Product Specifications

Nautilus™ LIMS

Nautilus sets the standard in delivering LIMS functionality into the laboratory. Designed to lower the cost of ownership and reduce payback time, Nautilus from Thermo Electron Corporation brings LIMS within the reach of laboratories both large and small. Easy to configure, Nautilus allows you to map the LIMS onto your laboratory workflow, without coding or the necessity for IS specialists. Nautilus offers new levels of user empowerment and sample traceability. Its highly flexible and dynamic capabilities for plate handling satisfy the requirements of bioanalytical information management.

The Nautilus customer list includes many of the biggest, and the most progressive, corporate names in industries such as biotechnology, forensics, pharmaceutical R&D, food and beverage and environmental services .

Nautilus' user interface will be instantly familiar to all users of Explorer on the latest versions of Microsoft® Windows®. The system is controlled using all the same mouse controls, maximizing efficiency and dramatically reducing the learning curve for new users.

Instrument integration, previously considered an add-on to the LIMS, forms an integral and easily configured part of Nautilus' core. Its in-built design brings unparalleled automation and productivity gains right from the start.

Compliance with Good Laboratory Practice (GLP), Good Automated Laboratory Practice (GALP), Good Manufacturing Practice (GMP), Good Automated Manufacturing Practice (GAMP) and ISO-9001 is facilitated; not only by the security model of Nautilus, but also by the extensive validation collateral prepared by Thermo and the validation services offered by Thermo Informatics global services team. In addition, the implications of the FDA's ruling 21 CFR part 11 on electronic records and signatures have been carefully considered in the design of Nautilus.

In terms of technology, Nautilus is designed using industry-standard tools and has been developed using Oracle and the latest versions of Microsoft Windows, thereby future-proofing your investment and ensuring you can benefit from the latest technology. Nautilus uses the full Oracle® RDBMS functionality to enforce data security including the use of both check and referential integrity constraints.

With support for Microsoft Windows Terminal Services, Nautilus can be deployed to client workstations using an ultra thin client. This can significantly reduce system management and administration overheads leading to a reduced cost of ownership for customers.

LIMS Explorer

To ensure that the system is intuitive, the Thermo design team has developed a user interface that will be familiar to all users of Microsoft Windows (see figure 1). Operators will immediately be at home opening folders, modifying entries, printing and working productively within a very short timeframe. The unrivaled ease-of-use of Nautilus Explorer reduces staff training requirements, speeds up deployment and ensures that return on investment is quickly realized. As an example, a single right-button mouse click presents the user with a menu of context-sensitive actions that can be performed on that item. To also aid ease of use while minimizing risk of error, Nautilus uses the color-coding of dynamic data entities, such as samples, aliquots, tests and results, through phases in their life cycles.

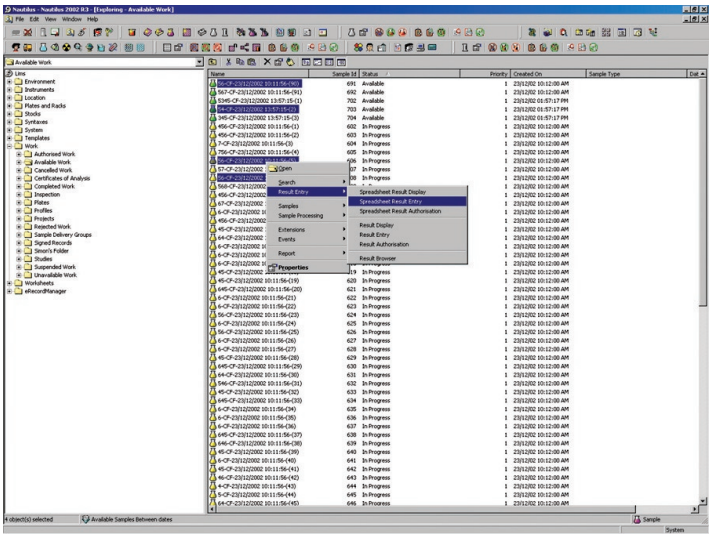
Additionally, users can create their own personal toolbars. Operators can create a simplified, productive and secure LIMS environment. This can be achieved through user-defined folders that can be public, private, static or dynamic and that contain only those items they want to work with. The hierarchical structure of Nautilus Explorer allows the user to drill down for information, for example to retrieve an inventory of items stored at a particular location, or within any sub-location.

Thermo has also incorporated the concept of 'Shortcuts' into the Nautilus Explorer, allowing users to create quick links to items that are frequently used.

Workflows

With Nautilus, there is no longer a requirement to customize a LIMS by means of a programming language. Nautilus allows the user to graphically design a Workflow of a life cycle in the laboratory. An international patent is pending on this Workflow technology. Workflows are best described as graphical representations of laboratory and business processes. The life cycle of a new item, e.g. a sample, can be mapped onto Nautilus. This results in the assignment or creation of relevant aliquots, tests, results and associated reports.

By including project and study-level information into the Workflow hierarchical structure, Thermo is introducing 'study management' into Nautilus. It is important to note that Nautilus has full support for sample aliquoting and, indeed, aliquot splitting and composition.



LIMS Explorer

In Nautilus, the Workflow editor provides users with an easy-to-use graphical tool for modeling laboratory processes, with no programming experience required. Users can simply adapt Workflows to reflect changes to laboratory procedures and they can be created as separate models and joined to describe a larger laboratory process. This means an individual process needs only to be defined once and reused.

Decisions which affect the life-cycle of a sample can be based on the results obtained for that sample and whether they pass or fail pre-defined specification limits. These automated decisions help ensure error-free processing.

Sample Login

It is important for the LIMS to be both simple and intuitive to achieve user-acceptance and increase productivity. Thermo has developed a user interface that allows all related key functions such as sample login, edit sample data, edit aliquots, edit tests, enter results and produce reports, to be performed from a single screen.

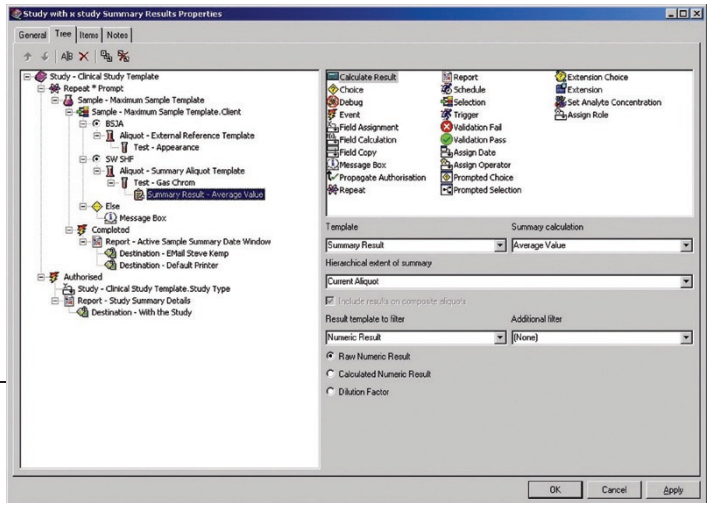
To add flexibility to the processing of samples, Nautilus has been designed to permit sample login both automatically and manually including XML (eXtensible Markup Language).

Result Entry

Nautilus' spreadsheet format offers a familiar and efficient method of data entry. The presence of ancillary information relating to the result is graphically indicated in the cell, just like Microsoft® Excel. Data mining direct from the result provides access to all associated information such as audit records, eSig, the source instrument and its raw data, result specifications and any relevant notes.

Once entered, an approved user can authorize the results. From the Result Entry screen, the operator is able to enter authorization mode and verify individual or groups of results. Through the use of Workflows, automated actions can be triggered including business decisions to undertake additional tasks, such as login further samples or send a report.

A wide variety of result types can be handled by Nautilus to satisfy customer requirements from a range of laboratory environments. These include calculated results, results derived from standard phrase lists, Boolean results, text entries and data files.

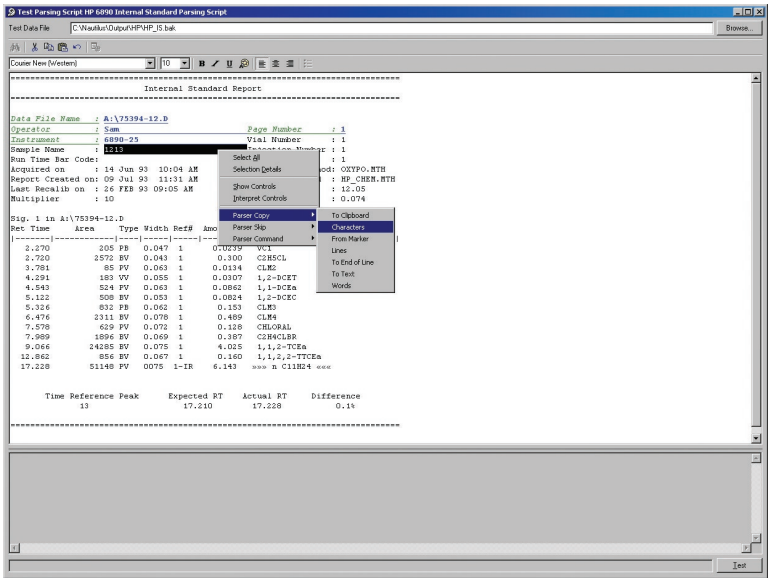


Workflow Configuration

In the typical modern laboratory, output is generated by a wide array of instruments performing an increasing number of techniques. However, in order to realize the benefits of automation, many LIMS demand considerable programming skills to enable instrument integration. Nautilus represents a new paradigm in terms of connectivity.

Instrument integration has been broken down into two simple parts. The first, or parsing phase, provides the user with the ability to extract data from an output file including instrument and third party applications using simple 'point-and-click' technology. In the second phase, these values are then mapped into the Nautilus LIMS. The system can store the original data file within the LIMS and permits authorized users to datamine any acquired result to review the original raw data.

Such integration enables the automation of data transfer and removes the possibility of transcription errors. This relieves trained personnel from tedious, time-consuming data entry tasks and maximizes the resources and investment of the laboratory.



Electronic data capture

Instrument Management

Today, instruments are commonly a configuration of many parts, for example pumps, columns, detectors and autosamplers. Nautilus satisfies the increasing demand for management and traceability of these instruments. This includes the scheduling of calibrations and servicing, as well as the retrieval of the calibration, service and configuration history of each instrument and its relevant component parts. For accredited laboratories, this functionality supplies compliance with ISO 17025.

Additionally, Nautilus provides full inventory control over these laboratory assets. This instrument management functionality dramatically increases the efficient use of laboratory resources and effortlessly generates information required for regulatory compliance.

Plate Handling

For high throughput laboratories, Nautilus features advanced functionality for the handling of microtiter plates and arrays. Plate configurations and fill orders may be defined using a simple graphical user interface, plate processing such as replication, compositing, and pooling may be handled, and plate pedigrees may be viewed to allow parent and child plates to be determined and tracked.

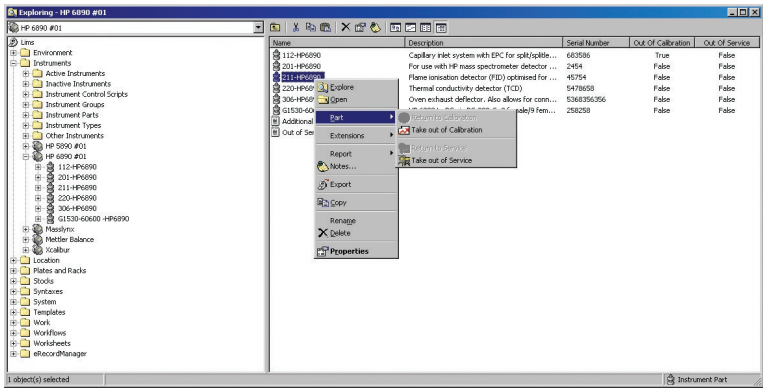
A plate's lifecycle is determined by the Plate Workflow used to build the plate. As in the standard Nautilus Workflows, these are used to automate decisions and actions throughout a plate's lifecycle. This permits a full work action and decision tree process to be built and formatted against user project requirements.

Nautilus also features a Result Browser that provides users with a visualization tool for the presentation of plate and aliquot results. This enables the dynamic querying of results and subsequent review in either tabular or graphical format, within a highly user-friendly interface.

Worksheets

Most laboratories incorporate some form of worksheet list model in their day-to-day operation. Nautilus Worksheets can be viewed as a working list of samples that share a similar analytical requirement such as the performance of a preparation, test or assignment to an instrument or analyst. Functionality that allows the automatic creation of worksheets saves valuable operator time. This process also allows a printable list to be generated of all information for a defined task and assigned to an operator.

Nautilus provides a range of aliquot types that can be added to a worksheet to enhance its QA/QC functionality. These aliquot types allow you to create assays that reflect the working practices of your laboratory.



Instrument Management

AQC

Users of Nautilus are able to easily create statistical charts to assist in monitoring control data, including charts that plot individual results, mean and range values, and percentage difference between two results acquired from duplicate entries on the LIMS worksheet. All charts are generated in Nautilus according to the industry-standard Shewhart rules on statistical control techniques.

Notes

The ability to create notes is available for all items in the Nautilus LIMS, providing the users with the ability to record any additional, item specific information that may be required.

For example, it is possible to link Microsoft® Word, Adobe® PDF-based Standard Operating Procedures (SOPs) or other sets of working instructions against instruments or Workflows within Nautilus.

In a similar way, item-specific comments and extra information can also be added as short textual notes. Web Notes allow external information sources on the Internet to be accessed in the click of a mouse. A useful example of this might be a link to an instrument manufacturer's web site and the pages of an on-line instrument reference manual.

Auditing

Nautilus offers new levels of auditing control in response to the demands of regulatory compliance, making auditing in Nautilus undoubtedly the most advanced of any LIMS.

Auditing can be used to record individual changes or groups of changes to information held in the Nautilus LIMS. Nautilus is unique in permitting the auditing of any item, e.g. instrument or operator records.

Audits can be silent or interactive. Interactive audits can be either transactional or field-based. A transaction audit will prompt the user to enter a single reason for all the changes made, and a field level audit will prompt for a reason for each individual modification.

Nautilus not only records the new and old values of the entry that has been updated, but it also allows the recording of any additional related information that is regarded as important.
If required, the activation of an audit can automatically trigger the sending of notifications to key personnel.

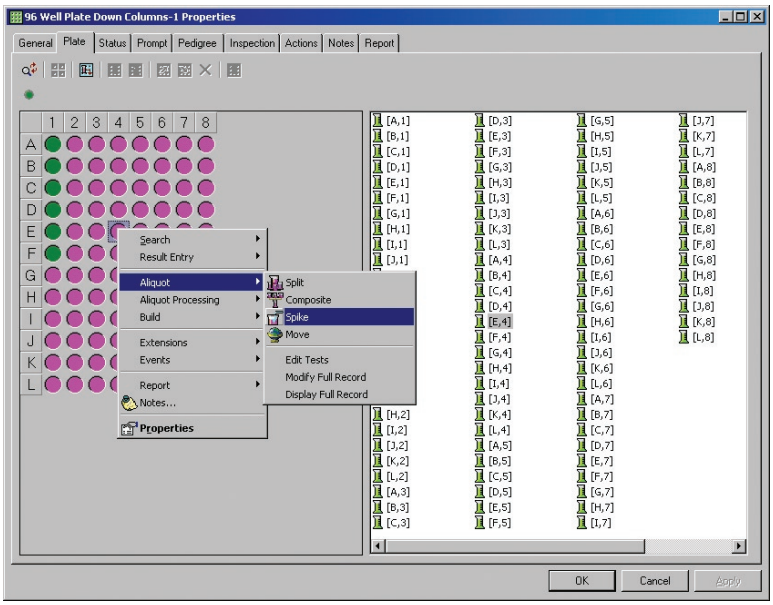


Plate Handling

A unique and major feature of Nautilus' auditing capabilities is that they operate when the database is being modified using third party applications, such as InfoMaker™ and Crystal Reports™, even without Nautilus running.

Import/Export

The Nautilus Import/Export module provides an easy-to-use and structured method by which information may be taken from one Nautilus database and inserted into another. The module utilizes XML (eXtensible Markup Language) files as the medium for exchanging information, a format which has rapidly become the worldwide standard for file transfer.

Users can import and export any static data item (or a set of static items) using the Nautilus Explorer, including workflows, instruments and calculations.

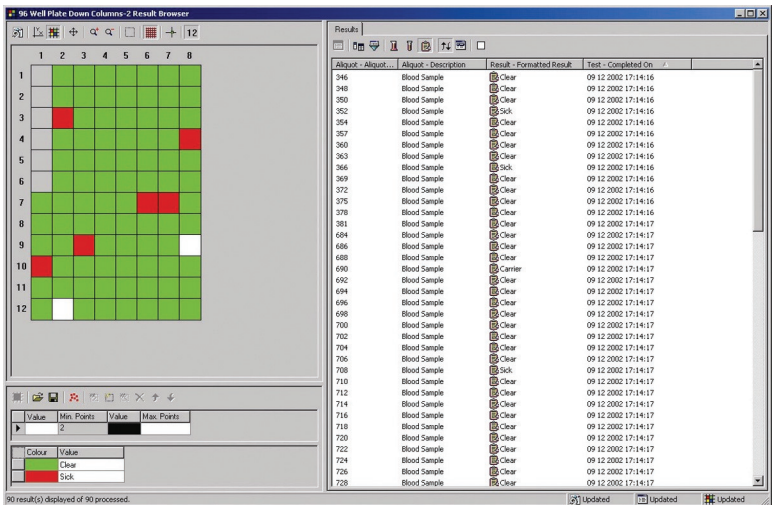


Plate Result Browser

Electronic Signatures

As you would expect from a world class modern LIMS, Nautilus delivers a complete suite of tools to enable you to configure a 21 CFR Part 11 compliant LIMS, in accordance with your specific laboratory working practices. Nautilus offers direct support for electronic signature compliance through configurable mechanisms for electronically signing both static and dynamic data entities.

Signing of dynamic and versioned static data is enabled by defining a configurable 'Signature Template' on the data entity to be signed. This template specifies the data to be included when generating the signature. On authorization, the user is then prompted to 'sign' the data by re-entering their user name and password.

Extensions

The boundaries of Nautilus have been further widened with Extensions. This feature provides a means by which users are able to create and perform additional specialist tasks on any item within Nautilus. For example, Extensions can be used to integrate Nautilus with third-party applications to provide the LIMS with BLAST searching, DNA sequencing, and data visualization functionality.

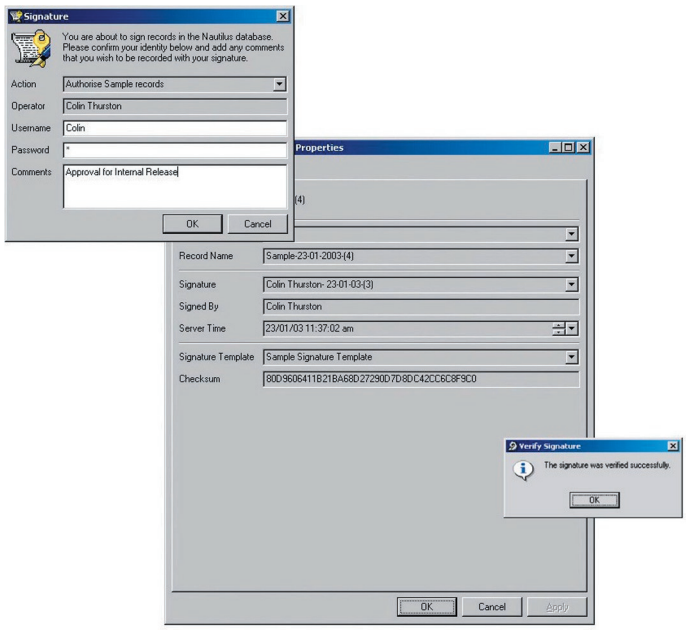
Security

Nautilus provides a completely secure operating environment; crucial for the controlled operation within a multi-user LIMS environment. This is accomplished through the implementation of two main modes of security:

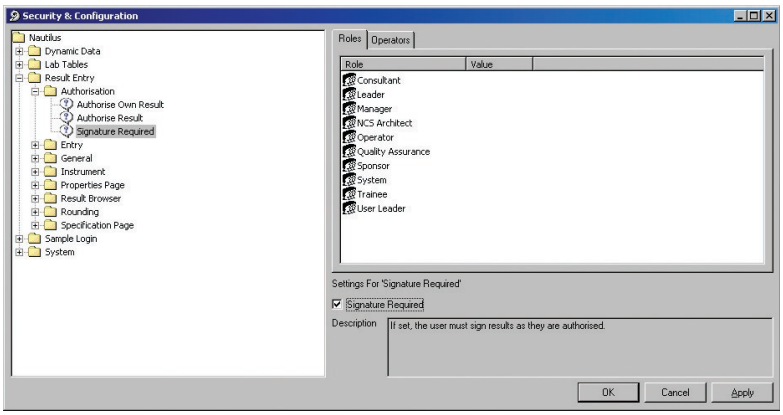
- Data Security - security that is implemented at the database layer. This security mode manages the ability to access, and the level of access to, specific data within the Nautilus database. Data security satisfies the essential LIMS requirement that security is maintained when accessing the database from third party applications, e.g. from within a reporting package.
- Application Security - security that is implemented within the application itself. This security mode manages the ability to perform specific functions/actions/tasks within the Nautilus system, e.g. limiting result approval to only laboratory managers.

The business rules and data access security controls of Nautilus are stored in the database. This means that access via third party applications, for example Microsoft® Excel or Crystal Reports, remains controlled by the Nautilus security management system and audit trail.

Application security is implemented by defining access to security items. A security item defines access to a particular function, such as logging in samples.



Electronic Signatures



Security and Configuration

Implementation, Training and Support

Thermo Informatics has a global services network of experienced project managers, project analysts and consultants focused on the successful implementation of our customers' projects. Teams specialize in industry-specific areas including Forensics, Pharmaceutical, Chemical and Environmental/Contract Testing. Wide-ranging services include project planning, management of user workshops, business requirements definition, milestone delivery, systems integration, workflow modeling, validation consultancy – in short, everything from installation to complete integration and automation of the laboratory, depending on customer requirements.

This group understands that identifying and qualifying your business needs is key to a successful system deployment ensuring an early payback and that you are positioned to maximize the return on your investment.

We recognize the importance of effective user training and support and we will work with you to deliver the right level of product knowledge to the right people in your organization. Training courses for all levels of users can be carried out at Thermo offices around the world, or provided as an on-site service.

Thermo is committed to delivering superior levels of software support. The right people, giving the right response when you need it. Thermo is also at the forefront of our industry in optimizing use of the Internet to make support as accessible and as effective as possible for your users.

Product Specifications

Regulatory Compliance

Each of our solutions delivers peace of mind, offering functionality that enables compliance with Good Laboratory Practice (GLP), Good Automated Laboratory Practice (GALP), Good Manufacturing Practice (GMP) and Good Automated Manufacturing Practice (GAMP) under the auspices of all major regulatory authorities, including US FDA, US EPA and OECD.

This includes extensive functionality to support customers to comply with regulatory rulings such as 21 CFR Part 11 and other similar protocols.

If you are considering investing in a solution to protect your corporate assets and intellectual property, you need the assurance that the vendor itself has a quality management system that satisfies an internationally-recognized standard. Thermo Informatics has BS EN ISO 9001:2000 accredited registration under the TickIT scheme. The scope of our certification is "The design, development, sales, implementation and support of computer based laboratory information and automation systems."

Our Credentials

As one of the largest scientific instrumentation companies in the world, Thermo Electron Corporation (NYSE: TMO) believes in "customers for life". Our ethos is to continually develop products, services and business practices to meet your changing business requirements.

Thermo Informatics, formerly separately trading as Thermo LabSystems and Thermo Galactic, is part of Thermo's Life & Laboratory Sciences sector. No supplier is more committed to the market for laboratory informatics, demonstrated by our 20+ year track record of success. Your company is assured of long-term commitment from Thermo. Your business is valued and your investment protected.

With technology in mind, Thermo is committed to industry standards, with solutions optimized for supporting the latest versions of Microsoft® Windows® 2000 and Oracle. We are positioned with our solutions to adopt all of tomorrow's technology standard, as they become available and are proven.

The Next Step

Hopefully this has given you an appetite to find out more. Why not contact us? We'd be happy to bring Nautilus to you, and give you a personal demonstration of how Nautilus and Thermo can increase your company's productivity.

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UK (44) 161 942 3000

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Germany (49) 6103 408 111 0

Spain (34) 91 657 49 34

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