Amelung Haemostasis Instruments
SAFETY INSTRUCTIONS

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SI.0 Introduction to Safety Instructions

This brochure is a listing of general safety procedures which should be implemented when using the following Amelung Haemostasis Instruments:

KC1Δ, KC4Δ, AMAX Destiny, AMAX 200 and AMAX 400.

The Amelung Haemostasis Instruments may be used as a coagulation analyzer for the detection of fibrin formation utilizing either mechanical principles (ball method) only (KC instrument line) or utilizing mechanical principles, photo-optical principles, chromogenic kinetic enzyme analysis and micro particle agglutination assays on the AMAX series.

ATTENTION!

Potential Risk: samples **may** contain micro clots which can lead to the generation of false results. In order to reduce the probability of generating such outliers, take the necessary precautions when withdrawing blood samples and take into consideration that results in duplicate dramatically reduce outlier rates.

ATTENTION!

Use only reagent applications approved, verified and provided by Trinity Biotech Plc.

ATTENTION!

The Trinity Biotech reagents have been optimized for use on the Amelung Haemostasis Instruments. Trinity Biotech recommends the use of these reagents on their haemostasis instruments.

SI.1 Installation (AMAX series)

A Trinity Biotech authorized representative is responsible for unpacking, installing and initial setup of the Amelung Haemostasis Instruments.

SI.2 Location Requirements

1. Locate the Amelung Haemostasis Instrument on a level, stable, vibration and dust free counter area that allows air circulation to the back of the instrument. To allow for adequate instrument cooling, there must be at least 10 cm (4 inches) between the back of the instrument and any wall. It should not be positioned next to centrifuges or other equipment that many cause vibration.
2. Minimum Space Requirements (includes instrument and peripheral equipment):
   a) **AMAX Destiny**
   Benchtop version: 56 cm H x 68 cm L x 82 cm W (22 in H x 27 in L x 32 in W)
   b) **AMAX 200**
   Benchtop version: 56 cm H x 82 cm L x 69 cm W (22 in H x 32 in L x 27 in W)
   With base cabinet: 127 cm H x 82 cm L x 69 cm W (50 in H x 32 in L x 27 in W)
   c) **AMAX 400**
   Benchtop version: 62.5 cm H x 140 cm L x 67.5 cm W (25 in H x 56 in L x 27 in W)
   With base cabinet: 130 cm H x 140 cm L x 67.5 cm W (52 in H x 56 in L x 27 in W)
   d) **KC1Δ**
   Benchtop version: 8 cm H x 21 cm L x 14 cm W (3.25 in H x 8.25 in L x 5.5 in W)
   e) **KC4Δ**
   Benchtop version: 12 cm H x 45 cm L x 35.4 cm W (4.7 in H x 17.7 in L x 13.9 in W)
3. Locate the Amelung Haemostasis Instrument in an area of low humidity and little temperature fluctuation. It should not be positioned in an area directly below ventilating ducts, which produce strong air currents.
4. Locate the instrument in an area not illuminated by direct sunlight.
5. The instrument must be located no further than 1.5 m (5 feet) from an electrical outlet. A total of two (2) outlets will be required for the AMAX Destiny and AMAX 200. A total of three (3) outlets will be required for the AMAX 400. One (1) outlet is required for KC1Δ and KC4Δ. The instrument should not be operated from an extension cord that does not employ protective grounding. The electrical outlet line should not be shared with large power-consuming devices, which are frequently turned on and off (e.g. centrifuges, air conditioners or refrigerators). When these types of device power on and off, there may be enough voltage drop on the line to interfere with proper functioning of the instrument.

SI.3 Electrical Requirements and Precautions

1. The instrument is factory equipped with a three-pronged grounding plug designed to be connected with a matching three-pronged receptacle. This procedure is in accordance with the National Electrical Code and other applicable ordinances for this type of installation. Under no circumstances should it be connected to an ungrounded two-pronged plug.
2. Do NOT use an extension cord not equipped to provide protective grounding.
3. Prior to connecting to the electrical outlet, check to ensure that the instrument operating voltage (100 –240 VAC; 50 Hz/60 Hz) (180-265 V or 90-132 V) corresponds to the local line voltage.
4. It is recommended that a Trinity Biotech service representative performs any repair work other than routine maintenance and minor adjustments.
5. Instrument safety is uncertain if the instrument is not operated according to the instructions in the Operation Manual.

SI.4 Removal of Shipping Safety Clamps (AMAX series)

1.

WARNING!
The cable binders (resp. tapes) must be removed from the robot arm X and Y axis drive belts prior to system activation.

2.

WARNING!
The protection on the tip of the probe be removed prior to system activation.

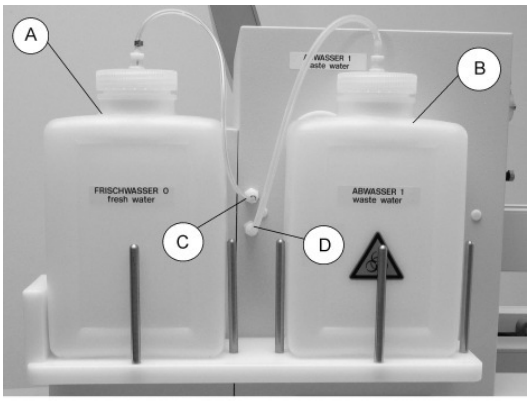
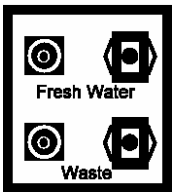
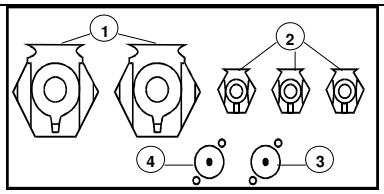
3.

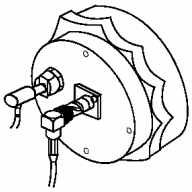
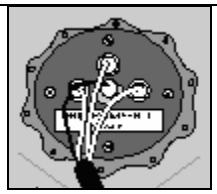
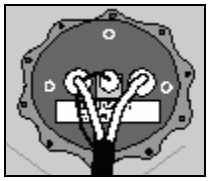
WARNING!
Shipping safety clamps holding the probe must be removed prior to system activation.

SI.5 Fresh Water and Waste Water Connections (AMAX series)

Fresh water for probe rinsing and washing is supplied from a 2 liter container (AMAX Destiny) / 21 liter container (AMAX 200/AMAX 400).

1. Fill the fresh water container to the "Max. Level" line with deionized water. Optimum performance will be obtained if the water is allowed to degas prior to installing on the instrument. Degassing is most easily accomplished by allowing the filled container to sit for 8-12 hours prior to installing on the instrument.
2. **AMAX Destiny:** The fresh water (A) and waste water (B) reservoirs are located on the left side (when facing the instrument front) of the AMAX Destiny.
   a. Place the fresh water in the back position and the waste container in the front position of the holder mounted on the left hand side (when facing the instrument front) of the instrument.
   b. Connect the waste water tubing to the AMAX. The waste water connection (D) is the lower connector.
   c. Connect the fresh water tubing to the AMAX. The fresh water connection (C) is the upper connector.
3. **AMAX 200, AMAX 400:** The fresh water and waste water reservoirs are located under the instrument. See illustrations below for connectors “fresh water in” and “waste water out” respective fresh water sensors and waste water sensors.

<table>
<tr><th>AMAX Destiny</th><th>AMAX 200</th><th colspan="2">AMAX 400</th></tr>
<tr><td rowspan="2"> 
</td><td> 
</td><td colspan="2"> 

1. Waste out 2. Fresh in
3. Fresh sense 4. Waste sense</td></tr>
<tr><td>  </td><td> 
Fresh water (in) container</td><td> 
Waste water (out) container</td></tr>
</table>

WARNING!

The AMAX Destiny waste water tubing is larger than the fresh water tubing.

The connectors at the instrument are different.

DO NOT ATTEMPT TO FORCE THE CONNECTORS!

SI.6 Connection of Power Cables

WARNING!
Ensure that ON/I / OFF/0 switch is set in the OFF position for the Instrument and printer.

WARNING!
The Instrument and associated printer should not be placed on the same electrical line as air conditioners, refrigerators or centrifuges.

WARNING!
Do not connect to an ungrounded two-pronged power outlet.

1. Plug the Instrument power cable into the power socket located on the back of the Instrument. Connect to line voltage.
2. **If applicable**: Plug the printer accessory power cables into the corresponding accessory power sockets. Connect to line voltage.
   For the KC1Δ, AMAX Destiny and AMAX 200 a total of 2, for the AMAX 400 a total of 3 and the KC4Δ 1 line socket(s) must be available.
3. **AMAX 200** / **AMAX Destiny**: Connect the mouse, keyboard and printer to the integrated PC (appropriate) connection points are clearly marked on each PC.

ATTENTION!
The mouse is connected to the bottom connector and the keyboard connector is on top.

SI.7 Power ON

(AMAX series)
WARNING!
Assure that the shipping safety clamps and tape have been removed.

1. (AMAX series) As appropriate ensure that the instrument safety shield is in position. The alignment plug/rods on the instrument lid must be properly seated in the corresponding hole/clips on the top of the instrument.
2. (All instruments) Power up the instrument by pressing the power supply switch from **OFF** / **0** to **ON** / **I**.

WARNING!

Do not switch OFF/0 and ON/I rapidly.
Wait 10–15 seconds after switching OFF before switching ON.

3. (AMAX series) If the instrument has an automated sample and reagent dispense system, at power ON/I, the robot arm (if positioned in the well) will move to the home position and the cuvette tray/cuvette box transport drive belts will reset itself.
4. (All instruments) The instrument will self start the user interface software.
5. (AMAX series) If any one of the instrument module elements fails during power up an error message is displayed. In this situation the operator should contact Instrument Service for assistance.
6. (AMAX series) The instrument start menu displays on the monitor screen
7. (AMAX series) Initially, an **<Error>** message/symbol will display as temperature may be out of range. After 10-20 minutes the system should reach operating temperature.
8. (AMAX series) As appropriate, if the onboard cuvette supply is insufficient a warning message will display.

SI.8 Safely Using the Amelung Instruments

If the Instrument is operated according to the instructions of use there will be no danger to life and health of operating personnel.

SI.8.1 How to Avoid Danger to Life & Health of Operators

1. (AMAX series) The Instrument should not be operated without the safety shield in position.

WARNING! (AMAX Destiny)

The Instrument should not be operated without the safety shield in position. The safety shield ensures that extraneous light does not cause interference to the photometer and protects the operator from injury, which could be caused by the movement of the robot arm.

2. Safety clothing, especially disposable gloves, which may have been in contact with biological material (for example infectious plasma) should be changed immediately and disposed of appropriately.

WARNING!

Plasma, reagents, cuvette trays, cuvettes and waste water are potentially biohazardous waste.
Handle according to laboratory safety regulations for disposal of biohazardous materials.

WARNING!

If the Instrument exhibits defects, which may cause danger to life and health of patients or operators the system must not be used.

Breakdowns or defects on the Instrument, which have caused damage to a patient or operator, have to be immediately referred to the direct supervisor.

SI.8.2 How to Avoid Damage to the Instrument

WARNING!

Use only original Trinity Biotech accessories.

WARNING!

Regard the displayed error messages.

SI.8.3 Intended Use

The Amelung Haemostasis Instruments are intended to be used as a coagulation analyzer for the detection of fibrin formation utilizing either mechanical principles (ball method) only (KC instrument line) or utilizing mechanical principles, photo-optical principles, chromogenic kinetic enzyme analysis and micro particle agglutination assays on the AMAX series.

WARNING!

This instrument is classified as Class A equipment. This equipment can cause radio interference in residential areas. In this case it is possible that the user may be required to take appropriate action.

WARNING!

This instrument is classified as an In Vitro Diagnostics Device.

SI.8.4 Who May Use the Amelung Haemostasis Instruments?

The instruments should only be used by trained personnel, whose knowledge, training and experience guarantees correct handling of the system.

1. Operators must have been instructed in the use of the Amelung instruments and must operate exclusively in accordance to the instructions contained in this manual.
2. Refer to appropriate sections in this manual for instructions on how to operate the Amelung Haemostasis Instruments.

WARNING!

Under no circumstances should any software other than that authorized by Trinity Biotech Plc be installed on the (integrated) AMAX series PCs.

WARNING!

Under no circumstances should any consumables other than that authorized by Trinity Biotech Plc be used on the Amelung Haemostasis Instrument.

SI.9 Symbols used on the Amelung Haemostasis Instruments and Consumables

Symbol	Meaning	Used on/in
	Do not reuse	Cuvette boxes, Cuvette Trays, Cuvettes & Balls
	In Vitro Diagnostics Device	Operation Manuals, Cuvette boxes
	Biological risks	AMAX Destiny AMAX 200 AMAX 400
	Consult instructions for use	AMAX Destiny AMAX 200 AMAX 400 KC1Δ KC4Δ
	Batch code number	System Cleaner
	Manufactured by	Diverse Consumables
 YYYY-MM	Use By Date YYYY-MM	System Cleaner
	Temperature limits for storage	Cuvettes, Cuvette Trays System Cleaner
	By no means operate without the cover plate. The cover plate ensures that extraneous light does not cause interference to the photometer.	AMAX Destiny
	Do not touch while instrument is in operation. May be hazardous to operator. May cause damage to instrument	Robot Gantry (AMAX Destiny AMAX 200, AMAX 400)
Position of model/ serial number label	Back of instrument	AMAX Destiny AMAX 200 AMAX 400 KC1Δ KC4Δ

Symbol	Meaning	Used on/in
COM Port connection for keyboard, mouse and printer	Right hand side of instrument	AMAX Destiny AMAX 200
COM Port connection for keyboard, mouse and printer	On back of PC	AMAX 400
Consumables	Use only consumables recommended by Trinity Biotech Plc.	Operation Manual
Reagent Applications	Use only reagent applications approved, verified and provided by Trinity Biotech Plc.	Reagent box inserts, application sheet and Operation Manual

KC 4 Amelung

OPERATION MANUAL

Software Version 2.3

Instrument manufactured by:
Trinity Biotech plc,
IDA Business Park,
Bray, Co. Wicklow,
Ireland

IVD

CE

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Tel. +1 908 898 1500

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TRINITY BIOTECH INSTRUMENT WARRANTY

Trinity Biotech Plc ("Trinity Biotech") warrants that instruments it sells are free from defects in workmanship and materials during normal use by the original purchaser or designated agent.

This Warranty shall continue for a period of one year from the date of invoice to the original purchaser, or until title is transferred from the original purchaser, whichever occurs first (the "Warranty Period").

If any defects occur during the Warranty Period, contact the Trinity Biotech Service Centre or its authorised distributor representative immediately, and be prepared to furnish pertinent details concerning the defect, the model number, installation date and the serial number.

Warranty service for instrumentation purchased direct from Trinity Biotech is provided 8:30 a.m. through 5:00 p.m., Monday through Friday, except on Trinity Biotech observed holidays. For hours of service in areas other than the USA, UK and Germany, please contact your local authorised Trinity Biotech distributor. Any service performed at other times, and all service required to correct defects or malfunctions not covered by this Warranty, will be billed on a time-and-material basis at Trinity Biotech's labour rates then in effect.

This Warranty does not cover defects or malfunctions which: (1) are not reported to Trinity Biotech or it's authorised distributor during the Warranty Period and within one week of occurrence; (2) result from chemical decomposition or corrosion; (3) are described in the applicable Trinity Biotech Guide; (4) result from maintenance, repair, or modification performed without Trinity Biotech's or it's authorised distributor's prior written authorization; or (5) result from misuse, abuse or accident.

Trinity Biotech's liability for all matters arising from the supply, installation, use, repair, and maintenance of the instrument, whether arising under this Warranty or otherwise, shall be limited solely to the repair or (at Trinity Biotech's or it's authorised distributor's sole discretion) replacement of the instrument or of components thereof. In no event shall Trinity Biotech or its authorised distributors be liable for injuries sustained by third parties, incidental or consequential damages, or lost profits.

Replaced parts shall become the property of Trinity Biotech or its authorised distributors.

THE FOREGOING IS THE SOLE WARRANTY MADE BY TRINITY BIOTECH REGARDING THE INSTRUMENT, AND TRINITY BIOTECH SPECIFICALLY DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND OF FITNESS FOR A PARTICULAR PURPOSE.

1. Introduction

1.1 Intended Use

The KC4Δ Amelung is a semi-automated mechanical clot detection system designed for the determination of prothrombin times (PT), activated partial thromboplastin times (APTT), fibrinogen concentrations and other clotting tests. Any clotting time test that has fibrin formation as its endpoint may be performed on the KC4Δ. Measurement can be qualitative or quantitative. When used in conjunction with appropriate reagents, the sample can be plasma or whole blood. Addition of both sample and reagents is manual. The time measurement of the clotting endpoint is automated.

1.2 Principle of Operation

The system utilizes a special cuvette in which there is a stainless steel ball. Sample is added to the cuvette. After an appropriate incubation period, the cuvette is placed into the measuring well of the KC4Δ. The measuring well rotates slowly causing the cuvette to rotate along its longitudinal axis. Because the cuvette is positioned at a slight angle, gravity and inertia always position the ball at the lowest point of the cuvette. Exactly opposite the ball-position is a magnetic sensor. With the addition of appropriate reagent, a timer is started. As coagulation takes place fibrin strands form in the reaction mixture. The fibrin strands pull the ball away from its inertia position that triggers an impulse in the magnetic sensor. This impulse electronically stops the timer (see illustration).

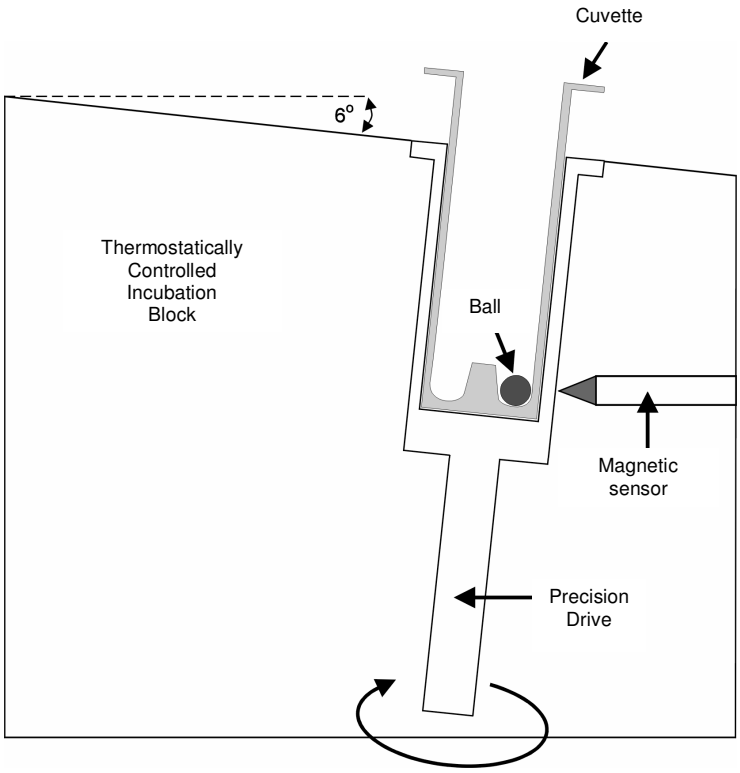


Figure 1.1

1.3 Instrument Specifications

Type:	Coagulation Analyzer; Bench-top
Online:	Unidirectional
Principle:	Ball Method
Measuring Channels:	4
Display:	Liquid Crystal Display (LCD)
Incubation Wells:	8
Reagent Well:	5
Dimensions:	
Height:	12 cm
Width:	35.4 cm
Depth:	45.0 cm
Weight:	6.3 kg
Power supply:	
Primary Voltage:	100–240 V/50–60 Hz
Power Consumption:	1.5 A at 100 V; 0.4 A at 230 V
Measurement Time	
Minimum:	4.5seconds
Maximum:	999.9 seconds

1.4 Performance Characteristics

The overall performance of any testing performed with the KC4Δ is not only dependent on the instrument but is also a function of specimen collection, sample handling techniques and on the accuracy and precision of the sample and reagent dispensing system used.

1.4.1 Correlation

The following linear regression data were obtained during evaluation to show equivalence with a commercially available mechanical coagulation analyzer.

	Prothrombin Time	APTT
Number	121	110
Correlation Coefficient	0.998	0.896
Slope	1.051	1.235
Intercept	–0.241	0.873

The following linear regression data were obtained during evaluation to show equivalence with a commercially available photo-optical coagulation analyzer.

	Fibrinogen	Factor X	Factor IX
Number	109	112	101
Correlation Coefficient	0.930	0.974	0.897
Slope	1.067	1.010	0.958
Intercept	30.749	–0.166	3.403

The following linear regression data were obtained in three physician's office laboratories (POL) during evaluation to show equivalence with manufacturer derived results on the KC4Δ

POL #1	Thromboplastin Time	APTT
Number	47	44
Correlation Coefficient	0.991	0.960
Slope	0.981	1.066
Intercept	0.492	0.379

POL #2	Thromboplastin Time	APTT
Number	45	46
Correlation Coefficient	0.989	0.965
Slope	1.019	1.029
Intercept	–0.248	1.021

POL #3	Thromboplastin Time	APTT
Number	52	47
Correlation Coefficient	0.974	0.927
Slope	1.012	0.786
Intercept	0.326	9.470

1.4.2 Precision: Prothrombin Time (PT)

Imprecision on the KC4Δ was evaluated at three levels according to the NCCLS EP5-T2 protocol.

	Low	Mid	High
Mean	13.20	33.53	39.66
Total imprecision (CV %)	2.03	2.50	4.18
Within-run imprecision	1.02	1.28	1.53

PT total imprecision was evaluated at three physician's office laboratories at three levels according to the NCCLS EP10-T protocol. Within-run imprecision (n = 20 on each level) was evaluated at three physician's office laboratories at two levels.

POL # 1	Low	Mid	High
Total Mean	13.1	26.8	42.9
Total Imprecision (CV %)	1.97	1.63	2.47
Within-Run Mean	12.7		44.1
Within-Run Imprecision (CV %)	1.3		1.1

POL # 2	Low	Mid	High
Total Mean	12.1	23.3	40.7
Total Imprecision (CV %)	2.59	7.12	3.0
Within-Run Mean	12.1		41.7
Within-Run Imprecision (CV %)	2.6		1.8

POL # 3	Low	Mid	High
Total Mean	11.3	22.8	34.2
Total Imprecision (CV %)	1.57	7.41	0.50
Within-Run Mean	11.4		34.7
Within-Run Imprecision (CV %)	2.0		1.3

1.4.3 Precision: Activated Partial Thromboplastin Time (APTT)

APTT imprecision on the KC4Δ was evaluated at three levels according to the NCCLS EP5-T2 protocol.

	Low	Mid	High
Mean	28.55	51.01	75.78
Total imprecision (CV%)	3.12	3.41	3.21
Within-run imprecision	1.47	1.60	1.37

APTT total imprecision was evaluated at three physician's office laboratories at three levels according to the NCCLS EP10-T protocol. Within-run imprecision (n = 20 on each level) was evaluated at three physician's office laboratories at two levels.

POL #1	Low	Mid	High
Total Mean	29.0	43.3	57.6
Total Imprecision (CV %)	2.83	3.15	1.87
Within-Run Mean	30.8		57.5
Within-Run Imprecision (CV %)	2.7		1.6

POL #2	Low	Mid	High
Total Mean	29.2	42.7	57.0
Total Imprecision (CV %)	4.38	2.29	2.84
Within-Run Mean	28.2		57.1
Within-Run Imprecision (CV %)	2.1		1.7

POL # 3	Low	Mid	High
Total Mean	30.0	54.7	68.6
Total Imprecision (CV %)	1.87	1.80	2.13
Within-Run Mean	26.9		64.4
Within-Run Imprecision (CV %)	1.4		2.5

1.4.4 Precision: Fibrinogen

Fibrinogen imprecision was evaluated at three levels according to the NCCLS EP5-T2 protocol.

	Low	Mid	High
Mean (mg/dl)	104.09	154.10	323.53
Total imprecision (CV%)	3.53	6.21	4.36
Within-run imprecision	2.05	2.86	2.12

1.4.5 Precision Factor X

The imprecision was evaluated at three levels according to the NCCLS EP5-T2 protocol.

	Low	Mid	High
Mean (mg/dl)	31	57	102
Total imprecision (CV %)	8.28	5.71	5.22
Within-run imprecision	2.63	2.22	2.20

1.4.6 Precision: Factor IX

The imprecision was evaluated at three levels according to the NCCLS EP5-T2 protocol.

	Low	Mid	High
Mean (mg/dl)	24	49	98
Total imprecision (CV %)	5.88	6.89	4.06
Within-run imprecision	3.96	4.04	2.54

1.5 Front View KC4Δ Amelung

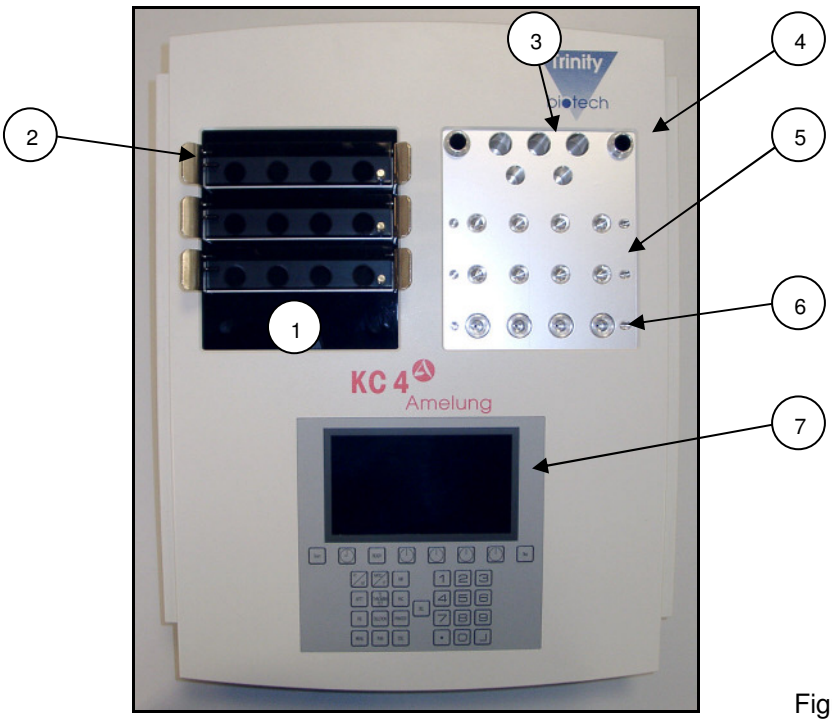


Figure 1.2

Item		Function or Description
1.	Preparation area	Used for preparing samples before the incubation step.
2.	Sample holders	Used for transferring cuvettes from preparation area to reaction incubation wells and rotating test positions.
3.	Reagent warming wells (5)	Three 15 mm, and two 11 mm heated used to warm reagents.
4.	Pipette Tubes (2)	Used to store and preheat the pipettes when not in use.
5.	Reaction incubation wells (8)	Heated wells used for incubation of sample and first reagent.
6.	Rotating test positions (4)	Positions where start reagent is added and the clotting time is measured.
7.	Display Screen	Displays incubation times, clotting times, programming selections and other menus.

1.6 Keypad

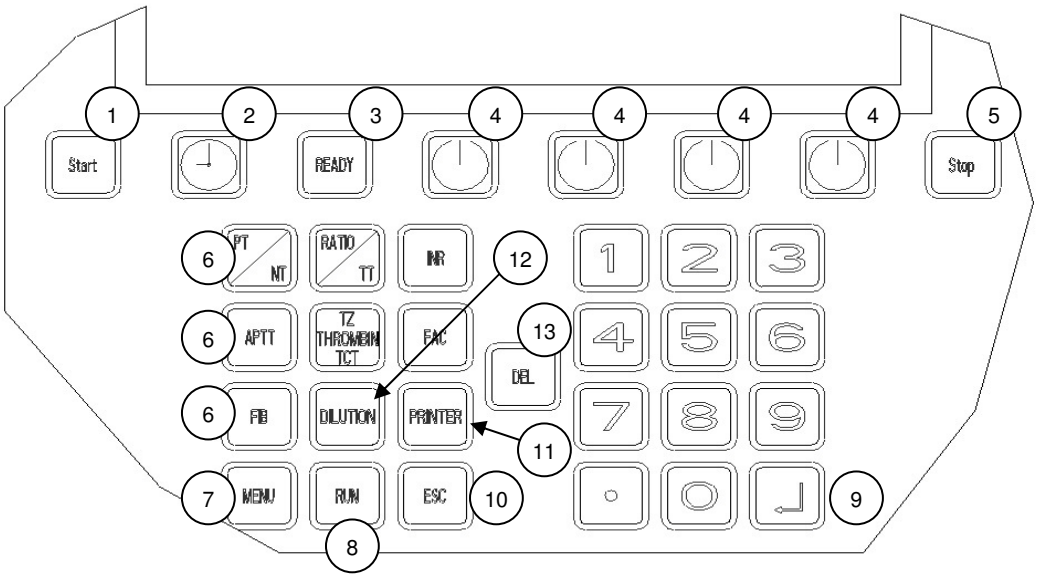


Figure 1.3

Item		Function/Description
1.	**START** Key	Activates the automatic measurement timer
2.	**Incubations Key**	Starts the incubation timers
3.	**READY** Key	Skips the incubation time
4.	**Channel** Key	Activates the corresponding measuring channel for incubation time, measurement or abort
5.	**STOP Key**	Interrupts measurement
6.	**Function** Keys	Used for programming or selecting tests
7.	**MENU** Key	Returns to Main Menu
8.	**RUN Key**	Returns to RUN menu
9.	↵ (Enter)	ENTER
10.	**ESC Key**	Cancels a function
11.	**PRINTER Key** (Printer/LIS)	Activates the output menu
12.	**DILUTION Key**	Used to change the patient dilution for the FIB test (Section 5.10)
13.	**DEL Key** (Delete)	Deletes the previous entry

1.7 Back View

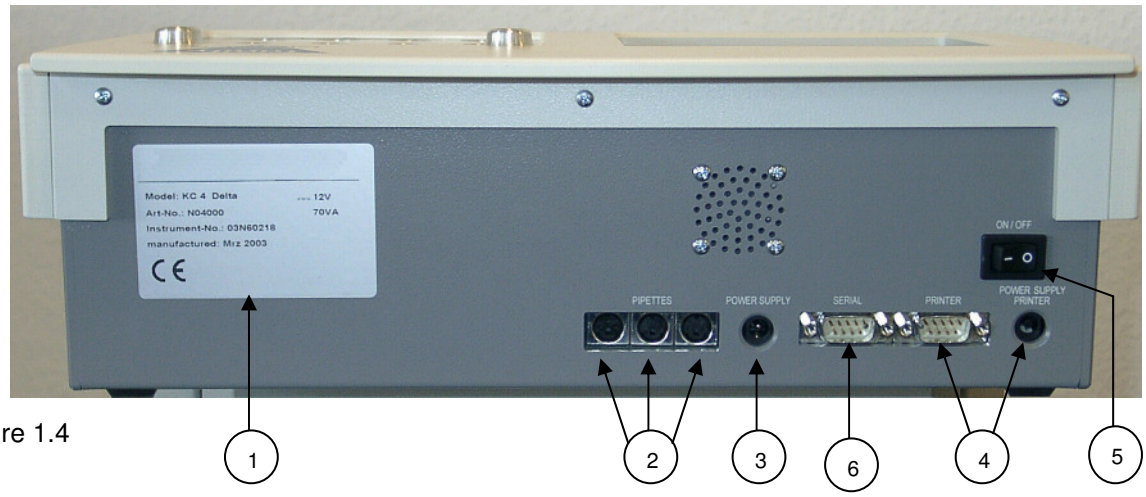


Figure 1.4

Item		Function or Description
1.	Label	
2.	Automatic Multipette(s)® sockets	Used to connect Multipipettes® (remove the cap plug in the Multipette®)
3.	Power input	Used to connect the instrument to the power supply
4.	Thermal printer port	Thermal printer connection
5.	Power switch	Powers the instrument ON/OFF
6.	Serial interface (RS232)	Used for transferring data to the LIS (Laboratory Information System)

1.8 Multipette®

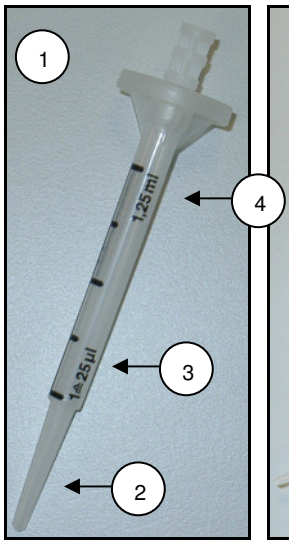


Figure 1.5 Combitip®

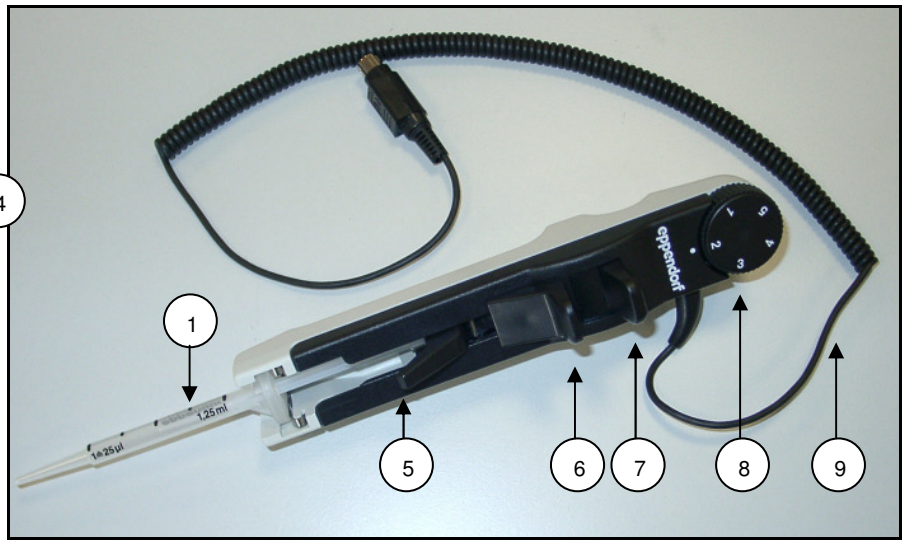


Figure 1.6 Multipette®

Item	Function/Description
1. Combitip®	Tip used on the Multipette®
2. Combitip®-aspiration/dispense cone	Portion of the tip that aspirates reagent.
3. Combitip® smallest pipetting volume	
4. Max. filling volume for the Combitip®	
5. Locking Clamp	Used to firmly clamp the Combitip® in the Multipipette®.
6. Filling lever	The Combitip® is filled by sliding the lever upward.
7. Dispense lever	The volume is dispensed by pressing the dispense lever down until it stops
8. Volume selection dial	Determines pipetting volume: setting (1-5) multiplied by the minimum pipetting volume of the Combitip (1.25 ml or 2.5 ml pipette tips).
9. Start cable	Connects pipette to instrument.

Detailed instructions for the use of the Multipipette® can be found in the Multipipette® instruction booklet.

1.9 Thermal Printer (Optional)

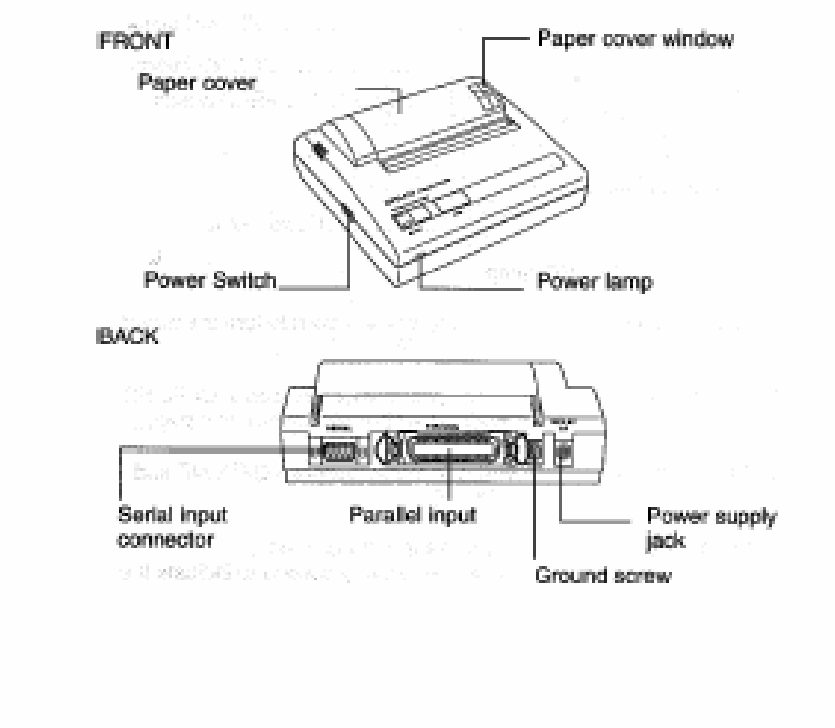


Figure 1.7

More detailed description and instructions for the use of the Thermal Printer can be found in the Thermal Printer instruction booklet.

2. Installation

2.1 Unpacking

The KC4Δ Coagulation Analyzer is shipped in a transport box designed to protect the instrument from damage during shipment. If damage is apparent, immediately notify the shipping company. Note the damage on the shipping bill of lading and notify your Trinity Biotech Sales Representative.

2.2 KC4Δ Startup Kit

Carefully remove the instrument and accessories from the transport box. Check that the following items have been included:

- ► **KC4Δ**
- ► **Power Supply and Power Cable**
- ► **Starter-Set KC4Δ:**

Catalogue #	Description	Quantity
Z04140	Tetravettes Micro Box with 150 pieces	1 Box
848040	Dust Cover KC4Δ	1 each
832150	Tubes, Glass 14,5x85mm	50 each
832155	Tubes, Plastic 14,5x85mm	100 each
838012	Combitip® 1,25ml	5 each

Additional Products and Consumables:

Catalogue #	Item
Z09165	Printer DPU 414-30B KC Delta
852015 *	KCΔ Series Thermal Printer Paper
P02100	KC4Δ Multipette® with Starter Cable
838012 *	KC4Δ Combitips® 1.25 ml
838025 *	KC4Δ Combitips® 2.50 ml
838830	Pipette Delta 50/100/200µl
837045 *	Pipette Tips, Yellow, 200µl, 10 trays
832150 *	Tubes, Glass 14,5x85mm (50 pieces)
832155 *	Tubes, Plastic 14,5x85mm (100 pieces)
Z04140 *	Tetravettes Micro Box with 150 pieces
Z05111 *	KC Micro Cuvettes with Ball Dispenser
111028 *	KC Pipette Tube Sleeves

*** These are consumable items and should be ordered as needed.**

Pipettes are required for the test performance. Although the use of a Multipette® will ensure the start of the timing measurement is simultaneous with the addition of the reagent, it is not mandatory.

Read the Operation Manual carefully prior to using the KC4Δ Coagulation Analyzer. The Operation Manual has been written to provide the most comprehensive understanding of the operation of the KC4Δ Coagulation Analyzer and to enable you to fully utilize the features of the instrument.

2.3 Location Requirements

1. Place the KC4Δ Coagulation Analyzer on a stable, vibration and dust free work surface. It should not be positioned next to a centrifuge or other equipment, which may cause vibration. The KC4Δ Coagulation Analyzer should also be protected from moisture.
2. To avoid exceeding the control range of the instrument, place the KC4Δ Coagulation Analyzer in an area with a maximum room temperature of 30°C. It should not be positioned in an area directly below ventilating ducts which produce strong air currents. Do not expose the KC4Δ Coagulation Analyzer to direct sunlight. Sunlight influences the temperature control.
3. It is preferable to place the KC4Δ Coagulation Analyzer in an area which is no further than (6 ft.) 1.8 m from an electrical outlet. The instrument should not be operated from an extension cord which does not employ protective grounding. The electrical outlet used should not be shared with any devices, which consume large amounts of power on a cyclic basis (e.g., centrifuges, air conditioners, and refrigerators). When these type of devices cycle on and off, there may be a voltage drop in the line which could interfere with the proper functioning of the instrument.

2.4 Electrical Requirements and Precautions

The KC4Δ is connected to the mains power circuit by way of an external power pack. Using the power pack connection cable connect the power pack to the KC4Δ. Using the power supply cable provided connect the power pack into the mains supply circuit.

1. Do NOT use an extension cord not equipped to provide protective grounding.
2. The KC4Δ is factory equipped with a three-pronged grounding plug designed to be connected with a matching three-pronged receptacle. Under no circumstances should it be connected to an ungrounded two-pronged plug. This procedure is in accordance with the National Electrical Code and other applicable ordinances for this type of installation.
3. It is recommended that a Trinity Biotech service representative perform any repair work other than routine maintenance and minor adjustments.
4. If instrument safety is uncertain the instrument may no longer be operated.

WARNING!

Use only the external power supply provided with the instrument otherwise damage will be caused to the KC4Δ.

2.5 Preliminary Check of Instrument Performance

The preliminary function checks of instrument operation should be performed prior to using the instrument. This preliminary function check is to ensure that the instrument is functioning properly prior to reporting patient results.

1. Connect the power supply to the POWER SUPPLY socket on the back of the instrument (DC6.5V 2A). Connect the power supply cable to the power supply and plug the power cable into the electrical supply socket. A green light will shine on the power supply.
2. Connect the Multipette® Starter cables into the corresponding sockets (PIPETTES) on the back of the KC4Δ instrument making sure that the Multipette® locking mechanism is securely seated.

Note: To protect the instrument from static electrical disturbance, some of the connection sockets have protection caps. Please remove these caps before connecting the peripheral equipment.

3. If the optional printer is being used connect the printer "SERIAL" input connector with the printer port "PRINTER" on the KC4Δ. Connect the printer to the mains supply circuit by connecting the „POWER SUPPLY PRINTER" socket on the KC4Δ to the "DC6.5V 2A" socket on the printer. Switch the printer on by sliding the "POWER" switch to 1.

Note: In order to speed up the warming of the KC4Δ thermostatically controlled measuring block, the power supply to the thermal printer will be activated when the measuring block temperature has reached 35°C. The printer will then be automatically switched on.

4. Activate the KC4 Δ Coagulation Analyzer by pressing the off/on switch located on the left hand side of the back of the instrument.
5. Observe that the display screen lights up. A screen showing a thermometer (see section 3.3) appears and will remain displayed while the instrument warms up to 35°C. Then the display will switch to the Main Menu (se section 3.4).
6. Observe that all four of the measurement wells are rotating. The wells will rotate continuously whenever the instrument is on.
7. Place a KC4Δ Micro cuvette or Tetravette into each position of the cuvette rack. Place the cuvette rack on the rotating test positions such that the cuvettes are sitting flush in the holes. If using a KC4Δ Micro cuvette, dispense one ball into each cuvette using the ball dispenser. Observe that the ball falls to the front of the cuvette and stays there.
8. Verification of temperature can be performed by placing approximately 3 ml of water into a 15-mm reagent tube. Place the reagent tube into the "Reagent warming wells" (section 1.5.3). Place a thermometer into the tube and allow to equilibrate until the temperature has stabilized. Approximately 15 minutes will be required for temperature stabilization. The temperature should be 37.3° ± 0.5°C.

Note: **The use of smaller diameter tubes is not recommended due to inadequate heat transfer.** The thermometer should not drain heat from the measuring medium (water). To verify the functionality of the sensors the Multipette® with the starting cable should be used.

Note: **Settings made during the Performance Checks may vary from the previous settings and may require that changes be made to the programming.**

9. In the Main Menu press **<3> to enter the Configuration Menu.**

10. Enter the password: default password is **1 2 3 4. Press <↵>**. The Configuration Menu will display.
11. To select language press **5** Change language/ keypad.
12. Make an appropriate language and keypad assignment selection. **Press <↵>**.
13. Press **3** Change Single test program; press **TCT (Thrombin Clotting Time)** key. Confirm with **<↵>**.
14. To access the program settings press **<↵>**.
15. Press **1 (YES)**, to change the TCT settings.
16. Press **2 (duplicate testing)** and **"10"** for the allowed CV; press **<↵>**, to store entry and continue.
17. Enter incubation time of **"10" seconds**. Press **<↵>** to store entry and continue.
18. Press 2 **(No)**. The settings will be stored.
19. Press **<RUN>**, to access the RUN Menu (see section 3.6).
20. Select 3 **(Start single program).**
21. Press the **TCT (Thrombin Clotting Time)**. This activates the TCT-Test.
22. For **Quantity** (Samples per rack) press **"2".** Then press**<↵>** twice to bring up the operating screen (see section 3.16).
23. Activate all four incubation timers by pressing the **Incubation Key** and then all four **Channel Selection Keys**. All four incubation timers run backwards from 10 (seconds) to 0. At **"5"**and **"0"** a beep tone will sound. The screen display **„ ***** in the **Ready** field indicates that the incubation time has been completed.
24. When all incubation timers display **"10",** press and hold the **<START>** key. Press the dispense lever on the Multipette® 4 times. Observe that beginning on the left all 4 measuring channels will be activated. Release the **<START>** key.
25. After at least 10.0 seconds, remove the cuvette rack from the rotating test positions. Observe that the timers stop and are indicating the elapsed time in seconds and tenths of seconds. The ******* in the **Ready** field will be replaced by **---.**
26. If the optional printer is connected, after about 1 second the measurement timers will reset to „0" and the patient result protocol will be printed.
27. If the printer is not in use, not properly connected or not switched on, an error message will be displayed: "Printer error". Please check if the printer is properly connected and switched on. Otherwise press **<ESC>**, to switch off the print program. The result protocol from the first patient will be displayed on the screen. Press **<↵>**, to scroll to the next result protocol. Press **<↵>**, to return to the Operating Screen.

With the completion of the Preliminary Checks of instrument Operation, installation is complete and the KC4Δ instrument is ready for operation. If the instrument fails to perform any of the tests with the specifications listed, call Instrument Service at Trinity Biotech

Note: **The settings for the TCT Test must be returned to the original settings (see section 5.8).**

3. General Operation

3.1 KC4Δ Programs and their Function

The KC4Δ coagulation analyzer has 4 different operation programs:

- **Single Test Program**
- **Routine Program**
- **Emergency Program**
- **Test Mode**

Program selection is made in the **RUN Menu** (see section 3.6).

Single Test Program: In the Single Test Program **one** programmed **Test** can be activated. **All samples** will be processed using this test until the Single Test Program has been deactivated. Patient IDs may be entered individually or counted upwards from a user definable starting number. Tests result data will be processed according to the selected replicate configuration i.e.; duplicate or single testing.

Routine Program: In Routine Program **several different tests** can be put together in a **Test** Group. Each test will be processed as in the Single Test Program-one test on several patients. To switch to the next test in the group press **<↵>**. The next test in the Test Group will be automatically activated. Patient IDs may be entered individually or counted upwards from a user definable starting number. Tests result data will be processed according to the selected replicate configuration i.e. duplicate or single testing. When the processing of the last test in the Test Group is completed, select **<↵>** to exit the Routine Program operation.

Emergency Program: In the Emergency Program **several different tests** will be allocated to and processed from **one** patient. Tests result data for all tests in the Emergency Program will be processed according to the selected replicate configuration i.e. duplicate or single testing. After all tests have been completed the Emergency Program will be deactivated.

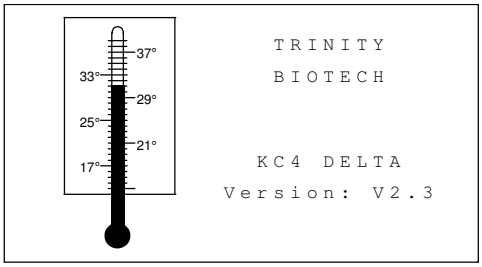
Test Mode: In this program selection defined test will **not** be processed and **no** IDs will be allocated. Only time measurements are performed. No results will be transmitted to the printer or to the LIS (Laboratory Information System). The measuring channels can be individually activated. The incubation timers can be individually activated. The incubation timers will start at "0" and be counted upwards by seconds.

3.2 Switching on the KC4Δ Coagulation Analyzer

The KC4Δ Coagualtion Analyzer ON/OFF switch is on the back of the instrument (see section 1.7). Switch the instrument on. The 4 measuring channels will rotate and the display screen will be activated.

3.3 Temperature Indicator Screen

After switching on the KC4Δ, the temperature indicator screen will be displayed until the thermostatically controlled measuring block has reached 35°C.

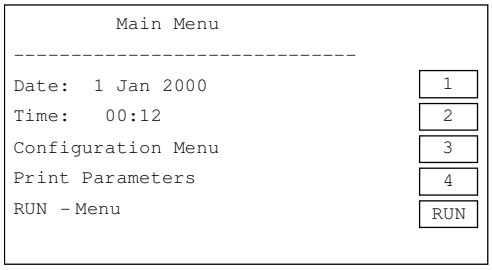


Temperature-Display

In approximately 20 minutes the analyzer will reach operating temperature (37.3°C ± 0.5°C). The display will change to the **MAIN MENU:**

3.4 Main Menu Functions

The Main Menu Screen will be activated using the **<MENU>** key. This is possible when no measurements are currently being performed and no data entries have been made. The Main Menu will also be automatically displayed after switching on the KC4Δ and attainment of a measuring block temperature of >35°C.



Main Menu

Main Menu Functions:

Key	Function
<1>	Date entry: the new date will replace the old date.
<2>	Time entry: the new time will replace the old time.
<3>	Activates the Configuration Menu (see section 3.5).
<4>	If the optional printer is connected, selection of <4> will print out all the tests defined in each of the processing options Routine, Emergency, Single and the settings of all tests.
<RUN>	Activates the RUN Menu (see section 3.6)

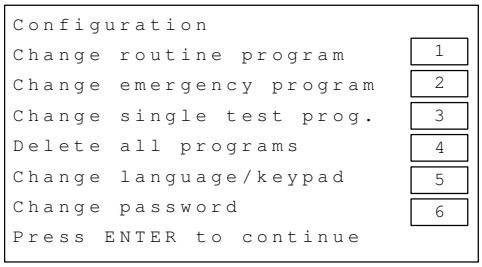
Note: **When the KC4Δ is switched off, the Date/Time and test settings will remain active for approximately 2 weeks. If the instrument remains unused for longer periods the test settings must be re-entered.**

3.5 Configuration Menu Functions

The configuration menu is selected from the Main Menu (see section 3.4).
In the Main Menu press **3 Configuration Menu**.

The Configuration Menu is protected from access by unauthorised personnel by a 4 digit password. The default password is **"1234".**

Enter the password and press the **<↵>** key. (Incorrect entries can be deleted using the **<DEL>** key.) The Configuration Menu will be displayed.



Configuration Menu

1 Change Routine Program: (see also section 4.1)
This function allows the operator to select the tests available to be run in the **Routine Program**. The tests are selected by pressing keys (**INR**, **APTT**, **FIB**, etc.) and confirming with **<↵>**. Incorrect entries may be corrected by pressing the **<DEL>** key. Terminating is possible with **<ESC>**. Upon termination, the previously set values will remain valid. In this program, the analyzer will allow a sequential operation of tests (**Batch – mode**).

2 Change Emergency Program (see also section 4.2)
This function allows the operator to select the tests available to be run in the **Emergency Program**. The tests are selected by pressing keys (**INR**, **APTT**, **FIB**, etc.) and confirming with **<↵>**. Incorrect entries may be corrected by pressing the **<DEL>** key. Terminating is possible with **<ESC>**. Upon termination, the previously set values will remain valid.

3 Change Single Test Program: (see also section 4.1)
This function allows the operator to individualize the test menu by sample if desired. The tests in the **Individual Program** are chosen directly from the keyboard by pressing keys (**INR**, **APTT**, **FIB**, etc) and confirming with **<↵>**. Incorrect entries may be corrected by pressing the **<DEL>** key. Terminating is possible with **<ESC>**. Upon termination, the previously set values will remain valid.

Detailed information for modifying the processing options is described in **section 4.**

Note: After selecting 1, 2 or 3 the Configuration Menu is exited by pressing ENTER or ESC. Now the assay parameters can be defined or modified. These entered or modified assay parameters definitions will be valid for all processing options. Only the selected configuration of single/duplicate testing in the Emergency program has priority over the assay definition replicate selection.

4 Delete All Programs:
The test selections for all of the processing options will be deleted. All assay definition settings will also be deleted.

WARNING: All tests in all processing options and all assay definition settings can be deleted with one keystroke. A complete new installation of programs is necessary if all programs are deleted.

5 Change Language / Keypad

After pressing **<5>** a new menu will be activated in which the languages **German**, **English** or **French** may be selected. In the same menu the keypad options <PT> or <NT> and <Ratio> or <TT> may be selected.

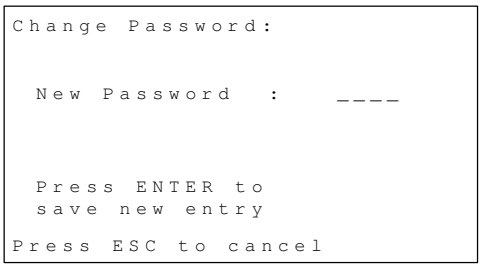
Language: By pressing **<1>** (GERMAN), **<2>** (ENGLISH) or **<3>** (French) the corresponding language will be selected. The current selection is indicated by **"*"** after the number.

Keypad: By pressing the key **<7>** (PT und RATIO) or **<8>** (NT und TT) activates the keypad for the corresponding tests. The current selection is indicated by **"*"** after the number.

Note: If the keypad configuration is modified all tests selected for all processing options: Routine, Emergency and Single Test Programs will be deleted (section 4). The assay definitions will remain stored.

6 Change Password: The Configuration Menu is protected from interference by unqualified personnel by a 4 digit password. The default password is **"1234" and** may be changed to a laboratory-specific password. The default password is then invalidated. **For that reason please make sure that the new password does not get forgotten. Without the new password the Configuration Program can no longer be accessed.**

Press **<ESC>** during the new password entry and the old password will remain valid.

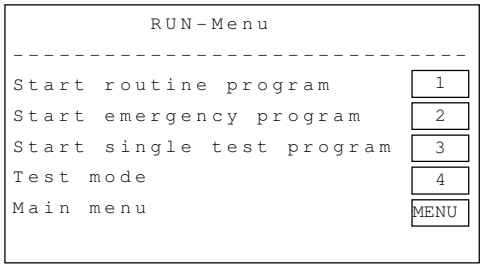


To change the password enter the new password (4 digits); press **<↵>**.
To confirm, re-enter the new password and complete the entry with **<↵>**. If both new password entries were identical, the new password is now valid. If the new password entries were not identical the old password remains valid.

Repeat the "Change Password" procedure if the error message "Incorrect Password" is displayed.

3.6 Run Menu Functions

The Run Menu is activated by selecting the **<RUN>** key. Selection is only possible when the measuring mode is not active or when no other actions have been activated



RUN-Menu

1 Start routine program: The Routine Program is activated (sections 3.1 + 3.15.1)

2 Start emergency program: The Emergency program is activated (sections 3.1 + 3.15.2)

3 Start single test program: The Single Test Program is activated (sections 3.1 + 3.15.1)

4 Test mode: Clotting times will be measured using this program, without using any of the pre-programmed test definitions (see sections 3.1 + 3.15.3).

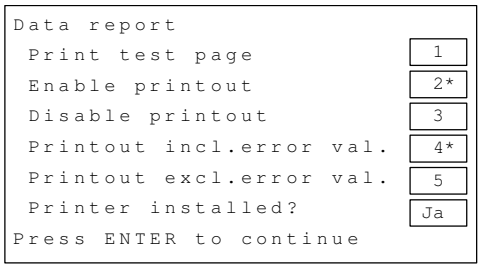
MENU Main Menu: The Main Menu is activated (section 3.4)

Note: When the measurement mode is inactive all programs can be exited using the <RUN> or <MENU> keys.

3.7 Printer Menu Functions

The Printer Menu is activated by selecting the **<Printer>** key. Selection is only possible when the measuring mode is not active or when no other actions have been activated

The currently selected options are flagged with **"*".**



Data Report

Key <1>: Using this selection, when the optional printer is connected a test-text will be printed. The printer is correctly connected if this text is readable.

Key <2>: Using this selection results will be automatically printed, when the printer is correctly connected. The result display on the KC4Δ screen will be deactivated. This selection must be made every time the KC4Δ instrument is powered up. During active operation this function can only be selected when the word "Yes" is displayed in the box beside the question Printer installed?" (See below).

Key <3>: Use this selection to disable the automatic printout. Result data will be displayed on the screen. Deferred printing of results is no longer possible.

Key <4>: If the KC4Δ is connected online to a Laboratory Information System (LIS, see section 3.18.3), use this selection to enable the transfer of data including error values (e.g. values exceeding the max. CV)

Key <5>: Use this selection to enable the transfer excluding error values (e.g. values exceeding the maximum CV).

The data transfer will be automatically performed at the completion of measurement and need not be manually activated.

If the KC4Δ is not connected an LIS, **Keys <4>** and **<5>** have no function and any selection may be made.

Printer installed?: When the printer is correctly installed, switched on and on-line, the box will display **"YES".** If **"NO"** is displayed the printer is either switched off, is off-line or the data line is incorrectly connected.

3.8 Reagent Handling

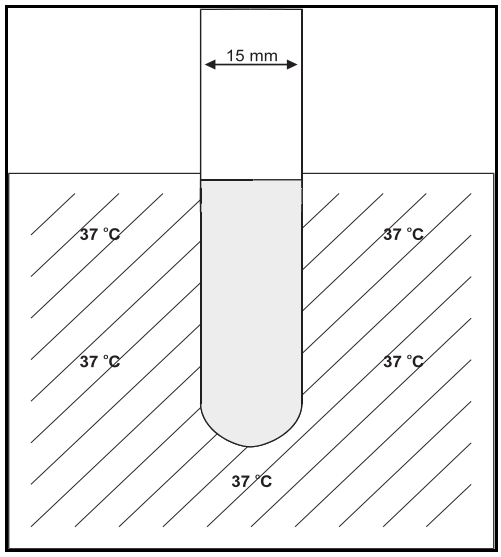


Figure 3.1

Reagents for the appropriate test are prepared according to the manufacturer's instructions. Refer to the manufacturer's reagent application for specific instructions on preparation and handling of reagents. Any reagent requiring pre-heating should be placed into a 15-mm tube and inserted into the reagent incubation well. The fluid level in the tube should not be above the top edge of the incubation well. A minimum of 15 minutes will be required to warm reagent to 37.3°C ± 0.5°C.

Note: **If reagents are taken directly out of the refrigerator, they will need longer to equilibrate.**

All reagents should be used before the end of the manufacturer's recommended expiry date. Do not place open reagent vials on the instrument!

3.9 Cuvette Preparation

ATTENTION!

The cuvettes are disposable and should not under any circumstances be reused.

ATTENTION!

Used cuvettes are potentially biohazardous.

Handle according to laboratory safety regulations for disposal of biohazardous materials.

Unused cuvettes are not biohazardous.

ATTENTION!

After the cuvette carton has been opened the cuvettes and balls should be protected from dust, humidity and any other dirt and should be stored according the recommended storage conditions printed on the cuvette package.

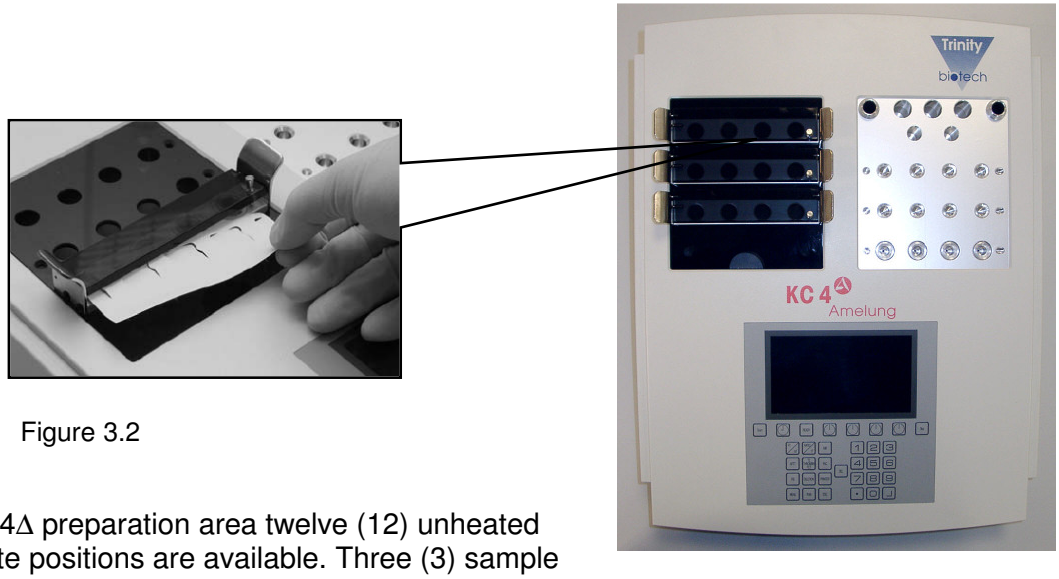


Figure 3.2

In KC4Δ preparation area twelve (12) unheated cuvette positions are available. Three (3) sample holders each containing four (4) cuvettes may be positioned there.

Place one Tetravette in the sample holder (see figure 3.2) and remove the paper ball retainer.

Unpacked cuvettes (bulk ware) may also be placed in the preparation area positions. The ball is then added using the ball dispenser.

ATTENTION!

The operator must check that every cuvette positioned in the instrument contains a ball.

Place the Tetravettes or Microcuvettes in the preparation positions. Up to twelve (12) cuvettes can be positioned in the instrument at one time. The exact size and surface quality of the cuvettes is critical to the proper performance of testing. Absolute cleanliness of cuvettes is mandatory for correct performance. The cuvettes are intended as one-time use items.

Tetravettes are cuvettes in group in packs of four. Each cuvette contains a stainless steel ball and can be used without any additional preparation.

The balls in the cuvettes are manufactured from a special stainless steel. Purity, weight, size, surface quality and magnetic characteristics of the balls are all critical to the proper performance of testing. The balls manufactured by Trinity Biotech have been tested to ensure compatibility with the instrument measurement process and that they are inert when used with plasma and coagulation reagents. Rust, slight impurities or oil residue can have a deleterious effect on coagulation testing results. The balls are also one-time use items.

3.10 Sample Preparation

Plasma samples and reagents are added with appropriate microlitre pipettes. Refer to the manufacturer's reagent application to determine the sample and reagent(s) volume required for each test. Pipetting technique is critical to the performance of testing. Refer to the Pipetting section for guidelines in proper pipetting technique (section 3.11). Although the use of a Multipette® will facilitate initiation of measurement timing, special pipettes are not required. If a Multipette® is not available, measurement timing can be started using the start button and channel buttons.

Sample is dispensed into the cuvette. Twelve o'clock is the recommended dispense position. After sample has been dispensed, close the Plexiglas flap, pick the cuvette rack up and swirl gently to evenly disperse the sample over the bottom of the cuvettes. Place the rack with cuvettes in the rotating test positions ensuring that the cuvettes are pressed firmly down to the bottom. Two additional racks of cuvettes (4 each) may also have samples pipetted and placed in the reaction incubation wells.

Care must be taken not to over-incubate the samples. It is advisable to stagger the time interval between the cuvette racks in the heated incubation wells and rotating test positions to prevent over-incubation. Allow the samples to pre-incubate for the recommended time. It will take slightly longer (a minimum of 120 seconds) for a sample that has been stored at refrigerator temperature (2–8°C) to reach 37°C than for samples stored at room temperature (18–26°C). Several of the coagulation factors, (Factors V, VIII, XIII, and fibrinogen) are labile at 37°C. To avoid loss of these factors, samples should not be pre-incubated longer than 5 minutes.

Timing is critical in coagulation testing and the reagent manufacturer's guidelines for incubation times should be followed. Any particulate reagent must be well mixed prior to use. For those tests having more than one reagent, all incubations prior to measurement start can be accomplished in the reaction incubation wells. Nine o'clock is the recommended first-reagent dispense position (section 3.13).

Care must be taken to avoid contact of the reagent pipette tip with previously dispensed sample. After addition of reagent, close the Plexiglas lid, pick up the cuvette rack and swirl gently 5–6 times to mix the reagent and previously pipetted sample. The reaction mixture should be evenly dispersed around the channel at the bottom of the cuvette. No more cuvettes should be prepared for testing than can be completed within the specified guidelines.

In most instances, addition of a start reagent begins the coagulation process. It is important that the **Measurement Timer** be started simultaneously to the addition of the start reagent in order to ensure accuracy and precision of the assay. Test measurement timing can be started either manually using the **Channel Key** or automatically by using the Multipette® fitted with a starter cable. Use of a Multipette® will ensure that the reagent addition starts measurement timing.

The location of the start reagent dispense is important. To ensure that mixing of start reagent with the previously pipetted sample or sample/reagent mixture begins immediately, the start reagent should be dispensed just to the right side of the ball. This is best accomplished by holding the pipette angled obliquely from the right rear side of the cuvette towards the ball position and dispensing the reagent just to the right of the ball. Care must be taken to avoid splashing the reagent out of the cuvette. The dispense rate should be of moderate speed and forcefulness.

3.11 Pipetting

The overall performance of the KC4Δ Coagulation Analyzer is dependent on the accuracy and precision of pipetting both sample and reagent(s).

Testing can be performed with either standard microlitre pipette(s) or with the Multipette® fitted with a starting cable. When the Multipette® is used to dispense the final start reagent, the timer is automatically started simultaneously with reagent dispense. When a standard microlitre pipette is used for addition of the final start reagent, the timer is started manually using the **Specific Channel Key** ⏻.

Regardless of what kind of pipette is used, the care taken with pipetting is directly proportional to the overall accuracy and precision of testing.

To avoid contamination of reagents, if the same pipette is being used for both sample and reagent, a new tip must be used when transitioning between sample and reagent.

To avoid cross-contamination between samples, a new tip should be used for each sample, whether running plasma or whole blood samples.

Pipetting technique for non-repeating pipettes

To fill the pipette tip: Depress the button to the first stop. With the button depressed, insert the tip into the sample or reagent to a depth of approximately 2–3 mm. If pipetting plasma directly from a centrifuged tube of blood, the tip should be kept well away from the blood/plasma interface. This will assure that no red cells or platelets will be aspirated into the tip. If pipetting a particulate reagent, the reagent should be well mixed prior to aspiration.

Release the button slowly in such a manner that the sample or reagent flows smoothly into the pipette tip. Slow aspiration will assure that the volume aspirated into the tip is accurate. If the button is allowed to snap back, an incorrect volume may be aspirated. In addition, sample or reagent can be aspirated into the barrel of the pipette. This can result in contamination of subsequent samples or reagents. Unless the pipette is dismantled and cleaned, inadvertent aspiration into the pipette barrel will result in eventual obstruction and incorrect operation of the pipette.

Once the tip is filled, no dripping should be observed. If dripping is observed, either the tip is not seated correctly on the pipette or the pipette requires maintenance. In such a circumstance, replace the tip. If this does not correct the problem, the pipette should not be used until maintenance can be performed.

Pipetting technique for Multipettes®

Only pipette tips recommended for use with the pipette should be used. Any pipette tip whose insertion opening is out-of-round should be discarded. Any pipette tips that are bent or otherwise damaged should be discarded. The tip opening must not be occluded.

Slide the filling lever down until it stops, then raise the locking clamp upward.

Insert the Combitip® until it clicks into position. Be sure the Combitip® plunger is fully inserted into the barrel before attaching it to the Multipette®. Be sure the filling lever is completely down and then lower the locking clamp to secure the Combitip® in place.

Verify that the volume selection dial is set to dispense the correct volume. Immerse the Combitip® cone into the liquid. Fill by slowly sliding the filling lever upward. Wipe the Combitip® cone with a lint-free tissue. Follow the guidelines for correct dispense positions described in the following sections.

3.12 To dispense the Sample

Sample should be dispensed to the 12 o'clock position of the cuvette (See diagram). Aim the pipette to the 12 o'clock position. Position the tip approximately 3–4 mm above the bottom of the cuvette. Depress the pipettor button to the first stop and hold for 1–2 seconds to allow the residual contents of the tip to collect at the bottom of the tip. Press the button to the second stop. This will deliver any residual sample into the cuvette. To avoid bubbling and splattering, the tip should not be placed so close to the bottom that at the completion of pipetting the tip is submersed in the dispensed sample. An alternative method is to touch the tip to the cuvette sidewall approximately 3–4 mm above the bottom of the cuvette and then depress the button slowly to the first stop. Wait 1–2 seconds and press the button to the second stop position. Sample should not be dispensed by touching the tip to the upper sidewalls of the cuvette. Any sample that is left on the upper walls will not participate in the coagulation reaction.

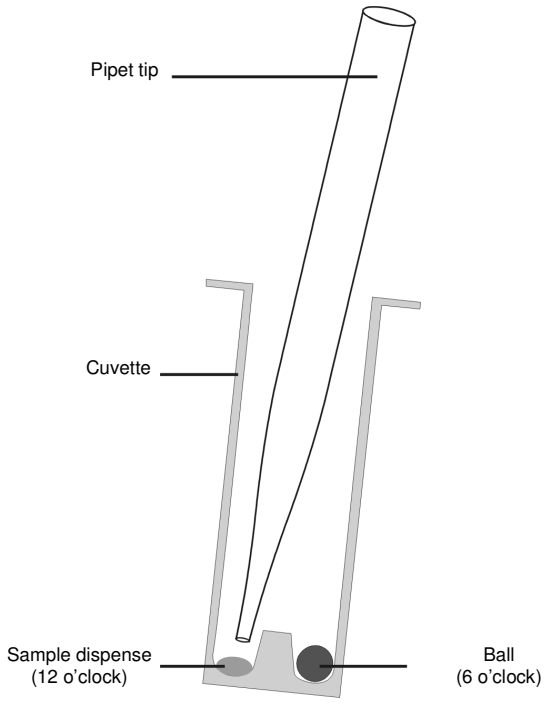


Figure 3.3

3.13 To Dispense the First Reagent

For those tests utilizing more than one reagent, the first reagent should be dispensed to the 9 o'clock position of the cuvette (See diagram). Aim the pipette to the 9 o'clock position. Position the tip approximately 3–4 mm above the bottom of the cuvette. Depress the pipettor button to the first stop and hold for 1–2 seconds to allow the residual contents of the tip to collect at the bottom of the tip. Press the button to the second stop. This will deliver any residual reagent into the cuvette. To avoid bubbling and splattering, the tip should not be placed so close to the bottom that at the completion of pipetting the tip is submersed in the dispensed reagent. An alternative method is to touch the tip to the cuvette sidewall approximately 3–4 mm above the bottom of the cuvette and then depress the button slowly to the first stop. Wait 1–2 seconds and press the button to the second stop position. To avoid contamination of reagent during subsequent reagent pipetting, care must be taken to avoid contact of the tip with the previously dispensed sample.

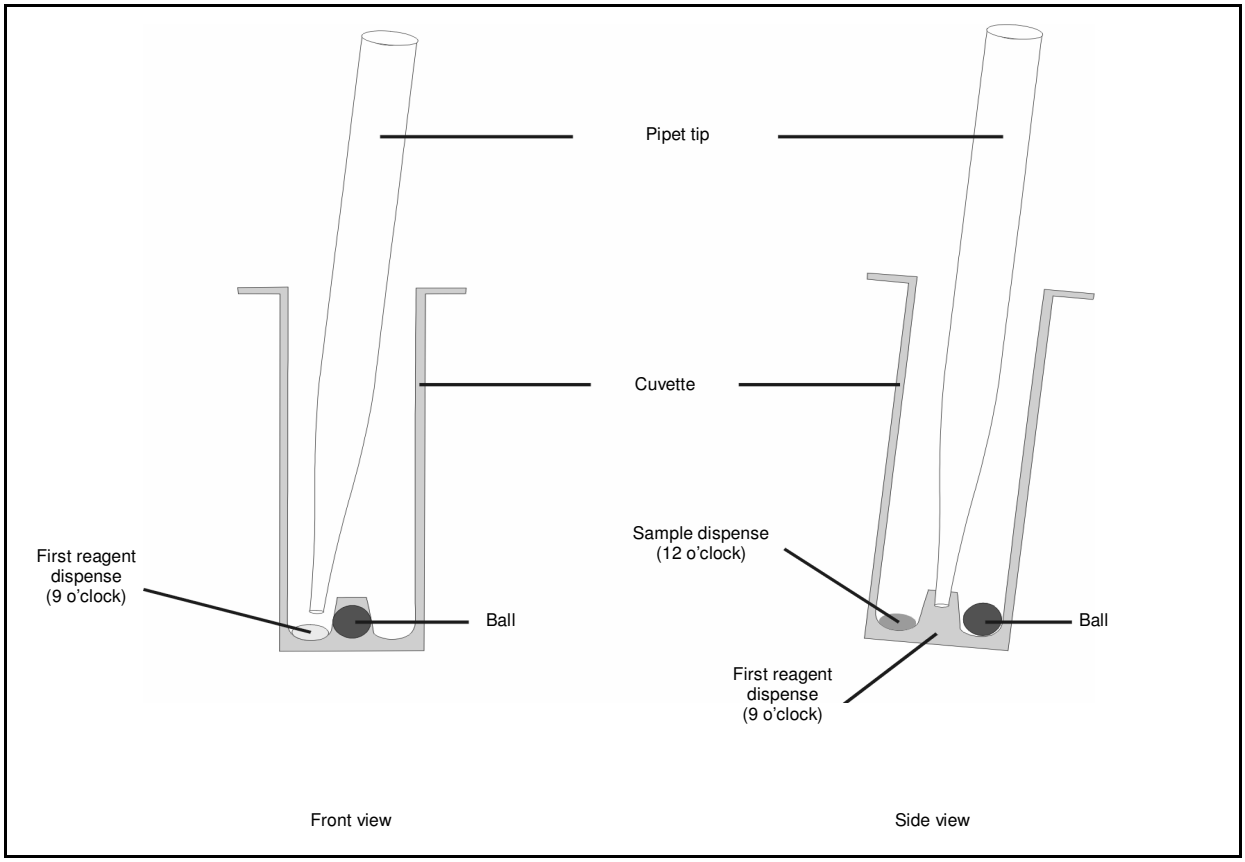


Figure 3.4

3.14 To Dispense the Starting Reagent

The Start Reagent is the reagent that, when added, begins the coagulation reaction. Start Reagent should be dispensed just to the right side of the ball. This positioning assures that mixing of reagent with the other reaction constituents begins immediately. Holding the pipettor obliquely from the right side, aim the pipette tip to the right side of the ball. Position the tip approximately 5–6 mm above the ball. Depress the pipettor button to the last stop position. The dispense rate should not be so rapid or forceful that reagent is splashed out of the cuvette. To avoid contamination of reagent during subsequent reagent pipetting, care must be taken to avoid contact of the tip with the previously dispensed sample and/or reagent. Refer to the General Operation section for further information on the use of the automatic pipettor with starter cable.

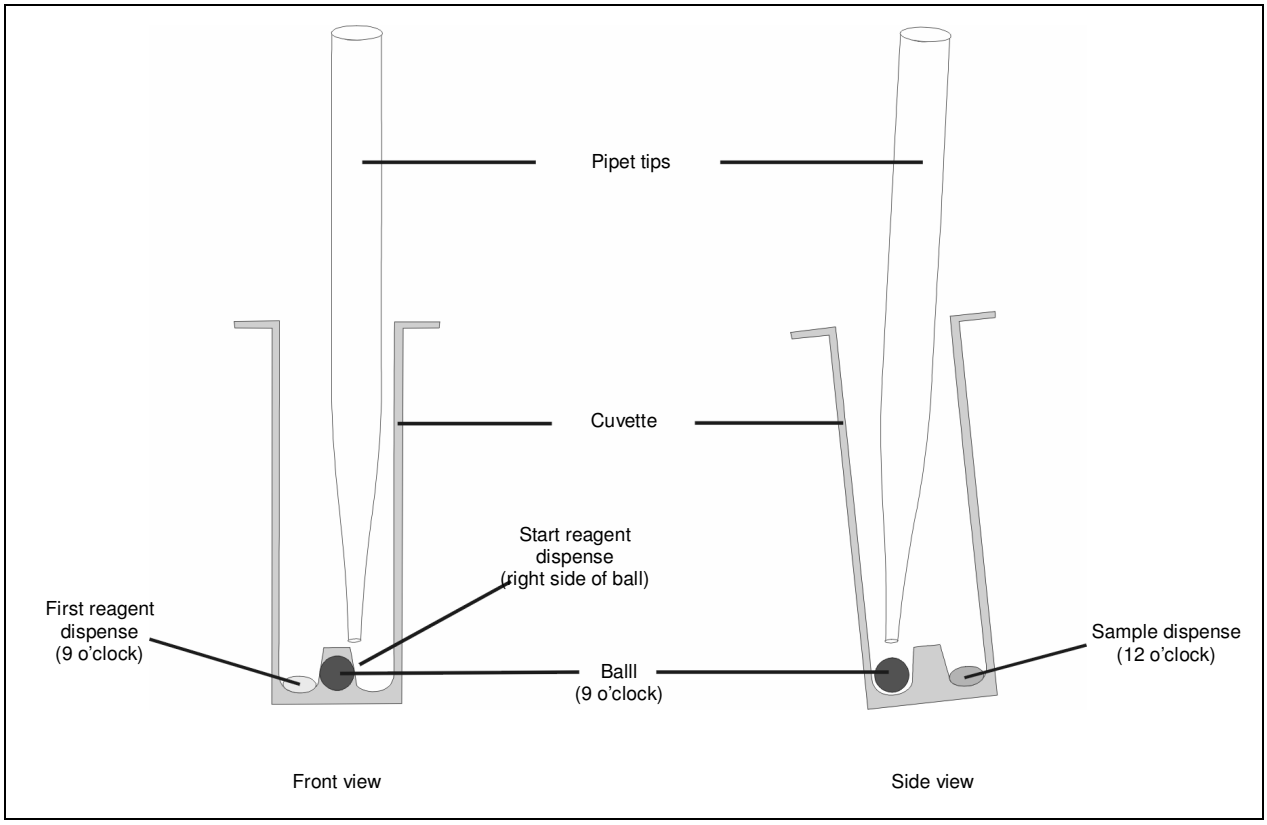


Figure 3.5

3.15 Selecting Operating Program and Starting

To activate the operating programmes bring up the RUN Menu (section 3.6) using the **<RUN>** key.

Using the keys **<1>**, **<2>**, **<3>** or **<4>** select the desired program (section 3.1).

Note: **Before the Routine/Single Test/ or Emergency Programs can be activated, the corresponding test must have been configured in the Configuration Menu (see section 4 Mode Programming).**

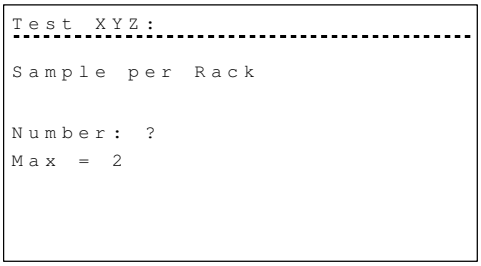
3.15.1 Starting Routine or Single Test Program

After selecting "**Start Routine Program"** or "**Start Single Test Program"** you will be asked how many samples are to be measured in one rack.

"Max" defines the maximum number of samples. For singleton testing it is four (4), for duplicate testing it is two (2) samples.

Enter the number of patients.

Note: Use the key **<↵>** to set the number to "Max".



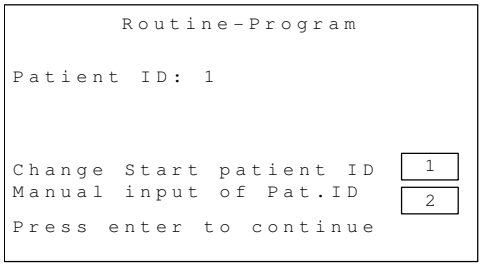
Requesting the number of patients/rack

After entering the number of patients, you will be asked how the sample IDs are to be assigned.

There are two possibilities:

1) The sample ID will automatically incremented by one beginning with the number displayed in Patient ID:
   Use key **<1>** to edit the starting number.
   Press **<↵>** to activate this option.

2) The sample ID can be individually defined:
   Press key **<2>** to activate this option. Then you will be asked for the sample IDs for the first group of samples.



Requesting the Sample ID

Note: **The patient ID may have a maximum of 9 digits.**

Then the Operating Screen will be activated. Sample measurement can now begin (section 3.16.1).

Note: If the patient ID is to be automatically incremented, the number of patients per rack and patient IDs will not be requested. It is possible to change this by selecting the corresponding test key (e.g. PT).

Note (only for Routine Program): **When processing of one for all samples has been completed, press the <↵> key to activate the next test programmed in the Routine Program.**

3.15.2 Activating the Emergency Program

After selecting the **"Start Emergency Program"** the patient ID will be requested.

Enter the patient ID and press the **<↵>** key.
Entry of up to 9 digits is permitted.

The Operating Screen will be activated.

```
 Stat
----------------------------------------

 Patient ID: ?



Press ENTER to save new
entry
```

Requesting patient number

In the Operating Screen footer the test to be performed are displayed (section 3.16.2). If there are more than 4 measurements to be performed the next ones will be called up when the first measurements have been completed.

3.15.3 Activating Test Mode Program

After activating the "Test Mode" the Operating Screen will display (section 3.16.3). No additional data entries are necessary. In this mode patient IDs are not allocated and only the time result will be displayed on the screen. Result data cannot be transferred to the printer or to an LIS. The measuring channels can be used independently of one another; this feature is unique to this mode.

3.16 Operating Screen

All measurements are directed using the Operating Screen. The basic display configuration is dependant on the active program e.g. patient number, test or patient number/rack.

3.16.1 Operating Screen in Routine and Single Test Program

Pat.ID: 1			FIB 1/10	
Position	1	2	3	4
Inc. time Meas.time	0 0.0	0 0.0	0 0.0	0 0.0
Start Inc				
Ready				
	1	2	3	4

e.g. four patients/rack in singleton

left: ID of first patient
right: Test to be performed
Measuring channel positions 1 through 4
Incubation time in seconds
Measuring time in seconds
"***" Incubation time is running
"***" Measurement can be started or is running
"***" Measurement is complete
active channels with patient allocation
displayed: 4 different patients in single mode

Pat.ID.: 1			FIB 1/10	
Position	1	2	3	4
Inc. time Meas.time	0 14.8	0 9.3	0 0.0	12 0.0
Start Inc				***
Ready	---	***	***	
	1	1	2	2

e.g. two patients/rack/duplicate testing

left: ID of first patient
right: Test to be performed
Measuring channel positions 1 through 4
Incubation time in seconds
Measuring time in seconds
"***" Incubation time ch. 4 running (12s left)
"***" Measuring channel 3 can be started
"***" Measuring channel 2 running (since 9.3s)
"***" Measuring channel 1 is done (Time: 14.8s)
active channels with patient allocation
displayed: two different patients in duplicate

3.16.2 Operating-Screen in Emergency Program

Pat.ID.: 123456			Stat	
Position	1	2	3	4
Inc. time Meas.time	0 0.0	0 0.0	0 0.0	0 0.0
Start Inc				
Ready				
	PT	FIB 1/10	TZ	

e.g. three test in Emergency Prog./singleton

left: patient number
right: Emergency Program
Measuring channels 1 through 4
Incubation time display in seconds
Measuring time display in seconds
"*"** Incubation time is running
"*"** Measurement can be started or is running
"*"** Measurement in complete
active measuring channels with test allocation
displayed: three different tests in single mode

Pat.Nr.: 123456			Stat	
Position	1	2	3	4
Inc. time Meas.time	0 15.1	0 7.4	0 0.0	3 0.0
Start Inc				***
Ready	---	***	***	
	PT	PT	FIB 1/10	FIB 1/10

e.g. two tests in duplicate

left: patient number
right: Emergency Program
Measuring channels 1 through 4
Incubation time display in seconds
Measuring time display in seconds
"*"** Incubation time ch. 4 running (still 3s)
"*"** Measuring ch. 3 can be started
"*"** Measuring ch. 2 running (since 7,4s)
"---" Measuring ch. 1 is complete, time: 15,1s
active measuring channels with test allocation
displayed: two different test in duplicate

3.16.3 Operating Screen in Test Mode

Test Mode			T= 37,3C	
Position	1	2	3	4
Inc. time Meas.time	14 0.0	0 0.0	0 12.3	0 0.0
Start Inc	***			
Ready		***	***	STOP
	1	2	3	4

Test Mode – all 4 measuring channels are always active

left: Program "Test Mode"
right: Measuring block temperature in [°C]
Measuring channels 1 through 4
Incubation time display in seconds
Measuring time display in seconds
"*"** Incubation ch. 1 is running (since 14s)
"*"** Measuring ch. 2 can be started
"*"** Measuring channel 3 running (since 12,3s)
"STOP" Measuring on ch. 4 was interrupted using the "STOP" key.

Note: In the bottom left of the Operating Screen, the action selected using the **<START>, <⏲>** or **<STOP>** keys will be displayed (see section 3.17).

3.17 Sample Processing

3.17.1 Starting Incubation Time

1. After the measuring program has been selected the Operating Screen will be displayed. With the transfer of the first rack to the rotating wells, press the **Incubation timer** ⏲. The bottom left of the Operating screen will display "START Inc" confirming that the incubation procedure has been initiated.
2. Start the incubation timers for each channel which is activated in the lower part of the Operation Screen and which contains a sample to be tested.

Press the **Channel timer key** ⏲. The "Start Inc" field will display **"***"** for the corresponding channels. At the same time each of these channels will begin the incubation countdown, starting with the incubation time defined for this test.

3. **Exception:** In measuring program "Test Mode" the incubation time will counted upwards. When the desired incubation time has been reached, press the **<READY>** key and then the **Channel Timer** key ⏲ to activate the channel.
4. When 5 seconds of the incubation time remain an audible beep will sound. The *** flag will be moved from the "Start Inc." field to the "Ready" field. When the Ready field is so flagged that channel may be started.

Note: Each channel may be started without an incubation time. However, the operator should adhere to the manufacturer's recommendations for the test procedure. To override or interrupt the incubation time, press the <READY> key and then the corresponding Channel Timer ⏲ key. The selection of the <READY> key will be confirmed with "READY" in the bottom left of the Operating Screen.

3.17.2 Testing

1. Install an appropriately sized tip onto the pipette.
2. Mix particulate reagent by covering the tube with Parafilm® and inverting gently. Do not shake. Many coagulation reagents are mixtures of lipids, which will undergo spatial rearrangement when shaken.
3. Aspirate reagent into the pipette tip. Dispense one aliquot of reagent into reagent container to prime the pipette tip.
4. Press the **<START>** key.
5. Dispense reagent just to the right side of the ball and simultaneously press the Specific Channel Key.

   There are two starting methods: **Automatic** (recommended) and the **Manual** start method.

Automatic Start Procedure

The KC4Δ Multipette® is recommended for use in the Automatic Start Procedure.
Assure that the Multipette® cable is plugged into the Automatic Pipette socket located on the rear of the KC4Δ Coagulation Analyzer. Up to three pipettes may be installed.
Press and hold the **<Start>** key during reagent dispense into the measuring channels. **The reagent is dispensed from left to right, starting with Channel 1.** Simulateously with the reagent dispense the timers will start counting- The next measuring channel to the right will be set for measurement start. It will be started simultaneously with the next reagent dispense and the following channel to the right will be set for measurement start.

If the operator releases the **<START>** key after the reagent is added to the first cuvette, it must be pressed before the addition of reagent to each cuvette.

Confirmation that the **<START>** key has been selected is confirmed by the display **"Start Meas."** in the bottom left of the Operating screen.

Manual Start Procedure

The manual start procedure is used when no pipette with starting cable is available. Press the **<START>** key. As a control the lower left field will display "Start Meas". Simultaneously with the dispensing of the start reagent the measurement timers must started. Therefore press the Channel Key ⏲ simultaneously with start reagent dispense. The measurement is started and the measurement timers beginns running.
Replace the pipette in the heated pipette sleeve.

Note: Replace the pipette tube holder sleeves daily and for each new reagent. Pipette tube holder sleeves should be treated as biohazardous waste.

With the addition of start-reagent, initiation of the coagulation process begins. As coagulation takes place, fibrinogen polymerizes to form strands of fibrin. The formed fibrin sweeps the ball out of its steady position, which triggers an impulse in the magnetic sensor. This impulse electronically stops the timer signifying the end of measurement time. The "Ready" field will display **"----".** Measurement has been completed. The elapsed time will be displayed in seconds and tenths of seconds. When all tests have been completed, the actual results will be calculated.

3.18 Manual Measurement Abort

If a measurement has to be manually aborted because no clot has formed or because a test was incorrectly started press the **<STOP>** key. In the bottom left of the Operating Screen "STOP" will be displayed confirming that the stop procedure has been initiated. Press the corresponding Channel timer key ⏲ to stop the measurement in that channel. "STOP" will display in the corresponding position in the Operating Screen. No result will be calculated for this measurement.
If more patients/rack were selected than will actually be measured, then these can be aborted without starting.
If patient numbers are set to automatically increment, patient number will still be allocated even for aborted measurements.

3.19 Result Output

3.19.1 Result Output in "Test Mode" Program

If measurements are performed using the Test Mode program, only the measurement timer will be stopped. The measuring time can be read off the Operating Screen. There will be no calculation of raw data, transfer of data to the printer or transfer of data to the LIS interface.

3.19.2 Result Output in Routine, Emergency or Single Test

Results will be automatically calculated and released when all activated measurements have been completed. Activated measuring channels are indicated by a number or a test code in the bottom line of the Operation Screen (section 3.16). If a measuring channel does not conclude a measurement while e.g. no clot is formed, then the measurement must be manually aborted (see section 3.18)

Result Output with Optional Printer

If the printer has been correctly installed (see section 1.10 +2.5.3) the raw data and calculated results will be transferred to the printer and printed. These results will not be displayed on the Operating Screen. New measurements can be performed on the KC4Δ coagulation analyzer during the printing of results.

Example: Result Output with Printer

---

05 Feb 2004 10:34
Single Test Program: PT
Patient ID: 123456
Measured values: 11.9 sec 12.1 sec
Average value: 12.0 sec
Difference: 0.8%
Result: 108.3%
INR: 1.17

Note: **The end of the paper roll is indicated with red diagonal stripes. When these stripes are visible insert a new roll of paper.**

Result Output without the Optional Printer

The KC4Δ coagulation analyzer default settings presume that the optional printer will be installed (see section 1.10). The first attempt to transfer data and results to the printer will provoke the screen display: “Printer error! Please check if printer is installed correctly and switched on. Or press ESC to disable printout.” Press the <ESC> key and the error message will be deleted.
The raw data and calculated results for each patient – or in Emergency program each test – will now be displayed on the KC4Δ screen. Press the **<↵>** key to scroll to the next result.
After the last result has been displayed press the **<↵>** to perform more tests in the Routine or Emergency Program.
If all tests in the Emergency Program have been performed, the Emergency Program will be deactivated after the last Emergency result has been displayed.

3.19.3 Result Output to LIS (Laboratory Information System)

Simultaneously with the output of result data to the display or the printer, the data will also be transferred to the LIS interface. It is an RS232 interface, and is on the back of the KC4Δ labelled with „PC Serial“. If this interface is not being used, there is nothing which needs to be observed or set. If the interface is to be used it is possible to select if results with error flags are to be transferred or not (section 3.7)

3.19.3.1 PC-SERIAL-Interface Specifications

- ► Baud rate 9600 Bit / sec
- ► Complete ASCII Character Set
  1 Start-bit, 7 Information bits (Bit 1-7), odd or even parity, (parity-disabled) or 8 Bit without parity, 2 Stop bits
- ► 9 pin Sub D-Connecter DB9
  Pin 2 = RXD
  Pin 3 = TXD
  Pin 5 = GND

3.19.3.2 Data protocol for the PC SERIAL Interface

Byte	7	6	5	4	3	2	1	0	Bit	Example	
↓ 1	0	0	0	0	0	0	1	0	STX	STX	*Start of text*
2									Program	A	Left justified
3										P	
4										T	
5										T	
6											
7	0	0	1	0	0	0	0	0	Blank		*Space*
8									ID-No. (Patient number)		Right justified
9											
10										1	
11										2	
12										3	
13										4	
14										5	
15										6	
16										7	
17	0	0	1	0	0	0	0	0	Blank		*Space*
18									Value 1 [Sec.]		Right justified
19										1	
20										2	
21										.	
22										3	
23	0	0	1	0	0	0	0	0	Blank		*space*
24									Value 2 [Sec.]	1	Right justfied If value 2 missing , will be filled with **"X"**
25										2	
26										3	
27										.	
28										4	
29	0	0	1	0	0	0	0	0	Blank		*space*
30									Ergebnis		Right justfied
31										1	
32										2	
33										.	
34										3	
35	0	0	1	0	0	0	0	0	Blank		*space*
36									Einheit	%	left justified
37											
38	0	0	1	0	0	0	0	0	Blank		*space*
39	*0 0*	*1 0*	*0 1*	*0 0*	*0 0*	*1 0*	*0 0*	*1 0*	Fehler (E)	E	With error " **E** ", no error " **Blank** "
40	0	0	0	0	1	1	0	1	CR	CR	*Carriage return*
41	0	0	0	0	1	0	1	0	LF	LF	*Line feed*
42	0	0	0	0	0	0	1	1	ETX	ETX	*End of text*

Example for program

A	P	T	T		*APTT*
P	T				*PT*
R	A	T	I	O	*RATIO*

(When a PT-/NT- o. TT-Test with INR is performed, the complete data protocol will be transmitted twice:
The first time for the PT/NT or TT Test,
The second time for the INR Test)

Example of value and result

	1	2	.	3	*12.3*
1	2	3	.	4	*123.4*
1	2	.	3	4	*12.34*
		1	0	0	*100*

Example of unit

%		*%*
G	L	*g/l (Grams per Litre)*
S		*s (Seconds)*

4. Processing Mode Programming

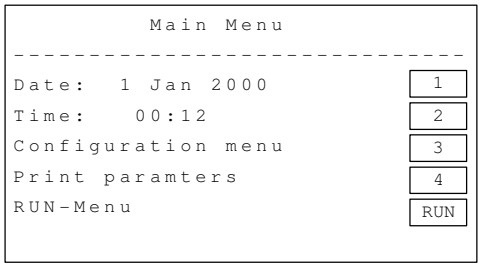
4.1 Routine and Single Test Mode Programming

Programming the Routine Program defines the tests which are to be performed in the Routine Program mode (section 3.1)

Programming the Single Test Program defines which tests can be called up and performed in the Single Test Program mode (section 3.1).

The programming method for both the Routine and Single Test Program is the same.

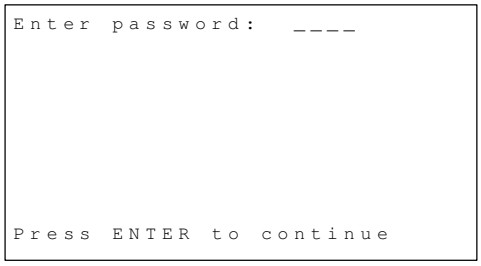
Main Menu



Activate the Main **Menu** using the **<MENU>** key (see section 3.4)

Select <3> **Configuration Menu**.

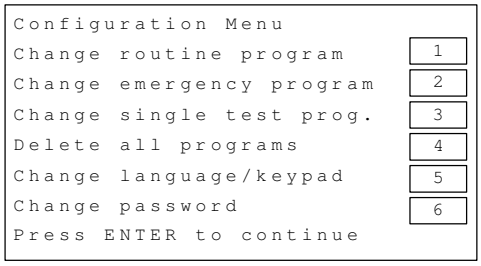
Screen Password Entry



Enter the password and press **ENTER <↵>**.

(The default password is 1234)

Configuration Menu



Select

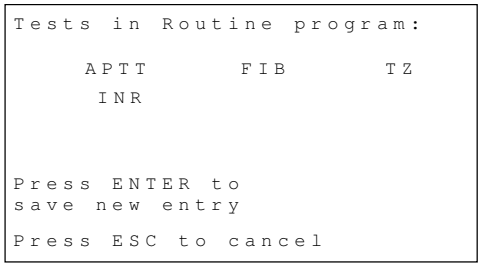
1 **Change Routine Program**, if the Routine program is to be programmed.

3 **Change single test program** if the Single Test Program is to be programmed.

For Routine Program programming

Select all of the tests which will form the Routine Program test group using the appropriate function keys (e.g. <APTT>). The tests will be processed in the “RUN” mode in the same order they have been selected. Wrong entries can be deleted using the **<DEL>** key. If programming is aborted using the **<ESC>** key, the test programmed in the original Routine Program will remain active. When all tests have been selected, press **<↵>** to return to the Configuration Menu.

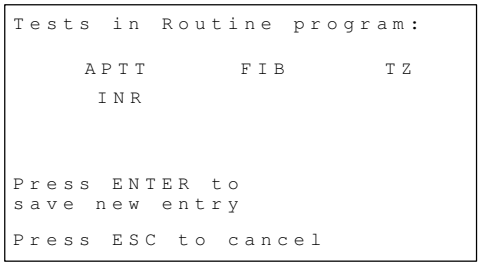
Example: Routine-Program



For Single Test Program programming

Using the appropriate function keys (e.g. <APTT>), select all of the tests which should be available in the Single Test Program mode. Wrong entries can be deleted using the **<DEL>** key. If programming is aborted using the **<ESC>** key, the test programmed in the original Single Test Program will remain active. When all tests have been selected, press **<↵>** to return to the Configuration Menu.

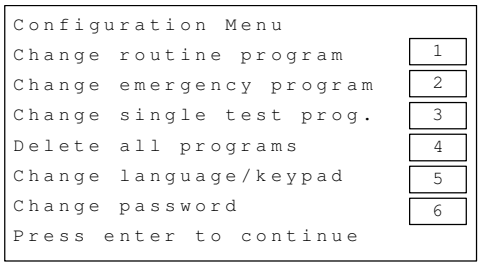
Example: Single Test Program



If the Configuration Menu is exited using the **<↵>** key, all of the programmed tests and their parameters will be displayed in sequence. Test parameters can be entered or changed during this sequence (section 5).

Note: The test parameters will always be displayed when the Configuration Menu is exited if at least one of the three menus "Change xxx program" is selected.

Configuration Menu

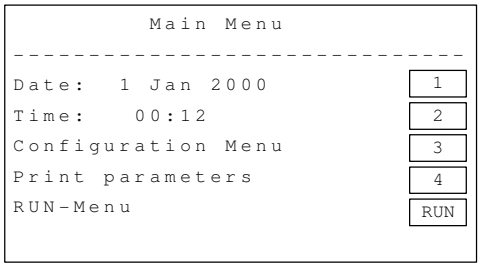


4.2 Emergency Program Programming

Programming the Emergency program defines which tests will be processed in the Emergency Program (section 3.1)

Activate the Main Menu using the **<MENU>** key (see section 3.4). Select <3> C**onfiguration Menu**.

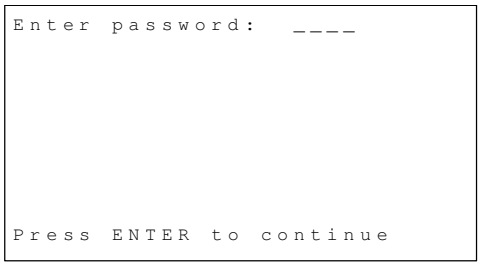
Main Menu



Screen Enter Password

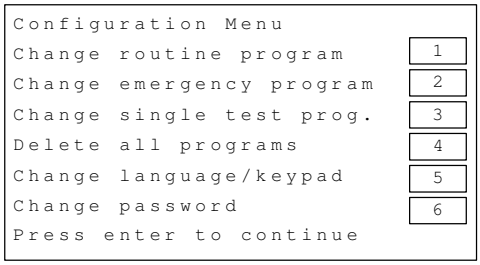
Enter the password and press **ENTER <↵>**.

(The default password is 1234)



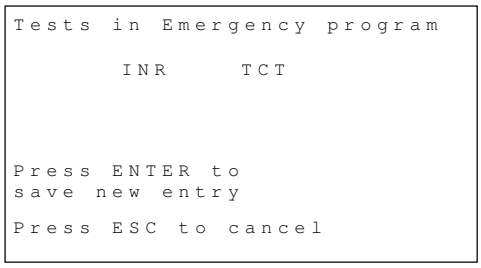
Configuration Menue

Press
2 **Change Emergency Program**.



Using the appropriate function keys (e.g. <INR>) select all of the tests which should be available in the Emergency Program mode. The tests will be processed in the "RUN" mode in the same order they have been selected.
Wrong entries can be deleted using the **<DEL>** key.
If programming is aborted using the **<ESC>** key, the test programmed in the original Emergency Program will remain active. When all tests have been selected, press **<↵>.**

Example: Emergency Program

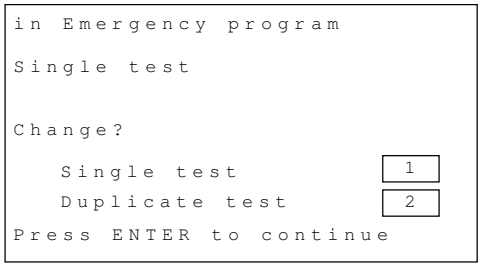


All tests in the Emergency Program will be processed either in single (key 1) or duplicate (key 2)

Press the **<↵>** key to retain the current setting.

Note: The selection of single or duplicate testing made for tests in the other processing modes are not valid for the Emergency Program (see section 5).

Singleton or duplicate testing



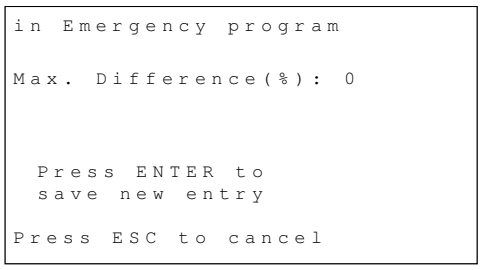
When duplicate testing has been selected the maximum permitted difference between duplicate measuring times in [%] must be entered. Press **<↵>** to close.

If the entry is aborted using the **<ESC>** key, the currently programmed maximum difference value will be retained.

The difference is calculated as follows:

$$\text{Difference(\%)} = \frac{\text{(difference between measuring and average value)}}{\text{Average Value}} \times 100$$

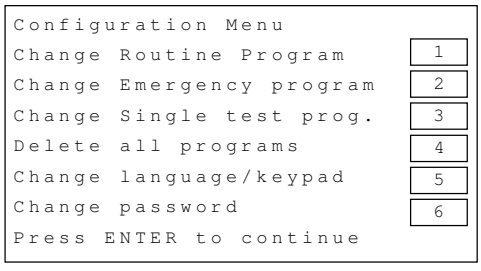
Enter difference



The Configuration Menu will be activated.

If the Configuration Menu is exited using the **<↵>** key, all of the programmed tests and their parameters will be displayed in sequence. Test parameters can be entered or changed during this sequence (section 5).

Configuration Menu



Note: The test parameters will always be displayed when the Configuration Menu is exited if at least one of the three menus "Change xxx program" is selected.

5. Test Configuration / Changing Configuration

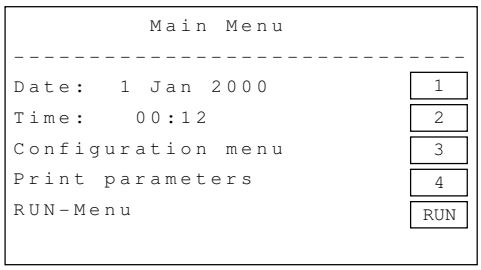
Prerequisite
In order for a test to be configured it must have been selected for use in at least one of the processing programs (see section 4).

If this is not the case, insert the test in one of the processing programs. Please note that the insertion of a new test in a processing program will deactivate the previous programming. The originally programmed test must be reselected by pressing the corresponding function key (e.g. INR). In the Routine and Emergency Program the order of entry is important. Tests will be processed in the same order that they are entered in these programs.

Configuring a Test or changing a test configuration
In order to change test parameters at least one of the menu options **"Change Routine", "Emergency" or "Single Test Program"** must be selected from the Configuration Menu (section 4). The menu option "Change XXX program" can be exited using the **<ESC>** key. The program retains the original settings. The Configuration Menu will be recalled. After pressing the **<↵>** key all of the tests and specific test programming will be displayed in sequence and may be changed. Any changes to the test configuration made here will be valid for all processing programs except the definition single/duplicate testing in the Emergency Program (section 4.2: max. difference entry).

5.1 Accessing Test Configuration

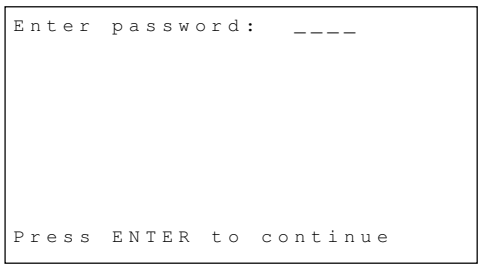
Press the **<MENU>** key to activate the **Main Menu** (section 3.4)



Select <3> **Configuration Menu.**

Enter the password:_ _ _ _.

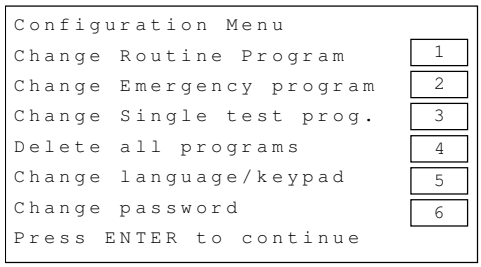
(The default password is 1234)



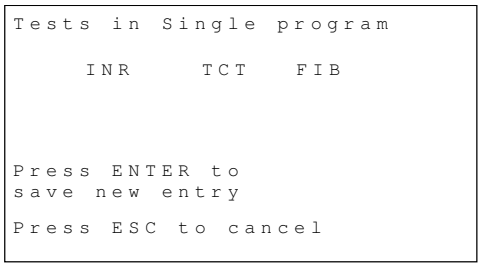
Press the **<↵>** key.

Select one of the menu options:
Routine, Emergency or Single Test Program using keys **<1>, <2> or <3>**

(Example: 3 „Change Single Test Program")



Abort programming using the **<ESC>** key. The original programming will be retained and the Configuration Menu recalled.



Press the **<↵>** to exit the Configuration Menu.

All of the tests which are programmed in at least one of the proceeding programs will be displayed in sequence. Tests may now be configured by pressing **<1>** "Modify? Yes". The configuration description will be described under the corresponding name in the following sections.

If the parameters are correct press **<↵>** or **<2>** "Modify? No" and the parameters of the next test will be displayed.

When the last test has been displayed the Main Menu will be displayed. The configuration is complete.

5.2 PT, NT, TT

PT: Thromboplastin Time or Prothrombin time
NT: Normotest™
TT: Thrombotest™

The method of configuration of the tests PT, NT and TT is the same. For example the PT test will be described.

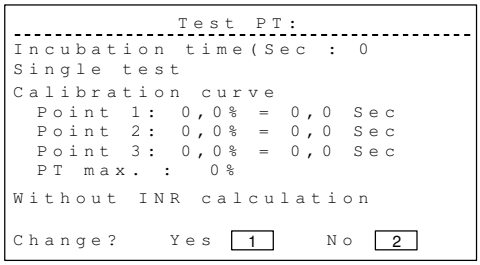
Note: Dependant on the keypad setting (section 3.5.5) the tests **PT** and **RATIO** or **NT** und **TT** can be activate.

The following values are only examples. The correct values should be taken from the reagent manufacturer's test application.

Call up the test configuration (section 5.1) and test PT. Following display will appear on the screen.

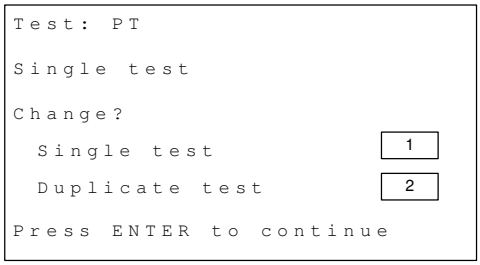
Select **YES <1>**, to change the settings.

Select **No <2>** or **<↵>** to retain the original settings. The configuration for the next test will be displayed.



For Singleton testing select **<1> Single Test.**
To perform the test in duplicate select
<2> Duplicate Test.

If **<↵>** is selected the original setting will be retained.



Thrombotest is a trademark registered by Axis Shield PoC as, Norway

If duplicate test is selected enter the max. difference (%CV) and press **<↵>** to save the new entry.
Press **<ESC>** to retain the original setting.

The difference will be calculated as follows:

$$\text{Difference(\%)} = \frac{\text{(Difference between Measuring and Average time)}}{\text{Average Value}} \times 100$$

```
Test: PT

Max. Difference(%): 5


  Press ENTER to
  save new entry
Press ECS to cancel
```

Enter the incubation time defined in the test application and press **<↵>** to save the new entry.
Press **<ESC>** to retain the original setting.

```
Test: PT

Incubation time(Sec) : 60


  Press ENTER to
  save new entry
Press ESC to cancel
```

Enter the reference values for the PT calibration Curve.

Point 1 is the point with the highest value and the shortest time. The value need not be 100%. It may vary according to the source of the reference plasma.

Example: 100 %

```
Calibration curve PT:

Point 1 (%) : 100,0


  Press ENTER to
  save new entry
Press ESC to cancel
```

Enter the clotting time for the first point on the PT calibration curve and press **<↵>** to save the new entry.

Press **<ESC>** to cancel and retain the original setting.

The value of point 1 is the one with the shortest value.

Example: 10.8 seconds

```
Calibration Curve PT:

Point 1 (Sec): 10.8


  Press ENTER to
  save new entry
Press ESC to cancel
```

Enter the second value for the PT calibration curve and press **<↵>** to save the new entry.

Press **<ESC>** to cancel and retain the original setting.

The second point is a reference plasma dilution.

Example: 25 %

```
Calibration curve PT:

Point 2(%) : 50.0


  Press ENTER to
  save new entry
Press ESC to cancel
```

Enter the clotting time for the second point on the PT calibration curve and press **<↵>** to save the new entry.

Press **<ESC>** to cancel and retain the original setting.

Example: 21.5 seconds

```
Calibration curve PT:

Point 2 (sec): 25.6


  Press ENTER to
  save new entry
Press ESC to cancel
```

Enter the third value for the PT calibration curve and press **<↵>** to save the new value.
Press **<ESC>** to cancel and retain the original setting.

The third point is the lowest point in the curve and is a reference plasma dilution.

Example: 12.5 %

```
Calibration curve PT:

Point 3(%) : 12.5


  Press ENTER to
  save new entry

Press ESC to cancel
```

Enter the clotting time fort he third point on the PT calibration curve and press **<↵>** to save.

Press **<ESC>** to cancel and retain the original setting.

The value for point 3 is the one with the longest time value.

Example: 31.4 seconds.

```
Calibration curve PT:

Point 3(sec): 31.4


  Press ENTER to
  save new entry

Press ESC to cancel
```

Enter the maximum value to be reported for the PT in % and press **<↵>** to save the new entry.

Press **<ESC>** to cancel and retain the original setting.

Values which are higher than the defined PT max. will not be evaluated and is reported as "> defined PT max. value".

Example: 130 %

```
Calibration curve PT:

PT max:(%): 130.0


  Press ENTER to
  save new entry

Press ESC to cancel
```

If the INR is to be calculated, the ISI value must be entered. Press **<↵>** to save the new entry.
The standard value does not need to be entered. It will be calculated from the calibration curve.
If the ISI value **"0"** is entered **no** INR value will be calculated.

Press **<ESC>** to cancel and retain the original setting.

Example: 1.03

```
Calibration Curve PT
Calculate INR
  With INR calculation
  enter ISI value
  Without INR calculation
  enter ISI value = 0
ISI value:    1,03
  Press ENTER to
  save new entry
Press ESC to cancel
```

In conclusion all values will be displayed.

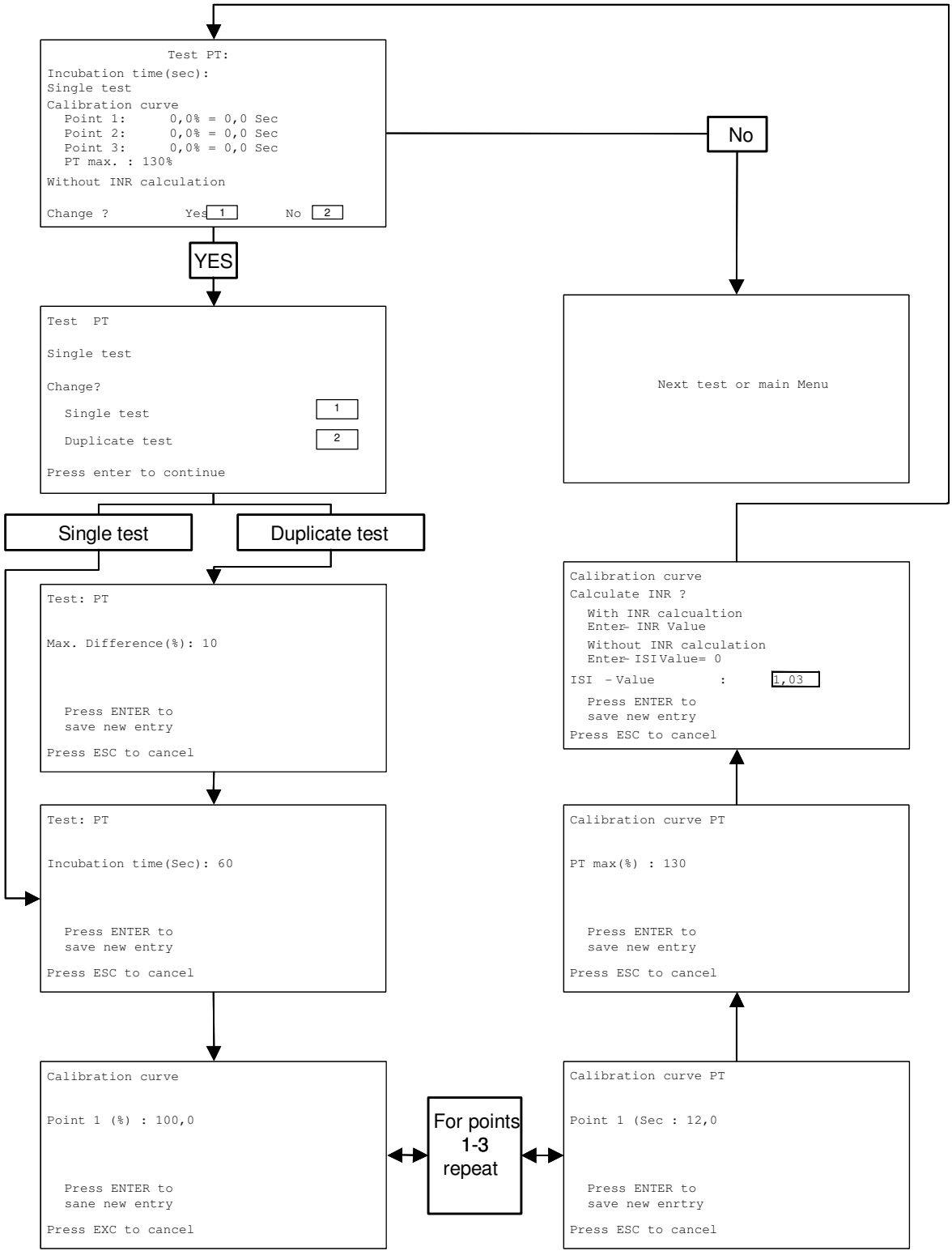
If the values have been correctly entered complete the entry with **No <2>** or **<↵>.**
The PT test is configured.

All parameters of the following tests are now displayed. If there are no tests to follow the Main Menu will be activated.

```
            Test PT:
-----------------------------------
Incbation time(Sec : 60
Single test
Calibration curve
  Point 1: 100,0% = 10,8 Sec
  Point 2:  25,0% = 21,5 Sec
  Point 3:  12,5% = 31,4 Sec
  PT max. :  130%
With INR calcualtion
ISI value   : 1,03
Change?     Yes 1      No 2
```

If incorrect values have been entered, press **Yes <1>** to repeat the data entry routine.

5.3 PT (% activity) Flow Chart



Note: The flow chart can also be used for NT and TT.

5.4 RATIO

Note: Depending on the keypad settings (see section 3.5.5), the tests **PT** and **RATIO** or **NT** and **TT** may be activated.

The following values are only example values and should be replaced by the values given in the test application.

Call up the test configuration and the RATIO test (section 5.1.). Following will be displayed on the screen.

Select **Yes <1>**, to change the settings.

Press **No <2>** or **<↵>** to retain the original settings. The next test will be displayed for configuration.

```
Test RATIO:
Incubation time(sec): 60
Mean Normal value: 12,8

Single test

Change ?  Yes [1]  No [2]
```

For single testing, select **<1> Single test**.
For duplicate processing, select **<2> Duplicate test.**

Press **<↵>** to cancel and retain original setting.

```
Test RATIO

Single test

Change?
  Single test      [1]
  Duplicate test   [2]
Press ENTER to continue
```

If duplicate test has been selected enter the maximum difference and press **<↵>** to save the new entry.
Press **<ESC>** to cancel and retain the original setting.

The difference will be calculated as follows:

$$\text{Difference}(\%) = \frac{\text{(Difference between Measuring and Average value)}}{\text{Average value}} \times 100$$

```
Test: RATIO

Max. Difference(%): 5


  Press ENTER to
  save new entry
Prees ESC to cancel
```

Enter the incubation time defined in the test application and press **<↵>** to save the new entry.

Press **<ESC>** to cancel and retain the original settings.

```
Test: RATIO

Incubation time(Sek) : 60


  Press ENTER to
  save new entry.
Press ESC to cancel.
```

Enter the Mean normal value in seconds and press **<↵>** to save the new entry.

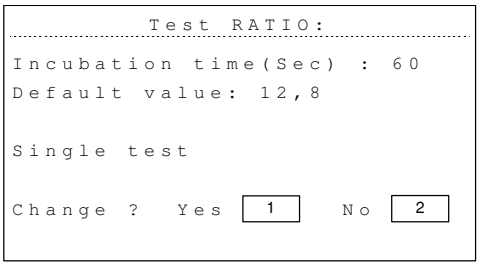
Press **<ESC>** to cancel and retain original settings.

```
Test: RATIO

Mean normal value: 12,8


  Press ENTER to
  save new entry
Press ESC to cancel
```

In conclusion all values will be displayed.

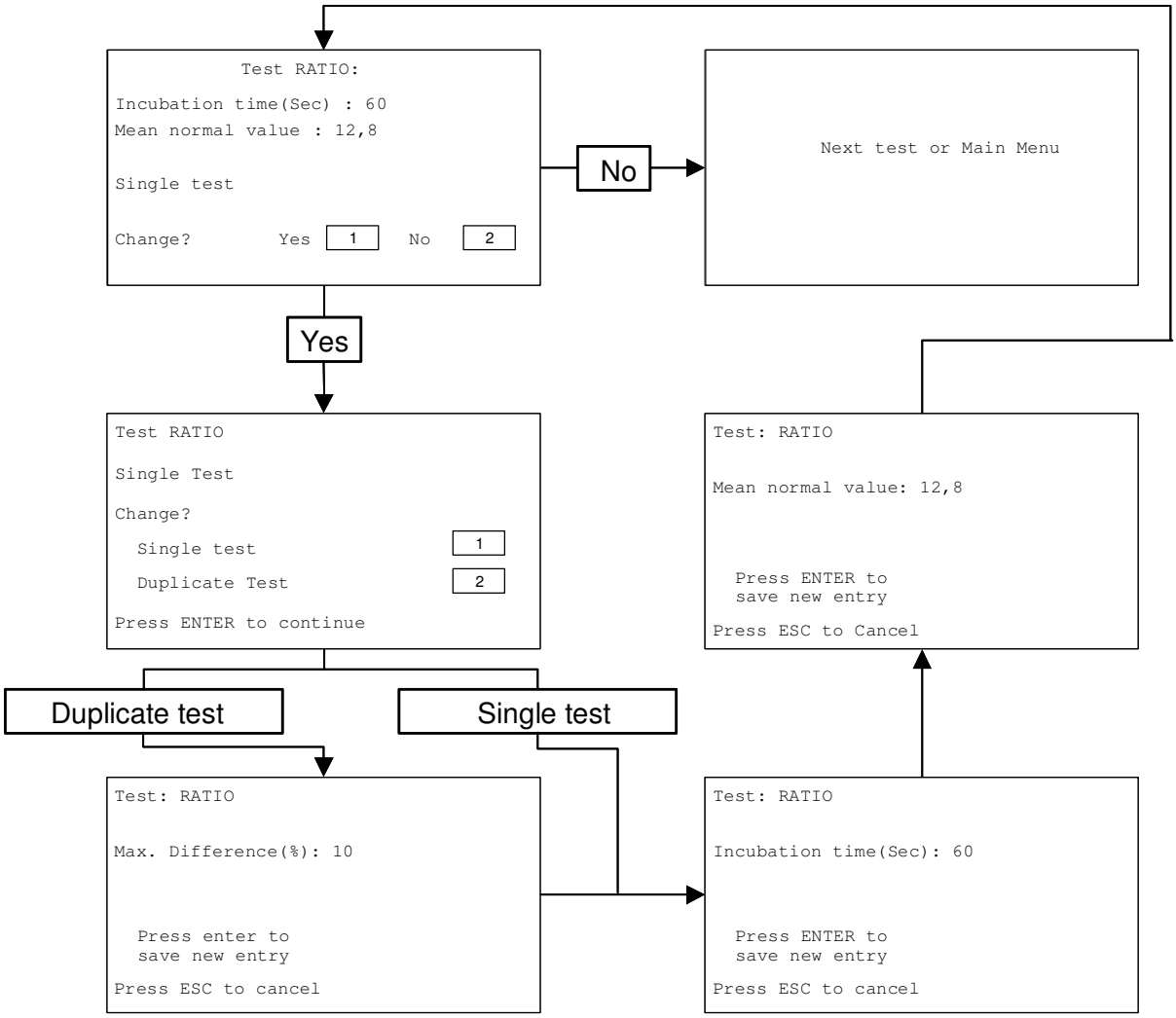
If the values have been correctly entered complete the entry with **No <2>** or **<↵>.**
The RATIO test is configured.

All parameters of the following tests are now displayed. If there are no tests to follow the Main Menu will be activated.



If incorrect values have been entered, press **Yes <1>** to repeat the data entry routine.

5.5 Ratio Flow Chart



NOTE: The keypad must be set to INR/Ratio.

5.6 INR (International Normalised Ratio)

The INR (International Normalised Ratio) is the preferred method for reporting prothrombin times in the USA. The PT % activity curve and ratio are preferred in Europe.

The following values are only example values and should be replaced by the values given in the test application.

Call up the test configuration and the INR test (section 5.1.). Following will be displayed on the screen.

Select **Yes <1>**, to modify the settings.
Press **No <2>** or **<↵>** cancel and retain the original settings for the INR configuration. The next test will be displayed.

```
Test INR:
Incubation time(Sec): 60
Default value: 12,8
ISI-Value:  1,03
Single Test

Change ?   Yes [1]   No [2]
```

For single testing, select **<1> Single test**.
For duplicate testing, select **<2> Duplicate test.**

Press **<↵>** to cancel and retain original settings.

```
Test INR

Single test

Change?
  Single test          [1]
  Duplicate test       [2]

Press ENTER to continue
```

If duplicate test is selected enter the maximum difference permitted between duplicates and press **<↵>** to save the new entry.

Press **<ESC>** to cancel and retain the original settings.

```
Test: INR

Max. Difference(%) : 5


  Press ENTER to
  save new entry

Press ESC to cancel
```

The difference will be calculated as follows:

$$\text{Difference}(\%) = \frac{\text{(Difference between Measuring and Average value)}}{\text{Average value}} \times 100$$

Enter the incubation time contained in the test application and press **<↵>** to save the new entry.

Press **<ESC>** to cancel and retain the original settings.

```
Test: INR

Incubation time(Sec) : 60


  Press ENTER to
  save new enrty

Press ESC to cancel
```

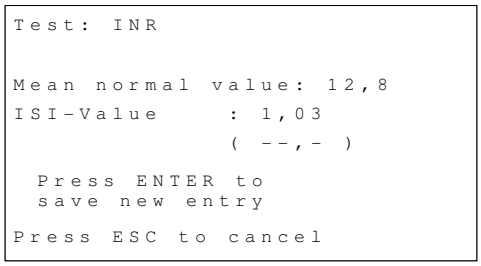
Enter the Mean normal value in seconds and press **<↵>** to save the new entry.

Press **<ESC>** to cancel and retain the original setting.

```
Test: INR

Mean normal value : 12,8
                ( --,- )

  Press ENTER to
  save new entry

Press ESC to cancel
```

Enter the ISI contained in the reagent box insert and press **<↵>** to save the new entry

Press **<ESC>** to cancel and retain the original settings.

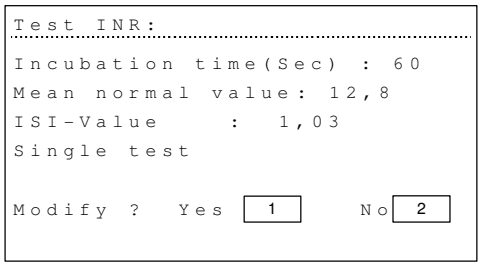


In conclusion all values will be displayed.

If the values have been correctly entered complete the entry with **No <2>** or **<↵>.**
The INR test is configured.

All parameters of the following tests are now displayed. If there are no tests to follow the Main Menu will be activated.

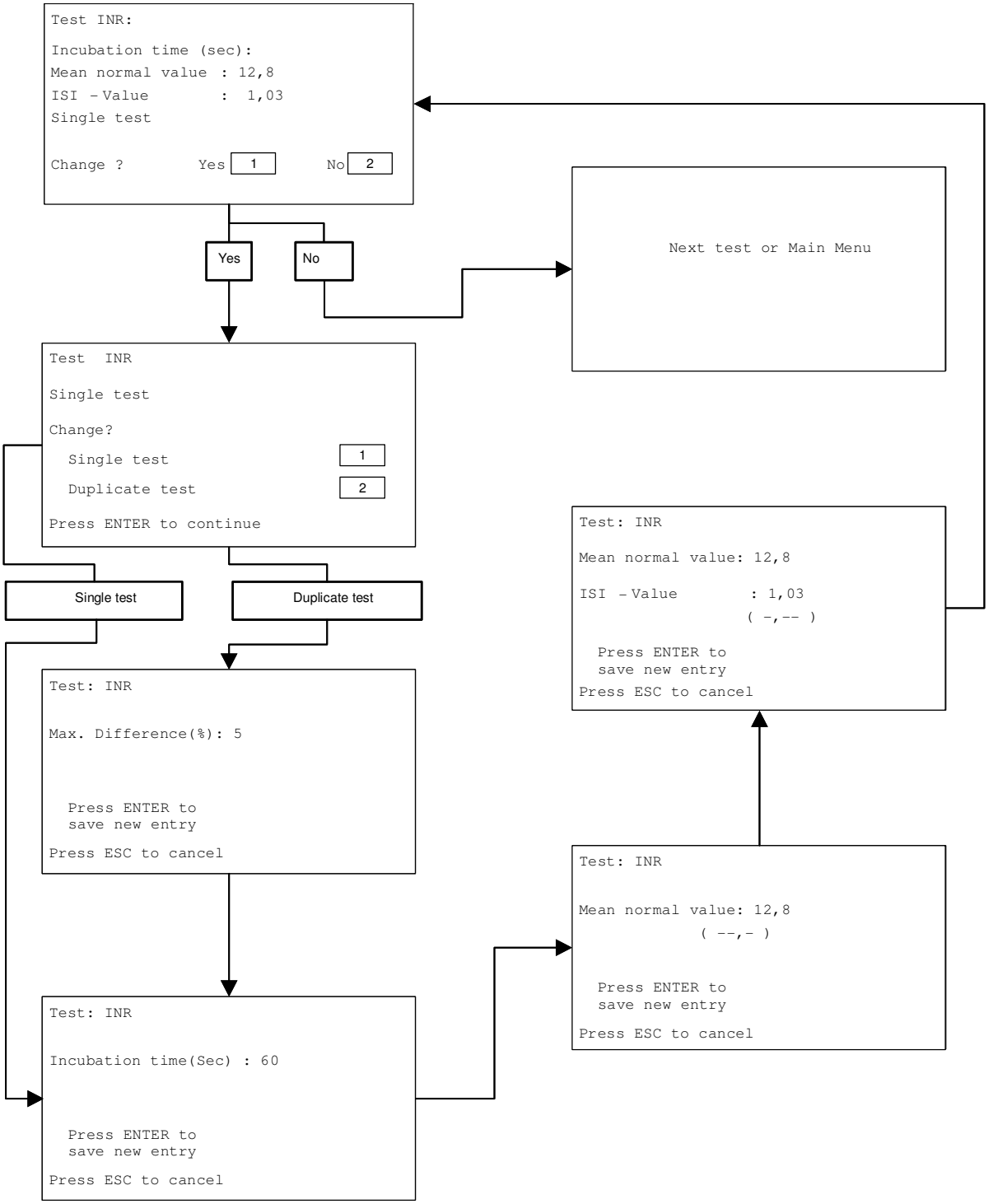
If incorrect values have been entered, press **Yes <1>** to repeat the data entry routine.



The KC4Δ calculates the INR automatically using the Mean normal value and the specific ISI value entered for the thromboplastin reagent in use.

Note: Before values are entered a mean normal value should be determined for the specific lot number of the thromboplastin being used. Because the mean normal value is dependant on the patient population, the laboratory and the thromboplastin reagent formulation being used, the mean normal value should be determined for the specific patient population/laboratory/reagent formulation combination. For a correct INR calculation the geometric mean of the normal patient population should be determined. When the geometric mean has been determined it can be programmed into the KC4Δ coagulation analyzer.

5.7 INR Flow Chart



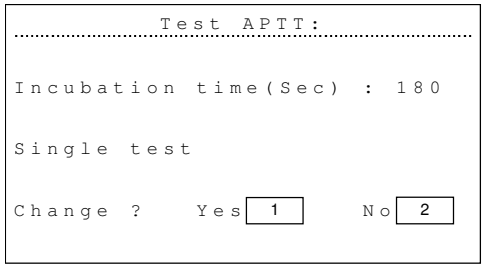
5.8 APTT or TCT

APTT: Activated partial thromboplastin time
TCT: Thrombin clotting time

The method for configuring the APTT und TCT test is the same. In the example below the APTT test will be described.

Note: The following values are only example values and should be replaced by the values given in the test application.

Call up the test configuration and the APTT test (section 5.1). Following will be displayed on the screen.

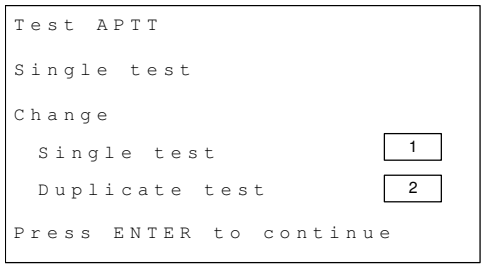


Select **Yes <1>**, to modify the settings.

Press **No <2>** or **<↵>** to cancel and retain the original settings. The next test will be displayed.

For single testing, select **<1> Single test.**
For duplicate testing, select **<2> Duplicate test.**

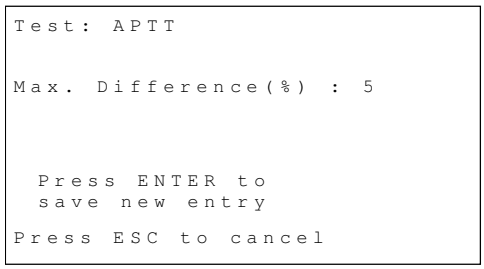
Press **<↵>** to retain the original settings.



If duplicate test has been selected enter the maximum permitted difference between duplicates and press **<↵>** to save the new entry.
Press **<ESC>** to cancel and retain the original settings.

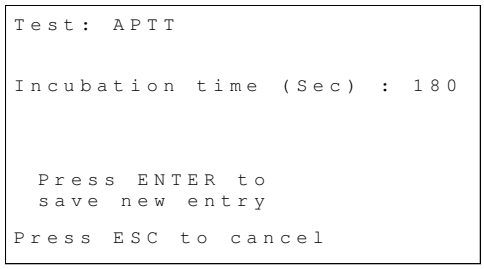
The difference will be calculated as follows:

$$\text{Difference}(\%) = \frac{\text{(Difference between Measured and Average value)}}{\text{Average value}} \times 100$$



Enter the incubation time contained in the test application and press **<↵>** to save the new entry.

Press **<ESC>** to cancel and retain the original setting.

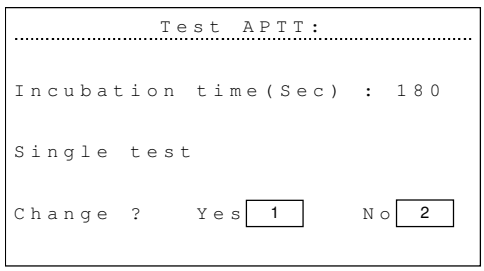


In conclusion all values will be displayed.

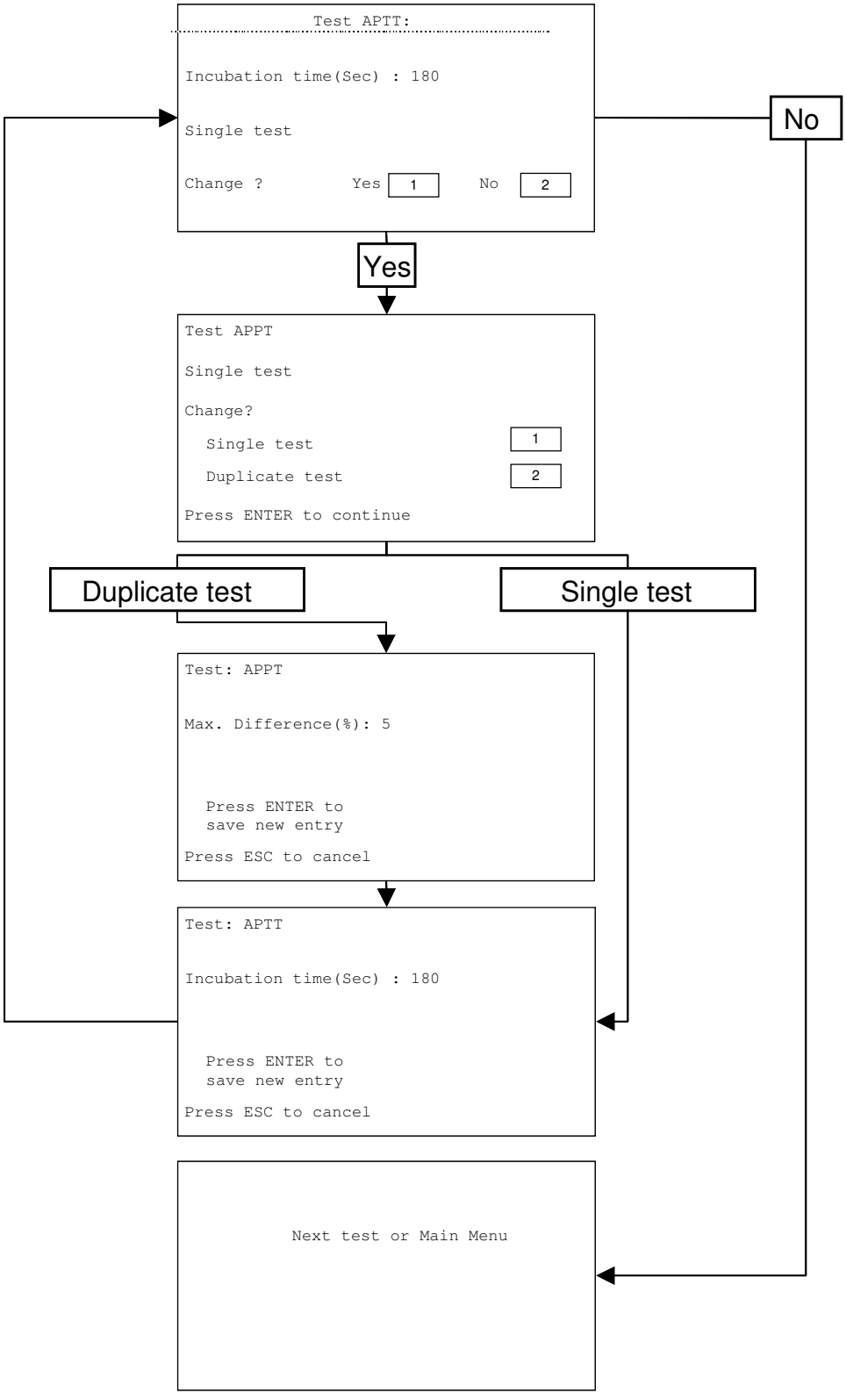
If the values have been correctly entered complete the entry with **No <2>** or **<↵>.**
The APTT test is configured.

All parameters of the following tests are now displayed. If there are no tests to follow the Main Menu will be activated.

If incorrect values have been entered, press **Yes <1>** to repeat the data entry routine.



5.9 APTT Flow Chart (valid also for TCT)



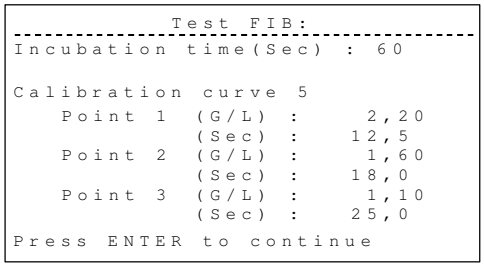
5.10 FIB (Fibrinogen)

Before the Fibrinogen test can be configured the concentrations and clotting times must be known for each calibration curve point.
Between 3 and 9 calibration points may be entered on the KC4Δ.

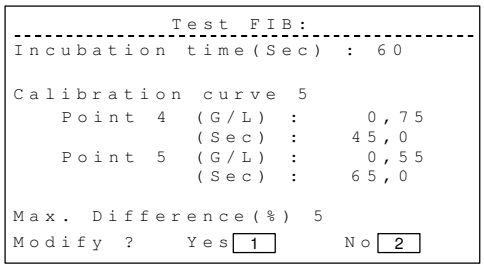
Note: The following values are only examples and should be replaced by the values contained in the test application.

Note: The **Dilution** will be reset to **1:10** when the KC4Δ is switched on and displayed in the Operating Screen (see section 3.16). This value can be modified in the (FIB test) measuring mode by pressing the **<DILUTION>** key, when no measurements are active. The modified dilution value will remain valid until the instrument is switched off or the value is modified again.

Activate the test configuration (section 5.1) and the FIB test. Following display will appear on the screen.



To enter more than 3 points press **<↵>**, until the question "Modify? Yes <1> No <2>" is displayed.

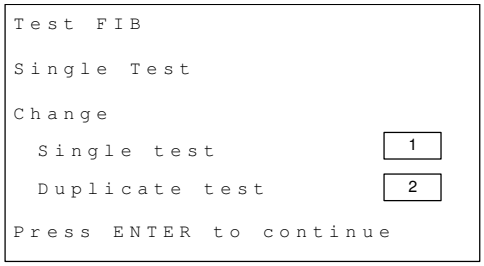


Select **Yes <1>**, to modify the settings.

Press **No <2>** or **<↵>** to retain the original settings. The next test will be displayed.

For single testing, select **<1> Single test.**
For duplicate testing, select **<2> Duplicate test.**

Press **<↵>** to cancel and retain original setting.

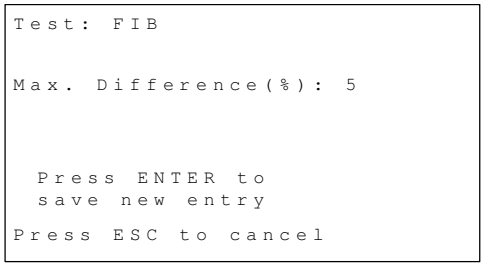


If duplicate test has been selected, enter the maximum permitted difference between duplicates and press **<↵>** to save the new entry.

Press **<ESC>** to cancel and retain the original setting.

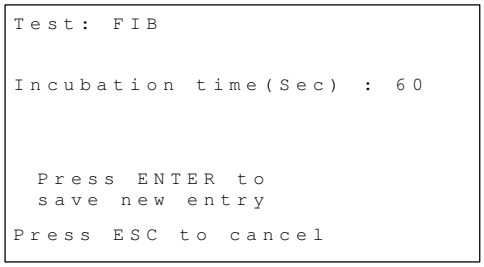
The difference will be calculated as follows:

$$\text{Difference}(\%) = \frac{\text{(Difference between Measured and Average value)}}{\text{Average value}} \times 100$$



Enter the incubation time contained in the test application and press **<↵>** to save the new entry.

Press **<ESC>** to cancel and retain the original setting.



Enter the number of calibration points and press **<↵>** to save the new entry.
(minimum of 3, maximum of 9 points).
Press **<ESC>** to cancel and retain original settings.

```
Test: FIB

Curve points: 5



  Press ENTER to
  save new entry

Press ESC to cancel
```

Enter the FIB calibration reference plasma value.
Point 1 is the point with the highest value (Gram/Litre) and the shortest time.

```
Calibration curve FIB

Point 1 (G/L) : 2,20



  Press ENTER to
  save new entry

Press ESC to cancel
```

Enter the clotting time in seconds for the first FIB calibration
curve point and press **<↵>** to save the new entry. Point 1 is the point with the shortest time.
Press **<ESC>** to cancel and retain the original settings.

```
Calibration curve FIB:

Point 1 (Sec) : 12,5



  Press ENTER to
  save new entry

Press ESC to cancel
```

Repeat the last two actions for all points until all of the defined points have been programmed. The last point is the point with the smallest g/l value and the longest time.

In conclusion all values will be displayed.

If all values entered are correct press **No <2>** or **<↵>** to save the new entries

The FIB test is configured.

The parameters for the next test will be displayed. If there is no next test, the Main Menu will be displayed.

```
          Test FIB:
----------------------------------
Incubation time(Sec) : 60

Calibration points:5
    Point 1  (G/L) :     2,20
             (Sec) :    12,5
    Point 2  (G/L) :     1,60
             (Sec) :    18,0
    Point 3  (G/L) :     1,10
             (Sec) :    25,0
Press ENTER to continue
```

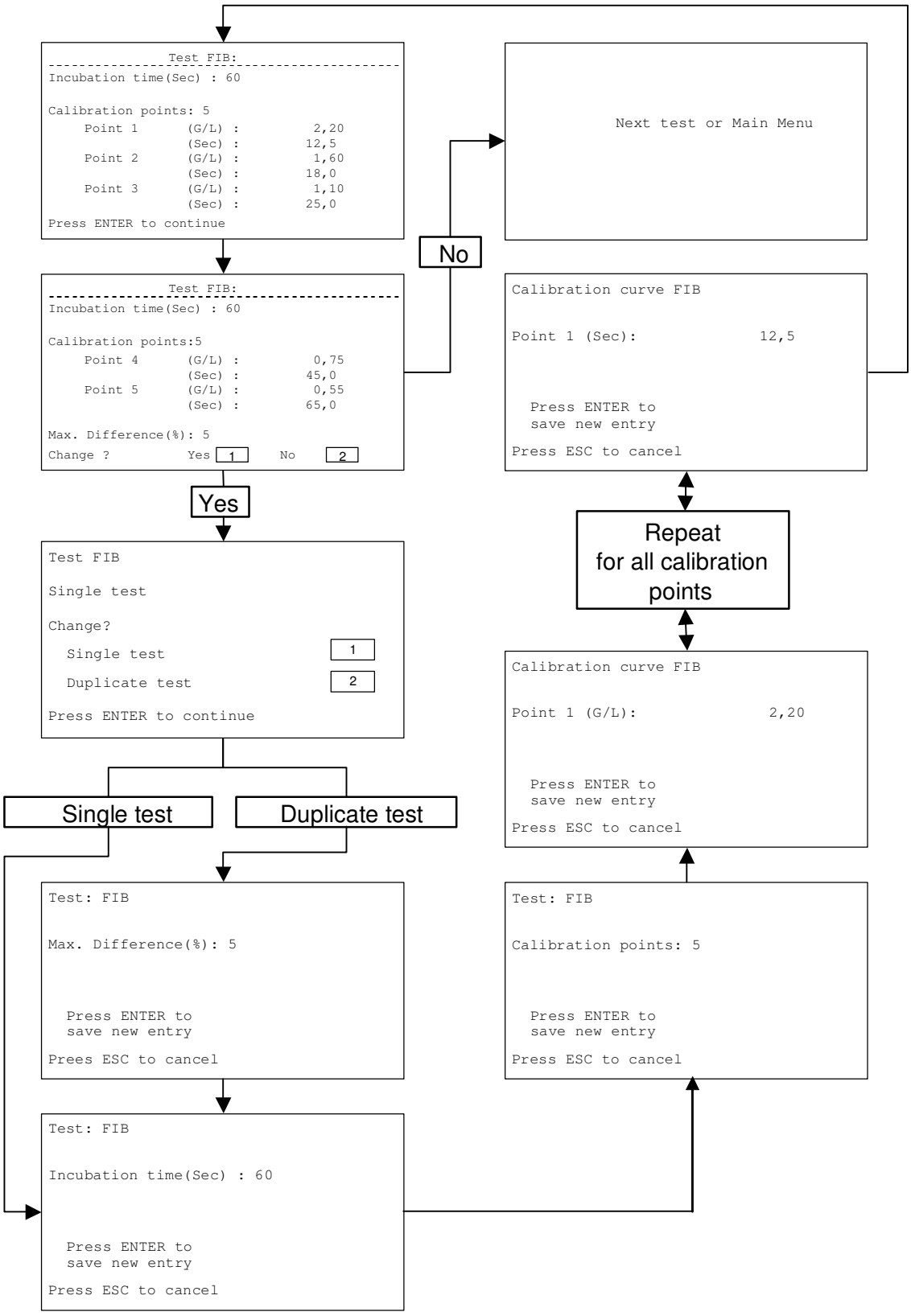
If incorrect values were entered by mistake select **Yes <1>** to repeat the whole data entry routine.

```
          Test FIB:
----------------------------------
Incubation time(Sec) : 60

Calibration points:5
    Point 4  (G/L) :     0,75
             (Sec) :    45,0
    Point 5  (G/L) :     0,55
             (Sec) :    65,0

Max. Difference(%): 5
Change?     Yes 1      No 2
```

Note: Enter the value in g/l of the Fibrinogen Reference Plasma for the first point in the curve. The value can vary from lot to lot. When using the KC4Δ coagulation analyzer please note that the clotting time for the highest point in the curve must be longer than the KC4Δ minimum measuring time (4.5 sec). This can be achieved by using the Trinity Biotech reference plasma and the optimised dilution ratio contained in the test application.

Note: The recommended dilution ratio and reagent volumes for the Fibrinogen test are contained in the KC4Δ Fibrinogen Test Application.

5.11 FIB Flow Chart



5.12 FAC (Factors) / FAC* (inverse Calibration Curve)

Note: **Only one factor curve can be entered and stored at any one time.**

Note: The following values are only examples and should be replaced by the values contained in the test application.

Note FAC*: Instead of a normal factor calibration curve an inverse calibration curve can be entered e.g. for Protein C or Protein S clotting tests. The inverse setting is indicated by the flag " * " after the test code FAC.

Activate the test configuration (section 5.1) and the FAC test. The following display will appear on the screen:

```
Test FAC:              Factor: 10
Incubation time(Sec) : 60
Calibration points:5
Calibration curve F 10
    Point 1  (%) :       100,0
             (Sec) :      10,8
    Point 2  (%) :        25,0
             (Sec) :      21,5
    Point 3  (%) :        12,5
             (Sec) :      34,4
Press ENTER to continue
```

To enter more than 3 points press **<↵>**, until the question "Modify? Yes <1> No <2>" is displayed.

```
Test FAC:          FACTOR 10
Incubation time(Sec) : 60
Calibration points:5
Calibration curve F 10
    Point 4  (%)    :        0,0
             (Sec)  :        0,0
    Point 5  (%)    :        0,0
             (Sec)  :        0,0


Max. Difference(%): 5
Change ?    Yes [1]        No [2]
```

Select **Yes <1>**, to modify the settings.

Press **No <2>** or **<↵>** to retain the original settings. The next test will be displayed.

```
Test FAC

Single test

Change?
  Single testmmung          [1]
  Duplicate test            [2]
Press ENTER to continue
```

For single testing, select **<1> Single test.**
For duplicate testing, select **<2> Duplicate test.**

Press **<↵>** to cancel and retain original setting.

```
Test: FAC

Max. Difference(%):5



  Press ENTER to
  save new entry
Press ESC to cancel
```

If duplicate test has been selected, enter the maximum perm between duplicates and press **<↵>** to save the new entry.

Press **<ESC>** to cancel and retain the original setting.

The difference will be calculated as follows:

$$\text{Difference}(\%) = \frac{\text{(Difference between Measured and Average value)}}{\text{Average value}} \times 100$$

```
Test: FAC

Incubation time(Sec) : 60



  Press ENTER to
  save new entry
Press ESC to cancel
```

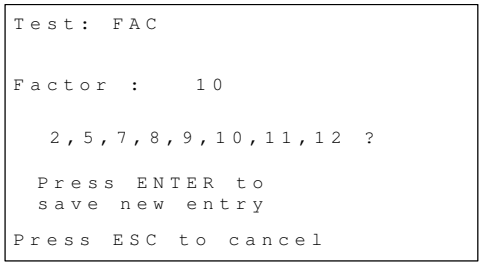
Enter the incubation time contained in the test application and press **<↵>** to save the new entry.

Press **<ESC>** to cancel and retain the original setting.

Enter the Factor code to be used and press **<↵>** to save the new entry.

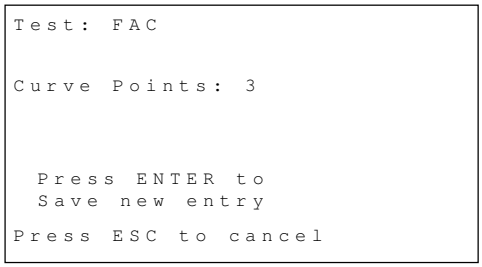
Press **<ESC>** to cancel and retain the original settings.

Note: If an inverse calibration curve is to be entered (FAC*) the factor code entry will not be used. If an inverse calibration curve is already entered, entry of the factor code will not be requested.



Enter the number of calibration points and press **<↵>** to save the new entry.
(minimum of 3, maximum of 9 points).

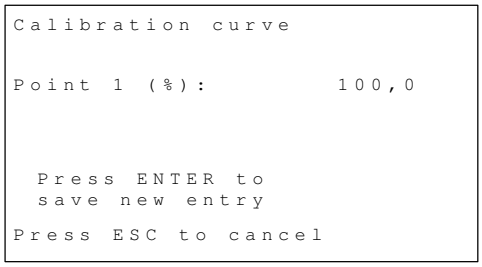
Press **<ESC>** to cancel and retain original settings.



Factor Calibration Curve data entry

Enter the FAC calibration reference plasma value and press **<↵>** to save the new entry.

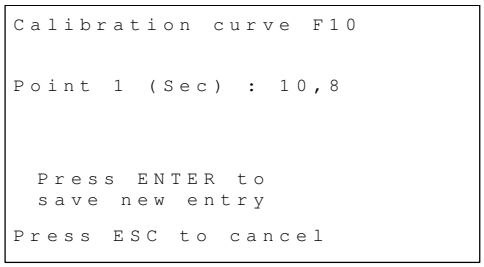
Point 1 is the point with the highest % and the shortest time. The value need not be 100%.



Enter the clotting time in seconds for the first FAC calibration curve point and press **<↵>** to save the new entry.

Point 1 is the point with the shortest time.

Press **<ESC>** to cancel and retain the original settings.



Repeat the last two actions for all points until all of the defined points have been programmed. The last point is the point with the smallest % value and the longest time.

FAC* Calibration Curve (inverse curve) Data Entry

Enter the FAC* calibration reference plasma value and press **<↵>** to save the new entry.

Point 1 is the point with the highest % and the longest time. The value need not be 100%.

```
Calibration curve FAC*

Point 1 (%):          100,0


  Press ENTER to
  save new entry

Press ESC to cancel
```

Enter the clotting time in seconds for the first FAC* calibration curve point and press **<↵>** to save the new entry.

Point 1 is the point with the longest time.

Press **<ESC>** to cancel and retain the original settings.

```
Calibration curve FAC*

Point 1 (Sec) : 54,6


  Press ENTER to
  Save new entry

Press ESC to cancel
```

Repeat the last two actions for all points until all of the defined points have been programmed. The last point is the point with the smallest % value and the shortest time.

If an inverse calibration curve (FAC*) has been entered confirm the data entry with key **<1>** (Yes).

```
 Inverse Calibration curve?

      Are you sure?

   Yes [1]              [2] No
```

In conclusion all values will be displayed.

If all values entered are correct press **No <2>** or **<↵>** to save the new entries

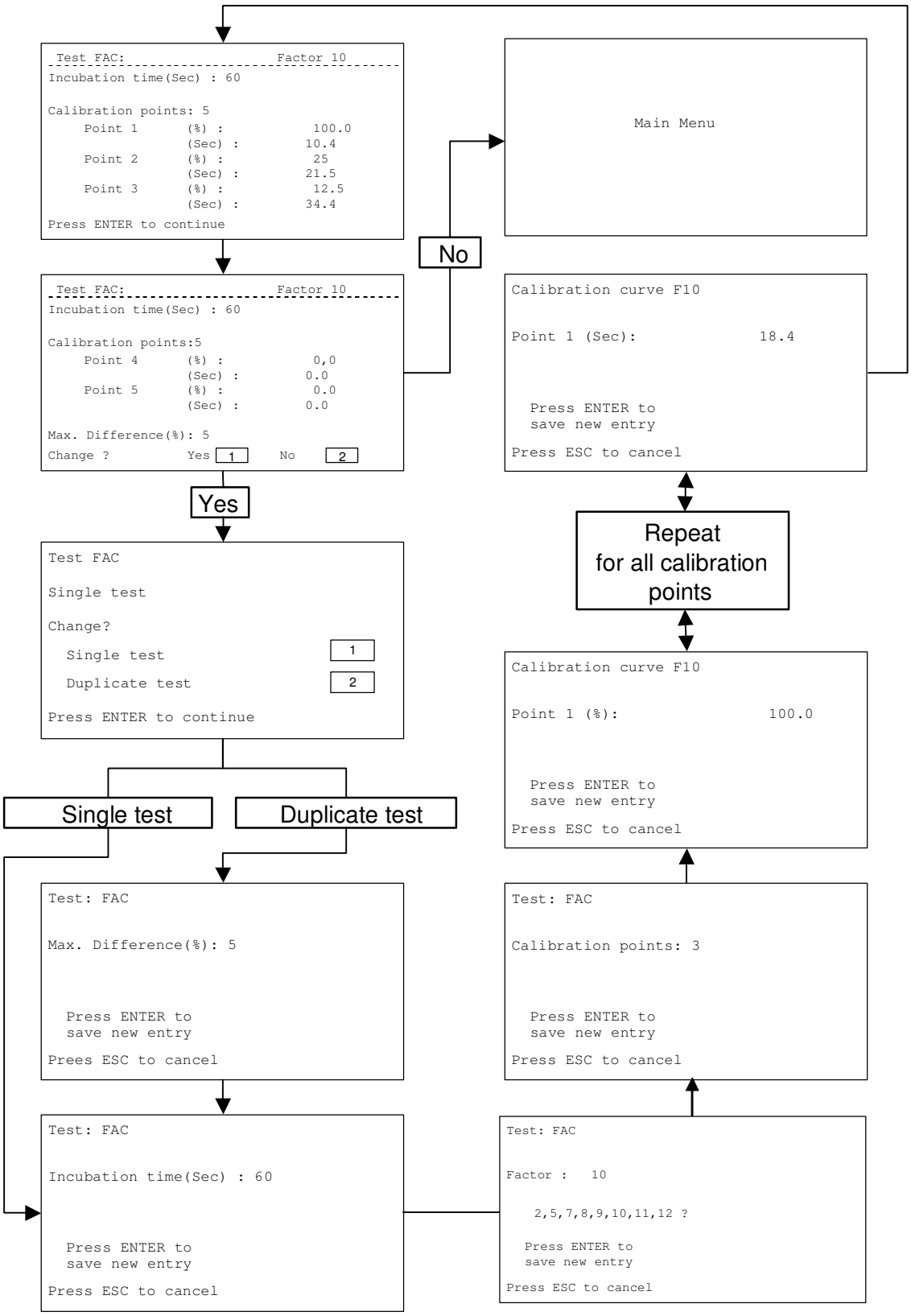
The FAC or FAC* test is configured.

The parameters for the next test will be displayed. If there is no next test, the Main Menu will be displayed.

If incorrect values were entered by mistake select **Yes <1>** to repeat the whole data entry routine.

```
Test FAC:          FACTOR : 10
Incubation time(Sec) : 60
Calibration curve points:5
    Point 1  (%)    :    100,0
             (Sec)  :     10,8
    Point 2  (%)    :     25,0
             (Sec)  :     21,5
    Point 3  (%)    :     12,5
             (Sec)  :     34,4
Max. Difference(%): 5

Change?      Yes [1]       No [2]
```

5.13 FAC (Factors) Flow Chart



6. Quality Control

Regularly performed quality control is the best monitor of test performance. To assure that control and unknown sample results are evaluated under the same test conditions, control material should be included with each run.

The reagent manufacturer's QC recommendations should be used as a guide for establishing a QC protocol. Control results deviating from established ranges are indicative of a system failure and should be investigated immediately. The more common sources of error and the corrective action to take are presented in the Troubleshooting section, **Section 8**.

7. Maintenance

There is no routine mechanical maintenance associated with the KC4Δ. The KC4Δ was factory calibrated for rotational speed, magnetic sensor strength and temperature.

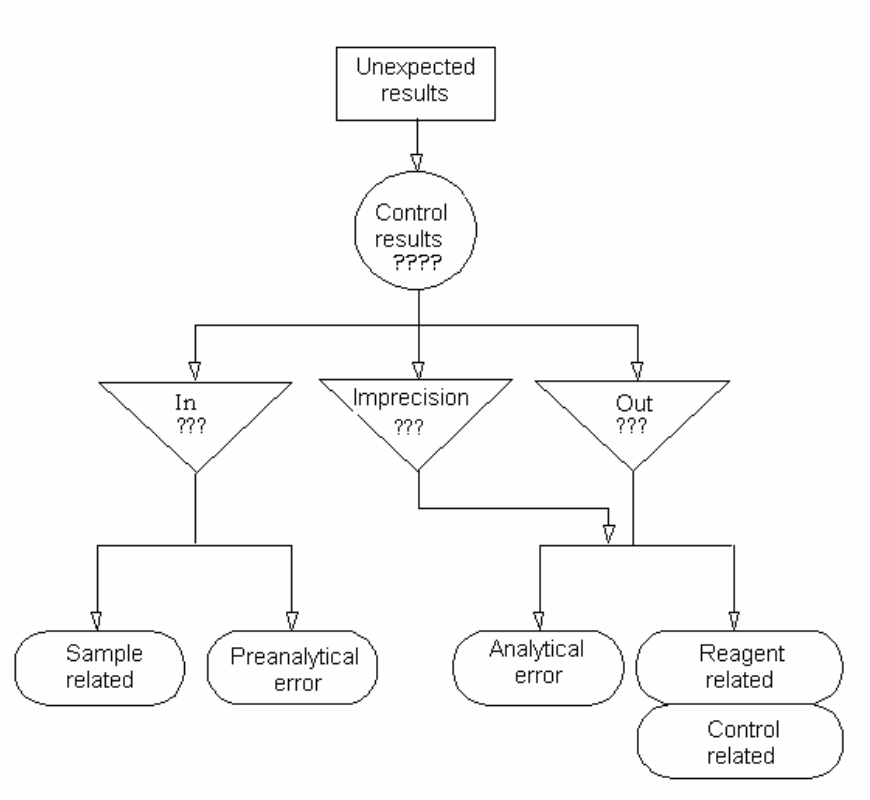
General housekeeping is the only maintenance that need be performed with any regularity. Occasional cleaning with a damp paper towel is recommended to remove accumulated dust or other material. Spills should be cleaned up as they occur.

Reagents can be corrosive and any spillage into the reagent incubation well should be cleaned up immediately. All sample spills should be considered to have created a potentially biohazardous environment and should be cleaned up immediately using appropriate safeguards to avoid personal contamination. If decontamination is required, wipe area with a paper towel moistened with a mild disinfectant.

Any balls that inadvertently find their way into the bottom of any of the wells can be removed using a magnet.

8. Troubleshooting

8.1 Troubleshooting Flow Chart



8.2 Troubleshooting Procedures Table

Symptoms	Possible causes	Corrective action
After **pressing On/ Off**, the display is empty; measurement well is not rotating.	**Instrument Error** KC4Δ not connected to power supply or power supply not connected to outlet.	Assure that the connecting cable is seated firmly in the power supply socket. Assure that the power supply cord is connected to the appropriate outlet.
After pressing On/ Off, temperature fails to stabilize at 37,3˚ C; measurement well is rotating.	**Instrument Error** Non-functional sensor or thermostat overheating.	Place approximately 3 ml water into a 15 mm test tube and place it in one of the reagent warming wells. Insert a thermometer in the reagent tube. Observe temperature after a 10–15 minute equilibration period.
		Additional information can be received from your Trinity Biotech Instrument Service Provider

Symptoms	Possible causes	Corrective action
Controls are in range Unexpected results on patient samples.	**Pre-Analytical error** Overfill or under-fill of collection tube.	Full draw in commercial vacuum tubes assures correct blood/anticoagulant ratio.
	Pre-Analytical error Incorrect volume, type (e.g., EDTA, heparin), concentration or lack of anticoagulant.	Use anticoagulant as recommended by the reagent manufacturer.
	Pre-Analytical error Ratio of anticoagulant to blood is inappropriate.	Failure to correct citrate volume for patients with high (>55%) or low (<21%) haematocrit.
	Pre-Analytical error Clotted specimen.	Testing should never be performed on specimens containing micro or macro clots.
	Pre-Analytical error Inadequate or too vigorous mixing of specimen.	Invert gently to mix well without mechanical trauma.
	Pre-Analytical error Contamination with heparin.	Do not draw blood from a heparin lock or any other heparinized line.
	Pre-Analytical error Delay in transporting or processing or the use of nonstandardized procedures for transporting, processing, storing or testing the specimen.	Follow manufacturer's instructions.
		Centrifuge immediately. Centrifuge at correct RCF for correct time interval.
		Store no longer than 4 hours at room temperature or refrigerated temperatures.
	Pre-Analytical error Contact with glass.	Transfer plasma to plastic storage tube using plastic transfer pipettes.
	Sample related Loss of Factors V and VIII	Avoid heating at 37°C for longer than 5 minutes.
Controls out of range Unexpected results.	**Sample related** Incorrect volume being used.	Follow manufacturer's instructions.
	Reagent related Contaminated reagents.	Reconstitute new reagent or open new bottle.
	Reagent related Wrong reagent being used.	Follow manufacturer's instructions.
	Reagent related Incorrect volume of reagent being used.	Follow manufacturer's instructions.
	Reagent related Reconstitution with incorrect diluent volume.	Follow manufacturer's instructions.

Symptoms	Possible causes	Corrective action
Controls out of range Unexpected results.	**Reagent related** Reconstitution with other than the recommended diluent.	Follow manufacturer's instructions.
	Reagent related New lot number of reagent with different reactivity.	Lot-to-lot variation in reagent reactivity is not unusual. Re-verify reference range. Prepare new reference curves as appropriate.
	Reagent related Reagent defective due to mishandling in shipping or storage.	First use of reagent in this shipment? Temperature of storage area appropriate?
	Reagent related Reagent deteriorated.	Do not use reagent beyond stated reconstituted stability time or beyond expiration date of un-reconstituted reagent.
	Reagent related Reagent deteriorated because of extended warming in reagent well.	Do not store reagent on instrument. At the completion of testing, remove reagent from instrument, cap and store according to the manufacturer's instructions.
	Reagent related Reagent contaminated.	Avoid contact of pipette tips with previously pipetted sample or reagent.
	Control related Deteriorated or contaminated control material.	Prepare fresh controls
		Incorrectly reconstituted control material(s). Reconstitute according to the manufacturer's instructions. Use only fresh deionised water for reconstitution.
	Analytical error Incorrect incubation time.	Follow manufacturer's instructions.
	Analytical error Incorrect reagent temperature.	15 mm tube must be used. No more than 3.5 ml of reagent should be placed in tube. Allow 15–20 minutes for reagent to come to temperature in the reagent well. Some reagents, (Thrombin Reagent for Fibrinogen) should not be warmed but must be equilibrated to room temperature prior to use. Follow reagent manufacturer's instructions.
	Analytical error Incorrect testing sequence.	Follow manufacturer's instructions.

Symptoms	Possible causes	Corrective action
Controls may be in or out of range. Erratic within-run test results.	**Analytical error** Imprecision in manual pipetting of sample and reagent.	Perform pipette maintenance. A pipette Operating Manual is included in the box of the automatic pipette provided with the KC4Δ
		Practice pipetting technique. Refer to the pipetting section for guidance.
		Incorrect dispense position. Consistent location for reagent dispense is important. Refer to Pipetting section for guidance.
		Failure to mix particulate reagent prior to use. Cover top of tube with cap or Parafilm®. and invert gently to mix.
		Failure to mix sample and first reagent. After dispense of sample and reagent, pick the cuvette up and swirl gently 5–6 times to evenly disperse the mixture in the bottom of the cuvette.
	Reagent related Inconsistent or inaccurate reconstitution of reagent or control material.	Reconstitute new reagent and/ or control material.
	Reagent related Reagent deterioration caused by extended heating in reagent well.	Remove reagent from instrument at the completion of testing.
	Reagent related Reagent concentration caused by evaporation.	Reagents should be capped when not in use.
	Sample related Improper specimen collection and handling.	Check sample integrity looking for micro-clots, haemolysis or other irregularities.
		Assure that ratio of anticoagulant to sample is correct (full draw).
		Draw a new specimen. If erratic results are again obtained, inquire about the clinical condition of the patient. Results on patients in DIC are characteristically erratic.
		Observe recommended sample storage conditions.
	Sample related No sample added.	Assure that sample has been added.

Symptoms	Possible causes	Corrective action
No clot formation	**Sample related** Low fibrinogen.	A deficiency of Fibrinogen will greatly prolong the results of many coagulation tests.
	Reagent related No or incorrect reagent added.	Assure that correct reagents are being used.
	Analytical error No ball in cuvette.	Assure that the ball has not fallen out of the cuvette prior to insertion into measuring well.
Clot formed but not detected. Timer does not stop.	**Analytical error** Cuvette not seated in well.	Ball is positioned above the sensor. Assure that there are no balls or other obstructing material in the bottom of the well.
	Sample related. Clot formed before 4.5 seconds.	If performing Fibrinogen, use next higher dilution.
		To stop the timer, insert a new cuvette with ball in the measuring well. After 10 seconds, lift the cuvette out of the well.

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A. Appendix

A.1 INR Fast Track

Note: Use the Multipette®. See section 5 for information regarding programming.

1. Activate the RUN Menu by depressing the **<RUN>** key.
2. Select **<3> Start Single Test Program**.
3. Select **<INR>**.
4. Enter the number of samples/rack.
5. Enter the Patient ID
6. Warm the **Thromboplastin** reagent to **37°C**
7. Place cuvettes in the sample rack positioned in the unheated preparation area.
8. Dispense one ball into each cuvette if not using Tetravettes.
9. Dispense 50µl of sample into bottom of each cuvette.
10. Close flap, remove rack from preparation area and swirl gently 4-5 times.
11. Transfer rack into the heated incubation area or into the rotating test positions.
12. Incubate for a minimum of **60 seconds** up to a maximum of **180 seconds***
13. Press ⏲ to prepare the **Incubation Timers** and then press ⏲ for each activated measuring channel. The activated measuring channels are indicated by 1, 2, 3 or 4 in the bottom line of the Operating Screen. Upon completion of incubation timing the corresponding READY field will display ***.
14. Upon completion of incubation timing, place rack into the rotating test positions and open the flap.
15. Press and hold the **<START>** key. Using the Multipette® dispense 100µl the PT reagent in the correct order into the cuvettes. Start with the measuring channel on the left (1). With the Multipette® the timer starts automatically as the reagent is dispensed. The timers stop when the samples clot.
16. Call up the results and record them.

*: See test application.

A.2 APTT Fast Track

Note: Use the Multipette®. See section 5 for information regarding programming.

1. Activate the RUN Menu by depressing the **<RUN>** key.
2. Select **<3> Start Single Test Program**.
3. Select **<APTT>**.
4. Enter the number of samples/rack.
5. Enter the Patient ID
6. Allow the APTT reagent to warm to room temperature.
7. Warm the **$CaCl_2$** reagent to **37°C**
8. Place cuvettes in the sample rack positioned in the unheated preparation area.
9. Dispense one ball into each cuvette if not using Tetravettes.
10. Dispense 50µl of sample into bottom of each cuvette.
11. Close flap, remove rack from preparation area and swirl gently 4-5 times.
12. Transfer rack into the heated incubation area or into the rotating test positions.

13. Add 50µl of APTT reagent to each cuvette.
14. Incubate for a minimum of **180 seconds** up to a maximum of **300 seconds***
15. Press to prepare the **Incubation Timers** and then press for each activated measuring channel. The activated measuring channels are indicated by 1, 2, 3 or 4 in the bottom line of the Operating Screen. Upon completion of incubation timing the corresponding READY field will display ***.
16. Upon completion of incubation timing, place rack into the rotating test positions and open the flap.
17. Press and hold the **<START>** key. Using the Multipette® dispense **50 µl $CaCl_2$*** in the correct order into the cuvettes. Start with the measuring channel on the left (1). With the Multipette® the timer starts automatically as the $CACl_2$ reagent is dispensed. The timers stop when the samples clot.
18. Call up the results and record them.

*: See test application.

A.3 FIB Fast Track

Note: Use the Multipette®. See section 5 for information regarding programming.

1. Activate the RUN Menu by depressing the **<RUN>** key.
2. Select **<3> Start Single Test Program**.
3. Select **<FIB>**.
4. Enter the number of samples/rack.
5. Enter the Patient ID
6. Warm the **Thrombin Reagent** to room temperature **(18 – 25°C)**
7. Prepare the 1:10 sample dilutions.
8. Place cuvettes in the sample rack positioned in the unheated preparation area.
9. Dispense one ball into each cuvette if not using Tetravettes.
10. Dispense **100µl of diluted sample** (patient sample 1:10 dilutions are prepared using **Imidazole buffer***) in the bottom of each cuvette.
11. Close flap, remove rack from preparation area and swirl gently 4-5 times.
12. Transfer rack into the heated incubation area or into the rotating test positions.
13. Incubate for a minimum of **60 seconds** up to a maximum of **180 seconds***
14. Press to prepare the **Incubation Timers** and then press for each activated measuring channel. The activated measuring channels are indicated by 1, 2, 3 or 4 in the bottom line of the Operating Screen. Upon completion of incubation timing the corresponding READY field will display ***.
15. Upon completion of incubation timing, place rack into the rotating test positions and open the flap.
16. Press and hold the **<START>** key. Using the Multipette® dispense **50 µl Thrombin Reagent*** in the correct order into the cuvettes. Start with the measuring channel on the left (1). With the Multipette® the timer starts automatically as the reagent is dispensed. The timers stop when the samples clot.
17. Call up the results and record them.

*: See test application.

A.4 FIB-Calibration Curve Dilutions

Dilution	Fibrinogen Reference (ml)	Buffer (ml)	Dilution factor
1:7	0.1	0.6	1.43
1:8	0.1	0.7	1.25
1:10	0.1	0.9	1
1:20	0.1	1.9	0.5
1:25	0.1	2.4	0.4
1:30	0.1	2.9	0.33
1:40	0.1	3.9	0.25

A.5 Extrinsic Factors II, V, VII und X Fast Track

Note: Use the Multipette®. See section 5 for information regarding programming.

1. Activate the RUN Menu by depressing the **<RUN>** key.
2. Select **<3> Start Single Test Program**.
3. Select **<FAC>**.
4. Enter the number of samples/rack.
5. Enter the Patient ID
6. Warm the **Thromboplastin** reagent to **37°C**
7. Place cuvettes in the sample rack positioned in the unheated preparation area.
8. Dispense one ball into each cuvette if not using Tetravettes.
9. Prepare 1:10 sample dilutions
10. Dispense **50µl of diluted sample** (patient sample 1:10 dilutions are prepared using **Imidazole buffer***) in the bottom of each cuvette.
11. Add **50 µl** of the appropriate **Factor Deficiency Plasma**.*
12. Close flap, remove rack from preparation area and swirl gently 4-5 times.
13. Transfer rack into the heated incubation area or into the rotating test positions.
14. Incubate for a minimum of **60 seconds** up to a maximum of **180 seconds***
15. Press ⏲ to prepare the **Incubation Timers** and then press ⏲ for each activated measuring channel. The activated measuring channels are indicated by 1, 2, 3 or 4 in the bottom line of the Operating Screen. Upon completion of incubation timing the corresponding READY field will display ***.
16. Upon completion of incubation timing, place rack into the rotating test positions and open the flap.
17. Press and hold the **<START>** key. Using the Multipette® dispense **100 µl Thromboplastin *** the correct order into the cuvettes. Start with the measuring channel on the left (1). With the Multipette® the timer starts automatically as the reagent is dispensed. The timers stop when the samples clot.
18. Call up the results and record them.

*: See test application.

A.6 Extrinsic Factor Standard Curve Dilutions

Dilution	Reference plasma (ml)	Buffer (ml)	Dilution factor
1:10	0.2	1.8	1
1:20	1.0 of 1:10	1.0	0.5
1:40	1.0 of 1:20	1.0	0.25
1:80	1.0 of 1:40	1.0	0.125
1:160	1.0 of 1:80	1.0	0.0625

A.7 Intrinsic Factors VIII, IX, XI und XII Fast Track

Note: Use the Multipette®. See section 5 for information regarding programming.

1. Activate the RUN Menu by depressing the **<RUN>** key.
2. Select **<3> Start Single Test Program**.
3. Select **<APTT>**.
4. Enter the number of samples/rack.
5. Enter the Patient ID
6. Allow the APTT reagent to warm to room temperature.
7. Warm the **$CaCl_2$** reagent to **37°C**
8. Place cuvettes in the sample rack positioned in the unheated preparation area.
9. Dispense one ball into each cuvette if not using Tetravettes.
10. Prepare 1:5 sample dilutions
11. Dispense **50µl of diluted sample** (patient sample 1:5 dilutions are prepared using **Imidazole buffer***) in the bottom of each cuvette.
12. Add **50 µl** of the appropriate **Factor Deficient Plasma**.*
13. Close flap, remove rack from preparation area and swirl gently 4-5 times.
14. Transfer rack into the heated incubation area or into the rotating test positions.
15. Add 50µl of APTT reagent to each cuvette.
16. Incubate for a minimum of **180 seconds** up to a maximum of **300 seconds***
17. Press ⏲ to prepare the **Incubation Timers** and then press ⏲ for each activated measuring channel. The activated measuring channels are indicated by 1, 2, 3 or 4 in the bottom line of the Operating Screen. Upon completion of incubation timing the corresponding READY field will display ***.
18. Upon completion of incubation timing, place rack into the rotating test positions and open the flap.
19. Press and hold the **<START>** key. Using the Multipette® dispense **50 µl $CaCl_2$*** in the correct order into the cuvettes. Start with the measuring channel on the left (1). With the Multipette® the timer starts automatically as the $CACl_2$ reagent is dispensed. The timers stop when the samples clot.
20. Call up the results and record them.

*: See test application

A.8 Intrinsic Factor Standard Curve Dilutions

Dilution	Reference Plasma (ml)	Buffer (ml)	Dilution factor
1:5	0.4	1.6	1
1:10	1.0 of 1:5	1.0	0.5
1:20	1.0 of 1:10	1.0	0.25
1:40	1.0 of 1:20	1.0	0.125
1:80	1.0 of 1:40	1.0	0.0625