

User's Manual

CA-01/02 Coagulometer

CLINDIAG SYSTEMS B.V.B.A.

Contents

1. Introduction	1
1.1 General Information	1
1.2 Test Parameter	1
1.3 Structure and Specification	1
1.3.1 Structure	1
1.3.2 Specification	4
1.3.3 The Function of Keypad	4
2. Operation	4
3. Test of CA-01	5
3.1 Blood Test	6
3.1.1 PT Test	6
3.1.2 FIB Test	8
3.1.3 APTT Test and TT Test	10
3.2 Q.C. Test	10
4. Test of CA-02	11
4.1 Blood Test	11
4.1.1 PT Test	11
4.1.2 FIB Test	13
4.1.3 APTT test and TT test	15
4.2 Q.C. Test	15
5. Edit	16
5.1 PT	16
5.2 FIB	18
5.3 APTT	20
5.4 TT	20
6. Data	21
7. Clear	23
8. Calibration	24
9. Setup	25
9.1 Time Setup	25
9.2 Print Setup	27
9.3 Baud Rate Setup	28
9.4 Motor Setup	29
9.5 Temperature Setup	30

9.6 Backlight Delay Setup	31
9.7 Concentration Unit Setup	32
10. Others	33
11. Reagents	34
11.1 Volume	34
11.1 Reference Time	34
12. Troubleshooting	34
13. Notes	36
14. Transportation and Storage	37
14.1 Transportation	37
14.2 Storage	37
	9.6 Backlight Delay Setup 9.7 Concentration Unit Setup 10. Others 11. Reagents 11.1 Volume 12. Troubleshooting 13. Notes 14. Transportation and Storage 14.1 Transportation 14.2 Storage

1 Introduction

1.1 General Information

CA coagulometer is widely used for plasma coagulation diagnostics. The principle is based on the measurement of optical changes when plasma forms into clots. The test results are in second, ratio or INR.

1.2 Test Parameter

PT: Prothrombin Time or Quick Time

APTT: Activated Partial Thromboplastin Time (also "PTT")

TT: Thrombin Time (also "T")

FIB: Fibrinogen Concentration

1.3 Structure and Specification

1.3.1 Structure

1.3.1.1 Structure of CA-01

Front view shows as Figure 1.



Figure 1

Back view shows as Figure 2.



Figure 2

Main Components show as Figure 3.

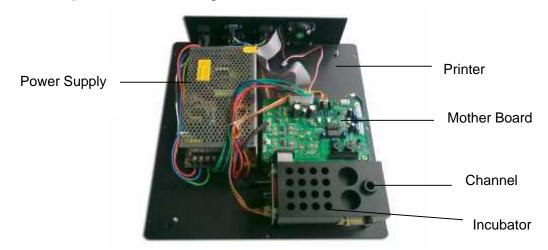


Figure 3

1.3.1.2 Structure of CA-02

Front view shows as Figure 4.



Figure 4

Back view shows as Figure 5.



Figure 5

Main components show as Figure 6.

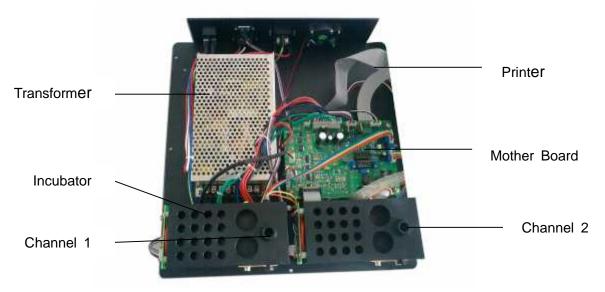


Figure 6

1.3.2 Specification

Table1 Specification

Item	CA-01	CA-02	
Channel	Single	Double	
Built-in Incubator	37℃±0.3,16 sample	37℃±0.3 , capacity for	
	positions and 2 reagent	2x16 positions and 2x2	
	positions	reagent positions	
Dimension	30cm×35cmX15cm	30cm×40cmX15cm	
Weight	4.5kg	5.5kg	
Measuring System	Photometric		
Beam Source	Halogen lamp		
Magnetic Stirring Motor	For measuring cuvette		
Data Input	Membrane keypad		
Display	Back-illuminated LCD		
Printer	Built-in thermal printer, 58mm wide paper		
Operation Language	English, other languages are available on request		
Power Supply	220V, 50HZ /	110V, 60 HZ	

1.3.3 The Function of Keypad

-- Numerical keypad: Input digit of from 0-9

-- .: Input decimal point

-- Feed: To feed printing paper

-- Enter: Confirm

-- Print: Print test results

-- Del: Delete -- Esc: Escape

2 Operation

Switch on the equipment, screen shows as Figure 7 and then Figure 8 or Figure 9.

System initialization please wait...

Figure 7

CA-01

CA-01 Coagulometer

CLINDIAG

25-05-2012 14:21:12

Figure 8

CA-02

CA-02 Coagulometer

CLINDIAG

25-05-2012 14:21:12

Figure 9

Then in 5 seconds, the screen will show the main menu as Figure 10.

1 TEST 2 EDIT
3 DATA 4 CLEAR
5 CAL. 6 SETUP
7 OTHERS

37 25-05-2012 14:21:12

Figure 10

TEST: Perform test

EDIT: Edit test program

DATA: Review data

CLEAR: Clear or recover data CAL.: Instrument calibration

SETUP: System setup OTHERS: Other services

37: The grey shadow will disappear when the incubator reaches 37

3 Test of CA-01

3.1 Blood Test

TEST can only be performed when the incubator reaches 37 .

3.1.1 PT test

Press "1" in the main menu shown as Figure 11 to enter TEST program.

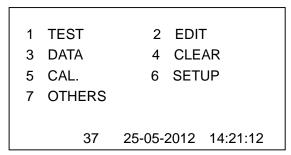


Figure 11

Then the screen shows as Figure 12.

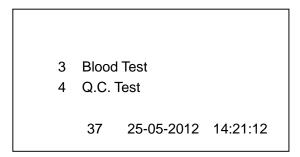


Figure 12

Press "1" to choose blood test, the screen shows as Figure 13.

Item	: -	Sample Test
1	PT	2 APTT
3	FIB	4 TT
	37	25-05-2012 14:21:12

Figure 13

Press "1", the equipment will be ready for PT test, and the screen shows as Figure 14.

Item:	PT	S	ample Te	st
No.	Time(S)	Α%	Incub.T	ISI
1	012.7	100	030	1.12
2	013.8	085		
3	015.5	068	TEST? (Enter/Esc)
4	018.9	051		
5	033.4	025		
	37	25-	05-2012	14:21:12

Figure 14

First one stirring bar has to be put into one cuvette, and then place the cuvette in the reading position.

Check the parameters on the screen, if all correct, press ENTER to begin incubation (if the default parameters need to be edited, press ESC and then refer to 5.1 for PT edit program). When the incubation is finished, the system will send alarms for sampling. Add the sample into the cuvette and the system will begin to account the coacervation time.

Note:

-- Do not remove the cuvette out of the incubator when sampling. When the test is finished, the screen shows as Figure 15.

Item:	: PT	Sa	ample Tes	st
No.	Time(S)	Α%	Incub.T	ISI
1	012.7	100	030 1	1.12
2	013.8	085		
3	015.5	068	Print? (I	Print/Enter)
4	018.9	051	ID	0001
5	033.4	025	Test T:	026.7
			Incub.T:	030.0
			Act.%:	037.0
			Ratio:	2.1
			INR:	2.3
	37	25-0	05-2012	14:21:12

Figure 15

ID: Code of sample test

Test T: Test time

Incub.T: Incubation time

Act.%: PT activity Ratio: PT ratio

INR: PT INR

Print? (Print/Enter): Print out test results or not

Press PRINT to print out test results, and then the equipment will be ready for next PT test.

Press ENTER to quit printing and enter next PT test program.

Please notice that when the automatic print is set before, the equipment will print out test results and then enter next PT test program automatically.

3.1.2 FIB test

Press "1" in the main menu shown as Figure 16 to enter TEST program.

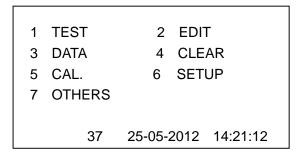


Figure 16

Then the screen shows as Figure 17.

```
1 Blood Test
2 Q.C. Test
37 25-05-2012 14:21:12
```

Figure 17

Press "1" to choose blood test, the screen shows as Figure 18.

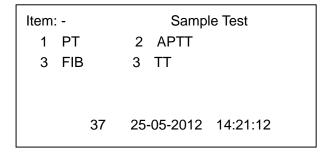


Figure 18

Press "3", the equipment will be ready for FIB test, and the screen shows as

Figure 19.

Item: F	ΊΒ		Sample Test
No.	Time(S)	mg/dL	Incub.T(S)
1	011.5	0305.0	030
2	012.0	0292.0	
3	013.0	0268.0	TEST? (Enter/Esc)
4	014.0	0245.0	
5	015.0	0220.0	
	37	25-05-2	012 14:21:12

Figure 19

First one stirring bar has to be put into one cuvette, and the cuvette be placed in the reading position.

Check the parameters on the screen, if all correct, press ENTER to begin incubation (if the default parameters need to be edited, press ESC and refer to 5.2 for FIB edit program). When the incubation is finished, the equipment alarms sound for sampling. Add the sample into the cuvette and the system will begin to time the coacervation.

When the test is finished, the screen shows as Figure 20.

Item: F	ΊΒ		Sample Test
No.	Time(S)	mg/dL	Incub.T(S)
1	011.5	0305.0	030
2	012.0	0292.0	
3	013.0	0268.0	Print? (Print/Enter)
4	014.0	0245.0	ID 0002
5	015.0	0220.0	Incub.T: 030.0
			Test T: 020.8
			mg/dL: 0075.0
	37	25-05-2	012 14:21:12

Figure 20

ID: Code of sample test Incub.T: Incubation time

Test T: Test time

mg/dL: FIB concentration

Print? (Print/Enter): Print out test results or not

Press PRINT to print out test results, and then the equipment will be ready for next FIB test.

Press ENTER to quit printing and enter next FIB test program.

Please note that when the automatic print is set before, the euipment will print out test results and then enter next FIB test program automatically .

3.1.3 APTT test and TT test

The procedures for APTT and TT are the same as for FIB.

3.2 Q.C. Test

In the main menu shown in Figure 21, press "1" to enter TEST program.

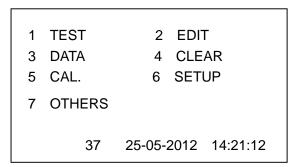


Figure 21

Then the screen shows as Figure 22.

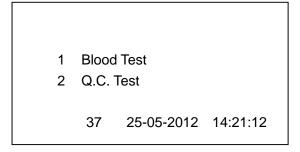


Figure 22

Press "2" to run Q.C. test, the screen shows as Figure 23.

Item	: -	Q.C. Test
1	PT	2 APTT
3	FIB	3 TT
	37	25-05-2012 14:21:12
	37	25-05-2012 14:21:12

Figure 23

Press 1-4 to run Q.C. test for related item. E.g. press "1", the screen shows as Figure 24.

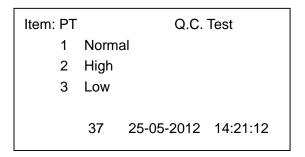


Figure 24

Press 1-3 to select Q.C. test levels. And the detailed operation procedure is the same as sample test (please refer to 3.1).

4 Test of CA-02

4.1 Blood Test

TEST can only be performed when the incubator reaches 37 .

4.1.1 PT test

Press "1" in the main menu shown as Figure 25 to enter TEST program.

3	TEST DATA	2 EDIT 4 CLEAR
_	CAL. OTHERS	6 SETUP
	27	05 05 0040 44:04:40
	37	25-05-2012 14:21:12

Figure 25

Then the screen shows as Figure 26.

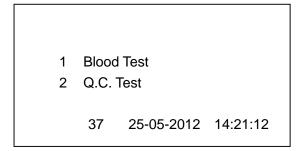


Figure 26

Press "1" to choose blood test, the screen shows as Figure 27.

Item	: -	Sample Test
1	PT	2 APTT
3	FIB	3 TT
	37	25-05-2012 14:21:12

Figure 27

Press "1", the equipment will be ready for PT test, and the screen shows as Figure 28.

Item	: PT	S	ample Te	st
No.	Time(S)	Α%	Incub.T	ISI
1	012.7	100	030	1.12
2	013.8	085		
3	015.5	068	Ch1? (E	nter/Esc)
4	018.9	051		
5	033.4	025		
	37	25-	05-2012	14:21:12

Figure 28

First one stirring bar has to be put into one cuvette, and then place the cuvette in the reading position.

Check the parameters and test channels (1 for channel 1; 2 for channel 2; 3 for channel 1 and 2) on the screen, if all correct, press ENTER to begin incubation (if you need to edit the default parameters, press ESC and refer to 5.1 for PT edit program). When the incubation is finished, the system will send alarms for sampling. Add the sample into the cuvette and the system will begin to account the coacervation time.

Note:

-- Do not remove the cuvette out of the incubator when sampling.

When the test is finished, the screen shows as Figure 29.

Item	: PT	S	ample Tes	st
No.	Time(S)	Α%	Incub.T	ISI
1	012.7	100	030 1	1.12
2	013.8	085		
3	015.5	068	Print? (P	rint/Enter)
4	018.9	051	ID	0003
5	033.4	025	Test T:	026.7
			Incub.T:	030.0
			Act.%:	037.0
			Ratio:	2.1
			INR:	2.3
	37	25-	05-2012	14:21:12

Figure 29

ID: Code of sample test

Test T: Test time

Incub.T: Incubation time

Act.%: PT activity Ratio: PT ratio

INR: PT INR

Print? (Print/Enter): Print out test results or not

Press PRINT to print out test results, and then the equipment will be ready for next PT test.

Press ENTER to quit printing and enter next PT test program.

Please note that when the automatic print is set before, the euipment will print out test results and then enter next PT test program automatically.

4.1.2 FIB test

Press "1" in the main menu shown as Figure 30 to enter TEST program.

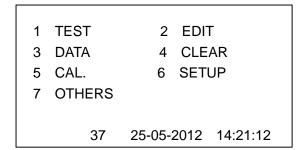


Figure 30

Then the screen shows as Figure 31.

1 Blood Test
2 Q.C. Test
37 25-05-2012 14:21:12

Figure 31

Press "1" to choose blood test, the screen shows as Figure 32.

Item: -		Sample Test
1	PT	2 APTT
3	FIB	3 TT
	37	25-05-2012 14:21:12

Figure 32

Press "3", the equipment will be ready for FIB test, and the screen shows as Figure 33.

Item: F	IB.		Sample Test
No.	Time(S)	mg/dL	Incub.T(S)
1	011.5	0305.0	030
2	012.0	0292.0	
3	013.0	0268.0	Ch1? (Enter/Esc)
4	014.0	0245.0	
5	015.0	0220.0	
	37	25-05-2	012 14:21:12

Figure 33

First one stirring bar has to be put into one cuvette, and the cuvette be placed in the reading position.

Check the parameters and test channels (1 for channel 1; 2 for channel 2; 3 for channel 1 and 2) on the screen, if all correct, press ENTER to begin incubation (if the default parameters need to be edited, press ESC and refer to 5.2 for FIB edit program). When the incubation is finished, the equipment alarms sound for sampling. Add the sample into the cuvette and the system will begin to time the coacervation.

When the test is finished, the screen shows as Figure 34.

Item: FIB			Sample Test
No.	Time(S)	mg/dL	Incub.T(S)
1	011.5	0305.0	030
2	012.0	0292.0	
3	013.0	0268.0	Print? (Print/Enter)
4	014.0	0245.0	ID 0004
5	015.0	0220.0	Incub.T: 030.0
			Test T: 020.8
			mg/dL: 0075.0
	37	25-05-2	2012 14:21:12

Figure 34

ID: Code of sample test Incub.T: Incubation time

Test T: Test time

mg/dL: FIB concentration

Print? (Print/Enter): Print out test results or not

Press PRINT to print out test results, and then the equipment will be ready for next FIB test.

Press ENTER to quit printing and enter next FIB test program.

Please note that when the automatic print is set before, the euipment will print out test results and then enter next FIB test program automatically .

4.1.3 APTT test and TT test

The procedures for APTT and TT are the same as for FIB.

4.2 Q.C. Test

In the main menu shown in Figure 35, press "1" to enter TEST program.

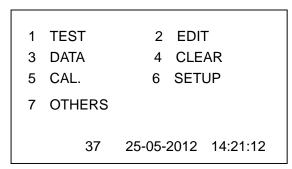


Figure 35

Then the screen shows as Figure 36.

```
1 Blood Test
2 Q.C. Test
37 25-05-2012 14:21:12
```

Figure 36

Press "2" to run Q.C. test, the screen shows as Figure 37.

Item: -		Q.C. Test
1	PT	2 APTT
3	FIB	3 TT
	37	25-05-2012 14:21:12

Figure 37

Press 1-4 to run Q.C. test for related item. E.g. press "1", the screen shows as Figure 38.

Item: PT		Q.C.	Test
1	Norma	al	
2	High		
3	Low		
	37	25-05-2012	14:21:12

Figure 38

Press 1-3 to select Q.C. test levels, and the detailed operation procedure is the same as sample test (please refer to 4.1).

5 Edit

5.1 PT

In the main menu shown as Figure 39.

```
1 TEST 2 EDIT
3 DATA 4 CLEAR
5 CAL. 6 SETUP
7 OTHERS

37°C 25-05-2012 14:21:12
```

Figure 39

Press "2" to enter EDIT menu, the screen shows as Figure 40.

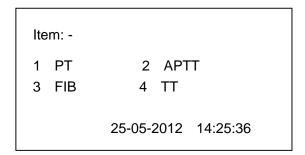


Figure 40

Press "1" to enter PT edit program, the screen shows as Figure 41.

```
Item: PT

Input (2-7)

Point: -

25-05-2012 14:25:36
```

Figure 41

Point: At least 2 points are needed for PT calibration curve. Input digits from 2 to 7 to edit the points you want. E.g. input "2", the screen shows as Figure 42.

```
Item: PT

Point Time (S) A% Incub.T(S) ISI

1 012.7 100 030 1.12

2 013.8 085

25-05-2012 14:25:36
```

Figure 42

Time: Test time

A%: PT activity

Incub.T: Incubation time

ISI: International Standardization Index

Note:

- -- "Time" should consist of 5 digits, e.g. 12.7 should be input as "012.7".
- -- "A" should consist of 3 digits, e.g. 85% should be input as "085", and normally the A% of point 1 is requested to be 100%.
- -- "Incub.T" should consist of 3 digits, the normal value is 30 seconds and input as "030".
- -- "ISI" should consist of 4 digits, and the value is provided by the reagent manufacturer (normally 1.12).

When finished inputting or editing parameters, press ENTER to confirm and save data.

5.2 FIB

Press ESC to come back to the main menu, the screen shows as Figure 43.

```
1 TEST 2 EDIT
3 DATA 4 CLEAR
5 CAL. 6 SETUP
7 OTHERS

37 25-05-2012 14:21:12
```

Figure 43

Press "2" to enter edit menu, the screen shows as Figure 44.

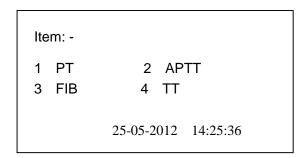


Figure 44

Press "3" to enter FIB edit program, the screen shows as Figure 45

Item: FIB

Input (2-7)
Point:
25-05-2012 14:25:36

Figure 45

Point: At least 3 points are needed for for FIB calibration curve. Input digits from 3 to 7 to edit the points you want. E.g. input "3", the screen shows as Figure 46.

Item: F	FIB		
Point	Time (S)	mg/dL	Incub.T(S)
1	011.5	0305.0	030
2	012.0	0292.0	
3	013.0	0268.0	
	25	-05-2012	14:25:36

Figure 46

Sample dilutions must be prepared with the buffer solutions supplied by the reagent manufacturer and the dilutions have to be one of the five ratios (1:5, 1:10, 1:15, 1:20 and 25). Edit concentration and the corresponding time value using the following method.

Record the sample dilution's concentration, and then test this sample dilution to get the corresponding time (for detailed operation, please refer to 3.1.2 or 4.1.2 for FIB test). Edit the points according to concentration and the corresponding time.

Note:

-- "Incub.T" should consist of 3 digits, the normal value is 30 seconds and input as "030".

When finished inputting or editing values, press ENTER to confirm and save data.

5.3 APTT

Press "Esc" to come back to the main menu, the screen shows as Figure 47.

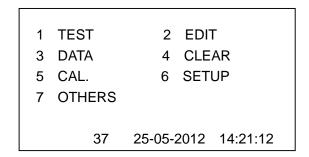


Figure 47

Press "2" to enter edit menu, the screen shows as Figure 48.

```
Item: -

1 PT 2 APTT
3 FIB 4 TT

25-05-2012 14:25:36
```

Figure 48

Press "2" to enter PT edit program, the screen shows as Figure 49.

```
Item: APTT
Ref.T (S) Incub.T (S)
030.0 180
25-05-2012 14:25:36
```

Figure 49

Ref.T (S): Reference time, there are 5 digits for Ref.T (S), e.g. we should input "030.0" meaning 30 seconds. It is used for expressing the final result as a ratio between the sample time and the calibration time or the normal plasma coacervation time.

Incub.T (S): Incubation time which is normally 180 seconds.

5.4 TT

The procedure is the same as APTT test. But normally, the incubation time for TT is 30 seconds.

6 Data

In main menu shown as Figure 50.

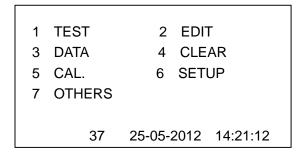


Figure 50

Press "3" to enter DATA program, the screen shows as Figure 51.



Figure 51

Data: Data of test results Curve: Linear test results

CAL.: Calibration
Q.C.: Quality control

Press "1" to enter data menu, the screen shows as Figure 52.

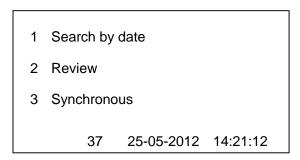


Figure 52

Search by date: Search for and view data of test results by date.

Review: View data of all test results in chronological order.

Synchronous: View data that is in synch with the computer.

Back to Figure 51, press "2" to enter Curve menu, the screen shows as

Figure 53.

```
1 Search by date2 Review37 25-05-2012 14:21:12
```

Figure 53

Search by date: Search for and view linear test results by date.

Review: View all linear test results in chronological order.

Back to Figure 51, press "3" to enter CAL. menu, the screen shows as Figure 54.

```
Item Target Time(S)
PT 012.0 012.0
APTT 012.0 012.0
FIB 012.0 012.0
TT 012.0 012.0
25-05-2012 14:21:12
```

Figure 54

Operators can view calibration data of all test items here.

Back to Figure 51, press "4" to enter Q.C. menu, the screen shows as Figure 55.

```
Item: -

1 PT 2 APTT
2 FIB 4 TT

25-05-2012 14:21:12
```

Figure 55

Choose "1" to enter PT Q.C., the screen shows as Figure 56.

```
Item: PT Level: -

1 Normal Level
2 High Level
2 Low Level

25-05-2012 14:21:12
```

Figure 56

Choose to view Q.C. levels by pressing 1-3, e.g., press "1", the screen shows as Figure 57.

ſ				
	Item:PT	Level: N	Normal	
	No. Q.C.	No. Q.C.	No. Q.C.	
	01 12.0	02 12.0	03 12.1	
	04 12.0	05 12.0	06 12.1	
	07 12.0	08 12.0	09 12.1	
	10 12.0	11 12.0	12 12.1	
	13 12.0			
	2	5-05-2012	14:21:12	

Figure 57

To view Q.C. data of APTT, FIB and TT, the operation is the same as PT.

7 Clear

Press "4" in the main menu shown as Figure 58 to enter CLEAR program.

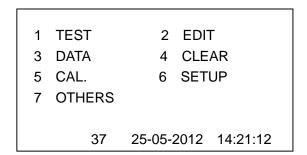


Figure 58

Then the screen shows as Figure 59.

```
1 Delete Sample Data
2 Delete Curve Data
3 Delete CAL. Data
4 Delete Q.C. Data
5 Recover Original Data

37 25-05-2012 14:21:12
```

Figure 59

Choose from 1-4 and then press DEL to delete related data (ESC to cancel deleting), or choose 5 and press ENTER to recover original data (ESC to cancel recovering).

8 Calibration

Please note that this step should only be performed by professionals.

Press "5" in the main menu shown as Figure 60 to run calibration program.

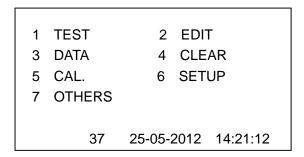


Figure 60

Then the screen shows as Figure 61.

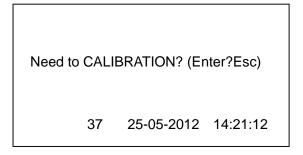


Figure 61

Press ESC to return to the main menu.

Press ENTER to perform calibration, the screen shows as Figure 62.

```
Item: -
1 PT 2 APTT
3 FIB 4 TT

37 25-05-2012 14:21:12
```

Figure 62

Choose from 1-4 to run calibration program for related items. E.g. press 1, the screen shows as Figure 63.

```
Target Time(S): (012.0)
Incub Time(S): (030.0)
37 25-05-2012 14:21:12
```

Figure 63

Edit the figures in the brackets and press ENTER to confirm, then the screen shows as Figure 64.

```
Target Time(S): (012.0)
Incub Time(S): (030.0)
Incub Counters(S): (000.0)
Test Time(S): (____)

Press "Enter" to start INCUB!
37 25-05-2012 14:21:12
```

Figure 64

Press ENTER to start incubation. When it is finished, add sample and reagents to do calibration, and the test time will be shown in the bracket.

9 Setup

9.1 Time Setup

Press "6" in the main menu shown as Figure 65 to run SETUP program.

1 TEST 2 EDIT
3 DATA 4 CLEAR
5 CAL. 6 SETUP
7 OTHERS

37 25-05-2012 14:21:12

Figure 65

Then the screen shows as Figure 66.

- 1 Time Setup
- 2 Print Setup
- 3 Baud Rate Setup
- 4 Motor Setup
- 5 Temperature Setup
- 6 Backlight Delay Setup
- 7 Concentration Unit Setup
 - 37 25-05-2012 14:21:12

Figure 66

Press "1", the screen shows as Figure 67.

- 1 Date Format Setup
- 2 Date & Time Setup

37 25-05-2012 14:21:12

Figure 67

Choose "1" to set up date format, the screen shows as Figure 68.

- 1 Year-Month-Day
- 2 Month-Day-Year
- 3 Day-Month-Year

37 25-05-2012 14:21:12

Figure 68

Press 1-3 to choose date format.

Choose "2" in Figure 67 to set up date and time, the screen shows as Figure 69.

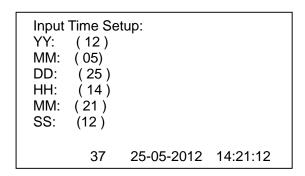


Figure 69

Edit the figures in the brackets, and press ENTER to confirm.

9.2 Print Setup

Press "6" in the main menu shown as Figure 70 to run setup.

```
1 TEST 2 EDIT
3 DATA 4 CLEAR
5 CAL. 6 SETUP
7 OTHERS

37 25-05-2012 14:21:12
```

Figure 70

Then the screen shows as Figure 71.

```
1 Time Setup
2 Print Setup
3 Baud Rate Setup
4 Motor Setup
5 Temperature Setup
6 Backlight Delay Setup
7 Concentration Unit Setup
37 25-05-2012 14:21:12
```

Figure 71

Press "2", the screen shows as Figure 72.

Automatic Print
Manual Print

37 25-05-2012 14:21:12

Figure 72

Automatic Print: The equipment will print out test results automatically.

Manual Print: The equipment will print out test results only when operators choose to print.

9.3 Baud Rate Setup

Press "6" in the main menu shown as Figure 73 to run setup.

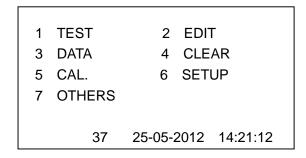


Figure 73

Then the screen shows as Figure 74.

1 Time Setup
2 Print Setup
3 Baud Rate Setup
4 Motor Setup
5 Temperature Setup
6 Backlight Delay Setup
7 Concentration Unit Setup
37 25-05-2012 14:21:12

Figure 74

Press "3", the screen shows as Figure 75.

```
0:2.4Kbps 1:4.8Kbps
2:9.6Kbps 3:14.4Kbps
4:19.2Kbps 5:28.8Kbps
6:38.4Kbps 7:57.6Kbps
8:76.8Kbps 9:115.2Kbps
Baud Rate Select: 4
37 25-05-2012 14:21:12
```

Figure 75

Press 0-9 to select communication speed.

9.4 Motor Setup

Press "6" in the main menu shown as Figure 76 to run setup.

1	TEST	2 EDIT
3	DATA	4 CLEAR
5	CAL.	6 SETUP
7	OTHERS	
	37	25-05-2012 14:21:12

Figure 76

Then the screen shows as Figure 77.

1 Time Setup
2 Print Setup
3 Baud Rate Setup
4 Motor Setup
5 Temperature Setup
6 Backlight Delay Setup
7 Concentration Unit Setup
37 25-05-2012 14:21:12

Figure 77

Press "4", the screen shows as Figure 78.

- 1 Motor Enable Setup
- 2 Motor Off Time Setup

37 25-05-2012 14:21:12

Figure 78

Motor Enable Setup: Enable or disable motor.

Motor Off Time Setup: If motor is enabled, set time for motor to be off.

9.5 Temperature Setup

Press "6" in the main menu shown as Figure 79 to run setup.

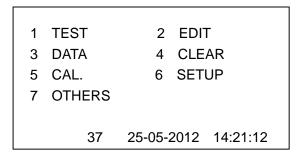


Figure 79

Then the screen shows as Figure 80.

- 1 Time Setup
- 2 Print Setup
- 3 Baud Rate Setup
- 4 Motor Setup
- 5 Temperature Setup
- 6 Backlight Delay Setup
- 7 Concentration Unit Setup

37 25-05-2012 14:21:12

Figure 80

Press "6", the screen shows as Figure 81.

Temperature Enable
Temperature Disable

37 25-05-2012 14:21:12

Figure 81

Temperature Enable: Temperature will show on the screen. Temperature Disable: Temperature will not show on the screen.

9.6 Backlight Delay Setup

Press "6" in the main menu shown as Figure 82 to run setup.

1 TEST 2 EDIT
3 DATA 4 CLEAR
5 CAL. 6 SETUP
7 OTHERS

37 25-05-2012 14:21:12

Figure 82

Then the screen shows as Figure 83.

1 Time Setup
2 Print Setup
3 Baud Rate Setup
4 Motor Setup
5 Temperature Setup
6 Backlight Delay Setup
7 Concentration Unit Setup
37 25-05-2012 14:21:12

Figure 83

Press "6", the screen shows as Figure 84.

Backlight Delay Time (03-99)
20 Minutes
37 25-05-2012 14:21:12

Figure 84

Edit backlight delay time and press ENTER to confirm. E.g. "20 Minutes" means the backlight of the screen will be off when the equipment is not operated for 20 minutes.

9.7 Concentration Unit Setup

Press "6" in the main menu shown as Figure 85 to run setup.

1 TEST 2 EDIT
3 DATA 4 CLEAR
5 CAL. 6 SETUP
7 OTHERS

37 25-05-2012 14:21:12

Figure 85

Then the screen shows as Figure 86.

1 Time Setup
2 Print Setup
3 Baud Rate Setup
4 Motor Setup
5 Temperature Setup
6 Backlight Delay Setup
7 Concentration Unit Setup
37 25-05-2012 14:21:12

Figure 86

Press "7", the screen shows as Figure 87.

Mg/dL g/L 37 25-05-2012 14:21:12

Figure 87

Choose the unit and press ENTER to confirm.

10 Others

Press "7" in the main menu shown as Figure 88 to enter OTHERS menu.

1 TEST 2 EDIT
3 DATA 4 CLEAR
5 CAL. 6 SETUP
7 OTHERS

37 25-05-2012 14:21:12

Figure 88

Then the screen shows as Figure 8.

1 Channel Test
2 Print Test
3 Hardware Test
4 Version Search
5 Parameter Print
37 25-05-2012 14:21:12

Figure 89

Channel Test: Test channel performance

Print Test: Test printer performance

Hardware Test: Test hardware performance Version Search: View software version Parameter Print: Print parameters

11 Reagents

11.1 Volume

PT: 100µl Reagent +50µl Plasma

APTT: 50µl Reagent +50µl Plasma +50µl Calcium chloride

TT: 100µl Reagent +100µl Plasma

FIB: 100µl Diluted plasma + 50µl Reagent

11.2 Reference Time

PT: 11~15seconds

APTT: 23~45seconds

TT: 13~19seconds

FIB: 200~400mg/dl

12 Troubleshooting

12.1 The equipment doesn't work

Possible causes:

-- The fuse is broken, or connection between power and equipment is out of order.

Solution:

-- Replace the fuse, or check if the power cable is well connected.

Note: The equipment has two fuses.

12.2 Unclear screen

Possible causes:

-- Voltage differs in different areas thus the voltage input into the screen is also different.

Solution:

- -- It is always a better choice that engineer adjusts the screen at the time of installation.
- -- User can also adjust the screen manually. Open the cover and find the cable between main board and the screen. Adjust the 203 resistance (green) till the screen is clear.

Note: please do not replace other parts by adjustment.

12.3 The printer doesn't work

Possible causes:

-- The equipment halts.

Solution:

-- Press Reset.

12.4 Continuous paper out

Possible causes:

-- Connection between the print head and the control board is loose.

Solution:

-- The wire is white. Open the cover, remove the head and press the connection by a screwdriver.

Note: Please be careful doing this procedure.

12.5 Only output of current report

Possible causes:

-- The 24C64 Memory is not working properly.

Solution:

-- Replace the memory card.

12.6 Test stops before coagulation

Possible causes and solutions:

- -- The cuvette is placed improperly or the cup is too large to reach the bottom. If the light is out, replace the cup.
- -- When the sample is added, the liquid of in the cup mixed with air. Please add it along the cup-border at a steady rate.
- -- Stirring Bar is not suitable, such as too large, too long or wrong material. It will disrupt the light.
 - -- The volume of the reagents for the test is not correct.

12.7 No results can be produced

Possible causes and solutions:

- -- Forget to put stirring bar into cuvette
- -- If the stirring bar doesn't revolve, please check the motor.
- -- If the outer light is too bright, please place a cap over the opening when test is running.

12.8 Incubation time is too long

Possible causes:

- -- Incubation time of the blood plasma and/or the reagents is not enough.
- Solution:
- -- Incubation time should be no less than 3 minutes normally. In winter, 5 minutes are recommended.

12.9 The equipment needs warming

Possible causes:

- -- Because of the circumstance (especially in winter)
- -- The heater is out of order.

Solution:

- -- Use the air conditioner
- -- Replace the heater

13 Notes

Please pay attention to the following items:

- -- Do not put the equipment in light of high intensity directly. Users can use the black cap to block the light.
 - -- Use a separate power supply to provide stable voltage for the equipment.
 - -- Please use a stabilized voltage supply.
 - -- Before testing, users should incubate the reagent and plasma.
 - -- Ensure that one stirring bar is in one cuvette. Do not leave out the bar.
- -- When doing the FI test, put plasma into the cuvette First, then reagent. For other tests, put reagent First and then plasma.
 - -- The sample should be added quickly and uniformly to prevent bubbles.

- -- Users should use aqua reagent of PTT.
- -- Volume of reagent should be precise.
- -- No object on the testing position during testing.
- -- No shaking when testing.
- -- Do not remove the cuvette during incubation or calculation.
- -- Do not insert opaque object in testing position.
- -- Do not switch the power supply continually.
- -- Do not open the cover if you are not a professional.
- -- Please refer to the reagent manual before operation.

14 Transportation and Storage

14.1 Transportation

The transportation of analyzer should be carried out according to the contract. Transportation with poisonous, harmful and corrosive substances is not allowed.

14.2 Storage

Packed equipments should be placed in the well-ventilated room, avoiding harm from poisonous and corrosive substances.

END

CLINDIAG SYSTEMS B.V.B.A.