GRIFOLS

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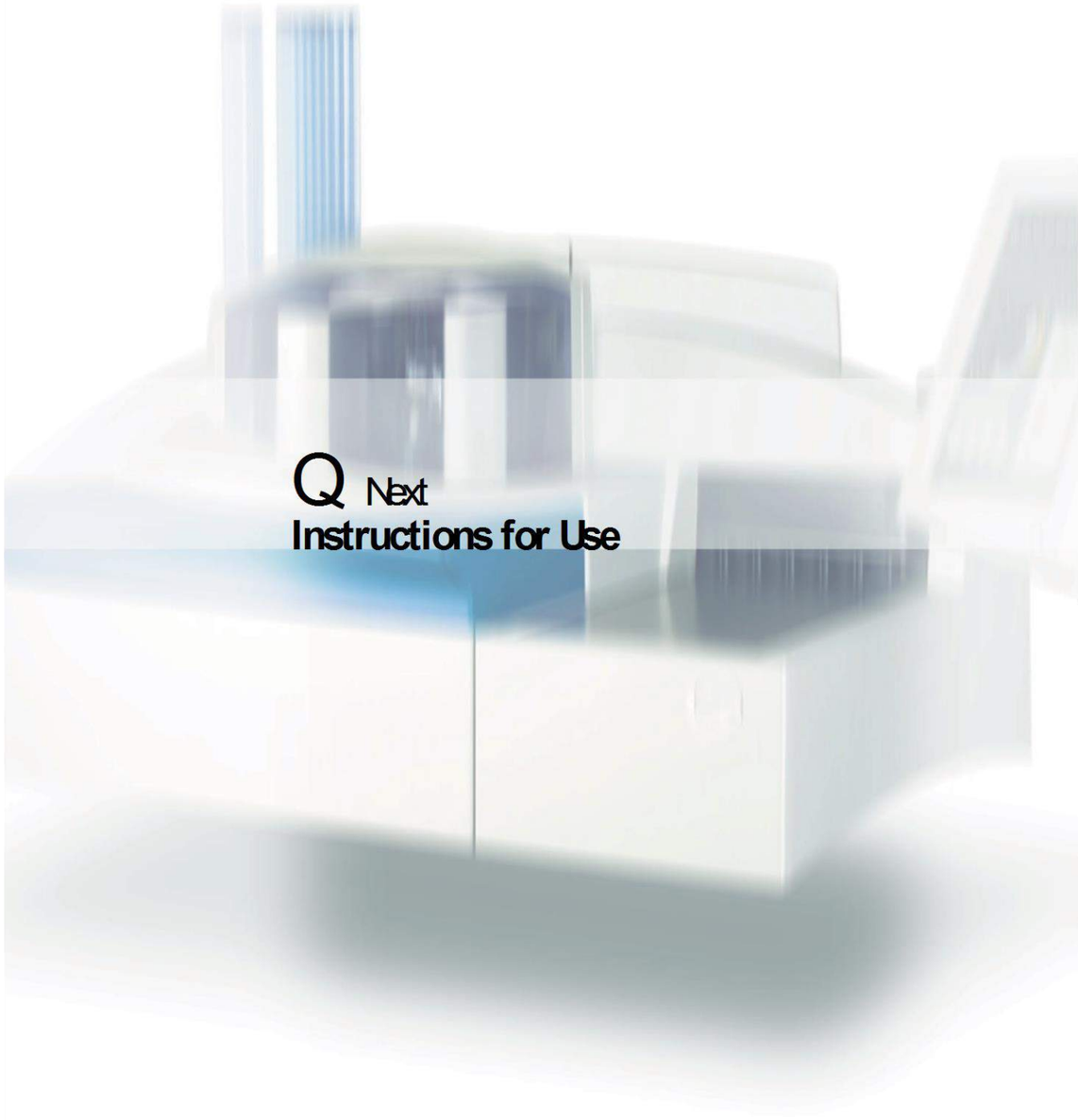
Q Next Instructions for Use



Q Next
Instructions for Use

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Manufactured by: **Diagnostic Grifols, S.A.**
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PLEASE READ THESE INSTRUCTIONS FOR USE CAREFULLY BEFORE STARTING TO WORK WITH THE QNEXT

Information about matters relating to the equipment Safety can be found in Section 2.

The symbols used in these Instructions for Use are as follows:

	**DANGER:** Indicates a hazardous situation – critical or not – for people (including patients), that can only be diminish following the instructions shown.
	**WARNING:** Indicates a hazardous situation for people (including patients) for which other protection systems are provided. Nonetheless, it is convenient the Supervisor and/ or the Operator know it.
	**CAUTION:** Indicates a hazardous situation that could result in material damages to the equipment or other properties. This situation can be prevented by following these instructions or using other types of protection.
	**NOTE:** Used for clarifications and supplementary or highlighted information.

Definitions

Supervisor:	Person or group responsible for using and maintaining the equipment and for providing appropriate training for Operators.
Operator:	Person who uses the equipment for the purpose for which it was designed. The Operator must have laboratory technician-level training and knowledge of hemostasis. He or she must also be familiar with the tests performed by the Q**Next** analyzer, and should have completed a training course to use the analyzer.
Qualified Personnel:	Person responsible for the installation, repair and special servicing of the equipment, who has been specifically trained for this purpose. All restrictions referring to the Supervisor shall also be valid for the Operator.

The design and specifications for this equipment are subject to modification without prior notice.

This instrument is protected by international patents which affect all the equipment and parts thereof.

This document is available in several languages. Translations have been made based on the master document in English. In case of doubt or discrepancy, the terms of the master document in English shall prevail.

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About this Manual

Highlighting and Quotation Conventions

Highlighting and quotation marks are used to convey specific meaning within the context in which they are used. The context and meaning of the highlighting and quotation marks are defined below:

All uppercase letters are used for:

- Acronyms.
- Copyrighted and trademarked terms where uppercase is the expected form.
- Main instrument parts and components.
- Specific software interface menus, buttons, fields, windows and options.
- Section names in cross-references.

Italics are used for:

- Titles of other documents.
- Minor emphasis within normal text.
- Tables and figures titles.

Bold is used for:

- Headings.
- Text that needs to be delineated from surrounding text.
- Commercial names: Analyzer name, accessories, etc.
- Specific software interface menus, buttons, fields, windows and options.
- Especially important information such as warnings, cautions and notes.

Trademarks

The following terms are trademarks:

These terms…	Are trademarks of...
Q	Diagnostic Grifols, S.A.
WINDOWS	Microsoft Corporation

Any other brand names in this manual are trademarks of their respective companies.

1 Introduction

THIS EQUIPMENT IS AN *IN VITRO* DIAGNOSTIC MEDICAL DEVICE (IVD).

These Instructions for Use, which are intended for the Operators of the Q**Next**, contain all the information that is necessary for safely and adequately working with the instrument.

Please, read carefully all this information before attempting to work with the equipment, especially on the maintenance section, the suggestions for correct use and the information about contaminating liquids.

If you have any doubt whatsoever, please contact your local service representative before starting any operation.

These Instructions for Use should be accessible to all the personnel who work with the instrument.

1.1 Intended Use

The hemostasis analyzer Q**Next** is a fully-automated, random-access instrument, intended for *in vitro* diagnostic clinical use to perform hemostasis testing using clotting, chromogenic and immunoturbidimetric methods.

NOTE: No chromogenic or immunoturbidimetric GRIFOLS hemostasis assay is currently available on the US market.

DIAGNOSTIC GRIFOLS, S.A. HAS VALIDATED TESTS WITH ITS PRODUCTS. THESE TESTS ARE PROVIDED WITH DIGITAL SIGNATURES AND MUST NOT BE MODIFIED.

THE TESTS HAVE BEEN INDIVIDUALLY VALIDATED.

ANY POSSIBLE COMBINATION OF TESTS (PROFILES) AND THE INTERACTIONS WHICH MAY OCCUR DUE TO CHANGES IN THE ORDER OF PROCESSES DETERMINED BY THE INSTRUMENT HAVE NOT BEEN TESTED. THESE CHECKS ARE SUBJECT TO VALIDATION BY THE SUPERVISOR.

FOR TESTS NOT PREVIOUSLY VALIDATED BY DIAGNOSTIC GRIFOLS, S.A., THE SUPERVISOR SHALL BE IN CHARGE OF INDIVIDUALLY VALIDATING EACH TEST WITH THE APPROPRIATE PRODUCTS IN THE Q**NEXT** BEFORE USING IT FOR ANALYTICAL PURPOSES.

1.2 Purpose, Limitations and Operator Training

1.2.1 Purpose

The Q**Next** has been designed to automatically perform all stages of the procedures associated to coagulometric, chromogenic and immunoturbidimetric hemostasis tests.

This kind of automation allows Operators to:

- Absorb the workload involved in running hemostasis laboratory tests profiles, optimising the execution of these profiles in the shortest time possible, and ensuring the maximum possible precision and accuracy in the results.
- Increase the reliability of the analytical process, eliminating any possible errors in the identification and treatment of samples and products and in the revision and transcription of the results.
- Reduce the risk of Operator contamination by minimising interaction between the Operator and samples and products during the analytical process.

1.2.2 Limitations

- The Q**Next** is only designed to run the hemostasis tests described in Section 1.1, it can not be possible to run tests different to the ones that have been used to design the analyzer.
- The Q**Next** can only use Q**cells** cuvettes. These are separate, individual cuvettes, specifically designed to work with the analyzer.
- The Q**Next** can only use accessories designed and supplied by Diagnostic Grifols, S.A.
- The samples used in the analyzer should be centrifuged, citrated and platelet-poor human plasma.
- The cap piercing system has only been validated for primary tubes with rubber caps, as described in Section 4.3.2.1.
- Positive identification of samples and products depends on the sample, diluent and reagent tubes or containers being identified with barcodes. To guarantee maximum safety of sample identification, the use of barcodes with control digit (checksum) is recommended.
- The processing of results includes a revision stage (see Section 13.3.2). Please pay special attention to any result which displays a warning in the Incidents Area (Figures 13.1, 13.2 and 13.3, no. 5).

⚠ **CAUTION:** The use of the Q**Next** for purposes other than specified by the manufacturer shall automatically invalidate any type of warranty.

1.2.3 Training

Only properly-prepared staff who has received specific training should use the Q**Next**. The Operator should also be a trained Laboratory Personnel with knowledge of hemostasis.

1.3 Basic Theory of Operation

To perform the operations for which it has been designed, the Q**Next** automatically follows the steps described in most coagulometric, chromogenic and immunoturbidimetric tests:

- Dilution and dispensing of Samples, Calibrators, Standards or **Controls**.
- Cooling and dispensing of Products.
- Homogenization of the sample-reagent mixture.
- Incubation.
- Optical reading.
- Mathematical processing and obtainment of analytical results based on the primary absorbance data.

The data analysed can be stored, displayed and printed. Additionally, the analyzer allows conducting integrated functions, such as the analysis of urgent samples or the **Quality Control** module.

Among other things, the analyzer provides:

- Positive identification of samples and reagents.
- Cap piercing system.
- Reagent refrigeration.
- Level and clot detection in samples and reagents.
- Increased tolerance to the presence of substances that produces optical interference in the sample (*e.g.* haemoglobin, bilirubin and triglycerides) for tests read at 620 nm or at 405 nm + 620 nm (bi-chromatic tests).
- Possibility of connecting several instruments forming a net (**QNet**).

1.3.1 General Description of Operation

Analysis starts once the **Worksheet** has been configured and the sample is inserted in the analyzer. To this end, the information for sample identification and the parameters of the test need to be previously entered.

1.3.1.1 Programming the Workload

There are four ways to program the workload in the analyzer:

1. **Samples positive ID and connection to the Host:** Automatic identification of samples tubes by barcode and automatic assignment of requests through the Laboratory Information System (LIS).
2. **Samples positive ID and programmed Profile:** Automatic identification of samples tubes by barcode and automatic assignment of requests through a programmed profile.

3. **Samples manual ID and programmed Profile:** Manual identification of samples tubes because they are not barcoded and automatic assignment of requests through a programmed profile.
4. **Samples manual ID and manual tests orders:** Manual identification of samples tubes because they are not barcoded and manual assignment of requests through the **Worksheet** of Q**Manager** window (see Section 12.2).

1.3.1.2 Running the Test

Once all the tests are assigned to the samples, these must be loaded into the analyzer.

Depending on the procedure described for each test, the Q**Next** performs dilution and dispensing of samples, reagent addition and incubation in disposable cuvettes. At the end, the cuvettes are placed in the Reading Area where the optical reader monitors changes in absorbance of the reaction mixture over time.

The cuvettes used for analysis are automatically discarded and the samples are retained in the analyzer until it determines that all requests have concluded (including reflexs and repetitions), except where otherwise indicated (see Section 7.3.2).

1.3.1.3 Obtaining Primary Data. Types of Tests

The absorbance-time relation and, therefore, the shape of the reaction curve vary depending on the principle of reaction, which allows classifying the types of hemostasis tests as follows:

- **Clotting methods:** Based on enchained enzymatic reactions that result in the formation of a fibrin clot (functional test).

On the one hand, the coagulation time can be measured (to determine the time elapsed until a fibrin clot is detected, *e.g.* PT, APTT) and, on the other hand, the density of the insoluble fibrin mesh can also be measured (*e.g.* derived fibrinogen). In both cases, the progressive fibrin clot formation increases the amount of absorbed light.

- **Chromogenic methods:** Based on an enzymatic reaction which results in the formation of colour (functional test).

It is possible to measure numerous coagulation parameters by means of enzymes and chromogenic substrates. In this type of measurement, the activity of an enzyme can be quantified by measuring the speed at which colour is formed (*e.g.* antithrombin, heparin) or by measuring the total amount of colour formed at a certain moment (*e.g.* protein C). In both cases, the increase of colour formation increases the amount of absorbed light, which is proportional to the enzymatic activity.

- **Immunoturbidimetric methods:** Based on an immunologic reaction which results in the formation of agglutinates (antigenic test).

It is possible to measure numerous coagulation parameters using latex particles coated with antibodies that agglutinate in the presence of the antigen to be measured. These agglutinates give rise to increased turbidity (light-scattering) of the mixture (*e.g.* D-Dimer), which is proportional to the amount of antigen in the sample.

NOTE: No chromogenic or immunoturbidimetric GRIFOLS hemostasis assay is currently available on the US market.

1.3.1.4 Mathematical Treatment of Primary Data

The analyzer has various **Algorithms**, which consist in applying mathematical treatments to the absorbance-time curves to obtain the parameters that characterise them and be able to provide a result. Selecting one or another will depend on each test. The algorithms available in the program can be classified in three groups, according to the type of test in which they are used (see Section 9.2.2.1):

- **Clotting:** These are used in clotting methods and calculate the time value of some of the stages of coagulation.
- **Chromogenic:** These are used in chromogenic methods and calculate reaction speeds (slopes) or absolute absorbance increase during a fixed time.
- **Immunoturbidimetric:** These are used in immunoturbidimetric methods and calculate differences of absorbance between two points.

The program also has some protections which detect, by using mathematical calculations, the existence of abnormalities in the primary curve and, depending on these, the instrument provides different **Warnings** about the results (see Section 9.2.2.5).

NOTE: No chromogenic or immunoturbidimetric GRIFOLS hemostasis assay is currently available on the US market.

1.3.1.5 Obtaining Analytical Results

Apart from the absorbance and time values obtained through processing of the primary reading curve with mathematical algorithms (**primary unit**), the analyzer can also provide the results in the **secondary units** (concentration, activity, ratio or INR) established in the Test Programming. To transform results from primary unit to secondary unit, the Q**Next** uses the following tools:

- Interpolation or extrapolation in a **Calibration Curve**.
- Calculation of ratios with regards to a **Standard** (representation of the normality), either commercial or population.

The results are automatically updated in the **Worksheet**.

1.3.1.6 Revision of Results

The analyzer program allows a detailed analysis of the results present in the **Worksheet**. Through the corresponding Results Box of each order, the curves of each of the measurements and the results of the analysis can be displayed.

The program also notifies the results obtained based on the **Quality Control Policy** configured for the analyzer (Control Range, Coefficient of Variation (CV) between duplicates, compliance with multiple statistical rules, etc.).

When accepting a result during the revision stage, apart from the result itself, any incidents derived from the status of the sample, of the analyzer, of the **Quality Control Policy** and any additional information, either population-based and/or clinical should also be considered.

The Operator can accept the results either by order, by sample, by test or of all the samples.

1.3.1.7 Management and Print-Out of Results

The program can be configured so that all samples and Controls reviewed results are sent automatically to the Laboratory Information System (LIS).

Additionally, and depending on the configuration, the program stores all the results, including primary curves (absorbance *versus* time) in a **Temporary Database** prior to sending the data to a **Historical Database** which is accessible to the Operator.

The Q**Next** also provides different types of reports. The results can be reported either by procedure, by sample, with duplicates by procedure, with duplicates by sample, or customised (see Section 14.2).

2 Safety Information

2.1 Please Read Before Use

- Only use the equipment for the purposes described in these Instructions for Use.
- Do not insert objects into any openings of the equipment, unless specified in these Instructions for Use.
- Do not use the equipment if it is not working properly or has suffered any damage. Examples of typical faults are:
  - Visible damage caused by dropping the equipment.
  - Visible damage caused by liquid spillage.
  - Visible damage caused by storage in inappropriate conditions for long periods of time or severe conditions of transport.
  - Damage to the flexible supplied cord or its plug.
- Do not use the equipment in hazardous environments or with hazardous materials for which the equipment has not been designed.
- Do not use any accessories not supplied or recommended by the manufacturer.
- Do not interchange accessories between instruments.
- To refill bottles of liquid, first remove them from the equipment.
- Keep air vents free of dirt such as threads, hair, dust, etc.
- The power fuses should only be replaced by Qualified Personnel.
- The equipment should only be dismantled by Qualified Personnel, either for internal cleaning and/or repairs. Prior to dismantling the equipment, unplug it from the wall socket.
- To avoid the risk of electric shock, this equipment must only be connected to an electrical network equipped with protective grounding.
- Turn off the equipment after use.

2.2 Warnings and Cautions

Before operating the equipment, review and become familiar with these warnings and cautions. Adherence to the warnings and cautions will help to protect you, your colleagues, the equipment, the test results, and ultimately your patients.

2.2.1 Health and Safety Notices

DANGER: Misuse of the equipment can impair the protection provided by itself.

	**DANGER:** This equipment works with some substances that carry a chemical or biological risk. The established regulations for working in laboratories in relation to the use of suitable gloves or other personal protective means should be followed.
	**DANGER:** In the event of any spillage into the equipment, it must be isolated from the electrical supply, cleaned up and decontaminated. In any case the instrument must be disassembled and the equipment must not be reconnected until it has been inspected by a Qualified Personnel.
	**DANGER:** Waste Bottles may contain hazardous liquids. Handle them as if they were potentially infectious substances.
	**DANGER:** The Q**waste tray** may contain Q**cells** cuvettes with hazardous liquids. Handle it as if it was a potentially-infectious substance.
	**DANGER:** The Probes pose a biological risk because they are in contact with samples and products. If, for any reason, you need to manipulate the Samples or Products Probes, they should be treated as being potentially contaminated.
	**DANGER:** During cleaning and/or decontamination, the Operator should wear protective gear (gloves, lab coat, laboratory goggles, etc.).
	**DANGER:** The Samples Probe could leak while unscrewing it. It should be treated as being potentially contaminated.
	**WARNING:** Basic safety precautions should always be taken, including those provided in Section 2.4. Before installing the equipment, also read the rules for installation given in Section 5.2.
	**WARNING:** This equipment should only be used by the Supervisor, Operators and Qualified Personnels.
	**WARNING:** Do not use the instrument in environment conditions outside the ones specified in this section.
	**WARNING:** Although the recommended relative humidity in the room where the equipment is installed should exceed 30%, the unit can operate normally in lower relative humidity conditions. However, in extremely dry environments, and rooms with floors covered with synthetic material, high-level electrostatic discharges may occur, which can damage the equipment.
	**CAUTION:** Do not use the equipment if it is not working properly or has been damaged.

2.2.2 Results Reliability Notices

⚠	**DANGER:** The results obtained by the Q**Next** should first be reviewed by the Supervisor and then interpreted and validated by medical staff. The revision of a result in the Q**Next** does not make it clinically valid, because it must be interpreted together with the patient's medical history and other laboratory tests.
⚠	**DANGER:** The tests provided by GRIFOLS have been validated so that the critical parameters cannot be modified. Copying a test validated by GRIFOLS and modifying it may lead to incorrect results. For tests not previously validated by GRIFOLS, the Supervisor shall be in charge of individually validating each test with the appropriate products in the **QNext** before using it for analytical purposes.
⚠	**WARNING:** The selection of "**None**" **Quality Control Policy** will be under Operator responsibility because it can provoke wrong sample results due to the non compliance of a Control result.
⚠	**WARNING:** The selection of "**None**" **Sample Review Policy** when connection to the LIS is enabled is not a recommended practice.
⚠	**WARNING:** After the Technical Service intervention, the Operator should verify the correct functioning of the analyzer by performing a *Performance Qualification* (PQ) test.
⚠	**CAUTION:** To obtain reliable and high-quality results, follow the product manufacturer's recommendations for use, handling, maintenance and stability thoroughly.
⚠	**CAUTION:** To obtain reliable and high-quality results, do not leave samples inside the instrument for long periods of time as it may not be suitable for its required stability.
⚠	**CAUTION:** The use of capped sample tubes with the option sample tube cap piercing disabled can lead to errors in the results.
⚠	**CAUTION:** The Extrapolation Minimum and Maximum Values should never be considered as the Limits of Quantification of a test, specially when **Redilution** or **Parallelism** options are programmed. The Limits of Quantification obtained during the test validation, which can be found in the **Test Characteristics** tab, must be considered to ensure that no sample result is validated outside the test measuring range.

2.2.3 Electrical Notices

	**DANGER:** To prevent electrical discharge, this equipment should only be connected to an electricity supply with protective grounding.
	**WARNING:** Electromagnetic compatibility and electrical safety tests have been conducted using the cable supplied by the manufacturer. However, if you need to use another cable, please ensure that it complies with the following specifications: Type of cable: Flexible cable with insulation, covered by PVC and with three conductors (neutral, live and grounding). Length: 2 m. Cross-section of conductor: 1 mm^2 or higher. Type of connector: For IEC socket. Class I equipment connector. Type of plug: Type of plug used in the country in which the equipment is installed, with grounding. Connector, cable and plug must comply with the electrical safety requirements applicable in your country.
	**WARNING:** Do not use this device in close proximity to sources of strong electromagnetic radiation (*e.g.* unshielded intentional RF sources), as these can interfere with the proper operation.
	**WARNING:** This equipment includes Radiofrequency Emitters which might interfere with other, nearby equipment. Check the equipment nearby to see whether it is working properly in the usual configuration.
	**WARNING:** To disconnect the instrument from mains, unplug the cable either from the wall socket or the connector located in the rear part of the instrument.
	**WARNING:** Any accessory connected to the instrument must conform with IEC 60950-1 standards.
	**CAUTION:** The changes or modifications in the Radiofrequency Emitters not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

2.2.4 Installation Notices

	DANGER: This instrument is considerably heavyweight, so it is advisable to follow the instructions for placement described in Section 5 very carefully. It needs four people to lift it, holding as indicated (hands on the handles and back straight, flexing the legs).
	WARNING: After the Installation, the Operator should verify the correct functioning of the analyzer by performing a *Performance Qualification* (*PQ*) test.
	WARNING: Only use the original packaging for transporting the equipment.
	CAUTION: To ensure proper traceability and management of expiry dates, check that the Date and Time configuration is correct for your geographical location. Otherwise, please contact authorised Technical Service.

2.2.5 Software Operational Notices

	WARNING: For a same test, it is not allowed to program a second Calibration Curve while the first one is still in the **Worksheet**.
	WARNING: It is not allowed to program Calibration Curves for different tests that share the Calibrator with the same Calibrator lot if the tests use different diluents in the same instrument.
	WARNING: The dilution programmed in the Test will also be applied to the Calibration Curve (Figure 9.6, no. 2).
	WARNING: It is always possible to enter new Standards except for a same test and a same instrument while the results of previous Standards are in the **Worksheet**.
	CAUTION: Do not touch or remove the sample tubes and/or the Q**sample holders** which are being controlled by the system until they output automatically from the Recirculation Area.
	CAUTION: The  stops the analyzer process completely cancelling all running tests and should only be used in case of emergency.
	CAUTION: To protect the data of the software, the **USB data storage device** used to update the language version, should be previously scanned to ensure the device is Virus Free.

⚠ **CAUTION:** When updating the language database version, do not modify the name of the language file, otherwise the analyzer will not be able to recognize it.

⚠ **CAUTION:** The Q**Next** is configured by the manufacturer with all **System options** of the **QExecutor Setup** window enabled by default, except the "Drain Waste" option. Disabling some of them means that the equipment is working under non-manufacturer recommended conditions.

⚠ **CAUTION:** The Q**Next** is configured by the manufacturer with the **Enable Passwords** option on, with 60 days of expiration, and with the **Auto Logout** every 5 minutes enabled. Disabling any of these options mean that the equipment is working under non-manufacturer recommended conditions.

⚠ **CAUTION:** The manufacturer does not recommend disabling the **Enable Passwords** option of the **Users Management** window, since the system is then unable to trace who has performed the actions and makes parts of the program designed to be maintained and controlled by Supervisor accessible to all.

⚠ **CAUTION:** Each laboratory should define the most appropriate **Quality Control** protocol in each case.

⚠ **CAUTION:** When the **Delete QC Data** option of the **QManager Setup** window is used, all the **Quality Control** data obtained until the date will be lost.

⚠ **CAUTION:** When a Calibration Curve is modified and accepted as valid, the analyzer automatically recalculates the results in the **Worksheet** associated with this test which are pending revision.

The determinations in process for this test will be directly calculated using this new, validated curve.

To recalculate results of this test which have been reviewed and/or exported, please see Section 10.3.3.

⚠ **CAUTION:** If the Operator presses **Accept** in the **Edit Calibration** window even if no modifications have been done, the instrument will consider that it has been manually edited and tag it with an asterisk (*).

⚠ **CAUTION:** The **Recalculate Results** option replaces the results calculated with the previous Calibration Curve and these cannot be recovered.

⚠ **CAUTION:** If the fluidic module is not properly initialized, neither is the reader module. When re-initialization is performed, both modules are checked.

⚠ **CAUTION:** If the analyzer has not started properly, re-start using the  button in the Q**Executor** window. If the problem persists, contact the Technical Service.

⚠ **CAUTION:** To configure the connection between the Q**Next** and the Laboratory Information System (LIS), contact authorised Technical Service.

2.2.6 Analyzer Operational Notices

	**DANGER:** Switching caps or positioning the Bottles incorrectly may cause cross-contamination between products and samples.
	**DANGER:** The use of Wash Solutions other than those specified may cause cross-contamination due to insufficient washing and lead to incorrect results.
	**DANGER:** Do not use expired Wash Solutions. Using degraded System Solutions may cause cross-contamination due to insufficient washing and lead to incorrect results.
	**DANGER:** The use of a Wash Solution with a concentration other than that specified may cause cross-contamination and lead to incorrect results. Make sure that solutions are properly homogenized before placing the bottles inside the analyzer.
	**DANGER:** Incorrect washing of the Q**stirrer** may cause cross-contamination and lead to incorrect results.
	**DANGER:** The Samples Probe could leak while unscrewing it, it should be treated as being potentially contaminated.
	**WARNING:** The Products Desk may condense water if the Upper Door is open for long periods of time. Keep the door open only as long as strictly necessary to complete these operations.
	**CAUTION:** To extend the life of the analyzer, the manufacturer recommends turning it off completely with the on/off switch when it is not used for more than 8 hours.
	**CAUTION:** Manual opening systems should only be used in the situations described in these Instructions and should not be used when the analyzer is operating normally. Using the manual system may lead to a cancellation of current orders, loss of data and even unexpected operation of the analyzer. The manufacturer recommends re-starting the analyzer and notifying Technical Service if problems persist.
	**CAUTION:** Do not place cards with magnetic strips or recording media on the Samples Entry and Delivery Area: They may be damaged.
	**CAUTION:** Insert the samples carefully in the Samples Entry Area, trying not to knock over the sample tubes.
	**CAUTION:** Do not insert or take the Q**sample holders** out of the recirculation chain.

⚠ **CAUTION:** Avoid objects and dirt entering through the Q**cells** cuvettes loading position, since they may cause damage to the analyzer.

It is recommendable to always have a rack placed in each position.

⚠ **CAUTION:** Taking the Q**cells** cuvettes rack out while it is in use may block the system or damage the equipment. Never take a rack out unless you are sure that it is empty or the analyzer is on standby.

The Q**Executor** screen indicates the level of cuvettes in each Q**cells** cuvettes rack.

⚠ **CAUTION:** Avoid damaging the Q**cells** cuvettes or racks by dropping or knocking them and keep them away from sunlight and sources of heat. If the grooves become deformed or there are any changes to the general appearance of the Q**cells** cuvettes or racks, discard them and replace them with new ones, since they may cause major damage to the analyzer.

⚠ **CAUTION:** Avoid dropping the Q**sample holders** accidentally: They may fall apart and/or break if they suffer knocks when they fall. If they drop, they should not be reassembled or reused.

Do not use Q**sample holders** if they are incomplete.

⚠ **CAUTION:** Do not use any individual or multiple holders other than the ones specified in the equipment.

⚠ **CAUTION:** Do not use Q**sample holders** if the wings are not symmetric or if the spring is not working well.

The tube should be centrally-aligned, vertical and stable.

⚠ **CAUTION:** When the Wash Solutions Bottles are inserted into the analyzer, ensure that each Bottle (A and B) is placed in its corresponding position.

⚠ **CAUTION:** When the Wash and Waste Solutions Bottles are inserted into the analyzer, ensure that the connections tubes to the bottles are not pinched or bended over as this could cause the analyzer malfunction.

⚠ **CAUTION:** If any Wash Solution Bottle is disconnected and connected again without changing significantly its volume (less than 1 L), a Priming of the Fluid Circuit after closing the Lower Door is strongly recommended (see Section 7.2.1).

⚠ **CAUTION:** While the analyzer is working, the bottles are subjected to pressure. For the system to work properly, ensure that the caps of the bottles are tightly fitted and that the tubes are properly connected.

⚠	**CAUTION:** The use of magnetised rods other than those specified may cause deterioration of the analyzer.
⚠	**CAUTION:** Before inserting a Q**stirrer** in a vial of reagent, check that there is not an earlier one inside.
⚠	**CAUTION:** Before discarding the vial of product, remove the Q**stirrer** from inside with a magnetic bar.
⚠	**CAUTION:** The equipment will stop if the discarded cuvettes counter of the Q**waste tray** reaches the maximum number permitted.
⚠	**CAUTION:** If the counter is reset without replacing or emptying the Q**waste tray**, this may cause overfilling of the tray with the corresponding risk of contamination and even damage or blockages in the equipment.
⚠	**CAUTION:** For an optimum performance of the analyzer, it is recommended to file the samples when there is a maximum of 200 samples in the Q**Manager**.
⚠	**CAUTION:** Do not force the trays to move manually, to remove the tray in the back, always press the **Move Trays** () button.
⚠	**CAUTION:** If the program displays a temperature outside the normal range, first ensure that the environmental conditions are as specified and, if so, contact the Technical Service.
⚠	**CAUTION:** If the program displays a pressure level outside tolerated margins, check that the connectors of the affected bottle are correctly attached and that the cap is tight. Once these have been checked, if the indicator still displays as red, contact authorised Technical Service.
⚠	**CAUTION:** Before emptying the Waste Bottles, check that the drain tube is correctly connected to the analyzer and that it is tightly fitted to the mouth of the drain. Also check that the total capacity of the drain is sufficient to transfer all the liquid contained in both bottles.
⚠	**CAUTION:** If there is no connection to the drain or it is no longer being used, replace the safety cap.
⚠	**CAUTION:** The Products Desk should always work with one Black Tray and one Grey Tray. Do not insert two trays of the same colour into the analyzer.

⚠	**CAUTION:** The Probes are a key component for the correct functioning of the analyzer, as well as one of the most delicate parts. Do not replace the Samples Robot Probe if it is not strictly necessary.
⚠	**CAUTION:** The instrument performs a Final Wash of the fluid circuit automatically when turning it off through the **Start/Stop** button to prevent the formation of precipitates which might disrupt normal liquid dispensing. Make sure that the analyzer completes it successfully.
⚠	**CAUTION:** Do not close the remote connection or manipulate the analyzer during the Technical Service intervention, unless otherwise indicated by the service personnel.

2.2.7 Products Notices

⚠	**DANGER:** Products may be hazardous. Handle them in accordance with the manufacturer's instructions.
⚠	**DANGER:** The presence of foam, bubbles or drops on the walls of the containers may cause alterations in products dispensing, leading to subsequent errors in the results.
⚠	**WARNING:** If the product requires magnetic stirring, place the Q**stirrer** in the corresponding product vial and load the vial in one of the four stirring positions (positions 9, 11, 13 and 15) of the Black Tray. If the product is loaded in any of the non-stirred positions, the system will advise the Operator that the stirrer should be removed.
⚠	**WARNING:** The Q**Executor** window always displays the same graph for the Trays Content. When replacing a product, the Operator must ensure that the product is placed in the correct position, checking that the number of the tray position indicated on the screen is the same as the number of the position in the tray.
⚠	**CAUTION:** Before inserting products in the Q**Next**, remove container caps.
⚠	**CAUTION:** For the proper functioning of the equipment, it is important that the barcode labels are well stuck to the containers, have nothing written on them, are not defective and that the direction of the bars is as shown in Figure 4.19.
⚠	**CAUTION:** For correct level detection, the minimum volume is 250 µL or 5% of the total volume for vials, and 250 µL for microtubes .
⚠	**CAUTION:** The use of containers other than those specified may cause damage to the analyzer.

CAUTION: Refilling of products is a risky practice that should be avoided**.**

CAUTION: The program will display alerts when the positions selected on the Product Layout do not comply with the specifications for the selected product or contradict analyzer configuration, *i.e.*:

( ): Diluent not in position no. 1.

( ): Stirred product placed in a non-stirred position. This product will not be stirred.

( ): This reagent needs the cleaning agent, which is not present.

( ): Product lot that has expired (when the option **Check Products Expiry Date** is disabled).

( ): Product vial has exceeded its on board stability (when the option **Check Products On Board Stability** is disabled).

( ): The product lot X cannot be automatically registered. Review lot name, format and barcode.

( ): Product that has been cancelled because the product lot has expired (when the option **Check Products Expiry Date** is enabled).

( ): Product that has been cancelled because the product vial has exceeded its on board stability (when the option **Check Products On Board Stability** is enabled).

CAUTION: If during the automatic products identification the label at the back of the Products Desk is read, the position is considered to be empty, regardless of a previous manual identification.

CAUTION: If during the automatic products identification the analyzer cannot read any barcode in a position (neither the product's label nor the label at the back of the Products Desk) and there is a product with manual ID in that position, manual identification will prevail.

Therefore, the Operator must ensure that the product's barcode is correctly faced in the Products Tray groove.

CAUTION: Manual identification of products is a risky practice that should be avoided. Repeated checks of manually identified products are strongly recomended.

CAUTION: To avoid condensation in the Products Desk, do not leave the Upper Door of Q**Next** opened for long periods of time when the instrument is turned on. It is recommended to have the products already prepared and open the Upper Door the minimum possible time, just to load and unload products.

2.2.8 Sample Notices

DANGER: The presence of foam, bubbles or drops on the walls of the sample tube can cause alterations in the dispensing of the sample, and subsequent errors in the results.

CAUTION: The use of sample tubes other than those specified may cause deterioration to the equipment. Before using any tubes other than those specified, please check with your local service representative.

CAUTION: For the proper functioning of the equipment, it is important that the barcode labels are well stuck to the sample tubes, have nothing written on them, are not defective and that the direction of the bars is as shown in Figure 4.19.

CAUTION: For the proper functioning of the equipment, it is important to place the sample tube in the Q**sample holder** in such a way that the holder's wings do not cover the corresponding barcode.

CAUTION: Do not load sample tubes in the equipment without their corresponding Q**sample holder**.

CAUTION: For the level sensor to work correctly, the level of sample in the capped tubes must leave a minimum space of 5 mm under the cap and the level of the sample should be at least 60 mm below this.

CAUTION: The use of recapped tubes may alter the behaviour of the cap piercing system. Avoid using this kind of tube in the analyzer.

CAUTION: For correct level detection, the minimum volume of sample should be 250 µL in conical microtubes.

CAUTION: Do not use 1.5 mL microtubes with volumes of over 1.0 mL since this may cause splashes in the Samples Entry Area.

CAUTION: Do not touch or remove the sample tubes and/or the Q**sample holders** which are being controlled by the system until they output automatically from the Recirculation Area.

⚠	**CAUTION:** If **Cap Piercing** option is disabled, remove container caps before inserting samples in the Q**Next**.
⚠	**CAUTION:** The use of samples which are excessively hemolysed, icteric, lipemic, turbid or with blood or fibrin clots may lead to wrong results. Do not use this kind of samples in the analyzer.
⚠	**CAUTION:** To obtain reliable and high-quality results, do not leave samples inside the instrument for long periods of time as it may not be suitable for its required stability.
⚠	**CAUTION:** To obtain reliable and high-quality results, do not use samples that have not been properly stored.
⚠	**CAUTION:** Before placing a sample tube in a Q**sample holder** for processing with the analyzer, please check its Instructions for Use (see Section 4.3.2).
⚠	**CAUTION:** Manual identification of samples is a risky practice that should be avoided. Repeated checks of manually identified samples are strongly recomended.
⚠	**CAUTION:** Do not touch, remove or change the position of the samples and/or their Q**sample holders** until the analyzer releases them automatically from the Recirculation Area.
⚠	**CAUTION:** For maximum safety when identifying an **Unknown Sample**, do not remove the sample tube from the Q**sample holder** until identification of the Q**sample holder** and the sample has been completed.

2.2.9 Maintenance Notices

⚠	**DANGER:** During cleaning and/or decontamination, the Operator should wear protective gear (gloves, lab coat, laboratory goggles, etc.).
⚠	**DANGER:** Isopropylic alcohol is highly flammable and irritating.
⚠	**DANGER:** Any part of the equipment which might be in contact with samples of blood, serum or any other biological liquid should be treated as potentially-contaminated.
⚠	**DANGER:** The sodium hypochlorite solution is corrosive and can irritate the skin and the eyes. It is toxic if inhaled, absorbed or ingested.

⚠	**WARNING:** Before cleaning and decontaminating, remove all samples, products and Q**cells** from inside the equipment.
⚠	**WARNING:** The Upper Door of the analyzer should be cleaned with soft, non-abrasive products to prevent scratching of the blue dome when cleaning.
⚠	**WARNING:** Take care to ensure that cleaning/decontaminating solutions do not enter the openings of the equipment.
⚠	**WARNING:** Do not dismantle the equipment under any circumstances. If liquid had leaked inside the analyzer unplug it from the power. In this case, cleaning should be performed by a Supervisor. Call the authorised Technical Service closest to you.
⚠	**WARNING:** Do not spray the screen directly with cleansers since they may filter inside, causing damage and danger of electric shock to the Operator.
⚠	**WARNING:** It is important to avoid cleaning the touch screen with caustic chemical agents.
⚠	**WARNING:** Take care that cleaning/decontaminating solution does not enter the openings of the reader covers, since it could damage the reader.
⚠	**WARNING:** Before using any cleaning or decontaminating product other than those recommended by the manufacturer, the Supervisor should check with the manufacturer that the proposed products will not damage the equipment.
⚠	**CAUTION:** Before using any means of cleaning or decontamination other than those recommended by the manufacturer, the Supervisor should check with the manufacturer that the methods proposed will not damage the equipment.
⚠	**CAUTION:** Due to the fragile nature of the removable parts (bottles, bottle caps, Q**waste tray**), special care should be taken when cleaning and/or decontaminating these parts.
⚠	**CAUTION:** In case of accidental spillage of a potentially-contaminating liquid or small spots of residue and incrustations, a towelette soaked in 0.5% vol. solution of sodium hypoclorite can be used to disinfect and clean the Products Trays and Desk.
⚠	**CAUTION:** In case of accidental spillage of a potentially-contaminating liquid or small spots of residue and incrustations, a towelette soaked in 0.5% vol.solution of sodium hypoclorite can be used to disinfect and clean the Samples Entry Area and the Q**sample holders**.

⚠	**CAUTION:** In case of accidental spillage of sample in the Samples Desk, clean the desk itself and the Q**sample holders** involved, as described in Section 16.4.1.4.
⚠	**CAUTION:** For the proper operation of the Q**Diagnostic** procedure, it is very important to place the required material in the indicated positions and perform all necessary actions, otherwise, its execution could fail.
⚠	**CAUTION:** Before the Qualified Personnel starts to work, remove the Q**sample holders** with the samples tubes from the Samples Entry Area and the products from the Products Trays and run the **Decontamination** process.

2.2.10 Disposal Notices

⚠	**DANGER:** This instrument should only be dismantled by a Qualified Personnel.
⚠	**DANGER:** The Q**waste tray** with the Q**cells** cuvettes used by the analyzer should be disposed of in accordance with current local legislation.
⚠	**WARNING:** The contents of the Waste Bottles should be eliminated in accordance with current local legislation.
⚠	**WARNING:** The analyzer contains electronics. Electronics can contain hazardous materials. Dispose of all electronics in accordance with local, state, and federal regulations.
⚠	**WARNING:** The analyzer must be completely cleaned and decontaminated prior to transport, storage and/or disposal.
⚠	**CAUTION:** Empty Q**cells** cuvettes rack should be discarded in accordance with current local regulations.
⚠	**CAUTION:** Full Q**waste tray** should be disposed of in accordance with current local regulations on infectious laboratory Waste.
⚠	**CAUTION:** The samples and products used in the analyzer should be eliminated in accordance with current local legislation.
⚠	**CAUTION:** Once the instrument has reached the end of its useful life, bear in mind that all current local legislation must be complied during disposal.

2.2.11 Warranty Notices

CAUTION: The use of the Q**Next** for purposes other than specified by the manufacturer shall automatically invalidate any type of warranty.

CAUTION: Repairs should be performed only by staff specifically authorised by GRIFOLS.

2.3 Equipment Labelling

The equipment is marked with the following labels:

(1) Biohazard of the Probes and the Samples Desk.
(2) Danger of injury with the Probes.
(3) Moving part.
(4) Bottle identification.
(5) Biohazard from the Q**waste tray.**
(6) Biohazard from the connection for the automatic emptying of Waste Bottles.
(7) Identification label and Basic Technical Specifications of the equipment.
(8) Switch and connection to the electricity supply.
(9) Electrical ratings label.
(10) Electrostatic Discharge (ESD).
(11) Connection to the Laboratory Information System (LIS).
(12) Laser product label.

(1) Label of biohazard with the Probes and the Samples Desk and (2) Label of danger of injury with the Probes

These labels are located behind the Samples Arm, at the front of the Samples Entry Area and at the two sides of the Products Arm head to warn of biohazard and danger of injury by the Probes.

(3) Moving Part Label

For the Products Arm, it is located on top of the arms head, and for the Samples Arm, it is located at the right side of the arm, on the inner part of the cover. It warns of the movement of these parts. For safety reasons, the arm movement requires the Upper Door to be closed.

(4) Bottle Identification Label

These labels are located at the front and on the cap of the Wash Solution and Waste Solution Bottles. They are also displayed at the bottom of the Q**Next**, and are visible when the Lower Door is opened. Their purpose is to identify the content and location of each bottle.

Label on the bottle of the diluted **System Solution A**.

Label on the bottle of the diluted **System Solution B**.

Label identifying each of the two Waste Bottles that the analyzer contains.

Biohazard label on the Waste Bottles. Identifies their location and warns that the contents pose a biohazard.

The red cap from these bottles should not be used with the other bottles, **A** and **B** of diluted **System Solutions**.

(5) Biohazard label from the Q*waste tray*

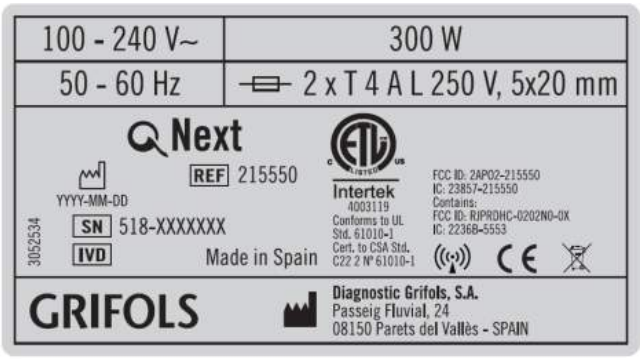
Located on the tab of the Q**waste tray**, it identifies and warns of the biohazard posed by the Q**cells** cuvettes it contains.

(6) Biohazard from the connection for the automatic emptying of Waste Bottles

Label located at the bottom of the right-hand side of the analyzer, it warns of the biohazard posed by the connection for optional, automatic emptying of Waste Bottles.

(7) Identification label and Basic Technical Specifications of the equipment

Label located on the left-hand side of the Waste and Wash Solutions Desk. It contains technical information about the equipment (voltage, frequency, strength, fuses), and the model, Serial Number (S/N), manufacturing date, name and address of the manufacturer and required information.



The following symbols are used:

Date of manufacture

Serial Number

In vitro diagnostic medical device

The Q**Next** meets the requirements of Directives 2014/53/EU RED and 98/79/EC.

The equipment includes Radiofrequency (RF) Emitters and equipment located nearby may suffer interference. These emitters are used to identify the Q**cell** cuvettes racks and the Q**sample holders**. See Section 3.1.

Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on Waste Electrical and Electronic Equipment (WEEE). See Section 19.

DataMatrix, which contains the following information:

(01) GTIN number

(11) Manufacturing year

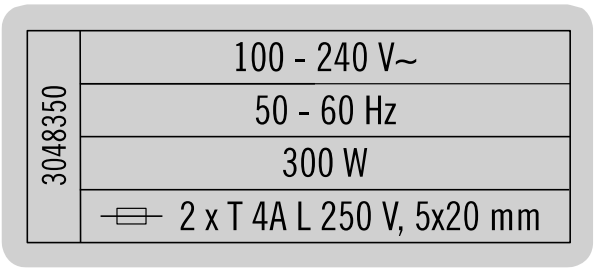
(21) Serial Number of the instrument

(8) Switch and Electricity supply connection label

Located at the bottom on the left-hand side of the back of the analyzer, the label indicates the position of the main switch and the connector for the mains cable.

(9) Electrical ratings label

Located at the bottom on the left-hand side of the back of the analyzer, next to the main switch, the label provides information about electrical requirements.



(9) Electrostatic Discharge (ESD) label

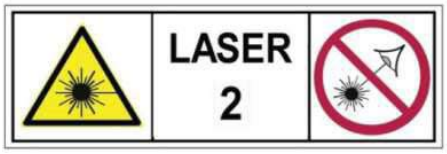
Located next to the connections for the computer, this warns of the risk of electrostatic discharge which might damage the analyzer and indicates that the pins of these connections should not be touched with the hand to avoid accidental discharges.

(10) Label for the Connection to the Laboratory Information System (LIS)

Located at the back of the analyzer, this label identifies the connector for the computer connection cable to the Laboratory Information System (LIS).

(11) Laser product label

Located in the Barcode Reader, these labels warn of the danger posed by the barcode laser. They also contain the information required by Standard EN 60825-1: "Laser product safety. Part 1: Equipment classification, requirements and safety guide."



2.4 Markings on Accessories and Consumables

(1) Q**cells** cuvettes racks box identification label.

(2) Q**cells** cuvettes rack identification label.

(3) and (4) Identification labels on the Q**sample holders** box.

(5) and (6) Identification labels on the Q**sample holders red** box.

(7) Q**stirrers** bag identification label.

(8) Q**waste tray** box identification label.

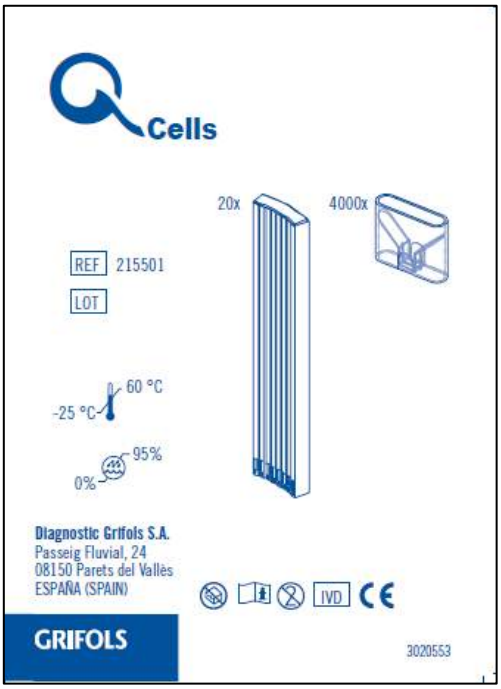
(9) **System Solutions A** and **B** identification label.

(10) and (11) Q**vials** box identification label.

(1) Qcells cuvettes racks box identification label

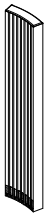
Label identifying the box containing the Q**cells** cuvettes racks. It contains information on the product (reference, lot, contents and manufacturer's identification) and on environmental conditions, storage and transport.

Each box of Q**cells** cuvettes contains 20 racks of 200 Q**cells** cuvettes each, *i.e.* a total of 4000 Q**cells** cuvettes.



The symbols used on this label or on the packaging that have not been described above are listed below:

Information for Operators:

REF	Catalogue number	LOT	Batch code
	Number of Q**cells** cuvettes racks		Number of Q**cells** cuvettes
	Do not use if package is damaged		Consult Instructions for Use of Q**Next**
	Do not re-use		Recyclable material

Environmental conditions:

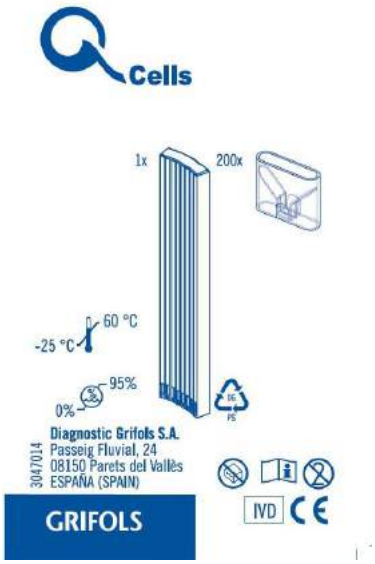
	Temperature limitation		Humidity limitation

Storage and transport conditions:

	This way up
	Keep dry

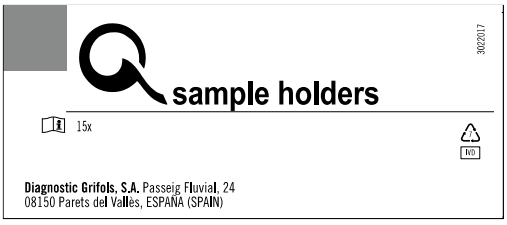
(2) Qcells cuvettes rack identification label

Label located on all Q**cells** cuvettes racks. Contains information on the product (content, manufacturer's identification, etc.) and environmental and storage conditions. Each rack contains 200 Q**cells** cuvettes.

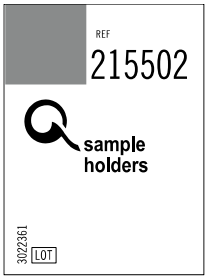


(3) and (4) Identification labels on the Qsample holders box

Each box of Q**sample holders** has two labels, one on the top and one on the side. The labels contain product information (reference, content, manufacturer's identification, lot) and information for the Operator. Each box contains 15 units of Q**sample holders**.



Top label

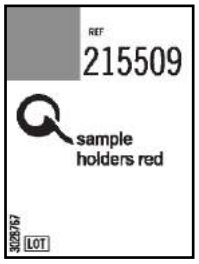


Side label

(5) and (6) Identification labels on the Q*sample holders red* box

The box of Q**sample holders red** has two labels, one on the top and one on the side. The labels contain product information (reference, content, manufacturer's identification, lot) and information for the Operator. Each box contains 6 units of Q**sample holders red**.

Top label



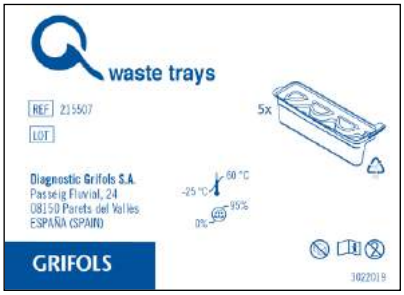
Side label

(7) Q*stirrers* bag identification label

Identification label on bags of Q**stirrers**, magnetic bars used to stir the reagents in the Q**Next**. The label contains product information (reference, content and manufacturer's identification) and important information for the Operator. Each bag contains 5 units of Q**stirrers**.

(8) Qwaste tray box identification label

Identification label on boxes of Q**waste trays**, used to store Q**cells** cuvettes discarded by the Q**Next**. It contains product information (reference, lot, content and manufacturer's identification) and important information for the Operator. Each bag contains 5 units of Q**waste trays**.



(9) System Solutions A and B identification label

Identification label on **System Solutions A** and **B**. It contains information on the product (reference, lot, content and manufacturer's identification) and on the environmental conditions for storage and transport.

The manufacturer advises that the Instructions for Use of these products should be studied prior to use.

(10) and (11) Qvials box identification label

Each box of Q**vials** has two labels: One at the top and the other on the side. These contain product information (reference, content, manufacturer's identification) and information for the Operator. Each box contains 6 units of Q**vials**.

Top label

Side label

GRIFOLS

3 Analyzer Specifications

3.1 Environmental Requirements and Measurements

Table 3.1. Technical Specifications

MODEL	**QNEXT**	
SUPPLY	**Voltage:**	100-240 V ~
	Frequency:	50-60 Hz
	Maximum input power:	300 W
	Input power on standby:	30 VA
	Fuses:	2x T4A L 250 V, 5 x 20 mm
PROTECTION AGAINST ELECTRIC SHOCK	**Class:**	I
INSTALLATION CATEGORY	Overload category II (local levels, instruments, portable equipment, etc.)	
RADIOFREQUENCY TRANSMITTERS FOR QSAMPLE HOLDERS IDENTIFICATION	**Reference:**	LF MultiTag RW Module
	Type:	Short-range device Inductive applications
	Units installed:	2
	Operating frequency:	125 KHz
	Transmitter field strength:	-20.4 dBμA/m or 0.1 μA/m (@ 10 m) Note: Both modules active
	Frequency range of the modulation band:	124 kHz – 126 kHz Note: Both modules active

RADIOFREQUENCY TRANSMITTERS FOR QCELLS CUVETTES RACKS IDENTIFICATION	**Reference:**		Multi-ISO RFID Reader
	Type:		Short-range device Inductive applications
	Units installed:		1
	Operating frequency:		13.56 MHz
	Transmitter field strength:		6.6 dBμA/m or 2.1 μA/m (@10 m)
	Frequency range of the modulation band:		13.553 MHz - 13.567 MHz
DIMENSIONS (cm)	59 (height) x 73 (depth) x 94 (width)		
WEIGHT (kg)	Approximately 80 kg		
POLLUTION DEGREE	2		
OPERATING CONDITIONS	Indoor use		
	Temperature:		15 ºC to 28 ºC
	Relative humidity:		15% - 80%
	Maximum altitude:		2500 m
	Power supply maximum voltage fluctuations:		±10% of nominal voltage
TRANSPORT AND STORAGE CONDITIONS	**Winter ambient:**	**Maximum time:**	72 h
		Maximum temperature:	-29 ºC
		Relative humidity:	Uncontrolled
	Tropical ambient:	**Maximum time:**	72 h
		Maximum	38 ºC

		temperature:	
		Relative humidity:	85 ± 5%
	Desert (dry climate):	**Maximum time:**	6 h
		Maximum temperature:	60 ºC
		Relative humidity:	30 ± 5%

WARNING: Do not use the instrument in environment conditions outside the ones specified in this section.

WARNING: Although the recommended relative humidity in the room where the equipment is installed should exceed 30%, the unit can operate normally in lower relative humidity conditions. However, in extremely dry environments, and rooms with floors covered with synthetic material, high-level electrostatic discharges may occur, which can damage the equipment.

3.2 Functional Specifications

Table 3.2. Functional Specifications

Sample load capacity	60 tubes simultaneously
Sample load system	Individual Q**sample holders**
Continuous sample load	Yes
Urgent sample management	Yes, simply by positioning the Q**sample holder** with the sample in front of the Samples Entry Area next to the Recirculation Area. There is also an option for entering the STAT samples as prioritized so that they are pipetted before all the other samples in the Samples Recirculation Area (see Section 6.1)
Sample containers	• Generally nonactivating plastic tubes (such as polypropylene) or silicon-coated glass tubes

	measuring 10 mm ≤ Ø ≤ 13.5 mm diameter and 47 mm ≤ h ≤ 75 mm height. • Microtubes of 1.5 and 2.0 mL.
Sample tube cap piercing system	Yes. Sample tubes with rubber cap and safety hood. (Type of tube: Vacutainer™, Vacuette™, Monovette™ and Venosafe™, specified in Section 4.3.2.1)
Type of samples	Citrated human plasma
Positioning of samples	Continuous and random
Samples identification	• Automatic, with Barcode Reader. • Manual, with position assignment.
Positive sample identification	Yes
Minimum volume for samples detection	250 µL in conical microtubes
Samples Dead Volume	200 µL in conical microtubes
Sample dilution and pre-dilution	Yes. Direct to the Q**cells** cuvettes or with serial dilutions in several consecutive Q**cells** cuvettes
Products positions	30 positions (16 vials + 14 tubes/microtubes)
Product loading system	With 2 removable trays with 15 positions each
Product vials	Vials with diameters between 16 and 35 mm and heights between 35 and 65 mm
Products tubes and microtubes	• Tubes measuring 10 mm ≤ Ø ≤ 13.5 mm diameter and 47 mm ≤ h ≤ 75 mm height. • Microtubes of 1.5 and 2.0 mL.
Products stirring	Yes, in 4 fixed positions of the black Products Tray: 9, 11, 13 and 15

Products conservation temperature (room temperature of 18-25 ºC)	15 ± 3 ºC
Products identification	• Automatic, with Barcode Reader. • Manual, through position identification.
Positive products identification	Yes
Bring to room temperature products during dispensing	Yes
Minimum volume for products detection	• Product vials: 5% of vial volume, with a minimum of 250 µL. • Conical microtubes: 250 µL.
Type of barcode	Code 2 of 5 interleaved, Code 3 of 9, Codabar and Code 128
Reaction container	Individual Q**cells** cuvettes
Minimum volume for reaction	150 µL
Maximum volume of reaction	500 µL
Cuvettes load capacity	400 Q**cells** cuvettes
Cuvettes load system	2 racks with 200 Q**cells** cuvettes each
Continuous cuvette loading	Yes
Incubation positions	100-position, random-access carrousel
Incubation temperature (instrument at room temperature of 18-25 ºC)	37 ± 2 ºC
Reading system	Absorbance reading through photodetector
Reading channels	8 separate, random-access

Reader temperature (instrument at room temperature of 18-25 ºC)	37 ± 2 ºC
Reading type	Bichromatic
Wavelength	Selectable, 405 nm and/or 620 nm
Maximum limit of optical density	Equivalent to 3000 mE (3.0 OD) for an optical path of 4 mm
Washing solutions	**System Solution A** for internal washing of the Probes and Priming of the fluid circuit (*e.g.* for initializing) **System Solution B** for external washing of the Probes and Final Wash of the fluid circuit (*e.g.* when shutting down)
Type of wash	Programmable number of cycles
Bottles	1 bottle for diluted **System Solution A**, 1 bottle for diluted **System Solution B**, 2 bottles for Waste Solutions
Bottle capacity	4 litres (each)
Bottle weight	< 5 kg
Bottle control	Volume control by weight
Automatic draining of waste liquids	Yes. To laboratory sink
Diluter volume	1000 µL, one for samples and another for reagents
Probe aspiration and dispensation capacity	• Sample Arm Probe without cap-piercing: 10-210 µL. • Sample Arm Probe with cap-piercing: 10-160 µL. • Product Arm Probe: 25-250 µL.

Level detection	Yes, in both Probes
Correct aspiration detection	Yes, in both Probes. Automatic and real-time, with detection of air bubbles and obstructions
Dispensation accuracy	Samples and Products Arms: • Precision: - For volumes ≥ 50 µL: ≤ 5%. - For volumes < 50 µL: ≤ 10%. • Accuracy: ≤ 10%.
Total speed	~200 PT/h
Useful life	7 years

3.3 Software Specifications

The Q**Next** works using a system of two programs: The Q**Manager** which manages the data and the Q**Executor** which handles operation itself. When a laboratory has a single Q**Next**, both programs start up simultaneously when the **Start/Stop** button is pressed (see Section 4.1.2) and behave as if they were two screens of the same program.

The system comprises two simple communicating interfaces of advanced and intuitive design, where the Operator accesses by means of a touch screen.

The most important performances and characteristics offered by the complete system are described below:

- User-friendly interface.
- Simple and open programming of tests and products.
- Programming of coagulometric, chromogenic and immunoturbidimetric tests.
- Programming of tests with parallelism.
- Association of tests into profiles and simultaneous programming of an entire profile to a sample.
- Automatic rerun of tests using an alternative pre-dilution of the sample and using an extended acquisition time.
- Reflex programming, *i.e.* tests depending on the results of tests performed previously.
- Programming of **Quality Control Policies** (Levey-Jennings, multiple statistical rules).
- Operator access control.

- Orders management via a **Worksheet**.
- Possibility of connecting several instruments forming a net with one management.
- Tests calibration by several dilutions of a single Calibrator or with several Independent Calibrators that have different levels.
- Calibration of tests concurrent with sample analysis.
- Management of Calibration Curves, not only by test or Q Analyzer, but also by products' lots of the test.
- Product lot management, allowing Operators to work with different products' lots loaded simultaneously in the analyzer, through lot-dependent Calibration Curves.
- Monitoring of products on board stability on Q Analyzers.
- Obtaining, standardization, revision and print-out of results.
- Export of results.
- Total traceability of results: Operators, analyzer, products' lots, reader, curve file, etc.
- Increased tolerance to the presence of substances that produce optical interference in the sample (*e.g.* haemoglobin, bilirubin and triglycerides) for tests read at 620 nm or at 405 nm + 620 nm (bi-chromatic tests).
- Availability of warnings in the reading algorithms which help to detect reading abnormalities and/or abnormalities in results (problems of linearity, turbidity, weak reactions, etc.).
- Display of status and autonomy of analyzer (Wash Solutions, Q**cells** cuvettes, products, etc.) and requests for samples.
- Colour-coding system which improves and facilitates the comprehension and analysis of data.
- Two-way interface with ASTM protocol (LIS-compatible).
- Remote connection for support, which allows the Technical Service operating at distance (Team Viewer QuickSupport).

3.4 Regulatory

The Q**Next** conforms to the following requirements:

- **Directive 98/79/EC** on *in vitro* diagnostic medical devices.
- **Directive 2012/19/EU** of the European Parliament and of the Council of 4 July 2012 on Waste Electrical and Electronic Equipment (WEEE).
- **Directive 2011/65/EU** of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.
- **Directive 2009/125/EC** of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products.

- **Directive 2014/53/EU RED** of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC.
- This device complies with **part 15 of the FCC Rules**. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

⚠ **CAUTION:** The changes or modifications in the Radiofrequency Emitters not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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4 Description of the Analyzer

4.1 General Description of the Analyzer

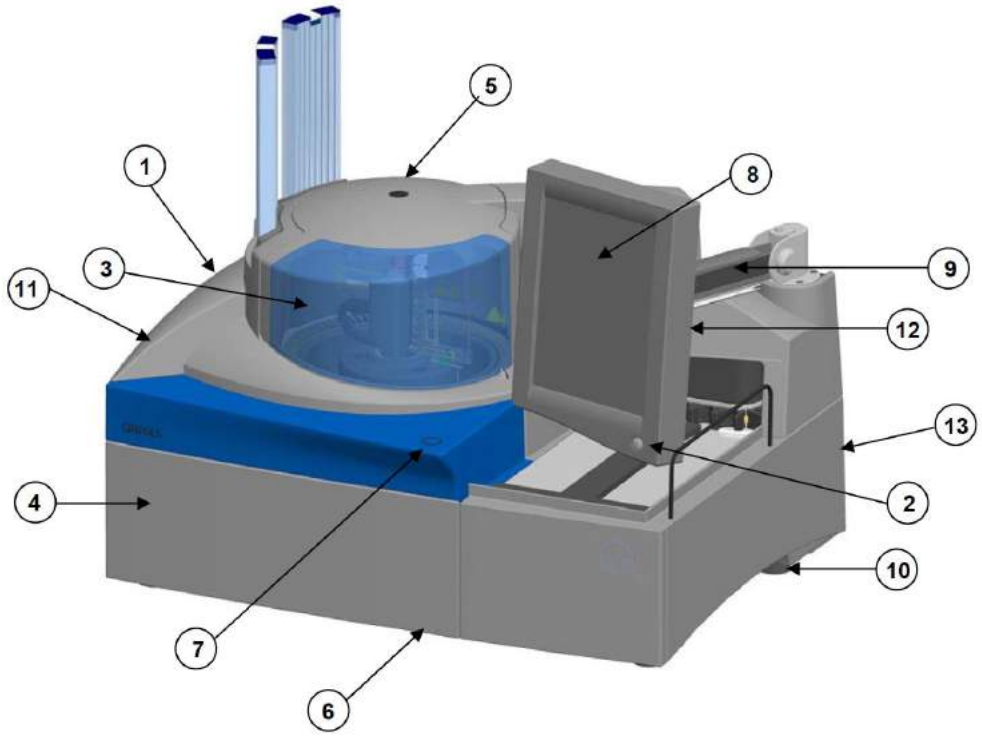

Figure 4.1. General View of the QNext

(1) On/Off switch and mains cable connector.

(2) Start/Stop button.

(3) Upper Door of the analyzer, for accessing the Working Area (Products Arm, Products Trays, Incubation Area and Reading Area).

(4) Lower Door of the analyzer for accessing the Waste and Wash Solutions Desk.

(5) Manual device for opening the Upper Door.

(6) Manual device for opening the Lower Door.

(7) External Qsample holders Identification Area.

(8) Touch screen.

(9) Articulated arm of the touch screen.

(10) Connection for automatic emptying of Waste Bottles.

(11) Ventilation window.

(12) USB connection.

(13) External connectors of the computer.

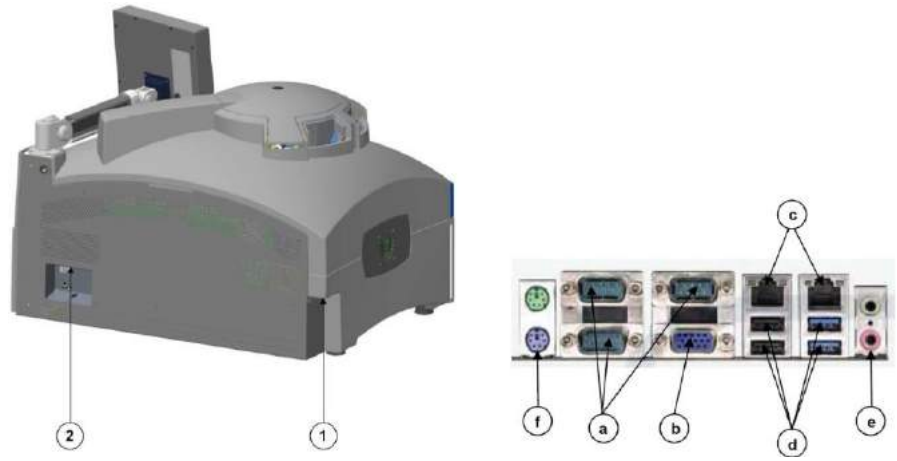

Figure 4.2. Rear Connectors

(1) On/Off switch and mains cable connector.

(2) External connectors of the computer:

   a. Three Serial Port (COM) connectors.

   b. One VGA connector.

   c. Two ethernet (LAN) connectors.

   d. Four USB connectors: Left USB 2.0 and right USB 3.0.

   e. Speaker (SPK) and microphone (MIC) connectors.

   f. PS/2 ports.

4.1.1 On/Off Switch and Mains Cable Connector

The On/Off switch and the mains cable connector are located at the back and to the left (Figure 4.1 and Figure 4.2, no. 1) of the equipment. Once the mains cable has been connected, the On/Off switch controls de supply of electricity to the analyzer. It has two positions:

1. |: On.
2. **O**: Off.

CAUTION: To extend the life of the analyzer, the manufacturer recommends turning it off completely with the On/Off switch when it is not used for more than 8 hours.

4.1.2 Start/Stop Button

The **Start/Stop** button is located on the front of the analyzer, on the screen (Figure 4.1, no. 2) and starts the application or stops it. When the analyzer is on, the indicator light on the **Start/Stop** button is green.

4.1.3 Upper Door

The Q**Next** has two doors at the front of the equipment. The Upper Door (Figure 4.1, no. 3) is opened through the **Open Upper Door (** ) option of the main menu in the Q**Executor** window.

If the analyzer does not respond, or is turned off, there is a system for opening it manually. For more information, please see Section 4.1.5.

The Upper Door leads to the analyzer Working Area: Products Arm, Products Desk, Incubation Area and Reading Area.

4.1.4 Lower Door

The Lower Door, located on the front and to the bottom of the equipment (Figure 4.1, no. 4) is opened through the **Open Lower Door (** ) option of the main menu of the Q**Executor** window.

If the analyzer does not respond, or is turned off, there is a system for opening it manually. For more information, please see Section 4.1.5.

The Lower Door leads to the Waste and Wash Solutions Desk.

4.1.5 Manual Opening Devices

The devices for opening the Upper (Figure 4.1, no. 5) and Lower (Figure 4.1, no. 6) Doors allow the respective doors to be opened if the analyzer is turned off or the electronic system for opening them through the Q**Executor** window on the Q**Next** is not responding.

CAUTION: Manual opening systems should only be used in the situations described above and should not be used when the analyzer is operating normally.

Using the manual system may lead to a cancellation of current orders, loss of data and even unexpected operation of the analyzer. The manufacturer recommends re-starting the analyzer and notifying Technical Service if problems continue.

4.1.6 External QSample Holders Identification Area

To facilitate manual identification of the sample tubes, the analyzer has an External Q**sample holders** (Figure 4.1, no. 7) Identification Area with a radiofrequency reader. This reader links the identification of a Q**sample holder** to a specific manual identification of the sample (see Sections 15.6.2.3 and 15.6.2.4).

4.1.7 Touch Screen

The Q**Next** is supplied with a built-in PC and 15" LED screen with VGA resolution of 768 x 1024 pixels, with vertical orientation (portrait) and touch-sensitive (Figure 4.1, no. 8). The portrait orientation allows a larger number of samples to be displayed, like report formats. It has a USB connection.

4.2 Description of Equipment Parts

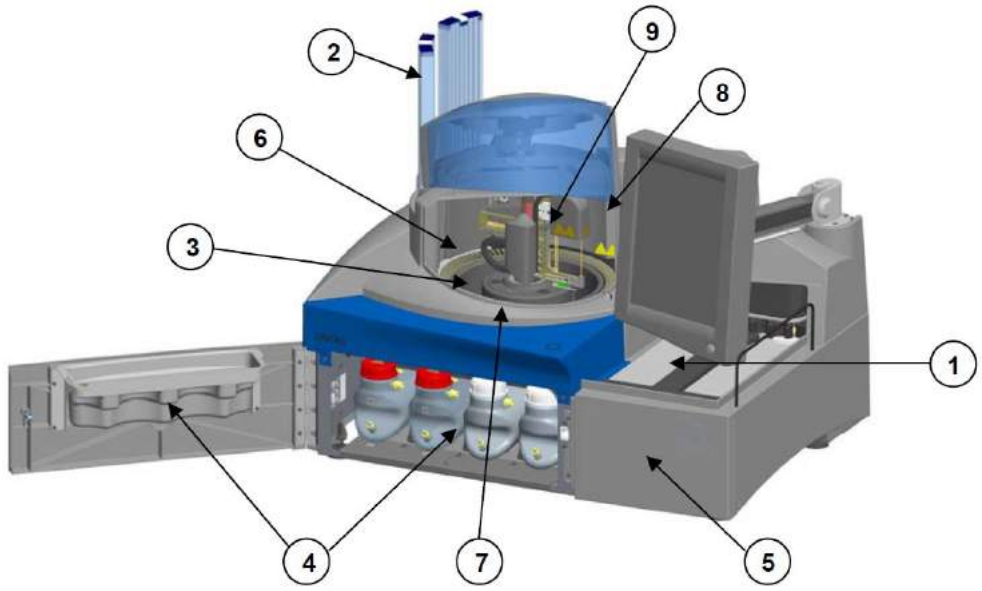

Figure 4.3. General View of the QNext with the Upper and Lower Doors Open

(1) Samples Desk.

(2) Qcells cuvettes racks Desk.

(3) Products Desk.

(4) Qwaste tray and Waste and Wash Solutions Desk.

(5) Fluids Area.

(6) Incubation Area.

(7) Reading Area.

(8) Samples Arm.

(9) Products Arm.

4.2.1 Samples Desk

The Samples Desk (Figure 4.3, no. 1) is the area of the Q**Next** which manages the sample tubes. That is to say, it is where the Operator inserts the samples in the analyzer and collects them once the workload associated with them has concluded.

The sample tubes are inserted in the analyzer using specially-designed holders, the Q**sample holders**, which have an internal radiofrequency identification system.

The Samples Desk has several parts, with different functions, for managing the sample tubes.

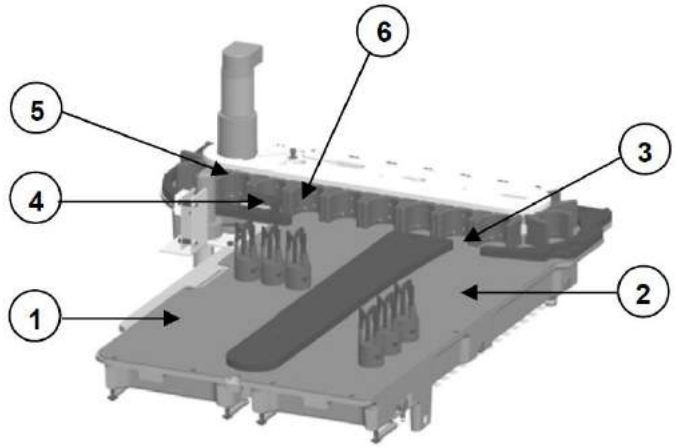

Figure 4.4. Samples Desk

(1) Samples Entry Area.

(2) Samples Delivery Area.

(3) Samples Recirculation Area.

(4) Internal Identification Area of Qsample holders.

(5) Position for identification, cap piercing and sample aspiration.

(6) Position for entering STAT samples.

A specific sample tube placed in the corresponding Q**sample holder** goes through the various positions of the Samples Desk until the results of the programmed requests are obtained, unless there are any repetitions or reflex pending. If the results of the tests are as expected, the Q**sample holder** is released through the Samples Delivery Area. Otherwise, if the test configuration specifies that, once the result is obtained, the determination should be repeated with a longer Reading Time, (see Section 9.2.1.1) or a new test needs to be tagged on (see Section 9.4), the Q**sample holder** with the sample tube remains in the Samples Recirculation Area (Figure 4.4, no. 3) and is moved again to the identification and aspiration position (Figure 4.4, no. 5). This occurs whenever the recirculation option is enabled (see Section 7.3.2).

When sample identification is manual, the analyzer manages the sample tube using the corresponding Q**sample holder** internal identification as it passes through the Internal Identification Area of Q**sample holders** (Figure 4.4, no. 4).

⚠ **CAUTION:** Do not place cards with magnetic strips or recording media on the Samples Entry and Delivery Area: They may be damaged.

4.2.1.1 Samples Entry Area

This is the part of the Samples Desk designed to store the Q**sample holders** with the sample tubes which, when inserted randomly by the Operator, wait to be processed by the Q**Next**. The analyzer drags the Q**sample holders** from any point in this area to the slots of the Recirculation Area.

To insert STAT samples, the Operator must place the Q**sample holder** with the urgent sample tube as close as possible to the Recirculation Area, *i.e.* putting it in front of any tube in the Samples Entry Area that is waiting to be processed. There is also an option for entering samples in a prioritized way so that they are pipetted before all the samples in the Samples Recirculation Area (see Section 6.1). There is a fixed position in the Samples Recirculation Area for entering these samples manually by the Operator (Figure 4.4, no. 6).

The Samples Entry Area can hold 60 units of Q**sample holders**.

⚠ **CAUTION:** Insert the samples carefully in the Samples Entry Area, trying not to knock over the sample tubes.

⚠ **CAUTION:** Do not insert or take the Q**sample holders** out of the recirculation chain.

4.2.1.2 Samples Delivery Area

This is the part of the Samples Desk where the Q**Next** releases Q**sample holders** with the sample tubes for which the workload has been completed. The Q**sample holders** will remain in this area until the Operator takes them out of the analyzer.

The Samples Delivery Area can hold 60 Q**sample holders**.

4.2.1.3 Samples Recirculation Area

This is the part of the Samples Desk with a recirculation chain with links which allow the Q**sample holders** to remain there from the time they enter the analyzer until they are released, once the workload associated with the sample has been completed.

The Samples Recirculation Area can hold 20 Q**sample holders**.

4.2.1.4 QSample Holders Internal Identification Area

The Q**sample holders** have a radiofrequency identification system in their internal structure which is unique and individual and can be read by the radiofrequency readers available in the analyzer's Samples Desk.

The Q**sample holders** internal Identification Area allows a specific Q**sample holder** to be identified and located and, indirectly, for the sample tube associated with it to be identified and located.

4.2.1.5 Sample Identification and Aspiration Position

The Q**sample holders** captured by the links on the recirculation chain are guided sequentially through the analyzer to the Identification position. At this point, the cap is pierced, the sample aspirated and the tub with barcode associated is read.

The Q**Next** also has a Q**sample holders** rotator, which allows the barcode on the sample tubes to be positioned correctly so that they can be read by the corresponding reader.

4.2.1.6 Position for Entering STAT Samples

This is the position at the Samples Recirculation Area for introducing the samples in a prioritized way (see Section 6.1). The Q**sample holder** with the sample must be manually introduced by the Operator.

4.2.2 QCells Cuvettes Desk

The main function of the Q**cells** cuvettes Desk (Figure 4.3, no. 2) is to supply the Q**cells** cuvettes to the system.

4.2.2.1 Location for QCells Cuvettes Racks

The Q**cells** cuvettes Desk has been designed to provide continuous cuvettes loading. To this end, the Q**Next** has 2 separate positions accessible to the Operator for inserting and storing up to 2 Q**cells** cuvettes racks.

The desk can hold a total of 400 Q**cells** cuvettes, distributed between 2 racks.

> ⚠ **CAUTION:** Avoid objects and dirt entering through the Q**cells** cuvettes loading position, since they may cause damage to the analyzer.
>
> It is recommended to always have a rack placed in each position.

4.2.2.2 QCells Cuvettes Loading System

The Q**cells** cuvettes loading system takes the Q**cells** cuvettes out of the rack individually. To do so, the Q**Next** has a carriage which moves from side to side, and a pusher which removes the Q**cell** cuvettes and inserts them into an Incubation position.

4.2.3 Products Desk

The Products Desk (Figure 4.3, no. 3) is the part of the Q**Next** which houses, refrigerates, identifies and manages the products required to perform the hemostasis tests.

There are several parts in the Products Desk, each with a different function:

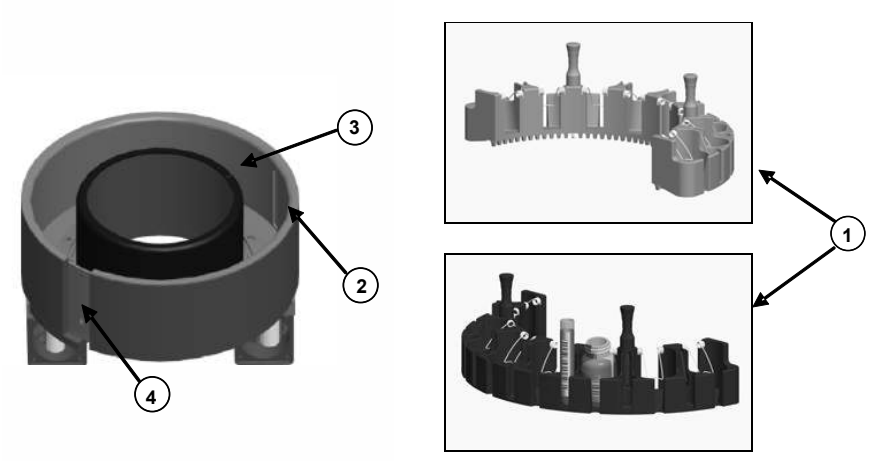

Figure 4.5. Products Desk

(1) Products Trays.
(2) Barcode Reader window.
(3) NR (No Reagent) label.
(4) Products Probe Washer.

4.2.3.1 Products Trays

The Q**Next** has two removable, semi-circular trays (Black and Grey, respectively) especially designed to house up to 15 product containers each, with different formats (vials, tubes and microtubes) without having to use adaptors. Each tray has 8 numbered positions for vials between 18 and 35 mm of diameter (except for positions 3, 5 and 7 of the Black Products Tray, which just admit vials between 16 and 30 mm of diameter, therefore, vials between 16 and 18 mm of diameter can only be placed in these positions) and 7 numbered positions for tubes or microtubes.

Positions 9, 11, 13 and 15 in the Black Tray have a stirring system consisting of a rotating magnetic field which stirs the Q**stirrer** magnetic bar inserted into the corresponding vial.

The trays have also been designed to minimize dead volume in vials.

The Products Desk has a traction system which allows the movement of the trays during the barcodes reading and their unloading from the analyzer.

4.2.3.2 Barcode Reader Window

The trays have a window so that the Barcode Reader can read the barcodes on the products vials labels.

The Operator must place the barcoded tubes and vials correctly centered in the trays windows so that they can be read by the Barcode Reader.

4.2.3.3 NR (No Reagent) Label

The Products Desk holds a label called NR (No Reagent) in front of the products Barcode Reading Area. This label speeds up products automatic identification in the vials positions of the trays that are empty.

4.2.3.4 Products Probe Washer

The Products Probe Washer, built into the Products Desk and connected to the Fluids Area, allows Products Probe to be washed internally and externally with the corresponding Wash Solutions: **System Solution A** and **System Solution B**.

4.2.4 QWaste Tray and Wash and Waste Solutions Desk

The Wash and Waste Solutions Desk is located at the bottom of the Q**Next** (Figure 4.3, no. 4).

This desk can hold 4 bottles and has a deposit for disposing of used Q**cells** cuvettes (the Q**waste tray**).

Diluted **System Solution A** and **System Solution B** are contained in 2 bottles (A and B), each with a 4 litres capacity. The Waste Solutions are stored in 2 Waste Bottles (W1 and W2) which offer a total capacity of 8 litres.

The desk has an automatic system for monitoring the volume of liquid in each of the bottles and, optionally, the Waste Desk has a system for emptying the Waste Bottles automatically (for more information, please see Section 7.2.5).

The analyzer also has a removable Q**waste tray** for storing the Q**cells** cuvettes discarded by the system and controlled by a counter.

The deposit holds a maximum of 400 discarded Q**cells** cuvettes.

4.2.5 Fluids Area

The Fluids Area has a system for the aspiration/dispensation of samples and products and for managing the Wash and Waste Solutions (Figure 4.3, no. 5).

The Fluid system also has two Probe Washers, one in the Products Desk and the other below the Samples Arm, for the internal and external washing of the respective Probes after they have been in contact with samples and/or products.

The solutions used by the two washers are contained in the A and B bottles, in the Waste and Wash Solutions Desk of the analyzer described in Section 4.2.4.

4.2.6 Incubation Area

The Incubation Area (Figure 4.3, no. 6) is formed by a crown-shaped rotating carrousel with a maximum capacity of 100 Q**cells** cuvettes, temperature controlled at 37 ºC. Its main function is to maintain the reaction mixture at 37 ºC. To do so, the Incubation Area previously warms the Q**cells** cuvettes which will shortly be used by the analyzer.

The Incubation Area has an optical sensor to locate the presence or absence of a Q**cell** in any position in the incubator.

Figure 4.6. Incubation Area

4.2.7 Reading Area

The Reading Area (Figure 4.3, no. 7) of the Q**Next** comprises a reader block with 8 reading channels, temperature controlled at 37 ºC and placed in an arch-shape around the Incubation Area. This design means that the Q**cells** cuvettes can be transferred from the Incubation Area to the Reading Area.

The design also allows the Q**cells** cuvettes to be disposed through the end of each channel and drop into the Q**waste tray** by a single movement of the arm.

For absorbance readings, the Reading Area has two LEDs (Light-Emitting Diodes), one which emits light at 405 nm and the other at 620 nm and a specifically-designed photometer for optical kinetic reading. This allows simultaneous reading at two wavelengths (see Section 9.2.1.1).

4.2.8 Samples Arm

The Samples Arm (Figure 4.3, no. 8) is a multi-task robotic arm which allows cap piercing of the samples tubes, aspiration, dispensation, dilution and homogenization of samples in the Q**cells** cuvettes.

There are different parts on the Samples Arm:

- Samples Probe.
- Tube Locker.
- Samples Probe Washer.

4.2.8.1 Samples Probe

The Samples Probe is the part of the Samples Arm connected to the Fluids Area that allows the aspiration/dispensation of accurate and precise volumes of samples. The Samples Probe has also been designed to allow the piercing of the sample tubes caps most frequently used in hemostasis laboratories (see Section 3.2).

The mechanism is connected to a level detection system and a correct aspiration detection system. This latter system detects incorrect sample aspirations due to the aspiration of air and/or an obstruction.

	NOTE: The Samples Probe could be replaced by the Operator in specific or emergency situations (see Section 7.2.6).
	DANGER: If, for any reason, you need to manipulate the Samples Probe, it should be treated as being potentially contaminated.

4.2.8.2 Tube Locker

Locker located on the Samples Arm designed to centre the sample tube correctly and facilitate the cap piercing by the Samples Probe.

4.2.8.3 Samples Probe Washer

Samples Probe Washer, connected to the Fluids Area for the internal and external washing of the Samples Probe with the corresponding diluted Wash Solutions **System Solution A** and **System Solution B**.

4.2.9 Products Arm

The Products Arm (Figure 4.3, no. 9) is a multi-task robotic arm which ensures aspiration and dispensation of products and later homogenization in the Q**cells** cuvettes. It is also the part which inserts the Q**cells** cuvettes in the Reading Area once all previous test steps have been finished to monitorize the reaction.

The Products Arm has the following parts:

- Products Probe.
- Q**cells** Cuvettes Pusher.

4.2.9.1 Products Probe

The Products Probe is the part on the Products Arm which is connected to the Fluids Area and allows the aspiration, thermostatisation and dispensing of accurate and precise volumes of products.

Like the Samples Probe, the mechanism is connected to a level detection system and a correct aspiration detection system.

DANGER: If, for any reason, you need to manipulate the Products Probe, it should be treated as being potentially contaminated.

4.2.9.2 QCells Cuvettes Pusher

The arm also has a Cuvettes Pusher at the base for transferring the Q**cells** cuvettes from the incubator to the Reading Area once all previous test steps have been finished, to monitorize the reaction. These are moved beyond the perimeter of the Products Area, facilitating the transfer of the Q**cells** cuvettes from the incubation positions to the respective channels in the Reading Area.

4.3 Accessories

Table 4.1. Accessories

CODE No.	NAME	DESCRIPTION	QUANTITY
215501	Q**cells**	Cuvettes	20 racks with 200 units (4000 units)
215502	Q**sample holders**	Adaptors to hold sample tubes	15

CODE No.	NAME	DESCRIPTION	QUANTITY
213679	**System Solution A**	Concentrated Wash solution (16x)	12
213678	**System Solution B**	Concentrated Wash solution (16x)	12
215506	Q**stirrers**	Magnetised bars	5
215507	Q**waste tray**	Disposable tray for used Q**cells** cuvettes	5
215508	Q**vials**	Products vials optimised for the analyzer	6
215509	Q**sample holders red**	Red adaptors to hold sample tubes	6
233590	**Samples Probe**	Replacement samples probe	1
233898	**Omnifit tool**	Tool to help replacing the Samples Probe	1

4.3.1 QCells Cuvettes

Q**cells** cuvettes are individual, separate and disposable cuvettes specifically designed for the Q**Next** to act as a reaction container and as intermediate containers during dilution.

Given the size of the Q**cells** cuvettes (24 x 20 x 6.4 mm) they can work with a range of volumes between 150 µL and 500 µL.

The cuvettes are made of inert plastic which does not activate coagulation.

Figure 4.7. QCell

The Q**cells** cuvettes come in disposable racks with 200 units (8 columns of 25 Q**cells**) which can be inserted directly into the Q**Next**.

Figure 4.8. QCells Cuvettes Rack

4.3.1.1 Instructions for Use

- Racks must be placed vertically in the loading position in the Q**cells** Desk (Figure 4.3, no. 2) with the label towards the outside.
- Before inserting the rack into the analyzer, check that the Q**cells** cuvettes are correctly positioned and aligned with the output window. Otherwise, invert the rack slightly to help the correct positioning of the Q**cells** cuvettes.
- To place them correctly in the analyzer, they will need to be lightly pushed downwards until they fit into place. Then, after the analyzer has identified the rack, the Q**Executor** window will display eight blue columns, confirming that it is well placed.
- Once all the Q**cells** cuvettes in the rack have been used, the Q**Executor** screen displays empty rack columns, thus indicating that the rack needs to be changed. If both Q**cells** cuvettes racks are used up, the Q**Executor** screen displays the rack columns in red. They are removed in the same way as they were inserted.

CAUTION: Taking the Q**cells** cuvettes rack out while it is in use may block the system. Never take a rack out unless you are sure that it is empty or the analyzer is on standby.

The Q**Executor** screen indicates the level of cuvettes in each Q**cells** cuvettes rack.

CAUTION: Empty Q**cells** cuvettes racks should be discarded in accordance with current local regulations.

NOTE: Under no circumstances should the blue top cover of the Q**cells** cuvettes rack be removed. Do not manipulate the flaps or attempt to reload any Q**cells** cuvettes rack along the output slot.

CAUTION: Avoid damaging the Q**cells** cuvettes or racks by dropping or knocking them and keep them away from sunlight and sources of heat. If the grooves become deformed or there are any changes to the general appearance of the Q**cells** cuvettes or racks, discard them and replace them with new ones, since they may cause major damage to the analyzer.

NOTE: The Qcells cuvettes racks could not be identified after replacement. If this is the case, retry the insertion process before contacting the Technical Service.

4.3.2 QSample Holders

Q**sample holders** are individual, separate adaptors, specifically designed for the Q**Next** to hold the sample tubes.

Figure 4.9. QSample Holder

Each Q**sample holder** is identified by an individual, unrepeatable code through a radiofrequency transmitter (TAG) and a device which carries the sample tubes from the Entry to the Delivery Areas of the **Samples Desk**, passing through the Recirculation Area.

The Q**sample holders** do not require any additional adapters to accomodate, centre and carry sample tubes with different formats.

The formats which have been validated with the Q**sample holders** to work with Q**Next** are described below.

4.3.2.1 Primary Extraction Sample Tubes with Cap

Since the Q**Next** has a cap piercing system, the tubes described below can be used directly in the analyzer with their respective Q**sample holder** without needing the cap to be removed.

Table 4.2. Primary Extraction Sample Tubes with Cap Allowed in the Analyzer

MANUFACTURER	MODEL	VOLUME (mL)	EXTERNAL DIAMETER (mm)	HEIGHT WITHOUT CAP (mm)
Becton Dickinson™	Vacutainer™ (*Hemogard* cap)	1.8	13	75
		2.7		
		4.5		
Terumo™	Venosafe™	1.8	13	75
		2.7		
		3.6		
Greiner Bio-one™	Vacuette™ *Sandwich*	1.0	13	75
		2.0		
		3.0		
		3.5		
Sarstedt™	Monovette™	1.4	8	66
		2.9	13	65
		3.0	11	66

4.3.2.2 Standard Tubes and Microtubes

The tubes which can be used directly in the analyzer with the Q**sample holders** without caps are described in the following table.

Table 4.3. Tubes and Microtubes without Cap Allowed in the Analyzer

TYPE	MODEL	EXTERNAL DIAMETER (mm)	HEIGHT (mm)
Tubes		10 ≤ Ø ≤ 13.5	47 ≤ h ≤ 75
Microtubes			35 ≤ h ≤ 75
			

The containers described above can also be used to insert Calibrator, Standard and Control plasmas. The microtubes should be placed directly in the Q**sample holder** in the Q**Next**, ensuring that the base of the microtube is standing firmly on the base of the holder.

⚠ **CAUTION:** The use of sample tubes other than those specified may cause deterioration to the equipment. Before using any tubes other than those specified, please check with your local service representative.

When labels with barcodes are used on the sample tubes, these should be placed at a height of > 5 and < 45 mm from the base of the tube, as shown in Figure 4.10.

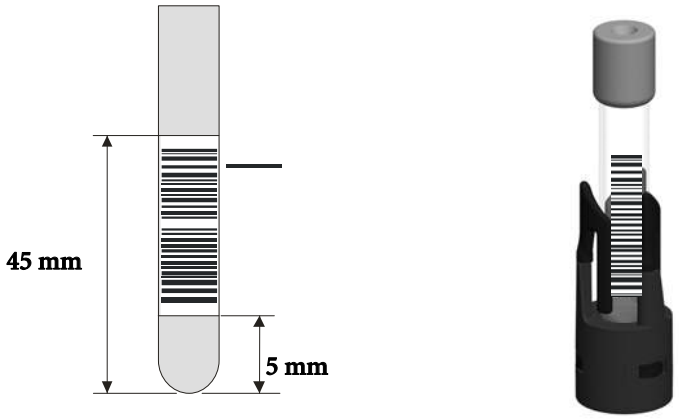

Figure 4.10. Position of the Barcode Label

> **CAUTION:** For the proper functioning of the equipment, it is important that the barcode labels are well stuck to the container, have nothing written on them, are not defective and that the direction of the bars is as shown in Figure 4.10.

4.3.2.3 Instructions for Use

- When sample identification is automatic, place the tubes directly in their corresponding Q**sample holder**.

> **CAUTION:** For the proper functioning of the equipment, it is important to place the sample tube in the Q**sample holder** in such a way that the holder's wings do not cover the corresponding barcode.

- If samples are manually identified, the Q**sample holder** needs to be identified first and this associated to the ID of the sample keyed in manually, as described in Section 15.6.2.3.
- Then place the Q**sample holders** with the sample tubes in the analyzer Samples Entry Area. The Q**Next** will automatically move the Q**sample holders** to the Identification and Aspiration position.
- Once the workload associated with the sample tube is completed, the analyzer will release the Q**sample holder** to the Samples Delivery Area.
- Remove the Q**sample holders** stored in the Samples Delivery Area.

⚠	**CAUTION:** Do not load sample tubes in the equipment without their corresponding Q**sample holder**.
⚠	**CAUTION:** Avoid dropping the Q**sample holders** accidentally: They may fall apart and/or break if they suffer knocks when they fall. If they drop, they should not be reassembled or reused. Do not use Q**sample holders** if they are incomplete.
⚠	**CAUTION:** Do not use any individual or multiple holders other than the ones specified in the equipment.
⚠	**CAUTION:** Do not use Q**sample holders** if the wings are not symmetric or if the spring is not working well. The tube should be centrally-aligned, vertical and stable.
⚠	**CAUTION:** For the level sensor to work correctly the level of sample in the capped tubes must leave a minimum space of 5 mm under the cap and the level of the sample should be at least 60 mm below this.
⚠	**CAUTION:** The use of recapped tubes may alter the behaviour of the cap piercing system. Avoid using this kind of tube in the analyzer.
⚠	**CAUTION:** For correct level detection, the minimum volume of sample should be 250 µL in conical microtubes.
⚠	**CAUTION:** Do not use 1.5 mL microtubes with volumes of over 1.0 mL since this may cause splashes in the Samples Entry Area.
⚠	**DANGER:** The presence of foam, bubbles or drops on the walls of the sample tube can cause alterations in the dispensing of the sample, and subsequent errors in the results.

4.3.3 System Solution A and System Solution B

The equipment requires the **System Solution A** (pink solution) and **System Solution B** (blue solution) to function. Both solutions are used, once diluted, to wash the Probes (internally and externally) and the fluid system.

4.3.3.1 Instructions for Use

- Dilute the contents of each 125 mL bottle with purified or de-mineralised water up to a final volume of 2 litres.
- Press the  button in the Q**Executor** window to open the Lower Door and remove the bottles of **System Solution A** and **System Solution B** from the analyzer.
- Transfer the diluted solutions to the corresponding bottles in the Wash Solutions Desk, attempting not to switch the caps and placing each bottle in the corresponding position.

	**DANGER:** Switching caps or positioning the Bottles incorrectly may cause cross-contamination between products and samples.
	**DANGER:** The use of Wash Solutions other than those specified may cause cross-contamination due to insufficient washing and lead to incorrect results.
	**DANGER:** Do not use expired Wash Solutions. Using degraded Wash Solutions may cause cross-contamination due to insufficient washing and lead to incorrect results.
	**DANGER:** The use of a Wash Solution with a concentration other than that specified may cause cross-contamination and lead to incorrect results. Make sure that solutions are properly homogenized before placing the bottles inside the analyzer.

4.3.4 QStirrers

Q**stirrers** are Magnetic Stirring Bars used for mixing the reagents in the Q**Next**.

Figure 4.11. QStirrer

	**CAUTION:** The use of magnetised rods other than those specified may cause deterioration of the analyzer.

4.3.4.1 Instructions for Use

- Before using the Q**stirrer**, check that it is in good conditions: Clean, dry and with no apparent defect of the white, teflon-made protective coating.

CAUTION: Before inserting a Q**stirrer** in a vial of reagent, check that there is not an earlier one inside.

- Place the Q**stirrer** in the corresponding vial of reagents and place the vial in one of the four stirring positions (positions 9, 11, 13 and 15) of the Black Tray in the analyzer Products Desk.
- Once the vial is empty, remove the Q**stirrer** using the magnetic bar, clean it with abundant soap and water and Rinse it with purified water. Dry it properly so that it can be used again in another vial of product.

CAUTION: Before discarding the vial of product, remove the Q**stirrer** from inside with a magnetic bar.

DANGER: Incorrect washing of the Q**stirrer** may cause cross-contamination and lead to incorrect results.

4.3.5 QWaste Tray

The Q**waste tray** is a disposable, polystyrene-made tray for storing the used Q**cells** cuvettes by the Q**Next**.

The Q**waste tray** can hold 400 discarded Q**cells** cuvettes.

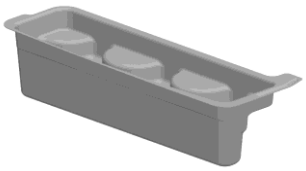

Figure 4.12. QWaste Tray

4.3.5.1 Instructions for Use

- Check that the Q**waste tray** is not deteriorated in any way. If it is, discard it and use a new one.
- Once the Q**Next** has started up, select the **Reset** Q**cells** () option from the **Other Options** menu () in the Q**Executor** window.

- Once the confirmation message displayed on the analyzer is accepted, the Lower Door will be automatically opened and the Waste Q**cells** cuvettes counter will be reset.
- Remove the Q**waste tray** from the equipment and dispose it of in accordance with legal requirements.
- Place the Q**waste tray** in its corresponding position in the Waste Desk, with the tab towards the front, as shown in Figure 4.3, no. 4.
- Close the Lower Door of the analyzer and continue working. The analyzer has a Q**waste tray** detector which ensures that it has been correctly positioned when the Lower Door is closed.
- When informed by the program (see Section 6.2.5.2), remove the full Q**waste tray** again and discard it in an appropriate container for contaminated material.

⚠ **CAUTION:** Full Q**waste tray** should be disposed of in accordance with current local regulations on infectious laboratory Waste.

⚠ **CAUTION:** The equipment will stop if the discarded cuvettes counter of the Q**waste tray** reaches the maximum number permitted.

⚠ **CAUTION:** If the counter is reset without replacing or emptying the Q**waste tray**, this may cause overfilling of the tray with the corresponding risk of contamination and even damage or blockages in the equipment.

4.3.6 QVial

The Q**vial** is a container that has been specially designed to be placed in the larger diameter positions of the Products Trays. It should be used when the original vial of a product is too big to fit in any of the positions of the Products Trays, in which case the product should be transferred to a Q**vial**.

Six labels with **UNKNOWN** as barcode are included with each product unit (comercial reference 215508) so that a product that is introduced with a Q**vial** can be automatically identified by Q**Next**. By default, the labels have the description "**Physiological saline**" because saline solution is a diluent used in several tests validated by Diagnostic Grifols, S.A. Physiological saline solution is not provided by GRIFOLS in a barcoded vial because each laboratory uses saline solutions from different sources.

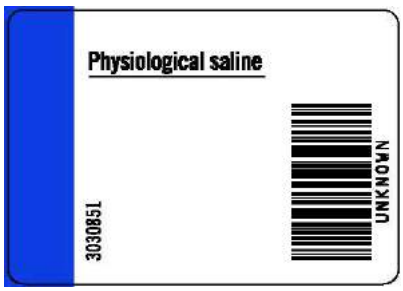

Figure 4.13. Barcoded Label for QVials

4.3.6.1 Instructions for Use

For using Q**vials** with Q**Next** see Section 4.3.11.1.

To use **"Physiological saline" labels**, the Operator must program an expiry date, a lot and UNKNOWN as barcode for the product with which the labels are going to be used. Next, stick the label on a Q**vial** and this is ready to be automatically identified by Q**Next**.

4.3.7 QSample Holders Red

The Q**sample holders red** are equivalent to the Q**sample holders** in features; the only difference is that they have red wings, which facilitates the visual localization of samples at the exit.

Figure 4.14. QSample Holders Red

4.3.7.1 Instructions for Use

For using them with Q**Next** see Section 4.3.2.3.

4.3.8 Samples Probe

The **Samples Probe** is a thin and cylindrical device with one side pointed end, specifically designed to hold and transport the liquids pipetted by the Samples Arm (plasma and diluents), and to pierce the sample tubes caps in the **QNext**.

Figure 4.15. Samples Probe

4.3.8.1 Instructions for Use

To replace the Samples Robot Probe of the **QNext**, see Section 7.2.6.

4.3.9 Tool for omnifit fittings

The omnifit tool is an accessory that helps to unscrew the omnifit connector where the Samples Probe is fitted when the Operator needs to replace the Samples Probe.

Figure 4.16. Tool for omnifit fittings

4.3.9.1 Instructions for Use

See Section 7.2.6 “Replace Samples Robot Probe” for instructions on how to use the omnifit tool.

4.3.10 Tool for Touch Screen position adjustment

The tool for the Touch Screen position adjustment is an Allen key M6 that allows fixing the Touch Screen in the desired height.

Figure 4.17. Tool for Touch Screen position adjustment

4.3.10.1 Instructions for Use

To adjust the position of the Touch Screen, follow these instrucions:

1. Unscrew the nut to untight the arm basis.
2. Move and hold the screen into the desired position.
3. Screw the nut to tight the arm basis and fix the screen position.

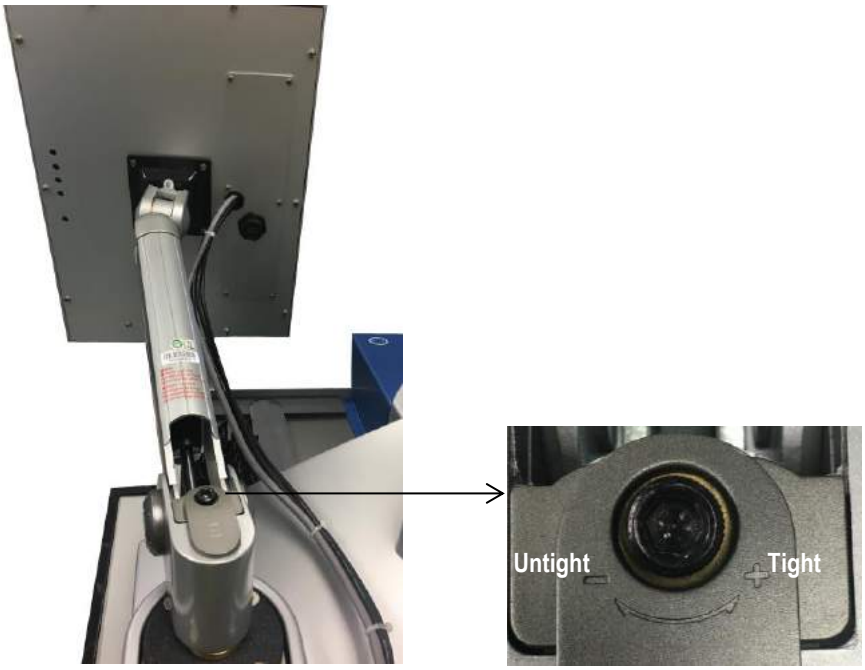

Figure 4.18. Nut to adjust screen position

4.3.11 Other Materials

4.3.11.1 Product Containers

The instrument allows the following types of containers for products to be used.

The use of any other container material will be subject to validation.

Table 4.4. Product Containers Allowed in the Analyzer

TYPE	MODEL	EXTERNAL DIAMETER (mm)	HEIGHT (mm)
Vials		16 ≤ Ø ≤ 35	35 ≤ h ≤ 65
Tubes and Microtubes		10 ≤ Ø ≤ 13.5	47 ≤ h ≤ 75
			35 ≤ h ≤ 75
			

4.3.11.1.1 Instructions for Use

- Place the vials, tubes and microtubes defined in the table above in the Products Trays. The external and minor diameter positions are used for placing tubes and microtubes.
- If barcoded labels are used on products vials, these must be placed at a height of between 1 and 40 mm from the base of the container, as shown in Figure 4.19.
- The Operator must place the barcoded tubes and vials correctly oriented in the trays windows to allow their automatic identification.
- Place the Products Trays inside the analyzer and close the Upper Door. The Q**Next** will automatically perform automatic identification.
- Once the workload is completed, remove the containers from the Products Trays.

Figure 4.19. Position of Barcode Labels on Product Vials

⚠	**CAUTION:** For the proper functioning of the equipment, it is important that the barcode labels are well stuck to the container, have nothing written on them, are no defective and that the direction of the bars is as shown in Figure 4.19.
📄	**NOTE:** The Q**Next** accepts barcodes on vials and tubes.
⚠	**CAUTION:** For correct level detection, the minimum volume is 250 µL or 5% of the total volume for vials, and 250 µL for microtubes.
⚠	**CAUTION:** The use of containers other than those specified may cause damage to the analyzer.
⚠	**DANGER:** The presence of foam, bubbles or drops on the walls of the container may cause alterations in product dispensing, leading to subsequent errors in the results.

5 Installation

5.1 What to Do when the Equipment Is Delivered

This equipment should always be installed by a Qualified Personnel.

The Qualified Personnel will give the appropriate instructions to the Supervisor for putting the equipment to work.

When the analyzer is delivered, please check that it includes all the elements specified in the *Packing List* which comes with it.

⚠ **WARNING:** After the Installation, the Operator should verify the correct functioning of the analyzer by performing a *Performance Qualification* (*PQ*) test.

5.2 Installation Requirements

The requirements for installing the equipment are the following:

- If the equipment has been stored in environmental conditions which differ from working conditions, it should remain in the environmental conditions under which it will be working for at least one hour before plugging in.
- Environmental conditions: See Section 3.1.
- Space required: The equipment shall be placed on a solid, horizontal surface holding more than 80 kg in weight, at least 80 cm deep and 100 cm wide.
- Do not place the equipment outdoors.
- Do not place the equipment where it may get wet.
- Do not place the equipment on a surface made of flammable material.
- Do not position the equipment in such a way that it is difficult to disconnect the mains cable (Figure 4.1, no. 1).
- Do not place the equipment in such a way that it is hard to access for servicing or Technical Service.
- Do not block the entries / exits of ventilation or place the equipment on a soft surface or on papers, plastic or textile covers which may prevent proper circulation of air.
- Do not place the equipment where it may be exposed to direct sunlight. Avoid focussing intense beams of light onto the Upper Door.
- Do not allow the equipment or its mains cable to come into contact with surfaces which are too hot to touch.

- Do not place any objects, except those indicated (*i.e.* Q**sample holders**), on the equipment.
- The electrical installation to which the equipment will be connected must comply with the requirements for supply, use and all regulatory requirements (including grounding).

5.2.1 Power Supply Connection

The Q**Next** requires a power supply connection. Check the specifications given on the corresponding label of Identification and Basic Technical Specifications of the Equipment (see Section 2.3, no. 7 and 9).

5.2.2 Water Supply

The Q**Next** does not require any external water supply because all the solutions used by the instrument are stored in removable bottles with 4 L capacity inside the equipment itself.

5.2.3 Drainage

All the Waste created is collected into two removable bottles, each holding 4 L, which need to be emptied manually into a drain or appropriate tank. However, the Waste liquid can be automatically emptied from the analyzer (Figure 4.1, no. 10) directly to a laboratory drain authorised for this type of Waste.

If you wish to use this option, please proceed as described below:

- Unscrew the cap on the racord for automatic drainage, located at the bottom, right-hand side of the analyzer (Figure 4.1, no. 10) and remove the white cap on the screw.
- Thread the drain tube (Figure 5.1, no. 4) through the centre of the screw (Figure 5.1, no. 3) and place the washer (Figure 5.1, no. 2) on the end, as shown in Figure 5.1.
- Screw it all on to the analyzer drain racord (Figure 5.1, no. 1).
- Finally, place the other end of the drain tube to the mouth of the drain, ensuring that it is firmly in place.

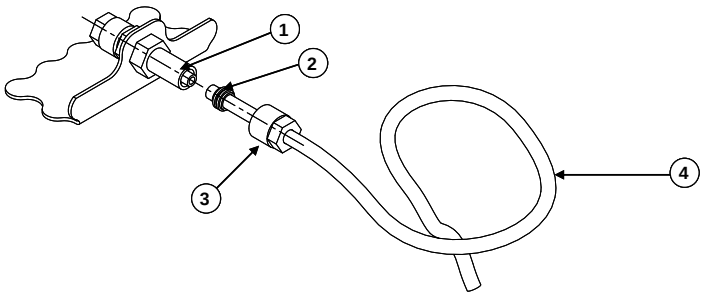

Figure 5.1. Connection for Emptying Waste Bottles Automatically

(1) QNext drain racord.

(2) Drain tube clamp washer.

(3) Drain racord screw.

(4) Drain tube.

5.2.4 Computer Equipment

The analyzer comes with a built-in computer and a touch screen monitor. The keyboard is virtual on the touch screen itself.

The operating system and the analyzer software come pre-loaded.

If you wish to install a printer, connect it directly to one of the analyzer's USB ports (one at the back of the touch screen and 4 at the back of the instrument). The operating system will recognise the printer without installing it. Otherwise, please contact Technical Service.

It is also possible to connect an external mouse in the USB ports available in the instrument.

CAUTION: To ensure proper traceability and management of expiry dates, check that the Date and Time configuration is correct for your geographical location. Otherwise, please contact authorised Technical Service.

5.3 Unpacking the Equipment

Once you have chosen an appropriate place to install it, place the Q**Next** on the floor upon the pallet, as close as possible to where it is going to be installed.

Then, unpack the equipment in accordance with the following instructions:

- Remove the wooden crate, taking into account the screws that attach it to the pallet.
- Remove the protective material covering the equipment.
- Unscrew the brackets which attach the equipment to the base of the packaging.
- Check that the equipment has not suffered any damage during storage and transport.

5.4 Placing the Equipment in the Chosen Location

Four people are required to move the equipment. Insert the hands in the spaces located at the bottom on the sides.

Keeping the back straight, lift all four sides simultaneously and place the Q**Next** in the chosen location.

DANGER: This instrument is considerably heavyweight, so it is advisable to follow these

	instructions for placement very carefully. It needs four people to lift it, holding as indicated (hands on the handles and back straight, flexing the legs).

5.5 Procedure for Installation

The procedure for installation is detailed in the *Installation Qualification* (IQ) document in the Technical Service manual.

6 QExecutor

NOTE: The information contained in these Instructions for Use refers to version 3.0.1 of Q**Next** program.

NOTE: The products, tests, Controls, Calibration Curves, samples and results which appear on the screens of these Instructions for Use have been included merely for illustrative purposes.

When the main switch of the Q**Next** (Figure 4.1, no. 1) is turned on and the **Start** button (Figure 4.1, no. 2) is pressed, the system automatically starts up the program which has two unique, interrelated work windows as interfaces:

- Q**Executor** is the window which controls the analyzer and the interface is similar to that of a **Status** window.
- Q**Manager** is the window which manages orders, results and later processing. The interface is similar to that of a **Worksheet**.

Once the program has started, the equipment will display the screen for the Q**Manager** window by default.

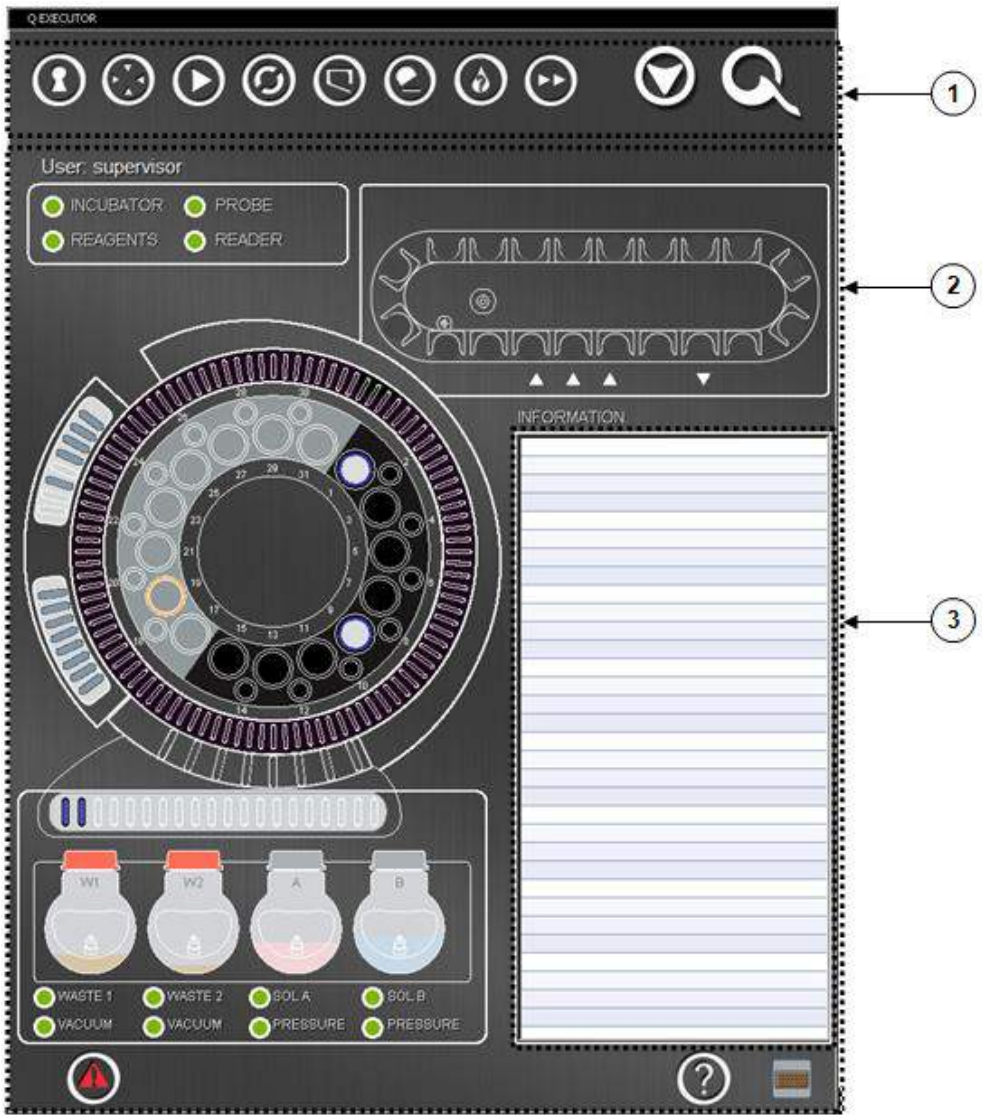

Figure 6.1. QExecutor Window

(1) **Action Buttons Area:** Includes the buttons normally used in work routines (identification of Operators, samples and products management, doors opening, etc.) and servicing the analyzer. The program also has a button for accessing to the Q**Manager** window.

(2) **Status Area:** Graphic display of the analyzer Working Area, of the Samples Recirculation Area and the Wash and Waste Solutions Area.

(3) **Information Area:** Area which displays information of a specific module of the analyzer when the corresponding graphic part of the Status Area is selected.

6.1 Action Buttons Area

Figure 6.2 shows the Action Buttons Area of the Q**Executor** window. It contains the following ten buttons:

Figure 6.2. Action Buttons

Login/Logout:

The **Login** option allows the new Operator to be identified (name and password), so that the privileges allocated by the Supervisor are available to him/her, as described in Section 9.10. The **Logout** option turns this Operator off and, when pressed again, requests the ID of the next one wishing to use the analyzer.

Insert Qsample holder:

This option allows to select the type of sample to be inserted (sample, Calibrator, Standard or Control) and to identify the Q**sample holder** in the External Identification Area, where the radiofrequency reader will read the Q**sample holder** internal identification and will associate it to the manual identification of the sample tube, which will be done next (if the sample's identification has been previously introduced in the **Worksheet**, choose the sample ID from the list shown, otherwise, enter the sample's identification by means of the keyboard) (see Sections 15.6.2.3 and 15.6.2.4).

For the manual introduction of Calibrators, Standards and Controls by means of this option, these must be transferred to a secondary tube.

Start/Stop Running:

By pressing the **Start** () button, the Samples Desk is enabled. In this way, the Q**sample holders** that are in the Samples Entry Area are moved towards the Recirculation Area, where they will be transported to the identification and aspiration position to start running all requested tests. At the same time, those sample tubes whose workload has been completed are released to the Samples Delivery Area.

Once the Samples Entry Area is enabled, the **Start** button changes to **Stop** button (). When the  button is pressed, the analyzer stops the Samples Desk, finishes samples processing, and the button once again changes to **Start** status.

Trays Content:

When the Upper Door is opened, this button activates, manages and allows the insertion of manually identified products. For working with previously-configured Products Trays, see Section 9.5. When the analyzer is working, this button informs about the Trays Content.

Open Lower Door:

Button for opening the Lower Door of the analyzer, allowing access to the Wash and Waste Solutions Desk.

The **Lower Door** opening while tests are in process causes the **Stop** button changing to **Start** status. To continue working, the Operator has to press the **Start** button after closing the door.

Open Upper Door/Move Trays:

The **Opening Upper Door** button () allows the access to the Working Area and, therefore, to the Products Trays.

Once the Upper Door is open, this button changes to the **Move Trays** button (). This button allows moving the trays with the Upper Door open. Once the Upper Door is closed, the icon returns to its original status ().

The **Upper Door** opening while tests are in process causes the **Stop** button changing to **Start** status. To continue working, the Operator has to press the **Start** button after closing the door.

Unknown Sample Identification:

Button which allows the samples marked by the analyzer as **Unknown Sample** to be identified.

The button allows the manual identification by the Operator of the samples which have not been identified during the automatic identification (see Section 15.7.3).

If the analyzer configuration has a **Default Profile** (see Section 9.3.4), these samples will be processed by applying this profile to them and, subsequently, they can be identified.

Otherwise, if the analyzer has no Default Profile, the samples labelled as **Unknown Sample** will be waiting to be identified and, therefore, must be placed in the Samples Entry Area again to be processed according to the allocated workload.

STAT samples: This option allows the introduction of samples in a prioritized way.

Samples can be introduced as prioritized so that the pipetting of this sample is performed before the pipetting of all the samples in the Recirculation Area (see Section 15.6.3).

The orders in the **Worksheet**, introduced manually or via Host, are executed, and besides, a special profile can be applied to these samples: **STAT Profile** (see

Section 9.3.5).

The entrance position of prioritized samples to the Recirculation Area is fixed and it is indicated with an intermittent red arrow (Figure 4.4, no. 6). Once all orders associated to the STAT sample have been completed, this is automatically released to the Samples Delivery Area (Figure 4.4, no. 2).

There is also an option to indicate that a sample is a STAT sample in the Q**Manager** (see Section 15.6.3).

Other Options:

Button for accessing complementary operations of the analyzer.

This button provides a series of options which are important for the way in which the analyzer works (**Maintenance** and **Technical Service** options).

Access to the Q Manager window:**

Button which allows the Operator to access the Q**Manager** window.

6.2 Status Area

Graphic display of the analyzer Working Area which provides real-time information on the operational status of the analyzer.

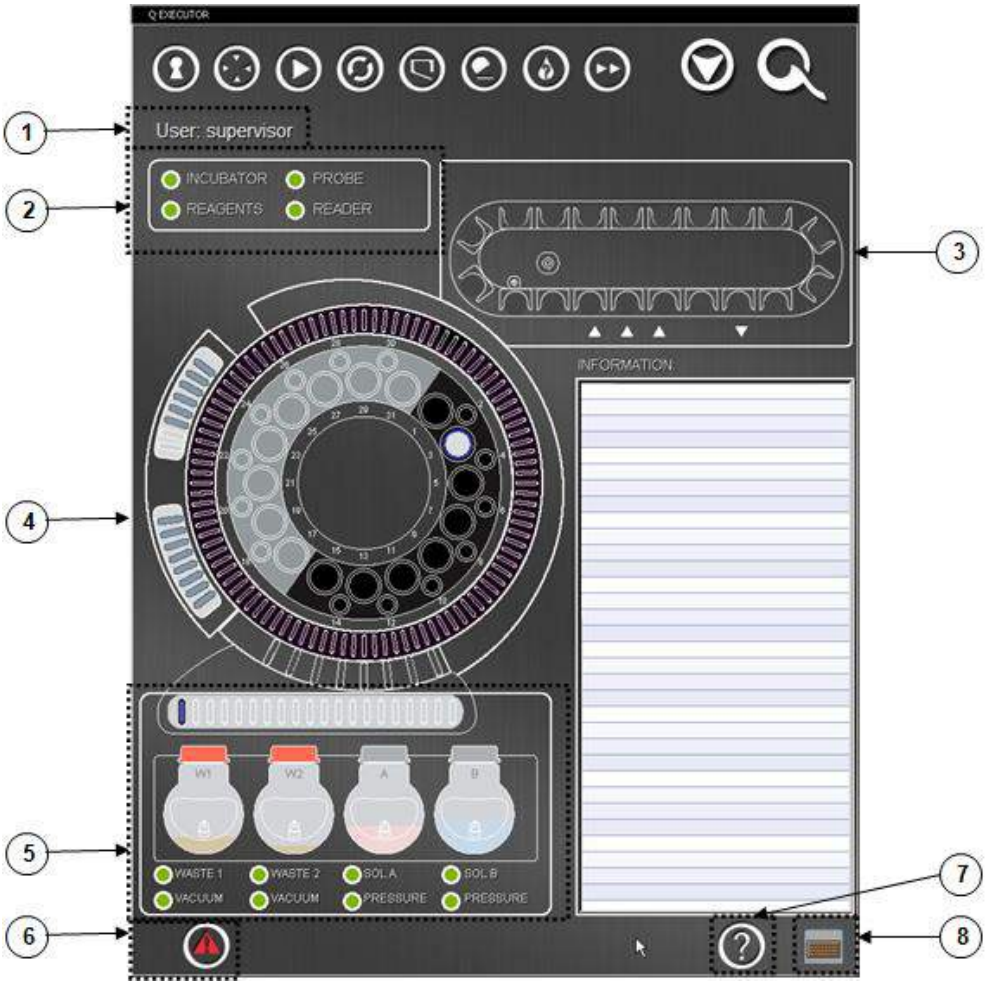

Figure 6.3. Status Area

(1) User Information Area
(2) Temperature Information Area.
(3) Samples Recirculation Information.
(4) Working Area Information.
(5) Wash and Waste Solutions Desk Information Area.
(6) Emergency Stop button.
(7) Help button.
(8) Display Keyboard button.

6.2.1 User Information Area

Located in the top, left-hand corner, it provides information on which operator is logged into the Q**Executor** window (Figure 6.3, no.1).

6.2.2 Temperature Information Area

Located in the top, left-hand corner, it provides colour-coded information on the temperatures controlled by the analyzer: Incubation Area, Products Arm Probe, Products Desk and Reading Channels.

- **Red:** Indicates that the temperature of a specific area is outside the permitted working temperature range. In this case, the analyzer finishes the tests that are in process and once finished, the observation that in these determinations the temperature was out of range appears, then the entrance of samples is stopped and the Technical Service needs to be involved. A high-level incident is also created in the **System Alerts Area** of the Q**Manager** (Figure 8.1, no. 5).

⚠ **CAUTION:** If the program displays a temperature outside the normal range, first ensure that the environmental conditions are as specified and, if so, contact the Technical Service.

- **Orange:** Indicates that the temperature of a specific area is at the upper or lower limit of the permitted working temperature range, although the analyzer keeps on working. The Operator also receives an alert in the **System Alerts Area** of the Q**Manager** (Figure 8.1, no. 5).

⚠ **CAUTION:** If the incident persists, first ensure that the environmental conditions are as specified and, if so, contact the Technical Service.

- **Green:** Indicates that the temperature in the corresponding modules remains within optimal **Working range**.

6.2.3 Samples Recirculation Area Information

This area displays interactive, graphic information on the status of the Samples Recirculation Area.

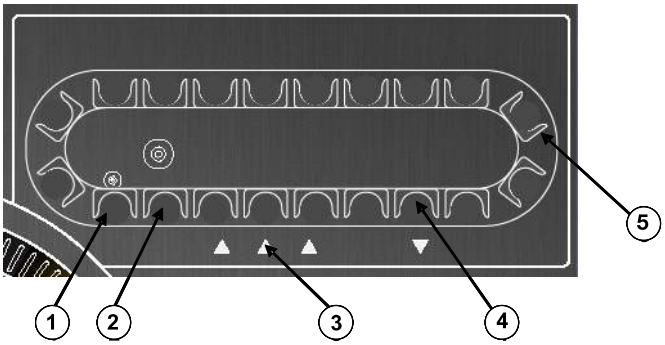

Figure 6.4. Samples Recirculation Area

(1) Position for identification, cap piercing and sample aspiration.

(2) Position for internal identification of Qsample holders.

(3) Qsample holders and STAT samples entry positions.

(4) Qsample holders and STAT samples delivery position.

(5) Qsample holders carriage links.

When the Recirculation Area is enabled by pressing the **Start** button, the Q**sample holders** located at the Samples Entry Area are captured by the links in the Recirculation Area and carried towards the inside of the analyzer. The program displays the occupational status of the links and their sample tubes in real-time, as indicated below:

Empty holder

There is a Q**sample holder** with no sample tube.

Pending

There is a Q**sample holder** in the link with a sample tube correctly identified pending to be or being processed.

STAT pending

There is a Q**sample holder** in the link with a sample tube correctly identified and introduced in a prioritized way pending to be or being processed.

Unknown Identification

There is a Q**sample holder** in the link with a sufficiently-full sample tube, but the analyzer has been unable to identify the sample tube using the internal Barcode Reader. The sample is catalogued as an **Unknown Sample** and the tube will need to be identified through the **Unknown Sample Identification** option (see Section

15.7.3).

Unknown STAT Sample

There is a Q**sample holder** in the link with a sufficiently-full sample tube correctly identified and introduced in a prioritized way, but the analyzer has been unable to identify the sample tube using the internal Barcode Reader. The sample is catalogued as an **Unknown STAT Sample** and the tube will need to be identified through the **Unknown Sample Identification** option (see Section 15.7.3).

Cancelled

There is a Q**sample holder** in the link with a sample tube which has been cancelled because some alert or incident has occurred which could not be solved (*e.g.* due to insufficient level in the sample tube and, therefore, it cannot be aspirated). The tube is expelled from the Recirculation Area and generates an incident which is reported in the Incidents Area of the **Test Result** window (Figures 13.1, 13.2 and 13.3, no. 5).

Finished

There is a Q**sample holder** in the link with a sample tube with all the orders finished.

Warning

There is a Q**sample holder** in the link with a sufficiently-full sample tube correctly identified, but the program alerts the Operator that one or more tests ordered to this sample have been cancelled for causes not related to the sample (*e.g.:* Test overincubated, insufficient level of any of the products, etc.).

Pressing any position in the Recirculation Area will cause the program to update, in the **Information Area**, the number of samples in the internal parts of the Recirculation Area which are being controlled by the analyzer and provides information on their ID's and the corresponding analyses underway.

The program also indicates the number of **Unknown Samples** pending identification and the number of samples which are accessible to the Operator (which are not yet controlled by the system).

When any of the sample icons located in the internal parts of the Recirculation Area is touched, the program offers information about this single position in the **Information Area:** Present/not present, ID, whether it has been manually or automatically introduced, the corresponding test/s underway, the estimated time to finish all tests and information about sample errors, if any

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NOTE: The program only displays the ID and the status of the samples located in closed, interior links (positions 1-14) in the analyzer. However, it does not display the occupational status, but rather the ID, of the six frontal links and the samples present in the Samples Entry Area to the Operator.

The status of the links is updated each time the Q**sample holders** pass through the respective Identification Area (Figure 6.4, no. 2).

CAUTION: Do not touch or remove the sample tubes and/or the Q**sample holders** which are being controlled by the system until they output automatically from the Recirculation Area.

NOTE: If the internal Q**sample holder** Identification Area detects more than 20 empty links one after the other, the analyzer stops the Samples Desk.

6.2.4 Working Area Information

Interactive status view of the main areas and desks of the analyzer.

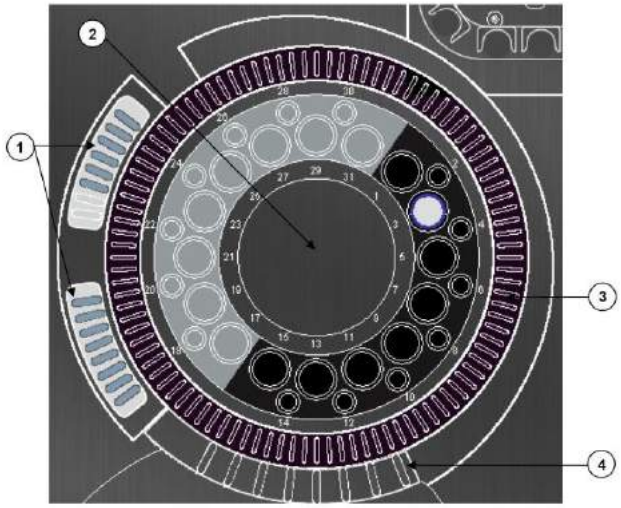


Figure 6.5. Worksurface

(1) Qcells cuvettes Desk Information Area.

(2) Products Desk Information Area.

(3) Incubator's Information Area.

(4) Readers' Information Area.

This is an interactive graphic representation for the Operator, *i.e.* when one of the areas and desks displayed above is touched, the program updates the occupational status of this in the **Information Area** (Figure 6.1, no. 3).

6.2.4.1 QCells Cuvettes Desk Information Area

This area notifies the load status of the Q**cells** cuvettes Desk:

- If a rack is present and has been correctly identified by the analyzer, the program displays the position of the occupied rack with a grey background and the columns of the rack which are not empty are represented in blue colour.
- Once the Q**cells** cuvettes of one of the columns are finished, the program displays this column as empty, *i.e.* only the outline of the column is represented in white colour.
- When all the cuvettes in both Q**cells** racks and the ones in the incubator buffer are exhausted, the cuvettes load positions are displayed in red, generating an incident which is reported in the **System Alerts Area** of the Q**Manager** window (Figure 8.1, no. 5).

When a loading position in the Q**cells** cuvettes Desk is touched, the program notifies the presence of the rack, the number of Q**cells** cuvettes available in it and whether it is the rack in use or not (active/not active) through the **Information Area**.

NOTE: When the analyzer detects that the total volume of available Q**cells** cuvettes is less than 20%, a warning appears in the **System Alerts Area** of the Q**Manager** window.

When the analyzer detects that there are no available Q**cells** cuvettes, it stops the Samples Desk and a red dialogue box appears informing the Operator that this situation needs to be corrected.

6.2.4.2 Products Desk Information Area

This area notifies in real-time the status of the 30 product positions, divided into two separate Trays (Black and Grey) with 15 positions each. Pressing the central area of the Products Desk will cause the program to update the information displayed in the **Information Area:** Position in the tray, product name and product lot.

The graphic information displayed is as indicated below:

Unknown Identification

Position theoretically occupied by a vial but the analyzer has not been able to automatically identify it.

Unknown Volume

Position theoretically occupied by a vial (depending if the identification has been automatic or manual, see Section 15.4) but the analyzer has not yet determined the available volume.

Known Volume

Product position occupied, identified and with a known volume. Moreover, the analyzer provides graphic information on the product level in the vial.

Alarm Volume

Product position occupied and identified, but the product volume is lower than the volume defined as Warning Volume in the programming of the product presentation (see Section 9.1.1).

Cancelled

Product position occupied and identified but the vial contains an insufficient volume or the product has expired or it is beyond its on-board stability or if an obstruction or air have been detected. If the product is expired, it is only cancelled if the **Check Products Expiry Date** option is enabled (see Section 7.3.2). If the product has exceeded its on-board stability, it is only cancelled if the **Check Products On-board Stability** option is enabled (see Section 7.3.2).

A high-level alert is also created in the **System Alerts Area** of the Q**Manager** and an alarm message is displayed notifying the Operator that the product vial in question must be replaced. If the Operator fails to interact with the analyzer within 1 minute, it will continue with the workload which does not depend on the product in question, cancelling all the orders that require it.

Warning

Product position occupied and identified, but the program alerts the Operator about any of the following situations:

- A product that requires stirring is placed in a non-stirred position.
- An expired product is detected, when the **Check Products Expiry Date** option is disabled (see Section 7.3.2).
- A product that has exceeded its on-board stability is detected, when the **Check Products On-board Stability** option is disabled (see Section 7.3.2).
  - A product that requires cleaning is detected, but the associated cleaning agent is not present in the Products Tray.
  - A diluent is placed in a non optimal position.
- A product that cannot be automatically registered. The Operator should review the Lot Number, the Presentation and the Barcode introduced in the **Edit Product** window (see Section 9.1.1).

When a position that is theoretically occupied by a product is touched, an orange outline is displayed around the position and the program offers information on the product in the **Information Area:** Name, stirring status (if applicable), available volume, alarm volume, number of theoretical determinations (only for reagents, but not for diluents, Controls or cleaning agents), presentation, lot number, expiry date, barcode, remaining on board time and whether it has been manually or automatically introduced.

NOTE: The level of product in a vial is only displayed when the analyzer has aspirated its content and checked the volume contained in the vial. Therefore, it is possible to find and select, at some point, vial positions which the analyzer has not been able to update yet.

NOTE: The time for the remaining stability starts to count when a new identification in a product position is found, and it only restarts counting when the product identification changes or when the Operator presses the **Reset Product** ( ) button for this position.

DANGER: Products may be hazardous. Handle them in accordance with the manufacturer's instructions.

6.2.4.3 Incubator's Information Area

When any position in the Incubation Area is touched, the analyzer displays, in the **Information Area**, the number of Q**cells** cuvettes present there at that time. It also specifies the cuvettes which are being used and which are waiting to be used.

6.2.4.4 Readers' Information Area

This area notifies the occupation of the channels in the Reading Area. Channels reserved or occupied by Q**cells** cuvettes currently being read are shown in blue. If a blue channel is pressed, it informs of the test that is being read in real time.

If there are disabled channels (**Configuration** menu, see Section 7.3.3) these are displayed in red.

Reading positions occupied by empty or used Q**cells** cuvettes are displayed as free positions.

6.2.5 Information Area for the Wash and Waste Solutions Desk

This area notifies the status of the two Bottles of Wash Solutions and the two Bottles of Waste Solutions that the analyzer has, as well as the status of the Q**waste tray**.

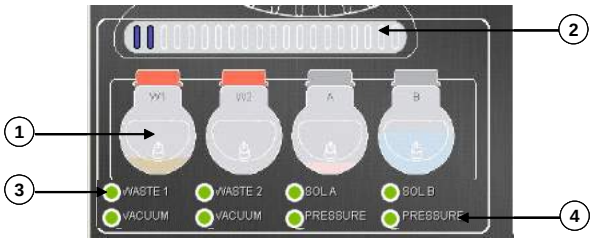


Figure 6.6. Wash and Waste Solutions Area

(1) Area with graphic information on the available volume of the diluted Wash Solution Bottles (**System Solution A** and **System Solution B**, respectively) and the Waste Bottles (W1, W2).

(2) Area with graphic information on how full the Q**waste tray** is.

(3) Alerts area related to the volume of the bottles in the Wash and Waste Solutions Desk.

(4) Alerts area regarding the pressures of the Wash Solutions Desk and the vacuum in the Waste Solutions Desk.

6.2.5.1 Bottle Volume Graphic Information Area

Each of the bottles graphically displays the level of liquid it contains. When any of the bottles in the desk is touched, the program indicates, in the **Information Area** (Figure 6.1, no. 3), the approximate volume of liquid contained in the selected bottle and, if it is a Waste Solution Bottle, it indicates whether it is being used at that time.

6.2.5.2 QWaste Tray Information Area

The program displays a progress bar to indicate the amount of Q**cells** in the Q**waste tray**. To do so, the analyzer has a counter that controls the number of discarded Q**cells** cuvettes. The program represents the discarded Q**cells** graphically, with filled positions displayed in blue. Each position represents 20 discarded Q**cells** cuvettes. The maximum capacity of the Q**waste tray** is 400 Q**cells** cuvettes.

When any position on the Q**waste tray** status bar is touched, the program indicates the number of discarded Q**cells** cuvettes in the **Information Area** (Figure 6.1, no. 3).

NOTE: When the number of discarded Q**cells** cuvettes exceeds 350, the program will update the positions on the status bar in orange and an incident will be created in the **System Alerts Area** of the Q**Manager** window.

When the number of discarded Q**cells** cuvettes reaches the maximum permitted (400), apart from updating the positions on the status bar in red, the program halts the process and the entry of samples and a red dialogue box appears informing the Operator of the need to solve this situation. A high-level incident alert also appears in the **System Alerts Area** of the Q**Manager** window.

6.2.5.3 Volumes Information Area

Area on the Q**Executor** window which warns the Operator about the volume of the Wash and Waste Solution Bottles in the Wash and Waste Solutions Desk:

- **Red:** Indicates that the volume in the bottle is inadequate to continue working.

If it affects a single Waste Bottle, the analyzer will automatically use the second bottle.

If it affects any Wash Solution Bottle or both Waste Bottles, the analyzer automatically stops working and a red dialogue box displays, informing of the incident and requesting immediate intervention by the Operator to deal with the situation. A high-level incident appears in the **System Alerts Area** of the Q**Manager** window. If the red colour refers to the Wash Solution Bottles, fill them up immediately with the corresponding diluted solutions, as described in Section 4.3.3.1. If it affects the Waste Bottles, empty them as described in Section 15.8.4.

- **Orange:** Appears in the Wash Solutions Bottles when they are below 20% of their capacity. In the Waste Bottles, the alarm is activated when they are above 80% of their capacity. A low-level incident is created in the **System Alerts Area** of the Q**Manager** window.
- **Green:** Indicates that no action is required from the Operator regarding the volumes of bottles solution.

6.2.5.4 Pressure Information Area

Area on the Q**Executor** window which warns the Operator about the levels of pressure and vacuum in the bottles of the Wash and Waste Solutions Desk, respectively:

- **Red:** Indicates that the pressure/vacuum in a specific bottle is outside the tolerated margins. In this case, the analyzer automatically stops working and a red dialogue box is displayed informing of the corresponding incident. A high-level incident also appears in the **System Alerts Area** of the Q**Manager** window.

⚠ **CAUTION:** If the program displays a pressure level outside tolerated margins, check that the connectors of the affected bottle are correctly attached and that the cap is tight. Once these have been checked, if the indicator still displays as red, contact authorised Technical Service.

- **Orange:** Indicates that the pressure/vacuum of a specific bottle is momentarily outside the expected margins, although the analyzer can still continue operating. Additionally, a low-level incident is created in the **System Alerts Area** of the Q**Manager** window.

⚠ **CAUTION:** If the indication persists, contact authorised Technical Service.

- **Green:** Indicates that the pressure/vacuum of a specific bottle is within optimal working margins.

6.2.6 Help Button

When the **Help** button (**)** is pressed, the program displays a dialogue box with the graphic representation indicating the different status of products and samples and the status of the analyzer regarding the parameters of pressure/vacuum and temperature. It also displays a little description beneath each icon about what it is used for.

6.2.7 Emergency Stop Button

The **Emergency Stop** button ( ) allows the Operator to stop the analyzer in case of incident. Once this has been solved, the analyzer should be re-started by pressing the **ON** button ( ).

⚠ **CAUTION:** The stops the analyzer process completely cancelling all running tests and should only be used in case of emergency.

6.2.8 Display Keyboard Button

To enter alphanumeric characters in specific fields of the program, such as samples manual identification or Operator ID, the application has a virtual keyboard, accessible by pressing the **Display Keyboard** button ( ), located in the lower, right-hand corner of the Q**Executor** window (Figure 6.3, no. 8). There are two versions of keyboard (Figure 6.7, a and b) with different keys available. To change from one to the other, press the **Shift** key.

(a)

(b)

Figure 6.7. Different Versions of the Alphanumeric Keyboard

6.3 Information Area

Area on the Q**Executor** window which offers the Operator information on the different modules of the Q**Next**. To obtain information on a module, the Operator touches the area on the screen (on the **Status Area**) which represents it, and the detailed information will be displayed in this area during 30 seconds. The modules for which it is possible to obtain information are:

- Samples Recirculation Area.
- Incubation Area.
- Product Area.
- Qcells cuvettes Desk.
- Reading Area.
- Qwaste tray Area.
- Wash and Waste Solutions Area.

7 QExecutor: Other Options

This section refers to the operations which can be run from the **Other Options** ( ) menu of the Q**Executor** window.

7.1 Reset QCells

The Operator should perform this operation each time the Q**waste tray** is emptied (see Section 15.8.5).

When the **Reset** Q**cells** option is selected, the program requests confirmation to open the Lower Door automatically and empty or replace the Q**waste tray**. The Operator should empty or replace the Q**waste tray** on the analyzer and close the door. The analyzer will automatically reset the discarded Q**cells** cuvettes counter.

The program also updates the chart for the Waste Desk in the Information Area of the Q**Executor** window.

7.2 User Maintenance Options

User Maintenance option gives access to several maintenance options, mainly related to the fluid circuit.

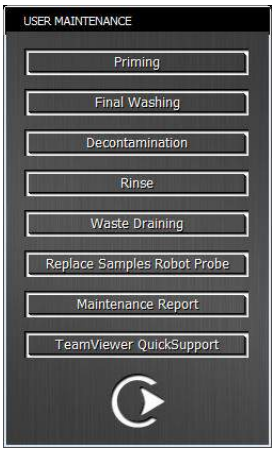


Figure 7.1. User Maintenance Window

7.2.1 Priming

This option performs an internal priming of the fluid circuit with diluted **System Solution A** and an external priming with diluted **System Solution B**. Priming is important to maintain liquid aspiration/dispensing specifications.

Complementary **Priming** is only necessary if the instrument has not been used for a long time, during installation, or if precision problems or other pipetting issues (air aspirations or probe obstructions) are detected in dispensation. In this case, it is recommended to perform first several **Final Washings** and, then, a **Priming** will be required to leave the instrument initialized and be able to continue working.

7.2.2 Final Washing

This option allows performing an external and internal wash of the fluid circuit with diluted **System Solution B** to prevent the formation of precipitates which might disrupt normal, liquid-dispensing operations.

The analyzer performs an automatic Final Washing of the fluid circuit prior to turning off.

Complementary **Final Washing** is only necessary if the instrument has not been used for a long time, during installation, or if precision problems or other pipetting issues (air aspirations or probe obstructions) are detected in dispensation. In this case, it is recommended to perform first several **Final Washings** and, then, a **Priming** will be required to leave the instrument initialized and be able to continue working.

NOTE: If, for any reason, the equipment is turned off (mains cable unplugged, main turn off, power cut) without following the standard turn-off procedure for the analyzer, the Operator should turn it on again (except when it has been turned off for safety reasons) and perform the Final Wash of the fluid system manually.

7.2.3 Decontamination

This option performs a **Decontamination** of the **QNext** fluid circuit. Follow the instructions given by the program, including replacement of the contents of the bottles. For more information, please see Section 16.4.2.

7.2.4 Rinse

This option performs an external and internal wash of the fluid system with distilled water. The **Rinse** needs to be done after the **Decontamination** process to remove the decontaminant solution from the fluid system. After the Decontamination, the instrument advises the Operator to perform the Rinse.

Follow the instructions given by the program. For more information, please see Section 16.4.2.

7.2.5 Waste Draining

If the laboratory has a drain specifically designed for biological Waste or a container for this purpose, a drain tube can be installed to the connection for automatic emptying of Waste Bottles (Figure 4.1, no. 10). To install and set up this option, please see Section 5.2.3.

The Waste Bottles can be automatically emptied through this **Waste Draining** option. To do so, the Operator must first have enabled the **Drain Waste** option in the **Setup** window (see Section 7.3.2). The system will request confirmation prior to emptying the Bottles.

NOTE: To Empty Waste Bottles, the samples entry must be stopped and there should be no tests in process.

CAUTION: Before emptying the Waste Bottles, check that the drain tube is correctly connected to the analyzer and that it is tightly fitted to the mouth of the drain. Also check that the total capacity of the drain is sufficient to transfer all the liquid contained in both bottles.

CAUTION: If there is no connection to the drain or it is no longer being used, replace the safety cap.

7.2.6 Replace Samples Robot Probe

The Samples Probe is annually replaced by the Technical Service as preventive maintenance action (see Section 16.1). However, in case of breakage, the Samples Probe could be replaced by the Operator through this option.

CAUTION: The Probes are a key component for the correct functioning of the analyzer, as well as one of the most delicate parts. Do not replace the Samples Robot Probe if it is not strictly necessary.

To replace the Samples Robot Probe, perform the following steps:

- Verify that the Upper and Lower Doors are closed and go to the **QExecutor** window.
- Select **Other Options** (), **User Maintenance, Replace Samples Robot Probe** and press **Accept**. The instrument will cancel the tests in process and empty the liquid of the Probe. When finished, the Upper Door will be automatically opened and the Samples Arm will be placed in an accessible position for the Operator.

- Unscrew slightly the Samples Probe from its fitting using the omnifit tool provided with the analyzer (see Figure 7.2) to unblock it.
- Open the metallic locker by turning it to the right and the Samples Probe will be released.
- Once the Samples Probe has been released, hold it with the hands and unscrew it completely from its fitting.

DANGER: The Samples Probe could leak while unscrewing it. It should be treated as being potentially contaminated.

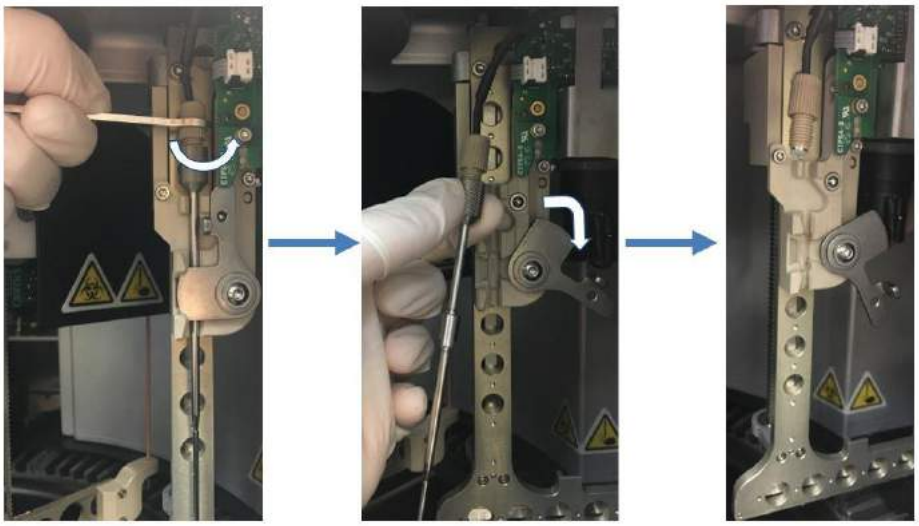


Figure 7.2. Replacement of the Samples Probe Procedure

- Screw the new Samples Probe with the hands as much as possible.
- Fit the Probe in its position and close the locker by turning it to the left until hearing the "click".
- Once the Probe is fixed in its position, screw it completely using the omnifit tool provided with the analyzer until hearing the "click'', which will block the fitting.

NOTE: To make sure that the new Samples Probe is properly connected, it is very important to screw it until hearing the "click".

NOTE: When fitting the Probe in its position, it may be necessary to turn it slightly around until it is perfectly fitted.

- Finally, close the Upper Door and press **Accept**.
- The analyzer will automatically adjust the new Samples Probe and verify that the replacement has been successfully performed:
  - If the automatic adjustment finishes succesfully, a window informing the Operator about the old and the new probe adjustments will appear. The Operator should note the results of the automatic probe adjustment and press **Accept**. Then, press  to initialize the system.
  - If the adjustment fails, the Operator should retry the process. If, after retrying, the adjustment still fails, the Operator has two options:
    - Accept that the adjustment has failed. This option will block the instrument until the Qualified Personnel fixes the problem.
    - Accept the previous correct adjustment. This option will allow the Operator to continue working with the analyzer under its responsibility. In this case, performing a *Performance Qualification (PQ)* will be essential to guarantee the correct functioning of the analyzer.

Despite the analyzer performs an automatic adjustment after replacing the Samples Probe, the Operator should verify the correct functioning of the analyzer by performing a *Performance Qualification* (*PQ*) test. If the *Performance Qualification (PQ)* test fails, contact your authorized Technical Service.

The replacement of the Samples Probe will be recorded in the **Maintenance Report** (see Section 7.2.7), so that the Operator or Qualified Personnel can later review the **Date**, **Time**, **User** that performed the replacement and **Result** of the operation.

NOTE: After replacing the Samples Probe, the Operator or Qualified Personnel should inform the Technical Service about the **cause** of replacement, the new Samples Probe **lot**, and the **results** of the automatic probe adjustment.

7.2.7 Maintenance Report

This option allows the Operator to generate a report in **.pdf** format, containing the results of all maintenance operations related to the fluidic circuit (Priming, Final Washing, Decontamination, Rinse, Waste Draining and Replace Samples Robot Probe) that have been performed in the analyzer, regardless whether they are finished or cancelled.

After clicking on the **Maintenance Report** button, there are two available options:

- **Create Maintenance Report:** This option allows creating a new report which is automatically saved in the system with the following format: "Maintenance (date){time}.pdf". This report can also be saved into an external USB data storage device in **.pdf** format, by means of the **Save** () button.
- **Open a Maintenance Report:** It allows browsing a previously generated report.

The Maintenance Report contains the following information (Figure 7.3):

- Instrument **Serial Number.**
- **Printing Date** and **Time**.
- **QExecutor Software Version**.
- **User** who has generated the Maintenance Report.
- **Date** and **Time** of the first maintenance operation performed**.**
- Information about each individual fluid circuit maintenance operation:
  - **Date** and **Time** at which the operation was performed.
  - **User** that has performed the maintenance operation.
  - **Result** of the operation: OK, FAIL, or CANCELLED.
- Section for Comments, Name and Signature.

518-P000005
06-07-2017 10:50:39
HSExecutor v3.0.0.477
supervisor
Tests since 04-12-2015: 6613

Maintenance Operation	Date & Time	User	Result
Replace Samples Robot Probe	02-12-2015 16:30:38	supervisor	CANCELED
Priming	11-12-2015 10:13:06	supervisor	CANCELED
Final Washing	11-12-2015 10:14:19	supervisor	CANCELED
Rinse	11-12-2015 10:14:38	supervisor	FAIL
Decontamination	11-12-2015 10:15:00	supervisor	FAIL
Decontamination	24-02-2016 09:12:01	supervisor	OK
Rinse	24-02-2016 09:46:38	supervisor	OK
Decontamination	29-07-2016 13:55:57	supervisor	OK
Priming	04-04-2017 13:18:34833	supervisor	OK
Replace Samples Robot Probe	20-04-2017 14:28:51843	supervisor	OK
Replace Samples Robot Probe	20-04-2017 14:32:27295	supervisor	OK
Priming	13-06-2017 09:22:36	supervisor	OK
Replace Samples Robot Probe	04-07-2017 08:36:31	supervisor	OK

Name:

Signature:

Comments:

Figure 7.3. Maintenance Report

7.2.8 TeamViewer QuickSupport

The TeamViewer is an application which allows the Technical Service to remotely connect to the **QNext** software to help solving issues faster or to guide the Operator on how to proceed in case of incidence.

The participation of the Operator is required to allow the remote connexion of the Technical Service to the instrument. Once the remote connection has been stablished, the Technical Service personnel will be able to see exactly the status of the **QExecutor** and **QManager** windows as they are in the analyzer.

NOTE: Before starting the procedure, contact your authorised Technical Service to notify the problem.

To establish the remote connection, perform the following steps:

- Select **Other Options** (), **User Maintenance**, **TeamViewer QuickSupport** and press **Accept**.
- A message reporting that the connection tool is active will be displayed at the top of the **QExecutor** window (see Figure 7.5).
- The **TeamViewer** window will be displayed, requesting the Operator's identification (User and Password).

NOTE: The User and Password are not those required to Login the instrument, but those requiered to Login the intranet.

NOTE: A window reporting that there is no connection with the server could be displayed after the identification step. If this is the case, make sure that the analyzer is properly connected to the intranet and then press **Retry** until the **TeamViewer** window with the ID and the Password of the instrument appear.

- Once the Operator has been identified, a window with the ID of the instrument and a 4-digits Password will be displayed.

NOTE: This process could take a while, please wait until the information window shown in Figure 7.4 is displayed.

Figure 7.4. TeamViewer Instrument ID and Password

- Provide the ID and the Password displayed to the Technical Service personnel, so that they can set the remote connexion up.
- Once the connection is set up, a **TeamViewer pop-up** window will appear at the lower right corner of the screen which offers the Operator several options to communicate with the Technical Service personnel (audio, message), if it is required (see Figure 7.5). From that moment on, the service personnel can perform the intervention in the instrument.

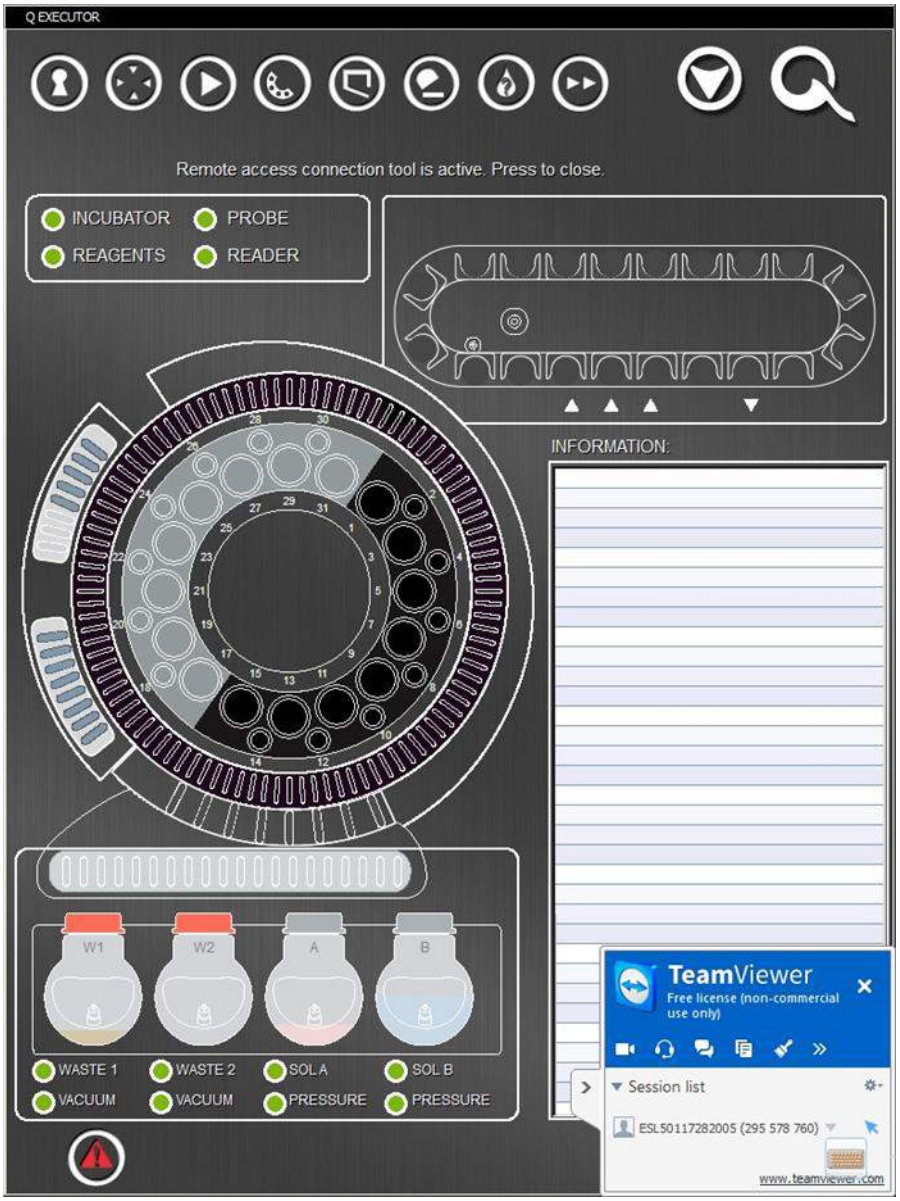


Figure 7.5. TeamViewer Remote Control Window

⚠ **CAUTION:** Do not close the remote connection or manipulate the analyzer during the Technical Service intervention, unless otherwise indicated by the service personnel.

- After the intervention, the Technical Service will close the connection and a message to inform the Operator that the connection has finished will be displayed. Press **Accept** to close the connection.

NOTE: If the Operator has to perform any additional action or restart the instrument before continuing to work, the Technical Service will notify it to the Operator during or after finalizing the intervention.

- Once the connection has finished, the Operator has two possibilities:
  - Initialize the instrument to continue working, by pressing the **ON** button ().
  - Turn off the analyzer by pressing the **Start/Stop** button of the screen.

7.3 Setup

The **Setup** option allows setting different options or configurations for the analyzer. Figure 7.6 shows the **Setup** window.

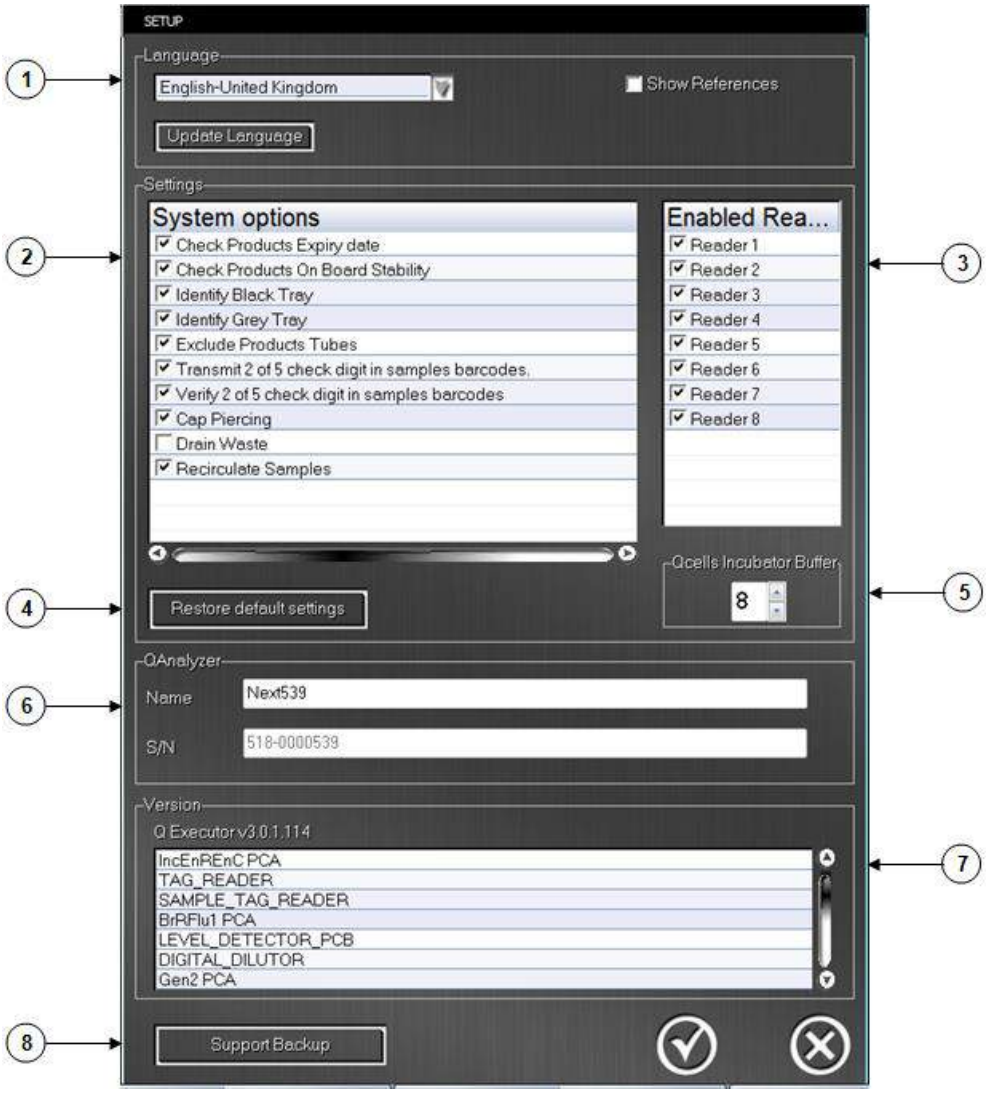


Figure 7.6. Setup Window

(1) Language Selection and Updating.

(2) System options.

(3) Readers selection.

(4) Restore default settings.

(5) Qcells Incubator buffer.

(6) Analyzer identification.

(7) Information on versions of submodules of the QNext program.

(8) Backup for support.

7.3.1 Language Selection and Updating

It allows changing the Q software language. After changing the language, a restart of the analyzer is required to update all system language.

In the Q Analyzers, the different software languages are defined in a language file called "**Lang.db**". The Q software language file version can be updated using an external **USB data storage device**.

When a new Q software language file version is released, it is recommended to update the instrument with the last version of this file. To install it, the Operator should proceed as follows:

- Save the new Language file version into an external **USB data storage device**.

CAUTION: Do not modify the name of the Language file, otherwise the analyzer will not be able to recognize it.

- Go to **QExecutor** window, **Other Options** (), **Setup** and press on the **Update Language** button (Figure 7.6, no 1).
- The program asks the Operator to introduce the USB in one of the analyzer's USB ports. Connect the USB and press **Accept**.

CAUTION: To protect the data of the software, the **USB data storage device** used to update the language version, should be previously scanned to ensure that the device is Virus Free.

NOTE: The detection of the **USB data storage** device could take a while.

NOTE: The program automatically detects the language file present in the USB, there is no need to browse it.

- The analyzer informs the Operator about the **New Version** number and the **Current Version** number of the language file. It also asks the Operator to select which software language desires to establish by default.
- Select the desired default language and press **Accept** to start the new software language version installation.
- A message informing the Operator that the installation has been completed appears. Press **Accept** and restart the analyzer to apply the changes.

NOTE: The software language version can also be updated from the **QManager Setup** window (see Section 9.11.1).

When the software language version is updated by means of one of the two options, the whole software (**QManager** and **QExecutor** programs) is updated.

NOTE: The language file version installed in the instrument can be found both, in the **QManager** and **QExecutor Setup** windows, in the **Version** sections (see Figures 7.6, no. 7 and 9.37, respectively).

7.3.2 System Options

Allows different options of the analyzer to be selected:

CAUTION: The Q**Next** is configured by the manufacturer with all options enabled by default, except the "Drain Waste" option. Disabling some of them means that the equipment is working under non-manufacturer recommended conditions.

- **Check Products Expiry date:** By enabling this option, the analyzer will not work with expired products.
- **Check Products On Board Stability:** By enabling this option, the analyzer will not work with products that have exceeded the on board stability programmed (see Section 9.1.1).
- **Identify Black Tray:** It allows enabling the products automatic identification to read the barcodes of the Products located in the Black Tray. If working without barcodes, this option can be disabled so that identification of products goes faster.
- **Identify Grey Tray:** It allows enabling the products automatic identification to read the barcodes of the Products located in the Grey Tray. If working without barcodes or if only the **Black Products Tray** is used, this option can be disabled so that identification of products goes faster.

- **Exclude Products Tubes:** It disables the barcode reading of the tube positions in the Products Trays, so that automatic identification of products goes faster.
- **Transmit 2 of 5 check digit in samples barcodes:** When this option is disabled, the checksum (last digit) of samples with Interleaved 2 of 5 barcode will not be transmitted (*e.g.* the checksum will not be shown in the **Worksheet**, but only the sample's ID).
- **Verify 2 of 5 check digit in samples barcodes:** When this option is disabled, the checksum of samples with Interleaved 2 of 5 barcodes will not be checked.

NOTE: This option should only be disabled when using samples barcodes without checksum.

- **Cap Piercing:** It enables the cap piercing system for sample tubes.

CAUTION: If **Cap Piercing** option is disabled, remove container caps before inserting samples in the Q**Next**.

CAUTION: The use of capped sample tubes with the sample tube **Cap Piercing** option disabled may lead to errors in the results.

- **Drain Waste:** This option allows the Operator to configure the analyzer for the automatic emptying of the Waste Bottles when selecting the **Waste Draining** option in the **User Maintenance Options** menu of the Q**Executor Other Options** menu (see Section 7.2.5).
- **Recirculate Samples:** This option prevents a sample being released to the Delivery Area when it still has pending orders, such as Reflex Testing, repetitions, etc.

7.3.3 Readers Selection

Allows the Operator to select and enable which reading channels will be used. First select the readers and then press **Accept**. This option is configured with all reading channels enabled by default.

7.3.4 Restore Default Settings

It allows the Operator to restore the default settings recommended by the manufacturer, which includes the System options, the Readers selection and the **Qcells** Incubator buffer.

7.3.5 Qcells Incubator Buffer

It allows the Operator to indicate the number of **Qcells** cuvettes that the analyzer should keep in the Incubator carroussel for thermostatization. This option is configured with 8 cuvettes by default.

7.3.6 Analyzer Identification

It is possible to define a **Name** for the Q**Next**. In case of connecting more than one analyzer to a same Q**Manager**, this will be the **Name** that will allow traceability of results by analyzer.

The Serial Number in the **S/N** field appears automatically.

7.3.7 Submodules Version

The program indicates the version number of the various submodules of the Q**Next** program which relate to its operation.

7.3.8 Support Backup

The Q**Next** software has an option called **Support Backup** that allows the Operator or Qualified Personnel to do a backup with software files, logs and results considered relevant for investigation of possible problems. To do this **Support Backup**, proceed as follows:

- Connect an external USB data storage device.

NOTE: The detection of the USB data storage device could take a while.

- Go to the Q**Executor** window, **Other Options** menu ( ), **Setup** and press the **Support Backup** button (Figure 7.6, no. 5).
- The analyzer asks the Operator to select the period of time to be included in the Support Backup folder.
- Press **Accept** and the Backup process will be performed. The analyzer will automatically recognise the unit of the USB data storage device and all Support Backup files will be zipped and saved there by default.
- The Support Backup folder is named with the following format: Serial Number_(dd-mm-yyyy){hh-mm-ss}_QBackup.zip.

NOTE: A Support Backup cannot be generated while there are tests in process.

NOTE: Only personnel from Diagnostic Grifols, S.A. have the password to unzip the Support Backup folder.

7.4 Technical Options

The **Technical Options** menu provides access to the **Technical Service** menu of the Q**Next**, amongst others.

This menu is password-protected and should only be used by Qualified Personnel.

The description of the options on the **Technical Options** menu is not included in these Instructions for Use.

8 QManager

NOTE: The information contained in these Instructions for Use refers to version 3.0.1 of the Q**Next** program.

NOTE: The products appearing on the screens in these Instructions for Use are merely given as examples.

If the program displays the Q**Executor** window, select the  button to access the main Q**Manager** window.

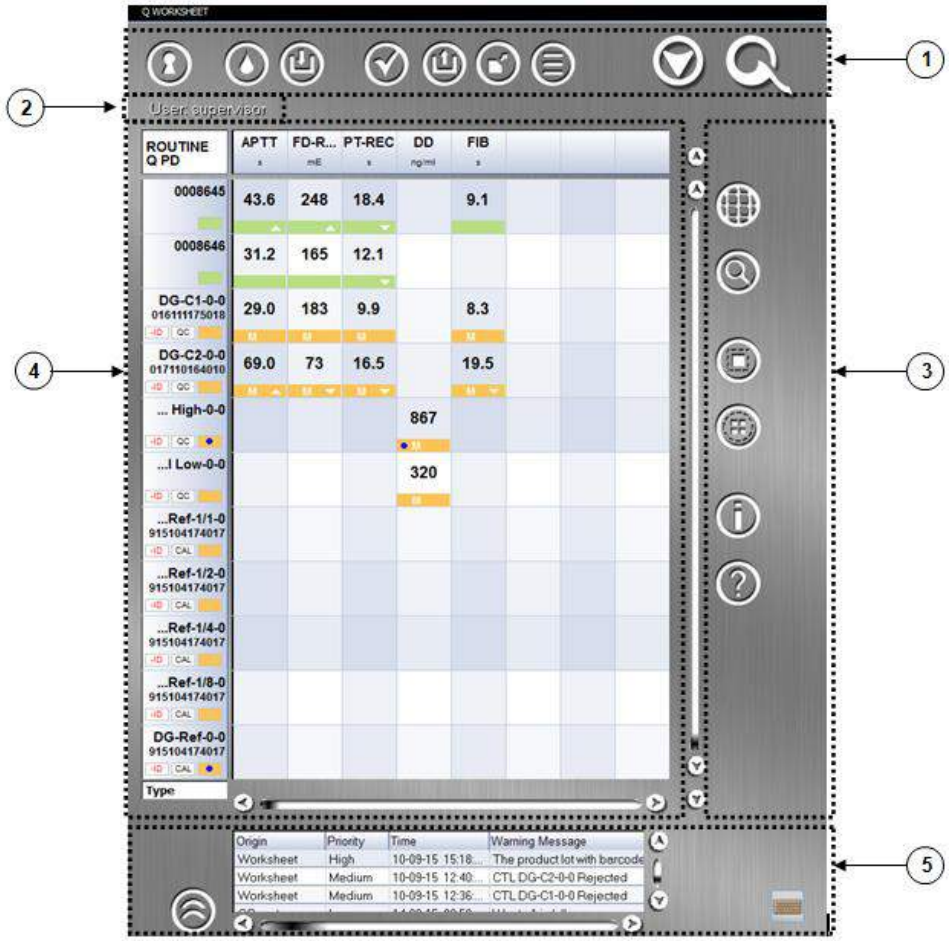


Figure 8.1. QManager Window

(1) **Action Buttons Area:** Includes the buttons normally used to manage the sample routine and results. The window also has a button for accessing the Q**Executor** window.

(2) **User Information Area:** Shows the username of the Operator logged in.

(3) **Other action buttons:** Includes the buttons which relate to search and query actions.

(4) **Worksheet Area:** This is a table listing the samples, the tests, the orders and the results.

(5) **System Alerts Area:** Notifies alerts and incidents created by the system which the Operator must solve.

8.1 Action Buttons Area

Figure 8.2 shows the Action Buttons Area in the Q**Manager** window. It contains the following buttons:

Figure 8.2. Action Buttons Area

Login/Logout: Operator Identification button (see Section 6.1).

New Sample: Button for manual sample identification. The program displays the **New Sample** window and allows Sample ID, Patient ID, the Ward requesting the analysis to be associated with it, and indicating if it is an STAT sample by means of a checkbox.

Import Orders: Button for importing all samples with pending orders from the LIS.

Review: After selecting the corresponding boxes for a series of samples, this button allows them to be tagged as reviewed with previous confirmation. Depending on the analyzer configuration (see Section 9.11.2), they can be exported to LIS at a later time.

Export Results: Button for exporting the result of the selected orders to the LIS.

File Results: After selecting a series of samples, this button removes the selected samples and their results (including reading curves) from the **Worksheet** and sends them to a **Temporary Database**. The results are later sent to a **Historical Database** (see Section 9.11.6).

Reports: This button provides access to the **Reports** window from which results reports from the **Worksheet** or the **Historical Database** can be obtained and printed out.

More Options: Button for accessing to additional programming options: **Profiles**, **Tests**, **Products**, **Products Layouts**, **Quality Control**, **Reflex Testing**, Q **Analyzers**, **Calibrations**, **Reports**, **Users** and **Setup**.

Access to Q**Executor:** Button which allows the Operator to access the Q**Executor** window.

8.2 User Information Area

Located in the top, left-hand corner, it provides information on which operator is logged into the Q**Manager** window (Figure 8.1, no.2).

8.3 Worksheet Area

Area in the Q**Manager** window where the tests, the samples for processing and the orders are listed. Once the samples have been processed, the program compiles the results in the corresponding interactive boxes.

Two scroll bars, one vertical and another horizontal, facilitate browsing in the **Worksheet**. Press the finger on the bar and drag towards the sides.

There are also buttons for scrolling to the top and bottom of the **Worksheet**. To go up or down a page, press on the scroll bar.

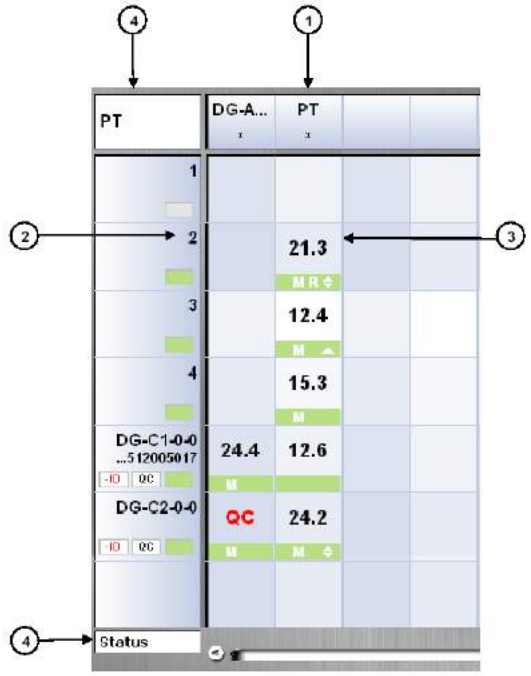


Figure 8.3. Worksheet

(1) Tests Boxes.

(2) Sample Boxes.

(3) Results Boxes.

(4) Information on Filters and Sample sorting.

8.3.1 Tests Boxes

Tests are displayed on the horizontal axis of the **Worksheet** (Figure 8.3, no. 1). The Tests Profiles which have been preselected in the **Filters** window are displayed (see Section 8.3.4).

NOTE: The order of the tests on the **Worksheet** is as shown in the **Tests** window (see Section 9.2). The change of the order of the Tests must be done in this window.

The Test Box contains the following information:

- **Name:** 6-digit label which the Operator allocates to a specific test in the **New Test** window (see Section 9.2.1).

NOTE: To identify the Tests properly, an appropriate label should be applied when programming the test, bearing in mind that the maximum length is 6 digits.

- **Measurement unit:** The default unit is selected in the **New Test** window (Figure 9.6, no. 6, Figure 9.11, no. 4 and Figure 9.13, no. 3).

NOTE: To modify the units displayed, press the corresponding Test Box. The program will display a list of the units available for this test, according to its programming. The selection of a specific unit automatically recalculates all the results in the **Worksheet** which refer to this test, using the recently-selected unit of measurement.

Keeping pressed a Test Box for a few seconds causes the program to show a drop-down menu with the following options:

- **Order tests:** This option allocates the test to all the samples available on the **Worksheet**.
- **Clear orders:** This option cancels the allocation of all the orders of this test to all the samples available in the **Worksheet**.
- **Uncancel orders:** This option uncancels the test for all the samples for which the analyzer had cancelled it.
- **Recalculate results:** This option recalculates the already checked or exported non primary results of all the samples for which this particular test has been finished using the last Calibration Curve, the last validated Standard value or the last ISI value entered. Then, the

sample changes its status to "Finished" and has to be reviewed and/or exported again (see Section 8.3.2). Non reviewed results are automatically recalculated.

- **Repeat tests:** This option allocates a repetition of the test to all the samples in the **Worksheet** which had already been analyzed using this test.
- **Standard (STD):** This option allows the order of a Standard to be manually allocated to a test in the **Worksheet**. The **Standard (STD) Order** window appears and the Operator can choose between a **Commercial Standard** (Product) programmed in the **Products** window, or a **Population Standard** (see Section 10.2.1).
- **Calibrator (CAL):** This option allows placing an order of a Calibration Curve for the test that will be performed with one Calibrator and a diluent to obtain different dilution points. The **Calibrator (CAL) Order** window is displayed and the Operator can choose the Calibrator, the diluent and program the different dilution points that will be automatically performed by the analyzer (see Section 10.1.1.1).
- **Independent Calibrators:** This option allows placing an order of a Calibration Curve for the test that will be performed with several Independent Calibrators that have different levels. The **Calibrator (CAL) Order** window is displayed and the Operator can choose the different Calibrators (see Section 10.1.1.2).
- **Control (QC):** This option allows the Operator to manually order a control for the test. The **Control (QC) Order** window is displayed and the Operator can select the Control lot.

8.3.2 Samples Boxes

Samples are displayed on the vertical axis of the **Worksheet** (Figure 8.3, no. 2). The Sample Box also contains the following information:

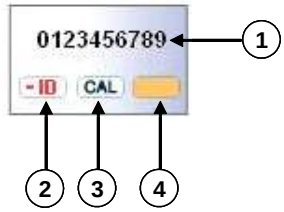


Figure 8.4. Sample Box

(1) **Sample ID:** This field can hold up to 24 alphanumeric characters to show the sample ID.

NOTE: To change the details of a sample, keep the finger on the corresponding Sample Box. The program will display the **Edit Sample** window for editing sample, patient or ward ID's and to indicate if it is an STAT sample by means of a checkbox. The Sample ID and Patient ID can only be modified when the sample has not yet been processed.

(2) **ID indicator:** This field provides information on the type of sample identification performed.

- **ID:** Manual identification.

If the sample has a barcode and thus positive ID, the field (+ID) does not appear.

NOTE: The program allows any sample to be edited before processing, regardless of how it has been identified.

(3) **Special samples indicator:** This field indicates whether it is a special sample and what type it is:

- **QC:** Control.
- **CAL:** Calibrator.
- **STD:** Standard.
- **STAT:** STAT sample.

(4) **Sample Status:** The program displays a colour-coded status of the samples.

Blue	Sample with orders still to be processed.
Light grey	Sample with orders being processed. To help identify the requests being processed, the centre of the box displays an ellipsis (…).
Dark grey	Sample with all orders cancelled. To help identify the requests which have been cancelled, the centre of the box displays a red cross (X).
Green	Sample with all orders finished.
Orange	Sample with all results of all the orders reviewed.
Pink	Sample with all results of all the orders exported to the LIS.

NOTE: When a sample has several tests allocated, the colour-coding of the sample refers to the status of the last test in the series.

Keeping pressed a Sample Box for a few seconds causes the program to show a drop-down menu with the following options:

- **Edit sample:** Use this option to modify the sample, patient or ward ID and to indicate if it is an STAT sample by means of a checkbox.
- **Order tests:** This option allocates all the tests available on the analyzer **Worksheet** to this sample.
- **Clear orders:** This option cancels all the tests previously allocated to this sample.

- **Uncancel orders:** This option allocates the petitions whose tests have been cancelled previously by the analyzer to the sample.
- **Recalculate results:** This option recalculates the already reviewed or exported non primary results of all the tests performed to a sample using the last Calibration Curve, the last validated standard value or the last ISI value entered. Then the sample status changes to finished and has to be reviewed and/or exported again (see Section 8.3.2). Non reviewed results are automatically recalculated.
- **Repeat tests:** This option allocates a repetition of the tests analyzed previously to the sample.
- **File:** Equivalent to the **File Results** button, this option sends the sample and the associated results to a **Temporary Database**, prior to sending them to the **Historical Database**, and eliminates the sample from the **Worksheet**. The data from the **Temporary Database** can be recovered by pressing the **New Sample** button and re-entering the sample ID. The program recovers the sample, its orders and results (primary result and concentrations or activities). Results sent to the **Historical Database** are recovered through the **Reports** option.
- **Review:** Equivalent to the **Review** button, this option tags the results of all the tests associated with this sample as reviewed (orange).
- **Export:** Equivalent to the **Export Results** button, this option allows all the results associated with the sample and which have been reviewed to be exported to the LIS.
- **Control (QC):** Allows a control to be entered for each of the tests available on the values table.

8.3.3 Results Boxes

Once all the orders for a sample, Calibrator (CAL), Control (QC), Standard (STD) or STAT sample have been processed, the results are displayed in the corresponding box intersecting with a specific test on the **Worksheet** itself (Figure 8.3, no. 3).

The Results Box may contain the information displayed in Figure 8.5.

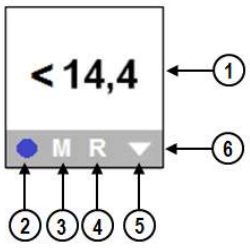


Figure 8.5. Results Box

(1) **Result:** The result will be displayed in numeric characters. The program may also display:

- **CND:** Clot Not Detected (in clotting tests). The algorithm applied has not been able to detect a clot in the primary curve (see Section 9.2.2.5).
- **LIN:** Lack of Linearity (in chromogenic tests). The algorithm applied has failed while checking the linearity of the primary curve (see Section 9.2.2.5).
- **OUT:** An absorbance value of the primary curve is out of the reader's working range (see Section 9.2.2.5).
- **IND:** Indeterminate result. It is impossible to calculate the result due to lack of data (Calibration Curve, Standard, ISI, etc.) or because the results of a Repetition have not been reviewed or due to an irregular entrance of the Q**cell** cuvette in the reader (see Section 9.2.2.5).
- **CV:** The Coefficient of Variation of duplicates (CVd) has exceeded the CV allowed in the Test Programming (Figure 9.6, no. 7 and Figure 9.11, no. 5).
- **PAR:** Some parallelism acceptance criterion (regression coefficient and/or slopes ratio) of a test with parallelism has failed (Figure 9.10, no. 3).
- **X:** Cancelled test.
- **Less (<) and Greater (>) than symbols:** Indicate that the result is less or greater than the extrapolation limits defined for the test. The extrapolation limits appear in the Test Programming (Figure 9.6, no.7 and Figure 9.11, no. 5) window.

(2) **Blue dot:** Indicates that there is some warning related to the test performance or with the result (over-incubation, anomalous behaviour in the primary reading curve, etc.). This information appears in the corresponding **Results** window (Figures 13.1, 13.2 and 13.3, no. 4), which is displayed by pressing on the Results Box.

(3) **M:** Indicates that the test has been manually ordered.

(4) **R:** It can indicate three things:

- That it is a Repetition and, therefore, the Operator must reject or confirm the new result.
- That an automatic rerun with an extended Reading Time has been performed (if there is an Alternative Reading Time programmed).
- That an automatic Redilution has been performed.

(5) **Arrows:** Indicate that the result is outside the normal clinical range defined in the test and in which direction it exceeds the margin.

(6) **Colour coding:** Indicates the status of the orders. The criteria for allocating colours are described in Section 8.3.2.

Keeping pressed a Results Box for a few seconds causes the program to show a drop-down menu with the following options:

- **Order tests:** This option allocates one test available in the analyzer **Worksheet** to this sample.
- **Clear orders:** This option cancels one test previously allocated to this sample.

- **Uncancel orders:** This option allocates a test which has been cancelled previously by the analyzer to this sample.
- **Recalculate results:** This option recalculates the already reviewed or exported non primary result of a test performed to a sample using the last Calibration Curve, the last validated Standard value or the last ISI value entered. Then the sample status changes to finished and has to be reviewed and/or exported again (see Section 8.3.2). Non reviewed results are automatically recalculated.
- **Repeat tests:** This option allocates the repetition of a test that has been previously performed to a particular sample.
- **Parallelism - Low**, **Parallelism - High** and/or **Parallelism - Default:** These options only appear for tests with parallelism and if different dilution sets are defined in the Test Programming (see Section 9.2.1.1.1). These options allow selecting the dilution set with which the sample wants to be processed.

8.3.4 Information on Filters and Sample Sorting

The **Worksheet** allows the information there to be filtered and sorted.

In the upper left white box of the **Worksheet** (Figure 8.3, no. 4) there is information on the filter applied to the **Worksheet**. This information can be the name of the visualization **Profile** and/or the selected Q **Analyzer**. This information is shown only if any of the two filter selections is different from the option **Display All**.

When an order of a test that is not on the selected profile arrives, the test is automatically added to the **Worksheet** and the profile name is modified with an asterisk.

The **Samples Sorting** in the **Worksheet** is displayed in the lower left white box of the **Worksheet** (Figure 8.3, no. 4).

8.4 Other Action Buttons

The **Query** and **Selection** buttons located on the right-hand side of the Q**Manager** window are described below:

Filters: Allows the Operator to select which information is to be displayed in the **Worksheet** and in what order.

The program displays a **Filter** window for selecting:

- **Profile filter:** The program only displays the orders associated with the chosen Profile. The order of the tests is as given in the **Tests** window (see Section 9.2).
- Q **Analyzer filter:** The program only displays the orders processed by the selected analyzer.
- **Sample Sorting:** The program allows samples to be sorted:
  - **ABC:** In alphabetical order.

- **Entry:** In chronological order, so that the most recent samples appear in the top.
- **Status:** Pending, processing, etc.
- **Type:** Samples, Standards, Control, etc.

The prioritized samples appear at the top of the **Worksheet** to ease its localization while they are pending or in process except if the samples sorting filter is by entry.

Search for Sample: Allows a specific sample to be searched for and located in the **Worksheet**.

Selection: Allows discrete selection of a series of samples in the **Worksheet**. Once selected, the program allows the results of the selected samples to be Reviewed, Filed, Exported and Printed at the same time.

To do a discrete selection, first press the button, then perform the desired selection and once finished, deselect the button.

Select all: Allows the Operator to select all the samples in the **Worksheet**. Once selected, the program allows the results of the selected samples to be Reviewed, Filed, Exported and Printed at the same time.

Information: Provides information on the number of Samples, Standards, Controls and Calibration Points present in the entire **Worksheet**.

Help: If this button is pressed and held, the program displays a graphical legend informing the Operator of the meaning of the abbreviations and colour codes used in the Sample and Results Boxes, and the meaning of the action buttons described above.

Display Keyboard: For entering alphanumeric characters in fields requiring them, the application has a keyboard which can be accessed by pressing the corresponding button. For more information on how it works, please see Section 6.2.8.

8.5 System Alerts Area

Area intended for displaying all alerts and incidents that the Operator must solve (because they have not been previously solved by the system) and which may arise during normal operation of the Q**Next**. This area displays:

- **Low-priority alerts:** These indicate a certain situation which needs to be considered and/or solved without the Operator being immediately involved, since the operation of the analyzer is not affected at any time. These are recommendations to be carried out at some point but which, if action is not taken, may turn into an incident.
- **Medium-priority alerts:** These warn the Operator of a specific problem which may affect analyzer operation, but which will not block it completely.

- **High-priority alerts:** These normally block the analyzer completely, not like low or medium level alerts. Also, apart from the information displayed in the **System Alerts Area**, the program displays a dialogue box with a red background and an acoustic alert indicating the cause.

Information on the **Origin** (name of the **Instrument** that has generated it, or if it has been the **Worksheet**), the **Priority**, the **Time** (date and time) at which the warning was reported and **Information** with the description of the warning also appear in the **System Alerts Area**.

The program also displays the following action button:

Display alarms: This button extends the display field of the **System Alerts Area**, showing the last 30 alerts which are pending resolution.

9 QManager: Other Options

This chapter provides information on the operations that can be performed from the **Other Options** () menu of the Q**Manager** window. These options are related to **Programming** and **Management**.

The Q**Next** can work with Tests profiles or directly with Tests to configure the **Worksheet**. To program it, please follow this order:

1. Programming of **Products.**
2. Programming of **Tests.**
3. Programming of **Profiles.**
4. Programming of **Reflex Testing.**
5. Programming of **Products Layouts.**

9.1 Products Programming

The **Products**  option on the **Other Options** menu () in the Q**Manager** window allows the Operator to create the lists of products (with Presentation and Lots) required for the various steps of a test.

The **Products** window allows to:

1. **View** the programmed **Products.**
2. **Select** the programmed **Products** that will be displayed in the list of products available to be manually introduced in the Products Trays.
3. Program **New products.**
4. **Edit** existing **products.**
5. **Delete products.**
6. Enter a **New lot** with the barcode (BC).

9.1.1 Programming a New Product

To program a New Product, proceed as described below:

- Press the **Products** option on the **Other Options** () menu in the Q**Manager** window. The program displays the **Products** window with the list of all the products programmed in the analyzer, the type of product (reagent, diluent, Calibrator, etc.) and a check that indicates its availability.

- If the product to be programmed does not appear on the list, press the **New Product**  button. The program offers a drop-down menu with the following options:

- **Reagent:** Any product dispensed in the reaction cuvette after sample's dispensation.
- **Diluent:** Any product used to perform sample's or Calibrator's dilution.
- **Calibrator (CAL):** Type of sample with an assigned value for a test.
- **Standard (STD):** Type of sample used to normalize samples results calculating a **Ratio**.
- **Cleaning agent:** Any product used to perform extra washings of the Probe after dispensing some reagents to avoid carry-over to other tests.
- **Control (QC):** Type of sample with an assigned range for one or several tests used as **Quality Control** of these tests.

9.1.1.1 Programming a New Reagent

To program a New Reagent, select **Reagent**. The **New Reagent** window opens:

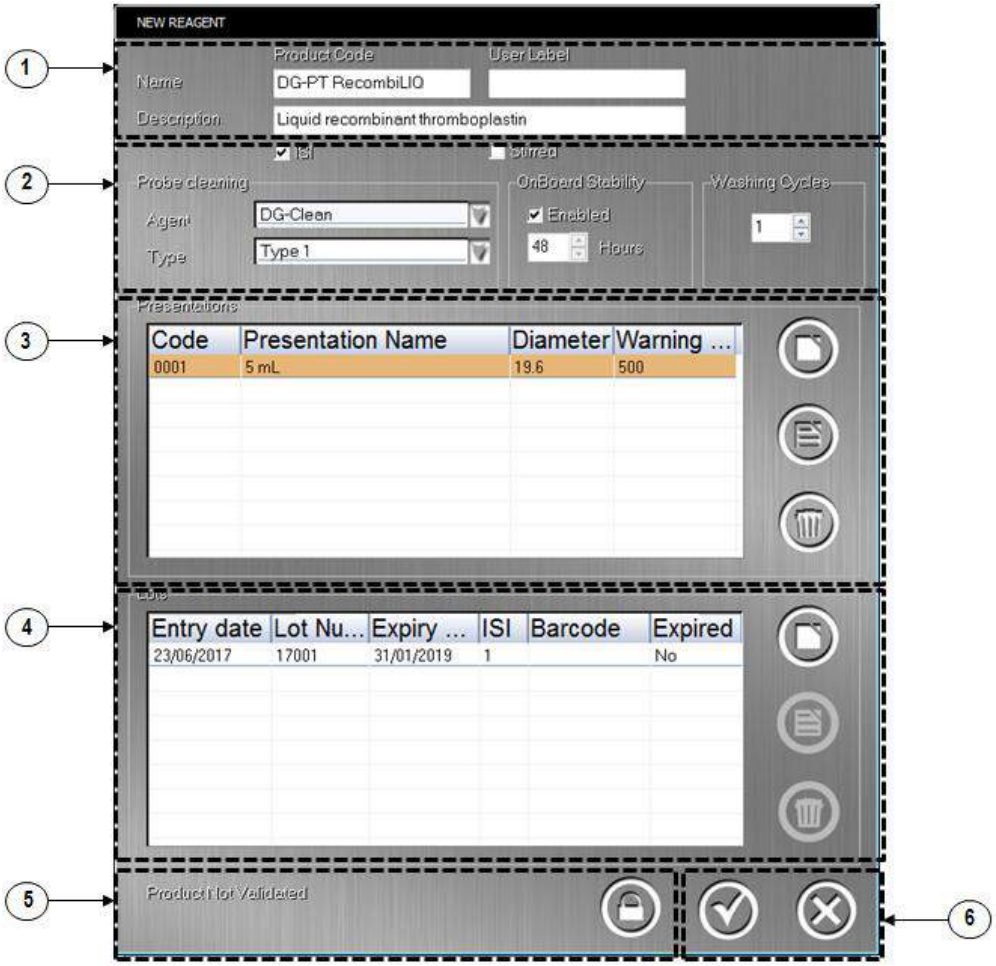


Figure 9.1. New/Edit Reagent Window

In the **New Reagent** window, the following information can be entered:

(1) **Product Identification:** Allows identifying and describing the product. The following parameters can be entered here:

- Product **Name.**
- Product **Description**.
- **User Label:** The name entered in this field will be the one that the program will later display and, therefore, it must be clear and easily identifiable. If this field is not filled in, the name introduced in the **Product Code** field will be used.

(2) **Product Requirements:**

- **ISI:** International Sensitivity Index (applicable for thromboplastin reagents).
- **Stirred:** Allows programming magnetic stirring for the reagent.
- **Probe Cleaning:** Allows programming an additional washing of the Products Probe with a cleaning agent, which will avoid cross-contamination.
- The Operator has to select the appropriate **Cleaning Agent** (previously programmed) and the **Type** of cleaning. There are four types of cleaning available:

Type of Cleaning	Q**Smart**	Q**Next**	Q**Xpert**
Type 1	1 cycle	1 cycle	1 cycle
Type 2	2 cycles	2 cycles	2 cycles
Type 3	2 cycles	2 cycles	1 cycle
Type 4	1 cycle	0 cycles	0 cycles

- **On-Board Stability:** Allows enabling or disabling the monitoring of stability on board the Q**Next**. It is programmed in number of hours and the value must be between 1 and 1000.
- **Washing Cycles** of the Products Probe with diluted **System Solution A** and **System Solution B**. Diluted **System Solution A** is used for the internal washing of the Probe and **System Solution B** for the external one.

(3) **Presentations:** Allows manually creating different vial presentations and entering the following parameters for each of them:

- **Code.**
- **Presentation Name:** Volume (in mL) of the vial presentation.

- **Diameter (mm):** It allows programming a vial internal diameter between 13.5 and 35 mm. The instrument uses this information together with the detected liquid level in the vial to estimate the remaining volume in the vial and the number of determinations that can be performed with it.
- **Warning Volume (µL):** Volume below which the program will notify the Operator the need of adding more product.

Using the  ,  or  buttons, the lists of product presentations can be updated.

NOTE: To obtain correct information about the products estimated volume, it is important to define the vial internal diameter, not the external one.

---

(4) **Lots:** Allows manually programming different reagent lots for each reagent presentation. To do so, select the desired Presentation, press the **New Lot** () button in the **Lots** section and enter the following information:

- **Expiry date.**
- **Lot Number.**
- **Barcode (BC).**
- **International Sensitivity Index (ISI)** (if applicable). By default, the value set in this field is 1.

Using the  ,  or  buttons, the list of product lots can be updated.

NOTE: There is no need of performing this action for GRIFOLS products as this information (presentation, lot number, expiry date and ISI, if any) is contained in GRIFOLS barcodes and the instrument automatically recognizes them as such and uploads the information into the system.

---

(5) **Product Status:** The program indicates whether the product is validated or not and the validation date. A validated product means that the product identification and the requirements cannot be modified.

The  button allows **validating** and **protecting** the product programming so that it cannot be modified.

(6) The action buttons  and  allow the changes to be saved or cancelled, respectively.

To program a new **Diluent, Cleaning agent or Standard (STD)**, please proceed in the same way as described in this section.

9.1.1.2 Programming a New Control

To program a New Control, select **Control (QC)** after pressing  in the **Products Management** window. Then enter the required information in the **New Control (QC)** window (Figure 9.2):

(1) **Product Identification:** Proceed in the same way as when programming a New Reagent (see Section 9.1.1.1).

(2) **Product Requirements:** Proceed in the same way as when programming a New Reagent (see Section 9.1.1.1).

(3) **Presentations:** Proceed in the same way as when programming a New Reagent (see Section 9.1.1.1).

(4) **Lots:** Proceed in the same way as when programming a New Reagent (see Section 9.1.1.1).

To manually enter the Values Table for a Control lot, press **Values Table** in the **New Lot** window. The program displays the window shown in Figure 9.2:

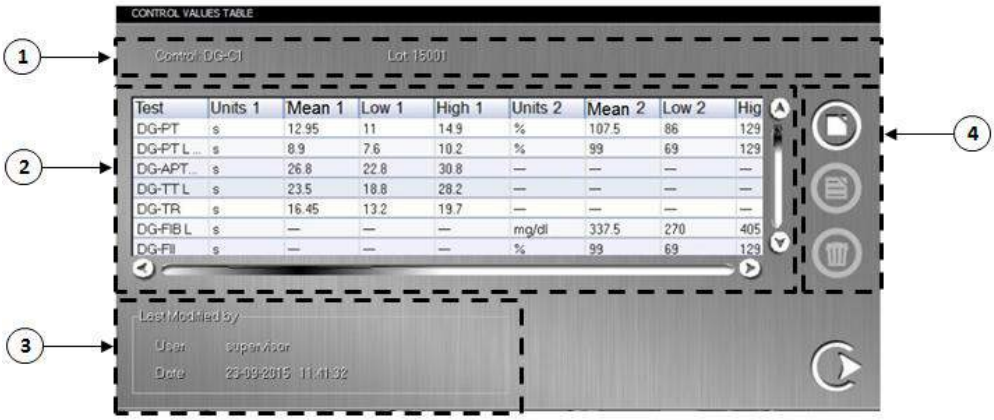


Figure 9.2. Control Values Table Window

(1) Description of the Control and the lot.

(2) Control Values Table.

(3) General information of the Control Values Table.

(4) Action buttons.

- **New:** It allows choosing a new test for which the Control values want to be entered. When this option is pressed, it appears the **Edit Control Values Table** window (Figure 9.3). This window shows fields in a table layout which allow entering, for the measuring unit and for

each unit of concentration or activity, the **Mean** of the corresponding control and the acceptable range (**low** and **high limit**). It is possible to enter Control values for more than one test.

- **Edit:** The **Edit Control Values Table** window (Figure 9.3) also appears when this button ( ) is pressed.
- **Delete:** It allows modifying the assignment of tests to this particular control.

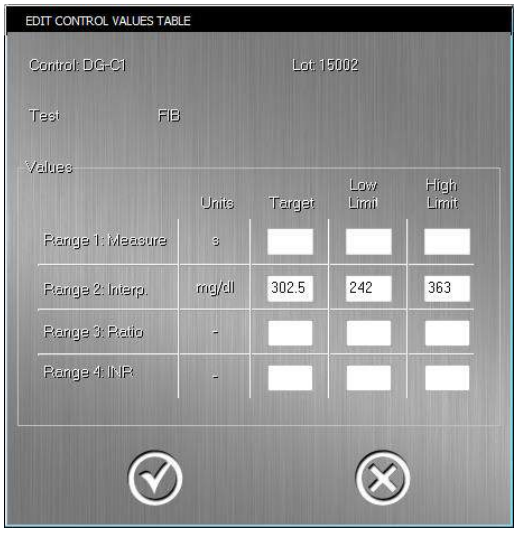


Figure 9.3. Edit Control Values Table Window

Press **Accept** in the successive windows to access again the **New Control (QC)** window.

Using the , , or buttons, the lists of Control lots can be updated.

There is also the possibility of entering the Values Tables for each lot of GRIFOLS Controls (**DG-C1** and **DG-C2**) automatically by means of the importation of the corresponding "**.ieq**" file (*e.g.* "**DG-C1 17001.ieq**"), which will be distributed by the authorized service representative in your country (see Section 9.11.3 for information on how to import an **.ieg** file).

(5) **Product Status:** Same as for New Reagent (see Section 9.1.1.1).

The button allows **validating** and **protecting** the control programming so that it cannot be later modified. However, the **Values Table** of the Control will remain editable so that it can be updated.

(6) The action buttons and allow the changes to be saved or cancelled, respectively.

9.1.1.3 Programming a New Calibrator

To program a New Calibrator, select **Calibrator (CAL)** after pressing  in the **Products Management** window. Then enter the required information in the **New Calibrator (CAL)** window (Figure 9.1):

(1) **Product Identification:** Proceed in the same way as when programming a New Reagent (see Section 9.1.1.1).

(2) **Product Requirements:** Proceed in the same way as when programming a New Reagent (see Section 9.1.1.1).

(3) **Presentations:** Proceed in the same way as when programming a New Reagent (see Section 9.1.1.1).

(4) **Lots:** Proceed in the same way as when programming a New Reagent (see Section 9.1.1.1).

To manually enter the Values Table for a Calibrator lot, press **Values Table** in the **New Lot** window. The program displays the window shown in Figure 9.4.

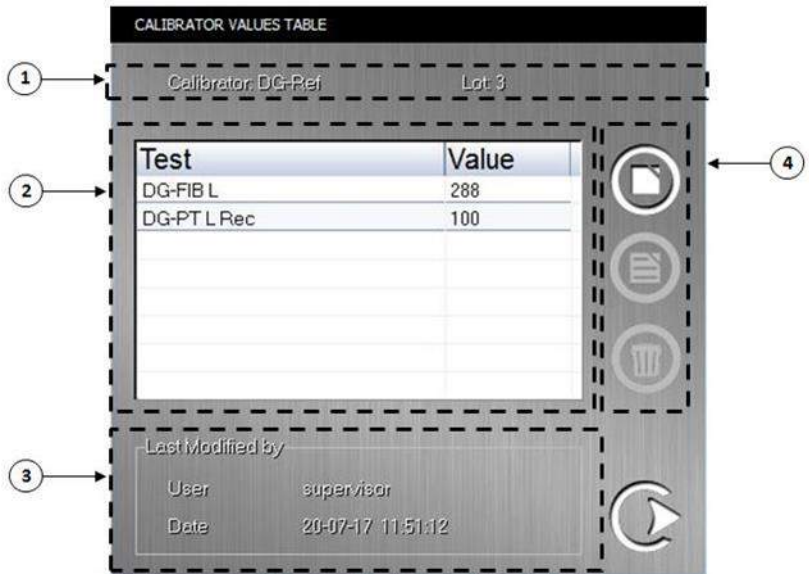


Figure 9.4. Calibrator Values Table Window

(1) Description of the Calibrator and the lot.

(2) Calibrator Values Table.

(3) General information of the Calibrator Values Table.

(4) Action buttons.

- **New:** When pressing the button, the **Edit Calibrator Values Table** window appears (Figure 9.5), which allows choosing the tests for which the Calibrator values want to be entered.
- **Edit:** The **Edit Calibrator Values Table** window (Figure 9.5) also appears when this button ( ) is pressed allowing the modification of the Calibrator values for the selected test.
- **Delete:** It allows deleting the Calibrator values for the selected test.

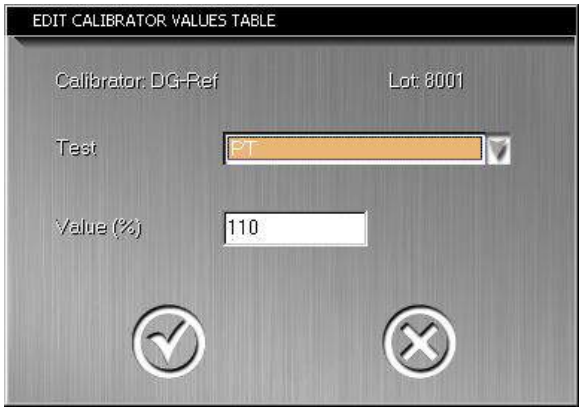


Figure 9.5. Edit Calibrator Values Table Window

Press **Accept** in the successive windows to access again the **New Calibrator (CAL)** window.

Using the , or buttons, the list of Calibrator lots can be updated.

There is also the possibility of entering the values tables for each lot of GRIFOLS Calibrator (**DG-Ref**) automatically by means of the importation of the corresponding "**.ieq**" file (*e.g.* "**DG-Ref 17001.ieq**"), which will be distributed by the authorized service representative in your country (see Section 9.11.3 for information on how to import an **.ieg** file).

(5) **Product Status:** Same as for New Reagent (see Section 9.1.1.1).

The button allows **validating** and **protecting** the Calibrator programming so that it cannot be later modified. However, the **Calibrator Values Table** will remain editable so that it can be updated.

(6) The action buttons and allow the changes to be saved or cancelled, respectively.

9.1.2 Programming a New Presentation or Lot

To program a **New Presentation** or a **New Lot** of a previously-programmed Product, please proceed as described below:

- Select the Product in question in the **Products** window and then press  . The program will display the **Edit Product** window which allows the desired parameters to be entered.
- To program a New Presentation, press  and enter the information requested by the program.
- To program a New Lot, select the corresponding Presentation and press  in the **Lots** section. Enter the corresponding details, as described in Section 9.1.1.1.

9.1.3 Editing the Settings of a Programmed Product

To modify the settings of a previously-programmed Product, select the product in the **Products Management** window and press the  button. The program will display the **Edit Product** window which will allow the desired parameters to be modified. To modify the parameters associated with a specific **Presentation** or **Lot**, select them from the corresponding list and press  . We can also Delete a Product, Presentation or Lot by pressing  .

If product programming is protected (), the program will only allow the parameters associated with the **Lot** and the **Presentation** to be modified.

9.2 Tests Programming

The **Tests** () option on the **Other Options** () menu in the **QManager** window causes the program to display the tests programmed into the analyzer and that are available in the **Worksheet** in the order in which they appear in the **Tests Management** window.

NOTE: To change the order in which the tests are displayed, select the corresponding test and, using the arrows (⇧⇩) located next to the progress bar, move the tests up or down until the desired level.

The **Tests** window also allows the Operator to:

- Programming **New tests**.
- **Edit** existing **tests**.
- **Delete tests**.

- **Copy tests**.
- **Restart counter**.

9.2.1 Programming a New Test

To program a new test, please proceed as follows:

- When **Tests** option is pressed on the  menu of the Q**Manager**, the **Tests Management** window displays the list of all the tests programmed in the analyzer to date.
- To program a new test, press the **New Test** () button. The program offers a drop-down menu with the following options, to be selected as required:
  - **Normal:** Test that is processed and generates primary results.
  - **Derived:** Test that consists in applying a different mathematical algorithm to the primary result obtained with a Normal Test.
  - **Combined:** Test which, using a mathematical calculation, can relate the results obtained with two Normal or Derived Tests.

9.2.1.1 Programming Normal Tests

To program a common test, select **Normal** after pressing  in the **Tests** window. The **New Normal Test** window has two tabs available: **Test Programming** and **Test Characteristics**.

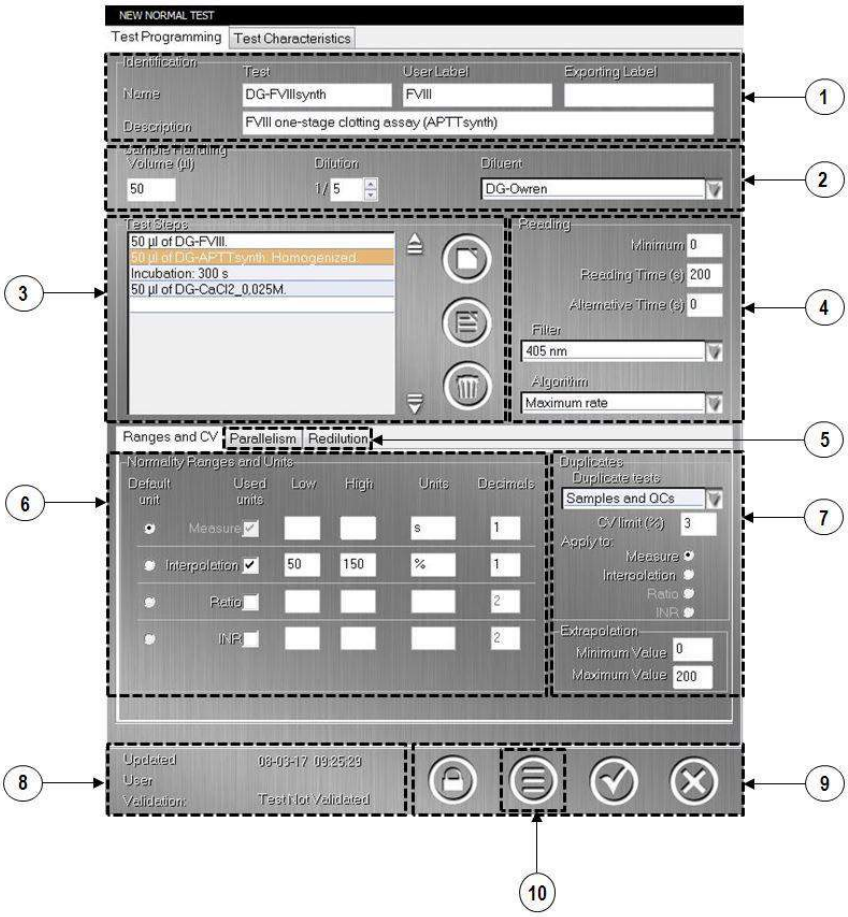


Figure 9.6. New/Edit Normal Test Window (Programming Tab)

In the **Test Programming** tab, enter all the information for:

(1) **Test Identification:** Information which allows the test to be identified and described. The following parameters are entered here:

- Test **Name.**

NOTE: The following symbols can not be introduced in the Test **Name**: *, |, :, ?, <, >, /, ".

- Test **Description**.
- **User Label:** Field which allows a label to be entered to make the test easily identifiable to the Operator, particularly with validated tests. The maximum length is 6 digits.
- **Exporting Label:** Field which allows a label to be entered to allow the LIS to identify the test.

(2) **Preparing the Sample:** This window allows the Operator to program:

- The final Sample **Volume** (diluted or not) to be dispensed in the Q**cell** cuvette: Value between 10 and 150 µL.
- Sample **Dilution:** Value between 1/1 and 1/200.
- **Diluent** used to carry out the sample dilution (it has to be previously programmed in the **Products Management** window, see Section 9.1.1.1).

(3) **Steps in the Test:** This part of the window displays two buttons with the possible steps to be performed during a test execution (**Reagent's** dispensation and **Incubation**) and, on the left, a box with the sequence of programmed steps.

The different steps can be entered in chronological order by means of the arrows located on the right side of the box containing the sequence. When performing the test, the sequence of steps will be executed from top to bottom.

The steps have definable parameters, which should be defined when they are added to the sequence. Once added, they can be modified by selecting the step in question and pressing the **Edit** ( ) button.

- **Reagent:** Allows the selection of the **Reagent** (see Section 9.1.1), defining the **Volume** to be dispensed (value between 25 and 250 µL) and **Homogenization** of the reagent with the sample can be enabled.

  Three options of homogenization exist:

  - **None:** The reagent is dispensed in the cuvette where the sample is.
  - **Normal:** The reaction mixture (sample and reagents) is aspired and dispensed altogether.
  - **Extra:** The reaction mixture is aspired and dispensed altogether and then 3 extra homogenization cycles are performed.

  If the product is not on the list, the program allows the new product to be programmed via the button which accesses the **New Reagent** window (see Section 9.1.1).

- **Incubation:** Allows **Time** (value between 0-3600 seconds) and **Tolerance** (value between 0-100 seconds) to be entered. After this time (incubation + tolerance), overincubation will be considered to have occurred.

To delete a programmed step, select it and press the **Delete** button.

(4) **Reading:** Allows the parameters for Reading to be entered.

- **Minimum Time:** Time (in seconds) below which no clotting time is expected. Clotting time is the total time elapsed from the time the starter reagent is added to clotting point, regardless of the Minimum Time programmed.
- **Reading Time:** Period of time during which the reaction is monitored (value between 15-420 seconds).
- **Alternative Time:** Establishing this parameter allows the analyzer to automatically program a rerun with an extended Reading Time when the instrument is not able to give a result with the **Reading Time**. The **Alternative Time** (value between 15-420 seconds) must be higher or equal to the **Reading Time**.

  It works as follows: The instrument will perform the test reading until the **Reading Time** programmed and, if it is not able to give a result, it will automatically repeat the test (new sample and reagents pipettig) reading until the **Alternative Time** programmed. For example, this is useful when the sample clotting time is too long and/or no clot has been detected (CND).

  If the analyzer has the **Recirculate Samples** option enabled (see Section 7.3.2), it will automatically perform the rerun because the sample has pending orders and so, keeps it in the Recirculation Area until all orders are finished. Otherwise, it will be necessary to introduce again the sample into the Samples Entry Area.

NOTE: If the **Alternative Time** is programmed as 0, no automatic repetitions are performed.

- **Algorithm:** Mathematical processing applied to the absorbance-time curve to obtain a parameter that characterises it and allows providing a result. Selecting one algorithm or another will depend on each test (see Section 9.2.2).
- **Wavelength:** Allows selecting the wavelength at which the reading wants to be performed (see Section 4.2.7). There are 3 available options:
  - **405 nm**.
  - **620 nm**.
  - **405 nm + 620 nm:** Option for programming tests with simultaneous reading at 405 nm and 620 nm (bi-chromatic tests).

  This option allows providing a result at 620 nm when it is not possible to give a result at 405 nm because the absorbance values of the primary curve are too high.

NOTE: When a sample result has been obtained at 620 nm because at 405 nm has not been possible, the following warning will appear in the Incidents Area of the corresponding results window (Figure 13.1, no. 4): "Sample with possible interfering substance. Check sample conditions."

NOTE: For Derived Fibrinogen Test programmed at 405 + 620 nm, as this test is based on an estimation of the fibrinogen concentration from the absorbance increase that occurs due to clot formation, when it is not possible to provide a result at 405 nm and as it is not correct to provide a result at 620 nm, the following warning will appear in the Incidents Area of the corresponding results window (Figure 13.1, no. 4): "CND: Sample with possible interfering substance. Re-run the sample by a Clauss Fibrinogen test."

(5) **Parallelism** and **Redilution** programming described in Sections 9.2.1.1.1 and 9.2.1.1.2, respectively.

NOTE: To program **Parallelism** or **Redilution**, the test must have a sample **diluent** programmed (Figure 9.6, no. 2).

NOTE: Parallelism and **Redilution** options cannot be programmed in the same test at the same time.

(6) **Normality Ranges and Units:** Allows the Operator to enter the normality ranges (**High** and **Low**) and a label for each working **Unit: Measure** (primary unit provided by the algorithm), **Interpolation** (secondary unit after interpolating/extrapolating in a Calibration Curve), **Ratio** (secondary unit obtained after having run a Standard) or **INR** (secondary unit for PT tests, obtained after having run a Standard and with the ISI value). It is also possible to define the number of **decimals** (from 0 to 6) with which the results will be shown.

(7) **Duplicates** and **Extrapolation Values:** Allows activating the possibility of programming **Duplicated tests** for samples and/or Controls (QC) as well as the acceptance criteria in relation to the Coefficient of Variation (**CV**) for the chosen working unit (**Measure**, **Interpolation**, **Ratio** or **INR**). There are 3 available options:

- **None:** Both samples and QCs will be run per single.
- **QCs:** QCs will be run per duplicate and samples per single.
- **Samples and QCs:** Both samples and QCs will be run per duplicate.

It also allows programming a **Minimum** and **Maximum Value** of permitted **Extrapolation** from the Calibration Curve. These are also used as redilution conditions to program a different dilution (higher or lower) so that the sample result obtained falls in the measuring range of the test (see Section 9.2.1.1.2).

CAUTION: The Extrapolation Minimum and Maximum Values should never be considered as the Limits of Quantification of a test, specially when **Redilution** or **Parallelism** options are programmed. The Limits of Quantification obtained during the test validation, which can be found in the **Test Characteristics** tab, must be considered to ensure that no sample result is validated outside the test measuring range.

NOTE: Given that the Calibrators (CAL), Standards (STD) and Repetitions are always processed per duplicate, a CV value must be entered, even if the test is processed per single.

NOTE: When **Redilution** is programmed in a Test, and a rediluted sample result is obtained for this test, the software internally corrects the Extrapolation Minimum and Maximum Values by the defined dilution factor, *e.g.* if a test has a 1/2 Redilution and a Maximum Extrapolation Value of 2000 programmed, the Maximum Extrapolation Value considered for a rediluted sample, in this case, will be 4000.

(8) **Test Status Information:** The program indicates whether the test is validated and, if so, the Operator who performed the **Validation** and in which **Date**. The **Date of modification** of the test is also provided.

(9) Finally the action buttons  and  allow the changes made to be saved or cancelled, respectively. The  button allows validating the Test Programming so that it cannot be later modified. To do this, a password has to be introduced and then confirmed. If later the test has to be devalidated to be able of modifying it, this same password will have to be introduced. Before being able to validate a test, the Operator must previously validate the products used in that test, as described in Section 9.1.1.1.

(10) By pressing the **Print Report** button it is possible to obtain a report with the Test's Programming. Figure 9.7 shows an example of the Test's Report provided.

The report includes the following information:

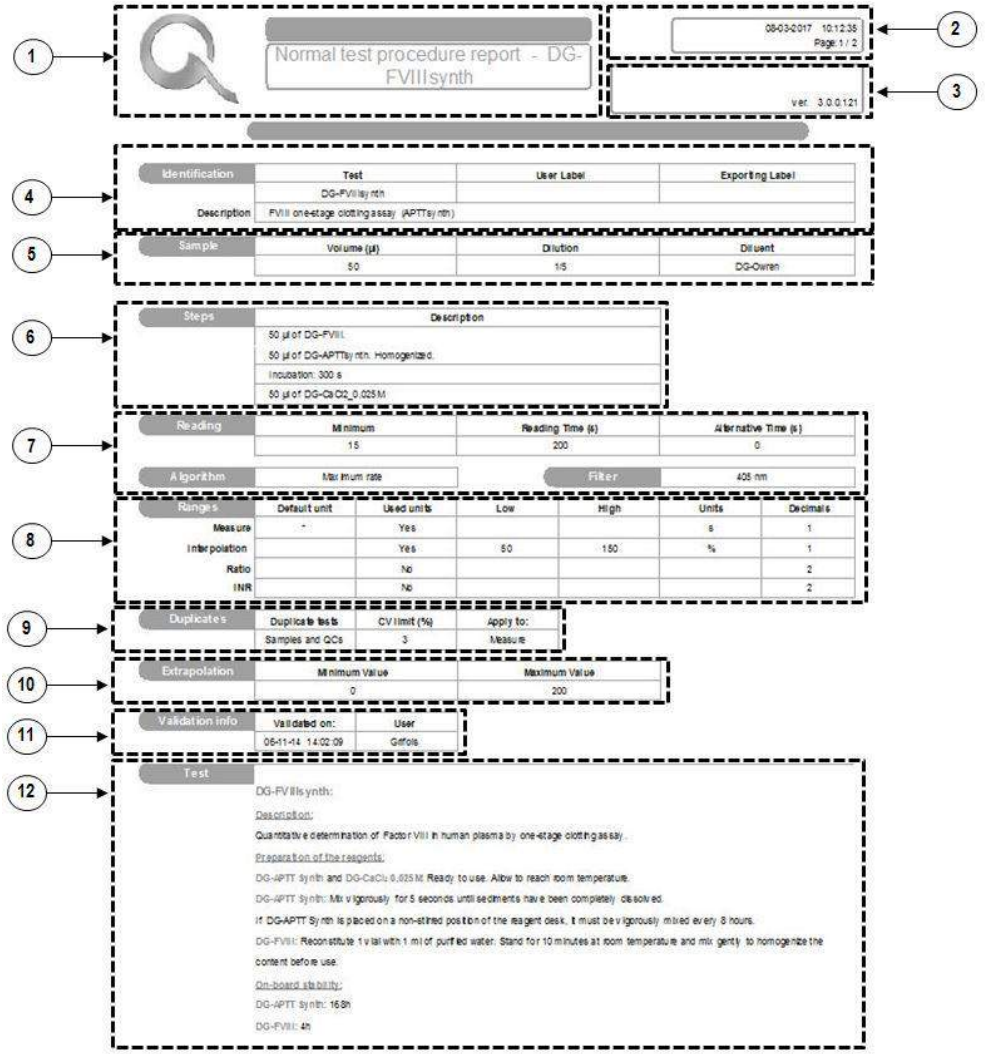


Figure 9.7. Normal Test Programming Report

(1) **Title** (Test type – Test name) and **Center's Name** (set up as described in Section 9.11.4).

(2) **Printing Date** and **Page Number** with regards to the **Total number of pages**.

(3) **QManager's Software Internal Version** with which the report has been generated.

(4) Test's **Identification** and **Description**.

(5) **Sample dispensation** programming: Sample volume, dilution and diluent.

(6) **Test Steps** programming: Incubations and reagent's additions.

(7) Programming of **Reading** (Minimum Time, Reading Time and Alternative Time), **Wavelength** used to obtain primary results and **Algorithm** (see Section 9.2.2).

(8) **Normality Ranges**, **Units** and number of programmed **Decimals**.

(9) Programmed **Duplicate tests** and **Limit** of **Coefficient of Variation (CV)**.

(10) **Maximum** and **Minimum Extrapolation** values of the Calibration Curve.

(11) Information about the test **Validation:** Date and Operator.

(12) Information contained in the **Test Characteristics** tab.

In the **Test Characteristics** tab, the Operator has a text box in which information or comments about the test can be entered.

NOTE: The **Test Characteristics** tab for the tests validated by Diagnostic Grifols, S.A. contains useful information such as: Intended Use, Preparation of the reagents, need of Cleaning Agent, Calibration Curve, recommended CVd, Linearity Range, Reference Intervals, Precision, Trueness, Limits of Detection and Quantification, Interferences, etc.

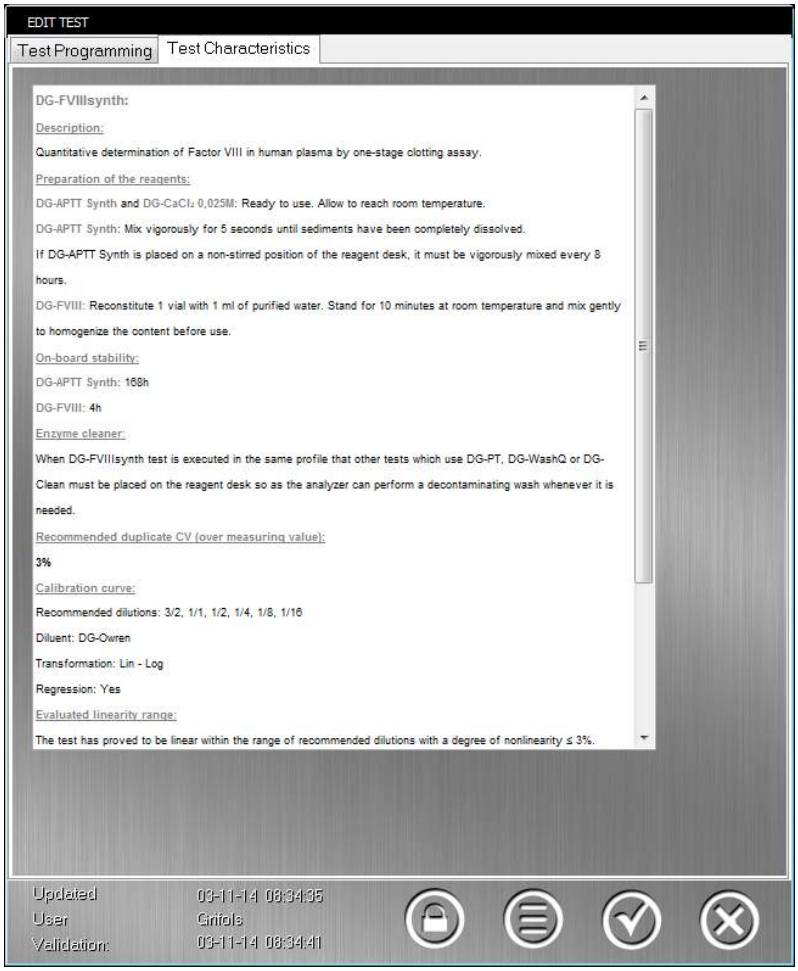


Figure 9.8. Test Window (Test Characteristics Tab)

9.2.1.1.1 Parallelism

By selecting the **Parallelism** tab in the **Test Programming** window, the Operator can enable or disable parallelism for the current test and define its performance:

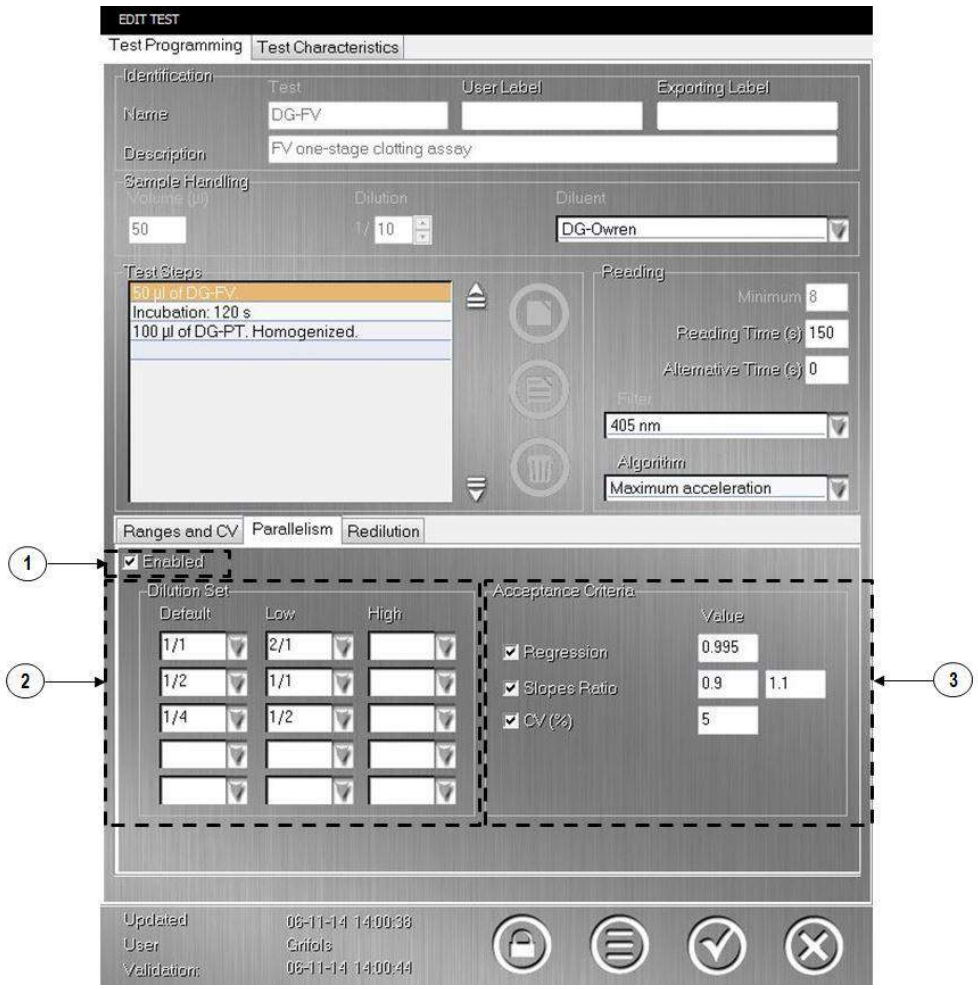


Figure 9.9. Parallelism Programming Tab

(1) **Enabled** check: When this option is activated, the Operator can program the fields on this tab to define the performance of the parallelism for the samples, and the samples will be processed with the programmed parallelism conditions.

(2) **Dilution Set:** Different sets of dilution factors can be programmed to be applied to the samples. The Operator can define a minimum of two and a maximum of five dilution points for each set. The dilution points will be performed per simple or per duplicate depending on the programming of the test (Figure 9.6, no. 7).

- **Default:** This set of dilutions will be applied to all the samples that have this test ordered.

- **Low:** This set of dilutions can be applied to those samples selected in the **Worksheet**, which have this test ordered, by changing the "Default" set by **Parallelism-Low** dilutions set (see Section 15.6.4).
- **High:** This set of dilutions can be applied to those samples selected in the **Worksheet**, which have this test ordered, by changing the "Default" set by **Parallelism-High** dilutions set (see Section 15.6.4).

(3) **Acceptance Criteria:** Different acceptance criteria can be programmed to check the reliability of the final averaged sample result.

- **Regression:** A linear regression and a regression coefficient of the results of the different dilutions performed are calculated to analyze the acceptability of curve linearity. A minimum value for the regression coefficient can be programmed so that a warning appears in the result if this is not fulfilled.
- **Slopes Ratio:** A comparison between the slope of the Calibration Curve and that of the sample curve is performed by calculating the ratio between both slopes to assess parallelism. A range of slopes ratio can be programmed so that a warning appears in the result if this is not fulfilled.
- **CV (%):** To provide the averaged result in secondary unit, the primary unit mean of each dilution point is interpolated in the Calibration Curve and corrected by its dilution factor. The **CV (%)** option allows programming the calculation of the Coefficient of Variation (CV) between dilutions and establishing a maximum value so that a warning appears in the result if this is not fulfilled.

NOTE: For the tests validated by GRIFOLS, it is not possible to modify the **Parallelism** settings.

9.2.1.1.2 Redilution

By selecting the **Redilution** tab in the **Test Programming** window, the Operator can enable and program different sample dilutions that will be automatically performed by the instrument depending on the obtained result:

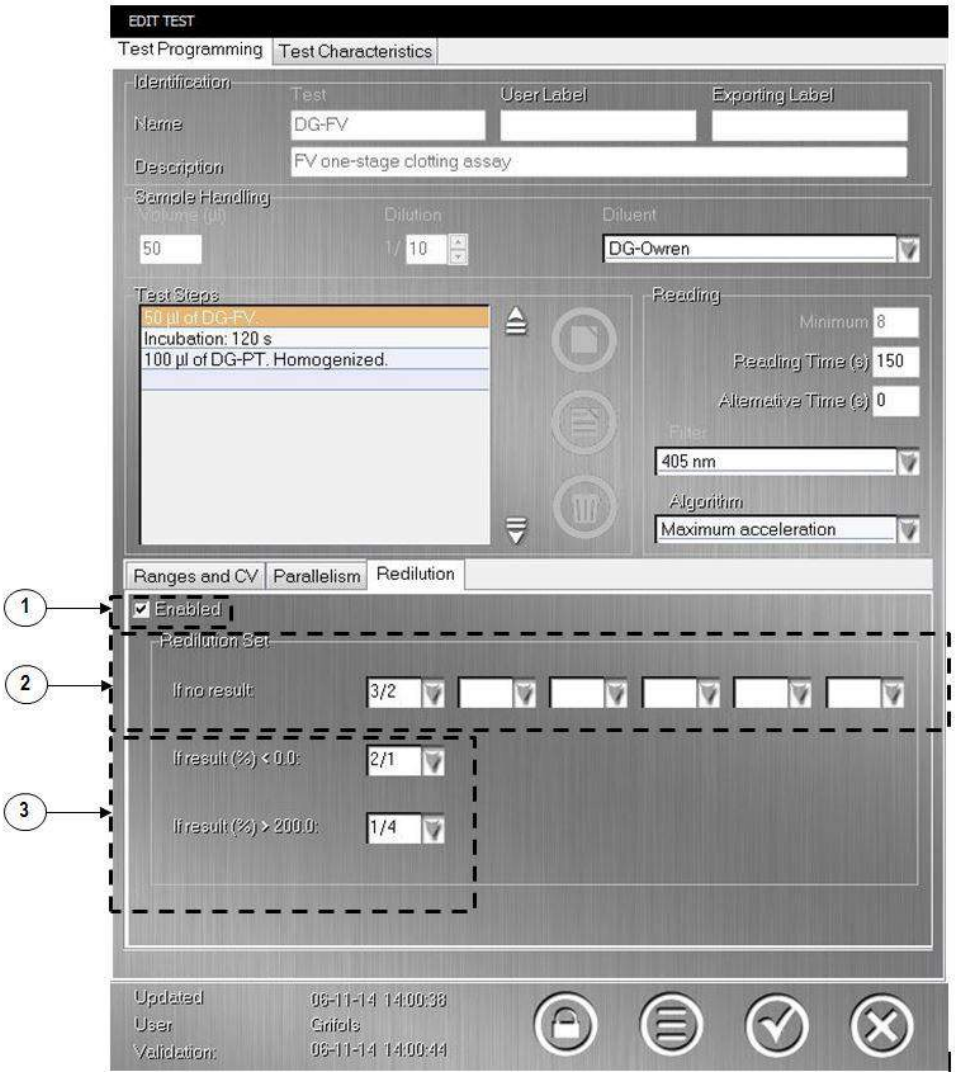


Figure 9.10. Redilution Programming Tab

(1) **Enabled** check: When this option is activated, the Operator should program the fields on this tab to define the performance of the automatic samples redilutions.

(2) **If no result:** When there is no result for the sample (*e.g.* CND, LIN, OUT) the Operator can program a series of dilution factors to be successively applied to the sample until a result is obtained with one of them. If no result is obtained with the first programmed re-dilution, the instrument will automatically repeat the test with the following programmed re-dilution and so on.

(3) **If result < Minimum Extrapolation Value:** A lower sample dilution should be programmed so that the sample result obtained falls in the measuring range of the test.

(4) **If result > Maximum Extrapolation Value:** A higher sample dilution should be programmed so that the sample result obtained falls in the measuring range of the test.

NOTE: For the tests validated by GRIFOLS, it is not possible to modify the **Redilution** settings.

NOTE: If in the Test Programming there is an **Alternative Time** programmed and an automatic redilution has to be performed, both the sample rerun and, subsequently, the automatic redilution will be processed with the **Alternative Time**. Otherwise, the test will be run with the standard **Reading Time**.

NOTE: To be able to perform an automatic **Redilution**, the option **Recirculate Samples** must be enabled in the **Setup** window (Figure 7.6, no. 2).

NOTE: When **Redilution** is programmed in a Test, and a rediluted sample result is obtained with this Test, the software internally corrects the Extrapolation Minimum and Maximum Values by the defined dilution factor, *e.g.* if a test has a 1/2 re-dilution and a Maximum Extrapolation Value of 2000 programmed, the Maximum Extrapolation Value considered for a re-diluted sample, in this case, will be 4000.

9.2.1.2 Programming Derived Test

To program a Derived Test, select **Derived** from the drop-down menu that is displayed when  is pressed in the **Tests** window.

Given that a Derived Test is obtained from a mathematical process added to a previously-executed Normal Test, the program displays the **Test Programming** tab of the **New Derived Test** window (Figure 9.11) similar to the one for the **Normal Test** window from which it is derived (Figure 9.6), with the following changes that need to be completed:

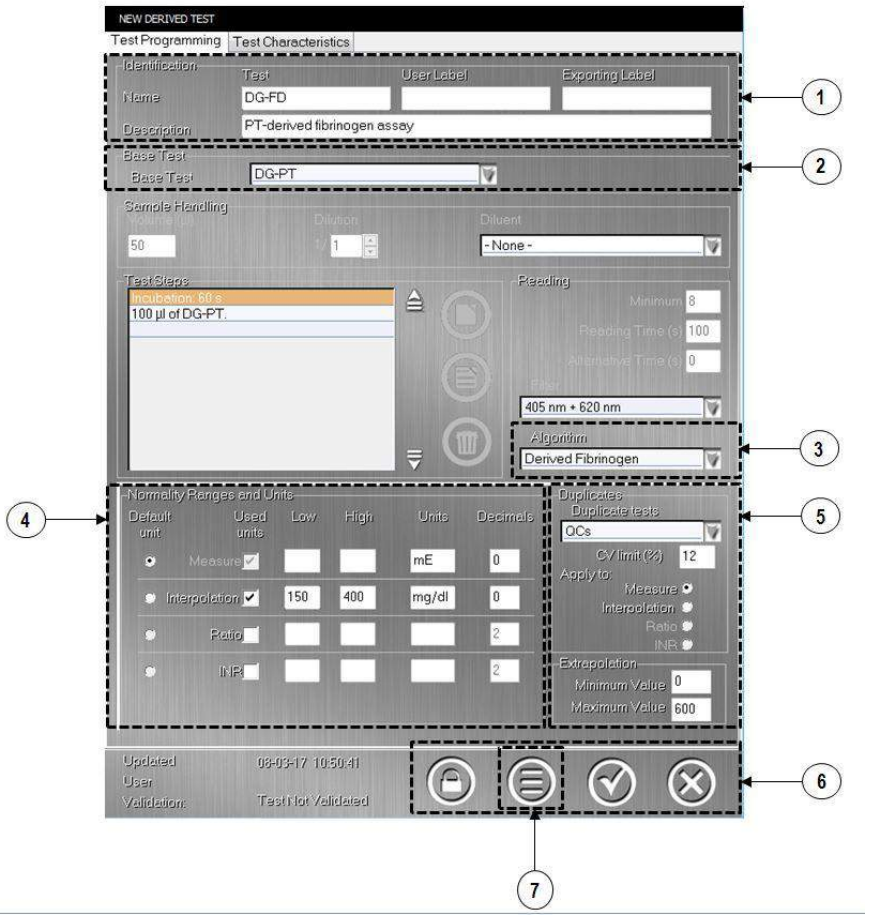


Figure 9.11. New Derived Test Window (Programming Tab)

(1) **Test Identification:** Information which allows the test to be identified and described. The following parameters are entered here:

- Test **Name.**

NOTE: The following symbols can not be introduced in the Test **Name:** *, |, :, ?, <, >, /, ".

- Test **Description**.

- **User Label:** Field which allows a label to be entered to make the test easily identifiable to the Operator, particularly with validated tests. The maximum length is 6 digits.
- **Exporting Label:** Field which allows a label to be entered to allow the LIS to identify the test.

(2) **Base Test:** Drop-down menu that allows choosing the Base Test to which the additional mathematical processing will be applied. The Base Tests must have been previously programmed as described in Section 9.2.1.1.

(3) **Reading:** The different mathematical **Algorithm** that wants to be applied to the Derived Test can be selected (see Section 9.2.2).

(4) **Ranges of Normality and Units:** It allows entering the specific ranges of normality and units for the Derived Test. It is also possible to define the number of decimals with which the results will be displayed.

(5) **Duplicates:** It allows programming the acceptance criteria with regards to the Coefficient of Variation (CV) of the Derived Test in the different working units.

(6) Finally the action buttons  and  allow the changes made to be saved or cancelled, respectively. The  button allows validating and protecting the Test Programming so that it cannot be later modified. Previously, the Operator must validate the products used in the test, as described in Section 9.1.1.1.

(7) By pressing the **Print Report** button, it is possible to obtain a Report with the Test's Programming. Figure 9.12, shows an example of a Derived Test's Report provided with the Q**Next**.

The report includes the following information:

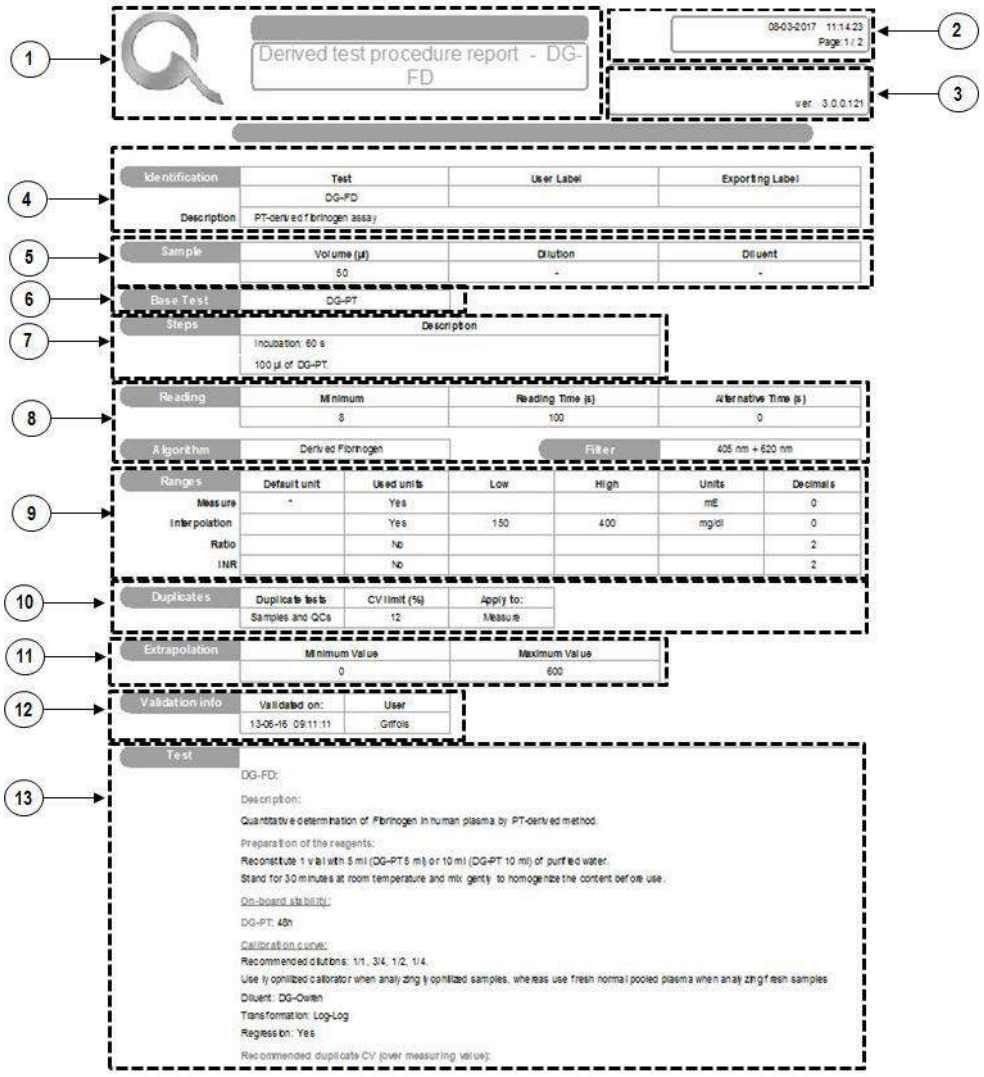


Figure 9.12. New Derived Test Programming Report

(1) **Title** (Test type - Test name) and **Center's Name** (set up as described in Section 9.11.4).

(2) Printing Date and Page Number with regards to the Total number of pages.

(3) QManager's **Software Internal Version** with which the report has been generated.

(4) Test's Identification and Description.

(5) **Sample dispensation** programming: Sample volume, dilution and diluent.

(6) **Base Test** to which the additional mathematical processing will be applied.

(7) **Base Test Steps** programming: Incubations and reagent's additions.

(8) Programming of **Base Test Reading** (Minimum Time, Reading Time and Alternative Time), **Wavelength** used to obtain primary results and **Algorithm** (see Section 9.2.2).

(9) **Normality Ranges**, **Units** and number of programmed **Decimals**.

(10) Programmed **Duplicate tests** and Limit of **Coefficient of Variation** (CV).

(11) **Maximum** and **Minimum Extrapolation** values of the Calibration Curve.

(12) Information about the test **Validation:** Date and Operator.

(13) Information contained in the **Test Characteristics** tab.

The rest of parameters of the test remain protected since they are inherent to the Base Test.

In the same way as with the Normal Test, the **Test Characteristics** tab is available to enter information or comments about the test.

9.2.1.3 Programming Combined Tests

To program a Combined Test, select **Combined** on the drop-down menu that the program displayes when  is pressed in the **Tests** window. The **New Combined Test** window has two tabs available: **Test Programming** and **Test Characteristics.**

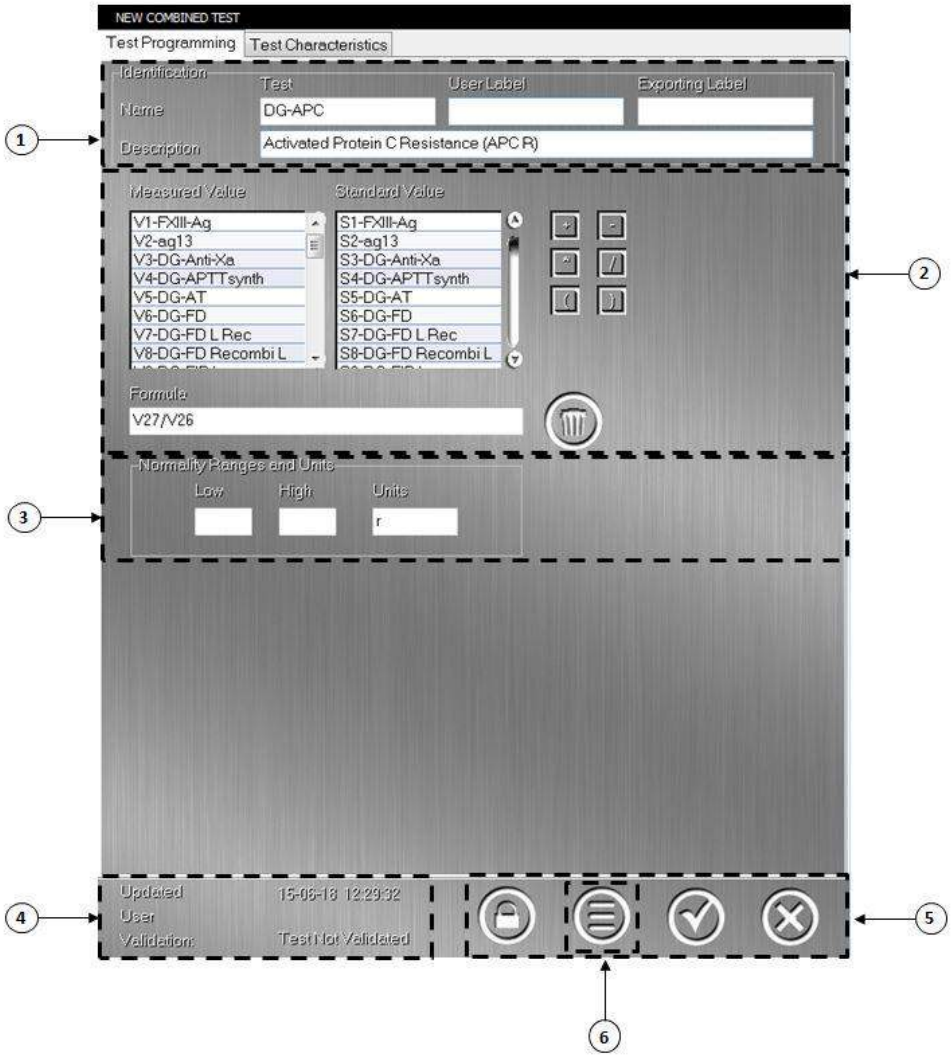


Figure 9.13. New/Edit Combined Test Window (Programming Tab)

In the **New Combined Test** window, the Operator can enter all the information for:

(1) **Identifying the Test:** Information which allows the test to be identified and described. The following parameters can be entered here:

- Test **Name**.

NOTE: The following symbols can not be introduced in the Test **Name:** *, |, :, ?, <, >, /, ".

- Test **Description**.
- **User Label:** Field which allows the Operator to enter a label to facilitate the identification of the test, in particular in validated tests. The maximum length is 6 digits.
- **Exporting Label:** Field which allows the Operator to enter a label for the LIS to identify the test.

(2) Mathematical **Formula:** This is the area which should relate, using a mathematical calculation, the results obtained with two Normal or Derived Tests which appear in the **Mean Value** and/or **Standard Value** drop-down menus, as appropriate. The tests are entered in the box corresponding to the mathematical formula by double-clicking on them and the mathematical symbol is inserted by pressing the corresponding button.

(3) **Ranges of Normality and Units:** Allows the ranges of normality and units specified for the Combined Test to be entered.

(4) **Test Status Information:** The program indicates whether the test is validated and, if so, the **Operator** who performed the **Validation** and in which **Date**. The **Date of modification** of the test is also provided, if applicable.

(5) Finally, the  and  action buttons allow the changes made to be saved or cancelled, respectively. The  button allows validating and protecting the Test Programming so that it cannot be modified later.

(6) There is the possibility of obtaining a **Report** with the **Combined Test Programming**, by pressing the **Print Report** button. See example on Figure 9.14.

The report includes the following information:

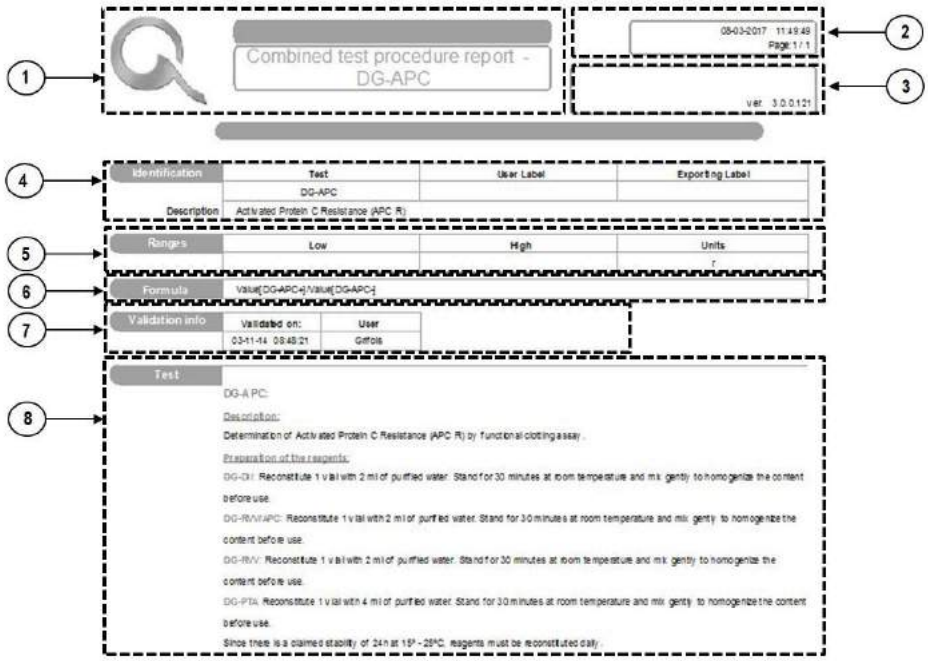


Figure 9.14. New Combined Test Programming Report

(1) **Title** (Test type - Test name) and **Center's Name** (set up as described in Section 9.11.4).

(2) Printing Date and Page Number with regards to the Total number of pages.

(3) QManager's **Software Internal Version** with which the report has been generated.

(4) Test's Identification and Description.

(5) **Normality Ranges**, **Units** and number of programmed **Decimals**.

(6) **Mathematical Formula** which will relate the results obtained with two normal or derived tests.

(7) Information about the test **Validation:** Date and Operator.

(8) Information contained in the **Test Characteristics** tab.

As with Normal Tests, the **Test Characteristics** tab is available for entering information or comments about the Test Programming.

9.2.2 Algorithms

The analyzer has various **Algorithms**, which consist in applying mathematical treatments to the absorbance-time curves to obtain the parameters that characterise them and be able to provide a result in primary unit. Selecting one or another will depend on each test.

The algorithms available in the program can be classified in three groups, according to the type of test in which they are used:

- **Clotting:** These are used in clotting methods and calculate the time value of some of the stages of coagulation or the absorbance increase produced as a result of clot formation.
- **Chromogenic:** These are used in chromogenic methods and calculate reaction speeds (slopes) or absolute absorbance increase.
- **Immunoturbidimetric:** These are used in immunoturbidimetric methods and calculate differences of absorbance between two points.

The program also has some protections which detect, by using mathematical calculations, the existence of abnormalities in the curve and depending on this; the instrument provides different **Warnings** about the results.

For the tests validated by GRIFOLS, the most appropriate algorithm for each test is already programmed so that the performance of the reagents in the instrument is optimized. The validated tests are provided by Diagnostic Grifols, S.A (see Section 9.11.3).

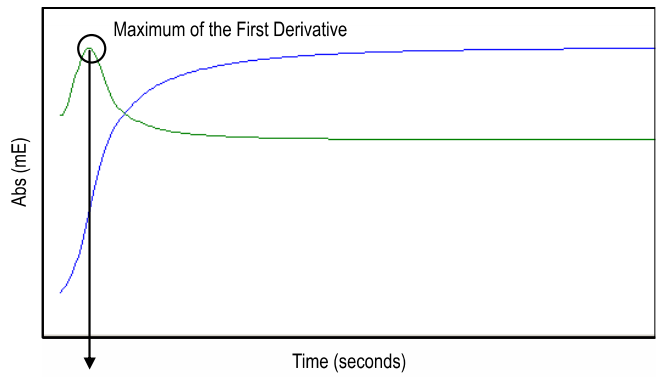
9.2.2.1 Types of Algorithms

9.2.2.2 Algorithms for Clotting Tests

The algorithms used in clotting tests calculate the clotting time (seconds) or the increase of absorbed light (mE) due to fibrin formation in the primary curve obtained.

Maximum Rate

The maximum of the first derivative, which is calculated from the primary curve, will be used to obtain the time in which the rate of clot formation is maximum. This time will be considered the clotting time result (in **seconds**).



Result in **seconds**

Figure 9.15. Graphic Description of the "Maximum Rate" Algorithm

Maximum Rate for PT

This algorithm is used in some GRIFOLS Prothrombin Time (PT) tests. It is based on the "**Maximum Rate**" algorithm and it includes an additional protection to avoid giving false results in those clotting curves where the absorbance does no stabilize. If this is the case, CND will be reported as a result (see Section 9.2.2.5).

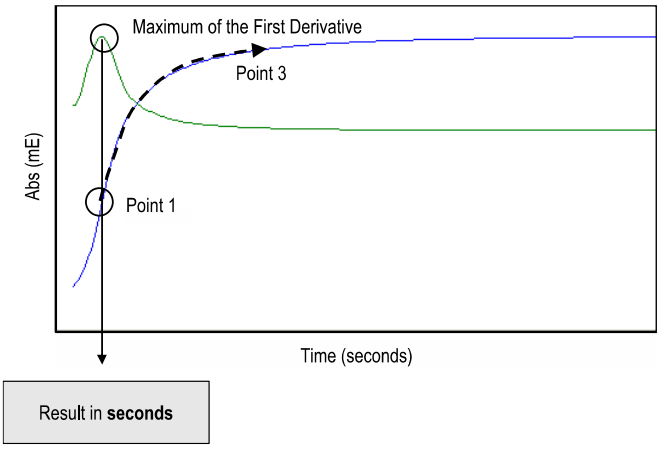


Figure 9.16. Graphic Description of the "Maximum Rate for PT" Algorithm

Maximum Rate for APTT

This algorithm is used in some GRIFOLS APTT-based tests. It is based on the "**Maximum Rate**" algorithm, but the primary clotting curve is further filtered before calculating the first derivative. This helps to give a result in those curves with longer clotting times.

It also includes an additional protection to avoid giving false results in those clotting curves where the absorbance does no stabilize. If this is the case, CND will be reported as a result (see Section 9.2.2.5).

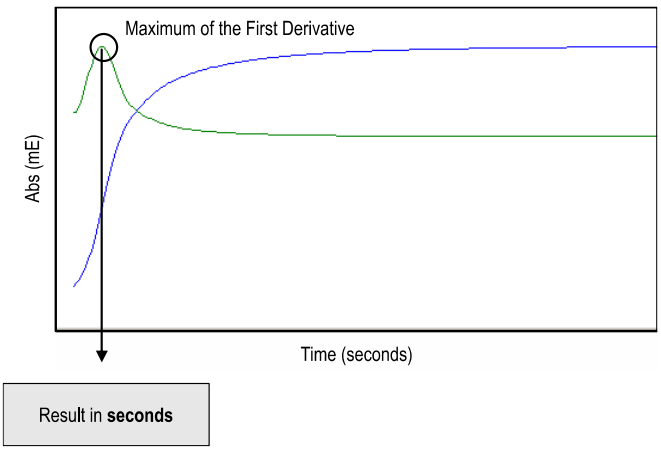


Figure 9.17. Graphic Description of the "Maximum Rate for APTT" Algorithm

Maximum Acceleration

The maximum of the second derivative, which is calculated from the primary curve, will be used to obtain the time in which the acceleration of clot formation is maximum. This time will be considered the clotting time result (in **seconds**).

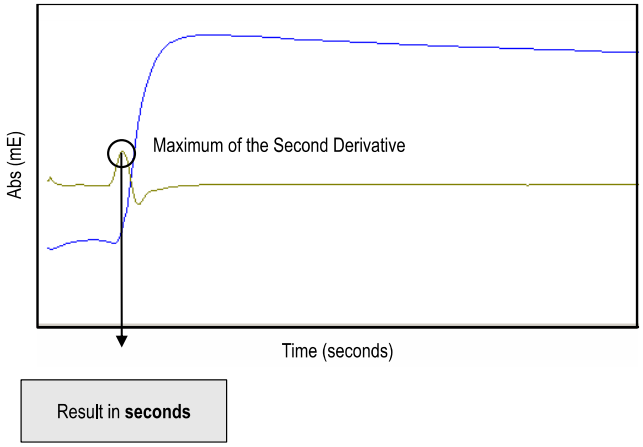


Figure 9.18. Graphic Description of the "Maximum Acceleration" Algorithm

Maximum Acceleration for PT

This algorithm is used in some GRIFOLS Prothrombin Time (PT) tests. It is based on the "**Maximum Acceleration**" algorithm and it includes an additional protection to avoid giving false results in those clotting curves where the absorbance does no stabilize. If this is the case, CND will be reported as result (see Section 9.2.2.5).

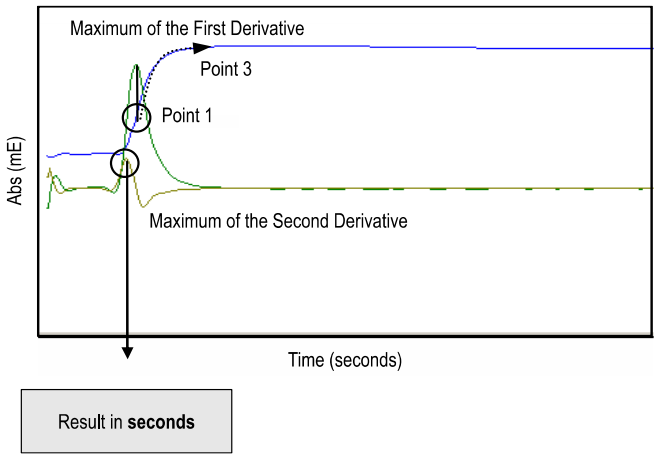


Figure 9.19. Graphic Description of the "Maximum Acceleration for PT" Algorithm

Maximum Acceleration for TT and TR

The algorithm Maximum Acceleration for TT and TR is based on the "**Maximum Acceleration**" algorithm, but this includes an additional protection to avoid giving false results in those clotting curves where the absorbance does not stabilize at the beginning of the reaction. If this is the case, CND will be reported as a result (see Section 9.2.2.5).

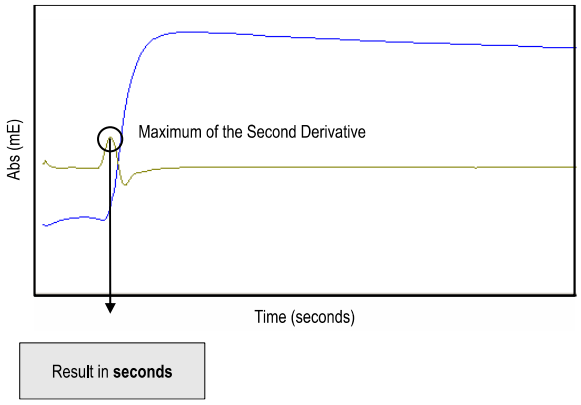


Figure 9.20. Graphic Description of the "Maximum Acceleration for TT and TR" Algorithm

Maximum Acceleration for Extrinsic Pathway

The algorithm Maximum Acceleration for Extrinsic Pathway is based on the "**Maximum Acceleration for TT and TR**" algorithm, but this includes an additional protection to avoid giving false results in