0932300_EN

CE IVD

Rx only

# STart Max

# Reference Manual

Stago
At the Heart of Haemostasis

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Visual representations (diagrams, photos, icons, pictogra

# Contents

# Revision table

The software version number is displayed in the [**System**] - [**Configuration**] menu.

| Reference | Date (YYYY-MM-DD) | Software | Modification list |
|---|---|---|---|
| 0932300 | 2016-07-31 | 1.7.15 | Creation. |

# 1 Symbols and Warnings



## 1.1 Symbols

**Meaning of symbols that may be displayed on the analyzer and the disposables**

| Symbol | Meaning |
|---|---|
|  | Manufacturer of the medical device. |
|  | Separate collection: do not discard with other waste.<br><br>Additional information about the disposal procedure, ***Warnings concerning analyzer disposal*** page 11. |
|  | In vitro diagnostic medical device |
|  | Part number |
|  | Serial number |
|  | Date of manufacture |
|  | Direct current |
|  | Caution, biohazard |
|  | Stirred reagent position |
|  | Do not re-use<br><br>Indicates a medical device that can only be used once or on a single patient during a single procedure. |

### Symbols and Warnings

| Symbol | Meaning |
|---|---|
|  | Caution, refer to accompanying documentation for warnings and precautions |
|  | Temperature limit |
|  | Keep away from magnetic fields |
|  | Lot code |

### Meaning of the symbols found in the documentation

| Symbol | Meaning |
|---|---|
|  | Warning<br><br>Danger for the user or patient (risk of injury or incorrect results) |
|  | Precautions to take in order to use the analyzer in accordance with its specifications and to avoid damaging it |
|  | Additional information |
| Fig. | Figure |

## 1.2 General warnings

The system must only be used by duly trained laboratory personnel.

Please read carefully and comply with all the information, warnings, instructions, and procedures in this manual.

It is essential to comply with the legislation, regulations, and standards applicable locally to medical laboratories and medical laboratory procedures.

All the information, warnings, instructions, and procedures contained in this manual and/or in all later versions updated by Diagnostica Stago, as well as all legislation, regulations, and standards relating to the use of in vitro diagnostic medical devices in force and applicable to users locally (where "locally" means in the territory where the system is installed) are hereinafter collectively referred to as the "Recommendations".

Under no circumstances can Diagnostica Stago, its employees, suppliers, or third parties referred to in this manual be held contractually or criminally liable, in respect of any proceedings of any kind

whatsoever, for the safety and effectiveness of the system or for any damage whatsoever, be it direct or indirect, tangible or intangible, incidental or consequential, or of any kind whatsoever, or for any damage whatsoever, including but not limited to in the cases listed hereunder:

(I) if the Recommendations are not followed and if procedures not described by Diagnostica Stago are used,

(II) if reagents other than those manufactured by Diagnostica Stago are adapted, even if the use of said reagents with the system has been the subject of an adaptation protocol,

(III) if washed and/or reused cuvettes are used (reaction cuvettes are disposable), or if cuvettes other than those manufactured by Diagnostica Stago and sold by Diagnostica Stago and/or by its official distributors are used,

(IV) if the standard, regular cleaning, calibration and maintenance procedures described in this manual, required to ensure the constant proper working order and safety of the system, are not carried out,

(V) if the system is not decontaminated in accordance with the decontamination procedures described in this manual,

(VI) in the event of damage caused by the use of disposables or spare parts that are not recommended or by incorrect use of the pipette.

## 1.3 Warnings concerning the use of biological products

For how to handle reagents, calibrator plasmas, control plasmas, and patien

Prior to any intervention on the system and to ensure the safety of staff working with biohazardous products, and to enable proper execution of the biological analyses, please comply with the following instructions:

(I) heed all the warnings and precautions,

(II) make sure that the analyzer is decontaminated in accordance with the decontamination procedures stated in this manual,

(III) observe all the standards and precautions imposed on laboratories for the execution of biological analyses involving potentially contaminated products, in accordance with the regulations in force locally.

For instance, the following precautions must be observed:

- Do not eat, drink, or smoke in areas where these products are handled.
- Immediately consult a physician if these products are ingested or come into contact with mucous membranes or skin lesions (wounds, cuts, etc.).
- Use disposable gloves and handle all products as potentially infectious materials.
- Dispose of all these products as if they were infected, in accordance with the legislation and regulations in force locally (for example: autoclaving, incineration of disposable material, disposal of liquid waste, etc.).

## 1.4 Warnings concerning methodologies

**Failure to comply with the conditions concerning the methodologies can affect the reliability of the results. The following conditions must therefore be respected when executing any biological analyses on the system:**

### Pre-analytic conditions relating to samples:

In order to maintain the activity of the various coagulation factors, the sample must be taken with care and in accordance with professional standards, in tubes with a specified citrate concentration.

Next, the quality of centrifugation should be ensured and the sample stored at the correct temperature before analysis:

- hemolysis, partial coagulation (presence of micro-clots), heat or cold damage, or bubbles at the surface of the plasma can cause incorrect results.
- plasma that has been frozen may contain precipitates when thawed, which must be removed before the measurement is performed.

### Pre-analytic conditions relating to products and reagents:

The laboratory must strictly comply with the instructions provided by the manufacturer in the product and reagent documentation. Poor preparation of the reagent with respect to reconstitution volume, stabilization time, stirring, the presence of bubbles, or the omission or inappropriate presence of a magnetic stir bar may lead to incorrect results.

The ISI value of the thromboplastin used for the determination of the prothrombin time should be the one indicated on the product insert or that determined by the laboratory. The ISI value must be checked following each lot change, software update or intervention.

### Analyzer setup and status:

The laboratory must make sure that the methodology complies with the reagent manufacturer's instructions, especially with respect to the volumes used, incubation times, diluents, etc. It is the laboratory's responsibility to choose the appropriate methodology for a given analysis.

In addition, the analyzer gives results using biological material, and although this material is used and measured by highly sophisticated computer-controlled automated systems that aim to optimize reliability and safety, it is impossible to guarantee an error rate of zero.

clinical examination and any other laboratory results.

The laboratory must ensure that maintenance is performed on a regular basis and in accordance with the Recommendations stated in this manual.

### Conditions relating to validation of the methods and techniques:

The methodologies supplied by Diagnostica Stago have been individually validated for this analyzer. It is the responsibility of each laboratory to choose and validate the test method used, taking into account the regulations applicable in each country, the specific characteristics of the laboratory's patient population and the nature of each test.
If the laboratory decides to use other reagent lines and methodologies that have not been validated by Diagnostica Stago as compatible with this analyzer, validation of this new system will be required. This validation must make it possible to verify the characteristics of the method (see point 1 in references).

### References

**1.** VASSAULT A. et al. :

Ann. Biol. Clin., 44, 686

- 745, 1985.

**2.** KOEPKE J. A., McLAREN C. E., WIJETUNGA A. AND HOUWEN B. :
"A Method To Examine the Need for Duplicate Testing of Common Coagulation Tests". Am. J. Clin. Pathol., 102, 2, 242-246, 1994.

## 1.5 Warnings concerning the analyzer

The present reference manual, the copyright of which is owned by Diagnostica Stago, facilitates the use of the analyzer.

To ensure the safety and effectiveness of the system, it is essential that users familiarize themselves and comply with all the warnings, procedures and recommendations contained in the latest updated version of the reference manual.

Please be careful to comply with the installation requirements described in this manual.

Once the analyzer has been switched off, wait for at least 30 seconds before switching it back on.

The analyzer has been designed and tested according to CISPR 11 (International Special Committee on Radio Interference) standards for class B equipment. In a domestic environment, it may cause radio interference, in which case measures will have to be taken to reduce this interference.

The equipment complies with standard EN 61326-2-6:2006.

It is recommended that an assessment of the electromagnetic environment be conducted before using the analyzer.

Keep the analyzer away from all sources of high electromagnetic radiation (cell phones, unprotected sources of radio frequency, etc.) as they may interfere with the correct operation of the analyzer.

To avoid any risk of electric shock, the procedures described in this manual must be followed scrupulously.

Any hardware modification to the analyzer that has not been expressly approved by Stago is formally prohibited.

To ensure that the analyzer operates correctly, some components have to remain at their initial location at all times:

- the ball dispenser,
- the pipette.

If the analyzer needs to be switched off for more than one week, follow the decontamination procedure described in this manual, then put the cover provided over the analyzer. Before switching the instrument on again, follow the same decontamination procedure.

Static electricity can damage the sensitive electronic components inside the analyzer.

Do not use sharp objects to point to an item on the screen.

The expiry dates of the products used are entered when the analyses are run. The analyzer does not allow the tests to be run if the expiry date has been exceeded. The operator must therefore check the expiry date of products before loading them in the analyzer.

Stability and volumes are not managed by the analyzer. They remain the sole responsibility of the user.

### Symbols and Warnings

#### Warnings regarding the use of the pipette

WARNING! Danger to personal safety in the event of gross negligence:

- Never point the opening of a Multipette® M4/Repeater® M4 fitted with a Combitip® towards yourself or other people.
- Do not start liquid emission unless this can be safely performed.
- Before executing any assay task, make sure that there are no risks to yourselves or others.

WARNING! Safety failure due to incorrect disposables and spare parts:

Disposables and spare parts not recommended in this manual have an adverse effect on the safety, operation and precision of the pipette.

Only use disposables and spare parts recommended in this manual.

Incorrect use of a Combitip® can result in a residual liquid volume and incorrect assay. A Combitip® must not be re-used. Multiple uses can have a negative impact on assay precision.

- Only use a Combitip® once.
- Do not use a cleaned and/or autoclaved Combitip® to perform an assay.

Damage to the pipette if any liquid gets inside it.

- Do not allow liquid to get inside the casing.
- If any liquid gets inside the casing, contact your Stago FSE.

Damage to the pipette due to incorrect storage

- Do not store the pipette with a tip in place.
- Choose a safe storage place.
- Do not expose the pipette to aggressive gases for long periods.

Damage due to UV rays

- Do not expose the pipette and tips to high levels of UV rays.

## 1.6 Warnings concerning analyzer disposal

Waste Electrical and Electronic Equipment (WEEE).

The use of this symbol means that the analyzer must not be disposed of with household waste; that it must be subject to separate collection and that it was brought to market after 13 August 2005.

For more information about the appropriate disposal of the analyzer (waste sorting, collection, processing of analyzer waste), contact the local authorities, the manufacturer, or the distributor who sold this analyzer.

# 2 System presentation



## 2.1 Intended use

The system presented in this manual is a four-channel blood coagulation analyzer designed to be used with disposables and reagent products to perform in vitro assays.

The system has been designed to perform in vitro tests for the diagnosis and monitoring of disorders related to hemostasis.

It can be used to perform chronometric tests (measurement of clotting time) on plasma samples.

A unique detection system based on electromagnetic sensors makes it possible to detect even small clots.

A pipette connected to the analyzer enables automatic triggering of measurements when the start reagent is distributed.

## 2.2 System description

### 2.2.1 Chronometry measurement principle

The principle consists in measuring changes in the oscillation amplitude of the ball inside the cuvette, using electromagnetic sensors.

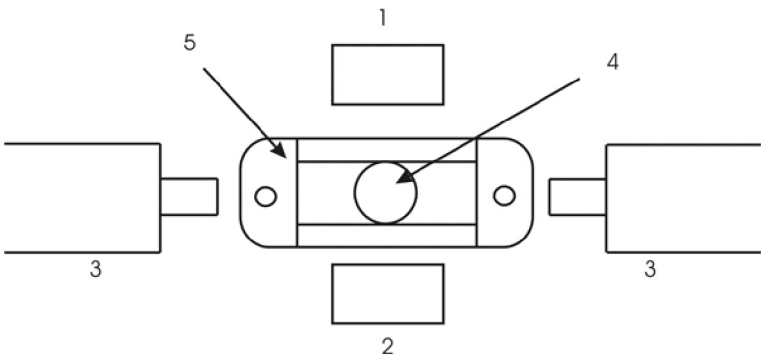
The ball has a pendulum-like motion, obtained:

- due to the two curved rail tracks in the bottom of the cuvette
- and an alternating electromagnetic field generated by two independent drive coils.

The oscillation amplitude is constant when the viscosity of the medium through which the ball moves remains constant.

The oscillation amplitude decreases when the viscosity of this medium increases.

Fig. 1 - Physical principle of the measurement system




1. Emitter measurement coil
2. Receiver measurement coil
3. Drive coils
4. Ball
5. Cuvette

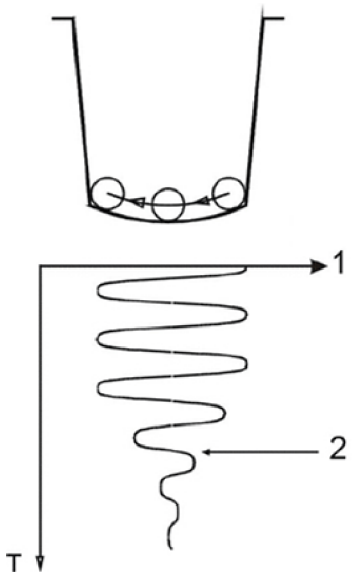
The intensity of the magnetic field varies depending on the analyses to be carried out (PT, APTT, etc.) and on the type of clot expected.

The system for detecting a change in oscillation amplitude of the ball consists of two measurement coils.

The emitter coil emits an electromagnetic field. The signal received by the receiver coil depends on the position of the ball inside the cuvette.

An algorithm uses these magnetic field changes to calculate the oscillation amplitude to precisely determine the clotting times.

Fig. 2 - Amplitude of the ball oscillation during the coagulation process

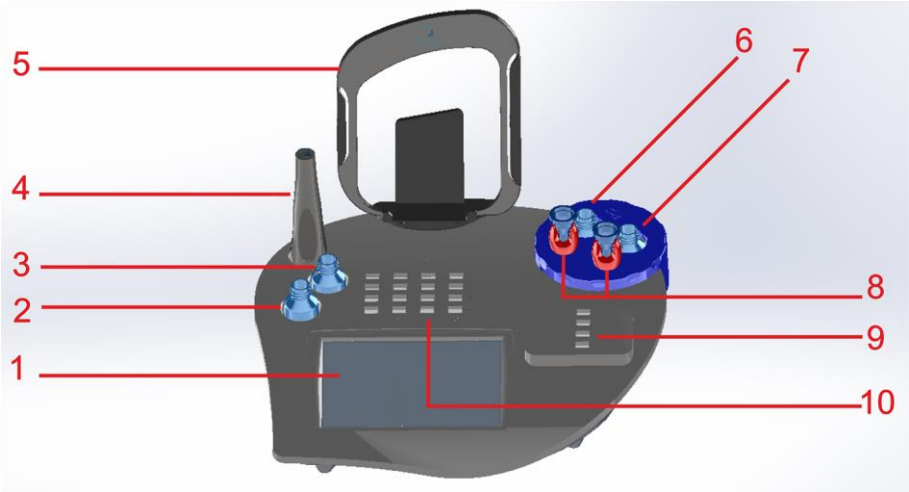



1. Ball oscillation amplitude
2. Coagulation

## 2.2.2 Analyzer presentation

### 2.2.2.1 Top view

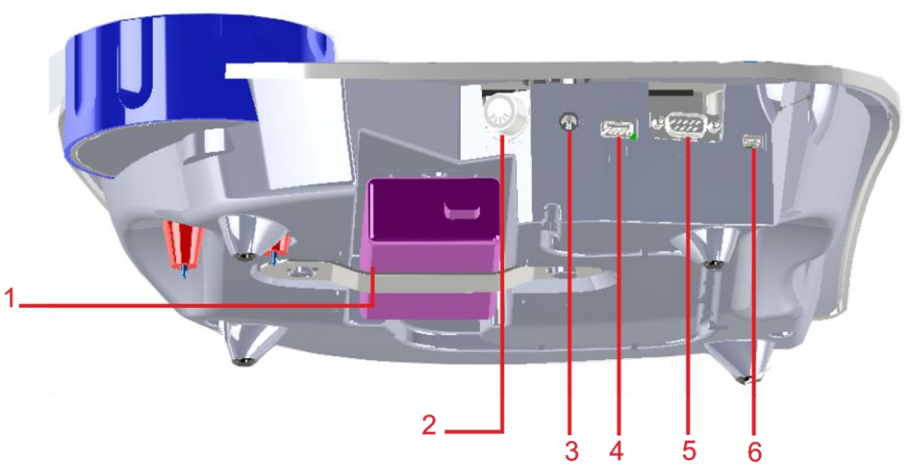
Fig. 3 - Top view




| | |
|---|---|
| 1. Display and entry screen (virtual keyboard). | 6. 15 ml (18 mm) vial position thermostatically controlled at 37°C with stirring motor |
| 2. 15 ml (18 mm) vial position with variable temperature. | 7. 15 ml (18 mm) vial position thermostatically controlled at 37°C. |
| 3. 15 ml (18 mm) vial position with variable temperature. | 8. Pipette and/or pipette tips position thermostatically controlled at 37°C. |
| 4. Ball dispenser position. | 9. Measurement zone thermostatically controlled at 37°C. |
| 5. Stago reagent Application Notebook holder position. | 10. Incubation area thermostatically controlled at 37°C (4 columns of 4 wells). |

### 2.2.2.2 Rear view

Fig. 4 - Rear view




1. Power pack.

2. Connection of the cabled pipette.

3. Mains power cable.

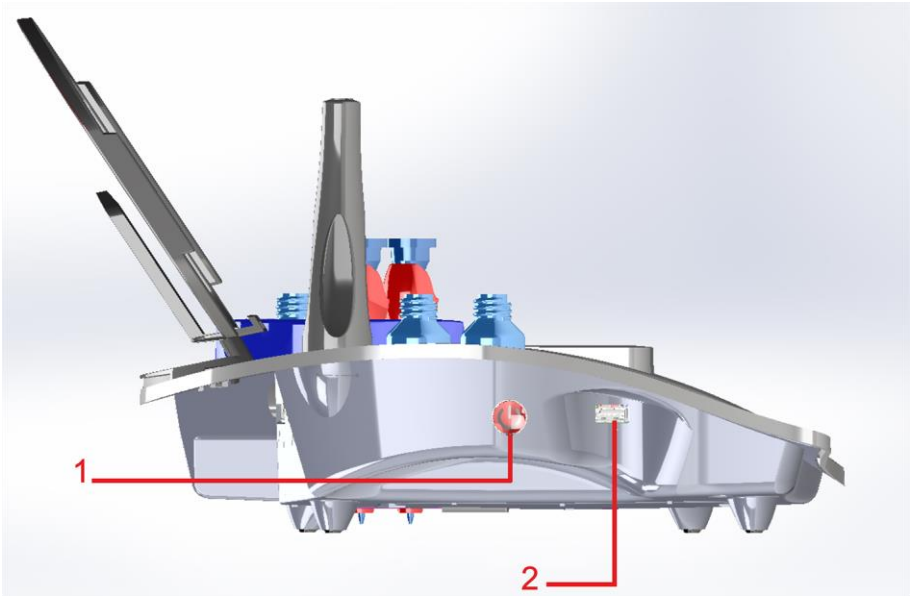
4. USB port for printer.
**Note:** the printer selected must be compatible with the PCL 5 GUI or PCL 3 GUI protocol.

5. RS232 port for serial connection. In particular, this port is used to connect the host computer or a workstation to the analyzer.

6. Mini USB port for the connection of a hand-held scanner (optional).

### 2.2.2.3 Left view

Fig. 5 - Left view




1. Analyzer on/off button.

2. Port for connection of a USB key to be used to back up data.

### 2.2.2.4 Auxiliary materials

Fig. 6 - Auxiliary materials


*Photo not contractually binding: the appearance of the parts supplied may vary*

1. Protective cover.

2. Holder for Stago reagent Application Notebook.

3. Plug (also called cap) to be used when the notebook holder is not installed.

4. Reductor rings.
Three types of reductor rings are supplied to ensure good thermal conduction. Hence vials with a diameter of 18 mm and 22 mm can be used, along with tubes with a diameter of 13 mm (5 ml) for storage of reagents.

5. Pipette thermal conductors (pipette support).
The thermal conductors must be in place to ensure good thermal condition at the pipette tip.
The color of the thermal conductor has no impact on thermal conduction. The thermal conductors are interchangeable.

6. Magnetic stirring bars.
Magnetic stirring bars are used to evenly mix reagents that require stirring.

7. Ball vial.

8. Single-use cuvette strips.

RISK OF INCORRECT RESULTS

Reagent cuvettes are disposable consumables. Diagnostica Stago cannot be held liable for any damages whatsoever - direct, indirect, material or immaterial - if washed and/or reused cuvettes and/or cuvettes other than those manufactured and distributed by Diagnostica Stago or distributed by its official distributors are used.

9. Ball extractor.
The magnetic tip of this extractor allows you to recover a ball that has fallen to the bottom of an incubation or measurement well.

10. Ball dispenser.

RISK OF INCORRECT RESULTS

The ball dispenser must never be placed in one of the reagent storage positions. This would make the balls magnetic and hence interfere with the results.

11. Combitips advanced® 2.5 mL single-use tips.

For correct use of the connected pipette, only Eppendorf® 2.5 mL Combitips advanced® disposables should be used.

12. USB key containing the analyzer documentation. This key may also be used to back up data.

13. Eppendorf® Multipette® M4/Repeater® M4 pipette.

Also see: ***Use of the pipette*** page 43

## 2.2.3 Technical specifications

### 2.2.3.1 Technical specifications - part 1

#### Type

- In vitro diagnostic instrument
- Operating mode: patient by patient
- Chronometry

#### Operating conditions

For indoor use only

- Temperature: 15°C to 32°C (59°F to 89.6°F)
- Relative humidity: 20% to 80%, without condensation
- Altitude: less than 2000 m

#### Storage and transport conditions

- The product must not be stored outdoors
- Impact resistance: according to the standards in force
- Temperature: -20°C to +60°C (-4°F to 140°F)
- Relative humidity: 20% to 80%, without condensation
- Altitude: less than 2000 m

#### Environment

- Maximum volume level: 0 dB to 40 dB ± 3 dB at 1 m
- Heat generated at an ambient temperature of 20°C: 13 Whr (once the analyzer temperature has stabilized)

#### Analyzer dimensions and weight

- Height: 100 mm
- Width: 350 mm
- Depth: 330 mm
- Weight: 2.62 kg

#### Power supply

- Power supply voltage and tolerance: primary 100-240 V 50-60 Hz, secondary 24 V
- Maximum power: 65 W
- Power or current characteristics: NA
- Number of sockets: 1 15 A or 16 A earthed socket, depending on the local nominal value
- Fuse rating and characteristics: NA
- UPS required for micro-power cuts: No
- Consequences of complete outage: loss of the analyses in progress.
- Specific battery types: CR25032 button battery

### 2.2.3.2 Technical specifications - part 2

#### Standards and directives

- CE marked (in accordance with European Directive 98/79/EC)
- EN 61326-2-6:2006
- FCC Part 15
- CAN/CSA-C22.2 NO. 61010-1-12
- RoHS
- REACH

#### Classification

- Electrical supply connection: by mains power cable depending on country
- Type of protection against electric shock: class 1 equipment
- Degree of protection against ingress of water: splash-proof analyzer
- Degree of safety of application: equipment not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide
- Pollution degree: 2
- Method recommended for disinfection: see Cleaning and Maintenance chapter
- Mode of operation: continuous

All the devices connected to the analyzer must comply with IEC 60950, UL 60950, CAN/CSA 60950, EN 55022 class B, and EN 55024 standards.

### 2.2.3.3 Technical specifications - part 3

#### Sample and product management

- Incubation and measurement positions at 37°C ± 0.5°C including:
  - 16 incubation positions for samples (4 columns of 4 wells)
  - 4 measurement positions (1 column of 4 wells)
- 2 unheated positions for reagent vials
- 1 storage position for ball dispenser
- 2 positions heated to 37°C for reagent vials (including one with a magnetic stirrer)
- 2 positions heated to 37°C for pipette tips

#### Measurement principle

Electromagnetic motion sensor. Manual or automatic triggering of measurements by the cabled pipette.

#### Incubation time management

- 4 independent timers for incubations
- Management of incubations with an audio signal

#### Performance

Refer to documentation included in reagent kits.

#### Warm-up time

- approximately 30 min (variable, depending on the ambient temperature)

### 2.2.3.4 Technical specifications - part 4

**Computer connections**

- RS232 serial port: communication with the LIS (ASTM protocol) or workstation (if used)
- 3-pin female DIN connector: start reagent pipette

**Interfaces**

- 2 USB ports:
  - 1 port at the rear for the printer (not supplied),
  - 1 port on the side for a USB key
- 1 USB mini-port on the rear for the hand-held scanner (optional)

  Note: the hand-held scanner requires a mini-USB adapter.
- Touchscreen with virtual keyboard

**Touchscreen**

- Technology: resistive, use of gloves
- Active area diagonal: 7"
- Minimum resolution: 800 x 400

### 2.2.3.5 Technical specifications for the pipette

**Weight:**

- 105 g

**Environmental conditions:**

- For indoor use only
- Ambient temperature: 5°C to 40°C
- Relative air humidity: 10% to 95%, without condensation
- Atmospheric pressure: 795 hPa - 1,060 hPa

**Transport conditions**

- Air temperature: -25°C to 60°C (general transport); -40°C to 45°C (air freight)
- Relative air humidity: 10% to 95% (general transport and air freight)
- Atmospheric pressure: 300 hPa - 1,060 hPa

**Storage conditions**

- Air temperature: -25°C to 55°C (in original packaging); -5°C to 45°C (without packaging)
- Relative air humidity: 10% to 95% (with or without packaging)
- Atmospheric pressure: 700 hPa - 1,060 hPa (general transport and air freight)

# 3 Installation of the analyzer



## 3.1 Installation requirements

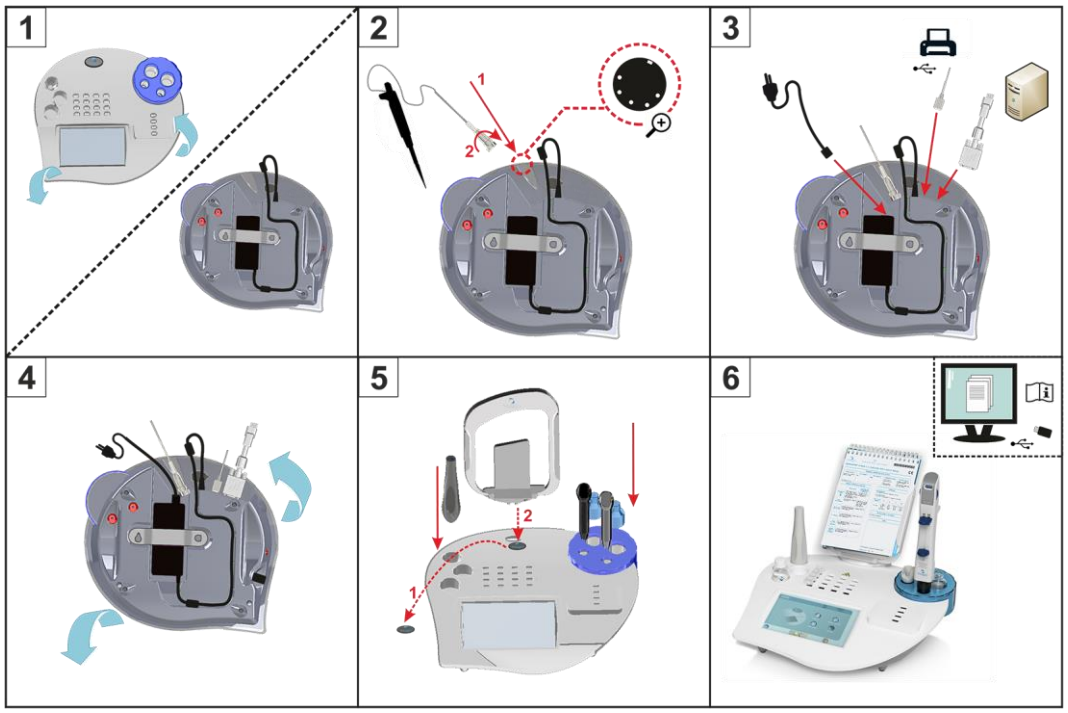
Check the contents of the packagings delivered (see packing list supplied with the analyzer).

Make sure that the analyzer is positioned in such a way that it can be easily unplugged. It must be installed on a stable support that is insensitive to vibrations.

Never obstruct the vents located underneath the analyzer.

## 3.2 Installation procedure

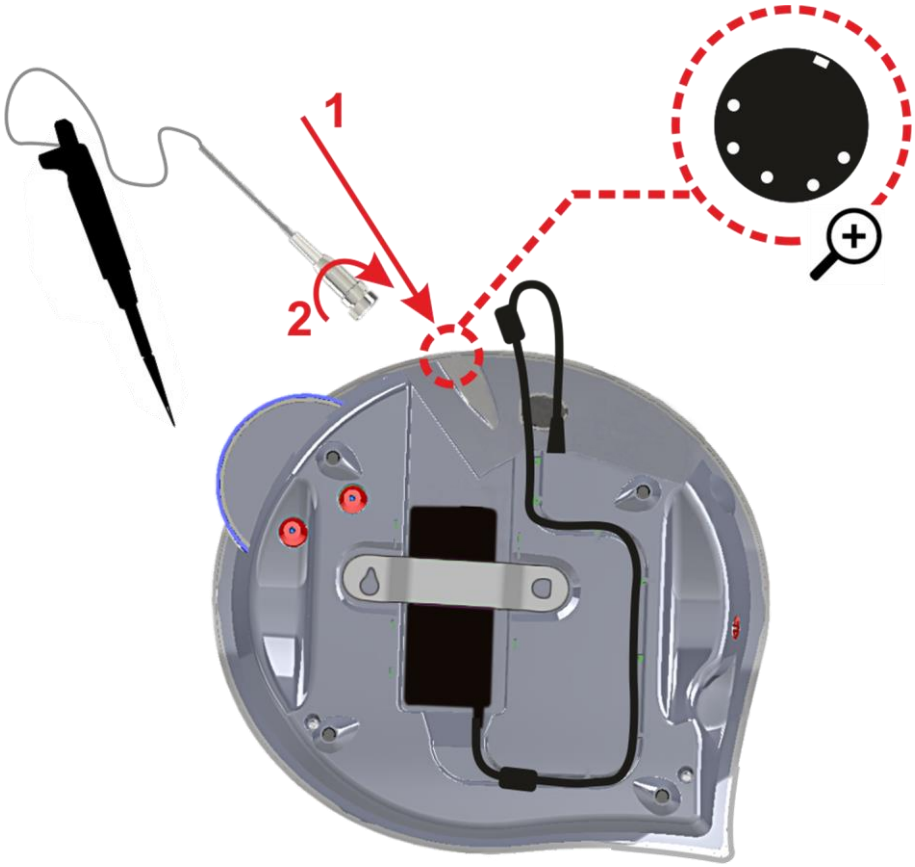
Fig. 7 - Installation of the analyzer




➤ Install the analyzer on a stable support.

➤ Connect the pipette as indicated below.

Fig. 8 - Connection of the cabled pipette




1. Turn the analyzer upside-down to be able to see the connector.
2. Fully insert the cable into the PS/2 port then lock by rotating through a quarter turn.

➤ If necessary, connect the printer to the the USB port on the rear of the instrument, following the instructions supplied with the printer.

The printer connected to the analyzer must comply with the PCL 5 GUI or PCL 3 GUI protocol.

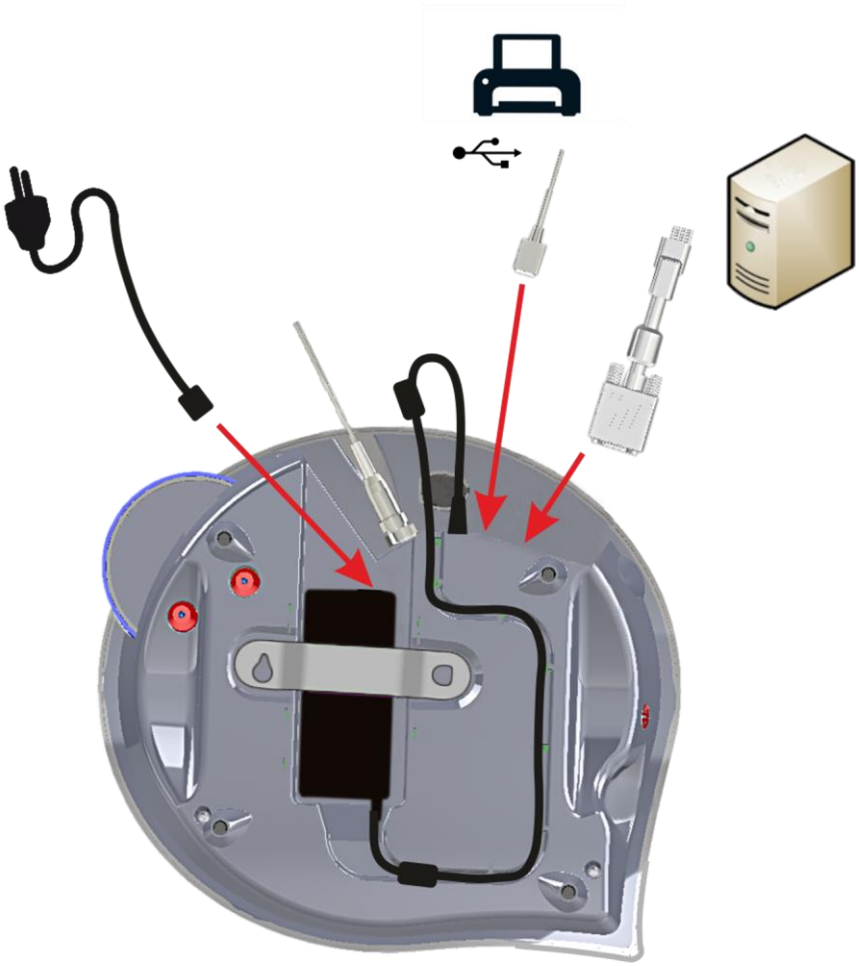
➤ If necessary, connect the host computer to the RS232 port located on the rear of the analyzer.

➤ If necessary, connect the hand-held scanner (optional) to the mini USB port located on the rear of the analyzer.
Note: the hand-held scanner is fitted with a USB cable, which requires a mini USB adapter for connection to the analyzer.

➤ Connect the power cord to the socket underneath the analyzer.

➤ Plug the power cord into a grounded outlet.

Fig. 9 - Installation of the analyzer



All the devices connected to the analyzer must comply with IEC 60950, UL 60950, CAN/CSA 60950, EN 55022 class B, and EN 55024 standards.

- Press the on/off button on the analyzer.
- Switch the printer on (if used).
- ✓ When the analyzer starts up, the identification page is displayed.

Verify the date and time at instrument start-up. If necessary these parameters can be set from the [**System**] menu, in the [**Global**] tab.

See paragraph ***Setting the language, keyboard, brightness, date and time*** page 25.

- Enter a user name (maximum of 10 alphanumeric characters) and press [**Save**].
- ✓ An alarm  is displayed on the lower part of the screen while the analyzer warms up.

The analyzer takes around 30 minutes to warm up (variable, depending on the ambient temperature). The alarm disappears once the analyzer has reached a temperature of 37°C.

Once installation is complete, define the analyzer and methodology settings, then run the quality controls to make sure that the analyzer is working properly.

**In order to obtain all results within the application working range, it is highly recommended to activate option [Linear Interpolation], in menu [System], tab [Incu/Measure], before using the system.**

See ***Setting the incubation/measurement options*** page 27.

See also:

***Adjusting the analyzer settings*** page 25

***Methodology management*** page 30

***Running an analysis (all sample types)*** page 45

# 4 Adjusting the analyzer settings



The analyzer settings are adjusted in the [**System**] menu. This contains the following sections:

| | |
|---|---|
| **[Back-up]** | Automatic and manual back-up settings. |
| **[Global]** | Global options settings: date and time, language, keyboard and brightness. |
| **[Tests]** | Methodology settings.<br>See ***Methodology management*** page 30 |
| **[Incu/Measure]** | Patient identifier settings and options relative to incubation and measurement. |
| **[ASTM]** | ASTM communication protocol option settings. |
| **[Print Out]** | Print option settings. |
| **[Configuration]** | Display of version numbers:<br>- of firmware<br>- of the analyzer and<br>- of the methodology base.<br>Pipette and audible alarm settings. |

## 4.1 Setting the language, keyboard, brightness, date and time

**[System] - [Global] menu**

**Purpose:** to set the options relative to the language, keyboard, brightness, date and time.

| | |
|---|---|
| [**Format - Language**] **section** | ➤ Press the [**Language**] field and select the language. |
| | ➤ Press the [**Date**] field and select the date format. |
| | ➤ Press the [**Time**] field and select the time format. |
| | ➤ Select the keyboard type: [**AZERTY**] or [**QWERTY**] |

| | |
|---|---|
| ➤ [**Miscellaneous**] **section** | ➤ Press the [**Set Date**] field to define the current date.<br>➤ Enter the day, month then year in the corresponding fields of the [**Replaced by**] line then save. |
| | ➤ Press the [**Set Time**] field to define the current time.<br>➤ Enter the hour, minutes and seconds in the corresponding fields of the [**Replaced by**] line then save. |
| | ➤ Press the [**Brightness level**] field to define the screen brightness.<br>➤ Enter the brightness level (from 0 to 100) in the [**Replaced by**] line then save. |
| | ➤ Press the [**Keyboard test**] field to display the virtual keyboard.<br>➤ Press keys and check that they are displayed on the screen.<br>**Note:** to display digits and symbols, press [**alt**]. |

## 4.2 Setting the pipette and sound volume and checking system information

[**System**] - [**Configuration**] **menu**

| | |
|---|---|
| [**Versions**] **section** | This section is used to display the version numbers of the following:<br>- The analyzer<br>- The firmware<br>- The installed methodology base |
| [**Pipette**] **section** | ➤ Select [**Connected**] to enable the connected pipette.<br>Test the connected pipette:<br>➤ Position the pipette filling lever in the upper position.<br>➤ Press the pipette control lever (upper lever).<br>✓ The following symbol  is displayed and a beep sounds if the option is enabled (see below). |
| [**Alarm** ] **section** | ➤ Select [**Enabled**] to enable the alarms and beeps on the analyzer.<br>➤ Set the sound level by entering the level in [**Alarm Level** ].<br>**Note:** even if the value entered is "0", the alarms and beeps remain audible. If you do not want the alarms to be heard, uncheck [**Enabled**].<br>➤ Press [**Test**] to hear the sound emitted by the analyzer. |

## 4.3 Back-up settings

**[System] - [Back-up] menu**

This menu enables calibrations, quality controls and archives relating to patients (results, identities, etc.) to be backed up onto a USB key. Information concerning pipette connection/disconnection and temperature range inputs/outputs is also tracked and can therefore be exported to a USB key. All this data is saved in ".csv" format, which can be used with a spreadsheet, such as Microsoft Excel.

**Tool required:** 1 USB key. The USB key containing the documentation supplied with the analyzer can be used for back-ups.

Stago cannot be held liable in the event of contamination and/or malfunction of users' computer equipment resulting from the use of USB keys or any other hardware, particularly during file back-up and/or transfer operations, as described in this manual.

| | |
|---|---|
| **[Automatic back-up] section** | ➤ Select [**At start-up**] to automatically back up the data when the analyzer is started up.<br>The USB key must be inserted before the analyzer is switched on. |
| **[Manual back-up] section** | ➤ Select the date range and press [**Export**]. |

The backed up and exported identities correspond to the values entered at the time of the analysis request.

The data may be deleted once the back-up is complete by selecting the [**Delete data after back-up**] option before exporting.

## 4.4 Setting the incubation/measurement options

**[System] - [Incu/Measure] menu**

| **[Patient ID] section** | |
|---|---|
| **[ID prefix]** | ➤ Enter the value for automatic sample identification.<br>Example: if "lab" is entered, the samples loaded into the analyzer will automatically be identified as "lab_xx".<br>The "_" sign and a number are automatically added to the chosen prefix. |
| **[Incr.]** | ➤ Enter the value for the incrementation of the identifier numbers.<br>Example: if the value entered is "4", the identifiers will be automatically incremented by 4 ("lab_4", "lab_8", "lab_12" and "lab_16"). |
| **[Number of channels to identify]** | ➤ Enter the number of wells enabled automatically.<br>Example: if the value "2" is entered, only 2 wells will be enabled and displayed. |
| **The values chosen in this part can be modified before starting an analysis.** | |

| [QC rules] section | |
|---|---|
| [**Maximum QC per day**] | ➤ Enter the maximum number of Quality Controls (QCs) displayed in the table of the day's QCs. |
| [**Input QC time range**] | ➤ Enter the QC period. |
| Note: a maximum of 30 single controls or 60 duplicate controls are displayed by level and by methodology. | |

| [Options] section | |
|---|---|
| [**Do not transmit results "To Validate"**] | ➤ Select this option in order not to automatically transmit files for which the status is "to be validated". |

| [Interpolation] section | |
|---|---|
| [**Linear Interpolation**] | ➤ Selecting this option makes it possible to express a result in main units for a measured time less than the Min Time of the calibration curve or between the Max time of the calibration and the TMax of the methodology. |
| [**Rref coef**] | ➤ Enter the value of the min regression coefficient R for automatic validation of the calibration. |

## 4.5 Setting the ASTM communication protocol

[**System**] - [**ASTM**] **menu**

| Field | Default value | Meaning |
|---|---|---|
| [**Speed**] | 9600 | Transmission speed. |
| [**Data**] | 8 bits | Number of data bits. |
| [**Stop bits**] | 1 | Number of stop bits. |
| [**Parity**] | None | Parity type. |
| [**Station Number**] | / | Station number allowing the server (host computer) to identify the analyzer. |
| [**On-line Transmission**] | Option disabled | Online transmission of results to the host computer. |
| [**Connected to SCE**] | Option disabled | Connection to a STA Coag Expert (SCE) type workstation. |

| Field | Default value | Meaning |
|---|---|---|
| [**SunQuest Seq Number**] | Option disabled | The SunQuest sequence number is sent with each result (patient and QC). It is incremented by 1 at each emission. |

## 4.6 Setting the printout options

[**System**] - [**Print Out**] **menu**

| | |
|---|---|
| [**Header**] | ➤ Enter the text to be shown at the top of the printouts. It is possible to enter up to 4 lines in the header. Each line may contain up to 50 alphanumeric characters. At each change of page, the header is printed, along with the date and time of printing. |
| [**Online Printing**] | ➤ Select this option to automatically print test results at the end of the measurements. |

RISK OF LOSS OF RESULTS

In [**Raw**] mode, the results, expressed in seconds only, are neither backed up nor transmitted. A printout of these results on request is not possible.

To avoid any risk of loss of results and maintain the traceability of analyses performed in [**Raw**] mode, online printing must be enabled.

## 4.7 Selecting methodologies

[**System**] - [**Tests**] **menu**

The [**SYSTEM - Methodologies**] screen contains all the Stago methodologies available in the analyzer. The following procedure can be used to select methodologies frequently used by the analyzer. Only selected methodologies will be available in the [**Calibration**], [**Control**] and [**INCUBATION/MEASURE**] menus:

➤ From the [**Tests**] tab, select the methodology using the navigation arrows.

➤ Press the star to save in the list of favorites.

✓ The star turns green  .

➤ To remove a methodology from the list of favorites, press the star again.

✓ The star turns gray  .

Also see: ***Methodology management*** page 30

# 5 Methodology management



A methodology is the operating method implemented to perform an analysis. A set of parameters defines each methodology.

The [**System**] - [**Tests**] menu gives access to the consultation and modification of certain parameters of the Stago methodologies available in the analyzer.

Stago methodologies cannot be deleted and only some parameters can be modified.

Depending on the laboratory's requirements, new methodologies can be created by duplicating existing methodologies. The parameters of these duplicated methodologies are fully configurable.

The analyzer can contain up to 30 methodologies (all types combined).

RISK OF INCORRECT RESULTS

It is the laboratory's responsibility to check all the data entered and to choose the appropriate methodology for a given test.

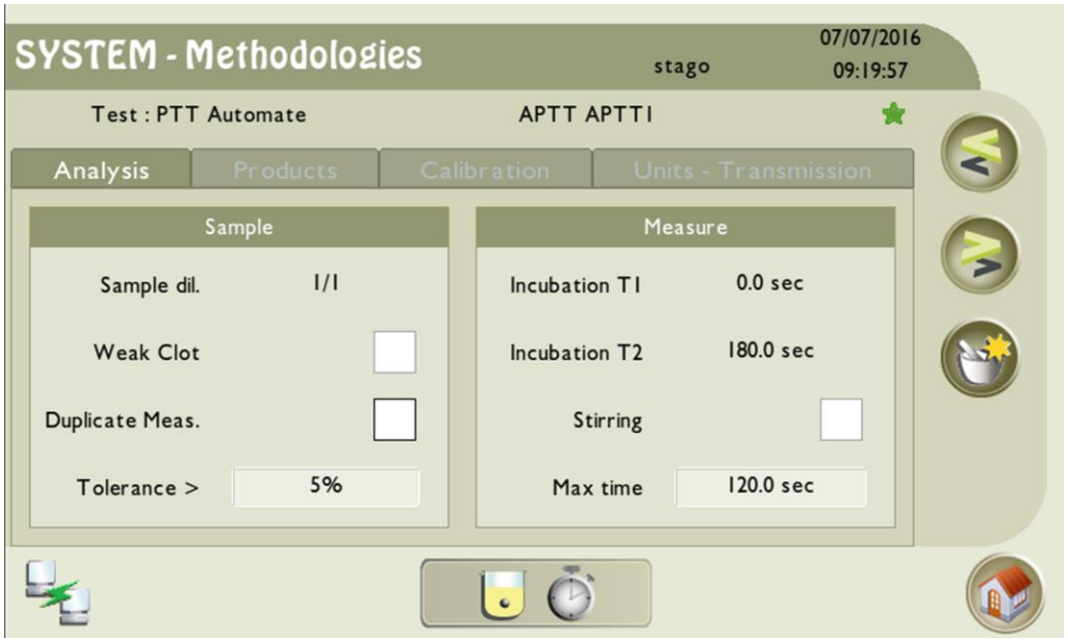
See also:
***Setting methodologies*** page 31
***Duplicating a methodology*** page 37

## 5.1 Setting methodologies

➤ From the home screen, press [**System**] then [**Tests**].

✓ The screen [**SYSTEM - Methodologies**] displays the first methodology.

Fig. 10 - [**SYSTEM - Methodologies**] screen




➤ Use the and arrows to access the required methodology.

As a reminder, the required methodologies must be added to the favorites to be available in the analyzer software:

➤ Press to add to favorites.

✓ The star turns green .

Each tab provides access to the modification of the parameters of the selected methodology.

Some Stago methodology parameters, indicated by the character ***** in the instructions below**,** cannot be modified.

### 5.1.1 Analysis tab

The [**Analysis**] tab contains the parameters specific to the sample and the measurement.

The parameters indicated by the character * cannot be modified in Stago methodologies.

| | |
|---|---|
| [**Sample dil.**]* | Dilution ratio for the selected methodology.<br>➤ If applicable, press the field and select the new required dilution (from 1/1 to 1/80).<br>Dilution ratio of the plasma expressed relative to the expression I/D with the following correspondences:<br>I = volume of pure plasma<br>D = total volume (plasma + diluent) |
| [**Weak Clot**]* | Type of clot.<br>➤ If applicable, check this box to indicate a weak clot (fibrinogen-type clot). |
| [**Duplicate Meas.**] | Duplicate measurements.<br>➤ If applicable, check this option to run measurements in duplicate. |
| [**Tolerance >**] | Maximum authorized difference for a determination in duplicate.<br>➤ If applicable, press the field. Enter the new tolerance and save.<br>The difference is expressed in % (relative deviation from the mean) and applies to the main unit.<br>Deviation/mean = $\left\lvert \frac{M_1 - M_2}{M} \right\rvert \times 100$<br>where M1, M2 = intermediate measurements in main units<br>M = (M1 + M2) / 2<br>Results exceeding the max. deviation are marked with an alert O (out-of-specification deviation for duplicate measurement mode) and allocated the to be validated status.<br>Note: if the tolerable difference is not defined or if it is equal to 0%, an alert will be associated with the patient's result whenever the two measurements are different. |
| [**Incubation T1**]* | First incubation time.<br>➤ If applicable, press the field. Enter a new incubation time and save. |

| | |
|---|---|
| [**Incubation T2**]* | Second incubation time.<br>➤ If applicable, press the field. Enter a new incubation time and save. |
| [**Stirring**]* | Manual stirring of the strip.<br>➤ If applicable, check this option for manual stirring of the strip immediately after distribution of the start reagent. |
| [**Max time**] | Longest time for an analysis. Above this limit, the error code **V>VMax** is indicated instead of the result.<br>➤ If applicable, press the field. Enter a new max time and save.<br>Note: modifying this parameter invalidates the associated calibration. To confirm, validate the message. |

## 5.1.2 Products tab

[**Products**] **tab**

The parameters indicated by the character * cannot be modified in Stago methodologies.

[**Reagents**] **section**:

| | |
|---|---|
| [**Ra**], [**Rb**] and [**Rc**]* | Intermediate reagents.<br>➤ If applicable, press the field and select the required reagent. |
| [**Rd**]* | Start reagent.<br>➤ If applicable, press the field and select the required reagent. |
|  * | Create reagents.<br>➤ If applicable, press the button to create reagents.<br>➤ In the window, enter a code (optional), a name (compulsory) and save.<br>The name must have at least 8 characters. |
|  * | Delete the created reagents and calibrators.<br>This button is used to simultaneously delete all the created reagents and calibrators that are not allocated to a methodology<br>➤ If applicable, press the button.<br>➤ Validate the confirmation message.<br>✓ All the created reagents and calibrators that are not allocated are deleted. |

[**Quality Controls**] **section**:

| | |
|---|---|
|  * | Create controls.<br>➤ If applicable, press the button to create controls.<br>➤ Enter the control reference (compulsory - minimum of 8 characters) and save.<br>➤ For level 1, enter a name (compulsory - minimum of 8 characters) and a code (optional) then save.<br>➤ If applicable, repeat for level 2. |
|  * | Delete the created controls.<br>This button is used to simultaneously delete all the created controls that are not allocated to a methodology.<br>➤ If applicable, press the button.<br>➤ Validate the confirmation message.<br>✓ All the created controls that are not allocated are deleted. |
| [**ID**] | Control reference identifier.<br>➤ If applicable, press the field and select the required control.<br>  RISK OF INCORRECT RESULTS<br>**[None] means that no system quality control will be performed before the patient analyses are run. To avoid any risk of incorrect results, the use of controls is recommended.** |
| [**Lev. 1**] | Level 1.<br>➤ If applicable, press the field and select the required control for the first control level. |
| [**Lev. 2**] | Level 2.<br>➤ If applicable, press the field and select the required control for the second control level. |
| [**Auto.**] | Run automatically.<br>➤ If applicable, check this option to run the two control levels on the same strip.<br>Note: this option is checked by default on all Stago methodologies. |

## 5.1.3 Calibration tab

**[Calibration] tab**

The parameters indicated by the character * cannot be modified in Stago methodologies.

**[Configuration] section**:

| | |
|---|---|
| **[ID]** | Calibrator identifier.<br>➤ If applicable, press the field and select the required calibrator.<br>OR<br>➤ Select [**< Brut >**] if no calibration is required. |
| **[Mode]*** and **[Scale]*** | The scales of the X and Y axes of the calibration curve can be set using the [**Scale**] X, [**Scale**] Y or [**Mode**] fields.<br>➤ If applicable, press one of the fields.<br>➤ Select the required calibration mode.<br>➤ Select the scale for the X axis.<br>➤ Select the scale for the Y axis.<br>➤ Select the main unit. |
| **[Calibration in Duplicate]** | Calibration in duplicate.<br>➤ If applicable, check this option to run measurements in duplicate.<br>Note: modifying this parameter invalidates the associated calibration. To confirm, validate the message. |
|  * | Create calibrators.<br>➤ If applicable, press the button to create calibrators.<br>➤ In the window, enter a code (optional), a name (compulsory) and save.<br>The name must have at least 8 characters. |
|  * | Delete the created reagents and calibrators.<br>This button is used to simultaneously delete all the created reagents and calibrators that are not allocated to a methodology<br>➤ If applicable, press the button to delete the created reagents and calibrators.<br>➤ Validate the confirmation message.<br>✓ All the created reagents and calibrators that are not allocated are deleted. |

[**Display points**]* **section**:

| | |
|---|---|
| [**Display points**]* **section** | Display point.<br>Note: minimum of 3 calibration points; maximum of 8 calibration points.<br>➤ If applicable, press the required fields and select the new dilutions (from 1/1 to 1/80).<br>Note: For graphic calibration using a set of pre-diluted calibrators, all the display points must be 1/1. If this is not the case and a single calibrator is used, then modify the display points as indicated previously. |

## 5.1.4 Units - Transmission tab

[**Units - Transmission**] tab

For the main ([**Main**]) or auxiliary ([**Aux 1**], [**Aux 2**] and [**Aux 3**]) units, it is possible to indicate the transmission ranks and enable online transmission.

| | |
|---|---|
| [**Transmission**] | ➤ If applicable, press the field. Enter the transmission rank (0 to 999) and save.<br>If necessary, press the magnifying glass to see the rank numbers already used.<br>✓ The online transmission box is automatically checked.<br>➤ Since online transmission is not compulsory, uncheck the box if necessary. |
| ☐ | Activation of online transmission.<br>➤ If applicable, check the box of the unit to be transmitted automatically.<br>➤ It is compulsory to enter the transmission rank (see above). |
| [**Low**] and [**High**] | ➤ If applicable, press these fields to define the capping limits of the main unit.<br>Note: when capping limits are entered, the result in main units displayed on the dashboard and transmitted to the host computer is a capped result. |

## 5.2 Duplicating a methodology

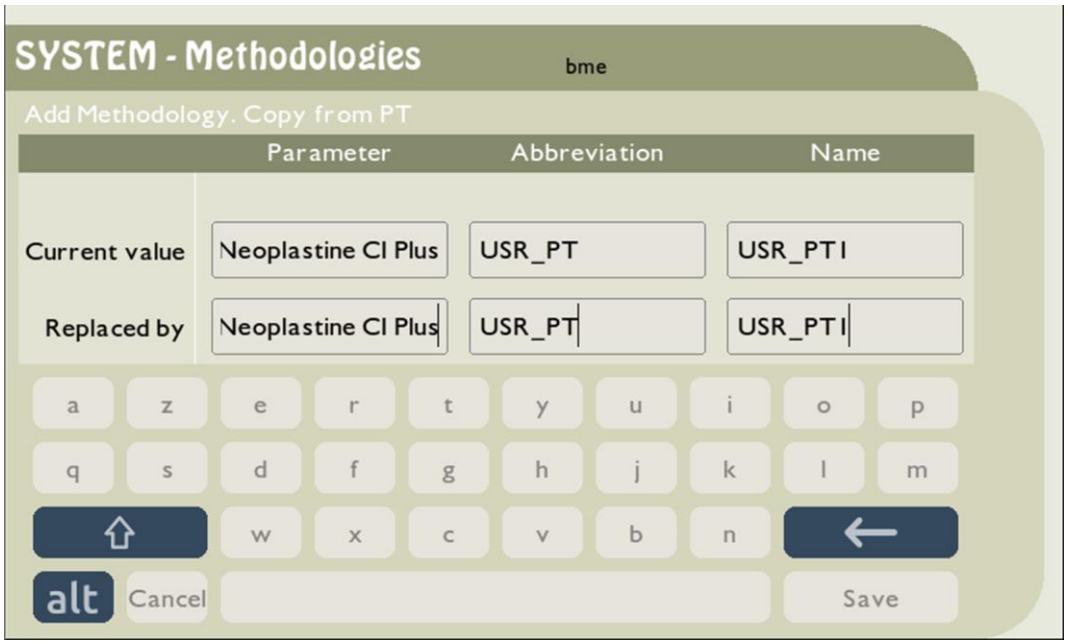
The [**SYSTEM - Methodologies**] screen is used to create new methodologies by duplicating an existing methodology.

➤ Use the  and  arrows to access the required methodology.

➤ Press  .

✓ The following screen is displayed.

Fig. 11 - [**Add Methodology**] screen




➤ In [**Replaced by**], enter the parameter, the abbreviation and the name.

- For the parameter, maximum of 25 characters.
- For the abbreviation, maximum of 8 characters.
- For the name, maximum of 20 characters.

➤ Press [**Save**].

✓ The methodology is created.

✓ If necessary, press  to add the methodology to the favorites.

See also:

- ***Saving a barcode for the duplicated methodology*** page *38*
- ***Duplicating, editing or deleting a duplicated methodology*** page 39

### 5.2.1 Saving a barcode for the duplicated methodology

The duplicated methodology can be identified by the icon, which is displayed in front of the abbreviation.

If necessary, a barcode (not generated by STart Max), can be associated with the methodology that has just been duplicated, making it possible to use a barcode reader (optional).

To enter the barcode, follow the instructions below:

RISK OF INCORRECT RESULTS

It is the laboratory's responsibility to check all the data entered and to choose the appropriate methodology for a given test.

➤ Press .

✓ The following screen is displayed.

Fig. 12 - [**Barcode Scanning**] screen


➤ In [**Replaced by**], enter the required barcode value (maximum of 10 characters).

➤ Press [**Save**].

The barcode value must be kept for subsequent use of the barcode reader.

## 5.2.2 Duplicating, editing or deleting a duplicated methodology

➤ Press  .

✓ A pop-up menu is displayed.

[**Copy Methodology**]

➤ Press this menu to duplicate the methodology.

✓ The [**Add Methodology**] screen is displayed.

➤ In [**Replaced by**], modify the parameter and the name (compulsory).

✓ If necessary, also modify the abbreviation.

- For the parameter, maximum of 25 characters.
- For the abbreviation, maximum of 8 characters.
- For the name, maximum of 20 characters.

➤ Press [**Save**].

✓ The methodology is duplicated.

[**Edit methodology**]

➤ Press this menu to modify the parameter, the abbreviation and the name.

✓ The [**Add Methodology**] screen is displayed.

✓ In [**Replaced by**], enter the values wanted.

✓ Press [**Save**].

[**Cancel Methodology**]

➤ Press this menu to delete the methodology.

✓ A confirmation message is displayed.

➤ Validate the message.

Note: the methodology can also be deleted by pressing  .

## 5.3 Deleting a methodology (non Stago)

➤ To delete a methodology created by duplication, press  .

➤ Validate the confirmation message displayed.

✓ The methodology is deleted.

Stago methodologies cannot be deleted. However, they can be removed from the favorites list as indicated in the paragraph ***Selecting methodologies*** page 29.

# 6 Routine use



RISK OF BIOLOGICAL CONTAMINATION

In order to avoid any risk of contamination:

Observe the proper precautions for handling biohazardous materials in accordance with local regulations: use disposable gloves, mask and/or protective goggles, and protective clothing.

## 6.1 Prerequisites

Check that the analyzer parameters and methodologies have been correctly configured.

After installing the analyzer and before running a series of analyses, it is recommended that quality controls be run.

RISK OF BIOLOGICAL CONTAMINATION

In order to avoid any risk of contamination:

Observe the proper precautions for handling biohazardous materials in accordance with local regulations: use disposable gloves, mask and/or protective goggles, and protective clothing.

See also:

***Adjusting the analyzer settings*** page 25

***Methodology management*** page 30

## 6.2 Analyzer preparation

Fig. 13 - Analyzer preparation

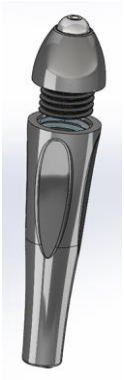

- Place the thermal conductors in the positions identified by point 1.
- Prepare the required reagents using the Application Notebook.
- Place the reagent vials requiring a heated position in the positions identified by point 2.
  **Note:** The two reagent positions are thermostatically controlled at 37°C. The position identified by the symbol is dedicated to reagents requiring stirring. Add a magnetic stirring bar if necessary.

The liquid level in each vial must not exceed the working area surface.

If the vial does not touch the edges of the storage positions, the reagents will not be at a correct temperature. In this case, it is necessary to use a reductor ring.

- Unscrew the body of the ball dispenser.

Fig. 14 - Ball dispenser unscrewed



- Pour the contents of the ball vial into the dispenser and screw tight again.
- Place the ball dispenser in the position identified by point 3.

RISK OF INCORRECT RESULTS

The ball dispenser must never be placed in one of the reagent storage positions. This would make the balls magnetic and hence interfere with the results.

- If this has not already been done, replace the plug with the holder in the position identified by point 4 and place the Application Notebook on the holder.
- Keep the plug for future use if necessary.
- Place a cuvette strip in the incubation column.
- Using the ball dispenser, place a ball in each cuvette.

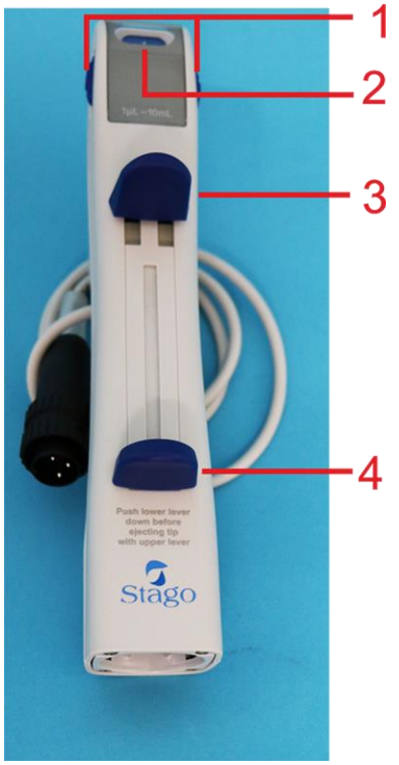
## 6.3 Use of the pipette

RISK OF BIOLOGICAL CONTAMINATION

In order to avoid any risk of contamination:

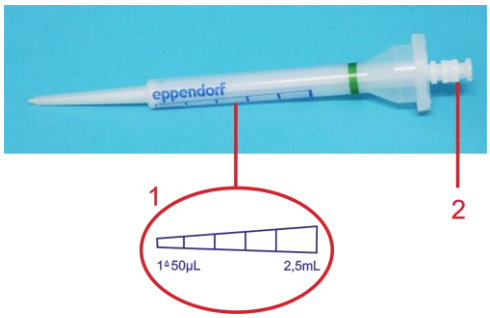
Observe the proper precautions for handling biohazardous materials in accordance with local regulations: use disposable gloves, mask and/or protective goggles, and protective clothing.

Fig. 15 - Pipette




1. Volume selection wheel
2. Position indicator
3. Control lever
4. Filling lever

Fig. 16 - Pipette tip




1. Graduation
2. Tip plunger

### Attaching the tip

- If the tip plunger is out, carefully push it inside.
- To insert the tip into the pipette, slide the filling lever to the lower position.
- Insert the tip, making sure it is straight, from the bottom of the pipette, holding the filling lever in the lower position.

### Setting the volume

The volume selection wheel has 20 positions. Every second position is marked by a figure. The other positions are marked by a dot. The distribution volume can be selected before liquid collection and can be modified during distribution if necessary.

The pipette can distribute a minimum of 25 µL (position 0.5) and a maximum of 500 µL (position 10).

The distributed volume corresponds to the minimum volume indicated on the tip, multiplied by the volume selected using the pipette wheel.

E.g.: to distribute 50 µL, select "1"; to distribute 100 µL, select "2".

➤ Adjust the wheel on the basis of the volume to be distributed.

Do not turn the selection wheel beyond the lower or upper stops.

### Collecting the liquid

➤ Slide the filling lever downwards.

➤ Immerse the end of the tip in the liquid.

➤ Pipette the reagent by gently sliding the filling lever upwards.

➤ Wipe the tip.

Depending on the methodology used, place the pipette and its tip in the reserved area, thermostatically controlled at 37°C to be at the correct temperature.

See paragraph ***Top view*** page 14.

Note: to empty the tip, slide the filling lever downwards.

### Distributing the liquid

➤ Discard the first volume in the reagent vial or in a container for disposal.

➤ Distribute the reagent into each cuvette by pressing the control lever.

RISK OF INCORRECT RESULTS

To avoid any risk of volume errors during reagent distribution, never go right to the lever stop.

Each press distributes the volume defined using the pipette wheel.

If the option has been selected, a beep sounds each time the lever is pressed.

➤ Allow the control lever to return to its initial position.

➤ To perform the next distribution step, press the control lever downwards again.

### Routine use

RISK OF INCORRECT RESULTS

When there is no longer enough liquid available for the selected distribution volume, liquid distribution is stopped.

However, to avoid any risk of volume errors, never wait until there is not enough liquid before reloading the pipette.

### Ejecting the tip

- To eject the tip, slide the filling lever downwards until the stop, then press the control lever.
- Remove the tip.

RISK OF BIOLOGICAL CONTAMINATION

Observe the usual precautions for the handling of tubes and containers as they may contain potentially biohazardous material.

## 6.4 Running an analysis (all sample types)

The analysis process is the same, whether it is a calibration, quality control or patient analysis.

The different types of samples (calibration, control or patient) or tests cannot be mixed on the same strip.

Prior preparation of the analyzer, as indicated in chapter 3, is required before every analysis. The procedure then consists of 3 steps:

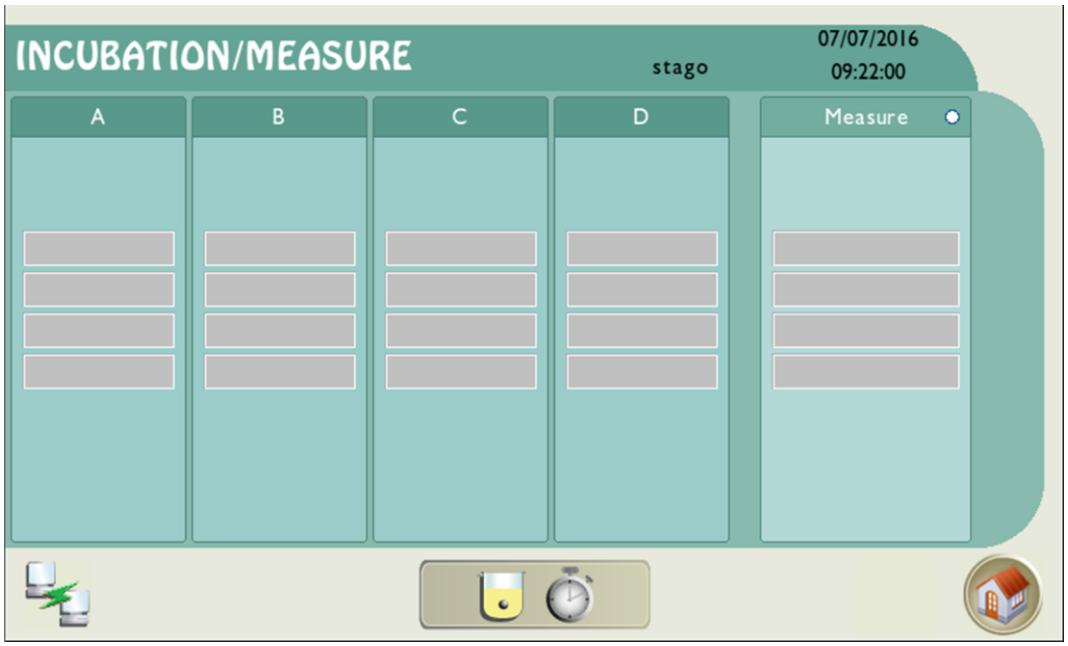
Step 1: definition of the analysis/sample type (controls, calibrations or patients) and entry of necessary information concerning the products used.

Step 2: distribution of the required samples and products.

Step 3: running of the measurement.

## 6.4.1 Description of the INCUBATION/MEASURE menu

Fig. 17 - [**INCUBATION/MEASURE**] screen




The [**INCUBATION/MEASURE**] screen is a graphic representation of the analyzer that allows the operator to view the progress of the analysis in real time and follow the graphic instructions displayed during the various phases of the analysis.

### Incubation section

The incubation area is represented on the left of the screen in the form of columns named [**A**], [**B**], [**C**] and [**D**], respectively. Each column is composed of 4 measurement wells. Incubation wells are activated in this screen, based on the options selected and information entered by the user during the analysis.

### Measurement section

On the right of the screen, the fifth column, named [**Measure**] displays the progress of the measurement phase. The measurement area is activated on the screen when the operator moves the sample to this area, following the graphic instructions displayed.

Also see: ***Running an analysis (all sample types)*** page 45

## 6.4.2 Definition of analysis type and entry of product information

Before starting the analysis, enter the analysis type and information concerning the products used in the strip by following the instructions below.

**Note:** the hand-held scanner, available as an option, can also be used to read the barcodes of the Application Notebook and patient tubes.

### Displaying the strip details

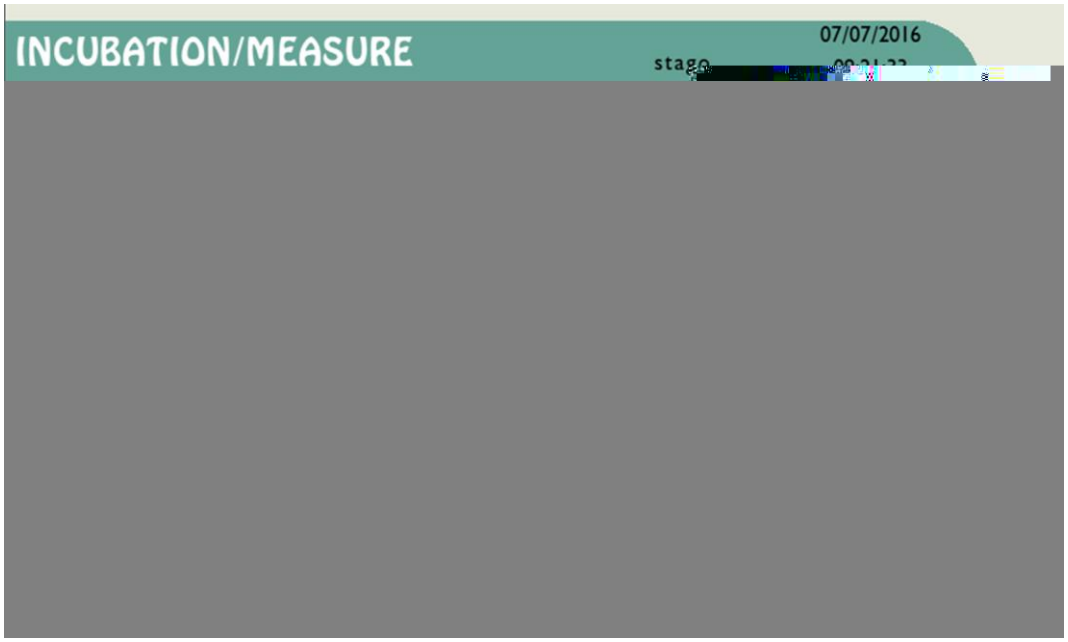
➤ Press  .

✓ The [**INCUBATION/MEASURE**] screen is displayed.

➤ Press the required column.

✓ The strip details are displayed.

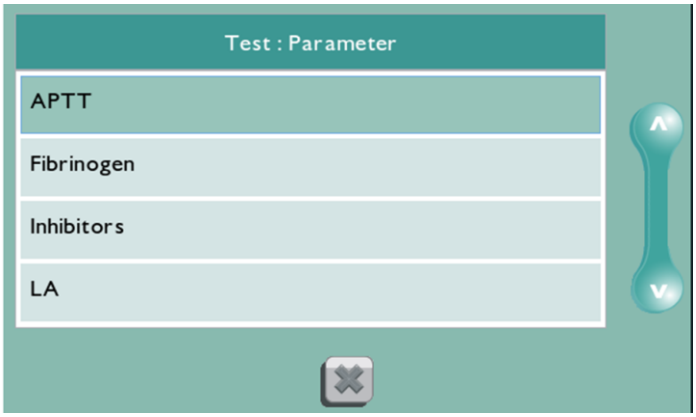
Fig. 18 - Strip details




### Entry of test parameters

➤ Press [**Parameter**] and select the test group.

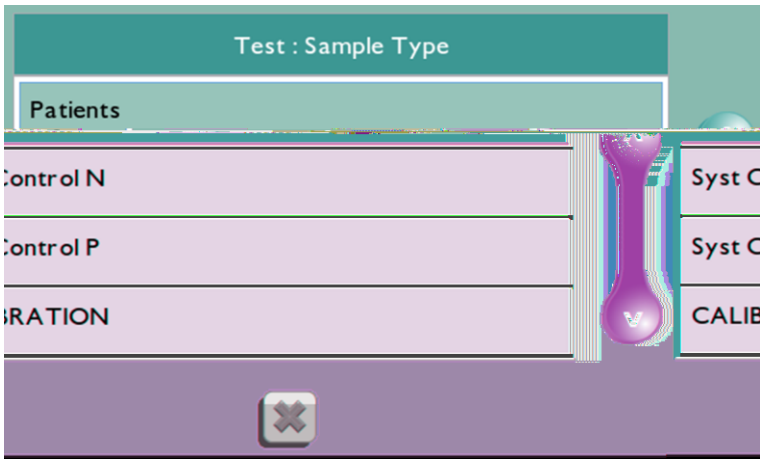
Fig. 19 - Selection of test group



➤ If the group includes several reagents, select the required reagent.

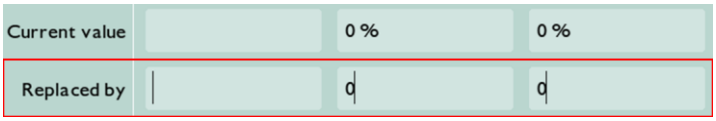
➤ In [**Sample Type**], select the sample type: Patients, Control or Calibration.

Fig. 20 - Selection of sample type




Different windows must be completed using the product insert depending on the products required for the analysis. The data must be entered on the [**Replaced by**] line.

Fig. 21 - Example of an entry zone




➤ Where necessary, enter the following information, saving the data entered each time:

- The lot number.
- The min and max ranges ([**Low**] and [**High**]).
- The expiry date, following the format indicated. If the day is not indicated, enter the last day of the current month.
- The titer of the calibrator in main units (see inserts).
- The reference time, if the configured auxiliary unit is the Ratio.
- The ISI, if the configured auxiliary unit is the INR.

RISK OF INCORRECT RESULTS

In order to avoid any risk of incorrect results:

The ISI value for the Prothrombin time must be the value indicated on the insert of the product or that recalculated by the laboratory in accordance with the procedures and regulations in force. The operator must check the ISI value before quitting the menu if there has been a lot change, a software update or any other major change.

If necessary, the information relating to the selected test can be displayed by pressing the magnifying glass icon, once the parameters have been entered:


➤ Press  .

✓ The selected test methodology is displayed.

➤ View the required information then press  again to return to the [**INCUBATION/MEASURE**] screen.

### Selecting the result expression mode

➤ If necessary, check [**Duplicate Meas.**] to perform the measurements in duplicate (option disabled by default).

➤ If necessary, check [**Main/Aux**] to express the result in main and auxiliary units or check [**Raw**] to express the result in raw units only.

The [**Main/Aux**] option is only available if the calibration of the selected test is valid ( ). It is used to obtain results in main and auxiliary units. These results are then saved and can be transmitted or printed out on request.

A valid calibration ( ) using expired reagents can block selection of the [**Main/Aux**] option. If necessary, repeat the calibration with a new reagent lot to make the option available again.

RISK OF LOSS OF RESULTS

In [**Raw**] mode, the results, expressed in seconds only, are neither backed up nor transmitted. A printout of these results on request is not possible.

To avoid any risk of loss of results and maintain the traceability of analyses performed in raw mode, online printing must be enabled.

### Modification of samples (if necessary)

The [**Sample**] section is automatically completed on the basis of the sample type. The number of wells used is doubled if measurements are expressed in duplicate, without exceeding a maximum of 4 wells.

**Calibrations**

The name of the calibrator and the calibration point dilution are displayed in the wells used.
The number of wells displayed corresponds to the dilution points defined in the methodology.

**Quality controls**

The quality controls, selected control level, lot number and ranges are displayed in the wells used.
It is only possible to run two control levels in the same strip if the [**Auto.**] option has been selected in the methodology parameters.

➤ If necessary, press on the required line to modify the lot number and/or the ranges.

➤ Enter the new values and save the modifications.

**Patient samples**

The patient identities, composed of a prefix (optional) and an automatically incremented number, are displayed in the wells used.
The prefix, the incrementation values and the number of wells automatically displayed correspond to the options selected in the system parameters.

➤ If necessary, press on the required line to modify the identity of a patient.

➤ Enter the new value and save the modifications.

---

The identities recorded in this menu will be identical in the analyzer and, if applicable, in exported files.

---

➤ If necessary, press to delete an identity or  to add one.

➤ Patient identities can also be added using the hand-held scanner (optional).

➤ Once the strip parameters have been entered, press  .

See also:
***Analyzer preparation*** page 41
***Setting the printout options*** page 29
***Setting the incubation/measurement options*** page 27
***Methodology management*** page 30

## 6.4.3 Distribution of samples and products

➤ Press  .

➤ Distribute the first sample into the first cuvette of the strip in the incubation position of the column selected in the software.

RISK OF BIOLOGICAL CONTAMINATION

To avoid contamination between reagents, it is essential to change the pipette tip each time the reagentBT1  Tf1 i277 T 411.19 63 reW* nBT/F1 son 11 552.19 Tm[( )] TJETqQ EMC  /P

## 6.4.4 Running a measurement

➤ When the analyzer beeps, press  and move the strip to the measurement area.

➤ Enable the pipette, distributing **only one** jet into the reagent vial.

✓ The timer continues.

➤ Wait until the end of the incubation time, then use the connected pipette to distribute the start reagent into each cuvette, carefully following the well order (from top to bottom).

✓ At each distribution, the measurement timer starts, successively displaying the following icons:

| | |
|---|---|
|  1 | First measurement well |
|  2 | Second measurement well (if used) |
|  3 | Third measurement well (if used) |
|  4 | Fourth measurement well (if used) |

➤ If the pipette is not connected, press each of these icons to start the measurement.

✓ Once the measurement has been performed, the result is displayed for each well.
Note: if the [**Main/Aux**] option has been selected, the results are displayed in main units.

➤ Press the measurement wells to view the raw times of the results.

➤ Discard the cuvette strip and press  .

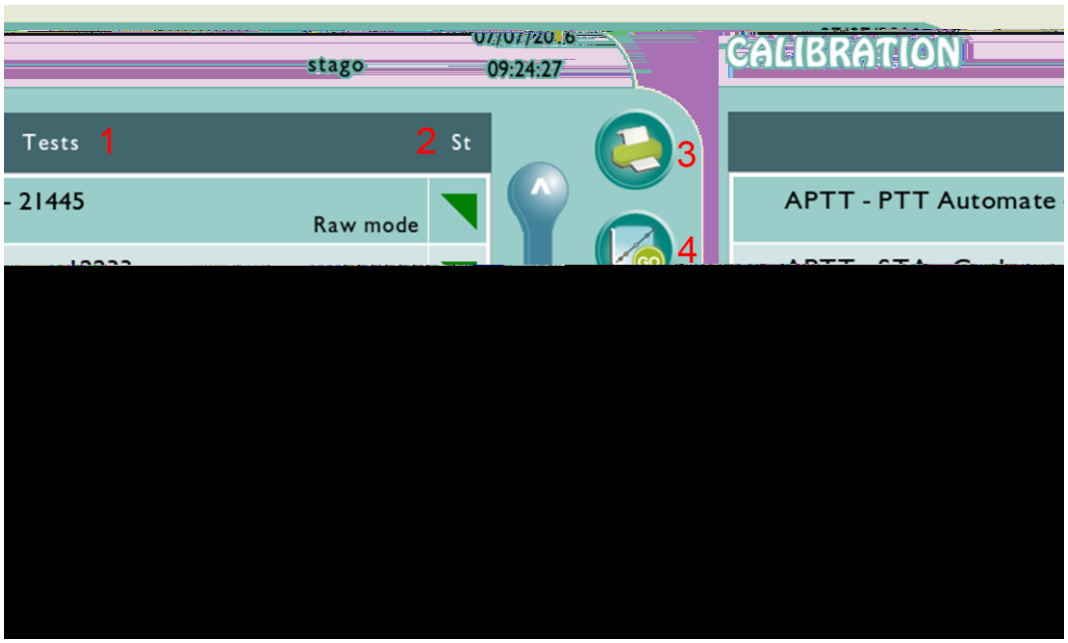
Also see: ***Alarms and statuses associated with the results*** page 69

## 6.5 Additional information concerning Calibration

As with patient analyses and quality controls, the [**INCUBATION/MEASURE**] menu is used to run calibrations. The steps to be followed to run a calibration are described in the paragraph ***Running an analysis (all sample types)*** page 45.

However, other options specific to calibrations are also possible using the [**Calibration**] menu, which can be accessed from the home screen.

Fig. 22 - Calibrations of favorite tests




1. Test information.

2. Colored triangle indicating the status of the calibration for each test.

| | |
|---|---|
|  | Calibration not done, erroneous or expired reagents.<br>E.g. insufficient number of points. |
|  | Calibration validated. |
|  | Calibration in progress. |
|  | Calibration to be validated.<br>E.g. Regression coefficient less than or equal to the coefficient defined in the system parameters ([**Incu/Measure**] tab of the [**System**] menu). |

3. Printout of calibration of the selected test (see ***Printing a calibration*** page 56).

4. Run/rerun of the calibration of the selected test (see ***Running or rerunning a calibration from the Calibration menu*** page 53).

5. View of the calibration results for the selected test (see ***Viewing the calibration results*** page 54).

## 6.5.1 Running or rerunning a calibration from the Calibration menu

➤ From the [**Calibration**] menu, select the test to be calibrated and press  .

✓ The calibration entry screen is displayed.

➤ For each product and calibrator used, enter the lot number and the expiry date, following the date format indicated.
If the day is not indicated, enter the last day of the current month for the expiry date.

➤ Enter the titer of the calibrator indicated on the insert in main units.

➤ Depending on the auxiliary units configured, enter the reference time and/or the ISI coefficient.

**Note**: If the reference time is modified, it is used as the reference for the INR calculation.

RISK OF INCORRECT RESULTS

In order to avoid any risk of incorrect results:

The ISI value for the Prothrombin time must be the value indicated on the insert of the product or that recalculated by the laboratory in accordance with the procedures and regulations in force. The operator must check the ISI value before quitting the menu if there has been a lot change, a software update or any other major change.

✓ The calibration is ready to be run ( ).

➤ Press  to access the [**INCUBATION/MEASURE**] menu.

➤ Distribute the samples in the order predefined in the strip details.

➤ Run the measurement as indicated in the chapter ***Running an analysis (all sample types)*** page 45.

Also see: ***Running a calibration manually*** page 53

## 6.5.2 Running a calibration manually

➤ Select the required test and press [**Manual**].

✓ The calibration entry screen is displayed.

➤ For each product and calibrator used, enter the new lot number and the new expiry date, if required, following the date format indicated.
If the day is not indicated, enter the last day of the current month for the expiry date.

➤ If necessary, enter the new titer and ISI values indicated on the inserts.

➤ In the table displayed, select a display point and press [**Edit**].

➤ Enter the values in raw measurements.

➤ Repeat for the other display points.

➤ Press [**Validation**].

✓ The calibration is automatically validated if the [**R coef.**] value of the curve is greater than the regression coefficient ([**Rref coef**]) defined in the [**System**] - [**Incu/Measure**] menu. Otherwise, the calibration must be validated manually.

### 6.5.3 Viewing the calibration results

➤ From the [**Calibration**] menu, select the required methodology and press  .

✓ The curve is displayed.

**Note:** the validation date is only displayed if the calibration is validated.

➤ Press  to display the information relating to the lots and expiry dates of the reagents and calibrators used.

➤ Press  again to return to the calibration curve.

➤ Press  to display the table of raw, interpolated and theoretical measurements.

### 6.5.4 Manual calibration validation

The calibration is automatically validated if the [**R coef.**] value of the curve is greater than the regression coefficient ([**Rref coef**]) defined in the [**System**] - [**Incu/Measure**] menu. Otherwise, the calibration must be validated manually as follows:

➤ From the [**Calibration**] menu, select the test for which the calibration must be validated  .

➤ Press  then press [**Validation**].

➤ Enter a comment then press [**Save**].

✓ The calibration is validated .

### 6.5.5 Canceling a calibration in progress

➤ From the [**Calibration**] menu, select the test for which the calibration is to be deleted .

➤ Press .

➤ Validate the confirmation message.

✓ If applicable, the previous calibration is retrieved irrespective of its status. Otherwise, the calibration is shown as not done .

### 6.5.8 Printing a calibration

➤ From the [**Calibration**] menu, select the test for which the calibration is to be printed.

➤ Press  .

✓ The curve and the calibration points table are printed.

If the [**Online Printing**] option has been selected in the settings options, the test results are automatically printed:

- at the end of the measurements,
- on validation of a modification or
- on validation of a deletion.

## 6.6 Additional information concerning Quality Controls

RISK OF INCORRECT RESULTS

In order to avoid any risk of incorrect results:

If the results of a quality control are out of range, the validity of all the results since the last correct quality control should be questioned.

As with patient analyses and quality controls, the [**INCUBATION/MEASURE**] menu is used to run quality controls (QC). The steps to be followed to run a control are described in the paragraph ***Running an analysis (all sample types)*** page 45.

However, other options specific to controls are also possible using the [**Control**] menu, which can be accessed from the home screen.

The [**QUALITY CONTROLS**] screen displays the following information:

- Information on the requested test and the control level.
  The levels are defined in the methodology (2 levels maximum).
- Date and time when the control was run.
- Icon to sort the controls by date or name: the number of controls displayed is limited to the maximum number defined in the [**Incu/Measure**] tab of the [**System**] menu. The controls are displayed from the most recent to the oldest. The oldest controls are deleted when the maximum number of controls to be displayed is reached.
- Results in main and raw units, along with a reminder of the min and max ranges entered.
- Colored triangle indicating the status of the control for each test.

| | |
|---|---|
|  | Quality control not done or erroneous |
|  | Quality control to be validated. |

The following operations are possible from this screen:

- Printout of the selected control (see ***Printing a control*** page *59*).
- Display of the controls for all the favorite tests (see ***Viewing the controls for all the favorite tests*** page *57*).
- Display of the QC graph (see ***Viewing the QC graph of each favorite test*** page *58*).
- Validation of the selected control (see ***Manual control validation*** page *58*).
- Deletion of the selected control (see ***Deleting a control*** page *59*).
- Transmitting the selected control (see ***Transmitting a control*** page *59*).

## 6.6.1 Viewing the controls

### 6.6.1.1 Viewing the controls for all the favorite tests

**Note:** to select favorite tests, see paragraph on Selecting methodologies.

➤ From the [**Control**] menu, press  .

✓ The favorite test controls are displayed in a table.

For each test, a colored triangle indicates the overall status of the control ([**St**] column). The status of each test is defined on the basis of the status of the two control levels. For each test, a colored triangle indicates the status of the two levels.

If the test has been defined with a single control level, the software will nonetheless display a status validated by default for the undefined level. The overall test status is defined on the basis of the least favorable result of the two levels.

Example:

| Level status | Control status |
|---|---|
| [**Coag Control N**] or [**Coag Control P**]  |  Validated |
| |  To be validated |
| | Not validated |
| | Not validated |

### 6.6.3 Deleting a control

- From the table of the day's controls or the table of methodology controls, select the control to be deleted.
- Press [**Delete**].
- Enter a comment then press [**Save**].
- The control is deleted. The line is displayed in gray. No colored triangle is associated with the deleted control.

✓ The comment can be viewed by pressing [**Comments**].

### 6.6.4 Transmitting a control

- From the table of the day's controls or the table of methodology controls, select the control to be sent.
- Press [**Transmit**].

✓ The control is sent to the host computer.

### 6.6.5 Printing a control

- The list of the day's controls, the QC graphs and the methodology controls can be easily printed by pressing  from the [**Control**] menu.

**Note**: the graph printout is accompanied by a printout of the methodology controls.

## 6.7 Additional information concerning patient analyses

RISK OF BIOLOGICAL CONTAMINATION

In order to avoid any risk of contamination:

Observe the proper precautions for handling biohazardous materials in accordance with local regulations: use disposable gloves, mask and/or protective goggles, and protective clothing.

As with calibrations and quality controls, the [**INCUBATION/MEASURE**] menu is used to run patient analyses. The steps to be followed to run an analysis are described in the paragraph ***Running an analysis (all sample types)*** page 45.

### 6.7.1 Viewing the results of patient analyses

Patient results are displayed in the [**Patients**] menu, once the [**Main/Aux**] option has been selected following the analysis request.

Display of the patient results is limited to 50 results. The oldest results are deleted once this number has been reached.

The result of each analysis is displayed in main and raw units. If the [**Duplicate Meas.**] option was checked during the request, the result displayed corresponds to the mean of the duplicate.

➤ Press  to consult the patient file.

✓ Each file contains detailed information concerning the requested analysis and the results obtained:

- identification of the sample
- the date and time when the analysis was performed
- the requested test
- the result in main units
  Note: the result is capped if printout limits have been entered.
- the result in auxiliary units (if defined)
  Note: these are measurements recalculated from the mean, if duplicate measurements have been requested.
- the column and the wells used
- the detailed values in raw units and main units for the single measurement
- the detailed values in raw units and main units for the duplicate, if duplicate measurements have been requested
- the associated alarms

See also:
***Methodology management*** page 30
***Alarms and statuses associated with the results*** page 69

## 6.7.2 Printing patient results

➤ From the [**Patients**] menu, select the required result and press  .

✓ The selected analysis is printed.

**Note:** the results can also be sent from the patient file.

## 6.7.3 Validating a patient result

If an out-of-tolerance result is obtained, an alarm is associated with the result and the status is "to be validated" ( ). The result can nonetheless be validated manually:

➤ From the [**Patients**] menu, select the result to be validated and press [**Validation**].

➤ Enter a comment and save.

✓ The "to be validated" status ( ) and the alarm disappear from the file.

Also see: ***Alarms and statuses associated with the results*** page 69

## 6.7.4 Transmitting a patient result

➤ From the [**Patients**] menu, select the required result and press [**Transmit**].

**Note:** the results can also be sent from the patient file.

# 6.8 Changing user and switching off

## Changing user

➤ From the home screen, press  .

➤ Enter a new user and press [**Save**].

## Switch the analyzer off

It is not necessary to shutdown the software before switching the analyzer off. It can be switched off from any screen by simply pressing the on/off button located on the left of the analyzer.

Raw measurements will not be saved. If necessary, print out or note the results before switching the analyzer off.

If the analyzer needs to be switched off for more than one week, follow the decontamination procedure described in this manual, then put the cover provided over the analyzer. Before switching the instrument on again, follow the same decontamination procedure.

See paragraphs:
***Routine cleaning*** page 64
***Curative and preventive maintenance*** page 63

# 7 Maintenance, routine cleaning and recommendations



## 7.1 Maintenance

### 7.1.1 Decontamination procedure

RISK OF BIOLOGICAL CONTAMINATION

In order to avoid any risk of contamination:

Observe the proper precautions for handling biohazardous materials in accordance with local regulations: use disposable gloves, mask and/or protective goggles, and protective clothing.

#### 7.1.1.1 Preparation of the decontaminating solution

The decontaminating solution is bleach containing 0.37% (approximately) of active chlorine.

➤ Prepare the decontaminating solution containing 0.37% of active chlorine from a bleach solution and distilled water at room temperature (see below).

OR

➤ Mix one part of bleach containing 9.6% of active chlorine with three parts of water to obtain a bleach solution containing 2.6% of active chlorine. Then mix one part of bleach containing 2.6% of active chlorine with six parts of water.

To obtain a decontaminating solution containing 0.37% (approximately) of active chlorine from a bleach solution and distilled water at room temperature:

add N parts of water to one part of bleach according to the following formula:

where B = % of active chlorine in the bleach used.

RISK OF BIOLOGICAL CONTAMINATION

In order to avoid any risk of contamination:

Allow the decontaminating solution to work on the potentially contaminated area for 15 minutes.

## 7.2 Routine cleaning

RISK OF BIOLOGICAL CONTAMINATION

In order to avoid any risk of contamination:

Observe the proper precautions for handling biohazardous materials in accordance with local regulations: use disposable gloves, mask and/or protective goggles, and protective clothing.

To ensure that the analyzer operates correctly, it is recommended that routine cleaning operations be performed on the basis of the laboratory's activities. Switch off the analyzer before performing the following cleaning operations:

- Clean the measurement and incubation wells using long swabs moistened with decontaminating solution.
- Clean the work surface and the reagent storage positions using absorbent paper towels moistened with decontaminating solution.
- Clean the thermal conductors of the pipette using long swabs moistened with decontaminating solution. Then rinse with purified water and dry with absorbent paper towels.

RISK OF BIOLOGICAL CONTAMINATION

In order to avoid any risk of contamination:

Allow the decontaminating solution to work on the potentially contaminated area for **15 minutes**.

- Clean the screen with a cloth moistened with ethanol diluted to between 20% and 40%.
- Clean the outside of the pipette with a soft cloth moistened with a mild detergent.

Do not allow product into the measurement wells or inside the pipette casing.

See also:

***Preparation of the decontaminating solution*** page 62
***Preparation of diluted ethanol (approximately 22%)*** page 63

## 7.3 Recommendations

In addition to routine cleaning recommendations, Stago recommends regular data back-up.

The back-up frequency should be adapted to the analyzer's activity.

See: ***Back-up settings*** page 27

# 8 Troubleshooting

## Error messages

- If any [**A fatal error occurred, please contact your vendor. Error code:**] error messages appear, restart the analyzer.
- If the problem persists, call your local authorized Service Representative.

Note: [**A fatal error occurred, please contact your vendor. Error code:**] means "Irretrievable error".

## Other problems observed

| Problem observed | Probable cause | Possible solution |
|---|---|---|
| The analyzer does not start up although it is switched on. | The wall socket is out of order. | Plug the analyzer in elsewhere. |
| | The power cord is not connected. | Plug in the power cord. |
| | The analyzer is out of order. | If the problem persists, call your FSE. |
| The screen does not come on. | The screen is out of order. | If the problem persists, call your FSE. |
| The selected timers do not start. | The screen is out of order. | If the problem persists, call your FSE. |
| No stirring on the reagent block (37°C). | The stirring motor does not start. | Switch off the analyzer then switch it back on until stirring starts.<br><br>If the stirring motor still does not start, call your FSE. |
| Ball error: the system does not detect ball oscillation. | There is no ball, or more than one ball, in the cuvette. | Repeat the measurement, being careful to make sure only one ball is distributed into each cuvette. |
| | The drive system is out of order. | Call your FSE. |
| The measured times are correct but the results in units are not. | The calibration data is not correct. | Enter the correct calibrator values, taking into account the corresponding units and times. |
| The  icon is displayed and the measurement is not run. | The incubation timer was started while a temperature alarm was in progress. | Discard the strip and repeat the analysis. |

# 9 Icons, symbols and alarms



## 9.1 Clickable icons

| Icon | Description |
|---|---|
|  | Go to the [**Patients**] menu. |
|  | Go to the [**Control**] menu. |
|  | Go to the [**Calibration**] menu. |
|  | Go to the [**System**] menu. |
|  | Go to the [**INCUBATION/MEASURE**] menu. |
|  | Analysis complete: discard the strip. |
| | Analysis not performed: discard the strip. |
|  | Confirm movement of the strip to the measurement area. |
|  | Confirm distribution of the first jet into the vial. |
|  | Confirm distribution of the first sample. |
|  | Confirm distribution of the second sample. |
|  | Confirm distribution of the third sample. |
|  | Confirm distribution of the fourth sample. |
|  | Start the timer. |

| Icon | Description |
|---|---|
|  | Start the timer. |
|  | Display the methodology or the information relating to the lots and expiry dates of the reagents and calibrators used. |
|  | Display the controls for the favorite tests or the table of raw, interpolated and theoretical calibration measurements. |
|  | Display the table of table of methodology controls listing all the controls performed for each favorite test. |
|  | Sort the results. |
|  | Delete identities. |
| | Add identities. |
| | Remove the methodology from favorites. |
| | Save the methodology in favorites. |
|  | Duplicate the methodology. |
| | Delete the duplicated methodology. |
|  | Create or modify a barcode for a non Stago methodology. |

## 9.2 Indicator symbols

| Icon | Description |
|---|---|
|  | Heating in progress or out of specification |
|  | Communication established. |
|  | Communication broken. |
|  | Not transmitted, transmission error. |

| Icon | Description |
|---|---|
|  | Transmission in progress. |
| | Customer methodology. |
| | Calibration in duplicate. |
| | Product stirring required |

| Symbol | Description |
|---|---|
|  | Calibration / Quality control not done or erroneous; patient result erroneous.<br>E.g. insufficient number of points. |
|  | Calibration validated. |
|  | Calibration in progress. |
|  | Calibration / Quality control / patient result to be validated.<br>E.g. Regression coefficient less than or equal to the coefficient defined in the system parameters ([**Incu/Measure**] tab of the [**System**] menu). |

## 9.3 Alarms and statuses associated with the results

| Codes | Meaning |
|---|---|
| **C** | Quality control out of range or not done. |
| **D** | Quality control out of range but validated by the operator |
| **H** | Result in main unit limited to printout values (capped value) |
| **O** | Incorrect duplicate tolerance |
| **V>VMax** | Measured time greater than the maximum time set in the methodology or greater than the max calibration time if the [**Linear Interpolation**] option is not selected. |
| **V<VMin** | Measured time less than the minimum calibration time if the [**Linear Interpolation**] option is not selected. |