

# C-4 Quad-channel coagulometer

**helena**  
Biosciences Europe

Operator's Manual



# Operation Manual for **Helena C-4** Software: C11.11b



For *In-Vitro* Diagnostic use



Instrumentation and reagents for human coagulation and haemostasis  
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- Warning** This manual is valid for firmware **Helena C-4 C11.11b**. 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 safety information must be followed.
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Sub-Distributor's stamp / address / label

## Firmware History Helena C-4

- 1.01 - First Release
- 1.02 - Keyboard Check introduced in service menu  
- Duplicate determination introduced
- 1.03 - Barcode functionality introduced
- 1.04 - 6 dialogue languages introduced  
- Auto sensitivity for clotting method  
- New Fib algorithm
- 1.05 - 6 dialogue languages introduced  
- Auto sensitivity for clotting method  
- New Fib algorithm  
- Result Flag R & S introduced  
- Autostart introduced
- 1.06 - Chromogenic method introduced (requires UV-LED optic upgrade)  
- New tests D-Dimer, Ecarin ECAH & ECAT  
- Coag & Time correction introduced
- 1.07 - Quick change with direct test keys  
- fixed profile measurement PT, PTT, TT & TT
- 1.08 - Tecam Smart interface implemented (LIS connection)  
- Improved optic check for high lipemic, bilirubin or other disturbance  
- Autostart sensitivity can be adjusted for every test individually  
- General improvements of measurements  
- D-Dimer can be adjusted with time & OD correction for any reagent
- 1.09 - Profile can be set free  
- Bugfix Tecam Interface & Print-Out  
- D-Dimer default adjustment for Amax Auto D-Dimer (400nm)
- 1.10 - Print routine optimized for new 32 character printer  
- Quick test change with direct keys or up/down key  
- Results (s,%,INR,..) are scrolled  
- Result Flag 'B' (Biphasic aPTT) introduced  
- Result Flag 'F' (low fibrinogen) introduced  
- new test LA (DRVVT) with automatic ratio calculation  
- new test APCR with automatic ratio calculation  
- statistic counter for PT,aPTT,FIB,AT,DD and all introduced  
- bugfix for high bilirubin samples  
- Autostart sensitivity can be set now within SETUP TEST menu
- 1.11 - Optic check before menu analyse removed  
- D-Dimer adapted to Helena Auto Blue D-dimer 400 reagent 2008  
- Bugfix DD: For zero D-Dimer curves the former system could reboot sometimes.

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## Symbols

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

## 1.0 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**

Ambient 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.

## 2.0 General

The **Helena C-4** is a manual 4-channel photo-optical instrument that offers clotting & chromogenic & immunoturbidimetric testing capabilities. The **Helena C-4** can be used for a wide variety of coagulation and fibrinolysis tests such as:

|  |   |
|--|---|
| <ul style="list-style-type: none"><li>• Prothrombin Time (PT)</li><li>• Activated Prothrombin Time (aPTT)</li><li>• Thrombin Time (TT)</li><li>• Venom Time (VT)</li><li>• Fibrinogen (FIB)</li><li>• Factors (FII - FXII)</li><li>• Antithrombin (AT3)</li><li>• Heparin (HEP)</li><li>• Activated PC resistance (APCR)</li><li>• Lupus Anticoagulant (Screen, Confirm)</li></ul> | <ul style="list-style-type: none"><li>• Protein-C (PC)</li><li>• Protein-S (PS)</li><li>• D-Dimer (DD)</li><li>• von Willebrand Factor (VWF)</li><li>• Ecarin Chromogenic Assay Thrombin (ECAT)</li><li>• Ecarin Chromogenic Assay Hirudin (ECAH)</li><li>• Plasminogen (PLG)</li><li>• a2-Antiplasmin (A2AP)</li></ul> |
|--|---|

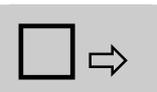
### FEATURES:

- Coagulation analyser for clotting, chromogenic and immunoturbidimetric assays.
- Highly reliable, longlife-span 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.
- Biphasic aPTT waveform curve detection to indicate DIC.
- Low fibrinogen curve detection.
- Fibrinogen concentration can be derived from a PT result. The standard CLAUSS method is also available.
- Calculation in Activity %, INR, Ratio, g/L or mg/dL.
- Calibration curves are programmable for up to 5 calibration points.
- Correlation analysis of calibration curve.
- 4 Stop-watch functions which can be used independently.
- Multi-language software (German, English, Spanish, French, Italian, Portuguese).
- Patient identification (No PID, manual input, autoseries, barcode).
- Duplicate testing mode.
- Free Profile testing (PT, APTT, FIB).
- APC-R with automatic ratio calculation.
- DRVVT with automatic ratio calculation.
- Micro volume testing (total of 75µL).
- Reagent stir position with magnetic stir bar.
- Routines for selftest (trouble-shooting).
- Routines for print outs (result, calibration, service, system).
- Optional autopipette for electronic triggered start.
- Automatic Start triggered by adding reagent.
- Optional data management and research software.
- Optional printer.
- Optional barcode scanner for patient identification.
- Easy software update.
- Interface for Laboratory Information & Management Systems (LIMS).
- CE marked.
- Small dimension and weight - fits on every desktop.

## 2.1. Intended purpose

The **Helena C-4** is designed to carry out coagulometric tests such as PT, aPTT, TT, fibrinogen, single factor tests, chromogenic tests, e.g. Antithrombin-III and immunoturbidimetric tests, such as D-dimer).

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

The **Helena C-4** must be operated by a specialist trained in clinical laboratory techniques who has also received instruction and training in operation of the **Helena C-4** and has read and understood this Operator's Manual.

## 2.2. Installation

No special precautions are necessary when starting up the **Helena C-4**. 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.

## 2.3. Technical data

### Instrument:

|                |  |
|----------------|--|
| Boards         | SMD (Small Mounted Devices) based              |
| Microprocessor | NEC V25  |
| Flash-EPROM    | 128 KByte                                      |
| RAM            | 128 KByte                                      |
| EEPROM         | 2 KByte  |
| AD-Converter   | 18 Bit (16 bit used)                           |
| Optics         | 4 LED's ultra bright, pulse modulation control |
| RS 232         | 9600 Bauds, 8 Data, 1 Stop, no parity          |

### Power Supply:

|                 |                                  |
|-----------------|----------------------------------|
| External,       | 42 W max                         |
| Input voltages  | 100 Vac to 240 Vac / 47 to 63 Hz |
| Output voltages | +5Vdc/5A; +15Vdc/2A; -15Vdc/0,8A |
| Approvals       | CE, EN60601-1, UL, RoHS          |

### Keyboard:

4x8 matrix, foil keyboard, with Test, Function and numerical keys

### Display:

4 lines x 20 characters Liquid Crystal Display

### Incubation block:

6x4 double-cuvette prewarming positions, 4 measuring and 3 reagent positions

### Dimension:

WxDxH: 230 x 280 x 120 mm

### Weight:

2,30 kg

### Ambient temperature/humidity:

18°C to 25°C / < 80%rH

## 2.4. 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-4**

REF

**C-4**

- 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 80/181/CEE*
- 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:

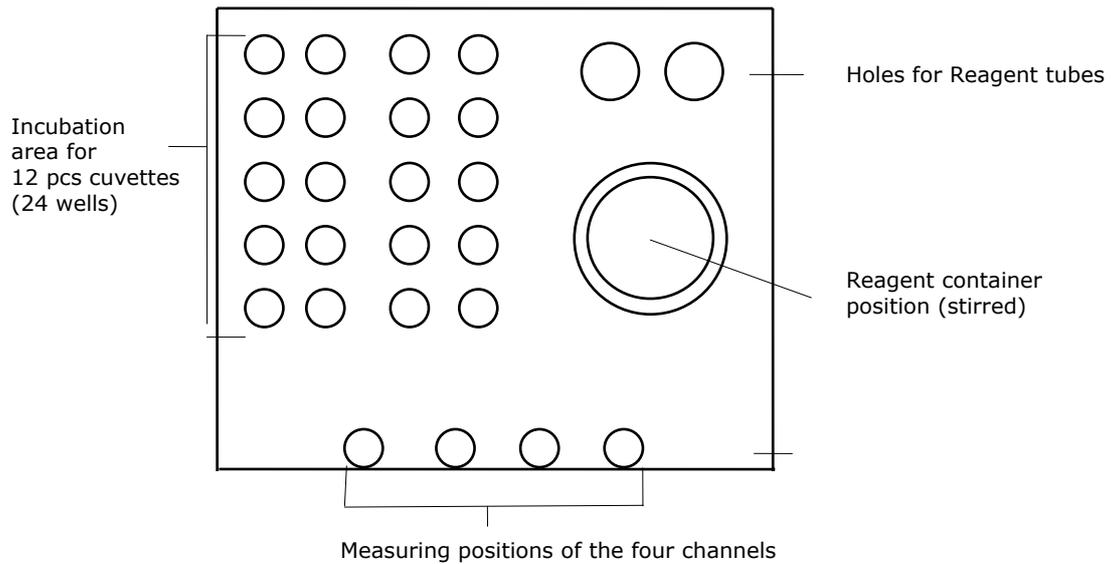
- the standards EN 60601-1, EN 60601-1-2, DIN EN ISO 14971:3/2001, DIN EN 1041:4/98 have been applied.
- *les normes EN 60601-1, EN 60601-1-2, DIN EN ISO 14971:3/2001, DIN EN 1041:4/98 ont été appliquées.*
- die Normen EN 60601-1, EN 60601-1-2, DIN EN ISO 14971:3/2001, DIN EN 1041:4/98 angewendet wurden.

This certificate is valid for all instrument produced of this type.  
Ce certificat est valable pour tous les appareils produits de ce type.

### 3.0 Instrument Components

#### 3.1. Incubator Block

The incubator block is made from aluminum, which ensures equal distribution of heat. The temperature of the incubator block is regulated between 36.5°C - 37.5°C



**Figure 1 - Incubator Block**



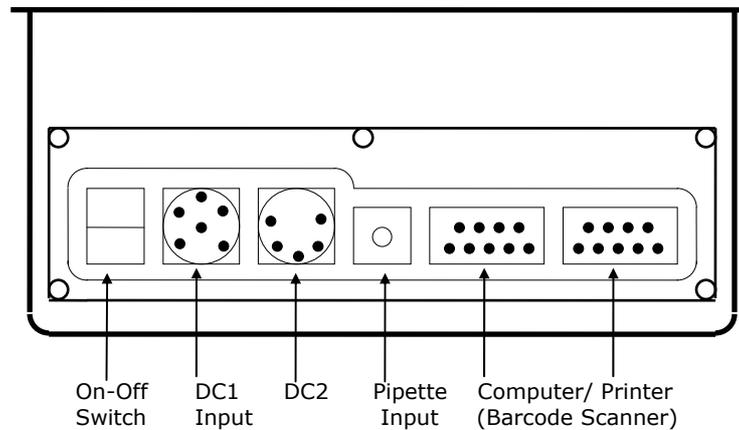
### 3.2. Control panel



|                    |  |
|--------------------|--|
| Temp.              | Indicates block is at optimal temperature  |
| Optic 1 - 4        | Activates channel 1, 2, 3, 4   |
| Unit 1 - 4         | Converts result into alternative options   |
| Timer 1 - 4        | Activates Timer function 1,2, 3, 4   |
| PT, aPTT, TT, STAT | Direct access to Test  |
| Menu               | Go back to Main Menu or next entry   |
| Cursor up          | Line up / Scroll down / select setup parameters  |
| Cursor down        | Line down / Scroll down / select setup parameters  |
| Numeric keys       | For input of calibration values and Patient Identification or Selection of Submenu and Selection of Test No. |
| Zero key           | Numeral Zero or Activation of <b>all</b> channel for double determination (Analysis mode)                    |
| Point key          | Decimal point or Activation of <b>all</b> channels for single determination (Analysis mode)                  |
| Enter              | Confirm entry, jump to next entry  |

Figure 2 - Control Panel

### 3.3. Rear of equipment



**Figure 3 - Rear of Equipment**

On-Off: Standby Switch

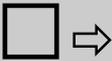
DC-Input: Two alternative connectors to Power Supply.

Pipette: For connector to Autopipette (Cat.No. C-010). Optional accessory for automatic test start. The pipette supports four different volumes (25, 50, 100 and 200  $\mu$ L)

Computer: For connector to PC (Firmware upgrading, TECAM Smart, LIMS) or connector to barcode scanner. By using an Y-adaptor this port can be used for both LIMS and BARCODE.

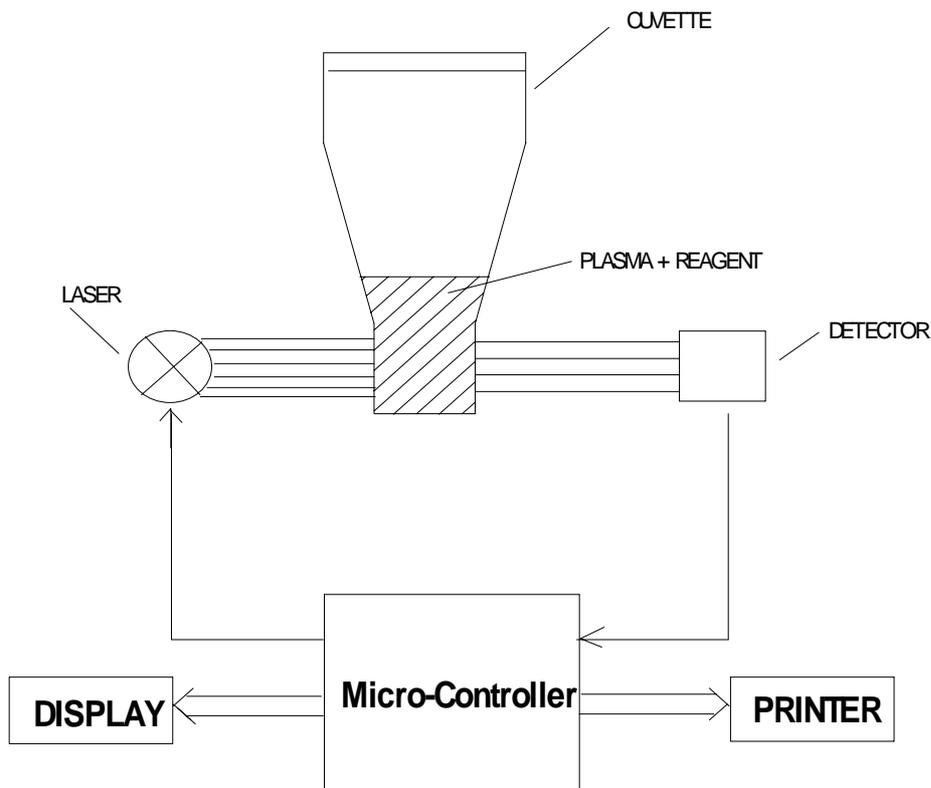
Printer: For connector to Thermal Printer (Cat.No. C-01)

 **The serial ports are always set to**  
9600 Baud, 8 Databits, 1 Stopbit, No parity.

 **Warning: The barcode-scanner is powered with 5V over PIN**  
**9 of the RS232 Interface of the analyser. Only use scanners**  
**with this feature.**

## 4.0 THEORY OF OPERATION

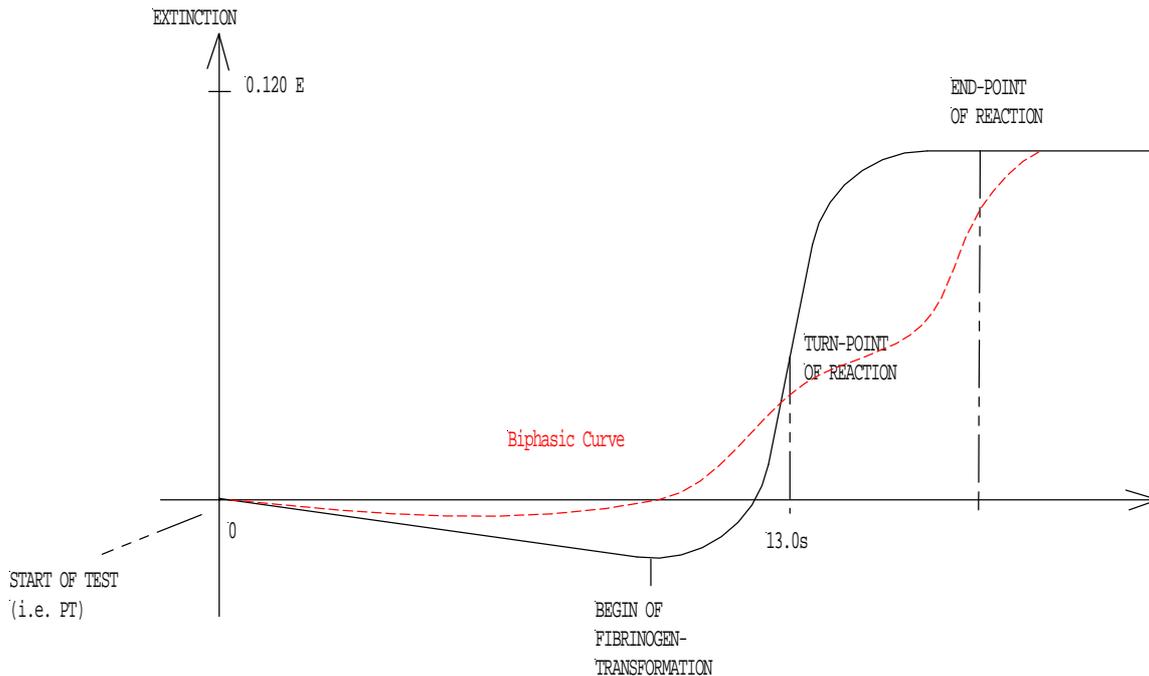
The *Helena C-4* is a highly sensitive 4-channel-photometer. A very intensive LED-Optic ensures accurate and precise results, even when iteric or lipemic samples are used. The receiver signal is detected and converted to an electrical current. During the actual test the system is searching for the best signal amplification, therefore it will support a wide range of different reagents (i.e. very turbid thromboplastins or very clear reagents). Additionally the software is based on optical density (extinction), which absorbs outside light effects.



**Figure 4 - The 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).

## 4.1 Clotting Assay (CLOT)

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 manually by pressing the "Optic" key, or automatic 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 5 - The Turbidity Method**

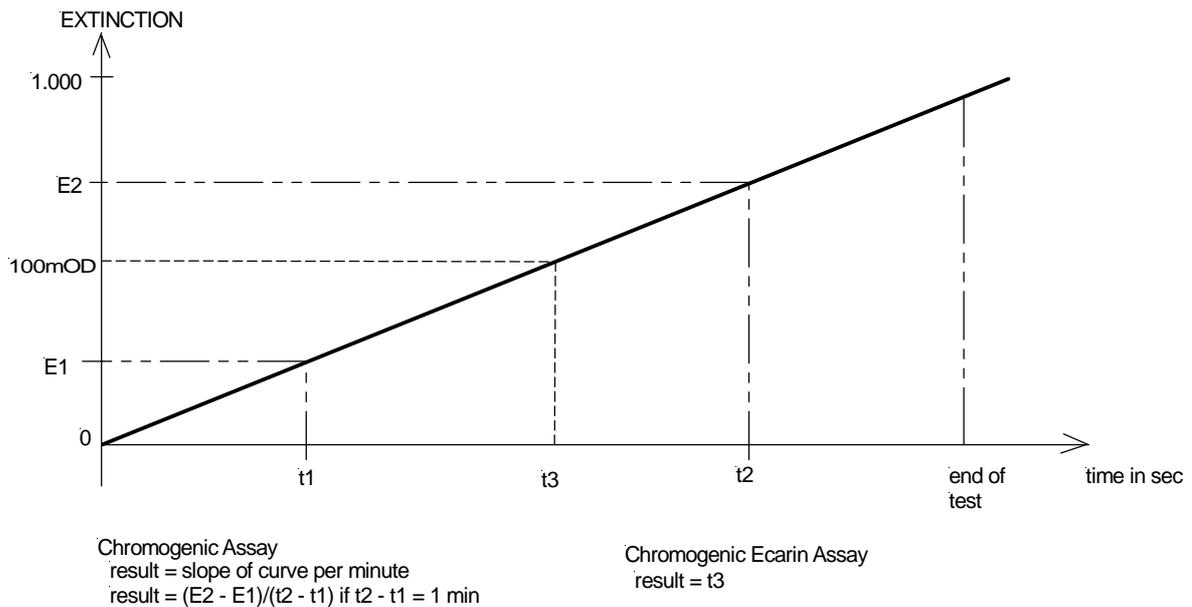
The diagram is representative of a typical PT curve with normal control plasma and a curve with biphasic reaction. Biphasic aPTT reactions are high indicators of disseminated intravascular coagulation (DIC)

## 4.2 Derived Fibrinogen (CLOT + FIB)

The derived fibrinogen concentration is determined using the clotting method described in section above. The fibrinogen concentration in the sample is proportional to the change in optical density in the cuvette that accompanies the conversion of fibrinogen to fibrin at the end of the reaction. The result is expressed as "E", which represents the optical density at the end-point.

## 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 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 ( $\Delta OD(E)/min$ ).



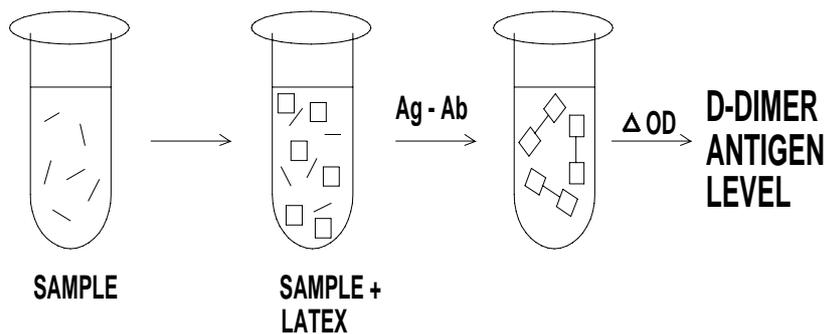
**Figure 6 - The chromogenic method**

### 4.4 Chromogenic Ecarin Assay (100mOD)

The measurement principle is similar to a regular chromogenic assays. But the result is the time between start of test and when signal brake through 100mOD.

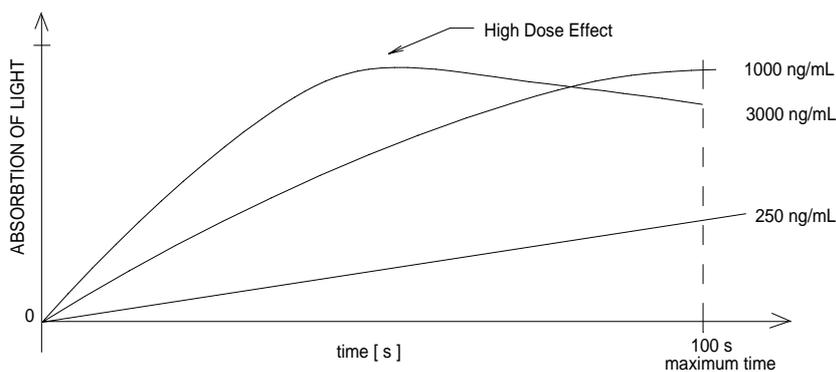
## 4.5 Immunoturbidimetric Assay (IMMUNO)

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 7 - 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 8 - 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".

## 5.0 Operating Instructions

This section provides general instructions necessary for the user to achieve maximal use and benefit from the *Helena C-4*. Please refer to section 9.0 for specific test applications.

The On/Off switch is located on the rear panel of the instrument. ***For optimal results, do not operate until the temperature indicator light is on.*** It takes approximately 10-15 minutes for the instrument to equilibrate to 37°C. The general sequence of operation for test analysis is:

- 1.) Enter the "SETUP SYSTEM" submenu to confirm/change system settings
- 2.) Enter "SETUP TEST" to select test parameters and enter calibration data if desired; and
- 3.) Enter the "ANALYSIS" submenu for sample testing.

From the **Main Menu**, the following options are available:

- |  |
|--|
| <ol style="list-style-type: none"><li>1. ANALYSIS</li><li>2. SETUP TEST</li><li>3. SETUP SYSTEM</li><li>4. SERVICE</li></ol> |
|--|

At each screen, selections are made using the Up/Down cursors. To proceed to the next menu item, press either the "Menu" or "Enter" key. If a mistake is made, press the "Menu" key until the main menu appears and start over.



***To return the system to default values,  
Press simultaneously "Optic 1" + "." + "Enter" keys.***

### 5.1. Setup System

To enter this submenu, press #3 from the main menu. The default values for the system parameters are:

|                  |                                 |
|------------------|---------------------------------|
| LANGUAGE:        | ENGLISH                         |
| FIBRINOGEN:      | mg/dL                           |
| TEMP.CONTROL:    | ON                              |
| SIGNAL:          | ON; VALUE 325                   |
| AUTOSTART        | ON                              |
| CONTRAST OF LCD: | VALUE: 25                       |
| SPEED OF MIXER:  | VALUE: 215                      |
| PAT.IDENT.:      | NO PAT.ID.                      |
| INTERFACE:       | 9600 Baud 8Data 1Stop No parity |

#### 5.1.1. Language

English, German, French, Italian, Spanish, Portuguese  
Use the cursor keys to select language required, press "Enter" or "Menu" to advance.

#### 5.1.2. Fibrinogen Concentration Units

Use the cursor keys to select mg/dL or g/L, press "Enter" or "Menu" to advance.

### 5.1.3. Temperature Control

On/Off - use the cursor keys to select desired option, press "Enter" or "Menu" to advance.  
For temperature adjustment, refer to section **8.2 Temperature Adjustment**

### 5.1.4. Signal

ON/OFF (A beep at the start and end of testing) - use the cursor keys to select desired option, press "Enter" or "Menu" to advance.

Higher/lower - use the cursor keys to change volume and "Enter" to advance.

### 5.1.5. Autostart

Use cursor keys to change and continue with "ENTER"

ON Measurement starts automatically with addition of reagent.  
No need for use of the Autopipette or additional pressing of the relevant Optic channel key.

Off Regular mode for start with optional available Autopipette, or manual start by pressing relevant Optic channel key



*Activate optic channel just before adding of reagent.  
Movements of the cuvette can pre-start measurement – Do not touch cuvette, if optic channel is active!*



*The sensitivity of the autostart can be set individually for every test.  
Refer to section 5.2.7 Autostart*

### 5.1.6. Contrast of the LCD (Liquid Crystal Display)

Higher/lower - use the cursor keys to change and "Enter" to advance.

### 5.1.7. Speed of the Mixer

Higher/lower - use the cursor keys to change and "Enter" to advance.

### 5.1.8. Patient Identification

Four choices are available:

- No Patient ID
- Extra Input
- Autoseries
- Barcode

Use the cursor keys to select desired mode, press "Enter" or "Menu" to advance. If *No Patient ID* is selected, results will be printed out without a patient identification number. If *Extra Input* is chosen, the user enters a patient identification number when running each test (in the Analysis mode). The third option, *Autoseries*, allows the user to enter a starting patient identification number. Each sample run (in the Analysis mode) is then automatically incremented by one from the starting patient identification number entered by the user. If *Barcode* is active, an alphanumeric Pat.Id. is entered by a barcode-scanner. No manual input or correction is possible. The maximum length of the Pat.Id. in that mode is 20 characters. Limited by the space on the LCD, only the first 10 characters will be displayed.

### 5.1.9. Date/Time

U.S. date format (mm/dd/yy) will be selected if "English" is chosen as the language. The date format is dd/mm/yy if German is selected. The Time format is not changeable. To return to the main menu, press "Menu".

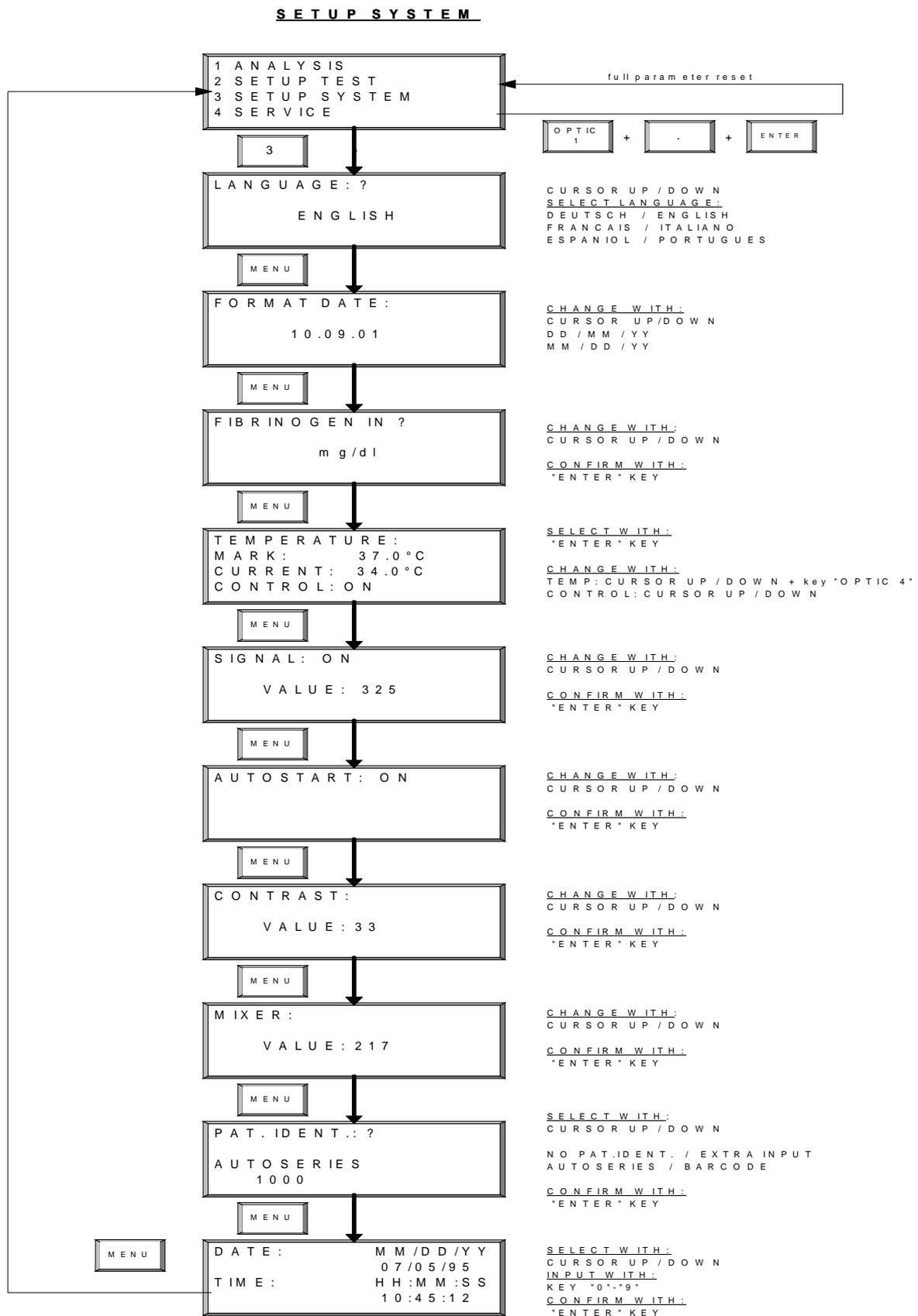


Figure 9 - Flow diagram for the "Setup" System" Submenu

## 5.2. Setup Test

The specific parameters for each test are entered in this menu. Once the initial data is entered and saved it is not necessary to go into this menu for routine testing. The submenu of "SETUP TEST" is illustrated in Figure 10. To enter this submenu, press #2 from the main menu. The default values for "SETUP TEST" are:

|                    |  |
|--------------------|--|
| METHOD:            | CLOT (FIB=Clauss; DD+vWF=IMMUN;<br>PLG+a2AP=Kinetic) |
| UNITS:             | seconds or dE/Min                                    |
| CALIBRATION CURVE: | Reset to zero  |
| AUTOSTART:         | 500 (FIB=250; DD=1000)                               |

### 5.2.1. Setup Test

To select a test enter the numeric code of the designated test. Alternatively, the Up/Down arrow keys can be used to scroll through the entire test menu. For example, key in #1 to select PT. Press "Enter" to confirm selection. The "METHOD" can also be changed when the area on the screen is 'blinking'.

|            |      |
|------------|------|
| TEST:      | PT   |
| METHOD:    | CLOT |
| AUTOSTART: | 500  |

Depending which test is active, following methods can be selected:

- CLOT Clotting assays
- CLOT+FIB Fibrinogen will be derived from PT
- CLAUSS Fibrinogen according to CLAUSS
- KINETIC Chromogenic Assay
- 100mOD Chromogenic Ecarin Assays
- IMMUNO Immunoturbidimetric Assays

## 5.2.2. Units

Every result is displayed in seconds [s]. However, the user can also choose to display PT results in % (% activity), R (ratio) and I (INR). Calibration data, the mean normal PT value, and/or the ISI of the thromboplastin reagent must be entered to obtain results in %, R and I. Refer to the next section for information on calibration data entry. Use the Up/Down cursor keys to select the desired units, "Enter" to confirm and "Menu" to advance.

|              |          |
|--------------|----------|
| UNITS:       | PT       |
| (s-%-R-I):   | s-%-I- - |
| NORMALVALUE: | 12.2s    |
| ISI-VALUE:   | 1.05     |

The **Helena C-4** reports results using the following units (which are test dependent):

|                                     |                  |
|-------------------------------------|------------------|
| E = Extinction (optical density)    | precision X.XXX  |
| s = seconds                         | precision XXX.X  |
| R = ratio                           | precision XX.XX  |
| I = INR                             | precision XX.XX  |
| % = percent activity                | precision XXX.XX |
| U = mg/L (except FIB: mg/dL or g/L) | precision XXX.X  |

## 5.2.3. Standard Curve

To obtain results in units of concentration (mg/dL, IU/mL...) or % activity, a calibration curve is needed. A minimum of **two** points is required, with a maximum of five available. Calibration data is obtained by testing plasma [in duplicate (2) or quadruplicate (4)] in the "Analysis" mode. An example of calibration data entry is shown below.

**Example:** A PT calibration curve with derived fibrinogen. Two different calibration curves are required. The order of entry is not critical, the instrument will automatically sort calibration points.

### 3-point Calibration Curve for PT

100% = 12.2s  
50% = 18.0s  
25% = 27.2s  
0% = 0.0s  
0% = 0.0s

### 4-point Calibration Curve for Derived Fib.

591 mg/dL = 0.413E  
377 mg/dL = 0.246E  
267 mg/dL = 0.140E  
95 mg/dL = 0.042E  
0 mg/dL = 0.0E



**A correct calibration curve is required to obtain results in units of concentration or % activity. Those points remaining with no data entry are not used in the calibration curve calculation. For those tests that require a zero calibration point a value greater than zero must be entered (i.e. 0,1 % and 0.1s). All calibration points can be reset to zero by simultaneously pressing the "0" and "Enter" keys. A full parameter reset will eliminate calibration data for all assays.**

#### 5.2.4. Correlation Factor (linearity index for calibration data)

Insert correct calibration data and confirm storing and printing. All test-parameters and in addition a correlation factor will be printed. The correlation factor ( $R^2$ ) indicates the linearity of the calibration curve.

It is 1.000 if the points are exactly on one line.

If  $R^2$  is less than 0.980, a calibration curve with more than 3 calibration points is recommend.

#### 5.2.5. Store Data

Yes/No. Use the cursor key to select.

#### 5.2.6. Print Test

Yes/No. Use the cursor key to select.

#### 5.2.7. Autostart

The sensitivity of the autostart feature can be adjusted for every test individually. The value represents the required optical change before the instrument triggers the measurement start.

Range of sensitivity:

- Very sensitive: 300 – 500
- Normal: 500 – 1000
- Insensitive >1000
  
- The default value is 500.
- 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

Some tips:

- Pipeting clear reagent in clear suspension will produce only low optical change and will require a sensitive setup. (example: FIB or chromogenic tests)
- Try to pipette directly into the suspension instead of onto or down the cuvette walls.
- Try to pipette with high force

***Do not use autostart below 300!***



***In this scenario, the optic could be triggered by touching the instrument.***

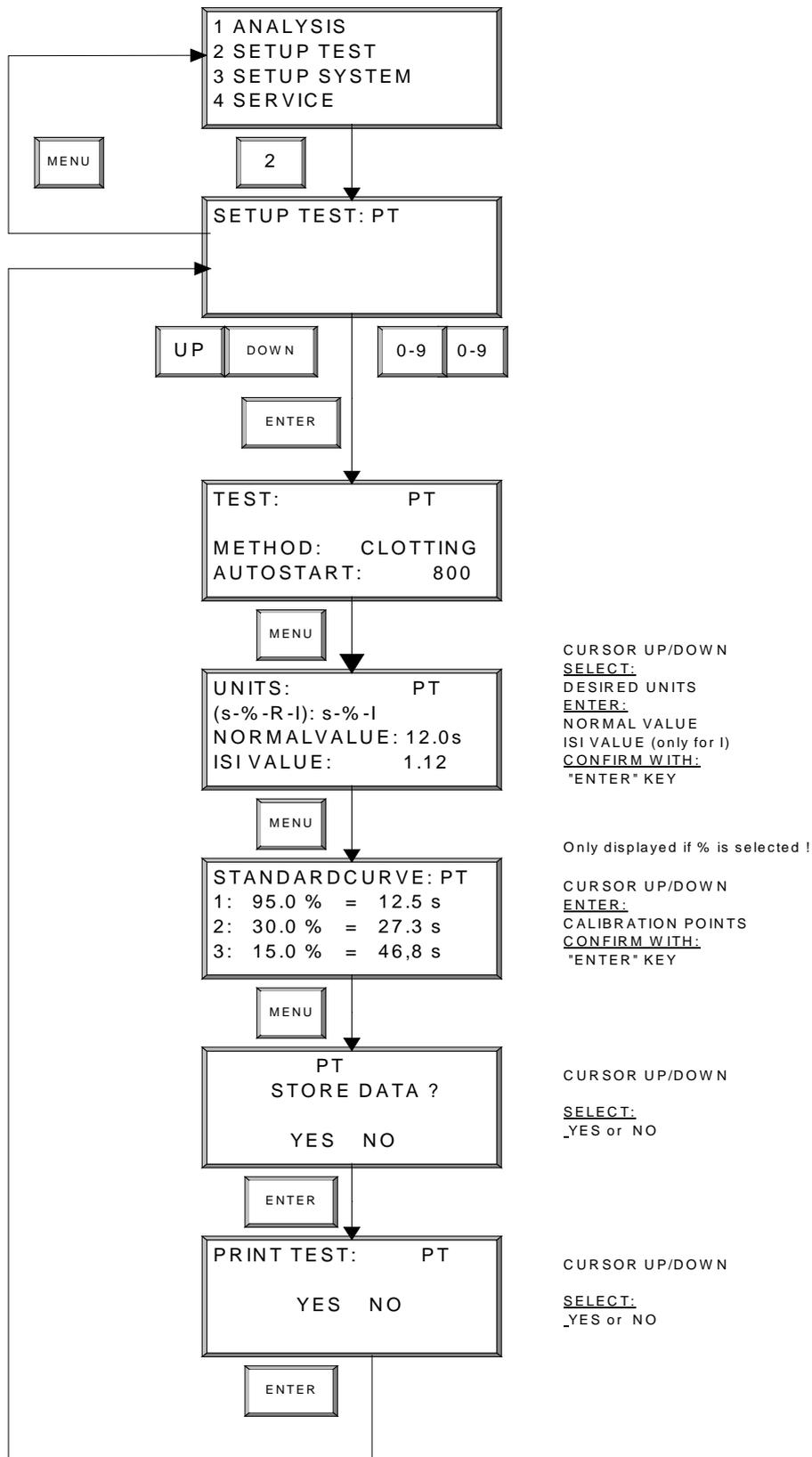


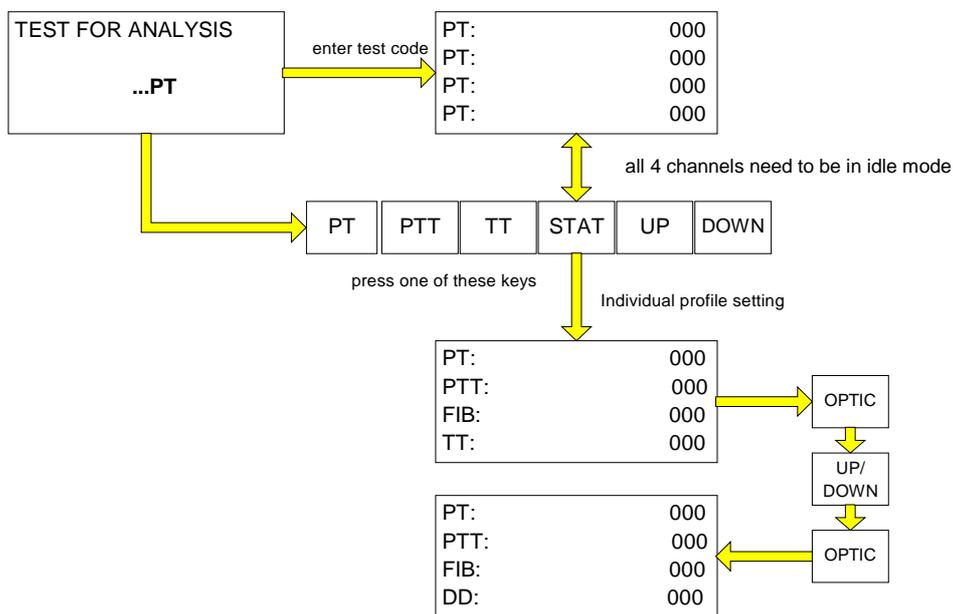
Figure 10 - Flow Diagram for the "Setup Test" Submenu

### 5.3. Test Analysis

To enter the submenu "Analysis", press #1 from the main menu.

#### 5.3.1. Test Selection

The first screen in the "Analysis" submenu will ask the user to make a test selection. This can be done in three ways: by pressing one of the 4 direct test keys; scrolling through the test menu with the cursor Up/Down keys; or by entering a numeric test code (i.e. - "01" for PT test). The test selection is confirmed with the "Enter" key.



#### **STAT / Profile:**

All 4 channels can be set individually, If test "STAT" is selected. Press the corresponding optic key and change the test with cursors keys. Confirm test by pressing optic key again.



Within the analysis menu the actual test can switched by pressing the direct test keys or cursors keys if no measurement is ongoing.

### 5.3.2. Optic Activation & Entering Patient Identification Numbers

The optic can be activated in three different ways.

#### Single activation:

- Press optic key
- Enter / Change PID
- Press optic key again → PID is confirmed and channel active  
Repeat procedure for each desired optic channel

#### Multi activation with single PID

- Press key "." (dot)
- All four channels will be activated  
All patient ID numbers will be set logically if "autoseries" is active (PID = 100,101,102,103)

#### Multi activation with double PID

- Press key "0"
- All four channels will be activated in duplicate mode.

If "**Autoseries**" was chosen in "**Setup System**", "press the "Optic 1" key.

|                 |       |
|-----------------|-------|
| FIB: <u>100</u> | 00:00 |
| FIB:            | 00:00 |
| FIB:            | 00:00 |
| FIB:            | 00:00 |

The patient identification number for channel one will be the number that was manually entered by the user. If this is not the correct patient identification number, the Up/Down scroll keys can be used to increase or decrease this number. Press the "Optic 1" key to confirm and activate the channel. Press the "Optic 2" key to continue. The patient identification number will be automatically incremented by one for each subsequent channel.

|                    |       |
|--------------------|-------|
| FIB: <u>ACTIVE</u> | 00:00 |
| FIB: <u>101</u>    | 00:00 |
| FIB:               | 00:00 |
| FIB:               | 00:00 |

If "**Extra Input**" was chosen in "**Setup System**", the patient identification number shown for the channel will be the last entered PID. Confirm or enter a new patient ID using the numeric keyboard. Press the "Optic" key to confirm patient identification number and activate the channel. Repeat for the remaining channels.

To enter the patient ID. with a **Barcode** scanner, press the "Optic 1" key ("Barcode" is displayed), scan the barcode (the first 10 characters of the patient ID. are displayed). Continue with the next barcode.

If "**No Pat Id**" was selected in "**Setup Test**", "**No PID**" will be seen for each channel. Press Optic 1 to confirm and activate channel. Repeat for remaining channels.

### 5.3.3. Duplicate testing

If duplicate testing is desired, enter the same patient identification number for channels 1 & 2 or 3 & 4 twice. The mean result will automatically be printed along with the individual channel data.



**If the duplicates differ more than 7.5% from the mean value, the mean result will be flagged with 'X' !**



**Pressing key "0" during optic activation, will activate all channels in duplicate mode**

### 5.3.4. Starting the Analysis

Place the required number of cuvettes in the cuvette pre-warming positions. To continue with the PT example, pipette 25 µL of sample to each cuvette well. Press the "Timer 1" button to start the stopwatch. Place the Thromboplastin / CA mixed reagent with magnetic stir bar in the center large reagent pre-warming position.

Transfer the first cuvette with sample to the measurement position. Once patient identification numbers have been entered, press the Optic keys again to activate the channels.

|                    |       |
|--------------------|-------|
| FIB: <i>ACTIVE</i> | 01:30 |
| FIB: <u>ACTIVE</u> | 00:26 |
| FIB:               | 00:00 |
| FIB:               | 00:00 |

When the timer has reached 1 minute, pipette 50 µl of mixed Calcium Chloride and Thromboplastin reagent into the first cuvette position. If autostart is enabled, the optic will start automatically. A beeping noise will indicate the start of the reaction. Repeat for the remaining cuvettes. The reaction can also be started either by pressing the optic key or by using the Autopipette, which electronically triggers the optic channel.

***In summary, press the optic key once for patient identification data entry, press again to activate the channel, and a third time if manually initiating the reaction. (Do not press a third time if using the Autopipette to start the reaction or if autostart is active).***



**If using the Autopipette,**

- **always pipette from left to right (channel 1 - 4)!**
- **Disable the autostart function in the SETUP SYSTEM**

### 5.3.5. Display during measuring

Once started, a short beeping noise is followed by a blinking screen "-----". After the test deadtime the actual optical density will be displayed. Avoid contact with the cuvette while this message is shown. A beeping noise will sound when the reaction is complete and the result will be displayed on the screen. If the thermal printer is attached, results will automatically be printed.

|     |         |       |
|-----|---------|-------|
| PT: | 29 mOD  | 01:48 |
| PT: | 185 mOD | 01:09 |
| PT: |         | 00:00 |
| PT: |         | 01:00 |

|     |           |       |
|-----|-----------|-------|
| PT: | S 31 mOD  | 01:52 |
| PT: | R 188 mOD | 01:13 |
| PT: |           | 00:00 |
| PT: |           | 01:00 |

channels are in measurement a result is found on channel 2, but the instrument waits until channel 1 is completed. Channel 1 is running in high sensitivity

The flag "S" indicates, that the analyzer has switched to high sensitivity  
The flag "R" indicates, that a result is found.

The instrument will display the results. If the instrument finds a result on optic channel x, it will not display as long as lower numbered channels are still in progress.. In this case the actual optical density is flagged with "R" (result found).

### 5.3.6. Manual break of measurement

To cancel the measurement, press both the "Enter" and "Optic" keys. This will stop the reaction. All optic channels must be inactive in order to return to the main menu.

### 5.3.7. Return to main menu

Press key "MENU". All optic channels must be inactive in order to return to the main menu. Stop any measurements (refer section above.). If an optic channel is active, start and break the measurement.

### 5.3.8. Unit Key Functions

Once the measurement is complete, results can be converted to units other than s, E, E/min, if this option has been selected in "Test Setup". For each optic channel, press the corresponding Unit key to convert.

### 5.3.9. Stopwatch Functions

To start each stopwatch, press the Timer keys 1-4. To stop and reset, press the Timer key again.

### 5.3.10. Result Warning Messages

In addition to the result, the instrument may inform the operator of critical samples by attaching status characters or error messages.

| DISPLAY | PRINTER           | MEANING  |
|---------|-------------------|--|
| *       | *                 | Out of calibration (i.e. *167 %)                   |
| >   <   | >                 | Out of scale (i.e. >999.9 mg/dL)                   |
| ++++    | NO CLOT DETECTED  | No clot detected within 300 seconds                |
| ----    | NO CLOT DETECTED  | Clot detected before deadtime                      |
| ???.?   | COAGULATION ERROR | Detected reaction was not valid for coagulation    |
| OPTIC   | LOW SIGNAL        | Light transmission was not sufficient.             |
| "S"     |                   | High sensitivity mode                              |
| "R"     |                   | Result found                                       |
| "B"     |                   | Biphasic APTT found (indicative ofDIC)             |
| "F"     |                   | Low fibrinogen found (indicative of liver disease) |

***Read section on troubleshooting for further details.***

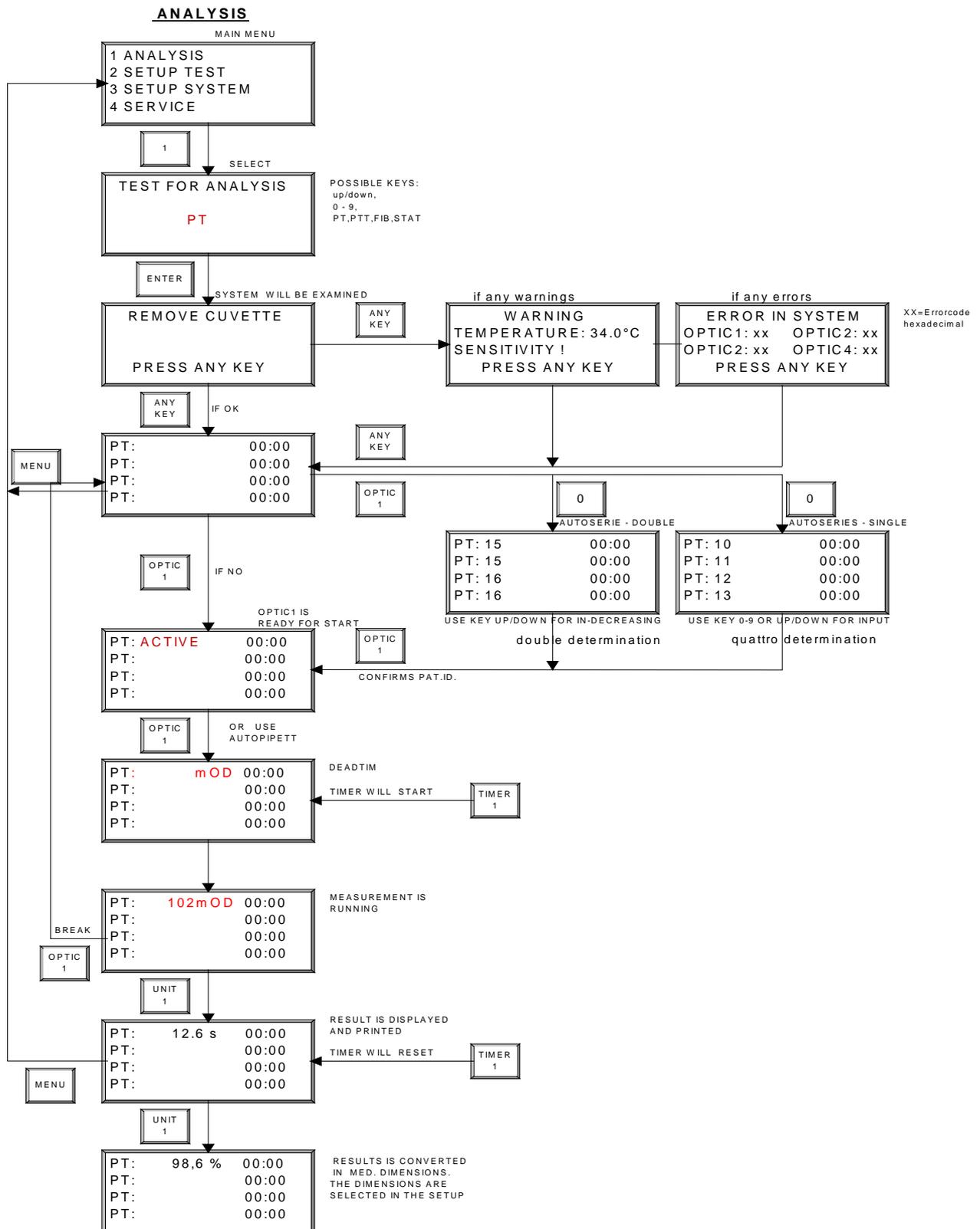


Figure 11 - Flow Diagram of "ANALYSIS" Submenu

## 6.0 Service Menu

```
1 SYSTEM ANALYSIS
2 ERROR LEVEL
3 OPTIC VALUES
```

### 6.1. System Analysis

Press #1 from the Service submenu to enter. Perform a “**SYSTEM ANALYSIS**” to check instrument operational status. In “**SYSTEM ANALYSIS**”, the Helena C-4 checks the optic, temperature, memory values and Analog to Digital Conversion. The error level for each channel is determined and displayed if a system error or warning is identified.

An example of a “**SYSTEM ANALYSIS**” screen is:

```
ERROR IN SYSTEM
OPTIC1: 18  OPTIC2:00
OPTIC3: 00  OPTIC4:00
PRESS ANY KEY
```

The number after CH1-4 is the error code displayed in hexadecimal format (see 5.2). Convert the number into binary format and compare bit by bit to the defined error level (see 5.2).

NOTE: Enter the “SERVICE MENU” and select “ERROR LEVEL”. The error codes will then be displayed in binary format. (see 5.2)

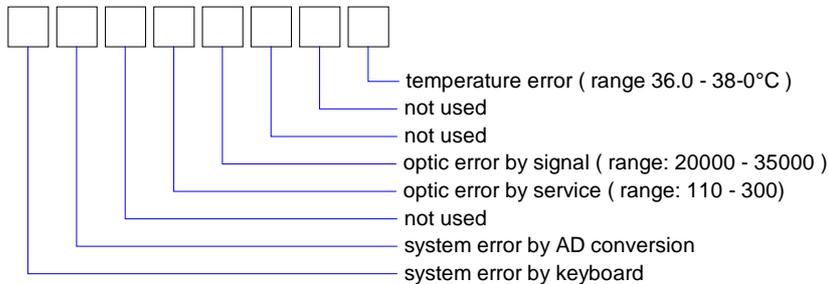
Some examples for error codes:

| HEX | BINARY    | MEANING                        |
|-----|-----------|--------------------------------|
| 00  | 0000 0000 | Error free                     |
| 01  | 0000 0001 | Temperature !                  |
| 08  | 0000 1000 | Signal                         |
| 10  | 0001 0000 | Service                        |
| 40  | 0100 0000 | AD-Conversion !                |
| 80  | 1000 0000 | Keyboard !                     |
| 19  | 0001 1001 | Temperature + signal + service |

After the self-check is complete, a service report is automatically printed. To determine the specific warning or error, enter #2, “**Error Level**”.

## Error Level

When the self-check is followed by an error message, an 8 BIT long number in binary code can be seen. Each BIT is indicative of a specific error or warning:



**Example:** The Error Level "00000001" indicates that the temperature is out of range.

Refer to the troubleshooting guide for information on corrective actions.

## 6.2. Optic-Values

From the "**SERVICE**" submenu, remove cuvettes and press #3 to enter "**OPTIC VALUES**". The values of signal, noise and service are displayed for each channel.

An example of an "**OPTIC VALUES**" screen is:

|      |       |       |
|------|-------|-------|
| CH1: | 32432 | (202) |
| CH2: | 32283 | (191) |
| CH3: | 32169 | (213) |
| CH4: | 32574 | (207) |

Recommended values: \*

|          |               |
|----------|---------------|
| SIGNAL : | 20000 – 35000 |
| SERVICE: | 110 – 300     |

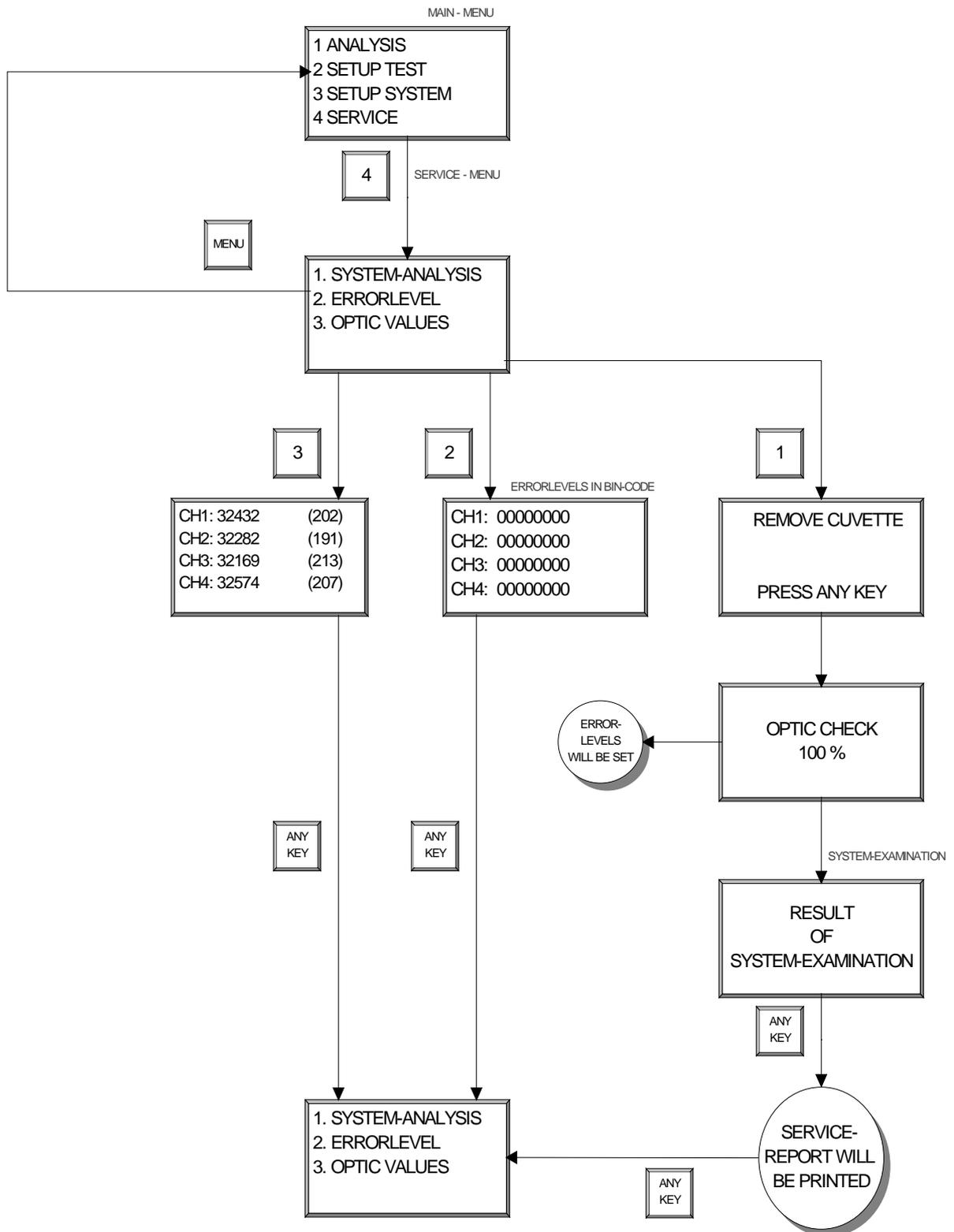


Figure 12 - Flow Diagram of "SERVICE" Submenu

## 7.0 Troubleshooting

| <b>TEMPERATURE ERROR</b> |   |
|--------------------------|---|
| DESCRIPTION              | Temperature is not between 36.0 – 38°C  |
| PROBABLE CAUSE           | <ol style="list-style-type: none"> <li>1. Temperature draft environment (window)</li> <li>2. Electronic error</li> <li>3. Temperature is not adjusted correctly</li> </ol>  |
| CORRECTIVE ACTION        | <ol style="list-style-type: none"> <li>1. Place instrument in a draft free environment without direct sun lighting</li> <li>2. Allow instrument to heat up at least 15 min after temp. adjustment or boot-up</li> <li>3. Adjust temperature (refer sections 8.1 &amp; 8.2)</li> <li>4. Contact technical services at local distributor if error persists</li> </ol> |

| <b>OPTIC ERROR : SIGNAL</b> |   |
|-----------------------------|---|
| DESCRIPTION                 | This error occurs if not enough light is flashing onto the receiver. The optical signal must be between 20000 - 35000   |
| PROBABLE CAUSE              | <ol style="list-style-type: none"> <li>1. Temp. out of range</li> <li>2. Dirt in optics</li> <li>3. LED's on optic block are defective</li> <li>4. Chip errors on boards</li> </ol>   |
| CORRECTIVE ACTION           | <ol style="list-style-type: none"> <li>1. Wait until instrument is temperatured to 37°C</li> <li>2. Clean optics (refer section 8.3)</li> <li>3. Replace optic block</li> <li>4. Contact technical services at local distributor if error persists</li> </ol> |

| <b>OPTIC ERROR : SERVICE</b> |  |
|------------------------------|--|
| DESCRIPTION                  | This error occurs if the required signal amplification is not between 110 - 300  |
| PROBABLE CAUSE               | <ol style="list-style-type: none"> <li>1. Temp. out of range</li> <li>2. Dirt in optics</li> <li>3. LED's on optic block defective</li> <li>4. Chip errors on boards</li> </ol>  |
| CORRECTIVE ACTION            | <ol style="list-style-type: none"> <li>1. Wait until instrument reaches 37°C</li> <li>2. Clean optics (refer section 8.3)</li> <li>3. Replace optic block</li> <li>4. Contact technical services at local distributor if error persists</li> </ol> |

| <b>SYSTEM ERROR : AD-Conversion</b> |   |
|-------------------------------------|---|
| DESCRIPTION                         | The photo receiver converts light intensity to analog direct current. This current is converted to a digital signal. Every digital value has its own signature. If a value is missing, a system error occurs. |
| PROBABLE CAUSE                      | <ol style="list-style-type: none"> <li>1. CPU defect</li> <li>2. ADC defect</li> </ol>  |
| CORRECTIVE ACTION                   | Contact technical services at local distributor   |

| <b>ANALYSIS ERROR : + + + +</b> |  |
|---------------------------------|--|
| DESCRIPTION                     | No clotting reaction is detected within 300s   |
| PROBABLE CAUSE                  | <ol style="list-style-type: none"> <li>1. There is really no clot</li> <li>2. The fibrinogen concentration in the sample is below 50 mg/dL.</li> <li>3. Started channel and pipetted channel are not equal</li> </ol>  |
| CORRECTIVE ACTION               | <ol style="list-style-type: none"> <li>1. Confirm correct handling</li> <li>2. Determine clotting time with research software "TECMONI" or observe the optical values on the display during screen. The time until a change in signal can be observed is the clotting time</li> <li>3. Change to recommended reagent provider</li> </ol> |

| <b>ANALYSIS ERROR : - - - -</b> |   |
|---------------------------------|---|
| DESCRIPTION                     | Clotting reaction starts and ends before deadtime   |
| PROBABLE CAUSE                  | <ol style="list-style-type: none"> <li>1. PT based test clots before 7 sec</li> <li>2. PTT based tests clots before 15 sec</li> </ol> |
| CORRECTIVE ACTION               | Change to recommended reagent provider  |

| <b>ANALYSIS ERROR : ? ? ? ?</b> |  |
|---------------------------------|--|
| DESCRIPTION                     | The instrument detected a reaction, but was not able to verify as a clot reaction.   |
| PROBABLE CAUSE                  | <ol style="list-style-type: none"> <li>1. Air bubbles</li> <li>2. Touching of cuvette</li> <li>3. Clot reaction starts before the deadtime</li> </ol>  |
| CORRECTIVE ACTION               | <ol style="list-style-type: none"> <li>1. Avoid air bubbles – pipette against cuvette wall</li> <li>2. Avoid touching the cuvette during measurement start</li> <li>3. Change to recommended reagent provider</li> </ol> |

| <b>ANALYSIS ERROR : OPTIC</b> |  |
|-------------------------------|--|
| DESCRIPTION                   | The received signal is below 400 digits  |
| PROBABLE CAUSE                | <ol style="list-style-type: none"> <li>1. Very turbid samples or reagents</li> <li>2. Dirt in optics</li> <li>3. Optic is defective</li> </ol>                         |
| CORRECTIVE ACTION             | <ol style="list-style-type: none"> <li>1. Clean optics</li> <li>2. Check optic value (refer section 6.2)</li> <li>3. Change to recommended reagent provider</li> </ol> |

| <b>ANALYSIS ERROR : &gt;, &lt;</b> |   |
|------------------------------------|---|
| DESCRIPTION                        | Assay range limitation  |
| PROBABLE CAUSE                     | <ol style="list-style-type: none"> <li>1. Calculated units are not within 0-999</li> <li>2. Calculated activity is not within 3 – 180%</li> <li>3. Calculated ratio is not within 0-9</li> <li>4. Calculated INR is or within 0-12</li> </ol> |
| CORRECTIVE ACTION                  | Check test setup and recalibrate test if necessary  |

| <b>ANALYSIS ERROR : *</b> |   |
|---------------------------|---|
| DESCRIPTION               | Calculated result is extrapolated. Extrapolated results can vary to intrapolated results. |
| PROBABLE CAUSE            | The obtained result is outside of calibration   |
| CORRECTIVE ACTION         | Extend the calibration curve. High and low standards are helpful.                         |

## 8.0 **MAINTENANCE**

### 8.1. Recommended Maintenance

- Daily: Check that the optic unit and the filters are free from dirt. Clean with lint-free tissue paper if necessary.
- Monthly: Check the temperature of the incubator block. When the green LED is on, place water in a reagent bottle and place in one of the reagent positions. Insert a thermometer and record temperature after 10 minutes. The temperature should be in the range of 36.5°C and 37.5°C. Proceed to next section if the temperature is incorrect.
- Yearly: Service check by authorized technical person.  
(total cleaning of instrument, function tests, quality-control routines)

### 8.2. Temperature Adjustment

1. When the green LED is on, fill a reagent container (bottle) with water and place in a reagent position on the incubator block. Place a thermometer in the water.
2. Allow to warm for 10 minutes.
3. Enter the submenu "Setup System" and advance to the temperature screen. The current temperature of the *Helena C-4* is displayed.
4. Compare the temperature displayed by the system and the thermometer. If the temperature is different, adjust the temperature on the *Helena C-4* by simultaneously pressing the Up/Down cursor keys *and* the "OPTIC 4" key. (To increase or decrease using larger increments, press additionally the numeric "1" key.)
5. Wait until a stable temperature of 37.0°C is displayed on the *Helena C-4*. Check and correct the system temperature if not equivalent to the external thermometer.
6. If both the thermometer and instrument display the same temperature, press the "Enter" key and exit back to the main menu.

### 8.3. Cleaning procedures

The casing should be cleaned with a light alcohol solution or with a light soap solution, using soft foam only. The optical filter should be cleaned with just light alcohol solution. Dry well with clean, fat-free wipes

**Warning:**

- **Do not use aggressive cleaning solutions.**
- **Do not use hard foam material or metallic foams.**

## 9.0 APPLICATIONS

A summary of the current test applications supported by the **Helena C-4**, the choice of medical dimensions and the numeric test codes are shown below:

| Test           | medical dimensions |        |
|----------------|--------------------|--------|
|                | Unit               | # CODE |
| STAT           | s -% -R -I - U     | 00     |
| PT +/- FIB     | s-%-R-I-E-U        | 01     |
| PTT            | s - R              | 02     |
| TT             | s - R              | 03     |
| FIB(CLAUSS)    | s - U              | 04     |
| VT             | s - R              | 05     |
| F2             | s - %              | 06     |
| F5             | s - %              | 07     |
| F7             | s - %              | 08     |
| F8             | s - %              | 09     |
| F9             | s - %              | 10     |
| F10            | s - %              | 11     |
| F11            | s - %              | 12     |
| F12            | s - %              | 13     |
| F15 (Fletcher) | s - %              | 14     |
| HEP            | s - U              | 15     |
| AT3            | s - % - U          | 16     |
| APCR           | s - R              | 17     |
| PS             | s - % - U          | 18     |
| PC             | s - % - U          | 19     |
| LA-S           | s - R              | 20     |
| LA-C           | s - R              | 21     |
| DD             | E - U              | 22     |
| VWF            | E - U              | 23     |
| ECAH           | E - % - U          | 24     |
| ECAT           | E - % - U          | 25     |
| PLG            | E - % - U          | 26     |
| a2AP           | E - % - U          | 27     |

### GLOSSARY

- ◆ E, result in optical density (Extinction); precision XXXX
- ◆ s, result in seconds; precision XXX.X
- ◆ %, result in activity; precision XXX.X
- ◆ U, result in mg/dl, mg/l, µg/ml, g/l; precision XXX (except HEP: X.XXX)
- ◆ R, result in ratio; precision XX.XX
- ◆ I, result in INR; precision XX.XX

***All applications can be run with a minimum volume of 75 µl. But in some cases it is recommend to use higher volume levels to keep high precision and accuracy. The next pages suggest test procedures, which are tested on the instrument and which guarantee a Coefficient Variation (CV) of below 5 % (depending on test, pipette). Please refer to Helena official application notes for accurate and up-to-date test procedures including any new reagent and test procedures.***

## 9.1. Prothrombin Time

### REAGENT PREPARATION

Prepare Thromboplastin reagents according to the package insert.

### SYSTEM PREPARATION

- 1 Turn on instrument and wait for green LED light to come on.
- 2 Turn on printer if connected.
- 3 Connect optional Autopipette to system.
- 4 Check setup system if necessary.
- 5 Check setup test if necessary. Enter new calibration curve data to obtain results in % activity; enter ISI of thromboplastin reagent and in-house determined mean normal PT if INR results are desired. Enter in-house determined mean normal value if results in R are required.
- 6 Return to main menu and enter "Analysis" by pressing #1. Select PT with the Up/Down arrow keys or enter the numeric test code, #01. If any warning or error message appears, refer to section 7.0.

### TEST PROCEDURE

#### Clotting Method:

1. Pipette **25 µL plasma** to cuvette(s).
2. Prewarm plasma for 60 secs, or the time indicated in the application guide. Press the "TIMER 1" key to start stopwatch 1.
3. Place Thromboplastin and calcium (1:1) reagent with stir bar in large central reagent position.
4. Transfer cuvette to measuring position.
5. While incubating, press "OPTIC 1". If selected, enter PAT-ID with numeric keys or Up/Down keys. Confirm by pressing "OPTIC 1" again. The message "ACTIVE" is displayed and channel 1 is ready to start the reaction. Repeat for the remaining channels.
6. Add **50 µL prewarmed and stirred Thromboplastin reagent. The test will start automatically on addition of the start reagent. If not**

simultaneously press the "OPTIC 1" key. The test will automatically start if using the Autopipette. (CAUTION: When the test procedure is running, pressing the "OPTIC 1" and the "Enter" keys will interrupt the test). Repeat for remaining channels.

7. The instrument will read for 300 secs. If no clot is detected, the display will read "\*\*\*".
8. The result is displayed in seconds. Press the corresponding "Unit" key for conversion of results.

### ASSAY CALIBRATION

For calibration curves, a minimum of two values is required, with a maximum of 5.

**It is highly recommended that more than two calibration points be used.**

1. Make dilutions of Calibrator (SARP Cat No: 5185) in 0.9% NaCl (saline). Refer to the table below for preparation of standards
2. Determine PT time with undiluted calibrator in duplicate.
3. Determine PT with diluted plasmas in duplicate.
4. If no clot time is detected for the diluted plasma samples (<25%), change the sensitivity in "Setup Test" to "High" and repeat.
5. Enter calibration data, % activity and seconds. Use the % activity as given on the accompanying SARP data sheet.
6. Check calibration curve with QC material (Norm-trol 1; 5186, Ab-Trol 2; 5187, Ab-Trol 3; 5183).

| % Activity | Dilution | Preparation                   |
|------------|----------|-------------------------------|
| 100        | none     |                               |
| 50         | 1:2      | 200 uL plasma + 200 uL saline |
| 25         | 1:4      | 100 uL plasma + 300 uL saline |
| 12.5       | 1:8      | 50 uL plasma + 350 uL saline  |

## 9.2. Derived Fibrinogen

### REAGENT PREPARATION

Reconstitute Thromboplastin reagents according to the package insert.

### SYSTEM PREPARATION

1. Turn on instrument and wait for green LED light to come on.
2. Turn on printer if connected.
3. Connect optional Autopipette to system.
4. Check system setup if necessary.
5. Check test setup if necessary. Select method clotting+fibrinogen, enter new calibration curve data.
6. Return to main menu and enter "Analysis" by pressing #1. Select PT with the Up/Down arrow keys or enter the numeric test code, #1. If any warning or error message appears, refer to section 7.0.

### TEST PROCEDURE

#### Clotting method with fibrinogen:

1. Pipette **25 µL plasma** to cuvette.
2. Prewarm plasma for 60 secs, or the time indicated in the application guide. Press the "TIMER 1" key to start stop-watch 1.
3. Place Thromboplastin and calcium (1:1) reagent with stir bar in large central reagent position.
4. Transfer cuvette to measuring position.
5. While incubating, press "OPTIC 1". If selected, enter PAT-ID with numeric keys or Up/Down keys. Confirm by pressing "OPTIC 1" again. The message "ACTIVE" is displayed and channel 1 is ready to start the

reaction. Repeat for the remaining channels.

6. Add **50 µL prewarmed and stirred Thromboplastin reagent**. **The test will start automatically on addition of the start reagent**. If not simultaneously press the "OPTIC 1" key. The test will automatically start if using the Autopipette. (CAUTION: When the test procedure is running, pressing the "OPTIC 1" and the "Enter" keys will interrupt the test). Repeat for remaining channels.
7. The instrument will read for 300 secs. If no clot is detected, the display will read "\*\*\*\*".
8. The result is displayed in seconds. Press the corresponding "Unit" key for conversion of results.

### ASSAY CALIBRATION

For the derived fibrinogen test a calibration curve must be entered. **It is highly recommended that more than two calibration points be used.**

1. Test fibrinogen reference plasmas in duplicate. e.g SARP Calibrator; 5185 For example, test fibrinogen reference plasmas with low (~100 mg/dL), normal (~250 mg/dL) and high (>350 mg/dL) fibrinogen concentration. Record the Extinction (OD) values for all samples.
2. Enter the fibrinogen data for the calibration curve, Extinction & fibrinogen values.
3. Check the calibration curve with controls.
4. Note - If % PT *and* derived fibrinogen values are required, two calibration curves must be entered.

## 9.3. Clauss Fibrinogen Assay

### REAGENT PREPARATION

Reconstitute Thrombin reagent 100 NIH U/mL according to the package insert (Cat. No: 5556).

### SYSTEM PREPARATION

1. Turn on instrument and wait for green LED light to come on.
2. Turn on printer if connected.
3. Connect optional Autopipette to system.
4. Check system setup if necessary.
5. Check test setup if necessary and enter new calibration curve data.
6. Return to main menu and enter "Analysis" by pressing #1. Select Fib with the Up/Down arrow keys or enter the numeric test code, #6. If any warning or error message appears, refer to section 7.0.

### TEST PROCEDURE

**All quality control and patient samples are diluted 1:10 in Owren's Veronal (OVB) for testing. If the clotting times fall outside of the linear curve, prepare and test 1:5 or 1:20 dilutions as needed.**

1. Pipette **50 µL of diluted sample** to cuvette.
2. Prewarm sample for 2 min, or the time indicated in reagent package insert. Press the "TIMER 1" key to start stopwatch 1.
3. Transfer cuvette to measuring position.
4. While incubating, press "OPTIC 1". If selected, enter PAT-ID with numeric keys or Up/Down keys. Confirm by pressing "OPTIC 1" again. The message "ACTIVE" is displayed and channel 1 is ready to start the reaction. Repeat for the remaining channels.
5. Add **25 µL 100 NIH U/mL Thrombin reagent**. **The test will start automatically on addition of the start reagent. If not** simultaneously press the "OPTIC 1" key. The test will automatically start if using the Autopipette. (CAUTION: When the test procedure is running, pressing the

- "OPTIC 1" and the "Enter" keys will interrupt the test).
6. The instrument will read for 300 secs. If no clot is detected, the display will read "+++" and "No Clot Detected" will print.
  7. The result is displayed in seconds, and both this result and the fibrinogen concentration are automatically printed. press the corresponding "Unit" key for fibrinogen concentration if a printer is not attached.
  8. For samples diluted 1:10, this is the final result. For other dilutions, the result must be corrected. For example, if the sample was diluted 1:5, divide the result by 2; if the sample was diluted 1:20 or 1:40, multiply the result by 2 or 4, respectively.

### ASSAY CALIBRATION

1. Prepare standards using the Fibrinogen Calibrator provided with the Fibrinogen Assay Kit (Cat No: 5556)  
A *suggested* standard curve is shown in the following chart:

| Dilution | Preparation                |
|----------|----------------------------|
| 1:5      | 200 µL plasma + 800 µL OVB |
| 1:10     | 250 µL plasma + 250 µL OVB |
| 1:20     | 250 µL plasma + 250 µL OVB |
| 1:40     | 250 µL plasma + 250 µL OVB |

2. Mix the standards and assay each in quadruplicate.
3. Enter the calibration data in the "Setup Test" submenu. For example: the assigned fibrinogen value for the plasma used to prepare the standard curve is 250 mg/dL. The 1:10 dilution corresponds to 100% activity, therefore it is equal to 250 mg/dL. The 1:5 dilution is twice as concentrated, it is equal to 500 mg/dL. (The 1:20 dilution = 125 mg/dL and the 1:40 = 62.5 mg/dL.)
4. Verify the calibration curve with QC material (Norm-trol 1; 5186, Ab-Trol 2; 5187, Ab-Trol 3; 5183)

## 9.4. Thrombin Time Assay

### REAGENT PREPARATION

Reconstitute Thrombin Reagent 3NIH/vial according to the package insert.

### SYSTEM PREPARATION

1. Turn on instrument and wait for green LED light to come on.
2. Turn on printer if connected.
3. Connect optional Autopipette to system.
4. Check system setup if necessary
5. Check test setup if necessary.
6. Return to main menu and enter "Analysis" by pressing #1. Select TT with the Up/Down arrow keys or enter the numeric test code, #1. If any warning or error message appears, refer to section 7.0.

6. The instrument will read for 300 secs. If no clot is detected, the display will read "+++" and "No Clot Detected" will print.
7. The result is displayed in seconds and is printed automatically printed.

### TEST PROCEDURE

#### Clotting Method:

1. Pipette **50 µL of undiluted plasma** to cuvette.
2. Prewarm sample for 3 min, or the time indicated in reagent package insert. Press the "TIMER 1" key to start stop-watch 1.
3. Transfer cuvette to measuring position.
4. While incubating, press "OPTIC 1". If selected, enter PAT-ID with numeric keys or Up/Down keys. Confirm by pressing "OPTIC 1" again. The message "ACTIVE" is displayed and channel 1 is ready to start the reaction. Repeat for the remaining channels.
5. Add **25 µL Thrombin Time Reagent. The test will start automatically on addition of the start reagent. If not** simultaneously press the "OPTIC 1" key. The test will automatically start if using the Autopipette. (CAUTION: When the test procedure is running, pressing the "OPTIC 1" and the "Enter" keys will interrupt the test).

## 9.5. APTT

### REAGENT PREPARATION

Refer to package insert for APTT and CaCl<sub>2</sub> reagents.

### SYSTEM PREPARATION

1. Turn on instrument and wait for green LED light to come on.
2. Turn on printer if connected.
3. Connect optional Autopipette to system.
4. Check system setup if necessary
5. Check test setup if necessary. Select method APTT
6. Return to main menu and enter "Analysis" by pressing #1. Select APTT with the Up/Down arrow keys or enter the numeric test code, #1. If any warning or error message appears, refer to section 7.0.

8. The instrument will read for 300 secs. If no clot is detected, the display will read "\*\*\*\*".
9. The result is displayed in seconds. To obtain results in R, press the "Unit 1" key.

### TEST PROCEDURE

#### Clotting Method:

1. Pipette **25 µL plasma** to cuvette.
2. Place CaCl<sub>2</sub> in large central reagent position.
3. Add **25 µL of the APTT reagent**. Incubate for 3 or 5 minutes (refer to package insert). Press the "TIMER 1" key to start stop-watch 1.
4. Transfer cuvette to measuring position.
5. While incubating, press "OPTIC 1". If selected, enter PAT-ID with numeric keys or Up/Down keys. Confirm by pressing "OPTIC 1" again. The message "ACTIVE" is displayed and channel 1 is ready to start the reaction. Repeat for the remaining channels.
6. Add **25 µL prewarmed CaCl<sub>2</sub> reagent**. **The test will start automatically on addition of the start reagent. If not** simultaneously press the "OPTIC 1" key. The test will automatically start if using the Autopipette. (CAUTION: When the test procedure is running, pressing the "OPTIC 1" and the "Enter" keys will interrupt the test).

## 9.6. PT-Based Factor Assays (II, V, VII & X)

### REAGENT PREPARATION

Reconstitute Factor Deficient Plasma and prepare Thromboplastin reagent according to package insert.

### SYSTEM PREPARATION

1. Turn on instrument and wait for green LED light to come on.
2. Turn on printer if connected.
3. Connect optional Autopipette to system.
4. Check system setup if necessary
5. Check test setup if necessary. Select method, enter new calibration curve data.
6. Return to main menu and enter "Analysis" by pressing #1. Select appropriate factor assay with the Up/Down arrow keys or enter the numeric test code. If any warning or error message appears, refer to section 7.0.

### TEST PROCEDURE

**All quality control and patient samples are diluted 1:10 in Owren's Veronal Buffer (OVB) for testing. If the clotting times fall outside of the linear curve, prepare and test 1:5 or 1:20 dilutions as needed. It is recommended to test 2 dilutions (1:10 & 1:20) for each sample. Refer to the reagent package insert for more information.**

### Clotting Method

1. Place Thromboplastin reagent with stir bar in large central reagent position.
2. Pipette **25 µL of diluted plasma and 25 µL of deficient plasma** to each cuvette. Refer to chart for sample preparation.
3. Incubate for 1 min, or the time indicated in reagent package insert. Press the "TIMER 1" key to start stop-watch 1.
4. Transfer cuvette to measuring position.
5. While incubating, press "OPTIC 1". If selected, enter PAT-ID with numeric keys or Up/Down keys. Confirm by pressing "OPTIC 1" again. The message "ACTIVE" is displayed and channel 1 is ready to start the reaction. Repeat for the remaining channels.
6. Add **50 µL prewarmed and stirred Thromboplastin reagent. The test will start automatically on addition of the start reagent. If not** simultaneously press the "OPTIC 1" key. The test will

automatically start if using the Autopipette. (CAUTION: When the test procedure is running, pressing the "OPTIC 1" and the "Enter" keys will interrupt the test). Repeat for remaining channels.

7. The instrument will read for 300 secs. If no clot is detected, the display will read "+++" and "No Clot Detected" will print.
8. The result is displayed in seconds. Press the corresponding "Unit" key for conversion of results if a printer is not attached.
9. For patient and control samples diluted 1:10, this is the final result. If other dilutions are tested, the calculated value should be multiplied by the appropriate dilution correction factor. (i.e., samples diluted 1:20, multiply result by 2; for 1:40 dilutions, multiply by 4, etc.)

### ASSAY CALIBRATION

For calibration curves, a minimum of two values is required, with a maximum of 5. **It is highly recommended that more than two calibration points be used.**

1. Make dilutions of Calibrator (SARP Cat No: 5185) in OVB. A *suggested* standard curve is shown below.
2. Assay standards in quadruplicate as described.
3. Enter calibration data (% activity and seconds) in "Setup Test". Check calibration curve with QC controls SAC-1; 5301 and SAC-2; 5302.

| Sample             | Dilution | Preparation                            |
|--------------------|----------|--|
| 100% Standard      | 1:10     | 100 uL reference plasma + 900 uL OVB   |
| 50% Standard       | 1:20     | 50 uL of reference plasma + 950 uL OVB |
| 25% Standard       | 1:40     | 25 uL of reference plasma + 975 uL OVB |
| 12.5% Standard     | 1:80     | 500 uL of 25% standard + 500 uL OVB    |
| Patient or Control | 1:10     | 100 uL sample + 900 uL OVB             |

## 9.7. APTT-Based Factor Assays (VIII, IX, XI & XII)

### REAGENT PREPARATION

Reconstitute Factor Deficient Plasma and prepare APTT reagents according to package insert.

### SYSTEM PREPARATION

1. Turn on instrument and wait for green LED light to come on.
2. Turn on printer if connected.
3. Connect optional Autopipette to system.
4. Check system setup if necessary
5. Check test setup if necessary. Select method, enter new calibration curve data.
6. Return to main menu and enter "Analysis" by pressing #1. Select appropriate factor assay with the Up / Down arrow keys or enter the numeric test code. If any warning or error message appears, refer to section 7.0.

### TEST PROCEDURE

**All quality control and patient samples are diluted 1:10 in Owren's Veronal Buffer (OVB) for testing. If the clotting times fall outside of the linear curve, prepare and test 1:5 or 1:20 dilutions as needed. It is recommended to test 2 dilutions (1:10 & 1:20) for each sample. Refer to the reagent package insert for more information.**

#### Clotting Method

1. Place CaCl<sub>2</sub> in large central reagent position.
2. Pipette **25 µL of diluted plasma and 25 µL of deficient plasma** into each cuvette. Refer to chart for sample preparation.
3. Incubate for 2 min, or the time indicated in reagent package insert.
4. Add **25 µL of APTT reagent**. Incubate for 3 or 5 minutes. Refer to package insert for appropriate activation/incubation times. Press the "TIMER 1" key to start stopwatch 1.
5. Transfer cuvette to measuring position.
6. While incubating, press "OPTIC 1". If selected, enter PAT-ID with numeric keys or Up/Down keys. Confirm by pressing "OPTIC 1" again. The message "ACTIVE" is displayed and channel 1 is ready to start the reaction. Repeat for the remaining channels.
7. Add **25 µL prewarmed CaCl<sub>2</sub>**. **The test will start automatically on addition of the start reagent. If not** simultaneously press the "OPTIC 1" key. The test will automatically start if using the Autopipette. (CAUTION: When the test procedure is running, pressing the "OPTIC 1" and the "Enter" keys will interrupt the test). Repeat for remaining channels.
8. The instrument will read for 300 secs. If no clot is detected, the display will read "+++" and "No Clot Detected" will print.
9. The result is displayed in seconds. Press the corresponding "Unit" key for conversion of results if a printer is not attached.
10. For patient and control samples diluted 1:10, this is the final result. If other dilutions are tested, the calculated value should be multiplied by the appropriate dilution correction factor. (i.e., samples diluted 1:20, multiply result by 2; for 1:40 dilutions, multiply by 4, etc.)

### ASSAY CALIBRATION

For calibration curves, a minimum of two values is required, with a maximum of 5. **It is highly recommended that more than two calibration points be used.**

1. Make dilutions of Calibrator (SARP Cat No: 5185) in OVB. A suggested standard curve is shown below.
2. Assay standards in quadruplicate as described.
3. Enter calibration data (% activity and seconds) in "Setup Test". Check calibration curve with QC controls SAC-1; 5301 and SAC-2; 5302.

| Sample             | Dilution | Preparation                            |
|--------------------|----------|--|
| 100% Standard      | 1:10     | 100 uL reference plasma + 900 uL OVB   |
| 50% Standard       | 1:20     | 50 uL of reference plasma + 950 uLOVB  |
| 25% Standard       | 1:40     | 25 uL of reference plasma + 975 uL OVB |
| 12.5% Standard     | 1:80     | 500 uL of 25% standard + 500 uL OVB    |
| Patient or Control | 1:10     | 100 uL sample + 900 uL OVB             |

## 10.0 SPECIAL FUNCTIONS

### 10.1. Software Upgrading

The **Helena C-4** supports a very easy procedure to upgrade any latest software developments. For more information about latest software revision, ask your local distributor.

Requirements :

- Windows PC,
  - Download cable,
  - Update files - flash.bat, download.exe, flashdl.exe, flashv25.exe and the analyser firmware xxxxx.img (i.e. c4u0111.img → Helena C-4 1.11 400nm)
1. Save any important test setups of the instrument by printing to paper
  2. Reboot your PC. This will reset your Comm ports !
  3. Extract "Flash Disk" to any local folder on your PC.
  4. Connect Helena C-4 to PC with 0 Modem cable (PIN 2-3-5 to PIN 3-2-5)
  5. Double click to "upgrade.bat" and follow dialogue.
  6. After a few minutes the Helena C-4 will reboot.
  7. Re-Initialisize the memory
    - a. Power off/on instrument
    - b. Press key "**Optic 1**" + "." + "**ENTER**" **simultaneously** -> message "INIT SYSTEM..." should appear and afterwards instrument should reboot automatically
  8. Restore test setup parameters manually.

Problems during updates:

-Update stays at the following screen:

```
C:\WINNT\system32\cmd.exe
D:\TECO\BAUMI\CA4\PROGRAMM>Download -cl -iflashCA4 -y -q
TECO-DOWNLOAD TestVersion 2.00 Sep 14 1998
(C) DOLI Elektronik GmbH,(1995-1998)

MinimalDownload
Start-Segment (Hex) : 100
Serieller Download (115200 Baud)
Serieller Download (DE-Adr=00000009)
D:\TECO\BAUMI\CA4\PROGRAMM>d1CA4 -cl -iCA4.bin -eC000 -q $r $x $v

DOLI FLASH-Programmierung
FLASHDL Version 2.03 Jun 2 1999
(C) DOLI Elektronik GmbH,(1995-1999)

Infile          CA4.bin
Backupfile      flash.sav
Kommunikation   COM1, 115200 Baud
Nur EraseBlock sichern!!!
NoSave!!!
NoVerify!!!

itarte Sync. zum SUB.
```

- ➔ Reboot PC and try again.
  - ➔ If transfer still fails, boot PC with MS DOS floppy disk and perform MS DOS update.
- Nothing happened after click to 'upgrade.bat'
- ➔ perform update with MS DOS commands

- MS DOS update (for Windows 2000 / XP)
  - Open data explorer and extract all files to drive "C", folder Helena Biosciences.
  - Go to MS Windows "START/RUN" and enter "cmd" -> DOS command window will open.
  - Change to directory with command "cd c:\Helena"
  - Enter command "dir" -> all files including upgrade.bat should be listed
  - Enter command "upgrade.bat" -> a dialog should open.
  - Follow dialog. Update will start and when finished the instrument will reboot.

## 11.0 **TECAM SMART the LIMS solution**

### 11.1. General

TECAM SMART is a user friendly software with LIMS functionality (Laboratory Information Management). It allows to sample all instrument results and manage it in a database application.

Requirements:

- Pentium III, 128MB Ram
- Microsoft Windows 2000 ,XP or Vista

DataBase:

- Microsoft Access Jet Engine 4.0
- Max. 4GB (400.000 results)

Key features:

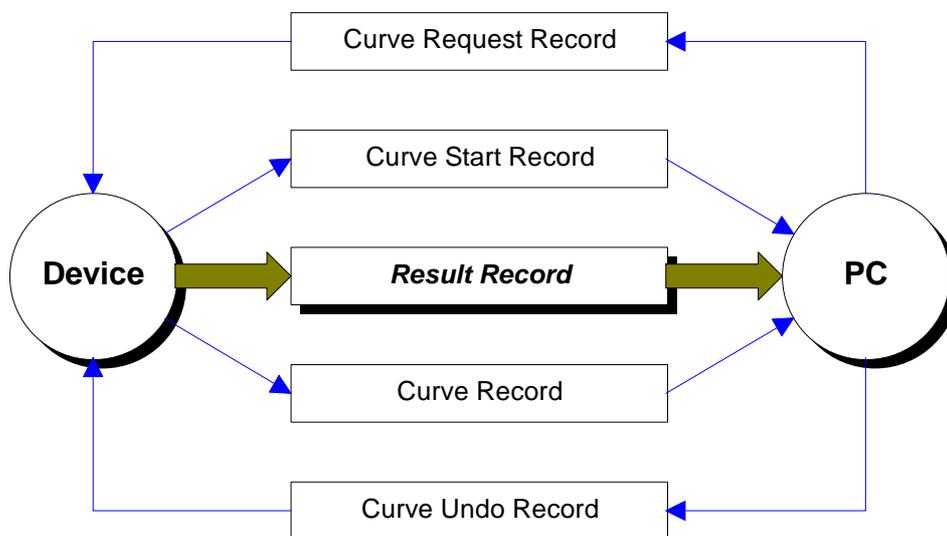
- Account Management: operator can log in as Administrator or user in order to control and manage the database with different access rights
- DataBase Management: operator can create, backup, import or export database
- Reaction Curve: can be displayed in fix or autoscale mode
- Patient DataBase: PID can be linked to patient names
- Filter functions: Every record field can be filtered (e.g. last 30 days all PT)
- Report Generator: Day report, patient report, or last x days report can created just by filter the fields
- Statistical analysis: includes mean, SD,CV for filtered data
- Online Update: software be updated by internet
- Multi-lingual: English, Spanish, Italian, Portuguese, Russian, Greek, Chinese

## 11.2. Interface Protocol

### ASCII command characters:

|     |                       |         |
|-----|-----------------------|---------|
| STX | start of transmission | asc(2)  |
| ETX | end of transmission   | asc(3)  |
| TAB | vertical tabulator    | asc(9)  |
| LF  | line feed             | asc(10) |
| CR  | carriage return       | asc(13) |
| DLE | idle                  | asc(16) |

### Overview of records and principle:



**Figure 13 – LIMS communication**

The result record is always transmitted.

The curve record transmission must be activated from PC with a request record.

**The curve request record:**

Function: enables curve transmission  
Definition: <DLE &"4" CR>

**The curve undo record:**

Function: disables curve transmission  
Definition: <DLE &"3" CR>

**The curve start record**

Function: Indicates that a new measurement had been started.  
The transmission needs to be enabled by the "Curve Request Record".

Definition: <STX &"P"><Optic><LF & ETX>

Fields: Delimiter: asc(9) = tabulator  
<STX &"P"> Record header ; STX=asc(2)  
<Optic> optic cannal 1-4 (channel 1 = 0)  
<LF & ETX> Record end; LF=asc(10), ETX=asc(3)

**The curve record**

Function: Sends actual optical density every second  
The transmission needs to be enabled by the "Curve Request Record".

Definition: <STX &"O"><Optic><mOD ><LF & ETX>

Fields: Delimiter: asc(9) = tabulator  
<STX &"O"> Record header ; STX=asc(2)  
<Optic> optic cannal 1-4 (channel 1 = 0)  
<mOD> milli optical density  
<LF & ETX> Record end; LF=asc(10), ETX=asc(3)

Example: Signal = 0,999 E in channel 1--> <STX "O"><0><999><LF & ETX>

### The result record

Function: send after every result

Definition: <STX &"R"><Optic><SID><Error><Date><Flags><PID><Test>  
<sec><mOD><%><R><INR> <Unit><Scale><LF & ETX>

|         |            |                                    |
|---------|------------|------------------------------------|
| Fields: | Delimiter: | asc(9) = tabulator                 |
|         | <STX &"R"> | Record header ; STX=asc(2)         |
|         | <Optic>    | optic channel 1-4 (channel 1 = 0)  |
|         | <SID>      | system identifier                  |
|         | <Error>    | System error, hexadecimal          |
|         | <Date>     | ddmmyy or 000000 if not used       |
|         | <Flags>    | Result flags : +, -, *, >          |
|         | <PID>      | Result or patient ID number        |
|         | <Test>     | name of test ("PT", "APTT",...)    |
|         | <sec>      | 12.5                               |
|         | <mOD>      | 000                                |
|         | <%>        | 100.0                              |
|         | <R>        | 1.00                               |
|         | <INR>      | 1.00                               |
|         | <Unit>     | 300.                               |
|         | <Scale>    | mg/dL, ng/mL, .....                |
|         | <LF & ETX> | Record end; LF=asc(10), ETX=asc(3) |

#### Examples:

Test PT with 12.5s 1.02INR 98.5% PID=1000 ERR=0 Kanal=1  
<STX R><0><1011000><0><311204><0><1000><PT>  
<12.5><0><98.5><1.02><0><><><LF ETX>

Test FIB with 10.0s 200 mg/dL PID=1000 ERR=0 Kanal=1  
<STX R><0><1011000><0><311204><0><1000><FIB>  
<10.0><0><0><0><200><mg/dL><LF TX>

Test AT3with 0.651E 78% PID=1000 ERR=0 Kanal=1 (chromogen)  
<STX R><0><1011000><0><311204><0><1000><AT3>  
<0><651><78><0><0><><><LF ETX>

### 11.3. Screenshots

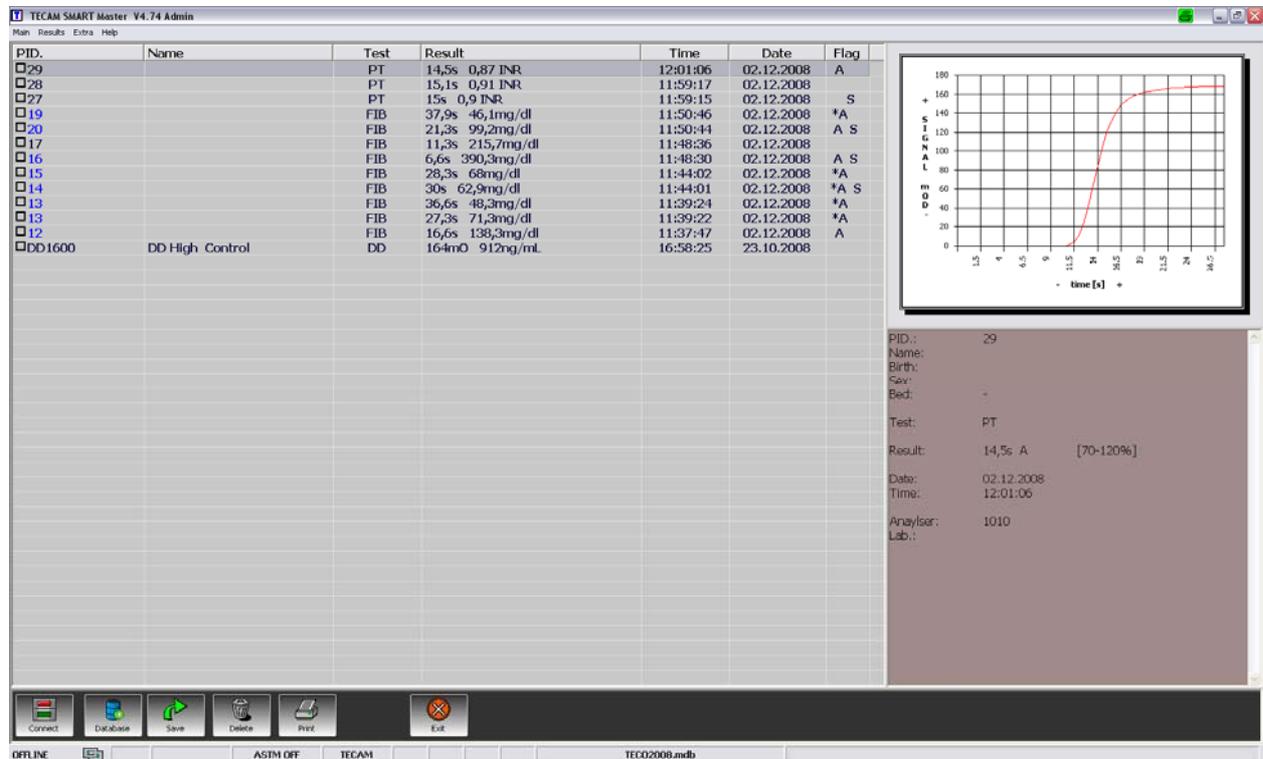


Figure 14 – Tecam Smart Results

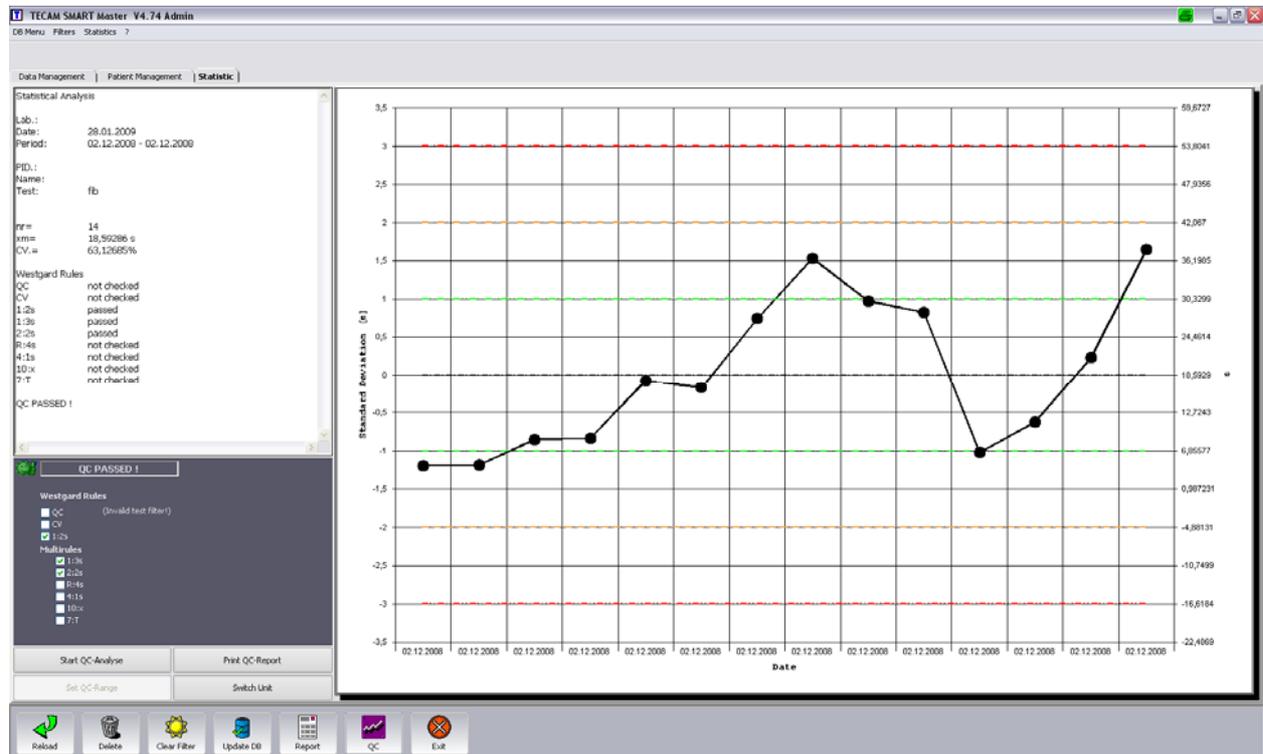


Figure 15 – Tecam Smart statistics

| Date       | Time     | PatientID | Name       | Birthday   | Sex | Testname | Result1 | Scale1 | Result2 | Scale2 | Result3 | Flag | Warning | SystemID | Comment |            |
|------------|----------|-----------|------------|------------|-----|----------|---------|--------|---------|--------|---------|------|---------|----------|---------|------------|
| 22.07.2004 | 13:02:38 | M07639    | TECcard N  | 20.03.2007 |     | APTT     | 30,8    | s      | 32,9    | s      |         |      |         |          | 10121   |            |
| 22.07.2004 | 12:58:59 | M07639    | TECcard N  | 20.03.2007 |     | A1       | 140     | E      | 126,4   | %      |         |      |         |          | 10121   |            |
| 22.07.2004 | 12:58:59 | M07639    | TECcard N  | 20.03.2007 |     | FIB      | 12,3    | s      | 366,0   | mg/dL  |         |      |         |          | 10121   |            |
| 22.07.2004 | 12:58:59 | M07639    | TECcard N  | 20.03.2007 |     | PT       | 11,6    | s      | 80,0    | %      | 1,01NR  |      |         |          | 10121   | test probe |
| 22.07.2004 | 14:47:29 | 0072004   | Xanthou    |            |     | APTT     | 22,3    | s      | 22,3    | s      |         |      |         | A        | 10121   |            |
| 22.07.2004 | 14:43:55 | 0072004   | Xanthou    |            |     | A1       | 156     | E      | 104,0   | %      |         |      |         |          | 10121   |            |
| 22.07.2004 | 14:43:55 | 0072004   | Xanthou    |            |     | FIB      | 11,0    | s      | 340,0   | mg/dL  |         |      |         |          | 10121   |            |
| 22.07.2004 | 14:43:54 | 0072004   | Xanthou    |            |     | PT       | 13,6    | s      | 43,3    | %      | 1,02NR  |      | ATC     |          | 10121   |            |
| 22.07.2004 | 14:41:18 | 00742004  | Moutzou    |            |     | APTT     | 34,7    | s      | 34,7    | s      |         |      |         |          | 10121   |            |
| 22.07.2004 | 14:37:59 | 00742004  | Moutzou    |            |     | A1       | 289     | E      | 113,1   | %      |         |      |         |          | 10121   |            |
| 22.07.2004 | 14:37:55 | 00742004  | Moutzou    |            |     | FIB      | 6,1     | s      | 895,0   | mg/dL  |         |      | A       |          | 10121   |            |
| 22.07.2004 | 14:37:54 | 00742004  | Moutzou    |            |     | PT       | 12,7    | s      | 48,6    | %      |         |      |         | A        | 10121   |            |
| 22.07.2004 | 14:35:15 | 0072004   | Triadellou |            |     | APTT     | 25,8    | s      | 25,8    | s      |         |      |         | A        | 10121   |            |
| 22.07.2004 | 14:32:00 | 0072004   | Triadellou |            |     | A1       | 285     | E      | 115,5   | %      |         |      |         |          | 10121   |            |
| 22.07.2004 | 14:32:00 | 0072004   | Triadellou |            |     | FIB      | 5,7     | s      | 746,0   | mg/dL  |         |      |         | A        | 10121   |            |
| 22.07.2004 | 14:31:59 | 0072004   | Triadellou |            |     | PT       | 13,5    | s      | 50,0    | %      |         |      |         | A        | 10121   |            |
| 22.07.2004 | 14:23:16 | 0062004   | Akrotou    |            |     | APTT     | 27,7    | s      | 27,7    | s      |         |      |         | A        | 10121   |            |
| 22.07.2004 | 14:23:09 | 0062004   | Akrotou    |            |     | A1       | 118     | E      | 108,9   | %      |         |      |         |          | 10121   |            |
| 20.07.2004 | 14:20:08 | 0062004   | Akrotou    |            |     | FIB      | 6,3     | s      | 816,0   | mg/dL  |         |      |         | A        | 10121   |            |
| 22.07.2004 | 14:26:08 | 0062004   | Akrotou    |            |     | PT       | 12,3    | s      | 75,8    | %      | 1,31NR  |      |         |          | 10121   |            |
| 22.07.2004 | 14:23:27 | 00702004  | Tevaden    |            |     | APTT     | 31,3    | s      | 31,3    | s      |         |      |         |          | 10121   |            |
| 22.07.2004 | 14:20:46 | 00702004  | Tevaden    |            |     | A1       | 204     | E      | 82,9    | %      |         |      |         |          | 10121   |            |
| 22.07.2004 | 14:20:46 | 00702004  | Tevaden    |            |     | FIB      | 7,7     | s      | 524,0   | mg/dL  |         |      |         | A        | 10121   |            |
| 22.07.2004 | 14:20:46 | 00702004  | Tevaden    |            |     | PT       | 13,4    | s      | 51,8    | %      |         |      |         | A        | 10121   |            |
| 22.07.2004 | 16:50:57 | 00702004  | Tevaden    |            |     | F10      | 22,1    | s      | 86,8    | %      |         |      |         |          | 10121   |            |
| 22.07.2004 | 16:50:57 | 0062004   | Akrotou    |            |     | F10      | 22,3    | s      | 85,0    | %      |         |      |         |          | 10121   |            |
| 22.07.2004 | 17:03:01 | 0072004   | Xanthou    |            |     | F10      | 21,1    | s      | 96,7    | %      |         |      |         |          | 10121   |            |
| 22.07.2004 | 16:55:49 | 00742004  | Moutzou    |            |     | F10      | 20,9    | s      | 98,9    | %      |         |      |         |          | 10121   |            |
| 22.07.2004 | 16:55:49 | 0072004   | Triadellou |            |     | F10      | 21,3    | s      | 94,6    | %      |         |      |         |          | 10121   |            |

Figure 16 – Tecam Smart DataBase followed by a report

**Patient 0**

|      |            |          |       |           |
|------|------------|----------|-------|-----------|
| PT   | 16.08.2004 | 11:45:01 | 15,9s | 97,7%     |
| PT   | 16.08.2004 | 11:45:01 | 14,9s | *105,7%   |
| FIB  | 16.08.2004 | 12:00:26 | 12,8s | 288mg/dL  |
| FIB  | 16.08.2004 | 12:00:26 | 14s   | 265mg/dL  |
| APTT | 16.08.2004 | 11:53:36 | 27,2s | 1,07RATIO |
| APTT | 16.08.2004 | 11:53:36 | 27s   | 1,06RATIO |

**Patient 1**

**Marco**

**01.01.2000**

|      |            |          |       |           |
|------|------------|----------|-------|-----------|
| PT   | 16.08.2004 | 11:45:01 | 27,1s | 44,8%     |
| PT   | 16.08.2004 | 11:45:01 | 27s   | 45%       |
| PC   | 17.06.2004 | 14:34:30 | 88s   | *115,9%   |
| PC   | 17.06.2004 | 15:24:00 | 82,3s | *118,5%   |
| PC   | 17.06.2004 | 14:34:30 | 89,8s | *127%     |
| PC   | 17.06.2004 | 15:24:00 | 80,5s | 109%      |
| FIB  | 16.08.2004 | 12:00:27 | 24,7s | 134mg/dL  |
| FIB  | 16.08.2004 | 12:00:27 | 25s   | 133mg/dL  |
| APTT | 16.08.2004 | 11:53:36 | 51s   | 2,01RATIO |
| APTT | 16.08.2004 | 11:53:36 | 53,1s | 2,09RATIO |

**Patient 12345678**

**Mr. Smith**

**31.12.2001**

|     |            |          |      |           |
|-----|------------|----------|------|-----------|
| FIB | 11.08.2002 | 15:45:30 | 2,9s | >1423mg/d |
| FIB | 11.08.2002 | 15:45:30 | 2,9s | >1423mg/d |
| FIB | 11.08.2002 | 15:45:30 | 2,9s | >1423mg/d |
| FIB | 11.08.2002 | 15:45:30 | 2,9s | >1423mg/d |

## **12.0 PRODUCT CATALOGUE**

### **Helena C-4 (with Standard Package)**

Cat. Number: C-4

including:

- 1 pc Universal Power supply (93-240Vac/50-60Hz) with EU adapter
- 1 pc Dust Cover
- 25 pcs Double cuvettes (2 wells/each)
- 5 pcs Reagent container (Ø22.5mm)
- 1 pc Stirring magnet
- 1 pc Reagent adaptor (Ø22.5mm)
- 1 pc Printer cable
- 1 pc Pipette fastener (with 2 screws)
- 1 pc Warranty card
- 1 pc CD: Manual, Service, Application Guides

### **Consumables and Accessories**

| Cat.No. | Description   | Content | Qty    |
|---------|---|---------|--------|
| C-241   | Double-cuvette (2 pos/ea)   | 250     | 1 Pack |
| C-010   | 4-stage-Autopipette 25/50/100/200 µl  | 1       | 1 Pc   |
| AC-4601 | Reagent adaptor Ø=22,5mm  | 1       | 1 Pc   |
| AC-4602 | Reagent adaptor Ø=22,8mm  | 1       | 1 Pc   |
| AC-4603 | Reagent adaptor Ø=24,2mm  | 1       | 1 Pc   |
| C-06    | Reagent adaptor Ø=18,6mm  | 1       | 1 Pc   |
| C-07    | Reagent adaptor Ø=27,8mm  | 1       | 1 Pc   |
| C-08    | Reagent adaptor Ø=25,2mm  | 1       | 1 Pc   |
| C-09    | CCD Barcode Reader  | 1       | 1 Pc   |
| AC-4302 | Stirring magnets  | 4       | 1 Pack |
| C-244   | Universal Power Supply  | 1       | 1 Pc   |
| AC-4300 | Reagent container Ø 22,5mm  | 100     | 1 Pack |
| AC-4305 | Reagent tubes Ø 16mm  | 100     | 1 Pack |
| C-04    | Thermal paper for printer   | 5       | 1 Pack |
| C-03    | Printer cable for printer   | 1       | 1 Pc   |
| C-01    | Thermal printers  | 1       | 1 Pc   |
| C-02    | TECAM Smart Software<br>Patient management, Monitoring<br>Research CD and RS232 cable | 1       | 1 Set  |



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