General information

This section contains general information about the GSP instrument.

Changes from previous version

Changes made to this manual from its previous version are marked with underlined text.

Trademarks

DELFIA and AutoDELFIA are registered trademarks, and Wallac and PerkinElmer are trademarks of PerkinElmer, Inc.

Microsoft, Excel, Windows and Windows XP are registered trademarks or trademarks of Microsoft Corp.

Intended purpose

The GSP® instrument is intended to be used as an aid in screening with GSP reagent kits. It is a fully automated, high throughput batch analyzer for time-resolved and prompt fluorescence analysis of samples in microtitration plates. It is intended for in vitro quantitative/qualitative determination of analytes as described by the associated assays. The GSP instrument is intended to be used by trained laboratory personnel.

Contents of the package

The following components are included as part of the 2021-0010 GSP Instrument delivery:

- 61002144 GSP Instrument
- 1235-402 High volume reagent tips
- 2021-4020 Low volume reagent tips
- 61007159 Cassette pack for tips and reagents
- 61011401 Anti-evaporation kit (3x10 caps)
- 61010299 Magazine for 25 plates, input/output (2x)
- 61007252 External bottle system
- 11700146 External barcode reader
- 3060-0010 GSP Test kit
- 4080-0010 GSP Wash concentrate (1000 mL)
- 2204-0010 DELFIA Inducer (12 x 500 mL)
- External keyboard with touchpad
- Installation kit containing necessary cables and tubing
- 2021-8020 Wallac computer with preinstalled GSP workstation software
Introduction

Instrument overview

Microtitration plates with patient samples in them are loaded manually in magazines. The plates then enter a vertical plate manipulator. In GSP multiple tasks can occur simultaneously, e.g.

- Shaking and temperature-controlled incubating.
- Dispensing of buffer/tracer/antibodies
- Washing
- Detection of results by different technologies such as time-resolved fluorescence, prompt fluorescence, absorbance and luminescence
- Bulk reagent dispensing
- Disk removing

The plates and the GSP reagents are identified by barcodes.

Reactions take place in plates specific for each analyte where the required reagents are pipetted during the process. The system will give quantitative results for the markers.

The instrument is designed to be modular, so each module can be serviced or replaced or upgraded easily.

Information about the samples to be processed is entered in the GSP Workstation software running on a separate PC. This information is sent to GSP where it is used to control the processing of the plates that are loaded. After processing, results are sent to GSP Workstation for display, evaluation and quality control.

Notice regarding serious incidents

For a patient/user/third party in the European Union and in countries with an identical regulatory regime (IVDR; EU 2017/746/EU): if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority. The contact information for the manufacturer of this device to report a serious incident is:

Wallac Oy
Mustionkatu 6, FI-20750 Turku, Finland
http://www.perkinelmer.com
Phone: +358 2 2678 111
The GSP processor consists of a plate manipulator and the modules around it. Modules can be on four sides of the manipulator. They are stacked on each other to reduce footprint. Modules can be seen as individual "instruments" each of which does something to the plate.

The main modules are:

1. Air dryer
2. Reagent dispenser module with both high volume and low volume dispensers
3. Reagent storage: allows storage of tips and has place for anti-evaporation caps that the instrument takes off reagent bottles
4. Two stacker modules: an input stacker and an output stacker, each of which holds a plate magazine
5. Liquid module for handling waste liquids
6. Temperature control module
7. Plate storage module
8. Plate manipulator module: moves microtitration plates between the other modules
9. Plate washer module
10. Bulk reagent module
11. Disk remover module: removes dried blood spot disks from microtitration plate wells
12. Heated incubator module
13. Three shaking incubator modules
14. Measurement module
15. Electronics module
Plate manipulator module

The Plate manipulator module moves plates from one module to another. It forms the body of the instrument. All other modules are fixed to the plate manipulator.

The plate manipulator consists of a plate carrier that moves vertically. This carrier is able to turn 270 degrees so it can supply all modules around the manipulator.

Washer module

The washer washes 96-well assay plates, 24 wells at a time. The wash operation occurs as a result of vacuum in the waste bottle and overpressure in the wash solution bottle. One valve controls wash solution flow and another valve controls suction. A plate moves horizontally in one direction only. The manifold is set above the plate conveyor and it moves vertically during the process.

Disk remover module

Sample disks and liquid are removed from the sample plate by the action of this module.

The disk removal operation is based on vacuum in the waste bottle. The suction head moves in two directions above the plate. Vertical movement allows the head to enter the wells of the plate. Horizontal movement along a strip enables the suction head to go in each well of the strip. The plate itself moves horizontally so that each strip on the plate can be processed. A stepper-motor driven valve controls suction. During the removal cycle, the duct from the head to the waste bottle opens and because of the vacuum in the waste bottle the disk and liquid are sucked into the waste bottle.

Reagent storage module

The Reagent Storage Module is a cooled area (10 °C) used as storage for reagents (e.g. buffers, tracers, antibodies), high volume pipette tips, low volume pipette tips and anti-evaporation caps. It is cooled to keep reagents stable in the instrument. Cooling is achieved by Peltier elements and the module is insulated.

Reagents are loaded into the storage in reagent cassettes. A reagent cassette has place for one 175 mL buffer bottle and two 3 mL reagent vials. Each bottle is barcoded so that it can be identified.

High volume tips and low volume tips are loaded in their respective tip cassettes. 58 tips fit into a cassette. There is also a cassette for waste tips. Both high volume tips and low volume tips fit in the same waste cassette with the low volume tips stacked inside the high volume tips.

Reagent cassette (upper) and tip cassette (lower)

Cassettes fit into a carousel. There is place for 16 cassettes. A barcode reader detects the type of the cassette loaded.
Figure 1: Inside of the reagent storage module showing the carousel

Anti-evaporation caps are moved from reagent bottles to a caps stand.

Items in the reagent storage module are accessed by the pipettes via two slots in the top of the module. These are closed when access to the reagent storage module is not occurring. There is also a hole into which rinsing liquid can be dispensed. This is connected by tubing to the waste bottle.

Reagent dispenser module

The reagent dispenser is used to:

• dispense reagents from reagent vials or bottles to the wells of microtitration plates
• handle anti-evaporation caps
• detect liquid levels
• monitor tip, cap and reagent handling processes
• detect the presence of tips and caps

The X/Y-conveyor moves a plate under the pipettes, these dispense reagents from vials or bottles to the wells of the plate as follows:

• high volume pipette handles mainly buffers with a 1.2 ml tip
• low volume pipette handles reagents with a 50 µl tip.

The high volume pipette dispenses reagent volumes in the range 25-200 µl. It consists of a syringe, piston, linear stepper motor, pressure gauge, electronics and mechanics. It is used to dispense e.g. DELFIA buffers.

The low volume pipette dispenses precise small volumes from 5 to 50 µl. It can dispense reagents directly into the microtitration plate wells with no need for dilution vessels.

It is used to dispense e.g.

• DELFIA tracers
• DELFIA antibodies
• Reagents for enzymatic activity assays

Disposable tips are picked up and released automatically. The tips come from the tip cassettes in the reagent storage module and they are returned to the waste tip cassette.

Measurement module

The measurement module is used to measure TRF, FI and ABS labelled samples on 96-well plates.

The main parts of the unit are an X/Y-conveyor, detector unit, optical unit, flash lamp unit, photometric unit, case and measurement interface card.

X/Y-conveyor - moves the plate to the measuring position and then back to the plate manipulator. It also moves the plate so that each well can be measured.

Top measurement head - consists of a light source, excitation optics, emission optics and detector. The sample is illuminated at a selected wavelength and emission light is collected and detected at a selected wavelength. Wavelength selection is done by means of 12 optical blocks attached to a movable slide. An optical block consists of excitation and emission filters and an excitation mirror and a reference mirror.
**Bottom measurement head** - is used to measure absorbance using a photodiode. It can also check if a dried blood spot disk is in the well or not.

**Case** - is light-tight to eliminate background.

**Measurement interface card** - does the signal processing. The signal from the photomultiplier tube (PMT) is read in 10 µs slices. In TRF measurements photon counting mode is used. In the case of FI labelled samples, analogous detection is used.

Raw results from the measurement are sent to GSP Workstation for evaluation.

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**Bulk reagent module**

This module dispenses bulk reagents, e.g. DELFIA Inducer, into wells on microtitration plates. The module consists of a dispensing head, Y-conveyor and dispensing pumps connected to reagent bottles. These bottles are loaded into holders on the right hand door of GSP.

A barcode reader is attached to the door pointing. Each bottle that is going to be loaded should first be presented to the barcode reader to be identified.

![Bulk reagents are situated inside the right hand instrument door](image)

There is one dispensing head in each pump and a multi-way valve that connects the pump to reagent bottles. The dispensing head moves along the strips above the plate. The Y-conveyor moves the plate so that the dispensing head can reach each well. The dispensing pump gives the dosage of liquid in each well.

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**Shaking incubator module**

In the shaking incubator module, the plates are kept in individual cavities and are locked in place with springs. The incubator shakes the plates by circulating them in the horizontal plane. There are three shaking incubator modules in the GSP processor and each can hold up to six plates. The shaking incubator accelerates e.g. the DELFIA chemistry reaction in the microtitration wells.
**Liquid module**

The liquid module takes care of wash concentrate, wash solution, rinse and waste handling. The liquid module generates the vacuum and pressure that are used in several parts of the liquid system. It also mixes wash concentrate and dionized water to form wash solution.

![Liquid module diagram](image)

**Figure 3: Liquid module**

1. Waste Bottle
2. Wash solution Bottle Pressurized
3. Mixing Bottle
4. Wash concentrate Bottle
5. Rinse Bottle

Rinse solution (deionized water) is used for rinsing the washer, disk remover, bulk reagent dispenser and low volume pipette and their associated tubing. It is also used for diluting the wash concentrate. It is stored in the Rinse Bottle (5).

The shelf on which are the Waste and Rinse bottles can be partly slid out from the liquid module to make so that these bottles can be removed for emptying or filling as needed.

Wash solution is used for washing wells in a plate and water as the system liquid of the low volume pipette. Wash solution is a 1:25 dilution of DELFIA Wash Concentrate (bottle 4) and water (bottle 5). It is mixed in a separate bottle (3) and then pumped to the wash solution bottle (2). The waste bottle (1) collects waste liquid and blood spots. It can be emptied automatically or manually.

The instrument can be connected to the laboratory water supply provided that a suitable quality of water is available (deionized).

**Air dryer module**

The air dryer module controls humidity inside the plate storage area of the GSP processor. The relative humidity in that area is kept below 60%.
Stacker modules

There are two stacker modules, an input stacker and an output stacker:

- the input stacker module is used to move plates from a plate magazine and load them into the GSP processor
- the output stacker module is used to unload plates from the GSP processor and stack them in a plate magazine

The main parts of a stacker are: the lifting unit, pinch actuator, magazine detector, barcode reader (in the input stacker), plate detector and strips detector.

Plates are carried in plate holders while in the instrument. When the plate manipulator moves the plate in its plate holder from the stacker into the instrument, the barcode on the long side of the plate is read. The plate height, number of strips and heights of the strips are also detected.

Plate storage module

The plate storage module is used to hold up to 26 plate holders for sample plates and 3 holders for special adjustment plates. Usage of the plate storage with the stackers enables continuous loading of the plates. All plate holders are located in the plate storage module when they are not in use. The plate storage module comprises a set of shelves (one shelf for each plate holder).

Heated incubator module

The heated incubator is a temperature controlled area for twelve plates. It is used for assays that need an elevated temperature. Each plate and its plate holder fit into a separate heated cavity. The temperature is set to 37°C.

Temperature control module

This module maintains temperature inside the GSP processor at 25°C. Its operation is based on Peltier technology which heats or cools the heat sink situated inside the instrument. To stabilize temperature inside the instrument there are fans circulating air around the module and through the heat sink.

Measurement technologies

GSP DELFIA technology is based on the use of europium chelate labels with detection by time-resolved fluorometry. This technology has been proven and used for many years with other instruments from PerkinElmer.
With DELFIA labels the long decay time as well as the wide Stokes’ shift of these labels is the basis for the method’s sensitivity and robustness. Detection begins 400 ms after excitation, by which time non-specific fluorescence has died down.

The Stoke’s shift is the difference in wavelength between the excitation light and the emission light. The wider the Stoke’s shift, the greater the potential for sensitive measurement.

GSP can also be used to measure prompt fluorescence, absorbance and luminescence.

Blood disk monitoring

There are two different ways GSP monitors blood disks that have been punched into wells from dried blood spots:

Elution monitoring uses an absorbance measurement to verify that there is a blood disk in a well. If a blood disk is totally missing from a well or the elution of the blood from the blood disk has not been successful, GSP gives a warning and the results are flagged.

Additionally, for assays where the blood disk is not removed from the well, GSP checks if the blood disk is floating on top of the liquid in the well because a floating disk would cause erroneous results. Such results are flagged by GSP.

Calibration

The GSP instrument is calibrated by the manufacturer. This calibration must be checked by the user every third month by running GSP Test Kit 3060-0010 and following the Measurement module test procedure described in the User manual. GSP informs when the test needs to be run. If the test is unsuccessful, service must be contacted.

Application information

Neonatal screening samples are generally in the form of dried blood spots on filter paper. Blood disks are punched in wells in microtitration plates using e.g. AutoPuncher, the automated puncher from PerkinElmer.

Kit lot

Every kit belongs to a specific kit lot. This is given a unique number that applies to all the kit components. Components of separate kits can be used together if, and only if, they belong to the same kit lot.
The kit lot data is included in a separate certificate in both text and barcode format. When a new kit lot is taken into use, the kit lot data is fed into the GSP Workstation software using the hand-held barcode reader. The kit lot data includes:

- Analyte
- Kit lot number
- Expiry date of kit
- Lot numbers of each kit component
- Concentrations of each calibrator (1..6).

**Software and User Interface**

The GSP software controls the instrument and provides the user interface services needed by the operator. It runs in a master node computer which is fully equipped embedded PC module. The system is designed to run in Microsoft Windows XP Pro Embedded edition.

The software utilizes the latest Microsoft standards for user interface design and inter-process and network communication.

- Windows Presentation Foundation (WPF)
- Windows Communication Foundation (WCF)

Actual operation of GSP is controlled by a touchscreen which is built-in to the instrument.

In addition the instrument communicates with a PC running the GSP Workstation software for result viewing and quality control.

When a plate barcode has been read, the system queries GSP Workstation to obtain information about the assays to be run. This enables the GSP software to calculate how much consumables (reagents, tips etc.) are needed. If more need to be loaded, the user is informed by means of the touch screen.

After processing and measurement, raw results are returned to GSP workstation for evaluation. Final results are then linked with the demographic data which has been previously fed in to GSP Workstation.
Information about user instructions

There are several forms of user instructions in addition to this Instrument manual:

**Touchscreen**

The built-in touchscreen provides context sensitive instructions to guide the user in operation of the instrument.

**User manual**

This is a separate manual from this instrument manual and describes how to operate the instrument using the GSP User Interface via the touchscreen. The CD on the back cover of the user manual contains translations of the user manual in PDF format.

**GSP Workstation manuals**

There are two manuals, one describing result viewing, kit lot editing and plate information generation and the other quality control. The CD on the back cover of the Result Viewer manual contains translations of both the Result Viewer and Quality Control manuals in PDF format.

**Routine maintenance**

Routine maintenance is intended to be performed by the user and is described in the user manual. Any other maintenance than what is described there should be performed by personnel trained and authorized by PerkinElmer.

**Installation instructions**

Installation instructions are not included in this documentation because installation is only to be performed by personnel trained and authorized by PerkinElmer.
Warnings

For a complete list of symbols and explanations, refer to the GSP User Manual.

Regarding connection of the instrument to the mains:

Note: The instrument must be connected to a mains supply having a protective earth.

On the side of the instrument:

Warning: Disconnect supply before servicing

Inside the instrument:

Caution: To avoid the risk of electric shock or exposure to ultraviolet light do not unscrew any parts.

Symbols used:

Power on

Power off

The adhesive labels used with the instrument are:

Warning: This equipment must be installed and used in accordance with the manufacturer’s recommendations. Installation and service must be performed by personnel properly trained and authorized by PerkinElmer. Failure to follow these instructions may invalidate your warranty and/or impair the safe functioning of your equipment.

Warning: This biohazard symbol (yellow background, black symbol and outline) is on the waste bottles, indicating that the bottles, their contents and tubing should be handled as potentially infectious and should be handled and disposed of as potential biohazards. Use appropriate protection such as gloves. See also “WARNINGS AND PRECAUTIONS” in each kit insert.

Warning: This symbol warns the user to beware of moving parts in the instrument.

Other notes and cautions are:

Note: The GSP Workstation software running on a PC is designed to handle result collection and analysis. In normal use it is expected that the GSP Workstation software and other related tools will be the only applications run on the system PC. PerkinElmer offers no guarantee whatsoever as to compatibility of the GSP Workstation software and associated tools with other software installed or run by the user on the system PC.

Note: Should the system be connected to the internet, the administrator will be responsible for ensuring that protection by a proper firewall and appropriate antivirus software is available. By default, the Microsoft Windows firewall is turned on.

Note: The system administrator is responsible for ensuring that only adequately trained personnel are allowed to configure Microsoft Windows settings.

Warning: The system fulfils EMC requirements. However, it is strongly advised that the use of mobile phones around the system be avoided, since there is still a small risk that it could interfere with the instrument operation.
Note: Ensure clear access to the rear of the instrument so that it may be disconnected easily if needed.

Note: Use of an uninterruptible power supply (UPS) is recommended to avoid wastage of reagent and time in case of power cuts. Start up requires about two hours before the instrument is ready for operation.

Caution: Sodium hypochlorite is a corrosive liquid. Obtain and read the "Material and Safety Data Sheet" (MSDS) from the supplier before use.

This caution is for the disinfection procedure when hypochlorite solution is made from commercial sodium hypochlorite and used for disinfecting the instrument as described in the routine maintenance of the user manual.

Note: Operators should be trained in the operation of GSP and be familiar with the contents of the relevant user instructions supplied with the product. In the first part of this chapter there is a description of the documentation supplied.

Note: The Electromagnetic environment should be evaluated prior to operation of the device. 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.

Note: This equipment is designed for use in a professional healthcare facility environment. It is likely to perform incorrectly if used in a home healthcare environment.

Note: If you suspect that performance is affected by electromagnetic interference, increasing the distance between the equipment and the source of the interference may restore correct operation.

Cleaning and decontamination information

The following steps should be followed before performing any service with GSP:

Note: Use gloves when performing any service with parts that may have been into contact with patient samples (blood spots).

1. Clean the instrument surfaces with deionized water or with a 70-80% ethanol solution. Do NOT use any other liquid for cleaning. Do NOT use DELFIA Inducer for cleaning because it is highly corrosive.

2. Disinfect the instrument following the guidance given by the Instrument Disinfection Wizard (see the User manual/ Routine maintenance for details).

<table>
<thead>
<tr>
<th>Decontamination information form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product type ___________</td>
</tr>
<tr>
<td>Serial no ___________</td>
</tr>
</tbody>
</table>

This is to inform to those who maintain, repair or transfer the product that the instrument and its subunits have been treated according to the procedure given above.

Date ___________

Signature ___________________________

This procedure is also to be used in order to eliminate or reduce hazards when involved in removal from use, transportation or disposal.

Copy this page, fill in the data and include the page with the instrument.

Contact addresses

World Headquarters
PerkinElmer,
940 Winter Street
Waltham, MA 02451
USA.
(800) 551-2121
European Headquarters
PerkinElmer,
Imperiastraat 8,
B-1930 Zaventem,
Belgium.
Tel. 32 2 717 7911

Manufacturer
PerkinElmer, Wallac Oy,
P.O. Box 10,
FIN-20101 Turku,
Finland.
Tel: 358-2-2678111.
Fax: 358-2-2678 357.
Email: info@perkinelmer.com
Website: www.perkinelmer.com

Service
Please contact your local PerkinElmer representative
### Specifications

<table>
<thead>
<tr>
<th><strong>Physical dimensions</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Weight</strong></td>
<td>610 kg</td>
</tr>
<tr>
<td><strong>Height</strong></td>
<td>1960 mm (with the temp. control module assembled)</td>
</tr>
<tr>
<td><strong>Width</strong></td>
<td>1310 mm</td>
</tr>
<tr>
<td><strong>Depth</strong></td>
<td>760 mm</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Power requirements</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Power consumption</strong></td>
<td>1000 VA</td>
</tr>
<tr>
<td><strong>Mains voltage</strong></td>
<td>100 V - 240 V, 50/60 Hz</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Environmental conditions</strong></th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Temperature</strong></td>
<td>18 - 27°C</td>
</tr>
<tr>
<td><strong>Relative humidity</strong></td>
<td>10 - 80%</td>
</tr>
<tr>
<td><strong>Temperature</strong></td>
<td>28 - 30°C</td>
</tr>
<tr>
<td><strong>Relative humidity</strong></td>
<td>10 - 65%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Sample</strong></th>
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</thead>
<tbody>
<tr>
<td><strong>Sample</strong></td>
<td>blood disks punched into 96-well plates</td>
</tr>
<tr>
<td><strong>Sample identification</strong></td>
<td>barcode reader or keyboard input</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Capacity and reagent use</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sample capacity</strong></td>
<td>26 plates</td>
</tr>
<tr>
<td><strong>Reagent cassettes</strong></td>
<td>maximum of 13</td>
</tr>
<tr>
<td><strong>Reagent capacity</strong></td>
<td>4 plates/kit -&gt; 52 plates</td>
</tr>
<tr>
<td><strong>Manual water filling or waste emptying:</strong></td>
<td>11 plates before user intervention required</td>
</tr>
<tr>
<td><strong>Automatic water filling and waste emptying:</strong></td>
<td>no restriction</td>
</tr>
<tr>
<td><strong>Semi-automatic water filling and waste emptying:</strong></td>
<td>no restriction provided the user fills the external water container and empties the external waste container when needed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Low volume reagent pipette</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Range</strong> 5 - 50 µL</td>
<td></td>
</tr>
<tr>
<td><strong>Multiples of 5 µL</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Precision (CV%)</strong></td>
<td>&lt;1.5%</td>
</tr>
<tr>
<td><strong>Accuracy</strong></td>
<td>&lt; +/- 8%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>High volume reagent pipette</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Range</strong> 25 - 200 µL</td>
<td></td>
</tr>
<tr>
<td><strong>Precision with 100 µL doses (CV%)</strong></td>
<td>&lt;1.5%</td>
</tr>
<tr>
<td><strong>Accuracy</strong></td>
<td>&lt; +/- 4%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Stability</strong></th>
<th></th>
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</thead>
<tbody>
<tr>
<td><strong>Reagent onboard stability</strong></td>
<td>at least 24 hours</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Wash solution consumption</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Wash concentrate capacity</strong></td>
<td>2 L is enough for 65 to 80 plates, depending on the analytes used</td>
</tr>
<tr>
<td><strong>Wash solution capacity</strong></td>
<td>automatic mixing with water coming from a mains water line manual filling - 12 L</td>
</tr>
</tbody>
</table>
### Rinse water

**Rinse capacity**
Automatic filling from a mains water line or manual filling:

- 15 L bottle (usable volume 10.5 L), for 11 plates
- Deionized water is to be used

The water used for preparing wash solution and for rinsing comes from the same source (mains or water bottle).

### Liquid waste

Comprises wash solution, DELFIA Inducer, samples, buffers, reagents and rinse water. The usable volume in the 20 L bottle gives capacity for 16 plates.

**Waste capacity**
Automatic emptying

- or manual emptying: 20 L bottle, (usable volume 15 L), for 16 plates

### Loading

- Continuous sample loading
- Continuous reagent loading
- Continuous bulk regent loading

### Noise

- Level less than 60 dB.

### Humidity

- Inside the plate storage area is a maximum of 60%

### Analytes

- On-board analytes: 13

### Safety requirements

The instrument is designed to meet the following safety standards.

**Certification:**

- IEC-CB, CE and NRTL

The instrument fulfills the requirements of:

- IEC 61010-1
- IEC 61010-2-010
- IEC 61010-2-101
- IEC 62366-1
- IEC 61326-1
- IEC 61326-2-6
- CAN/CSA-C22.2 61010-1
- UL 61010-1

Every attempt has been made to minimize the risk of the user touching moving parts.

### EMC

**Electromagnetic compatibility according to EN IEC61326-2-6.**

The instrument complies with the emission and immunity requirements as described in IEC 61326.
### Packaging, storage and transportation requirements

<table>
<thead>
<tr>
<th></th>
<th>Temperature</th>
<th>Temperature gradient</th>
<th>Relative humidity</th>
<th>Vibration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Storage</strong></td>
<td>-25 to 60º C, IEC 68-2-56</td>
<td>20º C /hour</td>
<td>5 to 90%, IEC 68-2-56</td>
<td>IEC 68-2-6, IEC 68-2-27</td>
</tr>
<tr>
<td><strong>Transportation</strong></td>
<td>-25 to 60º C, IEC 68-2-56</td>
<td>20º C /hour</td>
<td>5 to 90%, IEC 68-2-56</td>
<td>Transportation tests according to ASTM D4169-96.</td>
</tr>
</tbody>
</table>

**GSP Genetic Screening Processor**  
**Specifications**  

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A label with a crossed-out wheeled bin symbol and a rectangular bar indicates that the product is covered by the Waste Electrical and Electronic Equipment (WEEE) Directive and is not to be disposed of as unsorted municipal waste. Any products marked with this symbol must be collected separately, according to the regulatory guidelines in your area.

The objectives of this program are to preserve, protect and improve the quality of the environment, protect human health, and utilize natural resources prudently and rationally. Specific treatment of WEEE is indispensable in order to avoid the dispersion of pollutants into the recycled material or waste stream. Such treatment is the most effective means of protecting the customer’s environment.

Requirements for waste collection, reuse, recycling, and recovery programs vary by regulatory authority at your location. Contact your local responsible body (e.g. your laboratory manager) or authorized representative for information regarding applicable disposal regulations. Contact PerkinElmer at the web site listed below for information specific to PerkinElmer products.

Web address:
www.perkinelmer.com/WEEE

Europe: follow the link provided above to access instructions on WEEE handling specific to different European countries

Customer Care USA: call 1-800-762-4000
Customer Care Rest of the World: call (+1) 203-925-4602

Products from other manufacturers may also form a part of your PerkinElmer system. These other producers are directly responsible for the collection and processing of their own waste products under the terms of the WEEE Directive. Please contact these producers directly before discarding any of their products.

Consult the PerkinElmer web site (above) for producer names and web addresses.
Glossary

Air dryer
Dries the air inside the instrument

Analyte
Substance or constituent for which the laboratory conducts testing

Note: This includes any element, ion, compound, substance, factor, infectious agent, cell, organelle, activity (enzymatic, hormonal, or immunological), or property, the presence or absence, concentration, activity, intensity, or other characteristics of which are to be determined.

Source: NRSCL8-A

Analyzer
See Measurement module

Antibody bottle
Bottle that contains antibody needed for an assay

Anti-evaporation cap
Cap to prevent evaporation from vials

Aspiration
Drawing up of liquids by suction. Used to remove liquid from wells or prior to dispensing e.g. in the dispenser module when liquid is aspirated from a reagent or buffer bottle

Assay
To analyze or to measure a sample of a specimen to determine the amount, activity or potency of a specific analyte or substance. Quantitative determination or measurement of the amount, activity, or potency of a constituent or characteristic

Note: Source: NRSCL8-A

Assay plate
Microtitration plate for running the actual assay

Note: Distinct from microtitration plates used for pretreatment etc.

Barcode reader
Component that scans an ID barcode. There are three in the GSP processor (reagent storage module, bulk reagent module and plate storage module)

Batch
More than 1 sample in a single run

Batch analyzer
Instrument that addresses more than 1 sample at a time

Batch loading mode
Loading many plates of the same or different assays at one time.

Blood disk
Disk punched from a dried blood spot

Bottom measuring head
Measuring head that is below the XY-conveyor. Part of the measurement module. It is used to measure absorbance and it uses a photodiode

Buffer
Solution or reagent that can resist a change in pH upon addition of either an acid or a base Source: NRSCL8-A

Buffer bottle
Bottle for buffer solution needed in assays.

Bulk reagent bottle
Bottle for bulk reagent solution

Bulk reagent bottles frame
Frame to hold bulk reagent bottles. Attached to the inside of the right hand door of the GSP processor. Barcodes should be read before bottles are loaded

Bulk reagent dispenser
Device for rapid filling of a microtitration plate with a common reagent. Part of the bulk reagent module

Bulk reagent module
Module for handling bulk reagents. It includes two bulk reagent dispensers and an X-conveyor. Part of the GSP processor

Bulk reagent solution
Generic solution for several assays such as wash solution / buffer or enhancement solutions for DELFIA assays.

Bulk reagent waste trough
Collects reagent waste and funnels it to the waste bottle. Part of the bulk reagent module

Case
That which encloses something e.g. GSP processor or a module
Glossary

Chamber
Part of the *Shaking incubator module*. In this module each plate is kept in a separate chamber, locked in position by springs.

Consumables
- Plates, tracer bottles, antibody bottles, buffer bottles, wash concentrate, bulk reagent solutions, tips and water

Continuous flow loading
Ability to load at scheduled intervals during the run.

Dead volume
The volume left in e.g. a tube or vial below a pipetting device's limits or physical reach.

DELFIA Inducer
Wallac product (a liquid) used in the DELFIA process to strengthen the fluorescence light signal. Used with N3 labels, DELFIA assays.

Disk
The part of a *dried blood spot* that has been punched out.

Disk remover module
Device to suck away disks from wells. Part of the *GSP processor*.

Disposable tip cassette
Holder for disposable tips. There are separate cassettes for 50 µL and 1.25 mL tips: See also *Waste tip cassette*.

Dried blood spot
Drop of blood deposited on *filter paper* and then dried.

Detector
Part of the top measuring head.

Dispensing head
The combination of the movement of the dispensing head along a strip of wells and the movement of the plate by the Y-conveyor enables dispensing to each well in a plate. Part of the *bulk reagent module*.

Dispensing pump
Gives the dosage of bulk reagent in each well of a plate via the dispensing head. Part of the *bulk reagent module*.

Electronics module
Location of the *instrument server* and instrument power supply.

Emission optics
These optical components direct the fluorescence emitted by a sample in a well to the detector. Part of the *measurement module*.

Excitation optics
These optical components direct the light from the light source to the well at the measuring position. Part of the *measurement module*.

Filter paper disk
Disk punched out from a *dried blood spot* on filter paper.

GSP processor
The automated device that processes a biochemical sample and determines the concentration value.

Heat sink
A unit, heated or cooled by Peltier elements and used to keep the inside temperature of the instrument at the desired level. Fans circulate air from the instrument over and through the heat sink. Part of the *temperature control module*.

High volume pipette
Dispenses reagents in the range 25-200 µl. A submodule of the *reagent dispenser module*.

ID reader
Identification reader, generally a *barcode reader*.

Incubator cavity
Enclosed space in an incubator module where a *plate* can be loaded for incubation.

Incubator module (heated)
Temperature controlled heater non-shaking incubator for assays requiring an elevated temperature.

Incubator module (shaking)
Shaking incubator for DELFIA kits. There are three of these modules.

Input stacker
A *stacker module* used to load plates into the GSP processor.

Instrument server
Controls operation of the whole instrument and communicates with the external GSP Workstation. Each hardware module has its own ELSO module to drive it. These are in contact with the instrument server. Part of the *electronics module*.

Lifting unit
Mechanism that lifts plates in the *Plate stacker*.

Light source
Generates the light used to excite samples via the *excitation optics*.

Liquid module
Module for handling liquid dispensing including *wash concentrate*, *wash solution*, *rinse* and *waste* handling.

Low volume pipette
Dispenses reagents in the range 5-50 µl. A submodule of the *reagent dispenser module*.

Magazine
Unit for stacking plates (plate magazine) It can be loaded into an instrument or stacker as appropriate

**Magazine detector**
Detects if a magazine is loaded in a stacker

**Manifold**
A unit with outlets for washing 24 wells at a time. Part of the washer module

**Manipulator module**
See Plate manipulator module

**Measurement module**
Module where measurement takes place.

**Measurement module case**
A light-tight box forming the outer part of the measurement module and intended to eliminate background at the measurement position. Access is by means of a light tight door

**Microtitration plate**
Otherwise known as Plate or Microplate. Plastic matrix of wells

**Modular**
Comprised of more than one piece (module). All the modules together make up the working system e.g. GSP processor

**Module**
A piece of the working system

**Optical block**
An assembly comprising excitation and emission filters, an excitation mirror and a reference mirror

**Output stacker**
A stacker module used to unload plates from the GSP processor

**Pinch actuator**
Part of the plate stacker. It supports the last but one plate thus supporting the stack and allowing the last plate to be moved to the instrument

**Pipette**
See High volume pipette and Low volume pipette

**Plate**
Microtitration plate

**Plate carrier**
Mechanism of the plate manipulator that moves plate holders from one module to another in the GSP processor

**Plate detector**
Detects a plate in the input stacker before loading it into the instrument

**Plate holder**
Holder for e.g. a microtitration plate so that it can be carried on the plate manipulator module and other modules

**Plate magazine**
Unit for holding plates. It can be fitted into a stacker

**Plate manipulator module**
Device that moves plates from one module to another in the GSP processor. Acts as the core structure of the instrument to which other modules are attached

**Plate stacker**
Unit into which a plate magazine can be loaded. There are two plate stackers in the stacker module

**Plate storage module**
Area in GSP processor where plates are stored when they have been taken in from a stacker

**Plate washer**
See Washer module

**Population screening**
Mass testing of perceived normal population for specific disorders

**Positive ID**
A way to positively identify a kit or part of a kit, generally a barcode

**Reagent cassette**
Holder for reagent bottles. Part of the reagent storage module

**Reagent carousel**
Rotating holder for reagent cassettes, disposable tip cassettes and waste tip cassettes. Allows continuous loading of reagents and tips. Part of the reagent storage module

**Reagent dispenser**
Pipette to dispense reagents at a known volume. Part of the reagent dispenser module

**Reagent dispenser module**
Comprises two reagent dispensers and an XY-conveyor.

**Reagent storage module**
Cooled storage place for reagents within the GSP processor

**Reagent vial**
A vial or small bottle that contains reagents needed for an assay

**Rinse bottle**
Bottle containing rinse solution

**Rinse solution**
Deionized water for rinsing the washer/disk remover and reagent dispensers after a run
Run
Processing of from 1 strip to 4 plates (same ID number)

Interval within which the accuracy and precision of a testing system is expected to be stable, but cannot be greater than 24 hours or less than the frequency recommended by the manufacturer

Note: In a series of observations of a qualitative characteristic, the occurrence of an uninterrupted series of the same attribute is called a "run". Between analytical runs, events may occur that cause the measurement process to be susceptible to variations that are important

Sample disk
Disk punched from a dried blood spot from a patient

Shaker incubator
See Incubator module

Shelf
Place for storing a plate holder with or without a plate. Part of the plate storage module.

Slide (movable)
Mechanism holding 12 optical blocks. Part of the measurement module

Single assay load
Single assay = 1 analyte load

Single batch processing mode
Single batch = 1 or more analytes load

Spot
See dried blood spot

SSL
Secure Socket Layer protocol is the de facto standard for encrypting communications that flow between browsers and web servers and vice versa

Stacker
Device to enable automatic transfer of sample plates to/from the instrument.

Stacker module
There are two stacker modules in the GSP processor, an input stacker and an output stacker. Each stacker has a detachable plate magazine

Strips detector
Detects how many strips are in a plate in an input stacker before loading the plate into the instrument

Suction head
Part of the disk remover for removing disks from wells by suction

Temperature control module
Module that maintains temperature inside the instrument at 25 ºC

Template plate
In the software a picture of a microtitration plate with a particular arrangement of samples. This acts as a ready template to make easier the definition of the plate layout

Test plate
Plate for service purposes

Tip
Disposable end of a pipette or a dispenser

Tip cassette
See disposable tip cassette

Top measuring head
Measuring head that is above the XY-conveyor. Part of the measurement module. It comprises a light source, excitation optics, emission optics and a detector. It is used to measure Time-resolved fluorescence and fluorescence intensity

Touch screen
A touch sensitive screen attached to the outside of the GSP processor. It displays the user interface and allows for user interaction without a keyboard or mouse

Tracer vial
Vial containing tracer for assays

Wash concentrate
Substance that forms "wash solution" when water is added to it

Wash solution
Liquid used for washing wells. It contains a detergent. A combination of components used to wash wells in plates

Washer manifold
Two sets of 24 needles. Part of the washer module. Liquid is pumped into wells through one set and then sucked out through the other set

Washer module
Device for washing wells of a microtitration plate. It dispenses liquid into wells and then sucks it out again

Waste liquid
Liquids that are used in assays and that need to be disposed of

Waste pump
Pump for removing the waste to an external drain. Part of the *liquid module*

**Waste bottle**
Recyclable container used to collect contaminated wash liquid. Part of the *liquid module*. Also collects condensation from the *air dryer* and possible overflow from several modules as well as waste from wells aspirated by the disk remover. Provides the vacuum for the *suction head*

**Waste collector**
Funnel for collecting waste from the *reagent dispenser*. Part of the *reagent storage module*

**WCF**
Windows Communication Foundation - new Windows communication protocol

**WPF**
Windows Presentation Foundation - the technology used to display information in *WCF*

**Vial**
Very small bottle

**Y-conveyor**
Mechanism for transporting a plate in the Y direction in the bulk reagent module

**XY-conveyor**
Mechanism for transporting a plate in the horizontal plane. One is in the *reagent dispenser module* and another in the *measurement module*
Appendix A- Hand-held barcode reader

The following barcode commands are specially designed proprietary barcode labels that allow you to reconfigure the default settings that allow the hand-held barcode reader to recognize the same barcodes as the internal readers in the instrument. By default the hand-held reader should be configured correctly and no reconfiguration should be necessary.

If, for some reason, it is necessary to reconfigure the hand-held reader, the easiest way is to do so is to scan all barcodes on the following pages in order and from top to bottom to ensure that the settings are set correctly. More information can be found in the manual of the Welch Allyn IT3220 Hand held barcode reader.

Please note that some system barcode commands (M_DEFAULT, PROGRAM, END) will take a few seconds to complete the operations. You user must wait for the completion beeps before scanning another bar code.

Reset the reader

Welch Allyn IT3220 Hand held barcode reader

Command barcodes to reset the barcode reader

To reset the instrument to its original factory defaults scan the Master Default (M_DEFAULT) barcode.

(Master Default)

M_DEFAULT

Note: After resetting the barcode reader one needs to reconfigure it by reading the barcodes on the following pages.

USB Keyboard Interface

Note: If you are using the USB interface connection scan the "USB Keyboard Interface" barcode in addition to the Master Default to configure the scanner to USB keyboard interface mode.
Record suffix

Command barcodes to set record suffix to TAB.

Read the barcodes starting from the upper barcode (PROGRAM) down to the lowest barcode (END).
Interleaved 2/5 check digit settings

**Without check digit**

Command barcodes to set code 2/5 family settings to Interleaved 2/5 without check digit check and with check digit transmission.

**Note:** These command barcodes are used to set the barcode reader to read Interleaved 2/5 barcodes **without check digit**. Use either **with check digit** settings or **without check digit** settings according to which type of barcode is to be read. **Interleaved 2/5 without check digit settings must not be used to read kit calibrator barcode because the kit calibrator barcode includes check digit.**

Read the barcodes starting from the first barcode (PROGRAM) down to the lowest barcode (END).
With check digit

**Command barcodes to set code 2/5 family settings to Interleaved 2/5 with check digit check and without check digit transmission.**

**Note:** These command barcodes are used to set the barcode reader to read Interleaved 2/5 barcodes with check digit. Use either with check digit settings or without check digit settings according to which type of barcode is to be read.

Read the barcodes starting from the first barcode (PROGRAM) down to the lowest barcode (END).

<table>
<thead>
<tr>
<th>Barcode</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROGRAM</td>
<td><strong>Program</strong></td>
</tr>
<tr>
<td>3</td>
<td>Code 2 of 5 Settings</td>
</tr>
<tr>
<td>8</td>
<td>Code 2 of 5 Settings</td>
</tr>
<tr>
<td>9</td>
<td>Code 2 of 5 Settings</td>
</tr>
<tr>
<td>END(Exit)</td>
<td><strong>End</strong></td>
</tr>
</tbody>
</table>
Codabar minimum length

Command barcodes to set Codabar minimum length to 2.

Read the barcodes starting from the upper barcode (PROGRAM) down to the lowest barcode (END).

PROGRAM

Codabar Min. Length

0

2

END(Exit)
Interleaved 2/5 minimum length

Command barcodes to set interleaved 2/5 minimum length to 1.

Read the barcodes starting from the upper barcode (PROGRAM) down to the lowest barcode (END).
Code 39 minimum length

Command barcodes to set code 39 minimum length to 1.

Read the barcodes starting from the upper barcode (PROGRAM) down to the lowest barcode (END).
Code 128 minimum length

Command barcodes to set code 128 minimum length to 1.

Read the barcodes starting from the upper barcode (PROGRAM) down to the lowest barcode (END).

PROGRAM

Code 128/EAN-128 Min. Length

0

1

END(Exit)
Warranty

The enclosed instrument comes with a limited warranty (the “Warranty”) from Wallac Oy (“Wallac”), a PerkinElmer company. This is only a summary of the warranty on the enclosed instrument and shall not be deemed to alter or amend the terms of the Warranty. Consult the terms and conditions, and rental or purchase agreement for a full explanation of the Warranty.

In general, for a period of twelve (12) months from the date of installation, or fifteen (15) months from the date of shipment (the “Instrument Warranty Period”), whichever comes earlier, Wallac warrants that this instrument is free from defects in materials and workmanship.

During the Instrument Warranty Period, Wallac will provide parts and labor to repair defects in materials and workmanship.

Note: The warranty on this instrument does not cover required Periodic Maintenance (“PM”), if any, the cost and expense of which must be borne by the purchaser or renter. Failure to perform required PM shall void the Warranty. PerkinElmer and authorized representatives are available to perform PM. Please contact your PerkinElmer representative for additional information on PM.

The full provisions of the limited warranty for this product are available at https://www.perkinelmer.com/corporate/policies/terms-conditions-of-sale.html.
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