

SERVICE MANUAL

COAGULOMETER

CC - 4000

The unit meets all safety requirements of the standard EN 61010-1 Safety requirements for electrical equipment for measurement, control and laboratory use.

Updated version: March, 2020

Table of contents

page

1. Application of the Coagulometer	2
1.1. Reagents and consumables	2
1.1.1. Reagents, calibration and control materials	2
1.1.2. Measuring cuvettes	2
1.1.3. Printer paper	3
2. Technical Parameters	3
2.1. General characteristics of the unit	3
2.2. Technical Parameters	3
2.3. Principle of unit's work	5
2.4. Rated operating conditions	5
3 Measuring programs	5
Table 1 Programs list	6
4 Operating the device	6
4.1. Installation	6
4.1.1. Connecting to the supply network	6
4.2. Arrangement and application of operating elements	7
4.2.1. Measuring block	7
4.2.2. The keyboard with the display	7
4.2.3. the display	8
4.3. Registration of the name of laboratory	8
Table 2. Symbols corresponding to the buttons with numerals	9
5. Unit usage	9
5.1. Measurements	10
5.1.1. Example of measurements for PT	11
5.1.2. Conditionality of the printout of fibrinogen	12
5.2. Results	12
5.2.1. Viewing, printing, sending or deleting of the results	13
5.3. Programming	13
Table 3. Programming of the coagulometer	14
Table 4. Types of results for chronometric measures	15
5.3.1. Conditionality of the result with fibrinogen for the determinations of PT	15
5.3.2. Performing of the programming	15
5.4. Calibration	16
5.4.1. Calibration – examples	16
5.4.1.1. Calibration – PT	16
5.4.1.2. Calibration fibrinogen (by the Clauss method)	20
5.4.1.3. Calibration - D-Dimer	21
5.4.1.4. D-Dimer for beginners - tips and examples	23
5.5. Technical programme (tests)	25
5.5.1. Test of light	25
5.5.2. Measuring module test	25
5.5.3. Printer Test	26
5.5.4. Display Test	26
5.5.5. Keyboard Test	26
5.5.6. Transmission Test	26
5.5.7. Settings	26
5.6. Printing of the measure results and of the kinetic of the reaction course	27
5.6.1. Setting the type of printer operation	27
5.6.2. Printing of the measure results - 3 ways	27
5.6.3. Printing the course of reaction kinetics	27
5.6.4. Printing the program parameters	28
5.7. Quality Control	28
6. Device Maintenance and servicing	28
7. The frequently asked questions and remedy	29
8. Messages	36
9. The transmission of the results the device - the computer	37
10. Decommissioning	38
10.1. Decommissioning for repair	38
10.2. Decommissioning with view to the liquidation	38
11 The symbols and markings	38
Annex 1 - MAIN MENU	39
Annex 2 - MEASUREMENTS	40
Annex 3 - RESULTS	41
Annex 4 - PROGRAMMING	42
Annex 5 - CALIBRATION	43
Annex 6 - CONTROL	44
Annex 7 - TESTS	45
Summary tables :	
Table 1 Summary of programs	6
Table 2 Characters corresponding to numeric keys	9
Table 3 Programming the Coagulometer	14
Table 4 Types of Results for chronometric markings	15

1. Application of the Coagulometer CC - 4000

The Coagulometer CC – 4000 is a semiautomatic specialized unit which is used in the *in vitro diagnostics* for performing the following coagulation tests:

- PT + fibrinogen
- APTT
- Fibrinogen (Clauss)
- TT
- Coagulation Factors II, V, VII + X
- Coagulation Factors VIII, IX, XII + XII
- AT
- D-Dimer
- Protein C
- Plasmin Inhibitor (alfa-2 antiplasmin) and other

1.1. Reagents and consumables.

1.1.1. Reagents, calibration and control materials.

In order to maintain correct operation of the device and to obtain reliable results (accuracy, repeatability, reproducibility) and correct quality control results, the user is required to use reagents, calibration and control materials only indicated by Slamed.

Slamed as a manufacturer of CC -4000 analyzer shall not be liable for errors in the results of the patients' marking and the results of quality control if the measurements which were carried out using other reagents than indicated by Slamed

Slamed has not released to their analyzers a different type of reagents.

1.1.2. Measuring cuvettes.

The system: coagulometer made by Slamed - Chrome cuvette is a closed Use only the cuvette Chrome.

Using other cuvettes will void the warranty and may void the Certificate of Technical Performance because of the possibility of damage the Coagulometr.

1.1.3. Printer paper.

Use only paper 110 mm purchased from the manufacturer of the analyzer.

Another type of paper causes dust and damage of the printer mechanism.

2. Technical Parameters

2.1. General characteristic of the unit:

- amount of the tested material or pattern – 50 μ l
- reagent's amount – 50 μ l (100 μ l)
- result's reading – automatically from the calibration curves or calculated in relation to the pattern
- types of results: time, index PT, index QUICK, INR, RATIO, fibrinogen concentration in g/l or mg / ml, % activity, U/l, U/ml, D-Dimer - μ g/l
- single or double measurement in the same material (substance)
- memory after disconnection from the supply network:
 - date and time
 - up to 16000 results
 - 30 calibration curves
 - calibration values & norms for each program
- measurement time: 4-300 sec (depends on the type of measurement)
- automatic systems of turbidity compensation (possible measurement of lipemic, hemolysed and hepatitis plasmas)
- self-acting compensation of the optical track's and cuvette's contamination.

2.2. Technical Parameters:

2.2.1. Dimensions/weight: 43 cm x 37 cm x 11 cm / 6,5kg

2.2.3. Type of electric isolation: basic insulation

2.2.4. Installation class (protective type): II

2.2.5. Degree of contamination: 2

2.2.6. Control systems of the technical state of the unit:

- Tests: elementary, of LCD display, of the keyboard, of the printer
- Automatic control of the measuring module

2.2.7. Memory after disconnection from the supply network

- date and time
- up to 16000 results, 30 calibration curves
- calibration values and norms for each program

2.2.8. Thermostat / warm – up time: $37^{\circ}\text{C} \pm 0,5^{\circ}\text{C}$ / 10÷20 min

2.2.9. Number of measuring channels: 5

2.2.10. Number of measuring paths: 3

2.2.11. Measurement range

- 4-300 s for time measurement
- 1-999% for % activity
- 0,01-9 U/ml for international units
- 0,01-9 g/l for balance units
- 1-999 mg/dl for balance units
- 1-9999 $\mu\text{g/l}$ for balance units
- 20-300 s for incubation stop – watch

2.2.12. Distributiveness / Distribution

- 0,1 s for time measurement
- 0,1% for % activity
- 0,01 U/ml for international units
- 0,01 g/l for balance units
- 1 mg/dl for balance units
- 1 $\mu\text{g/l}$ for balance units
- 1 s for incubation stop – watch

2.2.13. Precision / Exactitude

- $\pm 0,1$ s for time measurement
- $\pm 1\%$ for % activity
- $\pm 0,01$ U/ml for international units
- $\pm 0,01$ g/l for balance units
- ± 1 mg/dl for balance units
- ± 1 $\mu\text{g/l}$ for balance units
- ± 1 s for incubation stop – watch

2.2.14. Repetition / Recurrence: CV up to 2,5% (for time measurement)

2.2.15. Others:

- length of the light wave: 405 nm
- display - colored - graphical LCD display
- built – in thermal printer 110 mm, printing of results, setting of programmes and reaction course
- Output RS232- connecting device to the computer network
- USB slot- connecting a barcode reader (patient number) or connecting an external computer keyboard
- internal lithium battery

2.3. Principle of unit's work:

For chronometrical markings (PT, APTT, TT, Fibrinogen, Coagulation Factors) we use the method of measurement of time of the optical density's change that appears during the coagulation reaction along with the simultaneous analysis of the kinetics of the described reaction. Program of the unit checks the course of reaction from adding of the initial reagent up to the end of the course of coagulation reaction.

The basic result (time) is calculated in accordance with the unit user's program.

Measurement time is limited up to 300 s.

For measurements with usage of chromogen substrata we used the measurement of the calorimetric reaction's kinetics with the limit of measuring time.

After the qualification of the rapidity of sample material's absorption changes there follows its corresponding calculation in relation to the rapidity of pattern material's absorption changes and later – giving of the final result.

2.4. Rated operating conditions

– environment temperature	+15 ⁰ C ÷ +32 ⁰ C
– relative humidity	5 ÷ 85%
– atmospherically pressure	73 ÷ 106 kPa
– vibrations, water, salt, sand and dust content in the air	possible little
– unit position	horizontally ÷ 5%
– power supply	230 / 50-60Hz / 100VA
– fuse	1A
– installation class (protective type)	II

3. Measuring programs

The coagulometer **CC-4000** has 11 measuring programs.

Each program is marked with the number 1-2 (ex. 1PT, 2PT, etc), altogether there may be max. 22 programs. That allows the user, for example, memorisation of calibration values and measurement parameters for the reagents of different LOT's or modification of the same program from the point of view of the type of obtained results and prints.

Table 1

Programs list:

N.P.	Name of Program	Channel	Type of Results
1	(1-2) PT	A,B,C,D	Time, index PT, index Quick, INR, Fibrinogen
2	(1-2) APTT	A,B,C,D	Time, RATIO
3	(1-2) Fibrinogen	A,B,C,D	g/l, mg/ml
4	(1-2) TT	A,B,C,D	Time, RATIO
5	(1-2) Coagulation Factors (Group I)	A,B,C,D	% activity
6	(1-2) Coagulation Factors (Group II)	A,B,C,D	% activity
7	(1-2) AT III	D'	% activity
8	(1-2) D-Dimer	D'	µg/l
9	(1-2) Protein C	D'	% activity
10	(1-2) Plasmin Inhibitor (a2-Antiplasmin)	D'	% activity
11	(1-2) Plasminogen	D'	% activity

4. Operating the device

4.1. Installation

The analyzer is assigned for work and usage in closed and warmed-up spaces under following distinguishing conditions:

- environment temperature +15⁰C ÷ +32⁰C
- relative humidity 5 ÷ 85%
- atmospheric pressure 73 ÷ 106 kPa
- vibrations, water, salt,
sand and dust content in the air possible little
- unit position horizontally ÷ 5%
- power supply 230V / 50-60Hz / 100VA
- installation class (protective type) II
- contamination degree 2

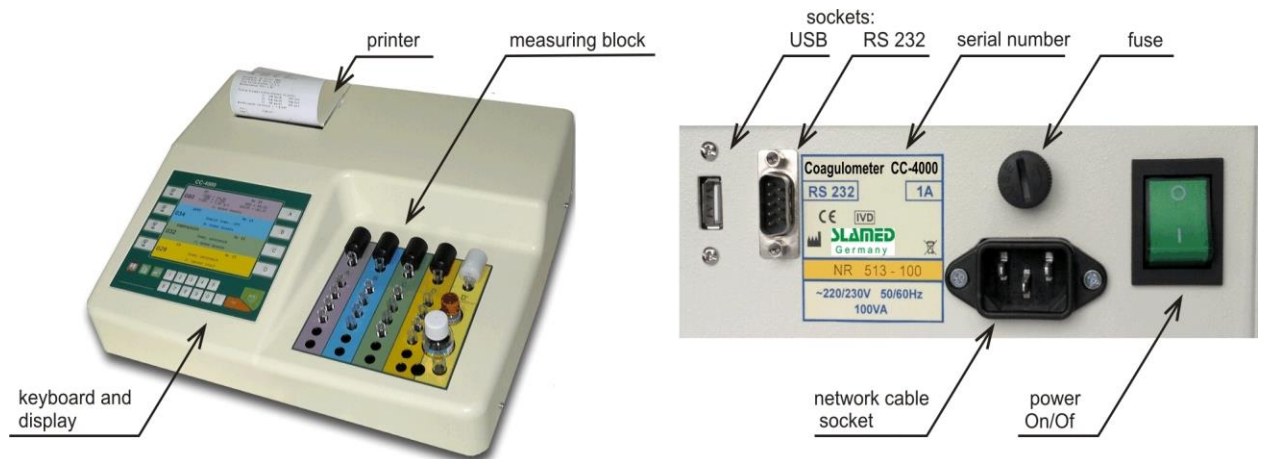
4.1.1. Connecting to the supply network

- Put connector of the network cable into the socket – contact on the back – wall of the unit (check whether it is put proper and up to the end).
- Joint the cable with power supply 230V

ATTENTION! According to the safety the unit can be connected only to the socket – contact with protective bolt!

- Switch on the unit with circuit – breaker situated on the back – wall.

4.2. Arrangement and application of operating elements



4.2.1. Measuring block

The measuring block with thermostat serves for reagents incubation, test-tubes incubation and for measure making.

Four left-side (A-B-C-D) measuring holes suit for the chronometrical measurements (PT, APTT, TT, Fibrinogen, Coagulation Factors). The right-side hole (D') suits for the chromogene measurements AT, Protein C, D-Dimer and other.

Over the measuring holes there are moving conductors with the holes for the pipette's end. That allows precise and repeated adding of the initial reagent.

4.2.2. The keyboard with the display

Application of the keyboard:



MAIN MENU – choice of the type of unit work, return to the beginning



ADDITIONAL MENU – change the type of measurement, setting how to print and broadcast audio signal, the time, the multiplier results and others (see Section 5.3.)



Stoppers – watches of the incubation time



Printing of the measure results; calibration curves, moving forward (out) the paper



Acceptance of results, positive answer at unit question



Lack of acceptance; negative answer at unit question; removal of the numeral



Additional buttons – manual start of the measurement; stoppage of the measurement

4.2.3. The Display

Applied graphical – text display assures comfortable and easy usage of the unit. The program of the unit delivers on the display the whole information about the present state of coagulometer's work and about the possibility of its change. In the lower part of the display one can find information about which buttons are to be used in order to move forward to the next stage of the unit work. During measurements four fields in the display (A-B-C-D) take colours corresponding to the colours of the measurements channels A-B-C-D-D' in the measurement block. On the left side, parallel to the buttons of the start of incubation time there are four independent stopwatches measuring the time of incubation separately and independently for each channel.

4.3. Registration of the name of laboratory


By usage of the buttons with numerals one may enter the name and other data of the laboratory on the results' list. The text field has 4 lines with 30 characters. Before entering the text we recommend its preparation with adjusting the margins and spaces because it is not possible later modification between words. The text is entered analogically as SMS in mobile phone.

TABLE 2

Symbols corresponding to the buttons with numerals

Button	Corresponding Symbols / Signs					
	<	>	“			
2	A	B	C1	Ą	Ć	
3	D	E	F			
4	G	H	I			
5	J	K	L			
6	M	N	O	Ń	Ó	
7	P	Q	R	S	Ś	
8	T	U	V			
9	W	X	Y	Z	Ż	Ź
0	-	/	space			
comma	dot / full stop	coma	apostrophe	star		


In order to write down the corresponding text it is necessary to enter:

- Main menu 
- Tests → Settings → Enter Code (220565) → Laboratory, in the space of flashing cursor enter the appropriate sign
- Right side moving of the cursor –with buttons **A** or **D**
- Left side moving of the cursor – upper or lower button with hourglass
- Up and down moving of the cursor – with buttons **B** and **C**
- Signs removal – with button **NO**

Errors correcting – put the cursor on the wrong sign, remove the sign with the button **NO** and write down a new one.

Validate the text by the button **YES**.

5. Unit usage

The choice of the kind of unit work is performed by pushing  “MENU” button.

Particular kinds of work select service activities of the unit:

- 1: MEASUREMENT** – execution of the tested or control material measures
- 2: RESULTS** – review, printing or sending to the computer network of the results of patents and quality controls filed in the memory of the unit
- 3: PROGRAMMING** – adaptation of the measuring parameters to various reagent applications; choice of number of the active measuring channels; choice of the type of results, registration of the dimension of factor CV, registration of the dimension of norms, choice of the measurement time
- 4: CALIBRATION** – insertion of reference (calibration) values
insertion of calibration curves
insertion of factor (coefficient) ISI for PT
- 5: CONTROL** – measurements of the quality control
- 6: TESTS** – execution of technical control of the unit

5.1. Measurements

Main menu  → **1: Measurement**

1:Measurement option serves for the execution of tested or control material measures.

Attention!

The main condition of getting proper measure results is to follow the required instructions of the execution of measurements and calibrations. It is required to use the same methodology, reagents of the same series and prepared correspondingly, the same pipettes and the same kind of work as during the calibration of the unit.

The Analyzer measurement channels operate independently of each other but the way of working, measurement parameters, the range of standards, etc. (see Table 3) is set in the " PROGRAMMING " for the type of measurement (e.g. PT) and is assigned to all channels.

The different channels may be performed independently from each other and simultaneously to the various types of tests in any combination selected (e.g., channel A - PT, in channel B - APTT, channel C - TT D channel - PT, etc.)

In the channels A, B, C, D you can perform the following tests:

- PT, APTT, fibrinogen, TT, factors

In addition, in the D-channel (slot D ') you can perform the test:

- ATIII, D -Dimer, α 2 AP, Protein C, Plasminogen.

Measurements can be performed using the following methods:

a) one measurement of the sample

Set in the " Programming " → "Measuring Patient " : → "single"

NOTE: The setting is assigned to all channels!

b) two measurements (doublet) of the sample - both measurements must be performed in sequence - one by one – in the **selected** channel.

Set in the " Programming " → "Measuring Patient " → "double "

NOTE: The setting is assigned to all channels!



5.1.1. Example of measurements for PT

(device is calibrated and programmed according to the points 5.4.1.1.a):

Preparatory work:

- Prepare the reagents following producer's instructions
- Check whether the series or type of the reagents was not changed (if this took place – perform the calibration of the unit – see item 5.4.)
- Collect blood with sodium citrate 3,2% in the proportion 1:10 (i.e. 1 volume of anticoagulant + 9 volumes of blood) and mix the sample slowly and gently in order to avoid hemolysis. Check that the sample is free from clots and centrifuge it at 1500 x g. The sample should be centrifuged within 30 minutes after collection and can be stored in the refrigerator (no longer than 3 hours)

Performing measurements:

- Check whether measuring holes are free from test-tubes
- With  button find **1:MEASUREMENTS** option and accept
- With one of the buttons A,B,C,D select the measurement channel
- find and select program "PT"
- using a barcode reader or keypad to enter No of patient.
- Fill the test-tubes with patient plasma and reagents following the methodology
- With  button set going the incubation stop watch

At the end of incubation time there comes sound signal (stop-watch continues time measure).

- Transfer the test-tubes into the measuring holes
- When the starting mark. "Add reagent" appears pipette vigorously the last (starting) reagent
- Automatic start of the measurement begins
- After measurement is fulfilled there appear the results and the variation between the channels signified Cv ... %

Before the acceptance of the results is possible:

- **the result multiplier** - the "Additional Menu." The result multiplier is used only for diluted sera (e.g., during measurement of high concentrations of fibrinogen or D-dimer). Multiplier range is from "0.1" to "10". After selecting and confirming the screen the results appear. If you make a mistake, the operation can be repeated. Maximum indication of the result is 9999 (see point. 2.2.11).
- **result printing:**
- the button "Printer" or
- automatic printing if it is set in this way in the Additional menu.
- **printing the reaction course** of coagulation in the graphic form – put the button with comma.

Attention: the analyser remembers only the graphic course of the last measurement.

Accepting the result of pressing YES will cause it to enter into the memory analyzer transmission to the computer network (if this option was previously selected in the "Programming" - if it is not selected transmission does not!), Print automatically or manually by pressing the "Printer" - depending on the option selected in the "Main Menu" → "Additional Menu".

5.1.2 Conditionality of the printout of fibrinogen

Usage result of the measurement of fibrinogen in the PT measurement depends on the programming of the analyzer - see Section 5.3.1.

5.2. Results

(see also : Table 3 Programming the device –Types of results, range of results – points 2.2.11, The result multiplier – points 5.1.1.)

"RESULTS" option serves for:


- a) review
- b) printing

c) sending to the computer network

d) clearing

results Patients and Quality Control stored in the analyzer memory.

5.2.1. Viewing, printing, sending or deleting of the results

- With the button  find the option **“RESULTS”** and accept
- Choose type of the activity:
 - Review and printing of the results – **“Patients”** or **“Quality Control”**
 - **“Clearing”** - clearing of the results and Quality Control
- Insert date of the measurements (DD-day, MM-month), the program suggests the current/ actual/ date along with the number of patients, whose results are to be shown (“from” - “to”) For the only patient e.g. No 3 give only number from 3. If no number is given the unit searches automatically for all numbers from 1 to 999.

For Quality Control only the date of the measure execution is given.

- After the acceptation the unit performs chosen activity:
 - for the transmission of the results –use the button “Additional Menu”,
 - for the printing of the result use the button “Printer”.

5.3. Programming.

Programming of the analyzer is divided into two stages:

- **Global settings** - for the entire analyzer
- **Setting measurement parameters** - separately for each type of measurement

Global settings covering all programs shall be Additional Menu :

Main Menu → Additional menu continue to select the NO :

1. Printing : - this is the status of the printer : blanket, automatic or off - choose and accept a combination of YES and NO keys (see paragraph 5.6).
2. Transmission : - this is the kind of data transmission to a computer network: collective or automatic (see paragraph 9) The method of election as above.
3. Sounds : - a choice of levels from 1 to 4 or the sound turned off. Select and accept a combination of YES and NO keys
4. Time: - summer or winter . Select and accept ibid.

Measurement parameter settings for each type of measurement is carried out in Option 2 : “PROGRAMMING” (see point 5.3.2.)

Table 3
Programming of the coagulometer

Questions	Possible Answers
Give incubation time	from 20 to 300 sec – write with the keyboard
Measurement for patient	Single or double – choose with button “NO”
Give Cvmax* (only for dual measurement)% - write with the keyboard
Give measurement duration	From 1 to 5 minutes– choose with button “NO”
Select type of result and range of normal results	<p>Results: Time, RATIO, index PT, INR, index QUICK, Fibrinogen – if given type of result is accepted nearby appears sign (√), if no sign (x). Choose with the button “NO”, accept with button “YES”</p> <p>Range of normal results: from.....to write in keyboard (you can not specify - to accept a blank space)</p>
conditionality due to the concentration of fibrinogen as a result of PT	<p>only for measuring PT "Programming" you can set one of three possible use of the measurement of fibrinogen obtained simultaneously with the measurement of PT:</p> <p>8 √ Fibre. – On the outcome of PT the fibrinogen result will always be present</p> <p>8 x Fibre. – On the PT result the result of fibrinogen will never be present</p> <p>8 ? Fibre. – Conditional fibrinogen - after the release for PT, the program will ask whether a result of PT is the result of fibrinogen</p>

* Cvmax % defines / qualifies measures repetition for double measure in the same calibration plasma. If Cvmax is exceeded there will be a warning sound signal. Measure should be repeated.

Table 4
Types of results for chronometrical measures

Result Dimension	Application	Quotient
Time (sec)	APTT, TT	
Index PT	PT	$\frac{\text{time calibration plasma}}{\text{time patient plasma}} \times 100\%$
RATIO	APTT, TT	$\frac{\text{time patient plasma}}{\text{time calibration plasma}}$
INR	PT	$(\text{RATIO})^{\text{ISI}}$

ISI – sensivity coefficient of thromboplastin

5.3.1. Conditionality of the result with fibrinogen for the determinations of

PT:

If you do not always need a result of the determination of fibrinogen obtained during the determinations of the PT must set the " conditionality " as a result of fibrinogen :

Main Menu → Programming → PT → 8 √ FIBR .

You can choose one of three options (press NO) :


8. √ Fibre . – On the outcome of PT the result of fibrinogen will be always present

8 x Fibre . – On the PT result the fibrinogen result will never be present

8 ? Fibre . – Conditional Fibrinogen - after the release for PT and its acceptance of the analyser, the program will ask whether a result of PT should be the result of fibrinogen:

- If you press the " YES" button, the final result will include patient determination of fibrinogen with the PT and so will be entered into the device's memory ,
- If you select the " NO ", the result of determination of fibrinogen with the PT will be removed from the final result of patient and will not be entered into the memory.

5.3.2. Performing of the programming:

- With  button find the option **3: "PROGRAMMING"** and accept
- Find the program e.g. **PT** and accept.
- Press "Additional Menu" you can choose one of two program numbers, eg PT1 or PT2 (selected program will appear here - no number - in later elections this program!)
- Confirm
- The display of the analyzer raises questions about the measurement parameters and types of results. Transitions between questions - the **NO**, the activation field for entering data - press **YES** - the field takes the green.
- Using the methodology (or leaflets reagents) to enter the relevant data analyzer memory.

NOTE: The entered data and setting measurement parameters are assigned to all channels!

The introduced program can be printed by pressing the button "Printer".

Exit programming – “Main Menu” button.

5.4. Calibration

"CALIBRATION" option makes it possible to insert into the program of the unit referential (calibration) values got from the calibration plasma measures.

Calibration is always performed after change of the reagent series or if control measures are not (proper) correct.

Referential values serve for the execution of the required calculations and obtaining of the final result.

Attention! Referential values read from the reagent leaflets of different types of coagulometers can't be applied for the unit CC-4000!

5.4.1. Calibration – examples

5.4.1.1. Calibration PT

a) Programme the unit for PT measurement according to item 5.3.

Assume that the following types of results for PT were programmed and selected:

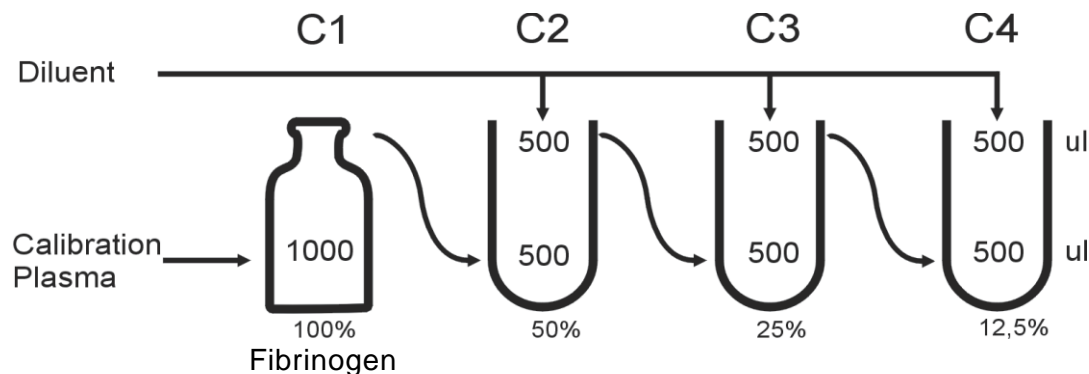
- “time’
- “index PT”
- “INR”
- “Fibrinogen”

During the calibration the unit program will measure referential time for calibration

plasma (for measuring of index PT and INR) as well as executed calibration curve (for measuring of fibrinogen from PT). If “Fibrinogen” as one of the types of results won't be selected and programmed beforehand (item 5.3) unit program won't perform the calibration curve.

b) With The special diluent Fibrinogen Diluent fulfil series 3 succeeding dilutions of the Calibration plasma.

Point b) done only if will be measured fibrinogen for PT



where: C1 – concentration of fibrinogen read from the leaflet of calibration plasma for the reagent PT.



c) With button select option **4: "CALIBRATION"** and accept

With **"NO"** button select program **PT** and accept.

Depending on the type of results prior to program for PT (see Section 5.3.) The analyzer program will sequentially perform necessary calibration measurements .

I. Calibration : PT

II. Calibration : PT FIBR

Coming to the next calibration measurements should be made to perform by pressing the [► D]

I. Calibration : PT

With button [► D] to select CALIBRATION : **PT**

Enter the data for the questions on the display :

" Reagent LOT: " - enter the LOT reagent (with vial) and confirm (in case of difficulty, see section. 4.3. Table 2)

" Calibrator LOT: " - enter No. series calibrator and confirm.

" Time Calibration =" - enter only if you do not perform calibration measurements

" The beta ratio =" - β read the correction factor of leaflets calibrator , enter and accept.

Correction factor beta (β) is used to introduce a small correction of the measured time in your laboratory calibrator ($T_{average}$), so as to obtain the proper time calibration (T_k) for a population of patients in which measurements will be performed . Time calibration T_k analyzer program calculates $T_{average}$ by multiplying the correction factor " β " :

$$T_k = T_{average} \times \beta$$

Where:

T_k - time calibration calculated by the analyzer program

$T_{average}$ - time calibration plasma measured in your lab
(average of several measurements by the program analyzer)

β - correction factor (the leaflet calibrator)

" Factor ISI =" - type of leaflets reagent PT

To start the calibration measurements should be from the keyboard to select.

Select and accept.

" Number of measurements per point [2-8] =? "

We recommend that you enter 4 and confirm. The analyzer takes 4 individual measurements sequentially in channels A, B, C and D. These measurements will be designated as :

T_p (1), for the first time calibrator measurement in the channel A

T_p (2), for the second time calibrator measurement in the channel B

T_p (3), for the third time measuring the calibrator in the channel C

T_p (4), for the fourth time measurement of the calibrator in the channel D

If you select a greater number of measurements per point (eg. 8) it will be repeated in subsequent channels.

Upon completion and acceptance of the results of measurements of the device,

the program calculates the average of all measurements determined as Tp_{sr} , Cv factor in% and will calculate the final time calibration Tk.

II. Calibration PT FIBR

With the button [D] select Calibration : PT FIBR

Enter data:

"Reagent LOT:" - enter the LOT reagent (with vial) and confirm (in case of difficulty, see section. 4.3. Table 2)

"Calibrator LOT:" - enter No. series calibrator and confirm

"Number of curve points [2-5] =? " - give 3 or 4 points depending on the number of the fulfilled dilutions of the calibration plasma

C1 = ...% - where: C1 – fibrinogen concentration is taken from the leaflet of calibration plasma for the "Fibrinogen with PT".

C2 = ...%

C3 = ...%

Concentration C2, C3 and other should be entered according to the dilution of the calibrator.

- Select 0. Execute calibration and accept.

Number of measurements on point [2-8] = ...?

We recommend enter 4 and accept. The device will execute 4 measurements on each point of the calibration curve.

Perform calibration measurements.

The results will be designated as :

D1 as the average of D1 (1) and D1 (2) for the first point of the curve .

Analogously perform measurements for the concentration of C2 and C3.

The results will be marked as :

D2 for the second point of the curve

D3 for the third point of the curve

List the entered values and the results of measurements for archiving.

After all measurements analyzer calibration program calculates the correlation coefficient "r" resulting curve . If "r" > 0.995 curve is correct - to accept press **YES**.

Otherwise negate the **NO** and repeat calibration .

The results of calibration (including calibration curve) can be printed by pressing the "Printer".

Note:

If the calibration parameters will be entered manually via the keypad, in the print program parameters and prints the results of the patients there will be signs # # # - evidence of interference in the calibration measurements .


5.4.1.2. Calibration – fibrinogen (by the Clauss method)

a) Programme the unit for Fibrinogen measure according to item 5.3.

b) With the special Diluent fulfil series 3 or 4 dilutions of calibration plasma:

Dilution	Fibrinogen Concentration (for example)	Calibration Plasma	Diluent
C1 1:10	3,6 g/l	50 µl	450 µl
C2 1:15	2,4 g/l	50 µl	700 µl
C3 1:20	1,8 g/l	50 µl	950 µl
C4 1:30	1,2 g/l	50 µl	1450 µl

where: **C1** – fibrinogen concentration is taken from the leaflet of calibration plasma for the reagent fibrinogen

With  button select option "CALIBRATION" and accept.

Select program – "**FIBRINOGEN**" and accept.

Enter data:

"Reagent LOT:" - enter the Batch reagent (vial) and confirm
(in case of difficulty, see section. 4.3. Table 2)

"Calibrator LOT:" - enter No. series calibrator and confirm.

"Number of curve points [2-5] =?" - give 3 or 4 points depending on the number of the fulfilled dilutions of the calibration plasma

C1 = ...% - where: C1 – fibrinogen concentration is taken from the leaflet of calibration plasma for the "Fibrinogen with PT.

C2 = ...%

C3 = ...%

Concentration C2, C3 and other should be entered according to the dilution of the calibrator.

- Select **0. Execute calibration** and accept.

"Number of measurements on point [2-8] = ...?"

We recommend enter 4 and accept. The device will execute 4 measurements on each point of the calibration curve.

Perform calibration measurements .

The results will be designated as :

T1 as the average of T1 (1) and T1 (2) for the first point of the curve .

Analogously perform measurements for the concentration of C2 and C3.

The results will be marked as :

T2 for the second point of the curve

T3 for the third point of the curve

List the entered values and the results of measurements for archiving.

After all measurements analyzer calibration program calculates the correlation coefficient "r" resulting curve . If "r" > 0.995 curve is correct - to accept **YES**.

Otherwise negate the **NO** and repeat calibration .

The results of calibration (including calibration curve) can be printed by pressing the "Printer".

Note:

If the calibration parameters will be entered manually via the keypad, in the print program parameters and prints the results of the patients there will be signs # # # - evidence of interference in the calibration measurements .

5.4.1.3 . Calibration - D-Dimer

a) Program the device for the determination of D- Dimer according to the point 5.3 selecting "type of reagent L".

Methodology of the needed information can be found in leaflets of the reagent.

b) Using saline follow plasma dilution calibration :

Dilution of calibration plasma	Concentration of D-Dimer (exemplary values)	Calibrator	Saline
C1 without dilution	1000 ug/l	Directly from the bottle	-----
C2 1:2	500 ug/l	100µl	100µl
C3 1:4	250 ug/l	100µl	300µl

where : **C1** value of D- Dimer read in the leaflet for reagent or calibrator

In the **Main Menu**, select **"Calibration"** and confirm.

Find a program **D-Dimer** and confirm.

Enter the data :

" Reagent LOT: " - enter the Batch reagent (vial) and confirm
(in case of difficulty , see section . 4.3. Table 2)

" Calibrator LOT: " - enter No. series calibrator and confirm.

" The number of points of the curve [2-5] = "

Give 3 points - the amount of dilutions of the calibrator.

C1 = g / l

The concentration of C1 to read in the leaflet calibrator, enter and accept.

C2 = g / l

C3 = g / l

The concentration of the C2, C3 and possibly enter by further dilution of the calibrator taken.

Select **0. Execute calibration** and accept.

" Number of measurements per point [2-8] =? "

We recommend you to enter and confirm 2 . The analyzer takes two consecutive measurements (channel D ') for each point of the calibration curve.

The results will be designated as :

D1 as the average of D1 (1) and D1 (2) for the first point of the curve .

Analogously to perform measurements for the concentration of C2 and C3.

The results will be marked as :

D2 for the second point of the curve

D3 for the third point of the curve

List the entered values and the results of measurements for archiving.

After all measurements analyzer calibration program calculates the correlation coefficient "r" resulting curve . If "r" > 0.995 curve is correct - to accept press **YES**.

Otherwise negate the NO and repeat calibration.

The results of calibration (including calibration curve) can be printed by pressing the "Printer".

Note: If the calibration parameters will be entered manually via the keypad , in the print program parameters and prints the results of the patients there were signs
- evidence of interference in the calibration measurements .

5.4.1.4 . D–Dimer for beginners - tips and examples.

The basis of the accuracy of the result is an initial sorting of patients and confirmation of negative results (ie, a numerical score below 250 mg/l, or the message "No response").

For non -treated patients and healthy message " No response" means the result of less than 250 mg / l (negative).

For patients treated with the measurement can be affected by medications administered and the emergence of a result of " no response " as a negative to be confirmed . Dilution of patient plasma this drug reduces the impact on the result.

Depending on the profile of clients please choose one of the ways

(practical examples from users):

1. Each plasma should be diluted 1:2

- If given the message " no response " it seems the result below 500 mg / l (negative)
- If it is given a numerical score to be used for the result you should apply the multiplier x 2

2. For all plasmas without dilution:

- If given the message "no response" confirm the negative result - semi-quantitative latex test
- For a positive test result latex 1:5 diluted plasma and perform measurement of the analyzer

3. A preliminary test of a semi-quantitative segregation of patients:

- A negative result is given as below 250 mg/l
- For a positive result 1:3 dilution execute and measure on the analyzer

4. Patients 'aimed with' high D- dimers :

- Perform the marking without dilution
- If given the message "no response" confirm the negative result marking the 1:3 or 1:5 dilution.

Examples obtained during device installation and training of the personnel:

1) Patient No. 1 (fibrinogen above normal):

- The first measurement of undiluted plasma -211 mg/l (at the sensitivity limit of the device)
- Second measurement of undiluted plasma - the message "no response"
- The third measurement of plasma dilution of 1:2 - 470 mg/l (235 on display x multiplier of 2)
- The fourth measurement of plasma dilution of 1:3 - message "no response".

Conclusions:

Measurement of plasma dilution gave a score higher than the measurement without dilution at evidence of the occurrence of the patient's plasma substance undercut the measurement. Test result is positive.

2) Patient No. 2 (fibrinogen above normal) :


- The first measurement without dilution of plasma - 720 mg/l
- Second measurement of plasma dilution of 1:2 -730 mg/l (365 on display x multiplier 2)

Conclusions:

A positive result of 720 mg/L. Plasma does not contain interfering substances.

5.5. Technical programme (Tests)

"TEST" option serves for the inspection of the technical state of the unit and other.

- With  button select option **"TESTS"** and accept.
- select type of the test and accept with button "YES".

5.5.1. "TEST of LIGHT "

The test must be carried out for empty measuring slots - remove the tubes!

During the test, the device displays the message " CONTROL OF LIGHT " and gives the light level for channel A, B, C and D, and when you press "NO " - for channel D'.

The display light level indicates the status of the optical path (light intensity). The correct value should be in the range of 3000 to 4060 and if so, you should complete the test by pressing "NO".

If the light level is less than 3000 or greater than 4060 you should:

- Purge the optical path (see section 6. " Maintenance of the Device"
- Perform automatic light control by 5.5.2 . " MEASURING MODULE TEST " .

If the values are still below the 3000 - to report for service. Until the repair can be carried out measurements . Occurred when the measurement message " Remove the tube " may be removed keys A, B, C or D.

5.5.2 . " MEASURING MODULE TEST"

This test is designed for automatic light intensity adjustment performed by the analyzer program without user intervention.

Sequentially as follows:

- Remove the cuvettes from the terminals
- Clean and blow measuring sockets
- Main Menu → Tests → Measurement Module

Screen appears with the measurements of the optical system for all channels.

In the following lines it is measured :

- Voltage of the measuring head (level of light)
- The level to LEDs
- Drift of light

Use the A, B, C, D and button with a dot (for channel D') to enable measurements.

An automatic light adjustment is made.

Wait for the display to stabilize.

You should now enter into the new memory of the analyzer automatic settings:

Press the "Additional Menu", accept the question "Adjusting the light?"

insert your code (220565). Indication of the selected channels are surrounded by a yellow border. When you press the keys A, B, C, D, and dot key (for channel D') followed by storing the new settings, and the frame changes colour to black.

5.5.3 . "PRINTER TEST" - this test should be carried out in case of any abnormal operation of the printer , press "YES" test execution , the " NO " end of the test .

5.5.4 . "DISPLAY TEST " - the program performs self-test display, showing all of the characters in turn, ending the test: press NO .

5.5.5 . "KEYBOARD TEST" - check the keyboard by pressing the keys one after another. End the test: Press the key twice to "NO".

5.5.6 . "TRANSMISSION TEST" - execution of the test confirm by pressing "YES", the device automatically sends characters to test the network.

Interrupt Test - press "NO " .

5.5.7 . "SETTINGS" - in this tab you can set:

1: The brightness of the LCD (display)

2: Change of time

3: Change of date

4: Laboratory - enter names, see section **4.3**.



5: Transmission - Select the type of transmission to a computer network - see point. **9**.

6. Language.

5.6. Printing of the measure results and of the kinetics of the reaction course.

5.6.1. Setting the type of printer operation

The type of printer operation is totally set for all types of measures:

- press in buttons:  →  → **"1.PRINTER"**
- with button **NO** choose one of the three types of printer operation:
 - a) **"bath"** – summary print-list of all the results for the given patient
 - b) **"auto"** – self-acting printing of the results after ending and acceptance of each measure
 - c) **"off"** – printer is off

5.6.2. Printing of the measure results – 3 ways :

- a) If printer is set in the type of printer operation "Automatic printing" (see item 5.6.1.) the print read out follows self-acting after ending of every measure and

after results acceptance with button "YES". Printed out is current / present accepted measure only (the other measures performed for the given patient aren't printed out). Despite of this the summary print read-out for the given patient can be obtained in "Results" option.

- b) If printer is set in the type of printer operation "Summary printing" the unit doesn't prints the results after ending of a single measure. The print read-out can be obtained at the end of series of measures in "Results" option.
- c) Print read-out can also be obtained (no matter which type of printer operation "Summary" or "Auto" is set) just after the ending of the measure before result acceptance:
 - wait for ending of the measure and appearing of the result on the display screen
 - press button "Printer"

Note! Attention! The above mentioned possibility is inaccessible if the type of printer operation is set on "Disconnected Printer".

5.6.3. Printing of the course of reaction kinetics

Print read-out of the reaction kinetics in graphical form:

- wait for the ending of the measure and appearing of results on the display
- press button with a coma

Note: The analyzer remembers graphic course only the last measurement process

5.6.4. Printing of the program parameters

- press button "Main Menu",
- select "MEASURES" or "PROGRAMMING" or "CALIBRATION"
- select program, e.g. "1 PT"
- press button "Printer"

5.7. Quality Control

Measures of Quality (Inspection) are performed in the following way:

- from "Main Menu" select option "Quality Control"
- Choose the level of control plasma (Normal or Abnormal_L or Abnormal_H)
- Enter LOT selected control plasma
- Select the type of measurement (the NO) and give successively expected ranges value (press YES) (from ... - to ...) with leaflets control plasma – active measured field takes the green
- twice using the key " Main Menu " to enter in the "Measurements ", select the

measurement channel (eg A) and the type of measurement (eg, PT) .

- By pressing the "Additional Menu " enter the measurements of plasma control choose the NO previously described control plasma
- Using plasma control measure
- Analyzer performs measurements or measurements (eg, PT) as previously programming (see Section 5.3.)
- After stopping the counter to check whether the results are within the scope values of control sera
- Pressing the "Printer" , you can print out the result of quality control
- Using the comma key , you can print graphic the reaction

If results are not correct:

- use new vial control plasma
- use new vial main reagent
- perform the calibration of the unit. Remember that this analytic activity was the same for the Calibration, Measures and Quality Insp.

6. Device maintenance and servicing

1. The analyzer requires periodic maintenance performed by the manufacturer or an authorized service (upon presentation of a document of authorization) once a year.

It is not allowed to perform inspections by others or business entities.

2. If the device does not work the next time, leave it connected to the mains (to charge the internal battery clock), including the status of "Main Menu". Do not leave the device in a different state of work, especially in the "Measurements", because they use a source of light, even though the analyzer transitions to "break in measurements"

3. Device maintenance.

Maintenance and cleaning of accessible external surfaces of the analyzer to perform using a soft cloth and washing and sanitizing agents for cleaning the surface of the medical device without the alcohol content. Do not use solvents, alcohol or abrasive agents.

- **daily:** after the fulfilment of the operations insert empty test-tubes into the measuring cavities in order to protect them from the dust. Put cover on the unit.
- **periodic:** once in 14 days clear the measuring cavities from the dust by blowing them through with the rubber pear

- in case the cavities are flood with same liquid clean and dry them with the gauze on the pincette. After the cavities get dry check the state of optical track (as in item 5.5.a) – light control.

7. The frequently asked questions and remedy

Note:

For proper operation of the device we absolutely require the use of cuvettes Chrome .

Do not use washed cuvette or cuvette of other manufacturers!

Use only clean, dry cuvette.

1. Why are there differences in INR results between laboratories ?

This is because of a reagent - thromboplastin derived from different manufacturers. Thromboplastin obtained is different for each manufacturer processes. As a result, there was obtained a satisfactory standardization INR.

2. Why is there a difference between the concentration of fibrinogen denoted in the PT measurement and Clauss fibrinogen?

These are two completely different methods of measuring the concentration of fibrinogen , which results in that the results are not identical. This applies especially to the higher concentrations.

One of the main reasons that affects the performance difference is the absence of a high concentration of the calibrator fibrinogen common to both methods.

3. Where to find help for calibration? Why calibration is so important?

The best help for calibration validation sheet is a analyzer that you filled during training on the use of the analyzer. Following on from the previous calibration , very easily done it for yourself. In addition, section 5.4. This manual describes how to properly calibrate. The calibration should be performed at each change of reagent lot . This is very important because of the differences in properties of each batch of reagent . With proper calibration , you will retain the continuity of the results in patients.

4. How to properly control quality ?

We recommend that quality control before each series of tests on at least two levels of control sera. The resulting best results sent to the computer, where by you will obtain

the appropriate software required quality control charts and statistical analysis.

5. The results of the control sera are incorrect - there are doubts as to the proper operation of the analyzer.

- Please check the hand temperature incubation block - block should be warm , if otherwise there is reason to believe that the analyzer is working properly.

- Please check the light in the optical path TESTS → LIGHT.

For each channel, the value should be between 3000 to 4060.

If the value is too low in one of the channels, this channel should be cleaned and then perform the " adjustment of light".

In the case of the 4095 is sufficient to perform only the " Regulations of light" without clearing the channel (see Owner's Manual point 5.5.1.) .

- If both the above conditions are met, you can assume that the analyzer is working properly.

6. PT inspection results and patients results are incorrect.

• The most common cause of such an event is not properly prepared or stored thromboplastin. Please prepare properly the new thromboplastin paying particular attention to the pipette and the water in which it is dissolved.

• Further, the most common causes:

- Contaminated water used to reconstitute the reagents

- Contaminated glass pipette

- The use of saline instead of water - often in identical containers

- Water for injection opened a few hours earlier , used for other purposes

- Water and reagent cold - straight from the fridge

- Incorrect freezing reagents

- Reagent stayed open too long or heated

- Pipette tips and pipette from different manufacturers/suppliers often do not match

- Damaged pipette - unevenly charge material

- Too slow starter reagent dosing (starting reaction)

7. What is the impact of drugs on the test results ?

Information about the influence of the drug on the coagulation system should be in the package insert of the drug. There is a list of drugs that would define precisely how the drug affects the result of a specific test of the coagulation system.

8. *How to adjust the system to the amount of work done per day?*

When you customize the way up to the amount made you should keep in mind several priorities :

- a) the reproducibility of the results - reliable results at all times use open reagent
- b) saving of reagents



A compromise between the points a) and b) give you an answer on how to best use the reagents for test.

The most important rule is to keep the reagents in accordance with the recommendations contained in the manufacturer's leaflet - primarily you should try to minimize the time in which the reagents are out of the refrigerator and remain open. Here are examples of three ways during test prothrombin time, thromboplastin applying.

Perform 5 tests per day :

After dissolving the thromboplastin reagent should be dispensed into few sterile vials (for example smaller bottles) with an airtight stopper and store in the refrigerator.

During the daily work to heat only the required amount of thromboplastin in a disposable cuvette Chrome on board of the device.

Perform 20 tests per day :

After dissolving the thromboplastin, the reagent should be stored in the refrigerator. The study casting the required amount of reagent for serological test tube, to which a special place is located in a block of incubation Coagulometer. Original thromboplastin bottle all the time must be stored in a refrigerator.

Performing 100 tests per day :

With so many signs we can heat the whole bottle thromboplastin block Coagulometer incubation.

The stability of the reagent is best verified by determining the PT test using control materials.

9. Where to find more detailed information on the study of hemostasis?

Please find the relevant literature in the country of use of the analyzer

10. What are the critical values for coagulation tests ?

The size of the critical values are also available on the website of the National Chamber of Laboratory Diagnosticians

11. A strange result Appears - it is Displayed PT and INR in addition the message "No blood clot."

A common cause of this phenomenon is the lack of or improper calibration for the determination of PT Fibrinogen parallel or lack of calibration for index Quick .

Check PROGRAMMING → PT or in the types of results is correctly set type of mark (√ or X). If you are not using the Quick Fibrinogen PT or they should be set to (x). However, if you use these results calibrate.

12. *When measuring a patient you get the message " No response".*

Repeat the test , check that the tube with the patient's plasma clot was formed .

13. *When measuring a patient you get the message " Dense plasma".*

Check the patient's plasma is lipemic or not. Check the level of light

Tests Menu → Tests → Lights, perform adjustment of light.

Again, take blood from a patient.

14. *CV% coefficient is high.*

Check the dosing pipette.

Check the level of light in the Menu → Tests → Lights , perform adjustment V

15. *What to do when the message " No communication with the measuring block " appears?*

- Turn off the device
- Remove the cuvette from the measuring channels
- Measurement channels blow out with the help of a rubber pear
- Turn on the device
- If the problem persists, contact the service center.

16. *The message " Remove the tube" even when the channel is without tube.*

- Check the light in the menu TESTS → LIGHT.

For each channel, the value should be between 3000 to 4060.

If the value is too low in one of the channels you should clean this channel and then perform the " adjustment of light".

In the case of the 4060 is sufficient to perform only the "Regulations of light" without clearing the channel (see Owner's Manual point . 5.5.1.).

17. *What to do if the device does not turn on?*

You should first of all check if the power switch is illuminated on the rear of the device. If so, replace the fuse in the device. If the switch does not turn on the device, it means that no power in the cable or 230V outlet in the wall.

18. *What to do if the device does not send the results to the laboratory network?*

Please check the connection of the Coagulometer with your computer. Both devices must be powered from a single point (PDU). Please check the settings of the Coagulometer whether the transmission is enabled. Whenever possible, it is worth mentioning coagulometer cable connecting to the computer. If the analyzer still does not send the results to be contacted in the first instance with the supplier of Laboratory Informatics Network .

19. Problems with the printer.

- What to do when the printout is garbled?

Be purged using a rubber pear visible part of the printer and replace the thermal paper on a new one. Remove visible contamination and visible scraps of paper .

- The printer does not print the results, and after selecting TESTS → PRINTER are printing .

It is when you start the analyzer select the " Additional menu" then PRINTER → AUTOMATIC . Press "Main Menu" (the symbol of a book) you go back to the main menu.

Now the printer will print the score immediately after its approval.

20. What to do if you cannot move the flap to facilitate dosing ?

You should try to clean up the flap of accumulated and dry the plasma using a wet swab. Make sure that water does not enter the swab into the hole measurement. Slippers do not remove from Coagulomeer .

21. Message: " Unstable light."

Check the cleanliness of the measuring holes , possibly blow a rubber bulb . If the problem persists contact customer service.

22. Measurement block is not heating.

Contact the service .

23. Measurement block is too hot.

Contact the service .

24. The message " Low battery"

Turn on the device and leave it turned on for about 6 hours. If the problem persists contact customer service .

25. *Scanner - does not read codes.*

You should program the scanner for barcode system

26. *Scanner - does not react to ON.*

Check the connection of the scanner to the device, turn the device off and turn on again.

If the problem persists contact the customer service .

27. *External keyboard - does not work.*

Check the keyboard connection to the device, turn the device off and on again.

If the problem persists contact the customer service .

28. *An automatic start does not turn on :*

- Too slow addition of reagent - add vigorously or when adding press the "A" or "B".

29. *The counter starts too fast before adding reagent:*

- an automatic start due to the deduction of the cuvette or shaking of the device. Stop the measurement by pressing the "A" or "B", remove the cuvette from the hole measuring and re- pressing the "A" or "B" lead to the appearance of the message "Please insert the tube"

- you have inserted the tube into the hole measurement when the screen said " add reagent". Follow *ibid*.

8. Messages

"Please wait <37 ° C."

- Incubation block heats up. If the message remains above 15 minute, Please contact the manufacturer's service.

"Remove the tube."

- Before the next measurement apparatus checks the optical path, and if the light level is too low, the above message appears. To start the measurement, remove the tube.

- If the message appears despite the empty slot measurement (without tube) indicates a dirty test socket or too weak light. It is possible to continue to work after pressing the "A" or "B", but you should take into account the deterioration of the camera parameters. Adjust the light intensity by point. 5.5.a.

"Wrong tube"

- Tube is dirty, dull or scratched or filled with a material of too high density, fault reset: press A or B.

"Dense plasma"

- After the start of measurement - automatic compensation of turbidity is impossible;

scratched tube, too "vague" plasma or incorrect reagent, delete the error press the A or B

"Absence of communication with measuring block"

Interruption or break in communication between measuring module and calculating module.

Reaction: press any button and repeat the function during which there appeared an error or switch off and in some seconds switch on the unit, check that measuring socket is free from test-tube which is to be taken out. If nothing mentioned above helps call for the service.

"Low Battery"

Tension of the inner accumulator is lower than possible 2,5V.

Reaction: press any button to continue the unit program. Service intervention is obligatory to replace the accumulator

"Printer Error"

The printer isn't ready for printing operation longer than 30 sec.

Reaction: press any button to continue the unit program. Select "TESTS" and perform PRINTER TEST. If the message appears again call for the service.

"Transmission Error"

During sending of the results to the computer network transmission was interrupted for more than 5 sec.

When the unit works normally such message doesn't appear.

“Take out the test-tube”

Putting aside empty measuring cavity (without test-tube). That testifies to dirty measuring cavity or too faint light. Further work is possible on pressing button “A” or “B”, remember about the worse state of the unit parameters. Service intervention is obligatory.

“No response”

There has been no response (for chronometric method and turbidimetric method).

“ ***** “

The result is out of range (up or down) of the apparatus. **Reaction:** change the dilution of the solution.

9. The transmission of the results of the device - the computer.

Notes:

1. The device and computer should be connected to a computer network with the power off!
2. The device and computer should be connected to the same phase of the grid.

To select the type of transmission :

Main Menu → Tests → Settings → Enter the code (220565) → Transmission

Select one of the proposed transmission protocols and confirm.

Using :

Main Menu → Additional Menu → Transmission

You can select one of the ways of transmission of measurement results :

- Automatic - transmission after accepting the result
- Cumulative - transmission of selected results from the analyzer memory in the "Results"

10. Decommissioning .

10.1. Decommissioning for repair.












Clean the exterior surfaces of the analyzer with a soft cloth and washing and sanitizing agents for cleaning the surface of the medical device without the alcohol content. Do not

use solvents, alcohol or abrasive agents. Insert an empty test tube to measurement opening to protect it from dirt. Cover the device.

10.2. Decommissioning for disposal.

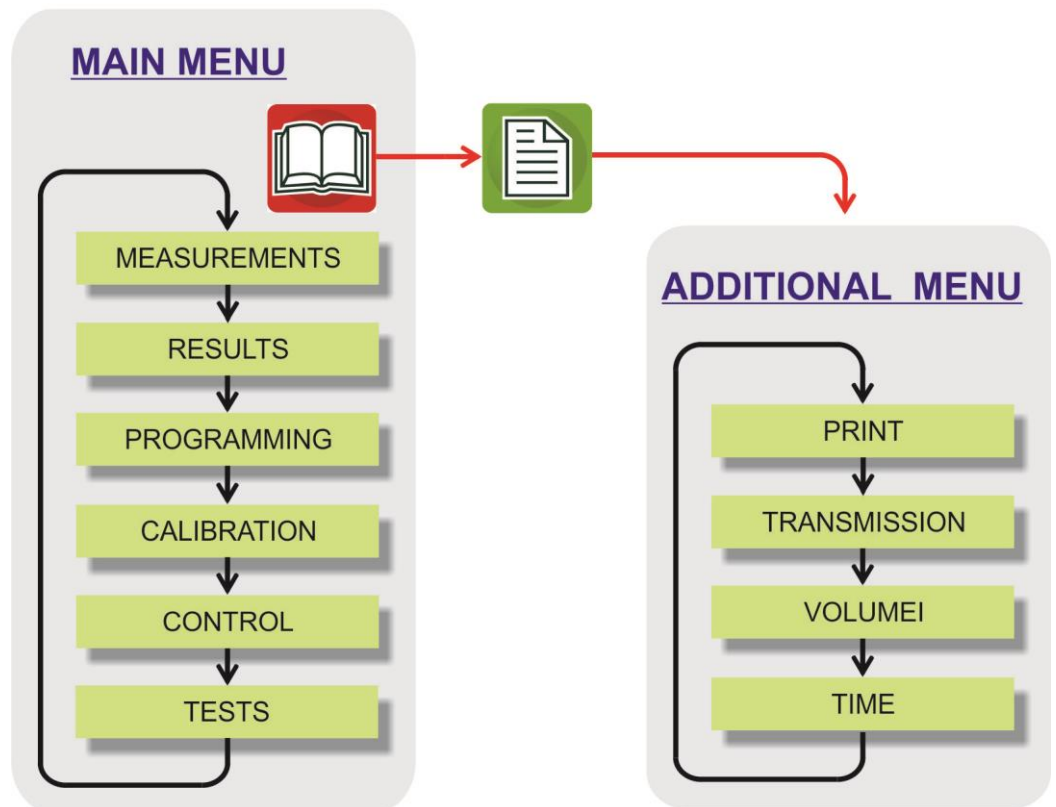
Perform the steps in paragraph 10.1. Proceed in accordance with the provisions of the Waste Electrical and Electronic Equipment, which are valid in the country of use of the analyzer.

11. The symbols and markings.

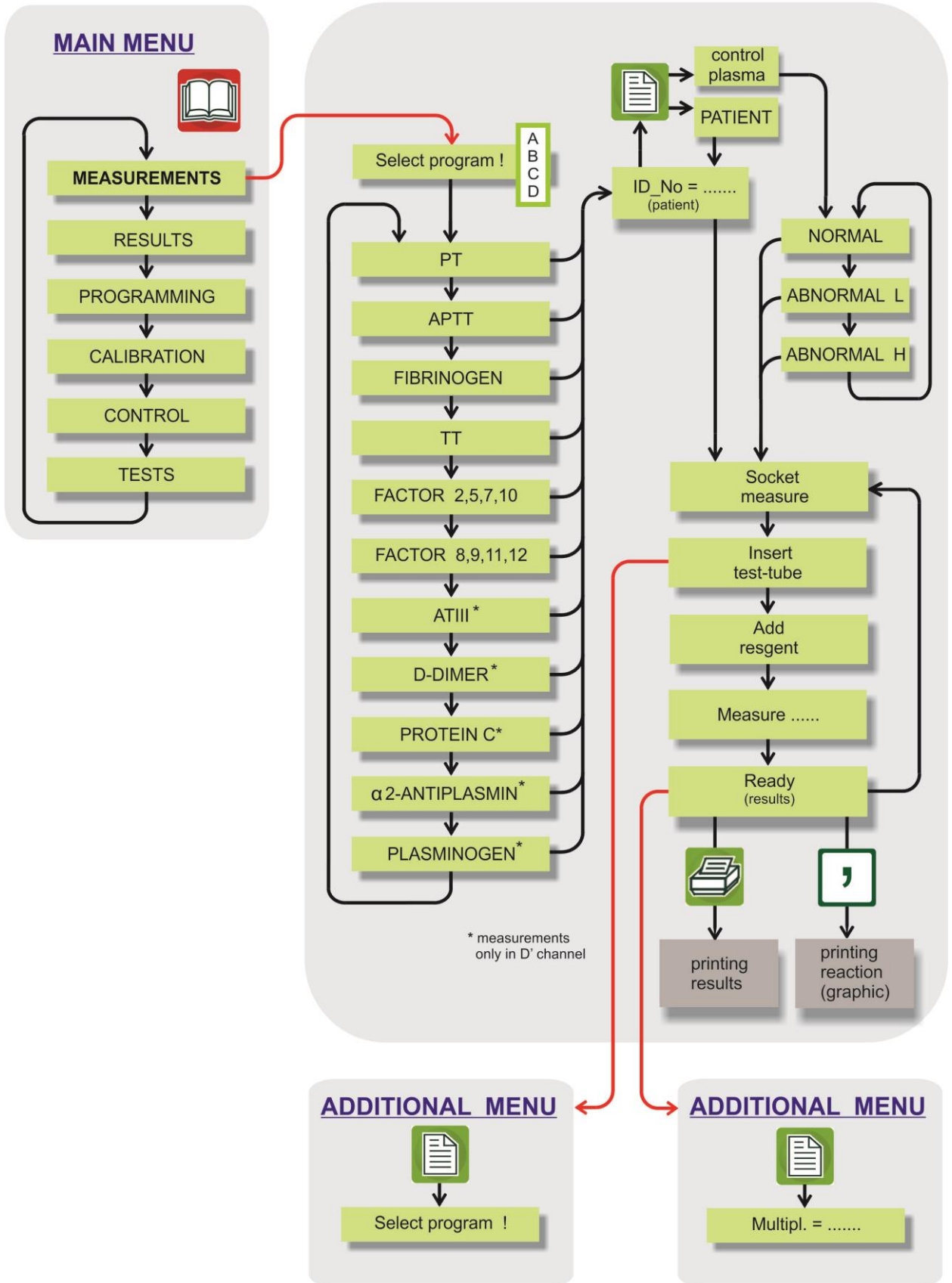
	Temperature range
	Series no
	For use in <i>In Vitro</i> diagnostics
	Use until (month and year)
	Manufacturer
	Biological danger
	Calibrator
	Control material
	Use in conformity with the service manual
	CE marking
	recyclable, do not throw

ANNEX 1

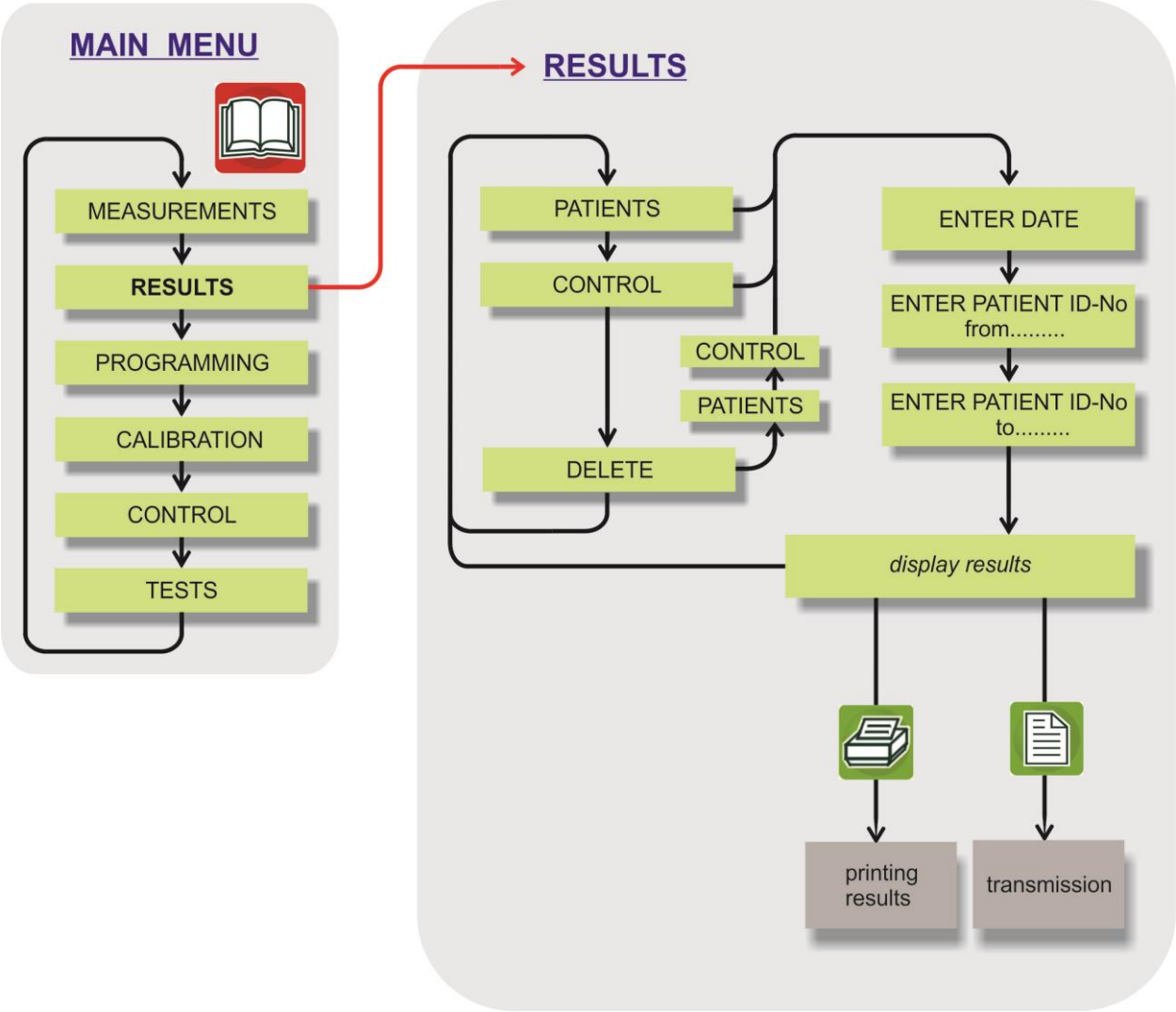
- MAIN MENU
- ADDITIONAL MENU



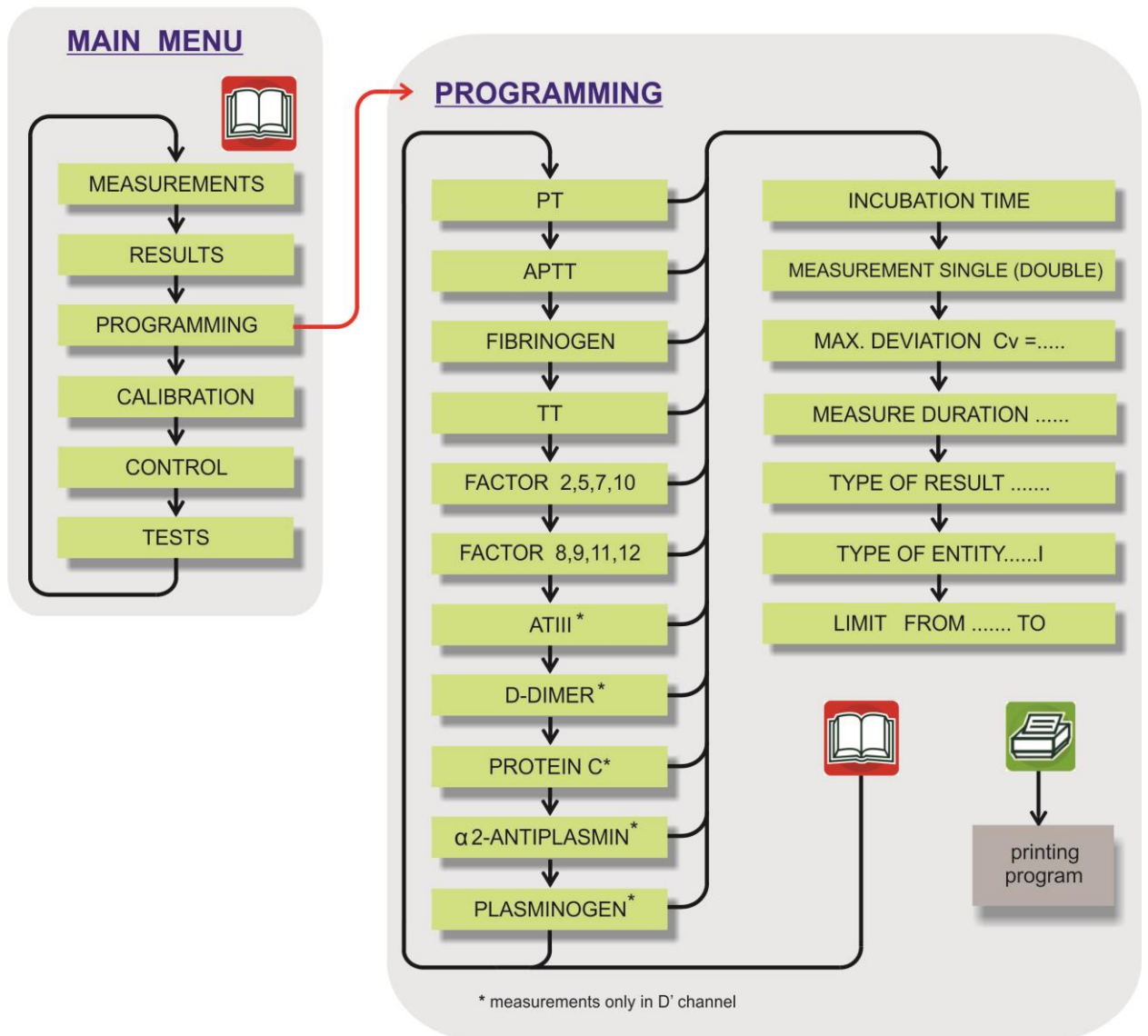
ANNEX 2 - MEASUREMENTS



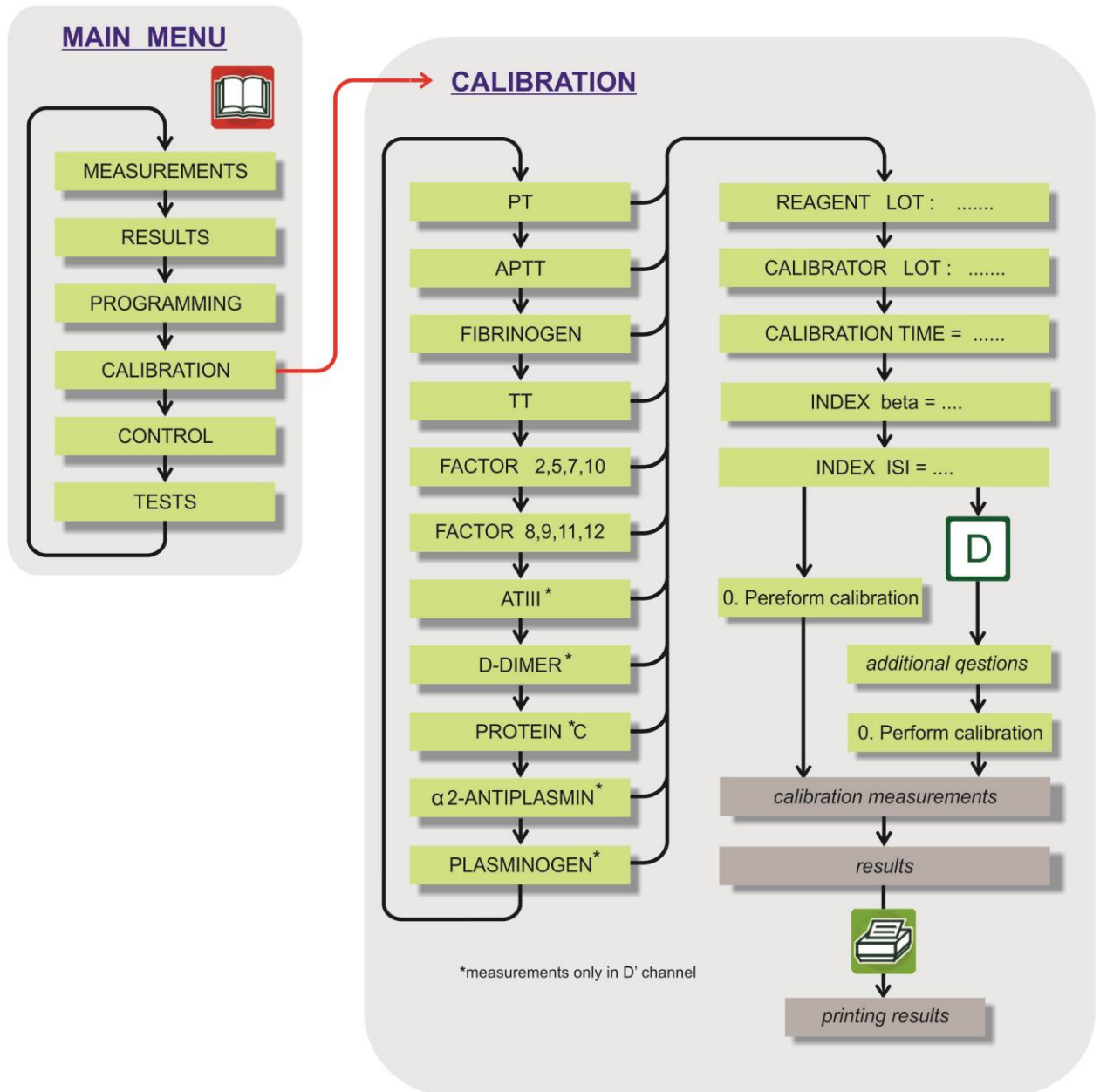
ANNEX 3 - RESULTS



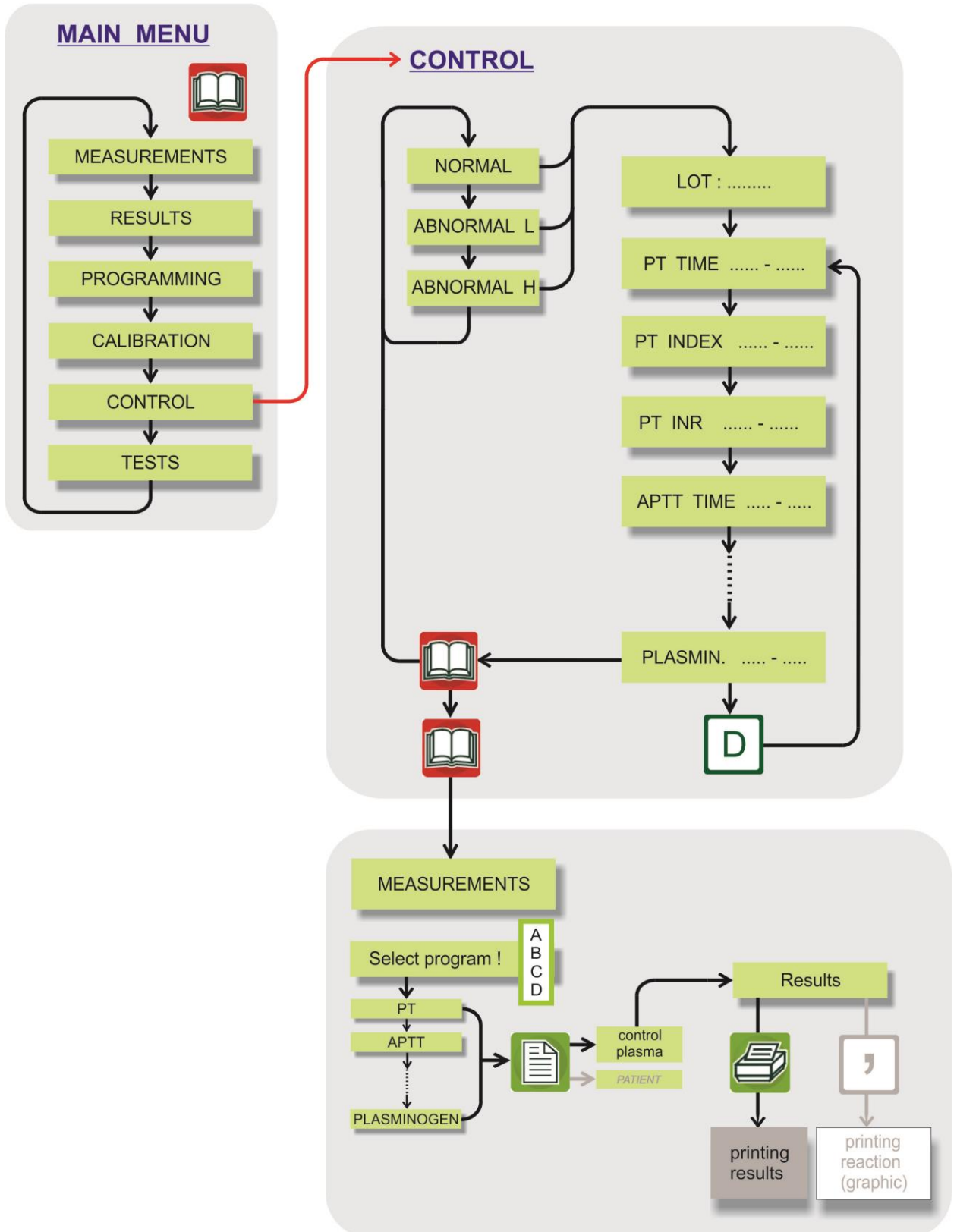
ANNEX 4 - PROGRAMMING



ANNEX 5 - CALIBRATION



ANNEX 6 - CONTROL



ANNEX 7 - TESTS

