

# Gyrolab<sup>®</sup> xPand

Product Information Sheet

D0029893/F

- **Nanoliter-scale immunoassays generate high quality data**
- **High throughput system with unattended operation**
- **Fast time to results:**
  - Up to 112 data points in <1 hour, 1120 datapoints per working day
- **Run multiple combinations of methods and CDs in a single run**
- **Samples and reagents cooled during run**
- **Flexible run setup and analysis:**
  - Mapping of which samples are going to be processed for which experiments
  - Run dilution linearity and spike recovery experiments according to guidelines



## Automated, high throughput immunoassay system to maximize productivity

Using proprietary Gyrolab<sup>®</sup> CD technology, Gyrolab xPand helps you optimize immunoassay development and performance. Nanoliter-scale immunoassays deliver exceptional reproducibility in less time than conventional ELISA and with lower sample and reagent consumption. Automated runs take approximately one hour per CD, and up to five CDs can be run unattended to maximize productivity. The samples and reagents are kept at 2–8 °C during the run.

A range of consumables includes CDs for different applications and assays, and buffers to optimize performance. You can develop assays using your own reagents, or use kits from Gyros Protein Technologies.

Regulatory compliance in GxP environments is supported by Gyrolab Functionality Check Kit, a comprehensive IQ/OQ validation, enabling QSR (21 CFR part 11) compliance, and a PQ guidance package.

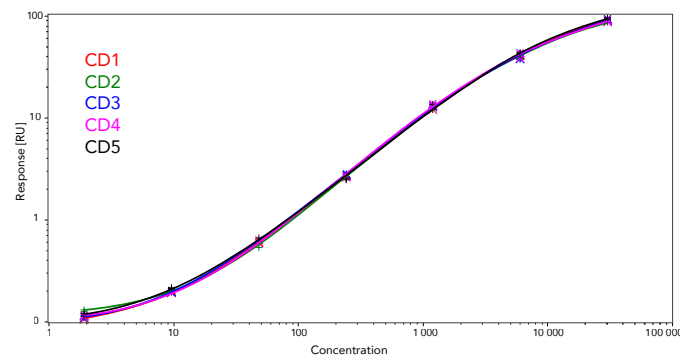
Gyrolab xPand comes with pre-installed software:

1. **Gyrolab Manager** to set up immunoassays for assay development or routine analysis
2. **Gyrolab Control** to control assay workflows
3. **Gyrolab Evaluator** to analyze data and generate reports.

In addition, five Gyrolab software modules are included: Gyrolab Viewer, Gyrolab ADA Software, Gyrolab Affinity Software, Gyrolab LIMS Interface and Gyrolab Control Report. Software tools are also provided to enable management of user privileges, import and export of method templates, generate status reports, review and back up the results database, and other routine functions. Gyrolab system can be

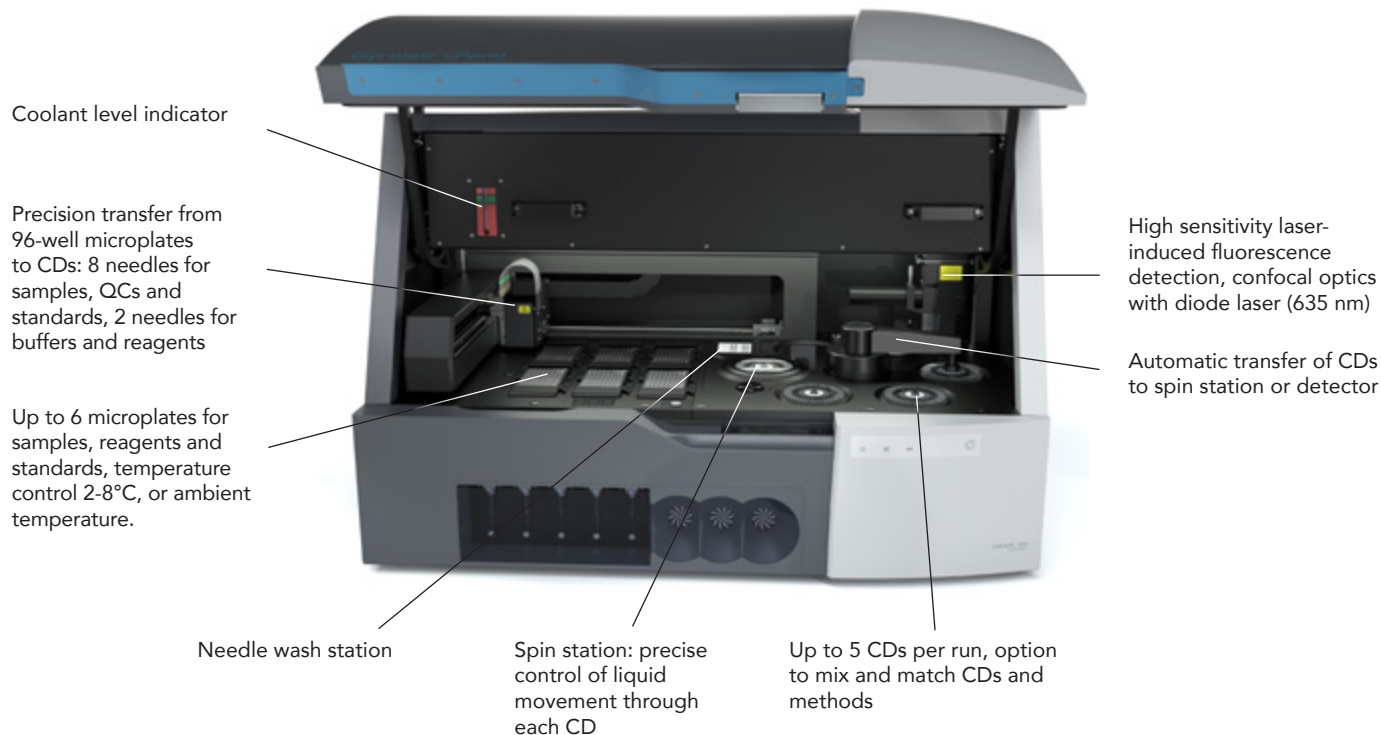
connected to a computer network to evaluate data remotely and communicate with other systems.

From discovery and preclinical R&D, to bioprocess and regulated bioanalysis, Gyrolab xPand helps you and your team develop assays in less time than required for manual methods and increase throughput – quickly, efficiently and reliably.



Gyrolab xPand with temperature control ensures high reproducibility among the five CDs in one run.

## Gyrolab xPand overview



### Gyrolab xPand is delivered with:

Item	Content/Description
Gyrolab Manager	Software to plan and set up Gyrolab runs
Gyrolab Control	Software that controls processing of Gyrolab CDs. Includes template methods (assay protocols) for each type of CD.
Gyrolab Evaluator	Software for analysis of immunoassay data
Gyrolab Software modules	Gyrolab Viewer, Gyrolab ADA, Gyrolab Affinity, Gyrolab LIMS Interface, and Gyrolab Control Report
User and Instrument Guides	Detailed instruction manuals and fast start-up
Wash bottles and tubing	For storage and transfer of wash solutions and pump liquid
Start-up kit	For sample handling: including microplates (25), microplate foils (50), microplate foil adapter (1)
Gyrolab User Licenses*	Software license for four (4) users
12 months warranty	Covers instrument installation and verification, defects in materials and workmanship, and repairs associated with the warranty

\* The End-User (as specified in the original Software End User license agreement) is responsible for ensuring that the number of users does not exceed the number of licenses purchased. User records must be maintained and made available for inspection by Gyros Protein Technologies upon request. Gyrolab software is supplied under license to the End-User and remains the property of the Gyros Protein Technologies Group. Gyrolab software is protected by copyright laws and international treaties.

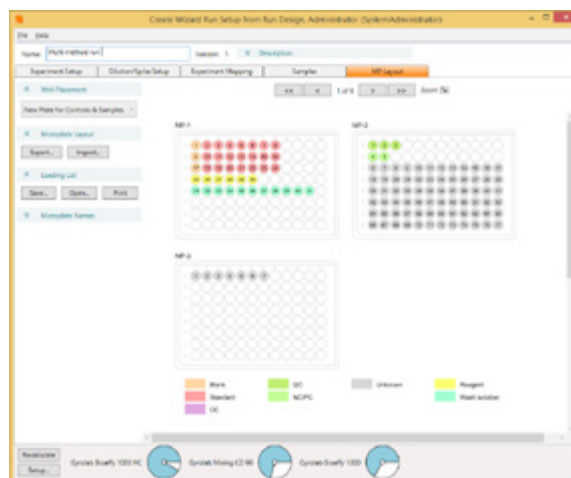
## Gyrolab software

### Gyrolab Manager

- **Plan and set up runs at your desk while the instrument is running**
- **Mix and match assays according to your needs**
- **Designed for 21 CFR Part 11 compliance**
  - defined user access levels and passwords
  - logged audit trails
- **Advanced settings:**
  - spike recovery and sample dilution linearity studies
  - mapping of which samples are going to be processed for which experiments

Gyrolab Manager helps you maximize productivity at your desk. You can plan your experiments away from the lab and run any combination of experiments you wish, from performing five CD runs with one assay and many samples to running different assays on different CDs, all in one operation. Run designs are stored in user-defined folders, allowing you to organize information according to your needs.

The advanced Dilution/Spike functionality provides a high level of flexibility and enables you to set-up advanced analyte concentration determinations, for example when testing assay accuracy and sensitivity by spike recovery studies or analyzing sample dilution linearity.



Gyrolab Manager simplifies the setup of experiments at your desktop.

#### Workflow:

1. Create a Run Design by defining Gyrolab methods, reagents, standards and control samples for the experiments
2. Create a Run Setup by adding samples to the experiments
3. View automatically generated loading list and arrange microplate layout

Optional settings include:

- a. Use cooling of microplates when executing Run
- b. Define spike recovery and sample dilution series
- c. Specify mapping of sample set to experiments

### Gyrolab Control

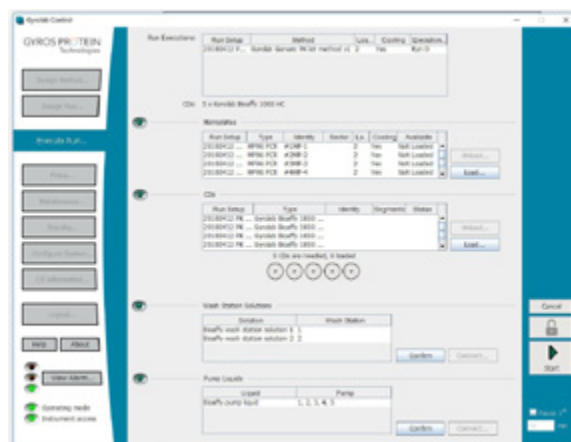
- **Gyrolab Control software to execute runs**
- **Run automated assays workflows, unattended**
- **Designed for 21 CFR Part 11 compliance**

Gyrolab Control is used to execute immunoassays for assay development or routine analysis. Gyrolab methods enable control of all steps in an assay workflow, including sample and reagent transfer, wash and incubation steps, spinning the CD and fluorescence detection, for each type of CD. Gyrolab Control executes the runs, which may have been created by different users with Gyrolab Manager. All instrument and software actions are logged in an audit trail.

#### Gyrolab Control in pre-clinical and clinical analysis

Users working with validation and analysis of clinical and pre-clinical samples can integrate with a LIMS through the Gyrolab LIMS interface software module.

Users analyzing raw data through their LIMS can use Gyrolab Control Report module to automatically generate non-editable raw data reports after each run.



Gyrolab Control is used to execute runs.

## Gyrolab Evaluator

- Evaluate results on completed CDs, including during a run
- Store all data in specified project folders
- Control consistency in evaluation
  - lock analysis settings for each project
- Designed for 21 CFR Part 11 compliance



Gyrolab Evaluator software is used to analyze data and generate reports.

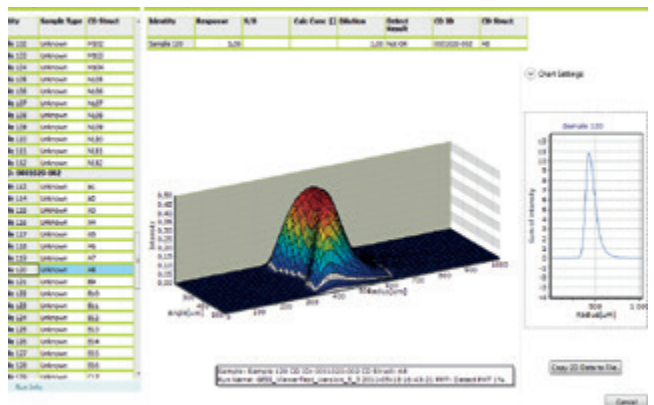
Gyrolab Evaluator enables all sample and run details, run data and analyses to be stored in specified project folders. The administrator can lock analytical parameters, such as curve-fitting options and acceptance criteria, to ensure consistency between different users during data evaluation. Samples from different experiments within a single run can be analyzed and quantified in a single step and data can be compared within and between runs. All software actions, such as changes in acceptance criteria or exclusion of data points, are logged in an audit trail.

Gyrolab Evaluator also includes advanced features, including visualizing dilution linearity and spike recovery data. Summarizing and plotting the dilution series enables assay qualification acceptance criteria to be set based on parameters defined by the user, such as maximum values or levels of variation, according to guidelines.

Quantification reports, including curve fit information, details on standard curves, control samples and unknowns can be generated for one or more samples from the same run or within the same project. Data comparison reports can be customized to include selected data tables and columns, with separate tables for each sample type.

## Expanding the functionality with Gyrolab Viewer

- Review each data point at your desk
  - See binding profile, sample and run details
  - Compare samples run under the same conditions on different CDs
- Facilitate assay development
  - Compare binding profiles
  - Identify optimal binding pairs
- Quality control data
  - Investigate outliers
  - Troubleshoot during development or routine analysis

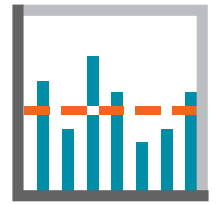


The unique Gyrolab Viewer software converts on-column fluorescence signals into binding profiles, revealing the interaction for each data point. Gyrolab Viewer is accessed directly through Gyrolab Evaluator to facilitate assay development and troubleshooting from research through to regulated environments.

Gyrolab Viewer visualizes the binding response for each data point. You can compare binding profiles and samples run under the same conditions on different CDs, quality-control data by investigating outliers, and troubleshoot during development or routine analysis.

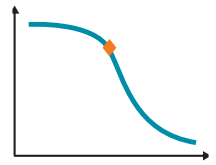
## Gyrolab ADA Software

Gyrolab ADA Software follows a standard assay workflow to provide time-efficient, drug-tolerant analysis of anti-drug antibodies (ADA). You can define the preferred cut point formula and view results according to predefined acceptance criteria and cut point. The software will help your confirmatory analysis by displaying results according to your acceptance criteria and confirmatory cut point, and highlight any samples that fall outside.



## Gyrolab Affinity Software

Gyrolab Affinity Software facilitates the design and evaluation of in-solution affinity experiments. The Affinity Design Type module guides you in setting up the affinity experiment. Once the run has been completed, the Affinity Evaluator Software generates affinity curves by plotting the response against the concentration of the variable interactant. The affinity curves are then fitted according to the selected interaction model. The affinity summary page presents fitted curves,  $K_D$  values, calculated (active) concentrations of fixed or variable interactants, and their confidence intervals. You can use the affinity curves to compare the affinity series originating from different interaction pairs or assay variants. You can also analyze multiple curves from one interaction pair obtaining globally fitted parameters.



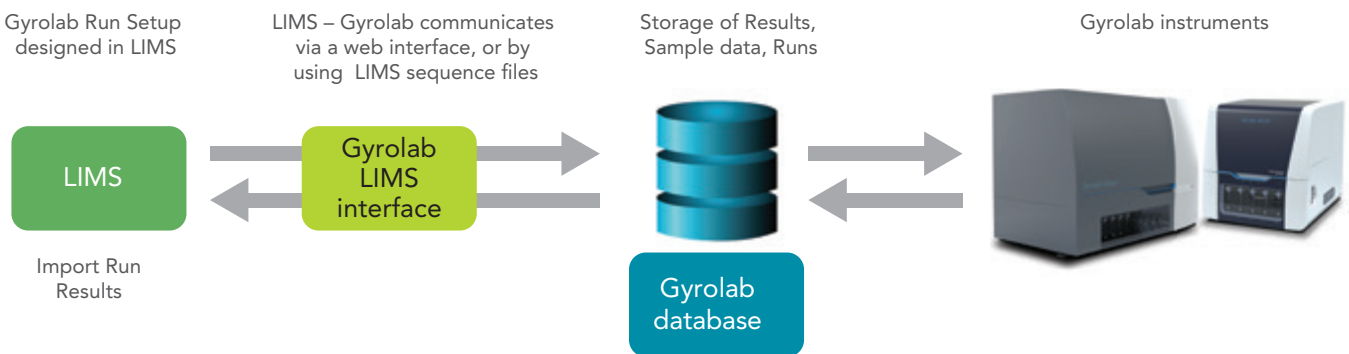
## Gyrolab LIMS Interface

Gyrolab LIMS Interface module enables full integration of Gyrolab systems into a Laboratory Information Management System (LIMS) in compliance with GxP requirements. The module enables a fully automated process where the entire setup is controlled by the LIMS, which communicates with Gyrolab via a web interface. Alternatively, Gyrolab LIMS interface provides options to transfer sample information from LIMS to Gyrolab using LIMS sequence files, including a direct transfer from LIMS into the Gyrolab database.



After the run execution, the Gyrolab LIMS interface can export result files to any location, or the LIMS can import run results directly from Gyrolab database.

Although Gyrolab LIMS sequence file format is based on the generic raw data file format for Watson LIMS 6.4, it can be supported by other LIMS as well.



Schematic of data workflow with Gyrolab.

## Gyrolab Control Report

Gyrolab Control Report automatically generates 21 CFR Part 11 compliant, non-editable raw data reports after each run.



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## *IQ/OQ validation support and PQ guidance*

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- Provides time-saving support for on-site qualification and validation
- Certifies instrument functionality and performance within published specifications
- Includes certificates and records to fulfill GxP, FDA and EMEA requirements
- IQ/OQ performed by Gyrolab certified service engineers using equipment calibrated to NIST traceable standards

Products from Gyros Protein Technologies are quality controlled and validated prior to delivery according to clearly defined processes. After delivery, the IQ/OQ/PQ support package extends this validation process to enable on-site qualification and validation for those instruments that are used in GxP environments.

### *Installation Qualification/Operational Qualification Process*

Prior to IQ/OQ, certain criteria must be fulfilled:

- Documentation must be customized to match the user's workflow and approved for use.
- The instrument should be fully operational and set up for normal use, e.g. linked to a network if applicable.
- A Preventive Maintenance (PM) check is strongly recommended and becomes mandatory if more than 6 months have elapsed since installation or the previous PM check.

### *The IQ/OQ process takes about 3 days on site*

During this time the user will monitor and approve every step of the IQ/OQ performed by the Gyrolab-certified service engineer as outlined below.

Installation Qualification procedures cover:

- Site qualification and environmental conditions
- Configuration and calibration
- Calibration certificates of all equipment used during validation
- Configuration and documentation of computer hardware and software

Operational Qualification procedures cover:

- Computer hardware and software functionality
- Instrument functionality
- System operation

Upon conclusion of all procedures, the user will approve the complete IQ and OQ documentation.



### *Performance Qualification*

The PQ guidance package includes recommended procedures to help the user validate the instrument's performance. After IQ/OQ the user is required to test and verify that specifications are met for the specific application and end-user handling i.e. a performance qualification. This process will require establishing acceptance criteria as well as inspecting and testing results with calibrated equipment, performed by trained, qualified end-users.

### *Re-validation*

IQ/OQ documentation must be updated to ensure that an instrument remains in a validated state after repair, upgrade or relocation. All IQ/OQ and re-validation services are performed by Gyrolab-certified engineers.



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## Gyrolab Functionality Check Kit

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- Ensure high quality results
- Support GLP/GMP and quality assurance requirements
- Verify instrument performance within 20 minutes
  - checks liquid transfer from microplate to CD
  - checks spinner functionality
  - checks detection functionality
  - checks software and database connection



Designed for one time use, this kit enables a repeat check in the event that the first check is unsuccessful.

The Functionality Check Kit provides a ready-to-use confirmatory test of instrument performance. The check is completed in a single run, takes only 20 minutes to perform and requires no additional training. An automatically generated report is stored within the database, detailing results. Routine runs can be started immediately after a successful check.

It is assumed that the instrument is maintained and handled according to the recommendations, for example, that Preventive Maintenance is performed regularly and that user maintenance procedures have been followed.

### Storage and shelf life

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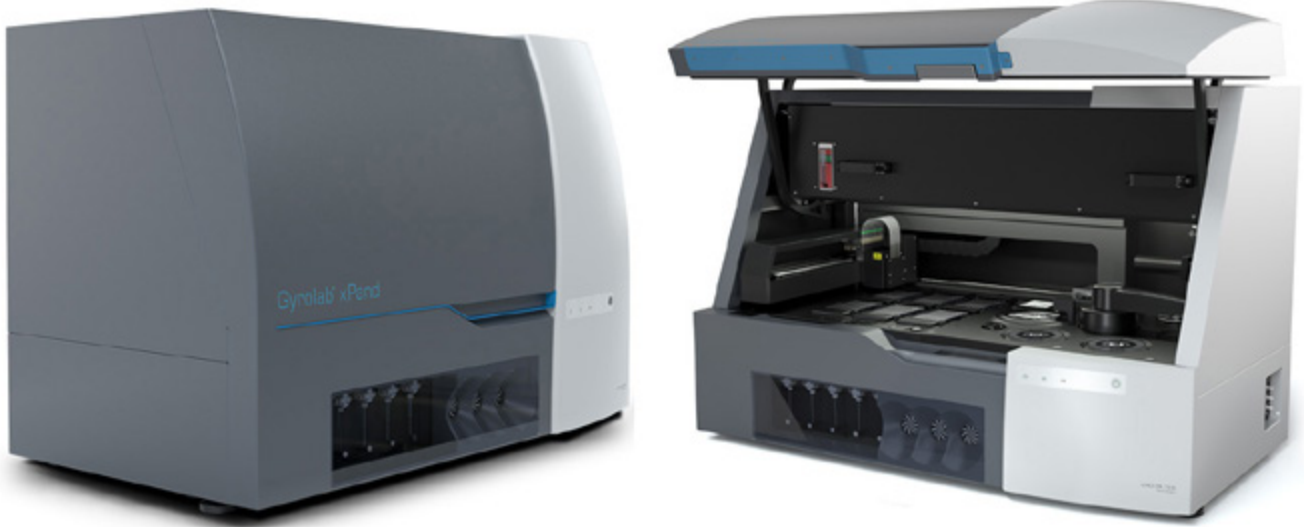
Unopened kit (CD and reagents)	Refrigerate at +4°C to +8°C. Do not freeze.
Shelf life unopened kit (CD and reagents)	Specified on product label.
Opened reagents	Store at room temperature. Discard after 12 hours.
CD after completion of first run	Return CD to original CD box and pouch, re-seal and store at room temperature. Discard after 12 hours.

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## Operational requirements for Gyrolab xPand

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Instrument dimensions (w × d × h)	1.21 × 0.67 × 0.82 m (48 × 27 × 33 in)
Bench dimensions (l × d)	2.20 × 0.62 m (87 × 24 in)
Bench load	160 kg (352 lb)
Overhead clearance	1.10 m (44 in)
Ambient temperature/ambient relative humidity	+20°C to +28°C (68°F to 82°F)/ 20% to 80%, non-condensing
Mains voltage	100 to 240 V (US and Japan standard 15 A power outlet, EU standard 10 A outlet)
Power/Frequency	880 VA/50 to 60 Hz
Air supply	Pressure: >66 to <145 psi; >0.45 to <1 MPa; >4.5 to <10 bar Average flow rate at 0.45 MPa: 5.3 cfm; 150 NL/min; 2.5 NL/s Maximum flow rate (during 5 seconds period at 0.45 MPa): 10.9 cfm; 310 NL/min; 5.2 NL/s
Air quality	Particle size not exceeding 1 micron Oil content not exceeding 0.1 mg/m <sup>3</sup> Water content not exceeding 940 ppm
Air connection	A hose barb suitable for a hose with an inner diameter of 10 mm (0.39 in) and outer diameter of 15 mm (0.59 in). The point of connection should be within 3 m (10 ft) of the instrument.

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Note:

- As specified above, the system periodically consumes compressed air which must be available throughout the run (up to 5 hours per run). Gyros Protein Technologies recommends the use of a compressor that continuously delivers compressed air. Additional information about compressor requirements and guidelines as well as tools and instructions on how to verify supply specifications can be provided. Place in a vibration-free location, away from direct sunlight and other heat sources.
- Gyrolab xPand will produce small amounts of liquid waste. A waste tube (2 m, or 80 in, long) will be supplied which can be directed to a waste reservoir or a drainage facility.
- If the system database is to be run over the local area network (LAN), a suitable network connection should be available in the proximity of the system.
- The operator needs 1 m (40 in) workspace in front of the Gyrolab xPand workbench.
- Do not install the instrument in a location where there is a risk for explosion or fire hazard.
- If hazardous chemicals are being used with the instrument, forced ventilation shall be provided for the work area.
- The instrument is IP class 20 and a Class 1 Laser Product.



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## PC requirements

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Gyrolab xPand requires an external computer (PC) on which the User Interface and database are installed. The external PC, including monitor, keyboard, mouse and Microsoft Excel, is either supplied by the Gyrolab user or purchased from Gyros Protein Technologies. Configuration guidelines are provided by Gyros Protein Technologies.

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Operating system	Windows 10 x64 – Professional and Enterprise editions – English
CPU	64 bits processor, 1.8 GHz or higher
RAM	Minimum 4 GB, preferable 8 GB or higher
Hard drive size	Recommended 500 GB or more (C: partition) <i>The data is stored in an application-specific Oracle Database installed by a Gyrolab-certified service engineer. Data generated from processing one CD is approximately 15 MB.</i>
USB port	USB 2 or 3 interface, minimum four ports. <i>The software communicates with the instrument via one USB port. The other three are intended for the mouse, the keyboard, and a USB device.</i>
Screen Resolution	Recommended 1366 X 768

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## Ordering information

Please contact your local Gyros Protein Technologies representative to discuss your exact requirements or for terms and conditions of purchase.

Product	Content/Description	Product number
Gyrolab xPand	Gyrolab system with content as listed under Gyrolab xPand overview	P0020520
Gyrolab xPand installation	Instrument installation performed by a Gyrolab-certified engineer	P0020521
<i>Accessories</i>		
Gyrolab User Licences	Grants an unlimited number of Gyrolab software users	P0004955
Microplate foil adapter	One (1) adapter for transfer of microplate foil to microplates	P0003697
<i>Performance and validation support</i>		
Gyrolab Functionality Check Kit	A confirmatory test of instrument performance compatible with Gyrolab Control v 5.2 or higher. Includes Functionality Check CD (1), reagent (1500 µL), wash buffer (1500 µL), microplates and foils (2 of each), instruction for use (1).	P0005002
IQ/OQ validation support and PQ guidance	Documented collection of procedures and test protocols for on-site installation, operational and guidance for performance qualification. Gyrolab-certified engineer performs IQ/OQ.	P0020523
Instrument re-validation	Re-validation performed by a Gyrolab-certified engineer after modification of a validated instrument e.g. repair, update, upgrade or relocation (travel and parts billed separately).	P0004979
Gyrolab Software Simulator Package	Laptop computer with a full installation of all Gyrolab software in a simulated instrument software environment."	P0020742
Gyrolab Software Validation Package	Documentation package with requirements and test specifications for Gyrolab Manager, Gyrolab Control, and Gyrolab Evaluator.	P0020755
<i>Consumables</i>		
Microplate foil	Pack of 50	P0003313
PCR Plate 96	Pack of 25	P0004861
Gyrolab CDs	Refer to product information sheet "Gyrolab CDs"	D0012493
Rexxip buffers	Refer to product information sheet "Rexxip buffers"	D0021887



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