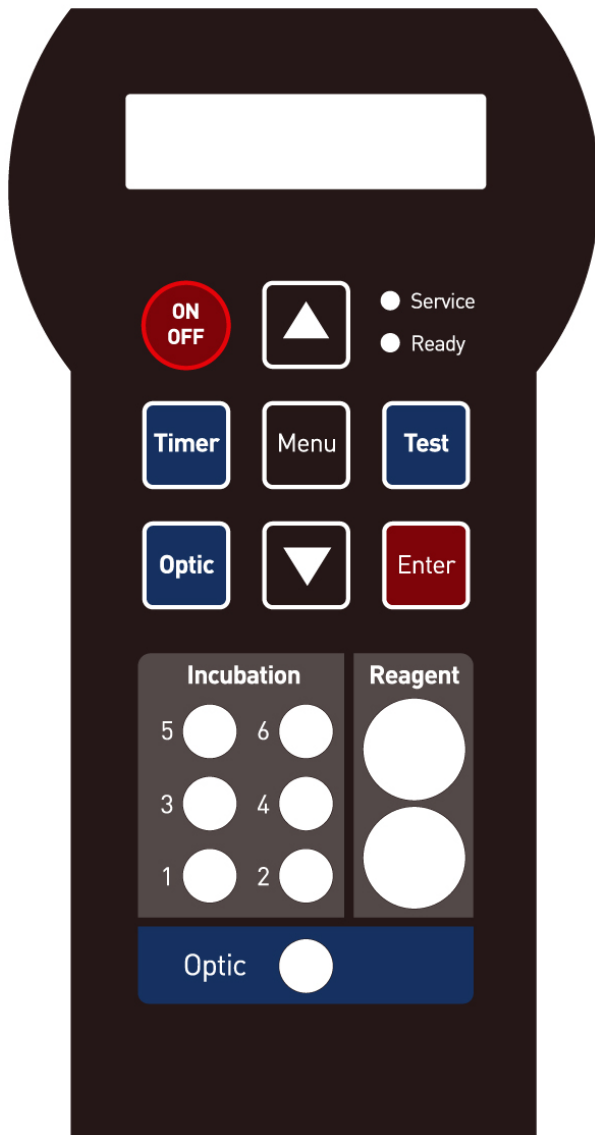


Figure 1 - Front panel

### Display

2x16 characters

### Service

Red LED to indicate system failure and temperature not in correct range (36° to 39° C)

### Ready

Green LED for system ready to operate

### Cursor keys

Change active parameter

### Menu

Calibration of active test

### Enter

Confirm active parameter

### Timer

Start, stop, reset

### Optic key

Activates start, stop measurement

### Incubation

37°C warmed positions for 6 cuvettes

### Reagent

37°C warmed positions for 2 reagent tubes  $\varnothing$  11mm

### Optic Position

Measurement position 37°C warm.



### 4.3 Technical Data

Dimension (LxBxH):	245 x 130 x 60 cm
Weight:	0,51 kg (without power supply)
Ambient Temperature:	18 - 23°C
Power Supply	Input : 90-264 V~ Output : 12 V, 1.0 A
Device:	Micro controller Board 14 Bit ADC ; On-chip controlling of LCD, RS232, Keyboard, Charging, Temperature, Optic.
Interface:	Serial - 2400 Baud, 8 Bits, 1 Stop, No parity used in print or debug mode.
Optic Cell:	Photometer with pulsed 400 nm LED's Variable pulse modulation. Variable detector amplification. Linear Range 0.001 - 1.000 OD
Keyboard:	Foil keyboard with 8 keys and 2 LED's
Display:	2 lines x 16 Characters, Liquid Crystal
Incubation block:	1 measuring channel, 6 samples, 2 reagent wells; warmed at 37°C.

## 4.4 Safety Standard Approvals

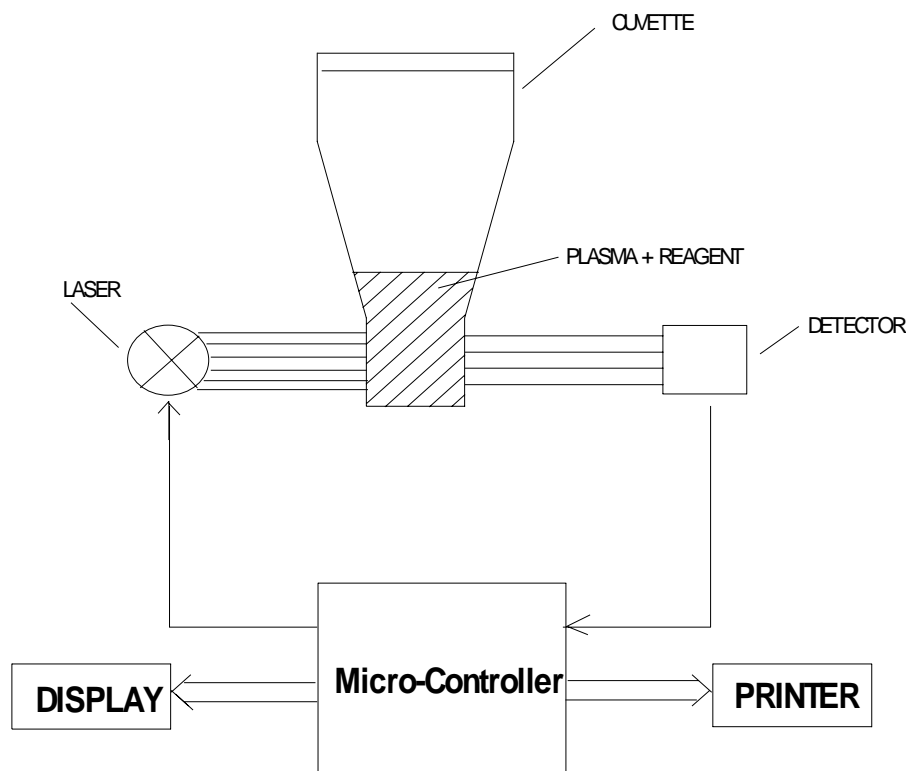
Manufacturer fulfills **EN ISO 9001:2000** and **EN ISO 13485:11/2000**

The **Helena C-1** is in full compliance with following approvals:

- |   |                              |   |
|---|------------------------------|---|
| ◆ | <b>EN 61010-1</b>            | Safety requirements, General                    |
| ◆ | <b>EN 61010-2-101</b>        | Safety requirements, particular for IVD devices |
| ◆ | <b>EN 61326-1</b>            | Electromagnetic compatibility- Requirements     |
| ◆ | <b>IEN ISO 14971: 3/2001</b> | Risk management                                 |
| ◆ | <b>EN 1041: 4/98</b>         | Information supplied by the manufacturer        |
- 
- ◆ Directive 98/79/EC on In-vitro-diagnostic medical devices
  - ◆ UK Medical Product law
  - ◆ Directive 80/181/EEC relating to units of measurements

## 5 Theory of operation

The **Helena C-1** is a highly sensitive single channel photometer. A very intensive laser LED-Optic at 405 nm ensures accurate and precise results, even when icteric or lipemic samples are used. The receiver signal is detected and converted to an electrical current. During the actual test the system is searching for the best signal amplification. The software algorithms are based on optical density (extinction), which absorbs outside light effects.

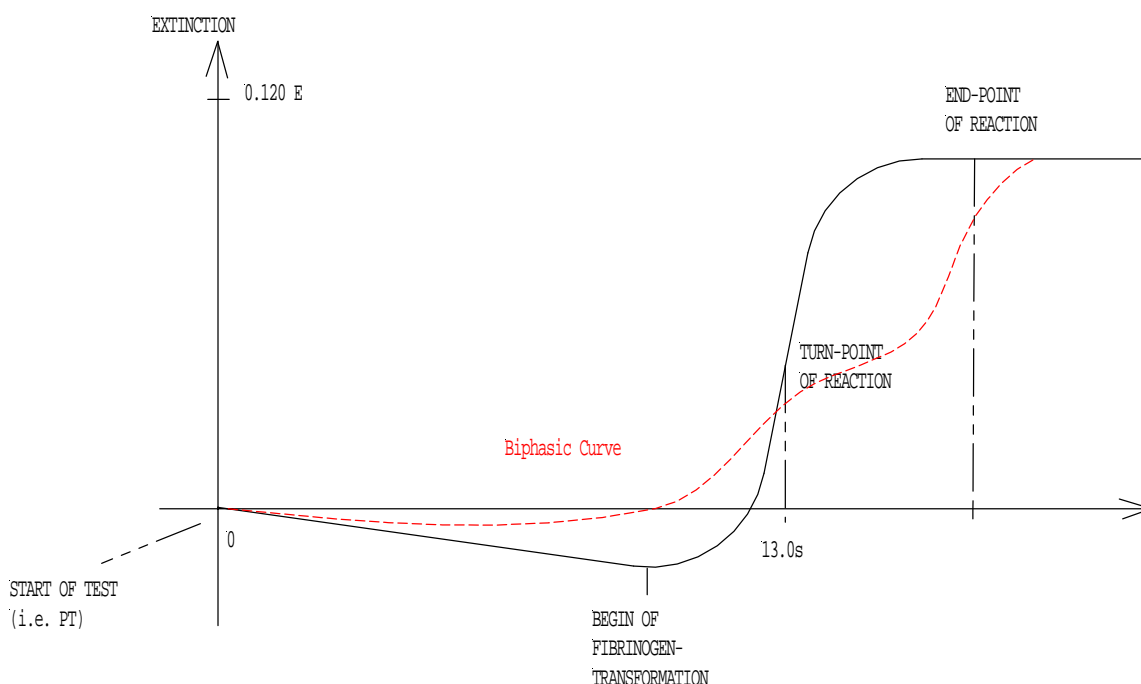


**Figure 2 - Detection principle**

Plasma and reagent absorb the transmitted laser light. The rate of absorbency is obtained by the detector and sent to the micro controller. Here a program analyses the signal and sends the result to the display and printer (optional).

## 5.1 Turbidity Method (Clotting Method)

The thrombin catalyzed conversion of fibrinogen to fibrin is the final reaction in the 'coagulation cascade'. Fibrin formation results in an increase in sample turbidity which is detected by the photometer. Photometric detection is started automatically on addition of reagent or manually by pressing the "Optic" key with simultaneous addition of the test reagent. Alternatively, the reaction is started by the addition of the test reagent using the Autopipette. The time between the start of the photometric detection, and the turning point of the reaction curve (see Figure 4) is the result. The result is displayed in seconds on the Liquid Crystal Display (and printed automatically to the optional Thermal Printer.)

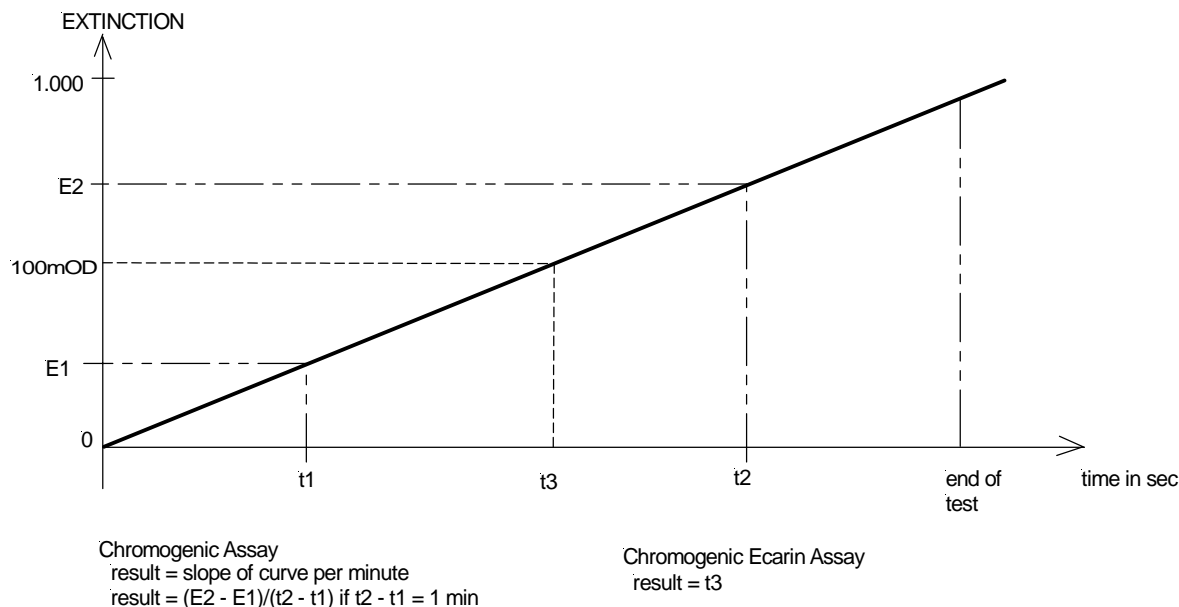


**Figure 3 - The Turbidity Method**

The diagram is representative of a typical PT curve with normal control plasma and a curve with biphasic reaction. At ~10 sec the liquid plasma starts to clot. This process ends at the "end-point". The plasma is agglutinated by fibrin-monomers. The maximum kinetic of the reaction (turn-point) is defined as clotting time and displayed. INR and/or %-activity will be displayed and printed if calibration data are entered.

## 5.2 Chromogenic Assay (KINETIC)

In this method, the end result is determined from the rate of optical density change. Test plasma is pre-incubated with an enzyme (i.e. – Factor Xa for the determination of AT-III) and residual enzymatic activity is detected by the addition of a chromogenic substrate. The concentration of the analyte in the test plasma is directly or indirectly proportional (depending on the reagent system) to the rate of substrate hydrolysis, and is reported as the mean slope of optical density per minute ( $\Delta OD(E)/min$ ).



**Figure 4 - The chromogenic method**

### 5.3 Immunoturbidimetric Assay (IMMUNO)

Intensive light is able to penetrate turbid solutions, such as latex suspensions used for the determination of D-dimer concentration. Latex particles, designed specifically for automated D-dimer testing, are coated with a monoclonal antibody specific for D-dimer. If D-dimer antigen is present in the sample, an antigen-antibody reaction occurs, with a simultaneous change in light transmission. The concentration of D-dimer in the sample is directly proportional to the rate of the antigen-antibody reaction. The result is reported as the mean slope of optical density per minute ( $\Delta OD$  (E)/min, E = Extinction, a unit of light-absorbance). The following diagram illustrates the measurement principle.

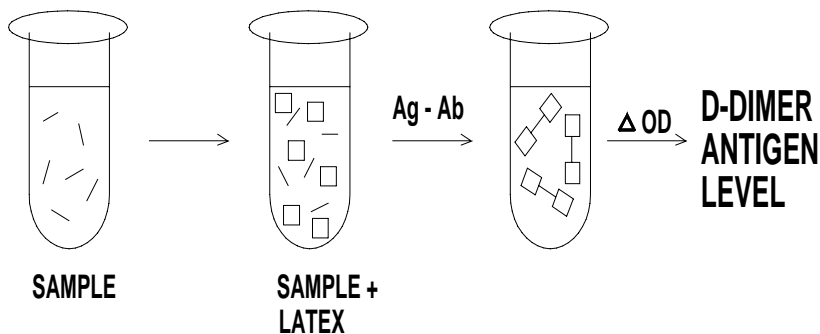


Figure 5 - Latex agglutination

The D-dimer concentration is proportional to the rate of change in optical density. The instrument calculates the average slope of reaction, using the linear portion of the curve only.

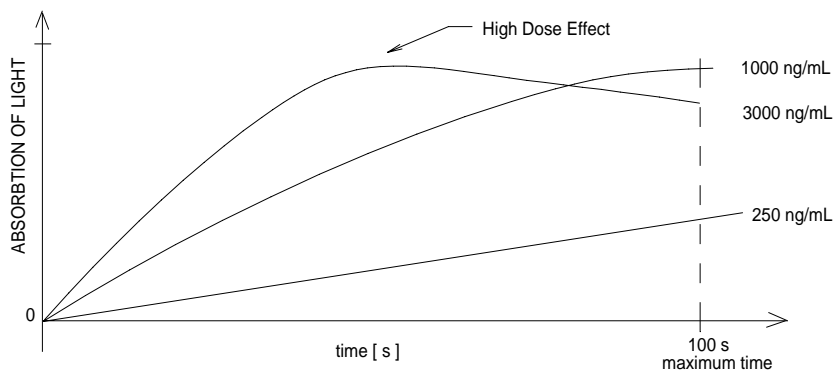


Figure 6 - Relationship of light absorbance and concentration of D-dimer

The kinetic algorithm for D-dimer testing is illustrated with three typical reaction curves. At high doses the linear relationship between signal and concentration is not valid. This is called "High Dose Hook Effect".

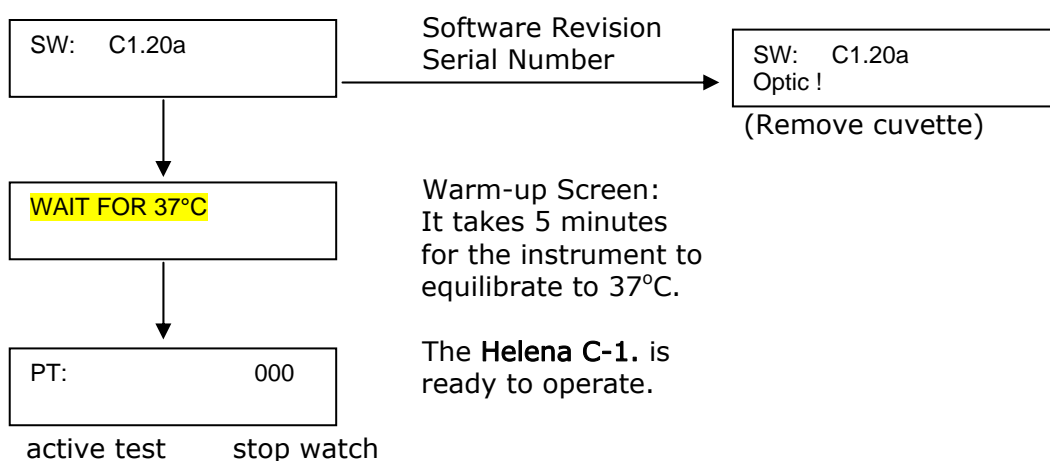
## 6 Operation Instructions

This section provides general instructions necessary for the user to achieve maximal use and benefit from the **Helena C-1**.

⇒ For specific test applications refer to section 7.

### 6.1 WARM UP

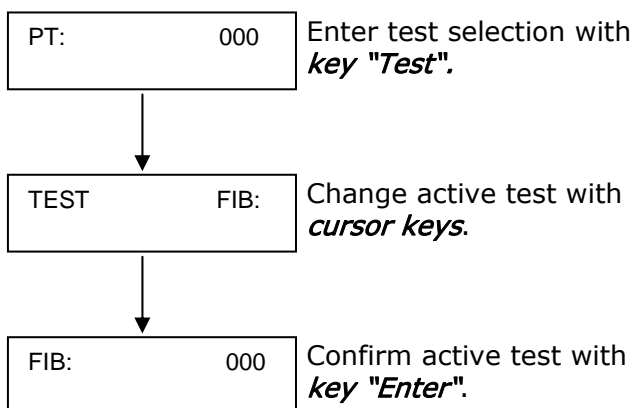
Remove cuvette from optic and power on the instrument. The first visible screen gives the operator the information on the installed software before changing to the warm-up screen. If low optic values are encountered during bootup, then the message "OPTIC" is display for two seconds before restarting the device. Check there is no cuvette in the optics.



**Remove cuvette before power up!**

**Do not operate the instrument until the green LED light is on.**

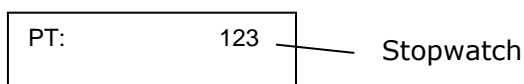
## 6.2 TEST SELECTION



To alternate between the tests, press key "**Test**" to activate test selection, **cursor keys** to change and key **Enter** to confirm.

## 6.3 STOPWATCH

A stop watch function helps the operator to control the correct incubation times. The timer stops after 999s automatically.



To start the stopwatch press **key "Timer"**.  
To stop and reset press **key "Timer"** again.



## 6.4 CALIBRATION

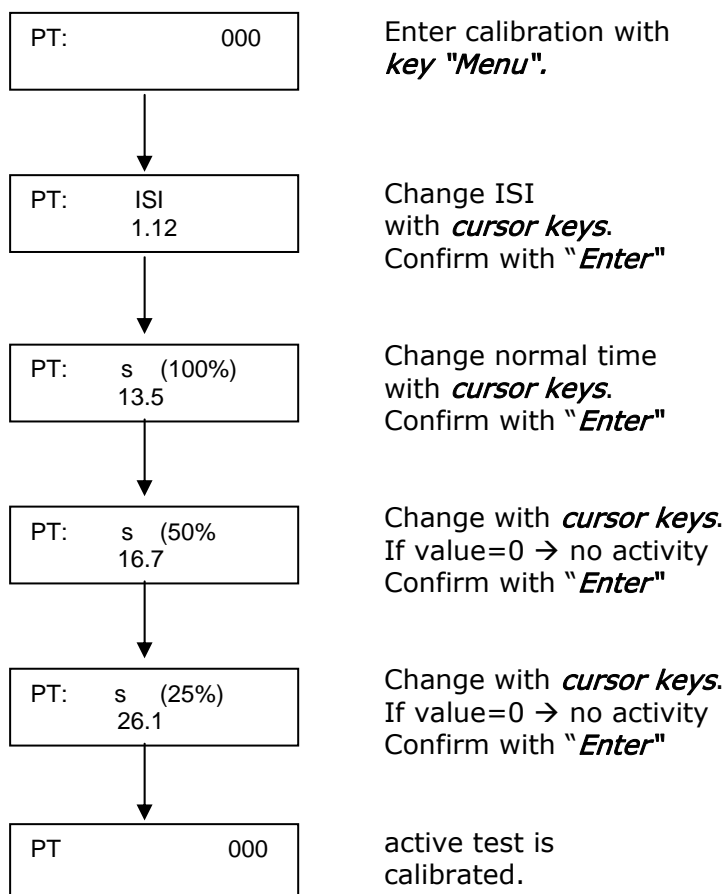
Calibration data are required if the instrument should display the result in %, INR or units. The specific parameters for the tests can be entered and stored into the **Helena C-1**. Up to 3 calibration points can be entered. Set calibration point to zero if not used.

### Change of values:

The initial change of value will increase or decrease the number firstly by 10. A change in direction will then change the number by 1.

Example: The change of ISI from 1.12 to 1.40:

- Press "key UP" 3 times. The ISI will change to 1.22 , 1.32 and 1.42
- Press "key DOWN" 2 times. The ISI will change to 1.41 , 1.40

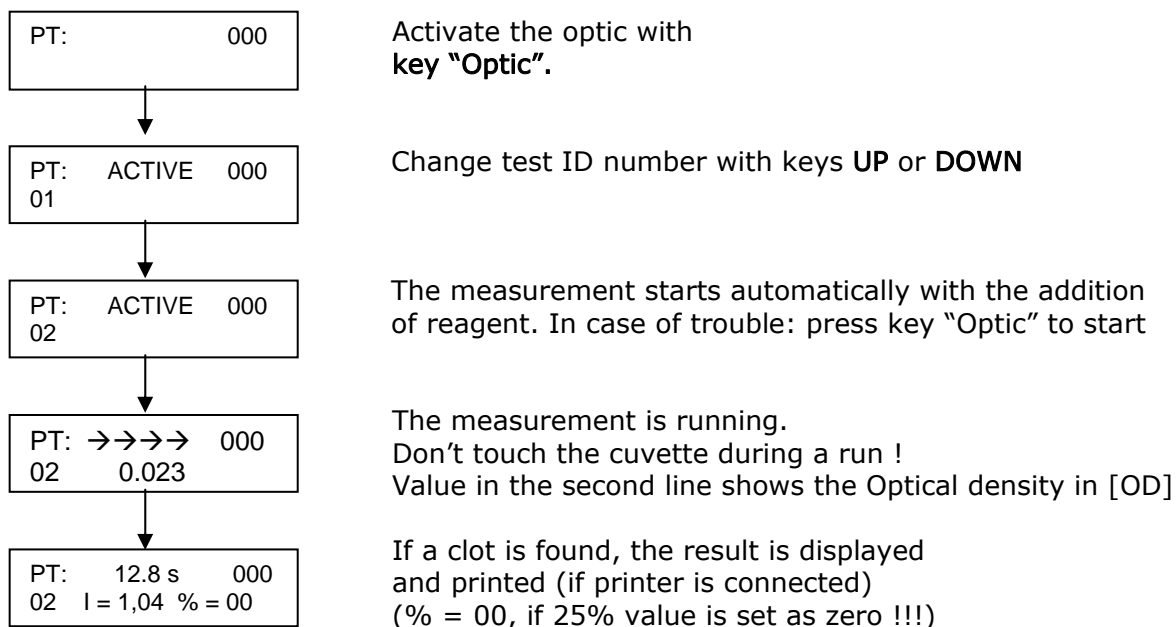


### Default values of tests:

PT: ISI = 1.10 (1) 100% (Normal) = 13.5 s, (2) 50% = 16,7 s, (3) 25% = 26.1 s  
 PTT: Normal = 30.0 s  
 TT: Normal = 15.0 s  
 FIB: (1) 300 mg/dL = 12.0 s (2) 150 mg/dL = 23.0 s (3) 75 mg/dL = 36.0 s  
 FAC: (1) 100 % = 32.5 s (2) 10 % = 60.0 s (3) 5 % = 70.0 s  
 DD: (1) 1600 ng/ml = 150 mOD (2) 200 ng/ml = 30 mOD (3) 0 ng/ml = 0 mOD

## 6.5 MEASUREMENT

Prepare and place the cuvette in the measurement position.



Before activating the channel the cuvette must be inserted into the measuring position and ready to add the start reagent. Press key "OPTIC" to activate the channel. Message "WAIT" indicates, that the instrument calibrates the optic to the actual optical value.

If "ACTIVE" is displayed on the screen, the measurement is ready to start. The actual result ID is also displayed. The ID value can be changed with the cursor keys.

If the optical value changes from the "trigger" value (e.g. by adding reagent), the measurement will start. The start can be also triggered by pressing the key "OPTIC".

Once started a small beeping noise is followed by a scrolling arrow. The current light absorbance (OD) can be read on the display. Avoid contact with the cuvette while this message is shown. A beeping noise will sound again when a clot-reaction is detected and the result will be displayed. If a printer is attached, the result will also be printed. If the clot reaction needs more than the maximum reading time of 300s, the optic will stop and display „+++.“, which means "no clot detected"



The measurement can be canceled by pressing key "Optic" again



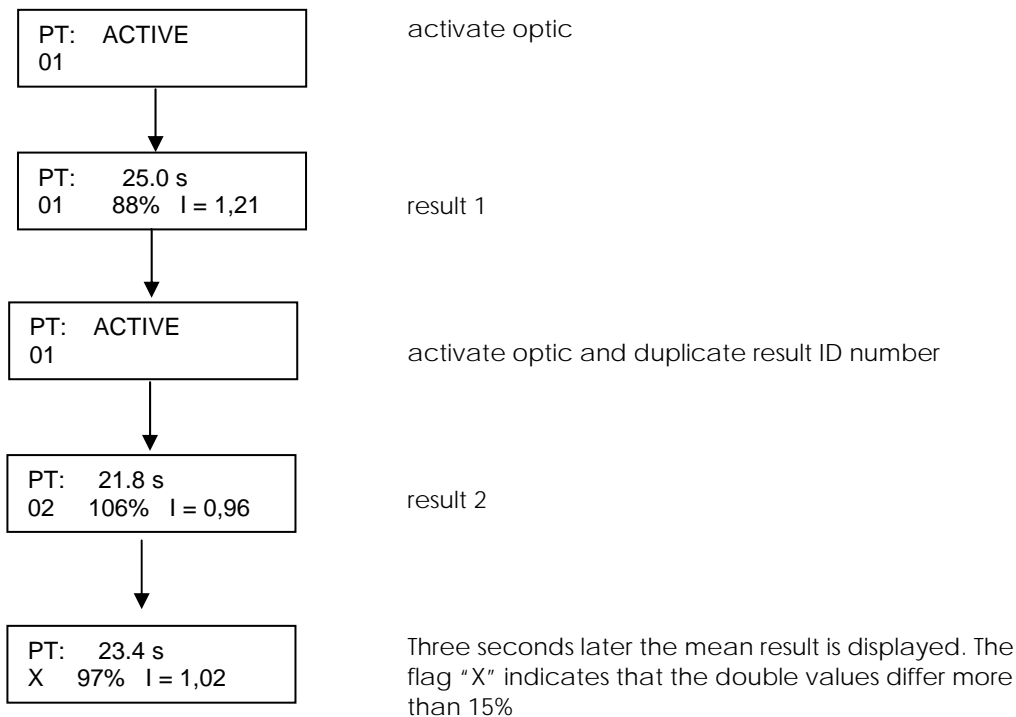
### Autostart:

The measurement will start automatically by addition of reagent, when the optic is set to active. In some cases, where the signal is too small (e.g. Fibrinogen, Thrombin) it may be necessary to press the 'Optic' key after addition of the reagent.

The sensitivity of autostart can be adjusted for each test within the service menu. Refer to service section for more information.

## 6.6 DOUBLE DETERMINATION

Activate the optic and start the measurement. When the result is displayed, activate the optic again and duplicate the result ID number with the cursor keys. Start the measurement. The following result will be displayed for 3 seconds. Then the instrument will display the mean value.



The mean value of units, % or INR is derived from the mean-result (s,E)

## 7 PT – Determination

### **SUMMARY**

The Prothrombin Time test, as originally devised by Quick, has been widely used for a number of years as a pre-surgical screen for assessing certain coagulation factors and in monitoring oral anticoagulant therapy. All Stage II and III factors are necessary for normal results when performing the Prothrombin Time Test, so it is sensitive to reduced levels or deficiencies in Factors I, II, V, VII and X. Dicumerol and related drugs reduce the activity of the so-called "Prothrombin complex" Factors, II, VII, IX and X. Since the Prothrombin Time test is sensitive to deficiencies of all these Factors, except IX, it has proven useful in monitoring oral anticoagulant therapy. The Prothrombin Time test is also used in the quantitative determination (Factor Assays) of Factors II, V, VII and X.

### **PRINCIPLE**

The one stage Prothrombin Time measures the clotting time of test plasma after the addition of Thromboplastin reagent containing Calcium chloride. The reagent supplies a source of "tissue thromboplastin", activating Factor VII, and is therefore sensitive to all Stage II and III Factors. Deficiencies of Stage I Factors (VIII, IX, XI, and XII) are not detected by the test.

### **INTERNATIONAL SENSITIVITY INDEX (ISI)**

The International Committee for Standardization in Haematology and the International Committee on Thrombosis and Haemostasis have agreed on recommendations for the reporting of Prothrombin Time results based upon an International Sensitivity Index (ISI) of Thromboplastin reagents and an International Normalized Ratio (INR). Thromboplastin reagents are assigned an ISI value by calibration against an International Reference Preparation, (IRP, 67/40) which by definition has an ISI = 1.0. The ISI value assigned to commercial Thromboplastin reagents therefore defines a comparative slope, or relative sensitivity, in comparison to the Reference Thromboplastin. The lower the ISI value, the more "sensitive" the reagent. By knowing the ISI of a particular Thromboplastin reagent, the ratio can be calculated which would have been the same as if the IRP 67/40 had been used as the reagent.

This is termed the International Normalized Ratio (INR), and is determined by:

$$\text{INR} = R^{\text{ISI}} = \text{Ratio}^{\text{ISI}} = \left( \frac{\text{Patient PT (s)}}{\text{Mean Normal PT (s)}} \right)^{\text{ISI}}$$

Each PT Reagent manufactured by Helena Biosciences is assigned an ISI value in relationship to the WHO Standardized Thromboplastin.

### **PLASMA PREPARATION**

Follow CSLI Guidelines H3-A4<sup>3</sup> and CLSI Guideline H21-A3<sup>4</sup> for correct sample preparation, handling and storage conditions

### **REAGENT PREPARATION**

Reconstitute and handle reagents as per IFU.

### **HELENA C-1 Preparation**

1. Turn on instrument and wait until the green "Ready" LED is displayed.
2. Turn on printer if connected
3. Select "PT" as active test
4. Check calibration

5. Allow reagent to prewarm for at least 5 min.

### PROCEDURE ON HELENA C-1

1. Pipette **25µl plasma** into cuvette
2. Prewarm plasma for 1 min
3. Transfer cuvette to measuring position
4. Activate optic (press key "Optic")
5. Add **50 µl of 1:1 prewarmed Thromboplastin, calcium** and simultaneously start the optic. (press key "Optic" again)
6. The instrument will read for a maximum of 300 secs. If no clot is detected, the display will read "+++ s"
7. The result is displayed in seconds and INR.

### ASSAY CALIBRATION

For INR-reporting of PT two parameters are required.

**The Mean normal value** (determine mean normal PT value by running at least 20 normal plasmas and deriving the geometric mean from the results)

**The ISI value** (Retrieve the ISI from the manufacturers assay sheet accompanying the Lot of Thromboplastin. Alternatively, run a local ISI calibration on the instrument)

Enter both values into the **Helena C-1**.

### QUALITY CONTROL

Control plasma should be tested in conjunction with patient samples. It is recommended that at least one Normal and one Abnormal be run at least each shift and a minimum of once per 20 patient samples. A Control Range should be established by the laboratory to determine the allowable variation in day to day performance of each Control Plasma.

### APPLICATION RECOMMENDATIONS

1. Don't use glass. Use only plastic.
2. Don't delay mixing of blood with anticoagulant.
3. Avoid extreme hemolysis or lipemic samples.
4. Avoid plasma contamination with tissue thromboplastin.
5. Avoid improper ratio of anticoagulant with blood.
6. Run patient samples in duplicate. At differences greater than 5 %, repeat tests.
7. Run quality controls regularly to confirm reagent & instrument functionality.
8. Don't run a test if the green LED is off.

## 8 APTT – Determination

### **SUMMARY**

From its origins through the work of Langdell and coworkers, and later modified by others, the Activated Partial Thromboplastin Time test has been widely used for a number of years as a pre-surgical screen for assessing certain coagulation factors and in monitoring Heparin therapy. All Factors of the Intrinsic Pathway are necessary for normal results when performing the APTT test. It is used principally, however, to detect deficiencies in the Stage I Factors, namely Factors VIII, IX, XI and XII, as well as Fletcher Factor. The APTT test is also used to monitor Heparin therapy, showing prolonged test results at approximately 0.1 units and above. The test is also used in the quantitative determination (Factor Assays) of Factors VIII, IX, XI, XII and Fletcher Factor.

### **PRINCIPLE**

The APTT test measures the clotting time of test plasma after the addition of APTT reagent, allowing an "activation time", followed by the addition of calcium chloride. Deficiencies of approximately 40% and lower of Factors VIII, IX, XI and XII will result in a prolonged APTT. Heparin, in the presence of adequate amounts of AT-III will also result in a prolonged APTT.

### **REAGENT**

APTT Reagent  
Calcium Chloride

### **PLASMA PREPARATION**

Follow CSLI Guidelines H3-A4<sup>3</sup> and CLSI Guideline H21-A3<sup>4</sup> for correct sample preparation, handling and storage conditions

### **REAGENT PREPARATION**

Reconstitute and handle reagents as per IFU.

### **HELENA C-1 Preparation**

1. Turn on instrument and wait until the green "Ready" LED is displayed.
2. Turn on printer if connected
3. Select "PTT" as active test
4. Allow CaCl<sub>2</sub> to prewarm at least 5 min.

### **ASSAY CALIBRATION**

APTT results can be normalized against a normal value, which is obtained from a reference range of normal APTT patient results.

Enter the normal value into the **Helena C-1**. The APTT is then displayed in seconds and normalized into Ratio.

## PROCEDURE ON HELENA C-1

1. Pipette **25µl plasma** into cuvette
2. Add **25 µl APTT** to plasma
3. Incubate exactly for **5 minutes (or 3 minutes for ellagic acid based APTT reagents)**
4. Transfer cuvette to measuring position
5. Activate optic (press key "**Optic**")
6. Add **25 µl prewarmed Calcium Chloride** and simultaneously start the optic (press key "**Optic**" again)
7. The instrument will read for a maximum of 300 secs. If no clot is detected, the display will read "**+++ s**"
8. The result is displayed in seconds and Ratio

## QUALITY CONTROL

Control plasma should be tested in conjunction with patient samples. It is recommended that at least one Normal and one Abnormal be run at least each shift and a minimum of once per 20 patient samples. A Control Range should be established by the laboratory to determine the allowable variation in day to day performance of each Control Plasma.

## APPLICATION RECOMMENDATIONS

1. Don't use glass. Use only plastic.
2. Don't delay mixing of blood with anticoagulant.
3. Avoid extreme hemolysis or lipemic samples.
4. Avoid plasma contamination with tissue thromboplastin.
5. Avoid improper ratio of anticoagulant with blood.
6. Run patient samples in duplicate. At differences greater than 5 % repeat testing.
7. Run quality controls regularly to confirm reagent & instrument functionality.
8. Don't run a test if the green LED is off.

## 9 FIB – Determination

### **SUMMARY**

The enzyme, Thrombin, is the penultimate protein in the clotting sequence, acting upon soluble Fibrinogen and converting it to insoluble Fibrin. Normal plasma Fibrinogen levels range from 200-400 mg/dl, although levels as low as 10-20 mg/dl may occur in acquired or congenital hypofibrinogenemia. The determination of plasma Fibrinogen levels has proven to be a useful test in the diagnosis of hemorrhagic disorders relating to plasma Fibrinogen content. These include hyperfibrinogenemia, hypofibrinogenemia, dysfibrinogenemia and a fibrinogenemia.

### **PRINCIPLE**

The Fibrinogen reagent utilizes the Clauss clotting time method for the determination of plasma Fibrinogen levels, wherein excess Bovine Thrombin is used to clot diluted plasma. First, a standard curve is prepared using a reference plasma of known Fibrinogen content. When Thrombin is added, the clotting time obtained is inversely proportional to the Fibrinogen content. Next, patient plasma, at a dilution of 1:10, is clotted with Thrombin and the resultant clotting time used to interpolate Fibrinogen concentration from the standard curve.

### **REAGENT**

Thrombin Reagent  
Fibrinogen Calibrator  
Owren's Veronal Buffer

### **PLASMA PREPARATION**

Follow CSLI Guidelines H3-A4<sup>3</sup> and CLSI Guideline H21-A3<sup>4</sup> for correct sample preparation, handling and storage conditions.

### **REAGENT PREPARATION**

Reconstitute reagents and handle as per IFU.

### **SAMPLE PREPARATION**

Dilute sample 1:10 with OVB  
(1 part sample + 9 part of dilution buffer)

### **HELENA C-1 Preparation**

1. Turn on instrument and wait until the green "Ready" LED is displayed.
2. Turn on printer if connected
3. Select "FIB" as active test
4. Check calibration
5. Allow reagent to prewarm at least 5 min.



**ASSAY CALIBRATION**

For the calibration of Fibrinogen, two (max three) parameters are required.

**Namely, the clotting time of the Fibrinogen Calibrator in the dilutions 1:10, 1:20, 1:40**

Use the fibrinogen concentration provided with the reagent, by the manufacturer.

A typical calibration would be	300 mg/dL	= 9.2 s
	150 mg/dL	= 25.0 s
	75 mg/dL	= 38.0

Enter all values into the **Helena C-1**.

**PROCEDURE ON HELENA C-1**

1. Pipette **50µl plasma dilution (1:10 with OVB)** into cuvette
2. Prewarm plasma for 1 min
3. Transfer cuvette to measuring position
4. Activate optic (press key "**Optic**")
5. Add **25 µl Thrombin** and simultaneously start the optic.  
(press key "**Optic**" again)
6. The instrument will read maximal 60 secs.
7. The result is displayed in seconds and mg/dL.

**QUALITY CONTROL**

Control plasma should be tested in conjunction with patient samples. It is recommended that at least one Normal and one Abnormal be run at least each shift and a minimum of once per 20 patient samples.

**APPLICATION RECOMMENDATIONS**

1. Don't use glass. Use only plastic.
2. Don't delay mixing of blood with anticoagulant.
3. Avoid extreme hemolysis or lipemic samples.
4. Avoid plasma contamination with tissue thromboplastin.
5. Avoid improper ratio of anticoagulant with blood.
6. Run patient samples in duplicate. At differences greater than 5 % repeat testing.
7. Run quality controls regularly to confirm reagent & instrument functionality.
8. Don't run a test if the green LED is off.

## 10 TT – Determination

### **SUMMARY**

The enzyme Thrombin is the penultimate protein in the clotting sequence, acting upon soluble fibrinogen and converting it to insoluble fibrin. As a reagent, Thrombin has proven useful in the laboratory evaluation of many fibrinogen disorders, including hypofibrinogenemia and dysfibrinogenemia. A prolonged Thrombin clotting time will result at Fibrinogen levels of about 100 mg/dL and below. Nonfunctional fibrinogen molecules (dysfibrinogenemia) will also result in a prolonged Thrombin Time. Heparin, in the presence of adequate amounts of AT-III, will also produce a prolonged Thrombin Time.

### **REAGENT**

Bovine Thrombin Reagent

### **PLASMA PREPARATION**

Follow CSLI Guidelines H3-A4<sup>3</sup> and CLSI Guideline H21-A3<sup>4</sup> for correct sample preparation, handling and storage conditions

### **REAGENT PREPARATION**

Reconstitute reagent and handle as per IFU.

### **HELENA C-1 Preparation**

1. Turn on instrument and wait until the green "Ready" LED is displayed.
2. Turn on printer if connected
3. Select "TT" as active test
4. Check normal TT value has been entered if Ratio is required.
5. Allow reagent to prewarm for at least 5 min.

### **PROCEDURE ON HELENA C-1**

1. Pipette **50µl plasma sample** into cuvette
2. Prewarm plasma for 1 min
3. Transfer cuvette to measuring position
4. Activate optic (press **key „Optic“**)
5. Add **50µl Bovine Thrombin** and simultaneously start the optic.  
(press **key "Optic" again**)
6. The instrument will read for a maximum of 300 secs.
7. The result is displayed in seconds and Ratio.

### **ASSAY CALIBRATION**

TT results should be normalized against a normal value, which is obtained from a reference range of local normal patient plasmas.

Enter the normal value into the **Helena C-1**. The TT is then displayed in seconds and normalized into Ratio.

### **QUALITY CONTROL**

Control plasma should be tested in conjunction with patient samples. It is recommended that at least one Normal be run at least each shift and a minimum of once per 20 patient samples. A Control Range should be established by the laboratory to determine the allowable variation in day to day performance of each Control plasma.

**APPLICATION RECOMMENDATIONS**

1. Don't use glass. Use only plastic.
2. Don't delay mixing of blood with anticoagulant.
3. Avoid extreme hemolysis or lipemic samples.
4. Avoid plasma contamination with tissue thromboplastin.
5. Avoid improper ratio of anticoagulant with blood.
6. Run patient samples in duplicate. At differences greater than 5% repeat testing.
7. Run quality controls regularly to confirm reagent & instrument functionality.
8. Don't run a test if the green LED is off.

## 11 Extrinsic Factor Determination

(Factors II, V, VII, X)

### **SUMMARY:**

Dysfunctions of the extrinsic coagulation pathway are indicated by prolonged Prothrombin Time (PT). The activity of an extrinsic pathway factor (Factors II, V, VII, X) is determined with a PT of the test plasma mixed with factor deficient plasma.

### **REAGENT**

Thromboplastin Reagent

### **DEFICIENT PLASMA**

Deficient Plasma F II  
Deficient Plasma F V  
Deficient Plasma F VII  
Deficient Plasma F X

### **PLASMA PREPARATION**

Follow CSLI Guidelines H3-A4<sup>3</sup> and CLSI Guideline H21-A3<sup>4</sup> for correct sample preparation, handling and storage conditions.

### **REAGENT PREPARATION**

Reconstitute reagents and handle as per IFU.

### **SAMPLE PREPARATION**

Dilute sample 1:10 with OVB  
(1 part sample + 9 part of dilution buffer)

### **Helena C-1 Preparation**

1. Turn on instrument and wait until the green "Ready" LED is displayed.
2. Turn on printer if connected
3. Select "FAC" as active test
4. Check calibration results for % activity have been entered.
5. Allow reagent to prewarm at least 5 min.

## PROCEDURE ON HELENA C-1

1. Pipette **25µl 1:10 plasma dilution** into cuvette
2. Pipette **25µl deficient plasma** into cuvette
3. Incubate for 1 min
4. Transfer cuvette to measuring position and Activate optic (press key "**Optic**")
5. Add **50µl prewarmed Thromboplastin/calcium mix (1:1)** and simultaneously start the optic (press key "**Optic**")
6. The instrument will read for a maximum of 300 secs. If no clot is detected, the display will read "**+++s**"
7. The result is displayed in seconds and activity %.

### ASSAY CALIBRATION

For % Activity -calibration of a factor, two (max three) calibration points are required.

Prepare standards according to recommendation:

- **1:10 plasma dilution** (~ 100 % activity)  
Mix 1 part Calibrator Normal with 9 parts OVB
- **1:100 plasma dilution** (~ 10 % activity)  
Mix 1 part Calibrator Normal with 99 parts OVB
- **1:200 plasma dilution** (~ 5 % activity)  
Mix 1 part Calibrator Normal with 199 parts OVB

Determine the clotting time for required dilutions and enter the values into the **Helena C-1**.

### QUALITY CONTROL

Control plasma should be tested in conjunction with patient samples. It is recommended that at least one Normal be run at least each shift and a minimum of once per 20 patient samples. A Control Range should be established by the laboratory to determine the allowable variation in day to day performance of each Control plasma.

### APPLICATION RECOMMENDATIONS

1. Don't use glass. Use only plastic.
2. Don't delay mixing of blood with anticoagulant.
3. Avoid extreme hemolysis or lipemic samples.
4. Avoid plasma contamination with tissue thromboplastin.
5. Avoid improper ratio of anticoagulant with blood.
6. Run patient samples in duplicate. At differences greater than 5 % repeat testing.
7. Run quality controls regularly to confirm reagent & instrument functionality.
8. Don't run a test if the green LED is off.

## 12 Intrinsic Factor Determination

### Factors VIII, IX, XI, XII

#### **SUMMARY:**

Dysfunctions of the intrinsic coagulation pathway are indicated by prolonged APTT. The activity of an intrinsic pathway factor (Factors VIII, IX, XI, XII) is determined with an APTT of the test plasma mixed with factor deficient plasma.

#### **REAGENT**

APTT-Reagent  
Calcium Chloride

#### **DEFICIENT PLASMA**

Deficient Plasma F VIII  
Deficient Plasma F IX  
Deficient Plasma F XI  
Deficient Plasma F XII

#### **PLASMA PREPARATION**

Follow CSLI Guidelines H3-A4<sup>3</sup> and CLSI Guideline H21-A3<sup>4</sup> for correct sample preparation, handling and storage conditions.

#### **REAGENT PREPARATION**

Reconstitue and handle reagents as per IFU.

#### **SAMPLE PREPARATION**

Dilute sample 1:10 with OVB  
(1 part sample + 9 part of dilution buffer)

#### **HELENA C-1 Preparation**

1. Turn on instrument and wait until the ready LED is lighting.
2. Turn on printer if connected
3. Select "FAC" as active test
4. Check calibration results for % activity have been entered.
5. Allow reagent to prewarm at least 5 min.

## PROCEDURE ON HELENA C-1

1. Pipette **25µl 1:10 plasma dilution** into cuvette
2. Pipette **25µl deficient plasma** into cuvette
3. Pipette **25µl APTT reagent** into cuvette
4. Incubate exactly 5 min (or 3 mins if using ellagic acid based APTT)
5. Transfer cuvette to measuring position and Activate optic (press key **"Optic"**)
6. Add **25 µl prewarmed CaCl<sub>2</sub>** and simultaneously start the optic (press key **"Optic" again**)
6. The instrument will read for a maximum of 300 secs. If no clot is detected, the display will read **"+++s"**
7. The result is displayed in seconds and activity %.

## ASSAY CALIBRATION

For % Activity calibration of a factor, two (max three) calibration points are required.

Prepare standards according to recommendation:

- **1:10 plasma dilution** (~ 100 % activity)  
Mix 1 part Calibrator Normal with 9 parts OVB
- **1:100 plasma dilution** (~ 10 % activity)  
Mix 1 part Calibrator Normal with 99 parts OVB
- **1:200 plasma dilution** (~ 5 % activity)  
Mix 1 part Calibrator Normal with 199 parts OVB

Determine the APTT clotting time for the required dilutions and enter the values into the **Helena C-1**.

## QUALITY CONTROL

Control plasmas should be tested in conjunction with patient samples. It is recommended that at least one Normal and one Abnormal be run at least each shift and a minimum of once per 20 patient samples. A Control Range should be established by the laboratory to determine the allowable variation in day to day performance of each Control Plasma.

## APPLICATION RECOMMENDATIONS

1. Don't use glass. Use only plastic.
2. Don't delay mixing of blood with anticoagulant.
3. Avoid extreme hemolysis or lipemic samples.
4. Avoid plasma contamination with tissue thromboplastin.
5. Avoid improper ratio of anticoagulant with blood.
6. Run patient samples in duplicate. At differences greater than 5 % repeat testing.
7. Run quality controls regularly to confirm reagent & instrument functionality.
8. Don't run a test if the green LED is off.

## 13 D-dimer determination

### SUMMARY:

D-dimer antigen is always present in plasma as a result of plasmin breakdown of cross-linked fibrin. After an injury, or when suffering from conditions associated with increased haemostatic activity, there is a concurrent increase in plasma D-dimer concentration. The determination of D-dimer has become a prevalent aid in the diagnosis of thrombosis. Elevated levels of D-dimer are found in clinical conditions such as deep vein thrombosis (DVT), pulmonary embolism (PE) and disseminated intravascular coagulation (DIC)<sup>2</sup>. A negative D-dimer test result on a patient with a suspected thrombotic disorder has a high negative predictive value.

### INTENDED USE:

Auto Blue D-dimer 400 is a micro-particle enhanced immunoassay for quantitative determination of D-dimer in human blood plasma. Auto Blue D-dimer 400 is intended for automated and semi-automated coagulation and clinical laboratory instruments, using either turbidimetric or nephelometric detection in the 350 – 550 nm wavelength range. The micro-particle reagent consists of sub-micron sized polystyrene particles coupled to monoclonal antibodies specific for D-dimer. When the reagent is exposed to a plasma sample, D-dimer will agglutinate the particles, giving rise to an increased light-scattering. When exposed to the appropriate wavelength of monochromatic light, the increase in measured turbidity, or light-scattering, is proportional to the amount of D-dimer in the sample.

### REAGENT:

Latex Reagent  
Reaction Buffer  
Diluent  
Calibrator

### PLASMA PREPARATION:

Follow CSLI Guidelines H3-A4<sup>3</sup> and CLSI Guideline H21-A3<sup>4</sup> for correct sample preparation, handling and storage conditions.

### REAGENT PREPARATION

Reconstitute reagents and handle as per IFU.

### QUALITY CONTROL

Control plasmas should be tested in conjunction with patient samples. It is recommended that at least one Normal and one Abnormal be run at least each shift and a minimum of once per 20 patient samples. A Control Range should be established by the laboratory to determine the allowable variation in day to day performance of each Control Plasma.

### Helena C-1 PREPARATION

1. Turn on instrument and wait until the "ready" LED is displayed.
2. Turn on printer if connected
3. Select "DD" as active test
4. Check calibration results have been entered.
5. Allow reagent to prewarm at least 5 min.



### Procedure on HELENA C-1

1. Pipette **25µl plasma** into cuvette
2. Pipette **100µl reaction buffer** into cuvette
3. Incubate for 1-10min
4. Transfer cuvette to measuring position and activate optic (press key "Optic")
5. Add **50µl prewarmed Latex reagent** and **mix well** within the first 5s. Good mixing can be achieved by using the pipette.
6. The instrument will read the next 150sec to determine the rate of signal.
7. The result is displayed in extinction and concentration ng/mL.

### ASSAY CALIBRATION

For D dimer calibration, three calibration points are required.

Prepare standards according to recommendation:

- **Neat** (~ 3200ng/ml)
- **1:2 plasma dilution** (~ 1600ng/ml)  
Mix 1 part Calibrator with 1 part Dilution Buffer
- **1:16 plasma dilution** (~ 200ng/ml)  
Mix 1 part Calibrator with 15 parts Dilution Buffer

Determine the D dimer concentration for the required dilutions (taking the first concentration from manufacturers sheet) and enter the values into the **Helena C-1**.

### RESULTS

Test results are reported in ng/mL D-Dimer concentration. As there is no international standard available for D-dimer, each laboratory should establish its own normal reference range and cut-off values.

### REFERENCES

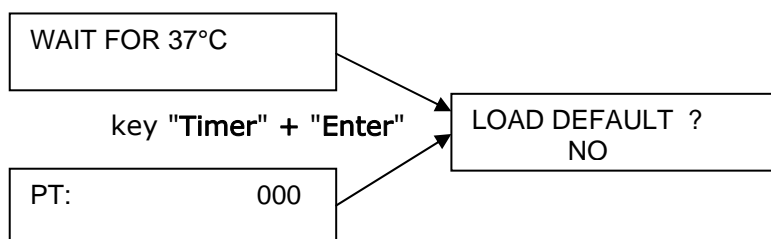
1. Bounameaux H, *et al.* Thrombosis and Haemostasis. 1994, 71: 1 – 6.
2. Gaffney PJ, *et al.* British Journal of Haematology. 1988, 68: 91 – 96.
3. National Committee for Clinical Laboratory Standards. H3-A4, Procedure for the collection of diagnostic blood specimens by venipuncture (1998).
4. National Committee for Clinical Laboratory Standards. H21-A3, Collection, transport, and processing of blood specimens for coagulation testing and general performance of coagulation assays (1998).
5. National Committee for Clinical Laboratory Standards. C3-A3, Preparation and testing of reagent water in the clinical laboratory (1997).

## 14 Service



Please read this section in its entirety prior to operating the *Helena C-1*. In order to ensure accurate and reliable performance of the instrument, only authorized personnel, should perform any service functions on the analyser

To enter the hidden submenu service, press key "Timer" and key "Enter" simultaneously.



Following service can be performed on the **Helena C-1**

- Reset to default values
- Temperature Adjustment
- OD-Correction
- Coag.-Correction
- Optic Check
- Set Trigger
- Set RS232

Use the **cursor keys** to change and key "Enter" to confirm !



**Wrong adjustments will influence the measurement decisively!**  
**Before changing anything, be aware of the consequence!**

## 14.1 Default values

The **Helena C-1** can store test and system parameter permanent on board.

Calibration PT:	ISI = 1.10 (1) 100% (Normal) = 12.8 s (2) 50% = 16,7 s (3) 25% = 25.0 s
Calibration APTT:	Normal = 30.0 s
Calibration PT:	Normal = 15.0 s
Calibration FIB:	(1) 300 mg/dL = 12.0 s (2) 150 mg/dL = 23.0s (3) 75 mg/dL = 36.0 s
Calibration FAC:	(1) 100 % = 32.0 s (2) 10 % = 60.0 s (3) 5 % = 70.0 s
Calibration DD:	(1) 1600 ng/ml = 150 mOD (2) 200 ng/ml = 30 mOD (3) 0 ng/ml = 0 mOD
Temperature	°C=370 (9085)
OD Correction PT:	100
OD Correction APTT:	100
OD Correction TT:	100
OD Correction FIB:	100
OD Correction PT:	100
OD Correction FAC:	100
OD Correction DD:	100
Coag Correction PT:	100
Coag Correction APTT:	100
Coag Correction TT:	100
Coag Correction FIB:	100
Coag Correction PT:	100
Coag Correction FAC:	100
Coag Correction DD:	100
Optic check (mw):	approx. 11000 (± 2000)
Autostart Trigger:	300
RS 232 Print Results	(Data->RS232 = NO)

## 14.2 Temperature Adjustment

The incubation block of the **Helena C-1** has a temperature of 37°C. When the green LED is on, fill a reagent tube with 1 ml water and place it in a reagent position. Place a digital thermometer in the reagent tube and let warm-up for approx. 10 min.

Allow to warm for 10 min and read the temperature.

SET TEMPERATURE °C=371 (9085)
----------------------------------

Example: The actual temperature is 37,1°C and the digital target value is 9085.

Compare the temperature displayed by the system and the thermometer. If the temperature is different, adjust the temperature on the **Helena C-1** by pressing the Up/Down cursor keys

Wait until a stable temperature of 37.0°C is displayed on the **Helena C-1**. Check and correct the system temperature if not equivalent to the external thermometer.

Use Up / Down keys for increase or decrease of temperature.

## 14.3 Result correction

### A. OD CORRECTION

OD-CORRECTION PT = <b>100</b>
----------------------------------

The measured optical density of the instrument can be corrected by a factor for each test.

(OD-Correction = 100 → optical density \* 1.00 -> no effect)

(OD-Correction = 120 → optical density \* 1.20)

OD-CORRECTION **below 100** will cause:

- longer clotting times
- reduce sensitivity of method (more results as +++.+ s)

OD-CORRECTION **above 100** will cause:

- shorter clotting times
- increase sensitivity of method, which can cause wrong results (short time results)

### B. COAG CORRECTION

COAG-CORRECTION PT = <b>100</b>
------------------------------------

With the Coag Correction the instrument can correct the result for better correlation to other systems or reagents.

Example: On different instruments, a plasma is measured with PT = 12,1 seconds, on the **Helena C-1** result is 11,0 seconds. To get equal results, the result have to be corrected by factor 1,10 (+10%).

This can be done by entering COAG CORRECTION = 110 (Factor 1,10).

### OD-CORRECTION for fibrinogen test

Run a 300 mg/dL calibrator. The result should be close to 10 sec. If it is above/below 10sec, in-/decrease the OD-Correction slightly.

### CORRECTION for D-Dimer test

OD CORRECTION is used for sensitivity limit. (100 = 100mOD)

COAG CORRECTION is used to set the maximum reading time (100 = 120s)

### 14.4 Optic Check

The Optic-check is recommended, if problems with measurements arise. Remove cuvette from optic. Ensure that no cuvette is placed in the optic.

mw=11301	004
81	

- signals      high=11301      digital value when optic LED is on
- low=81          digital value when optic LED is off
- amp=004      actual amplification

Optic calibration:              press key "MENU" to recalibrate the optic.  
    Remove cuvette before calibration !

- target range high:              10.000 – 15.000
- target range low:                0 - 250
- target range amp:                3-20

Manual change:      press key "UP" or "DOWN" to change the amplification



- Optic check will fail, if**
- optic path is blocked or spilt
  - LED is burnt (exchange optic block)
  - Controller malfunction (exchange)

### 14.5 Autostart Trigger

The sensitivity of the autostart feature can be adjusted. The value is the required optical change before the instrument triggers the measurement start.

SET TRIGGER
300

- The default value is 300.
- Increase value if test does start before adding the reagent
- Decrease value if test does not start at all.
- Set to 0 will disable the autostart for the test

## 14.6 Interface RS 232

The interface port is set to 2400 Baud, 8 Bits, 1 Stop, No parity

NO → result will be printed (default)

```
DATA → RS232
NO
```

### Example of a result print:

```
01    PT:    run #01
12.6 s
%=95
I = 1.03

01    PT:    run#02
13.2 s
%=85
I = 1.35

MEAN:    mean
12.9 s
%=90
I = 1.19
```

YES → result will be send to host with following syntax

```
DATA → RS232
YES
```

CURVE DATA: every 500ms the value of the optical density (eg. "123" = 123mOD)

### RESULT DATA:

[SYS][SN][TYP][NR][TEST][RES1][SCALE1][RES2][SCALE2][RES3][SCALE3][LF]

Delimiter:	TAB	(for each data field)
SYS:	"D1"	(system id)
SN:	"1234"	(serial number of instrument)
TYP:	"S"/"M"	(Single result or <u>M</u> ean result)
NR:	"12"	(Result ID number)
TEST:	"PTB:"	(name of test)
RES1:	"12.5"	(result 1)
SCALE1:	"s"	(unit 1)
RES2:	"100"	(result 2)
SCALE2:	"%"	(unit 2)
RES3:	"1.00"	(result 3)
SCALE3:	"I"	(unit 3)
LF:	Line feed	

Example: "D1 1234 S 1 PTB: 12.5 s 100 % 1.00 I"

## 14.7 LIS with TECAM SMART

The Helena C-1 interface be be used for uni-directional communication to any host computer.

The software TECAM SMART offers a stand-alone solution with following features:

- Requirement: Pentium III 1GHZ , 128 MB RAM for Windows 2000 or Windows XP
- Database: Microsoft Access Jet 4.0 SP3 Max 4GB (400.000 results)
- Receive result including the reaction curve
- Result management with database with enhanced filter (SQL) functions
- Patient management (PID, name , sex and birthday)
- Reporting of filtered data (eg. Print results PTB of patient XY of the last 30days)
- Statistic module

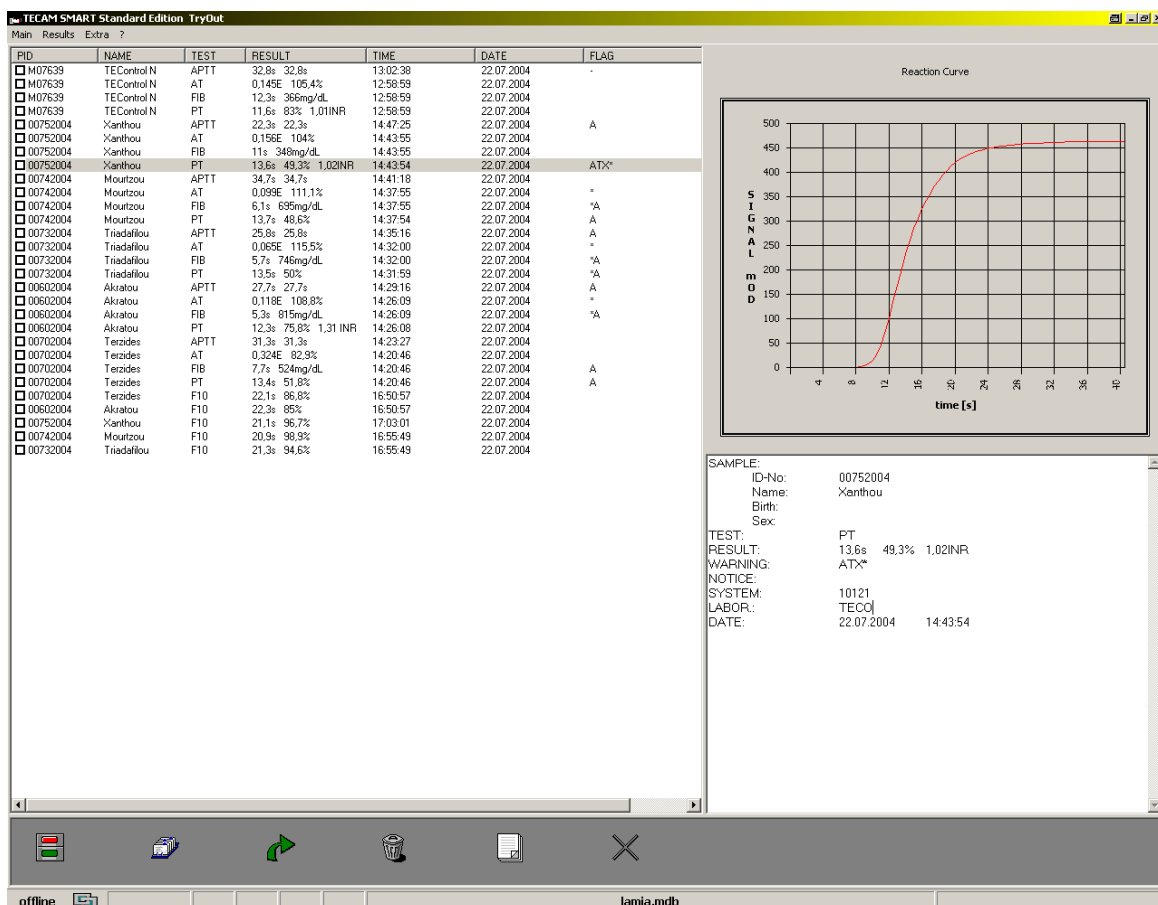


Figure 7 Result management of TECAM SMART



Date	Time	PatientID	Name	Birthday	Sex	Testname	TestLot	Result1	Scale1	Result2	Scale2	Flag	Warnings	SystemID
16.08.2004	11:45:01	0				PT	311203220	15,90	s	97,70	%			10008
16.08.2004	11:45:01	0				PT	311203220	14,90	s	105,70	%	*		10008
16.08.2004	11:45:01	1				PT	311203220	27,00	s	45,00	%			10008
16.08.2004	11:45:01	1				PT	311203220	27,10	s	44,80	%			10008
16.08.2004	11:47:15	2				PT	311203220	15,80	s	98,40	%			10008
16.08.2004	11:47:15	2				PT	311203220	15,90	s	97,70	%			10008
16.08.2004	11:47:15	3				PT	311203220	15,80	s	98,40	%			10008
16.08.2004	11:47:15	3				PT	311203220	15,70	s	99,20	%			10008
16.08.2004	12:11:32	4				PT	311203220	15,60	s	100,00	%			10008
16.08.2004	12:11:32	4				PT	311203220	14,40	s	109,90	%	*		10008
16.08.2004	12:16:09	5				PT	311203220	26,60	s	45,70	%			10008
16.08.2004	12:16:09	5				PT	311203220	26,50	s	45,90	%			10008
16.08.2004	12:24:03	6				PT	311203220	15,40	s	101,60	%	*		10008
16.08.2004	12:24:03	6				PT	311203220	15,60	s	100,00	%			10008
16.08.2004	12:26:24	7				PT	311203220	15,50	s	100,80	%	*		10008
16.08.2004	12:26:24	7				PT	311203220	15,40	s	101,60	%	*		10008
12.08.2004	16:09:20	EV1				PT	311203220	15,40	s	101,60	%	*		10008
12.08.2004	16:21:34	EV1				PT	311203220	15,20	s	103,20	%	*		10008
09.08.2004	10:32:27	EV1				PT	311203220	15,40	s	101,60	%	*		10008
09.08.2004	10:29:59	EV1				PT	311203220	15,50	s	100,80	%	*		10008
09.08.2004	10:29:59	EV1				PT	311203220	15,50	s	100,80	%	*		10008
09.08.2004	10:27:30	EV1				PT	311203220	15,50	s	100,80	%	*		10008
12.08.2004	16:06:53	EV1				PT	311203220	15,40	s	101,60	%	*		10008
12.08.2004	16:24:03	EV1				PT	311203220	15,40	s	101,60	%	*		10008
12.08.2004	16:24:03	EV1				PT	311203220	15,40	s	101,60	%	*		10008
12.08.2004	16:24:03	EV1				PT	311203220	15,40	s	101,60	%	*		10008
12.08.2004	16:21:34	EV1				PT	311203220	15,40	s	101,60	%	*		10008
12.08.2004	16:19:06	EV1				PT	311203220	15,30	s	102,40	%	*		10008
12.08.2004	16:19:06	EV1				PT	311203220	15,40	s	101,60	%	*		10008
12.08.2004	16:16:38	EV1				PT	311203220	15,60	s	100,00	%	*		10008
12.08.2004	16:16:38	EV1				PT	311203220	15,40	s	101,60	%	*		10008
12.08.2004	16:14:11	EV1				PT	311203220	15,30	s	102,40	%	*		10008
12.08.2004	16:14:11	EV1				PT	311203220	15,20	s	103,20	%	*		10008
09.08.2004	10:32:27	EV1				PT	311203220	15,50	s	100,80	%	*		10008
12.08.2004	16:11:44	EV1				PT	311203220	15,10	s	104,00	%	*		10008
09.08.2004	10:27:30	EV1				PT	311203220	15,50	s	100,80	%	*		10008
12.08.2004	16:09:20	EV1				PT	311203220	15,30	s	102,40	%	*		10008
12.08.2004	16:06:53	EV1				PT	311203220	15,40	s	101,60	%	*		10008
12.08.2004	16:11:44	EV1				PT	311203220	15,40	s	101,60	%	*		10008
09.08.2004	10:37:38	EV1				PT	311203220	15,40	s	101,60	%	*		10008
09.08.2004	10:42:29	EV1				PT	311203220	15,40	s	101,60	%	*		10008
09.08.2004	10:39:58	EV1				PT	311203220	15,50	s	100,80	%	*		10008
09.08.2004	10:39:59	EV1				PT	311203220	15,40	s	101,60	%	*		10008
09.08.2004	10:34:59	EV1				PT	311203220	15,60	s	100,00	%	*		10008
09.08.2004	10:34:59	EV1				PT	311203220	15,20	s	103,20	%	*		10008
09.08.2004	10:37:38	EV1				PT	311203220	15,30	s	102,40	%	*		10008
09.08.2004	10:45:00	EV1				PT	311203220	15,40	s	101,60	%	*		10008
09.08.2004	10:42:29	EV1				PT	311203220	15,50	s	100,80	%	*		10008
09.08.2004	10:45:00	EV1				PT	311203220	15,60	s	100,00	%	*		10008
09.08.2004	10:42:28	EV2				PT	311203220	26,60	s	45,70	%			10008
12.08.2004	16:16:39	EV2				PT	311203220	26,90	s	45,20	%			10008

Figure 8 Database of TECAM SMART

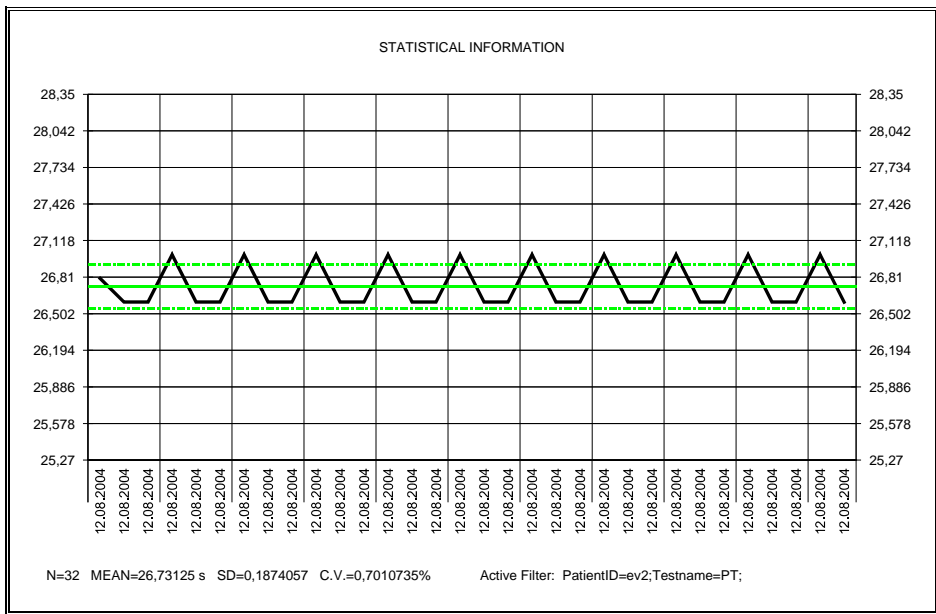


Figure 9 Statistics with TECAM SMART

## COAGULATION DATA REPORT

Date of Report: 13.12.2004

PID	Name	Date of Birth			
Test	Date & Time	Warnings	Result-1	Result-2	
<b>Patient: 0</b>					
PT	16.08.2004		97,7%	15,9s	
PT	16.08.2004		*105,7%	*14,9s	
<b>Patient: 1</b>					
PT	16.08.2004		45%	27s	
PT	16.08.2004		44,8%	27,1s	
<b>Patient: 2</b>					
PT	16.08.2004		98,4%	15,8s	
PT	16.08.2004		97,7%	15,9s	
<b>Patient: 3</b>					
PT	16.08.2004		98,4%	15,8s	
PT	16.08.2004		99,2%	15,7s	
<b>Patient: 4</b>					
PT	16.08.2004		100%	15,6s	
PT	16.08.2004		*109,9%	*14,4s	
<b>Patient: 5</b>					
PT	16.08.2004		45,7%	26,6s	
PT	16.08.2004		45,9%	26,5s	
<b>Patient: 6</b>					
PT	16.08.2004		*101,6%	*15,4s	
PT	16.08.2004		100%	15,6s	

Figure 10

Result report with TECAM SMART

## 15 Troubleshooting Guide

*Note : Always verify instrument performance by testing appropriate control samples.*

System Error Message	Interpretation and corrective action
<b>Optic Failure !</b>	<p><u>During bootup:</u> Low signal detected. Remove cuvette and reboot. If error remains, clean optics or replace LED or replace microcontroller.</p> <p><u>During service menu:</u> The <b>Helena C-1</b> is not operating in its optical specification. This can happen, if:</p> <ul style="list-style-type: none"> <li>• there is not sufficient light (i.e. with very turbid reagents or lipemic samples). Change to HELENA reagent. Avoid extreme samples.</li> <li>• light is too intense (i.e. direct sunlight). Protect against sunlight.</li> <li>• Laser LED is burned out. Replace device.</li> </ul>
<b>Red Service LED is on</b>	Electrical power is not sufficient. Use original power supply. Load battery-pack, if used.
<b>Green Ready LED is off</b>	Temperature is out of range. Wait a few minutes. If error remains contact technical services
<b>Temperature not correct</b>	Adjust the temperature

Test-specific errors	Interpretation and corrective action
<p><b>+++ + s</b>  <b>"No Clot Detect"</b></p>	<p>Always repeat the sample to verify result</p> <p>Possible reasons include the following:            Clotting time is longer than 300 secs            Clotting time is shorter than 8 secs            Incorrect reagent            Fibrinogen level of sample is below 100 mg/dL (i.e. sample dilutions)            Air bubbles            Debris in cuvette            Sample improperly collected            OD-Correction is set to zero</p>
<p><b>Clotting time too short</b></p>	<p>Always repeat the sample to verify result</p> <p>Possible reasons include the following:            Incorrect reagent            Air bubbles            Debris in cuvette            Sample improperly collected            Optic is wrong adjusted</p> <p>Action:            Use recommended materials            Decrease slightly OD-Correction            Increase OD-Range</p>
<p><b>Clotting time too long</b></p>	<p>Always repeat the sample to verify result</p> <p>Possible reasons include the following:            Incorrect reagent            Air bubbles            Debris in cuvette            Low fibrinogen level            Sample improperly collected            Optic is wrong adjusted</p> <p>Action:            Use recommended materials            Increase slightly OD-Correction            Decrease OD-Range</p>

## 16 Instrument, Consumables, Spare parts

### *Helena C-1 (Standard Package)*

Cat. Number: C-1

#### Including:

1 pc	Universal Power supply (93-240Vac/50-60Hz) with EU and UK exchangeable adapter
1 pc	Serial cable
25 pcs	Single cuvettes
5 pcs	Reagent tubes (Ø11mm)
2 pcs	Reagent Adapters (Ø11mm)
1 pc	Warranty card
1 pc	CD: Manual, Service, Application Guides

#### ACCESSORIES

Cat.No.	Product	content
C-01	Thermal printer	1

#### CONSUMABLES

Cat.No.	Product	content
C-101	Single cuvette	500
C-05	Reagent adapter Ø 11mm	1
C-103	Reagent tubes Ø 11mm	100
C-04	Thermal paper for printer	5
C-02	Research Software TECAM	1

#### SPARE PARTS

Cat.No.	Product	content	no. on drawing
20 001 05	Casing cpl. C-1 black, soft-touch	1	1; 2; 3
20 004 01	Power Supply 90-264 Vac EU	1	not on drawing
20 004 03	Power Supply 90-264 Vac USA	1	not on drawing
20 005 11	Keyboard C-1	1	4
20 010 01	Display cpl.	1	12
20 006 01	System board	1	11
20 007 01	Transmitter board	1	10
20 008 01	Receiver board	1	9
20 011 00	Mounting plate	1	5
20 012 00	Distance M3x16	1	29
20 013 00	Distance D6xH3	1	18
20 015 01	Optic block (w/o boards)	1	8
20 016 00	Heating foil	1	13
20 017 00	Temperature sensor	1	17
20 018 00	Cable RS232	1	14
20 019 00	Cable DC input	1	15
20 020 00	Heating block	1	6

### 17 Technical Drawing (3D-explosion)

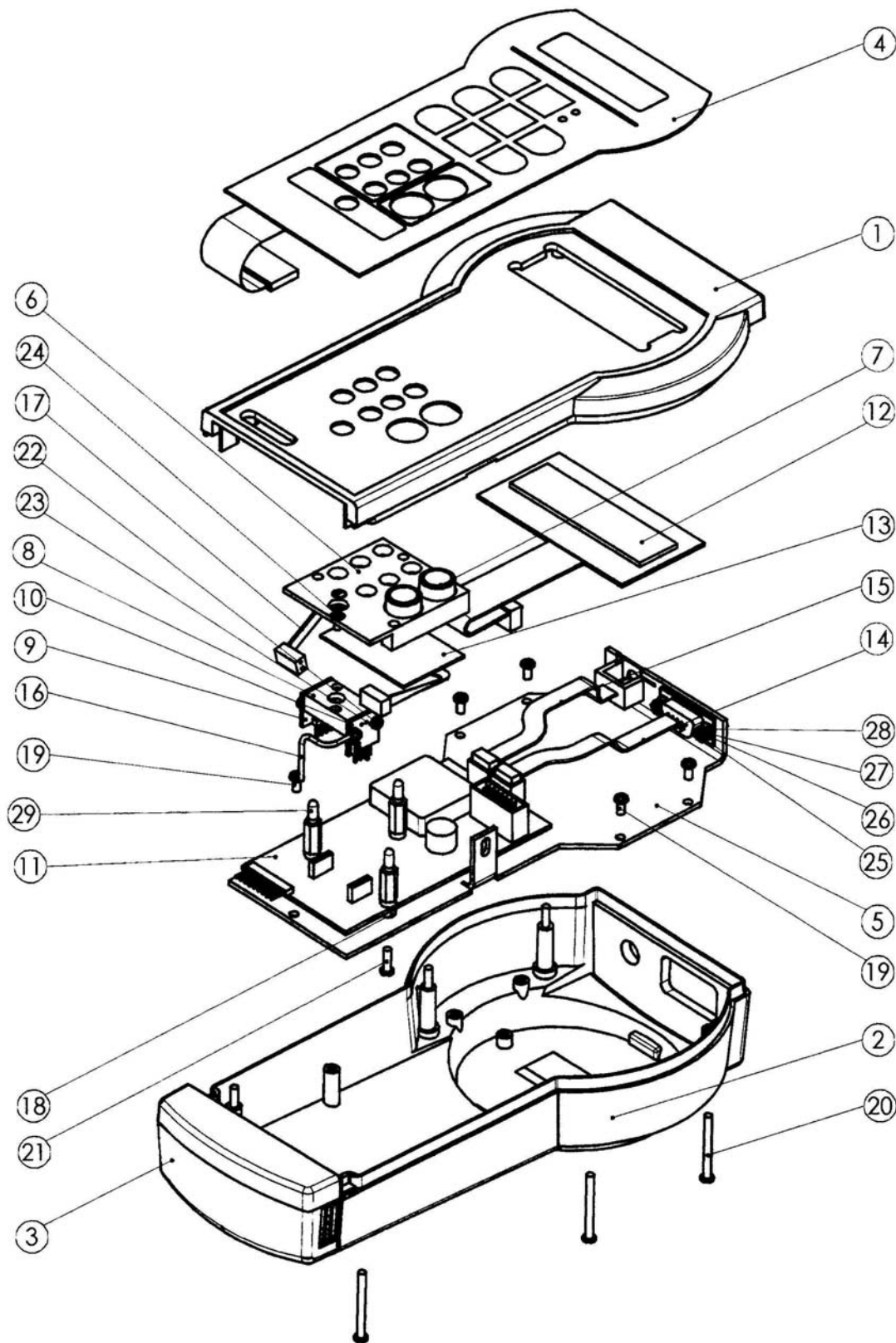


Figure 11 3D explosion drawing



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HL-2-1819P 2009/03(2) [English]

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