NucliSENS™ easyMAG

USER MANUAL

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BIOMÉRIEUX

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Revisions

The list of revisions below summarizes replacements or additional pages in your User Manual.

Version	Date of printing	Modifications	Pages modified
A - 2.0	2007/07	Creation	All
B	2009/09	Modification of legal and regulatory information	Covers, ii, iii, iv, v, vi, vii, viii, 1-2, 1-5, 1-7, 1-8, 1-9, 1-10, 1-11, 2-8, 4-16, 6-2, 8-14

Due to software evolution slight changes in the dialog boxes displayed in this document may occur. When a modification is made that may have adverse effects on operating the system using this document, an update or amendment will become available.

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*Supplementary information to this User Manual is supplied in the Addendum to the **NucliSENS easyMAG** User Manual, which accompanies this manual. Contact your local representative to obtain an additional copy.*

Intended Use

The ***NucliSENS easyMAG*** platform is intended for the automated isolation (purification and concentration) of total nucleic acids (RNA/DNA) from biological specimens. For *in vitro* diagnostic use.

Important Information

The ***NucliSENS easyMAG*** is an *in vitro* diagnostic medical device.

The components of the ***NucliSENS easyMAG*** system are supplied only for the purposes of the intended use specified.

The ***NucliSENS easyMAG*** has been designed to safeguard the user and specimens, provided it is operated according to the instructions in the accompanying documentation.

The user must not connect, install, replace or decommission equipment or software that is not approved by bioMérieux, or configure equipment or software in a manner that is not approved by bioMérieux.

If the equipment is operated in a manner not specified by bioMérieux, the protection offered by the equipment may be impaired.

Installation, commissioning, repairs and decommissioning must only be carried out by trained qualified service personnel authorized by bioMérieux.

The equipment is heavy and should not be lifted without following correct procedures. The equipment should not be lifted or re-located without the assistance of bioMérieux Field Service Support.

Sub-assembly	Weight
‘Dry’ Instrument including LCD monitor and keyboard	128 kg
Computer	8 Kg

Technical Assistance

For technical assistance, including spare parts and consumables, contact your local bioMérieux representative.

Disclaimer

bioMérieux specifically disclaims all warranties, express or implied, of the suitability of the instrument and disposables (the ‘System‘) and disclaims all liability, whether direct, indirect or consequential, for any use other than as set, forth in the package insert. Customer acknowledges and agrees that use of the System for testing of sample types or for indications other than those described in the package inserts is done solely at the Customer's own risk. The Customer acknowledges and agrees that it is Customer's sole and exclusive responsibility to validate the System for any such intended use, and to determine whether the System is suitable for that intended use. The performance of any validation studies and the subsequent use of the System based on Customer's validation studies shall be the Customer's sole risk and responsibility.

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Table of Contents

1 Safety

Safety Information

It is essential that the warnings, cautions and safety requirements contained in this document are read and understood by the user before operating the system.

Warning symbols have been placed on the instrument to draw the user's attention to areas of potential hazards.

A warning triangle means: 'Attention'. Consult the appropriate documentation or accompanying text before proceeding. Personal injury or damage to the system may occur if correct instructions are not followed.
Warnings and cautions appear both on the equipment and in the documentation, where appropriate.

All users must be familiar with the following symbols and their meanings:

This label warns that there is danger of damage from static electricity to components in the area of this label. When working in the area of sensitive components wear a properly connected grounding strap.

This label warns that there are items in the vicinity that may be hot enough to cause burns. Before working in an area where this label is present, switch off the instrument and allow sufficient time for cooling.

This label warns of the possibility of crushing. Keep extremities away from this area when parts of the instrument are moving.

This label warns of the possibility of pinching. Do not allow fingers or other extremities to intrude into an area containing this symbol while the instrument is operating.

This label warns that a strong magnetic field exists within the vicinity of this label.

This label warns that signals emitted by the instrument may adversely affect the correct operation of pacemakers.

This label warns that a substance is harmful by inhalation, harmful if swallowed, irritating to eyes and irritating to the respiratory system.

This label warns that a substance is corrosive and may attack either metal and / or naked skin.

Safety Precautions

Particular attention must be paid to the following safety precautions. If these safety precautions are ignored, the user may suffer injury. Each individual precaution is important.

Before undertaking electrical safety or other compliance testing on the instrument, contact bioMérieux.

When working around the instrument fans with the power switched on, take care not to place fingers near the fans.

Warning Messages

Electric Shock Precautions

Electronic equipment can be the source of electrical shocks.

Installation, service and repair should only be carried out by authorized and qualified bioMérieux personnel.

Power outlet. Risk of electric shock.

All power switches should be off when connecting or disconnecting cables to power outlets.

We recommend connecting this instrument to a main power circuit that is protected with a ground fault circuit interrupter.

Bio-hazardous Materials Precautions

All in vitro diagnostic equipment, patient samples, blood-based internal controls and quality control (QC) products assayed on this system, as well as all waste in the waste containers, should be treated as potentially bio-hazardous materials.

Ensure that appropriate decontamination is carried out if hazardous materials are spilt on or into the equipment or surrounding areas.

Hazardous chemicals (i.e. guanidine thiocyanate) are used in the reagent bay. Avoid contact with skin, eyes and clothing. Wear appropriate laboratory safety clothing, including protective eye wear and gloves, when working in the reagent bay or handling the reagent bottles.

Potentially hazardous chemicals and potentially biohazardous material are present in the aspirate head. Wear appropriate laboratory safety clothing, including protective eye wear and gloves, when working around the aspirate head.

Waste Material Precautions

Treat waste material, including consumable items, and any components coming into contact with waste material as having the potential hazards of the samples and reagents used in both preparing and processing the samples.

Handle and dispose of waste materials, including consumable items like Aspirator Disposables and sample strips, according to local, state, and federal procedures and regulations, and safety procedures at the installation site.

All users should be familiar with the MSDS for all materials used in the procedures relating to this instrument, and the correct procedures for handling these materials.

Specifically, treat all waste material from the instrument as being potentially biohazardous and corrosive, and do not allow to contact acidic materials.

Material in the waste bottle, drip tray, waste bottle connector, drip tray drain connector, and service pressure gauge connector may be potentially biohazardous.

Treat this material as having the potential hazards of the samples and reagents used in both preparing and processing the samples.

Wear appropriate laboratory safety clothing, including protective eye wear and gloves, when operating with these items.

Handle and dispose of waste materials, according to local, state, and federal procedures and regulations, and safety procedures at the installation site for hazardous chemicals and potentially biohazardous material.

Samples

Avoid direct contact with samples as they may be bio-hazardous. Wipe up spills immediately and decontaminate affected areas using procedures approved at the installation site. Wear protective gloves, a lab coat, safety glasses or goggles.

Hazardous Chemicals Precaution

*Do not allow the **NucliSENS easyMAG Lysis Buffer**, **NucliSENS easyMAG Extraction Buffer 1** or waste from the instrument to come into contact with acidic materials. **NucliSENS easyMAG Lysis Buffer** can potentially release cyanide gas on contact with acid. The quantities that may be released depend on the volumes of both the buffer and the acidic material. Refer to the MSDS for **NucliSENS easyMAG Lysis Buffer** and **NucliSENS easyMAG Extraction Buffer 1** for further information.*

Avoid contact with skin, eyes and clothing.

If spilt, isolate spill area. Do not allow entering drains or watercourses. Clean up the spill with absorbent material (for example, tissue) and clean affected area with copious amounts of water.

Crystallized Drops

The potential for exposure of the respiratory tract may occur in case of cleaning crystallized lysis buffer; extraction buffer 1; Guanidine thiocyanate (GuSCN) containing waste drops, and dusts may be generated.

Avoid generation of dusts.
Harmful by inhalation.
Do not breathe dust.
Avoid contact with skin, eyes and clothing.
Wear protective gloves (nitrile rubber), a lab coat, safety glasses or goggles.

Wipe up GuSCN drops immediately. Remove crystallized drops carefully with distilled water and clean the area with a fiber free towel containing a 5% Extran solution. After cleaning with the 5% Extran solution, clean the affected area with 70% Ethanol. Then wipe the area clean using a fiber-free towel containing a small amount of silicon oil. This to prevent any GuSCN crystals to re-occur.

Crystallized Spills

The potential for exposure of the respiratory tract may occur in case of cleaning crystallized lysis buffer; extraction buffer 1; Guanidine thiocyanate (GuSCN) containing waste spills, and dusts may be generated.

Avoid generation of dusts.
Harmful by inhalation.
Do not breathe dust.
Avoid contact with skin, eyes and clothing.
Wear protective gloves (nitrile rubber), a lab coat, safety glasses or goggles.
Respiratory protection required when dusts are generated (Filter FFP2, according to EN149).

Remove crystallized spills carefully. Spray the area carefully with water and absorb using absorbent material (for example fiber free tissue), clean the affected area with copious amounts of water. Then clean the area with a fiber free towel containing a 5% Extran solution. Then clean the area with the 5% Extran solution, and clean the affected area with 70% Ethanol. Finally wipe the area clean using a fiber-free towel containing a small amount of silicon oil. This to prevent any GuSCN crystals to re-occur.

Mechanical Safety Precautions

DO NOT remove or raise the protective hood when the instrument is in operation.

As with any mechanical system, certain precautions must be taken when operating the instrument. The instrument has a protective cover intended to prevent the user coming into contact with any moving parts and aerosols.

This cover is equipped with safety sensors that stop instrument operation when the cover is opened. bioMérieux does not assume any liability for damage caused as a result of de-activation of the safety sensors

The reagent door falling suddenly has the potential to cause injury.
Take care when working in the reagent bay.

Pinching hazard.
There are moving mechanisms inside the cover around the area of the aspirate head. Do not put hands or any part of the body in or near the working area.

The heater can be hot enough to cause burns.
Do not touch the heater while the instrument is operating, and allow at least ten minutes after turning off power to the instrument before touching the heater.

Burn hazard.
Hot parts are accessible when the drip tray is removed. Do not insert body parts into this area while the instrument is operating, or for at least ten minutes after power to the instrument is turned off.

Hazardous Magnetic Fields Precautions

This product contains very strong permanent magnet arrays.

Extreme care should be taken when handling tools and other magnetic material in close proximity to the magnet arrays, as sudden high mechanical forces may be generated.

Magnetically sensitive items such as computer discs and tapes, audio and video cassettes, and credit cards should be kept well clear of the magnet arrays, as these items may be damaged by strong magnetic fields.

People wearing a pacemaker should not use this product, as the strong magnetic fields associated with this product may adversely affect or damage the pacemaker.

Caution Messages

Samples

Make sure that samples do not contain fibres, dust or other insoluble contaminants. If insoluble contaminants are contained in a sample, correct assay results may not be obtained.

Handling Of Cleaning And Disinfecting Solutions

Cleaning and disinfecting solutions have corrosive properties. Always wear protective (chemical resistant) gloves and safety glasses when handling cleaning and disinfecting solutions.

Spillages

Any liquid spilt on the ***NucliSENS easyMAG*** may result in the malfunctioning of the system. If liquid is spilt on the ***NucliSENS easyMAG***, wipe it up immediately and apply disinfectant.

NucliSENS easyMAG Lysis Buffer and *NucliSENS easyMAG Extraction Buffer 1* Spills

Do not allow the ***NucliSENS easyMAG Lysis Buffer***, ***NucliSENS easyMAG Extraction Buffer 1*** or waste from the instrument to contact acidic materials. ***NucliSENS easyMAG Lysis Buffer*** can potentially release cyanide gas on contact with acid. The quantities that may be released depend on the volumes of both the buffer and the acidic material. Refer to the MSDS for the lysis buffer for further information.

Burn hazard.
Hot parts are accessible when the drip tray is removed. Do not insert body parts into this area while the instrument is operating, or for at least ten minutes after power to the instrument is turned off.

Damage To Packaging Materials

Inspect all incoming reagent and disposable packaging for damage. Damage to the packaging does not prevent the contents from being used. However, if the outer packaging is damaged the user must satisfy himself that the contents are intact before using them. Materials must not be used if damage is suspected.

Third Party Software

Only software that has been validated together with the ***NucliSENS easyMAG User Software*** may run on the ***NucliSENS easyMAG*** computer (PC). bioMérieux assumes no liability for adverse reactions to third party software installed without the written permission of bioMérieux.

Data Manipulation

Any manipulation of measured/calculated data by a user may cause incorrect results to be reported. The system has been designed to inhibit the modification of data by a user. However, if this should occur, bioMérieux assumes no liability for the data in the system, or results reported from such data.

Computer Virus Infection

The ***NucliSENS easyMAG*** system must be kept free from computer viruses. To this end bioMérieux advises to perform a virus scan on all media, removable and otherwise, prior to transferring data to or from the ***NucliSENS easyMAG*** system. Use an industry standard virus scanner and ensure that it has been updated for the most recent virus detection files.

Data Protection

To prevent data loss it is advised to make regular backups of the computer system. See section “Backups” on page 8-20.

Computer Configuration

The computer and its operating system have been carefully configured for optimal ***NucliSENS easyMAG*** performance. Altering the configuration may severely hamper the usability of the instrument.

The screen saver function of Windows XP is disabled by default.

Do not enable the screen saver as this may detrimentally affect software performance.

Do not put the computer in stand-by mode.

When the computer is put in stand-by mode it will disconnect from the instrument.

Magnetic Devices

Devices that emit strong magnetic fields may affect measurement data, or cause the instrument to malfunction. Do not operate such devices in the immediate vicinity of the instrument when it is in use.

Abbreviations

In this manual the following abbreviations are used:

Abbreviation	Definition
CE	Conformité Européenne
DNA	Deoxyribonucleic Acid
EN	European Norm
FCC	Federal Communications Commission
GuSCN	Guanidinethiocyanate
ISO	International Organization for Standardization
IVD	*In Vitro* Diagnostic
LAN	Local Area Network
LCD	Liquid Crystal Display
LED	Light Emitting Diode
LLS	Liquid Level Sensor
MAOI	Monoamine Oxidase Inhibitors
MSDS	Material Safety Data Sheet
NAD	Nucleic Acid Diagnostics
QC	Quality Control
RNA	Ribonucleic Acid
UL	Underwriters Laboratories Inc.
US	United States

Conventions

In this manual the following conventions are used:

DANGER: for safety reason.

CAUTION: to ensure that the instrument is maintained in good working condition.

IMPORTANT: to allow optimum use of the instrument.

▶ **Procedures**

Procedures describe actions to be followed by the user in order to safely accomplish a task.

<F1> Words that appear in angle brackets refer to the keys of the keyboard.

2 Introduction

The ***NucliSENS easyMAG*** platform is intended for the automated isolation (purification and concentration) of total nucleic acids (RNA/DNA) from biological specimens. For *in vitro* diagnostic use.

*Figure 2-1: The **NucliSENS easyMAG** system*

Functional Overview

This section provides an overview of the ***NucliSENS easyMAG***, briefly describing the major areas and their function.

The ***NucliSENS easyMAG*** system consists of:

- ***NucliSENS easyMAG*** instrument
- ***NucliSENS easyMAG*** computer, keyboard, hand-held barcode reader, and touch screen
- ***NucliSENS easyMAG User Software***
- ***NucliSENS easyMAG Disposables***
- ***NucliSENS easyMAG Lysis Buffer***
- ***NucliSENS easyMAG Extraction Buffer 1***
- ***NucliSENS easyMAG Extraction Buffer 2***
- ***NucliSENS easyMAG Extraction Buffer 3***
- ***NucliSENS easyMAG Magnetic Silica***
- Electronic multi-channel pipette
- Sample strip carrier

The following diagram outlines the major interactions of the system.

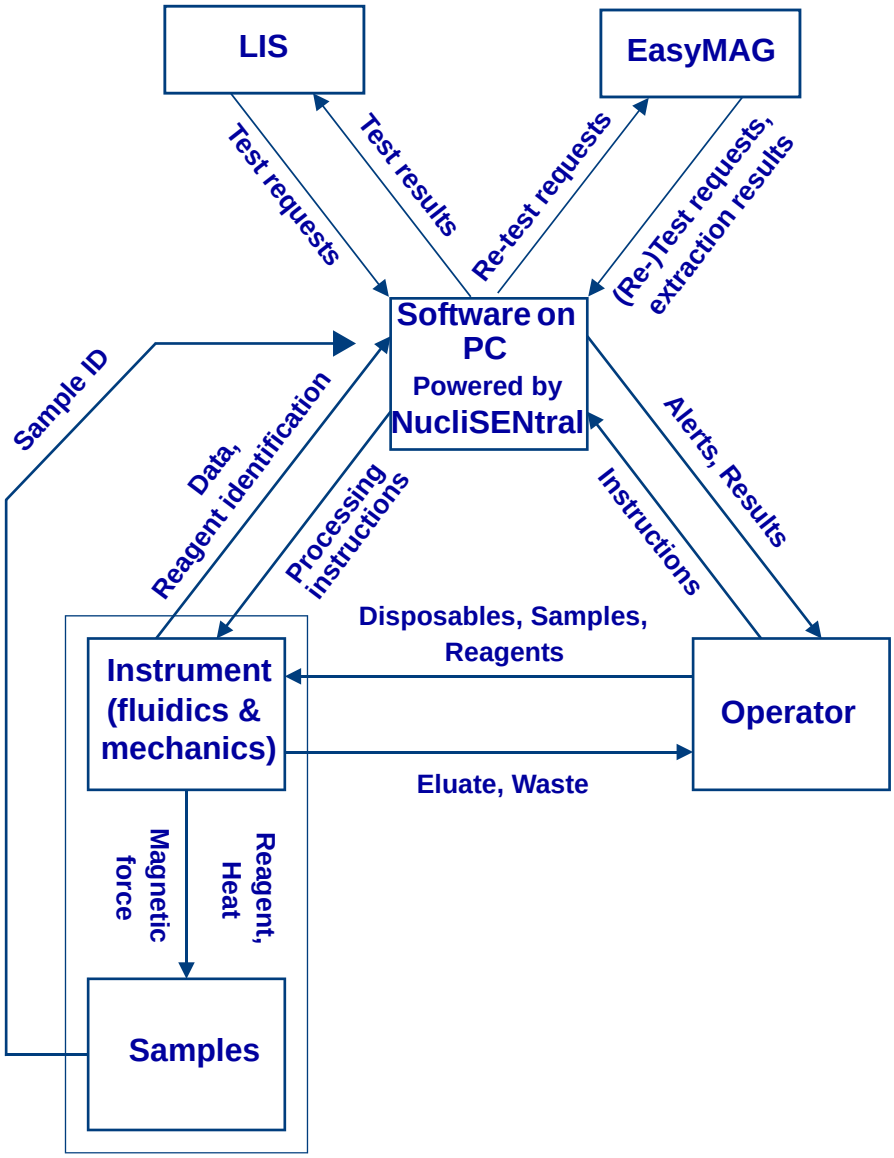


*Figure 2-2: Major interactions of the **NucliSENS easyMAG** system*

The user places sample strips and sample, aspirator, and reagents into the instrument, and identifies the samples and protocol required to the software.

The computer controls the instrument by issuing commands that run a protocol.

The instrument performs the protocol on the samples.
During the process the user is informed of progress and events via the software on the computer.

At the end of the process the user removes the eluate and disposes of the waste material.

***NucliSENtral** is an optional feature. All **NucliSENtral** related functions described in the manual are relevant only when **NucliSENtral** feature is configured (activated).*

Front View

Figure 2-3 shows the major areas at the front of the ***NucliSENS easyMAG***. The sections following describe the function of each of these areas.

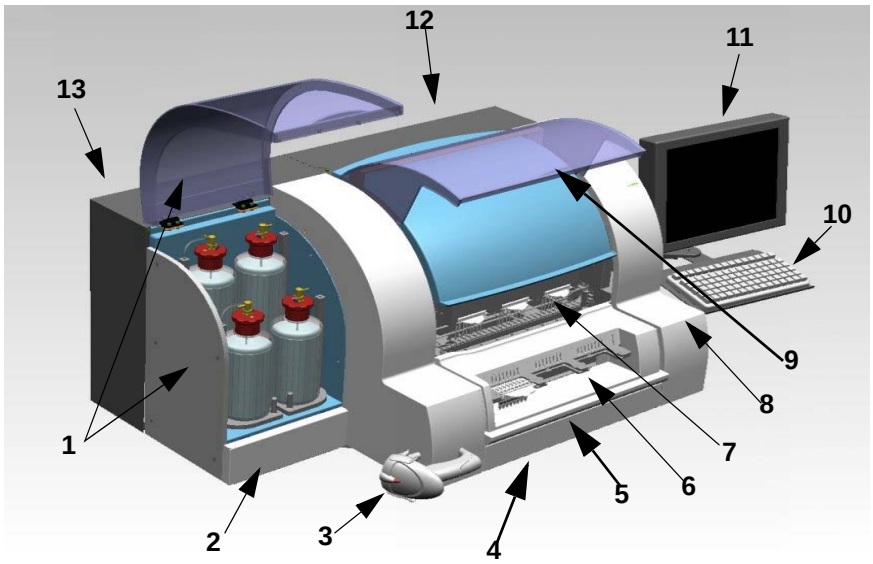


*Figure 2-3: Front view of the **NucliSENS easyMAG***

The following list identifies the items in Figure 2-3, and these items are described in the following sections.

1. Reagent module
2. Filter door
3. Barcode reader
4. Slide out tray
5. Drip tray
6. Work area
7. Processing area
8. Power / error indicator
9. Processing door
10. Keyboard
11. Touch-screen
12. Electronics compartment
13. Fluidics compartment

Reagent Module

The reagent module contains the reagent platforms and reagent mass sensors.

There are four 1 L reagent bottles that are placed on platforms. The platforms are part of a mass sensing system, which detects the amount of reagent in each reagent container.

The bottles are barcoded and can be used only once. The reagent must be ‘registered’ by reading the barcode on the bottle before the reagent can be used.

Filter Door

A carbon filter is located below the reagent module. The fold-down door allows users to change the filter.

Barcode Reader

The barcode reader is used to identify the Samples, Controls, Sample strips and Reagents to the User software.

For information on using the barcode reader, refer to “Using The Barcode Reader” on page 4-14.
For information on maintaining the barcode reader, refer to “Barcode Reader” on page 8-8.
For information on restoring the barcode reader’s factory settings, refer to “Barcode Reader Configuration” on page B-3.

Work Area

The work area includes the work surface, where users load sample strips into the sample strip carriage, a drip tray, and a tray that slides out from under the instrument. At the rear of the work surface there are LED indicators for sample position indication.

For more information on sample strips, the work area, and loading samples, refer to “Work Area” on page 4-2.

Processing Area And Door

The processing area is protected by a cover and a lid. Proximity switches and magnets detect when the lid is open to protect users while the instrument is operating. The instrument will not commence moving any motor or start heating while the lid is open. Still the user is advised not to open the cover when a run is in progress.
The cover is designed for removal by service personnel only.

The processing area contains moving mechanisms, hot devices, and sharp devices that may cause injury if contacted during operation. Do not remove the processing area cover. Close the processing door prior to operating the instrument. Do not attempt to by-pass the interlocks.

At the front of the processing area of the instrument there is an area where the user loads the Aspirator Disposables, which aspirate fluid from the sample strips during a run.

When a run is started, the sample strip carriage moves into the processing area, which contains the mechanisms the instrument uses to process the samples. These mechanisms, including Aspirator disposables, and the aspiration, dispensing, magnet, and heater mechanisms, are discussed in “Processing Area” on page 4-8.

Power Switch

The power switch is located on the right end of the instrument, in the lower corner of the panel near the back of the instrument. The power switch has two positions:

Position	State
	Power is off to the main instrument, but still available to the LCD monitor.
	Power is available to both the main instrument and the LCD monitor.

Power / Error Indicator

The power / error indicator is located on the front right cover of the instrument, and is a tricolor LED that uses the following states:

Color	State
Off	Power is off.
Orange	The firmware is not running, or the instrument is not ready to connect to the computer.
Green	The firmware is running, and the instrument is ready to connect to the computer.
Red	An unresolved error has occurred.

Keyboard And Touch-screen

The keyboard and touch-screen are connected to the computer. The computer contains the User software, through which users install protocols, enter details of samples, and request runs.

The computer communicates with the instrument.

For more information about the computer and associated components, including the keyboard and touch-screen, see “Computer And Peripherals” on page 4-13.

Electronics And Fluidics Compartments

The electronics and fluidics compartments of the instrument are located at the back of the instrument. Only service representatives should open these compartments; they are not discussed in detail in this document.

Back View

Figure 2-4 shows the major features at the back of the ***NucliSENS easyMAG***.
In this view the electronics compartment is at the left, and the fluidics compartment is at the right.

*Figure 2-4: Back view of the **NucliSENS easyMAG***

The items identified in Figure 2-4 are:

1. Main power input and fuses
2. Rating plate
3. Serial number
4. Fans
5. Communications connection
6. Waste connections
7. Vacuum gauge connection
8. LCD monitor power output and fuse

Power Connection And Fuses

This is where the main power to the instrument is connected, and also where the LCD monitor power is obtained.

The main power is connected to the lower-left plug, and the lower right socket provides power for the LCD monitor.

The user-replaceable fuses are also located here. Fuse replacement is described under “Fuse Replacement” on page 8-16.

Rating Plate

The rating plate contains essential regulatory information.

Serial Number

This number is unique to each instrument, and should be quoted when requesting support.

Fans

There is a fan in each of the back panels (electronics at the left and fluidics at the right). The fans should rotate under normal conditions.

Communications Connection

This is the cable that connects the computer to the instrument. Use only the red cable supplied with the system for this connection. Refer to “Computer Connections” on page 4-15 for the location of the communications connection to the computer.

Waste Connections

These provide the connections for the waste line from the instrument to the waste bottle, the connection to the liquid level sensor in the waste bottle, and a line for removal of waste in case the drip tray becomes too full.

See “Waste Connections” on page 4-17 for more information on these connections.

Vacuum Gauge Connection

This is for the use of service personnel only. Do not block or attempt to connect to this connection.

System Capabilities

Power Up

On power up, provided the lid is closed, the instrument will:

- Move mechanical parts to their home position
- Wash the dispense probes with ***NucliSENS easyMAG Extraction Buffer 3*** if that was not the last reagent dispensed before the instrument was last shut down.

The ***NucliSENS easyMAG*** system offers a number of tools and features to help the users. A handheld barcode reader helps with entering sample and reagent ID's, and also to identify a particular location for a reagent or sample strip. An array of LEDs, located above the sample strip positions, can guide the user during the addition of samples and reagent. The level of guidance depends on the chosen workflow as defined in the application settings window. A sample strip carrier is provided to assist with handling the sample strips when they are not on the instrument. An electronic multi-channel pipette, programmed with specific pipetting sequences, can be used to further simplify some of the remaining manual dispense steps. Finally, the application software has been designed around several workflows. The touch screen operated software provides easy and direct access to all instrument and run related functions.

The system is capable of performing the following functions:

Step	Action	Explanation
1.	Sample strip and Aspirator Disposable loading.	Done by the user.
2.	Incubation	Allows time for binding nucleic acid to Magnetic Silica in lysis buffer.
3.	Capture the Magnetic Silica	Captures the Magnetic Silica against wall of the sample strip.
4.	Guanidine wash	a. Removes lysis buffer and unwanted material from the sample strip leaving nucleic acid bound to the Magnetic Silica. b. Dispenses ***NucliSENS easyMAG Extraction Buffer 1*** (guanidine thiocyanate). c. Flushes Magnetic Silica in the buffer.
5.	Buffer 2 wash	Repeat the above process with ***NucliSENS easyMAG Extraction Buffer 2***.

6.	Elution	a. Repeats wash step with ***NucliSENS easyMAG*** *Extraction Buffer 3* (elution buffer). b. Removes all unwanted material from the sample strip. c. Dispenses ***NucliSENS easyMAG*** *Extraction Buffer 3* (elution buffer). d. Heats the fluid in the sample strip. e. While maintaining fluid temperature, flushes the Magnetic Silica by repeatedly transferring them from one side of the sample strip to the other, to ensure all nucleic acid is removed from Magnetic Silica.
7.	Remove Magnetic Silica	Moves capture magnets slowly upward to transfer the silica pellet out of eluate up the wall of the sample strip.

Run Completion

Upon completion of the run, the instrument will:

- Ensure that all components are at their home position
- Flush any lines that are necessary to return the instrument to an idle state

Urgent Stop

In the unlikely event of a serious problem or malfunction that requires the immediate cessation of instrument activity, remove the mains power connection from the instrument or main power source, and ensure that the instrument has ceased all activity before contacting any area of the instrument.
If such a circumstance does arise, please contact your local bioMérieux representative.

About The User Manual

Scope And Audience

This document is intended for users of the ***NucliSENS easyMAG*** system. It does not contain technical service procedures, which must be performed by bioMérieux or its representatives.

User Qualification

The ***NucliSENS easyMAG*** system should be operated by or under the supervision of a technician or manager who has undergone training by bioMérieux or local representatives.

Before operating the system the user should:

- Read and understand the User Manual and the "General safety and regulatory information" booklet.
- Be qualified to use the system
- Be aware of all relevant laboratory procedures
- Be aware of all relevant safety rules and regulations

Carefully follow the procedures specified in the User Manual for the operation and maintenance of the system. Maintenance not described in the User Manual should be left to qualified and properly-trained bioMérieux service engineers.

3 System Basics

Overview

Some sample types require a prehandling step to obtain a liquified solution. For information and advice on prehandling steps for handling specific sample matrices, contact your local bioMérieux representative or Global Customer Service.

The ***NucliSENS easyMAG*** system is intended to be used as a universal stand-alone tool for nucleic acid extraction.

NucliSENS easyMAG uses one single set of reagents, independent of the sample type and the nature of the nucleic acid to be isolated.

The ***NucliSENS easyMAG*** system is designed for batch-wise processing of samples. A batch may contain between 1 and 24 samples. Since the instrument uses a single protocol for different sample matrices, samples intended for different assay applications can often be combined in the same run.

The ***NucliSENS easyMAG*** system is designed for a throughput of 24 extractions in less than one hour.

Additional information about generic extraction can be found in the addendum of this manual, see “Addendum” on page E-1.

Workflow Options

NucliSENS easyMAG offers flexibility with respect to introducing primary samples to the system. Samples are added to a dedicated sample strip. In one scenario these strips are placed on the instrument during sample addition, whereas in another scenario sample addition to the strip is performed in a dedicated laboratory area (for example, a laminar flow cabinet) before loading the strips on the instrument.

Depending on the particular application or laboratory infrastructure, the user may choose for the instrument to perform the sample lysis step with the strips on board, or the user can perform this step with the sample strips outside the instrument. See “Workflow Description” on page 3-4 for more information.

Use Of An Internal Control

The ***NucliSENS easyMAG*** system supports the use of an internal calibrator or control RNA or DNA. Such calibrator or internal control is added to the lysed sample as an internal standard to monitor the overall system performance of a particular assay. This internal control is not a part of the ***NucliSENS easyMAG*** system.

Protocols

In principle, the ***NucliSENS easyMAG*** instrument uses a single extraction protocol to cover all applications, but the software has the flexibility to handle several protocols. A separate protocol might be necessary when the nucleic acid needs to be concentrated in a volume smaller than that defined in the generic protocol. Also it might be beneficial to use protocols designed and validated to be used in combination with a specific assay application.

Software And Data Management

The ***NucliSENS easyMAG*** user software offers several features such as:

- Supporting the user in preparing and performing a run
- Tracking specific information on samples and reagents used, errors and protocol settings.
- Controlling and monitoring the instrument.
- Storing run information including incidents and reagent information.
- Exchanging data with LIS (through ***NucliSENtral***)

The system supports sample and reagent identification via a barcode reader.

Principle Of The *NucliSENS easyMAG* Method

The ***NucliSENS easyMAG*** system is based on a generic method for binding nucleic acids from complex biological samples to Magnetic Silica.

The system works with a liquid specimen. A specimen is mixed with a lysis buffer containing a chaotropic agent (GuSCN). Any cellular matter, viral particles, bacteria, or fungi present in the specimen will be disrupted (lysed) in the presence of the chaotrope, thereby releasing the nucleic acids. The lysis buffer inactivates any nucleases present in the specimen. The isolation process is initiated by adding Magnetic Silica to the lysed specimen. Nucleic acids present in the lysate will bind to the Magnetic Silica under the high salt conditions.

The Magnetic Silica are then washed several times using 2 wash buffers.

Next, the nucleic acids are released (eluted) from the Magnetic Silica and concentrated in a specified volume of the elution buffer. This elution process is accelerated by flushing the Magnetic Silica in the elution buffer at an elevated temperature.

Finally, the Magnetic Silica are separated from the elution buffer before the concentrated nucleic acid solution is available for detection in a downstream application.

Using The System

Workflow Description

The ***NucliSENS easyMAG*** system supports two workflow scenarios.

The first scenario, called the **'on board'** workflow, aims to minimize the number of manual pipetting steps and provides optimal sample tracking capabilities. The lysis buffer is added to the sample strips while these are loaded on the instrument. The instrument adds the lysis buffer to the samples and controls the timing for the lysis step. For a diagram of the **'on board'** workflow, see Figure 3-1 on page 3-5.

With the second scenario, called the **'off board'** workflow, the lysis step is performed manually, away from the ***NucliSENS easyMAG*** instrument, using a dedicated lysis tube. After sample lysis, the lysates are transferred manually to the sample strips loaded on the instrument. The aim of this workflow is to offer sample handling flexibility to the user. The dedicated lysis tubes allow handling of infectious samples in a special laboratory area. Also, in case of performing several runs in a work shift, the **'off board'** workflow allows a high throughput of the system since sample preparation in lysis tubes can be performed in parallel with processing samples in the instrument. For a diagram of the **'off board'** workflow, see Figure 3-2 on page 3-6.

Both these workflows benefit from using an electronic multichannel pipette which semi-automates the transfer of Silica and, if used, an Internal Control to the lysate in the sample strips. However, in case the electronic multichannel pipette is not used, the **'off board'** workflow is recommended. Then the pre-mix as described in step 6 below should be added to the lysed samples before transfer to the sample strips, meaning before step 5 in the **'off board'** workflow. Immediately mix the samples properly after each transfer step.

The system allows minor deviations from these workflows to allow the user to further fine-tune the system to local needs. It is the responsibility of the individual user to validate the standard workflows and any deviations from these standard procedures.

Consult individual instructions for use for further details when using these reagents in conjunction with other bioMérieux products.

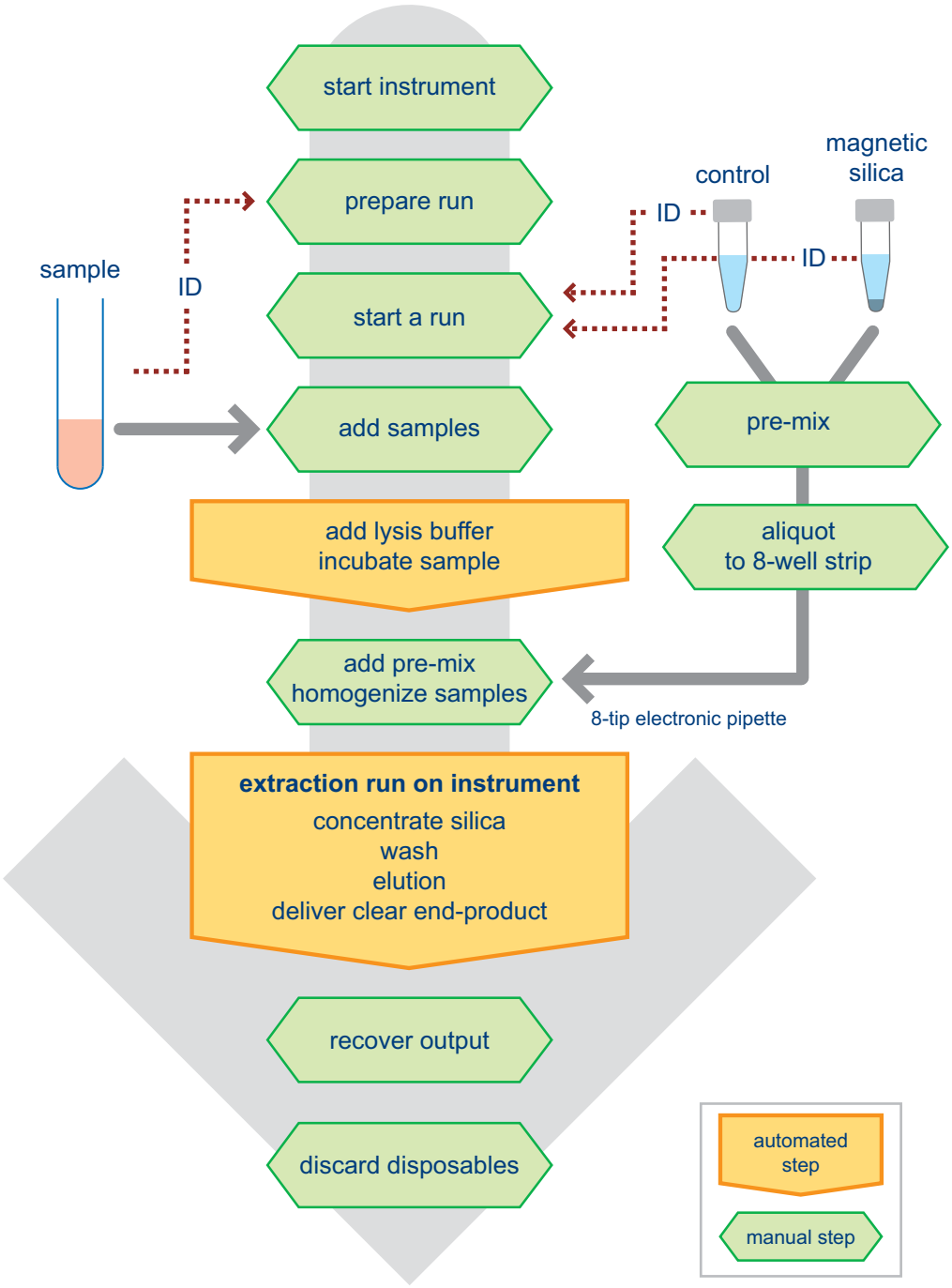


Figure 3-1: 'On board' workflow

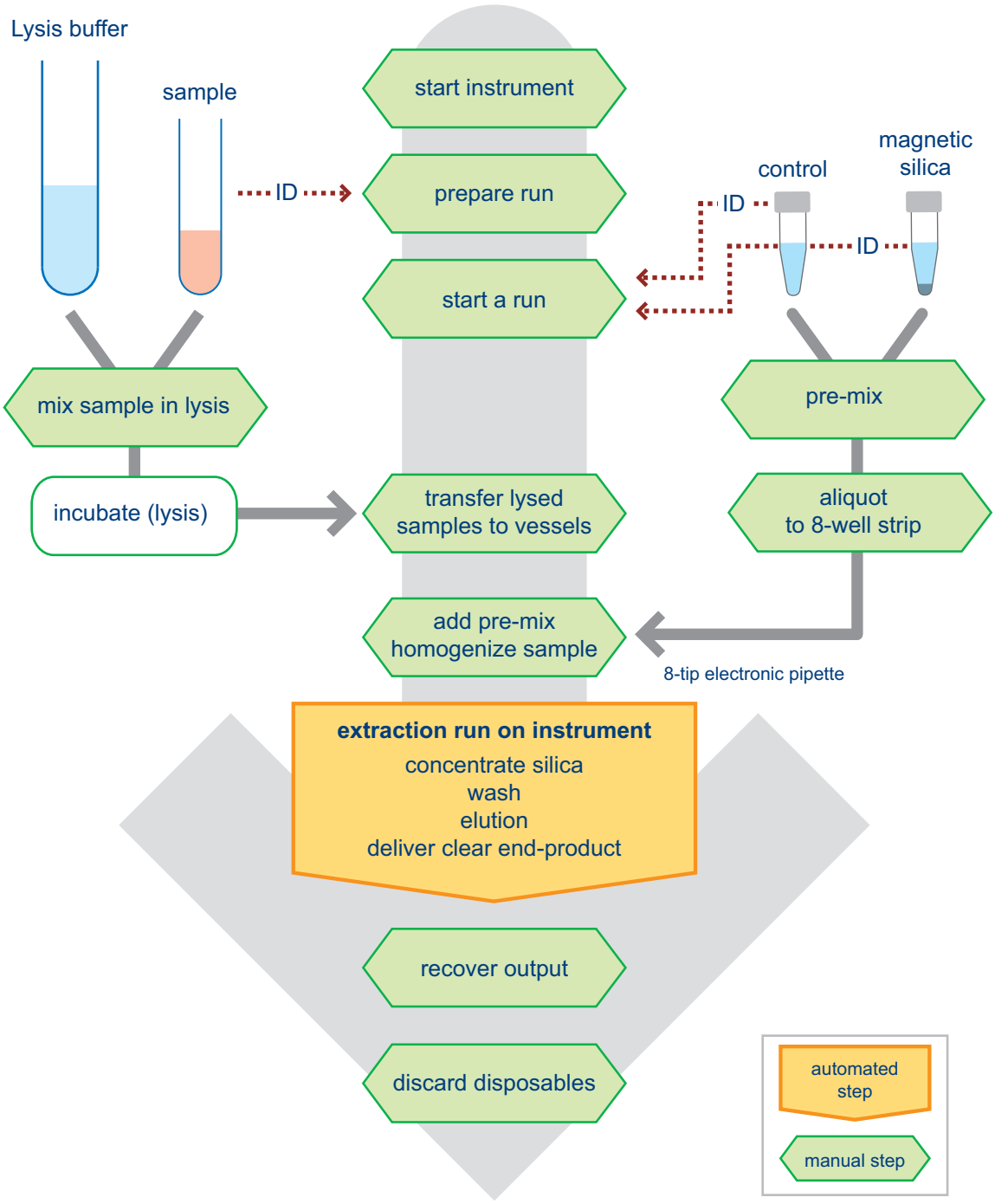


Figure 3-2: 'Off board' workflow

Detailed Description Of The ‘On Board’ Workflow

▶ On board workflow

1. Start the instrument
- Start the instrument and log in to the software.
2. Prepare a run
- Introduce the identification code of the samples to be processed into the software. Use the barcode reader or the keyboard.
- Select the extraction protocol, including sample volume and elution volume for each sample.
- Assign samples to a run.
3. Select a run
- Select a prepared run.
- Load the sample strips and aspirator disposables onto the instrument.
- Scan the reagent ID and the sample strip ID codes using the barcode reader.
4. Add samples
- Uncap the tube containing the sample.
- Transfer the amount of sample to be processed into the sample strip. Sample volumes of up to 1000 µl may be used.

Ensure that each sample is transferred to the corresponding strip as indicated by the software (see Run layout, LED, and/or print layout). Optionally the barcode reader can be used to re-identify each sample.

5. Start run
- Start the selected run. The instrument performs the specified lysis procedure.
- Meanwhile proceed with step 6.
6. Prepare pre-mix

   An internal control (RNA or DNA) can be added at this point of the procedure if the efficiency of nucleic acid isolation is to be monitored. Prepare a pre-mix containing internal control (RNA or DNA) and silica. This makes it possible to add these two components in one step. Dilute the control in a dedicated control buffer or sterile water in such a way that 50 µl is added per sample. The pre-mix is prepared as follows (sufficient for 8 samples):
- Add 550 µl silica solution to a tube containing 550 µl Internal control (RNA or DNA) solution or pyrogen-free sterile water.

- Vortex the prepared mixture.

Do not centrifuge the mixture.

- Aliquot 125 µl portions into an 8-well strip using, optionally, a programmable electronic multichannel pipette.

7. Add pre-mix to lysed sample

- Transfer 100 µl pre-mix from 8-well strip to sample strips containing the lysed samples and properly homogenize the mixture, for example using a programmable electronic multichannel pipette.

8. Continue Extraction run

- Continue the run. The instrument performs incubation, washing, elution and particle separation from elution buffer.

Silica incubation can also be performed off-board, depending on the workflow settings.

9. Recover output

- Recover concentrated nucleic acid from sample strip using a pipette (monochannel or multichannel depending on the format of the target disposable).

10. Close a run

- Discard disposables to waste. Make sure that used disposables are treated as a possible source of contamination, and consequently should be discarded in a closed waste container.

As an alternative to adding samples while strips are placed on the instrument (step 4), the user may also add samples with the strip placed on a laboratory bench or in a laminar flow cabinet. The system includes a dedicated carrier for holding and transporting sample strips.

To optimize system throughput, the user can prepare the reagent pre-mix (step 6) in parallel to step 5.

Detailed Description Of The ‘Off Board’ Workflow

▶ Off board workflow

1. Start the instrument

See step 1 of the ‘on board’ workflow.

2. Prepare a run

See step 2 of the ‘on board’ workflow.

3. Select a run

See step 3 of the ‘on board’ workflow.

4. Add samples to lysis buffer

- Refer to instructions supplied with the *NucliSENS Lysis Buffer 2 ml tubes* product.

5. Transfer samples to sample strip

- Transfer the lysed samples to the sample strips placed on the instrument. **Note:** Ensure that each sample is transferred to the corresponding sample strip position as indicated by the software (see Run layout, LED, and / or print layout).

6. Prepare pre-mix

See step 6 of the ‘on board’ workflow.

7. Add pre-mix to lysed sample

See step 7 of the ‘on board’ workflow.

8. Start Extraction run

- Start the selected run. The instrument performs incubation, washing, elution and particle separation from output buffer.

Silica incubation can also be performed off-board, depending on the workflow settings.

9. Recover output

See step 9 of the ‘on board’ workflow.

10. Close a run

See step 10 of the ‘on board’ workflow.

Tubes containing 2 ml lysis buffer are supplied by bioMérieux.

With step 5, it is recommended that a 5 ml pipette be used to transfer lysed samples from the tube into the strips.

About *NucliSENS easyMAG* Reagents And Disposables

NucliSENS easyMAG reagents comprise the following items:

Reagent	Content	Description		Warning categories
NucliSENS easyMAG Lysis Buffer	48 x 2 ml	Contains guanidine thiocyanate *Color code: transparent*		R21/22 R32 S26 S36/37/39
NucliSENS easyMAG Lysis Buffer	4 x 1000 ml	Contains guanidine thiocyanate Color code: red		R21/22 R32 S26 S36/37/39
NucliSENS easyMAG Magnetic Silica	48 x 0,6 ml	Contains silica suspended in biocide solution Color code: transparent		
NucliSENS easyMAG Extraction Buffer 1	4 x 1000 ml	Contains guanidine thiocyanate Color code: red		R21/22 R32 S26 S36/37/39
NucliSENS easyMAG Extraction Buffer 2	4 x 1000 ml	Contains organic buffer and biocide solution Color code: white		
NucliSENS easyMAG Extraction Buffer 3	4 x 1000 ml	Contains inorganic buffer and biocide solution Color code: blue		
NucliSENS easyMAG Disposables	16 x 3	Each blister contains 3 sample strips and 3 Aspirator disposables. Each sample strip is labeled with a unique barcode.		

NucliSENS easyMAG reagents have the following functions:

- ***NucliSENS easyMAG Lysis Buffer*** (Z011LB) contains guanidine thiocyanate. The lysis buffer is designed to disrupt viral particles or cells and to inactivate any nucleases upon addition of specimen.
- ***NucliSENS easyMAG* Magnetic Silica** (Z011MS) is used as a solid phase for binding the released nucleic acids to facilitate washing of sample components and guanidine that could interfere with nucleic acid detection.
- ***NucliSENS easyMAG Extraction Buffers 1*** (Z011EB) and ***2*** (Z012EB) are wash buffers.
- ***NucliSENS easyMAG Extraction Buffer 3*** (Z013EB) facilitates the release (elution) of purified nucleic acids from the Magnetic Silica.

NucliSENS easyMAG Disposables (Z10XXX) have the following functions:

- ***NucliSENS easyMAG Sample Strips*** provide 8 reaction vessels. They are designed to contain 2 ml of lysis buffer, up to 1ml of sample, Magnetic Silica (Z011MS) and an optional internal control.
- ***NucliSENS easyMAG Aspirator Disposables*** are used to aspirate liquid from the samples strip vessels during the wash cycles. They are not used to dispense reagents.

NucliSENS easyMAG Disposables *are designed for single use only.*

Warnings And Precautions

- Certain reagents contain guanidine thiocyanate.
- R21/22: Harmful in contact with skin and if swallowed.
- R32: Contact with acid liberates very toxic gas.
- S26: In case of contact with eyes rinse immediately with plenty of water and seek medical advice
- S36/37/39: Wear suitable protective clothing, gloves, and eye and face protection.

To prevent formation of toxic gases, do not mix buffers containing guanidine thiocyanate with cleaning solutions containing bleach.

- Do not mix waste from extraction and isolation procedures containing guanidine thiocyanate with other laboratory waste. This will prevent potentially harmful chemical reactions from occurring.
- Reagent spillage should always be handled appropriately (see “Procedural Precautions” on page 3-12).

Storage

- Reagents and disposables should be protected against excess heat or light.
- It is recommended to store the extraction reagents in the area of the laboratory dedicated to the isolation of nucleic acids, or in a clean separate room.
- Only the required quantities of reagents should be removed from storage.
- Return any unopened reagents to storage immediately.
- Storage of opened reagents is not recommended.
- Do not freeze reagents: this will lead to deterioration in the performance of specific components.
- Please refer to the reagents' boxes for any additional information regarding storage.

Stability

- Expiry dates shown on component labels indicate the date beyond which reagents or disposables should no longer be used. The barcode labels on the reagents and disposables contain information on the expiry date which is interpreted by the software. The software will alert the user when an expired reagent or disposable is detected.
- ***NucliSENS easyMAG*** *Lysis Buffer* may have a slight to appreciable yellowish color. This coloration is normal and will not have any effect on the performance of the reagents.
- Storage of ***NucliSENS easyMAG*** *Lysis Buffer* at 2 to 8 °C may give rise to the appearance of crystals due to the high salt concentration. These crystals have to be dissolved during reagent preparation.
- Other changes in the physical appearance of reagents may indicate instability or deterioration and they should not be used. Please contact the local bioMérieux representative for assistance if there is any doubt about the suitability of reagents for use.

Procedural Precautions

- Store and prepare reagents for nucleic acid release in the laboratory area where nucleic acid isolation is to be performed, or in a clean separate room.
- Once loaded in the reagent area of the ***NucliSENS easyMAG*** instrument, the ***NucliSENS easyMAG*** *Lysis Buffer* and ***NucliSENS easyMAG*** *Extraction Buffers 1, 2* and *3* are stable for up to 1 month under ambient conditions. It is not allowed to unload these buffers from the instrument for off-board storage. When the extraction buffers are disconnected and reconnected, there is a high risk of bacterial contamination.
- Prior to use, ensure that the Magnetic Silica solution does not come into close proximity with the magnets in the ***NucliSENS easyMAG*** as this may impair performance.

- Avoid contamination or specimen-to-specimen carry-over.

Opened reagents, stored for later use, are a potential source of contamination. Opened reagents that have been kept in storage should only be used when known to be free of all possible sources of contamination. Contamination of reagents with other reagents, with nucleic acids, and/or with nucleases will have a dramatic effect on the performance of nucleic acid isolation procedures. The storage of opened reagents is not recommended.

- Perform nucleic acid isolation in a dedicated laboratory area (a self-contained area or a fume hood in the case of off board workflow) that is not connected to laboratory areas where nucleic acid amplification or detection is to take place.
- Do not open the processing area door during processing. Opening the processing door may compromise the samples.
- Keep all tubes closed when not in use.
- Use dedicated laboratory accessories; pipettes and other equipment that have been used in one laboratory area must not be used in other areas.
- Pipettes and other equipment that have been used for nucleic acid isolation must not be used in laboratory areas where nucleic acid amplification or detection is to be performed.
- Use a fresh pipette or pipette tip for each pipetting action.
- Use pipettes with aerosol resistant tips for fluids possibly containing nucleic acid.
- Only one tube should be open at any given moment during pipetting steps. All other tubes should be kept closed and physically separated from the one being handled.
- ***NucliSENS easyMAG*** sample strips and aspirator disposables are for single use only. Re-use of disposables will lead to sample contamination and invalid results.
- Do not pipette any of the materials by mouth.
- Do not smoke, eat or drink in areas in which specimens or kit reagents are handled.
- Use disposable gloves when working with clinical material possibly containing target-nucleic acids. Change gloves after contact with potentially infectious material.
- Handle all materials used (including samples, reagents, pipettes etc.) cautiously as though capable of transmitting infectious agents.
- Consult a physician immediately in the event of infectious materials being ingested or coming into contact with open lacerations, lesions or other breaks in the skin.
- Crystallized drops:
  Wipe up GuSCN drops immediately. Remove crystallized drops carefully with distilled water and clean the area with a fiber free towel containing a 5% Extran solution. After cleaning with the 5% Extran solution, clean the affected area with 70% Ethanol. Then wipe the area clean using a fiber-free towel containing a small amount of silicon oil. This to prevent any GuSCN crystals to re-occur.

- Crystallized spills:
  Remove crystallized spills carefully. Spray the area carefully with water and absorb using absorbent material (for example fiber free tissue), clean the affected area with copious amounts of water. Then clean the area with a fiber free towel containing a 5% Extran solution. Then clean the area with the 5% Extran solution, and clean the affected area with 70% Ethanol. Finally wipe the area clean using a fiber-free towel containing a small amount of silicon oil. This to prevent any GuSCN crystals to re-occur.
- Collect used disposable materials in a container. Close and remove container after each nucleic acid isolation procedure.
- Dispose of all materials used for nucleic acid isolation as though they contain infectious agents.
- Soak tube racks used during nucleic acid isolation in a detergent (e.g. Extran MAOI alkaline, 5% solution) for at least one hour after each nucleic acid isolation procedure.
- When using a centrifuge, clean the centrifuge rotor used for nucleic acid isolation and the inside of the centrifuge with a detergent on a regular basis (for example, once per week), rinse with water and dry.
- Waste from the nucleic acid release procedures using ***NucliSENS easyMAG*** *Lysis Buffer* should be disposed of according to local requirements.

Materials And Accessories Needed But Not Provided

- Calibrated micropipettes, volume range 10 to 5000µl
- Sterile, disposable aerosol resistant tips
- Timer
- Vortex
- Absorbent tissue
- Disposable gloves
- Detergent (e.g. Extran MAOI alkaline)
- Waste container with cap
- 8-well strips (for distributing the pre-mix of Magnetic Silica and internal control).

Reagent Preparation

NucliSENS Lysis Buffer 2 ml

- Refer to the individual instructions for use accompanying the ***NucliSENS*** *Lysis Buffer* 2 ml kit.

NucliSENS easyMAG Lysis Buffer 1000 ml* and *NucliSENS easyMAG Extraction Buffer 1

- Pre-warm the reagent for approximately 30 minutes (recommended temperature: 37 °C) before starting the procedure if the reagent has been stored below room temperature.
- Mix thoroughly at regular intervals by inverting the bottle. Ensure that all the crystals have dissolved during reagent preparation, and that the solution is at room temperature before use.

NucliSENS easyMAG Magnetic Silica

- ***NucliSENS easyMAG Magnetic Silica*** are supplied in tubes containing sufficient reagents for 8 samples. If less than 8 samples are to be processed, any remaining reagents must be closed, marked with the date of opening, and returned to storage as soon as possible. After opening, the ***NucliSENS easyMAG Magnetic Silica*** can be stored for a maximum of 14 days.
- Vortex the tube until a homogeneous suspension is formed before commencing the isolation procedure.
- Vortex again at each pipetting step.

NucliSENS easyMAG Magnetic Silica *can be adversely affected by strong magnetic fields. Take care to store and handle the silica well away from such fields.*

NucliSENS easyMAG Extraction Buffer 2

- No special preparation is required.
- Ensure that the solution is at room temperature before use.

NucliSENS easyMAG Extraction Buffer 3

- No special preparation is required.
- Ensure that the solution is at room temperature before use.

Nucleic Acid Isolation Procedure

- When using the 2 ml ***NucliSENS Lysis Buffer*** tubes (‘off board workflow’), consult the accompanying individual instructions for use found inside the kit.

Limitations

- The user is responsible for the validation of the use of the ***NucliSENS easyMAG*** extraction system, in combination with any procedure used in their laboratory, according to local regulatory requirements.
  The ***NucliSENS easyMAG*** system fully supports the use of an internal control. It is recommended to use internal controls for monitoring the performance of the extraction process.
- Limited validation has been done for ***NucliSENS easyMAG Lysis Buffer***, ***NucliSENS easyMAG Magnetic Silica***, and ***NucliSENS easyMAG Extraction Buffers 1***, ***2*** and ***3*** using specific human specimens, that is, plasma, serum, whole blood, cerebrospinal fluid, sputum and faeces.
- ***NucliSENS easyMAG*** reagents have been manufactured with the utmost care according to stringent manufacturing procedures. However, these reagents cannot be guaranteed to be completely free of nucleic acid contamination, and therefore it is possible that their use may interfere in amplification and detection reactions for certain specific markers. Please contact your local representative for support.
- It is not recommended to mix left-over reagents to prepare a suitable volume for extraction run as this may involve the mixing of different lots with different expiry dates and mixing up of different reagents causing possible chemical hazards.
- The ***NucliSENS easyMAG*** sample strips are designed to extract DNA/RNA, not to store it. Remove the eluates from the strips as soon as possible and process them in an amplification and detection system or store them in a suitable storage container.
- In case of an electrical static discharge the system should be switched off and then on again. Failing to comply could cause the system to malfunction.
- The ***NucliSENS easyMAG*** system is a computer-controlled system that stores both extraction requests and extraction results electronically. If the power supply to the system is interrupted, data can be lost. It is the responsibility of the user to ensure that a reliable power supply is available. bioMérieux accepts no responsibility for loss of data due to interruptions or surges in the power supply. For installations where the mains power supply is unreliable, the use of an Uninterruptible Power Supply (UPS) is strongly recommended. For more information about the use of a UPS, contact a bioMérieux representative.
- The procedure and amounts given for the use of a pre-mix of silica and an optional Internal Control as it is described in this manual (chapter 2), are given as an example and are not intended to serve as a general procedure. It may well be necessary to adapt volumes to make the pre-mix option suitable for local procedures.

Specific Symbols

	Do not reuse

4 Hardware Description

"Functional Overview" on page 2-2 gives a brief introduction to the main hardware items. This section provides a more detailed description of the hardware components and operations involving those components.

Work Area

Sample Loading Area

The sample loading area is located at the front of the instrument. This is where the sample strips are loaded into the sample strip carriage. The sample strip carriage moves into the processing area for the samples to be processed.

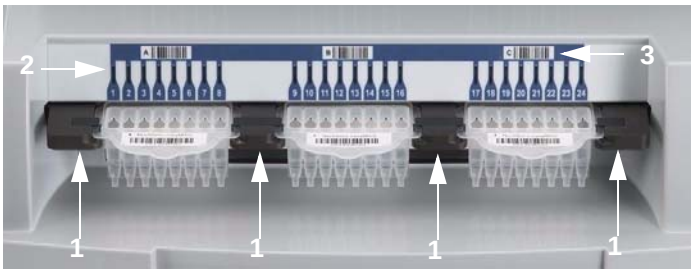


*Figure 4-1: The Sample loading area of the **NucliSENS easyMAG***

The items in Figure 4-1 are:

1. Sample strip carriage arms.
2. One of the LEDs used to guide the user when loading samples.
3. Sample position indicator in the form of a barcode label above the LEDs.

The instrument provides an indicator (LED) for each sample position to allow specific strips to be identified for user actions. The indicators are located behind each sample strip, above where the sample strips fit into the sample strip carriage (refer to Figure 4-1).

Sample Strips

Sample strips are plastic disposables containing a row of eight vessels that can hold sample and all reagents necessary for the extraction process (refer to Figure 4-2). The sample strips can be loaded (clipped) into the sample strip carriage at the front of the processing area when the carriage is in the load / unload position at the front of the work area.

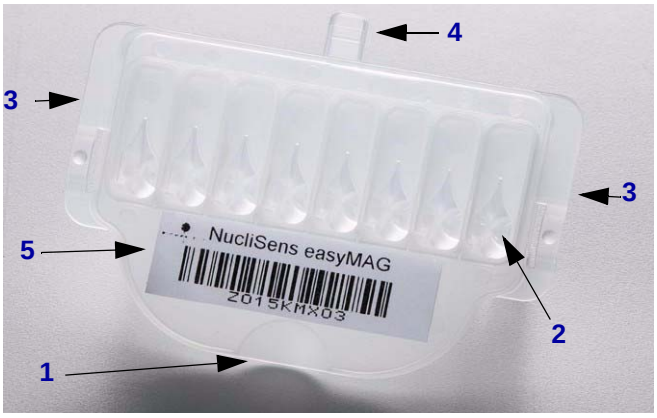


Figure 4-2: A sample strip

The items in Figure 4-2 are:

1. Tab. This tab and indent allow easy handling.
2. Sample vessel (1 of 8).
3. Flanges. These flanges slide under the tabs in the arms of the sample strip carriage when the sample strip is loaded into the ***NucliSENS easyMAG***.
4. Lock tab. This clicks into the sample strip carriage to hold the strip in place during processing.
5. Barcode label.

Handle and dispose of the sample strips according to procedures for handling and disposal of potentially bio hazardous material.

▶ To load a sample strip

Figure 4-3: Loading a sample strip

1. Hold the sample strip by the indent.
2. Slide the edges of the strip into the sample strip carriage arms, beneath the tabs in either arm.
3. Slide the strip back until the tab at the back clicks into the slot at the back.

Sample strips and Aspirator Disposables must occupy corresponding positions. For example, if there is a sample strip in the middle position, there must also be an Aspirator Disposable in the middle position.

▶ To unload a sample strip

Ensure that the sample strip carriage is in the unload position, hold the sample strips by the indent at the front, and carefully pull them out of the sample strip carriage.

Sample Strip Carriers

Sample strip carriers can hold three sample strips upright to aid the user with pipetting samples or solutions in and out of the strips when away from the instrument. They are also intended to be used as an aid to transporting the sample strips between instruments and / or rooms.

Figure 4-4: Sample strips in carrier

Drip Tray

The drip tray is located under the processing area. To remove it, carefully slide it out of the instrument.

Figure 4-5: Drip tray partially removed

*Before operating the **NucliSENS easyMAG** instrument, make sure that the drip tray is in place. Do not reach into the instrument while the instrument is on, as there are moving and heated parts that could cause injury.*

The fluids in the drip tray could contain corrosive reagents and potential biohazards. Always wear gloves when handling the drip tray and material that collects in it. Clean the drip tray and dispose of collected material and washing refuse according to procedures at the installation site for handling potential biohazards.

Check the drip tray daily and dispose of any waste according to procedures at the installation site for the handling and disposal of potentially hazardous chemicals. An increase in the amount of waste collecting in the drip tray may indicate that the system is leaking. Contact your local bioMérieux representative if the waste in the drip tray seems to be suddenly increasing or is excessive.

Sample Tray

The sample tray is mounted beneath the instrument. Slide the tray out to provide a surface on which to rest samples. Note that the barcode reader holder may be attached to either side of the sample tray.

*Figure 4-6: View of the front of the **NucliSENS easyMAG** showing the sample tray extended from under the instrument*

Processing Area

The processing area contains moving mechanical parts and heaters, and is covered to prevent injury. The process door can be lifted to allow placement of Aspirator Disposables and to load samples, however the process door must be closed for the instrument to run samples.

The following sections describe the functions of the devices in the processing area.

Dispensing

The dispensing system transfers reagent from the reagent bottles to the sample strips. The mechanisms of the dispensing system are designed to be accessible to service personnel only, and are not discussed in detail in this document.

The only action that is required by the user is to ensure that there is sufficient reagent for the run. Refer to “Reagent Area” on page 4-11 for more information.

Aspiration

Aspirator Disposables aspirate fluid from the sample strips during processing.

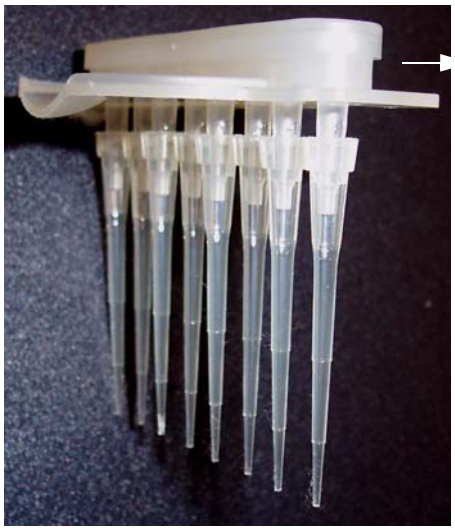


Figure 4-7: An Aspirator Disposable

Aspirator disposables are clipped into the instrument in order for the instrument to aspirate fluid from the sample strips. There must be an aspirator disposable in the corresponding position for each sample strip.

To load an Aspirator Disposable

1. Hold the aspirator disposable by the indent, with the pipette tips facing down and the body of the disposable facing away from the user.
2. Slide the sides of the disposable on an angle down into the aspirate head.

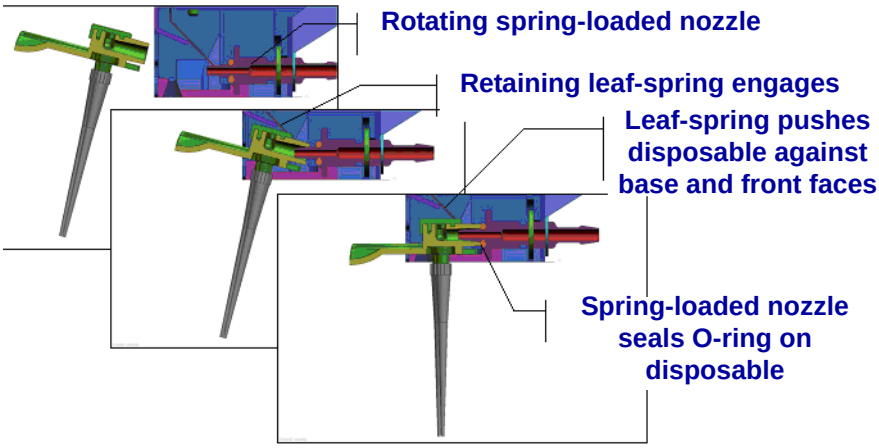


Figure 4-8: Loading an Aspirator Disposable

3. Continue gently pushing, at the same time placing gentle downward pressure on the indent at the front of the disposable. The disposable should initially move down, then horizontally backwards a short distance, and finally click into place.

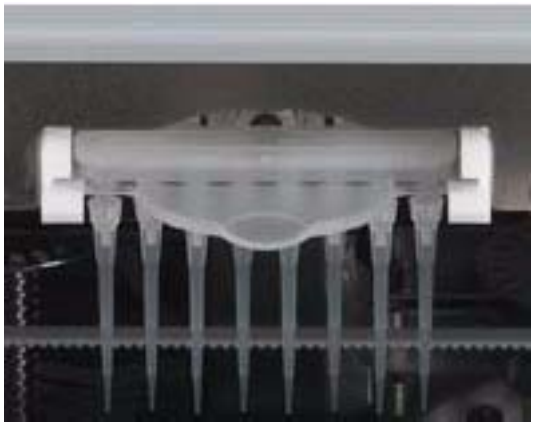


Figure 4-9: An Aspirator Disposable in position

▶ To unload an Aspirator Disposable

1. Hold the disposable by the indent, and gently lift until the disposable is released.
2. Slide the disposable up out of the aspirate head.

The connection point of the Aspirator Disposables should be inspected for reagent salt buildup and washed weekly. Refer to “Aspirator Disposable O-rings” on page 8-8 for more details.

Magnets

The magnet bars provide the means of moving and capturing Magnetic Silica during washing and aspiration.

There are no tasks for users to carry out in relation to the magnet bars.

Heater

The heater mechanism provides the means to heat the elution buffer to the required temperature for separation of the nucleic acids (DNA/RNA) from the Magnetic Silica.

The heater temperature is set using the software on the computer. If the software indicates problems with the heater, or if there is any overheating evident (smoking or blackening) on the heater, contact Global Customer Service.

Reagent Area

The reagent area is a module that can swing away from the instrument for access by service personnel.

There is space for four reagent bottles on platforms in the reagent area. A cover is provided to protect the reagent area from the surrounding environment.

The amount of reagent in the bottles is detected by mass-sensors in the hinged platforms. Do not impede the movement of the platforms.

Bottles

Each reagent bottle provides a source for the buffer used by the dispense system. The bottles are single use bottles supplied by bioMérieux.

Bottle caps are part of the instrument, and include right-angle connectors that connect to the reagent inlet tube on the instrument. The inlet reagent tubes are secured to the chassis.
An air inlet filter, which is built into the bottle cap, allows ventilation while preventing particle entry during aspiration. This system is illustrated in Figure 4-10.

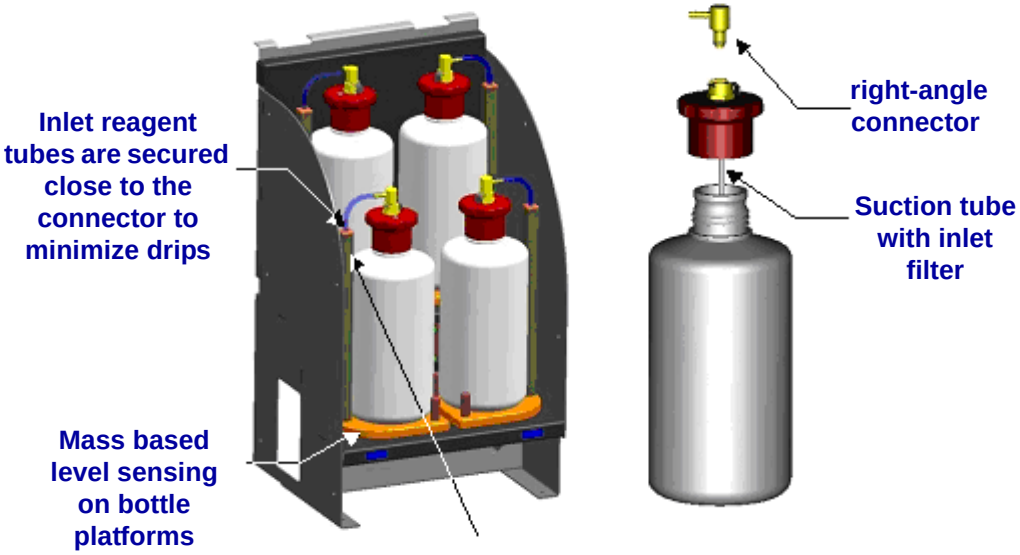


Figure 4-10: Reagent bottles and connector

Do not allow the reagent bottles to tip over. If the bottles tip over the filter may become blocked.

Do not replace a bottle while a run is in progress. If a reagent bottle is removed during a run a bubble may be introduced to the reagent tube, leading to a short dispense. A warning alarm (W112) will be issued if a bottle is removed when a run is in progress. This warning will also be added to the run to make this problem traceable.

To replace a bottle

Press the release button (refer to Figure 4-11), disconnect the connector, and lift the bottle out of the reagent area. Change the bottle by disconnecting it from the cap, then place the cap on a new bottle. Place the new bottle in the reagent compartment, then connect the right-angle connector to the cap using both hands so as to ensure that no excessive force is applied to the bottle platform.

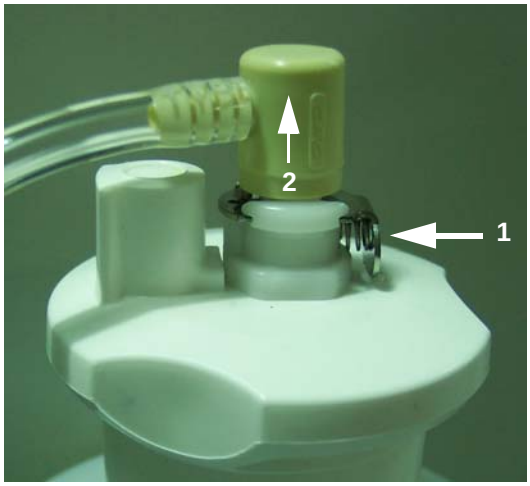


Figure 4-11: Bottle cap and connector with release button indicated

When removing connectors from reagent bottles, hold the connector in place while pressing the release button, and allow the connector to release slowly. If the connector is released suddenly, it may be possible for some reagent to flick off. Wear safety glasses while carrying out this procedure.

For more information on placing and registering reagent bottles, see “Step 2: Install On Board Reagents” on page 6-15.

Carbon Filter

The carbon filter is located beneath the reagent bottle platforms and should be replaced as per the maintenance schedule. Refer to “Carbon Filter” on page 8-15 for details of how often and how to replace the carbon filter.

Computer And Peripherals

The computer communicates with the ***NucliSENS easyMAG*** instrument via a cable connection. The user uses the keyboard and touch-screen that are connected to the computer to control the ***NucliSENS easyMAG*** instrument.

A barcode reader is also connected to the computer; this reader identifies reagents and samples to the software.

Keyboard And LCD Monitor / Touch-screen

The keyboard is a shortened version of a standard keyboard that is designed to fit securely on the holder provided. The keyboard cable plugs into the back of the computer.

The LCD monitor / touch-screen provides visual feedback and control through the ***NucliSENS easyMAG*** software. The software presents options as buttons that a user touches on the screen. The software is described in chapter “Software Description” on page 5-1.

There are three cables associated with the LCD monitor / touch-screen: power, touch screen and monitor. The power cable connects to a socket on the back of the instrument (refer to “Power Connections” on page 4-16 for more detail). The touch screen and monitor cables connect to the computer (refer to “Computer Connections” on page 4-15).

Only connect the supplied LCD monitor to the LCD power socket on the back of the instrument.

Should it become necessary to re-calibrate the touch-screen, please refer to Appendix “Touch Screen Re-calibration” on page C-1.

Barcode Reader

A barcode reader is attached to the instrument. This barcode reader facilitates the entry of barcodes into the system and therefore reduces the chance of entry errors.

Using The Barcode Reader

When the barcode reader is in its holder it will automatically attempt to scan barcodes which are held in front of it. Align the barcode along the red line. The line should extend at least to each end of the barcode.

When holding the reader out of the holder, point the window of the reader to the barcode, press and hold the trigger, and align the red line along the barcode.

The reader beeps and the indicator turns green when a barcode is recognized. If the barcode is not recognized the unit will beep repeatedly and the indicator on the top of the reader will glow red.

Do not hold the barcode too close to the reader.

If the reader does not recognize the barcode, try moving the barcode away from the reader until the barcode is recognized.

After a few seconds the barcode reader will turn off (unless it is in its holder). If this happens, release the trigger and start again.

The barcode reader has been pre-configured by bioMérieux with factory settings. However, the ***NucliSENS easyMAG*** can be made to work with other barcode families than those included in the factory settings. Please refer to the barcode reader user manual for instructions on how to prepare the reader.

Should it become necessary to reset the barcode reader to its factory settings, please refer to Appendix “Barcode Reader Configuration” on page B-1.

Computer Connections

The following table details the required connections between the instrument and computer for the ***NucliSENS easyMAG*** system:

Connector Style	Function	Identification
	Keyboard	Color = violet
	LCD monitor	None - unique connector
	Touch screen	Labeled ‘Touch-screen’
	Barcode reader	Labeled ‘Barcode Reader’
	Instrument communications	Labeled ‘Instrument Communications’
	Network communications	Labeled ‘Network Communications‘

Back Of The Instrument

An overview of the features at the back of the ***NucliSENS easyMAG*** are given in “Back View” on page 2-7. This section provides more detail on those features that may require user intervention.

See also:

- “Communications Connection” on page 2-8
- “Fuse Replacement” on page 8-16.

Power Connections

Ensure that the instrument and main power are off before connecting any power leads from or to the instrument.

As well as a socket for power input at the lower left of the back of the ***NucliSENS easyMAG*** instrument, there is a power output for the LCD monitor (see Figure 4-12).

Figure 4-12: Power connections

1 *into the instrument* ***2*** *to the LCD monitor*

Only connect the supplied LCD monitor to the LCD power socket.

Waste Connections

The figure illustrates the waste connections from the ***NucliSENS easyMAG***.

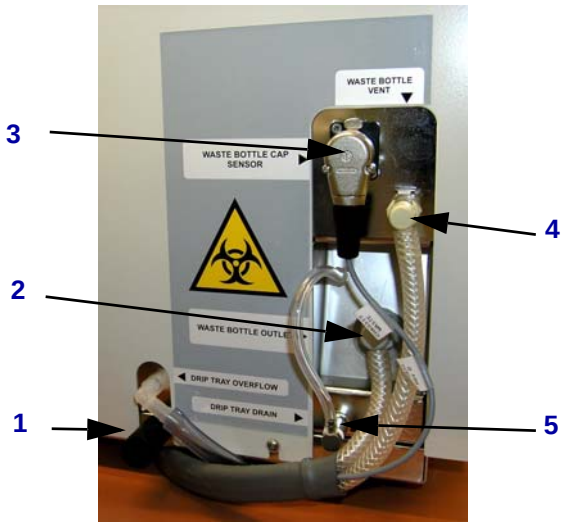


*Figure 4-13: Waste connections from the **NucliSENS easyMAG***

1 *Drip tray overflow*
2 *Outlet to waste bottle*
3 *Connector for waste bottle presence sensor*
4 *Service pressure gauge connector*
5 *Drip tray drain*

▶ To empty the drip tray

Connect the tubing provided to the drip tray drain, and allow the loose end to drain to a suitable receptacle, so that the liquid level will be below the top of the drip tray. If the drip tray frequently overflows, contact your local bioMérieux representative for advice.

▶ To empty the waste container

Use the waste bottle stand to help prevent the bottle tipping over. If the bottle tips over the filter may become wet and blocked and require replacing. Make sure to keep the filter dry when you dispose of the waste.

1. Make sure that the instrument is idle (not operating).The ***NucliSENS easyMAG*** software must be running.

Emptying the waste bottle should be done under software control, otherwise the software will not register that waste is empty.

2. Activate the waste disposal process with the *Empty out waste container* button (see “Emptying The Waste Container” on page 6-17 for more information).
3. While pressing the release button of the waste line, wipe around the connector with an absorbent tissue moistened with alcohol to catch any drips.

The waste liquid is a potential biohazard. Take care to avoid any spillage of waste liquid while disconnecting the waste line.

4. Remove the waste bottle cap and dispose of the contents according to local regulations at the installation site.
5. To re-connect the waste bottle, replace the cap, then re-connect the waste line.

5 Software Description

Software Basics

The computer that controls the instrument runs the Microsoft® Windows XP® operating system.

The application software has an intuitive graphic interface designed to guide the user through tasks.

The ***NucliSENS easyMAG*** system has a touch-screen monitor allowing the user to interact directly with the graphic interface. This makes the ***NucliSENS easyMAG*** system easy to use, and reduces the possibility of user errors.

Barcode Reader

The barcode reader is only active in the following work areas:

- Define Extraction Requests
- Load Run
- Reagent Inventory

The user does not need to have the input focus on the text field before scanning a barcode. A scanned barcode is printed in the user input field. When the barcode reader is not working the user may type a barcode in the text field and press <Enter>.

▶ To read and enter a barcode

1. Select the field in which the barcode is to be entered.
   Some barcodes automatically initiate the selection of the corresponding field.
2. Point the barcode reader at the barcode or position the barcode in front of the reader when it is in the holder. Ensure reader and barcode are aligned.
3. Press the *Trigger* button on the barcode reader when the reader is not in the holder. A beep confirms correct recognition.
4. The barcode appears in the field and is accepted by the software.

Touch-screen

The software is typically operated by tapping buttons on the touch-screen. These buttons can also be operated by using the keyboard mouse. The wearing of gloves is recommended when touching the touch-screen.

Throughout the rest of this document, instructions to ‘click’ or ‘select’ an element can be considered to be the same as ‘touch’.

When touching the screen, be sure to ‘tap’ rather than ‘press’. The ‘tap’ must be of a short duration.

To perform scroll actions or multi-select actions on the touch screen click on the screen and wait for moment before starting to scroll by dragging down or up.

Multi-select function

To select a number of adjoining rows in a table, click on the first row, then hold down the <Shift> key while clicking on the last row. Alternatively, once the first row has been selected, holding down the <Shift> key and pressing the <up> / <down> arrow keys will add one more row to the selection for each click on the <Arrow> key.

To select a number of non-adjoining rows in a table, click on the first row, then press the <Ctrl> key prior to clicking on each of the subsequent rows. Selected rows can also be deselected by clicking on them while holding down the <Ctrl> key.

The rows of a table can be sorted into different orders if required.

To sort by a particular column, click on the column header.

If the A↓Z button is present, press this button to reset to the original order.

Logging In / Logging Out

The *Login* dialog box allows users to login to the system. The *Login* dialog box is displayed when the system is started up, and when no user is logged in. When logged in, the current user can logout by clicking the *Key* button on the status bar. After Logout the *Login* dialog will again be displayed.

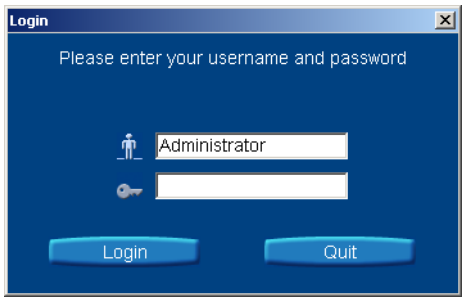


Figure 5-1: Login dialog box

The *Login* dialog box comprises the Name and Password fields, and the *Login* and *Quit* buttons. A valid user name and password are required to login. Please note that passwords are case sensitive although user names are not.

After power is applied to the instrument, it is necessary to wait until the instrument power indicator is green before attempting to login.

For information about setting user names and passwords, see “User Administration” on page 5-17.

When a user is logged in, but no user actions have been registered for 15 minutes, the user will be automatically logged out. When the user is logged out while the instrument is processing, the instrument will continue processing and will not be interrupted.

Screen Layout

The screen is divided into five areas

- Alarm area
- Menu bar: main menu bar and sub-menu bar
- Action bar
- Work area
- Status bar

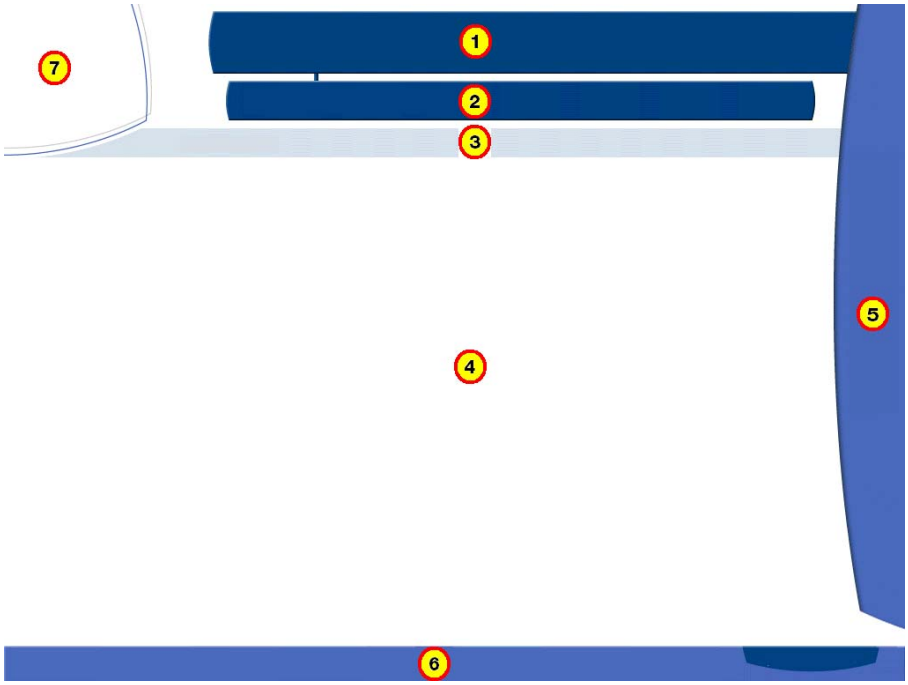


*Figure 5-2: **NucliSENS easyMAG** graphic interface*

1 *Main tool bar*
2 *Sub-tool bar*
3 *Work area title*
4 *Work area*
5 *Action bar*
6 *Status bar*
7 *Alarms area*

Alarm Area

The triangular area located in the top left corner of the screen represents the alarm board.

Three different alarms are defined:

- Instrument alarm
- Disposables alarm (for the reagents, all consumables and waste stored within the instrument)
- Connection alarm (for all data communication through ***NucliSENtral***)

Each alarm button may have three different states: OK, Warning, and Error.

An icon, differing by its color and its shape, represents each state:

Figure 5-3: Alarm states

Color and shape	**Meaning**
Green and square:	OK
Orange and triangle:	Indicates a warning.
Red and circle:	An error occurred. (The system can be partially or completely stopped.)

Each alarm is an active button, which allows displaying information in a specific working area. Instrument alarms, disposable alarms and software alarms are displayed in the *Device status* work area. Connection alarms are shown in the ***NucliSENtral*** *Status* work area.

Menu Bar

The *Menu* bar consists of navigation items within the software. Each button of the main bar represents a function or a group of functions. If the button represents a group of functions, a sub-navigation bar is accessible to allow the selection of an individual function. ToolTips are available for each button of the main and sub navigation bars, although these only work when a mouse is used; they do not work with the touch screen.

Figure 5-4: Menu Bar

The *Menu* bar is used to navigate among defined work areas. Navigating actions have no effect on the status bar and alarms sections.

If the access to a navigation button is prohibited for the currently logged in user, the navigation button is inactive and nothing happens when it is selected.

When the user selects a function in the main navigation bar, the first function in the sub navigation bar is selected by default and the corresponding work area is displayed. For each selected sub-function, the work area displays information and the action bar contains all operations that the user can perform on the contents of the work area.

Work Area

The center of the screen is the work area. The default work area will be *Device status*, unless ***NucliSENtral*** communication is enabled and a ***NucliSENtral*** alarm is present. In this case the ***NucliSENtral*** *Status* work area is displayed by default. If an instrument or disposable alarm is also present, the *Device status* work area is displayed by default.

The title of the current work area is always displayed directly underneath the sub-menus.

The work area is where the user performs a specific task. Selecting a menu or sub-menu displays the work area specific to that item. Each work area has its own action bar. The action bar only contains buttons relevant to that work area's function.

A work area often contains more than one window. For example, the *Define Extraction Requests* work area contains a list of existing extraction requests and a window displaying details of the currently selected extraction request.

Work Area Tabbed Windows

In a few work areas the windows are *tabbed*. Each window tab provides a different view on the task at hand. Within the *Execute Run* work area for example, there is a tab for monitoring progress of the run that is being executed, and another tab for displaying details about any errors or warnings that may have occurred.

Use the tab buttons in the top-right corner of a window to switch between the different views.

Action Bar

The action bar contains all available operations for the displayed contents of the work area. These actions are represented by buttons allowing the user to interact with displayed information.

ToolTips are available for each action item. Some actions that are used in many screens of the software, like ‘Print’, are always located in the same place and always appear in the same order.

The buttons that are displayed in the action bar are determined by the work area that is active. The buttons act only on the information displayed in the work area.

Figure 5-5: Typical Action Bar

Status Bar

The status bar is displayed at the bottom of the screen and gives general information about the application. Some of the items shown in the status bar will change along with changes in the work area that is displayed.

Figure 5-6: Status Bar

The status bar is composed of:

- Current date and time
- *Login Access* button
- Current user login name
- Instrument state
- Instrument progress indicator
- Application progress indicator
- Application name

Selecting the *Login Access* button displays a dialog box allowing the user to quit the application, logout, or change their password.

Confirmation Dialogs

Confirmation dialog boxes are displayed for various operations such as when modifying or deleting data.

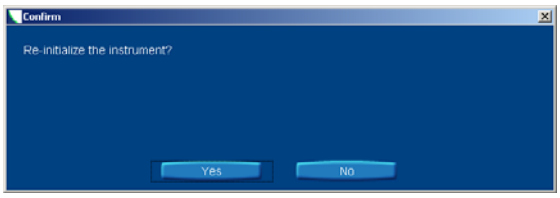


Figure 5-7: Confirmation dialog

The software requires confirmation if the user wishes to continue. Click *Yes* to continue with the action, click *No* to abort the action.

Warning Message Dialogs

Warning message dialogs indicate that the chosen action was not performed as expected. The message also includes advice on how to correct the situation.

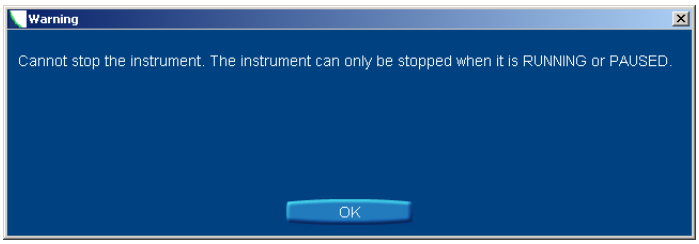


Figure 5-8: Warning message dialog

Click *OK* to dismiss the message.

Error Message Dialogs

Error message dialogs inform the user that one or more errors have occurred when starting lysis buffer dispensing, starting an extraction run or starting a maintenance protocol. An error can be caused by one or more alarms.

The error message dialog shows the error related alarms, which can be selected by the user.

The message dialog windows can also be closed by pressing the <ESC> key on the keyboard.
For a Confirmation (Yes/No) dialog pressing the <ESC> key automatically selects the No button.

The message dialog will show a description of the selected alarm, a reason why it occurred and advice on how to correct the problem.

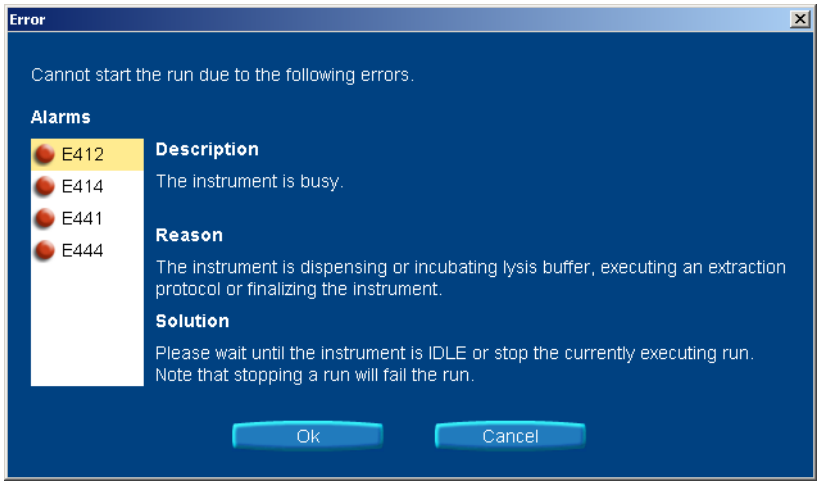


Figure 5-9: Error message dialog

Refer to “Troubleshooting” on page E-8 for a list of error messages.

Common Buttons

The following action buttons appear throughout the software and always have the same function:


Save


Delete


Define new


Edit


Print


Stop


Start


Add remark

Online Manual

The ***NucliSENS easyMAG*** application software has an online user manual available to help the user find information quickly and conveniently.

Clicking the *Help* button on the main menu bar or the *User Manual* button on the sub-menu bar will provide the online user manual to the user.

The online system provides information available in the User Manual in a convenient manner, when and where the user needs it.

Menu Bar

The main menu bar at the top of the screen provides a main menu with sub-menu items, that give access to the different work areas of the application. The following menu and sub-menu items are accessible from the main menu bar, depending on the access rights of the current user.

To select a menu and display its sub-menu tap the menu button. Then tap a sub-menu to display the corresponding work area.

Alternatively, use the keyboard function keys <F1>...<F5> to select a menu, from left to right. To select a sub-menu hold the <CTRL>-key while pressing a function key. For example, pressing <F1> selects the *Daily Use* menu. Subsequently pressing <CTRL>-<F3> selects the *Load Run* work area.

Menu Structure

Daily Use

Define Extraction Requests

Organize Runs

Load Run

Execute Run

View Results

Instrument

Reagent Inventory

Device Status

NucliSENtral Status

Settings

Application Settings

User Administration

Maintenance

Maintenance

Protocol Inventory

Assay Development

Help

About

User Manual

Daily Use Menu

The *Daily Use* menu contains menu items which are used on a daily basis when performing extractions on the ***NucliSENS easyMAG***.

Define Extraction Requests

Use this work area to enter extraction requests into the software, simply by scanning sample tubes. The software creates extraction requests for the sample tube scans by coupling default values for, for example, extraction, matrix, and input and eluate volume to the sample IDs. These values can then be edited for individual samples.

Organize Runs

The user combines extraction requests into one or more runs in the *Organize Runs* work area.

Load Run

The software can guide the user in adding samples to the sample strips on the instrument by activating the LEDs above the sample strip vessels. Guidance is also provided for the installation of disposables.

Should the user choose to pipette samples to the sample strips in a laminar flow cabinet, a printed work list created by the user software can be used as a guide.

Execute Run

During execution of a run the user can view progress using this screen.

Should any problems occur, this is indicated by the *Alarm* buttons in the upper left section of the screen. The user can then navigate to the *Incidents* tab to inspect and possibly solve the cause of the warning or error.

View Results

Results of an executed run can be viewed from within the *View Results* work area. All results belonging to a run can be viewed, for example run layout, used reagent lot-numbers, errors and warnings. From within this work area the user can print the run results or request repeat extractions for particular extraction requests.

Instrument Menu

The *Instrument* menu contains menu items that are instrument related.

Reagent Inventory

The user attends to the on board reagents via the *Reagent Inventory* work area. This work area supports bottle change and reagent data inspection. When the instrument signals that user intervention is needed for on board reagent related events, the user will be guided to this work area to solve any reagent inventory related problems.

Device Status

The user can monitor the instrument status from within the *Device Status* work area. When the instrument signals that user intervention is needed for instrument related events, the user will be guided to this work area to solve any instrument related problems.

NucliSENtral Status

The user can monitor the ***NucliSENtral*** status from within the ***NucliSENtral*** *Status* work area. Any incidents concerning data communication through ***NucliSENtral*** will be displayed in this work area.

Settings

The *Settings* menu contains sub-menus for application configuration and user management.

Application Settings

Application related configuration items can be set and defined from within the *Application Settings* work area. From within this work area, the workflow preferences, communication settings for the barcode reader, and communication settings for the ***NucliSENS easyMAG*** instrument and ***NucliSENtral*** can be set. It is also possible to enable or disable the various sounds used within the application software.

User Administration

Access to parts of the application functionality is restricted for certain groups of users. The *User Administration* work area contains functions to define and manage users' access rights. Users can be defined and assigned to predefined security groups. Passwords can be reset and status of user accounts can be set or disabled.

Maintenance

The *Maintenance* menu provides functions for execution and management of routine maintenance protocols.

Routine Maintenance

The *Routine Maintenance* work area provides functions to perform routine maintenance protocols on the ***NucliSENS easyMAG*** Instrument. From this work area, the user is able to select and start daily, weekly, and monthly routine maintenance protocols.

Protocol Inventory

Extraction protocols and maintenance protocols can be added to and removed from the software. Within the *Protocol Inventory* work area the user can import, view, deactivate and activate protocols.

Assay Development

New assay protocols can be created based on existing protocols and be added to the list of available protocols. Within the *Assay Development* work area the user can create, edit, delete, deactivate, activate and promote new assay protocols.

Help

The *Help* menu provides functions for displaying the user manual and information about the current system, application and licensing.

About

The *About* work area provides information about the installed application software, system settings and licenses for third-party software used by the ***NucliSENS easyMAG*** software.

User Manual

The user manual file can be displayed by clicking the *User Manual* button. The user manual opens in a separate window.

Preparing The System For Use

User Administration

The ***NucliSENS easyMAG*** system makes use of user names and access rights to track which user is currently operating the system, and also to restrict access to areas of the system by unauthorized persons. Each user has a unique user name and is assigned to one or more security groups with predefined access rights.

User names and their security groups are administered in the *User Administration* work area, which can be selected from within the *Settings* menu.

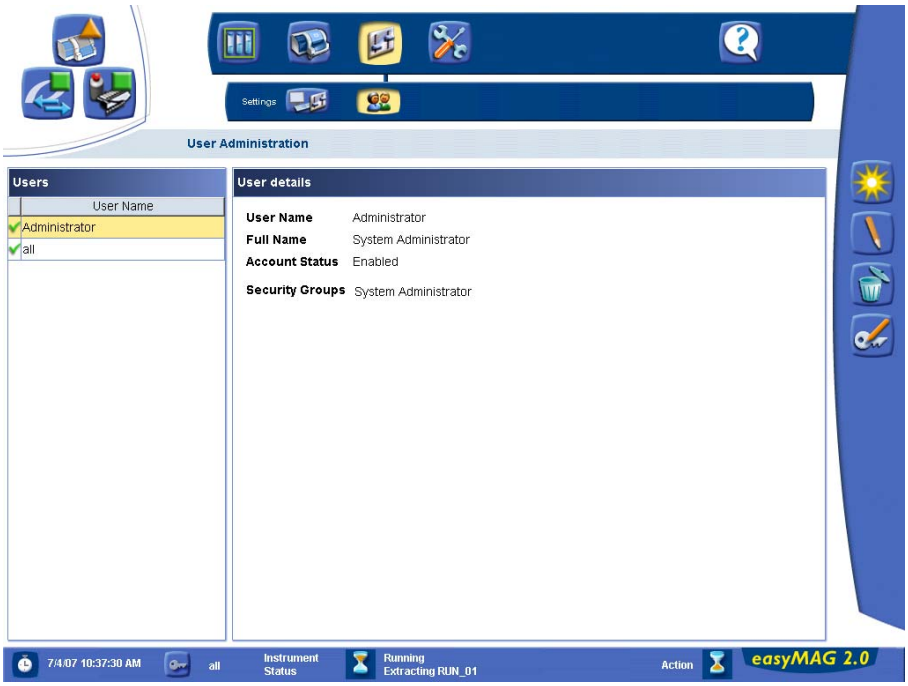


Figure 5-10: User Administration work area

To create, modify, and delete users or to reset user passwords requires System Administrator access rights.

Security Groups

The system supports four security groups:

- Laboratory Technician
- Laboratory Manager
- Maintenance Engineer
- System Administrator

A user must be assigned to at least one of these groups to be able to login. The following table lists the permitted actions for users in each security group. The first entry for every work area identifies whether or not a user is even permitted to view that work area by pressing its sub-menu button.

Work area	*Action*	*Lab Technician*	*Lab Manager*	*Maintenance Engineer*	*System Administrator*
Define Extraction Requests	Auto-generate	✓	✓	✓	
	New	✓	✓	✓	
	Save	✓	✓	✓	
	Delete	✓	✓	✓	
	Add remark	✓	✓	✓	
Organize Runs		✓	✓	✓	
	Create	✓	✓	✓	
	Edit	✓	✓	✓	
	Delete	✓	✓	✓	
	Add remark	✓	✓	✓	
	Move up	✓	✓	✓	
	Move down	✓	✓	✓	
	Auto fill	✓	✓	✓	
	Remove	✓	✓	✓	
	Move to	✓	✓	✓	

Load Run (all views)		✓	✓	✓	
	Dispense lysis buffer	✓	✓	✓	
	Start	✓	✓	✓	
	Delete	✓	✓	✓	
	Reagents inventory	✓	✓	✓	
	Abort	✓	✓	✓	
	Print	✓	✓	✓	
	Add remark	✓	✓	✓	
Execute Run (all views)		✓	✓	✓	
	Add remark	✓	✓	✓	
	Abort	✓	✓	✓	
View Results (all views)		✓	✓	✓	
	Repeat extraction	✓	✓		
	Assess	✓	✓		
	Delete	✓	✓	✓	
	Add remark	✓	✓		
	Export	✓	✓		
	Print	✓	✓		
	Send	✓	✓		
Reagent Inventory		✓	✓	✓	
	Empty waste container	✓	✓	✓	
	Back	✓	✓	✓	
Device Status		✓	✓	✓	✓
	Connect	✓	✓	✓	
	Disconnect	✓	✓	✓	
	Initialize	✓	✓	✓	
	Clear incidents	✓	✓	✓	
	Stop	✓	✓	✓	
***NucliSENtral* Status**			✓	✓	
	Connect	✓	✓	✓	
	Disconnect	✓	✓	✓	
	Clear alarms	✓	✓	✓	
Application Settings			✓	✓	
	Save		✓	✓	
User Administration					✓
	New				✓
	Edit				✓
	Delete				✓
	Reset password				✓

Maintenance				✓	
	Start			✓	
	Reagents inventory			✓	
	Abort			✓	
Protocol Inventory			✓	✓	
	Import		✓	✓	
	Activate		✓	✓	
	De-activate		✓	✓	
	Delete		✓	✓	
	Enable ***NucliSENtral***		✓	✓	
	Disable ***NucliSENtral***		✓	✓	
Assay Development			✓	✓	
	New		✓	✓	
	Edit		✓	✓	
	Promote		✓	✓	
	Activate		✓	✓	
	Deactivate		✓	✓	
	Delete		✓	✓	
About		✓	✓	✓	
User Manual		✓	✓	✓	

✓ = Available for user type

▶ To create a new user

1. Select the *Create New User* action button. The *New User* dialog box is displayed.

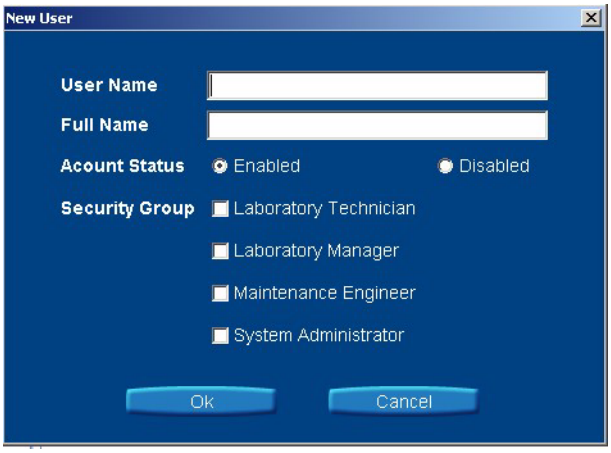


Figure 5-11: New User dialog

2. Enter the user name and full name into the designated fields.
3. Set the account status to enabled and select the appropriate security groups.
4. Press the *OK* button to add the new user information or Cancel to abort. The *New User* dialog closes.

   The entered user name will be added to the user list and the user's information will be displayed in the detailed information window.

▶ To modify user information

1. Select a user account in the Users panel.
2. Select the *Modify User* action button.
   The *Modify User* dialog box is displayed.
3. Change the user information as required.
4. Press the *OK* button. The *Modify user* dialog closes.

   The modified user information is shown in the detailed information window

▶ To reset a password

1. Select a user account in the Users panel.
2. Select the *Reset Password* action button. A confirmation dialog is displayed.
3. Select the *OK* button of the confirmation dialog. The confirmation dialog closes.

   The password for the selected user is equals the user name. Please note that passwords are case sensitive while user names are not.

▶ To delete a user

1. Select the required user account in the Users panel.
2. Select the *Delete User* action button. A confirmation dialog is displayed.
3. Press the *OK* button of the confirmation dialog. The confirmation dialog closes.

   The selected user is now removed from the user list, and the deleted user can no longer login to the application. Please note however that a user cannot delete their own account.

Protocol Inventory

The ***NucliSENS easyMAG*** system uses extraction protocols to instruct the instrument how to perform an extraction run. Some instrument maintenance activities are supported by one or more maintenance protocols that can be executed on the instrument in a manner similar to extraction protocols.

Protocols can be imported and managed from within the *Protocol Inventory* work area.

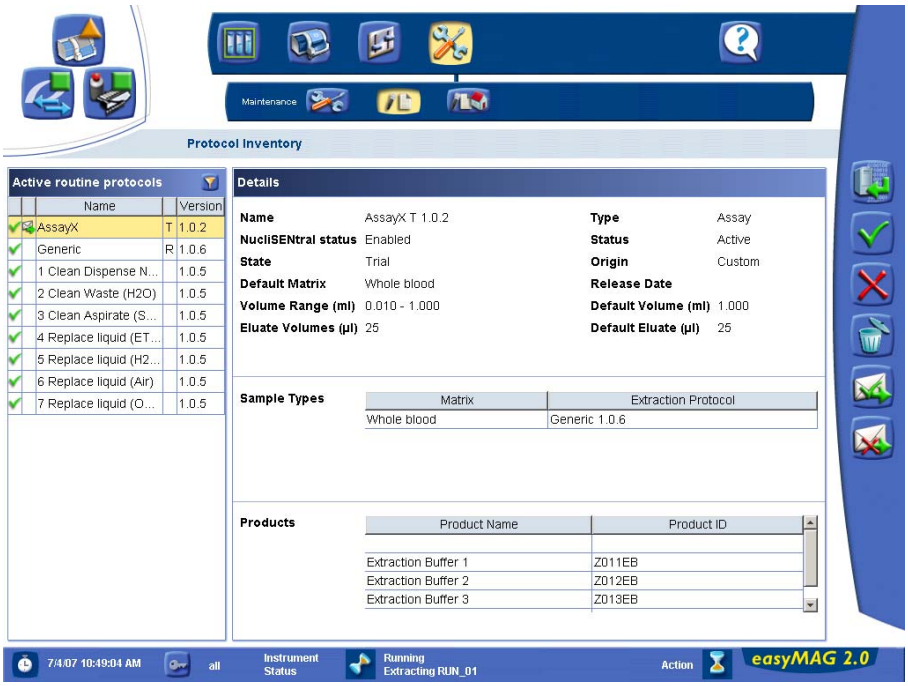


Figure 5-12: Protocol Inventory work area

Protocols

A protocol describes the steps the instrument needs to execute and the reagents needed to perform an extraction or maintenance run.

Protocols can be generic or assay protocols. An assay protocol is a protocol that is intended for a specific assay.

Protocols can be uniquely identified by their name and version number.

Protocols can be activated or deactivated. Only active assay protocols or generic extraction protocols can be selected when extraction requests are defined.

Assay protocols have a status assigned, depending on their state of promotion defined in the *Assay Development* work area. The displayed status can be ‘T‘ for ‘Trial’ and ‘R‘ for ‘Released’.

‘Trial’ and ‘Released’ assay protocols can be enabled and disabled for sending and receiving data to and from ***NucliSENtral***. When an assay protocol is active, it is also enabled for receiving data via ***NucliSENtral***. When the ***NucliSENtral*** ‘Send’ is enabled, the assay protocol is also enabled for sending data for this assay protocol via ***NucliSENtral***.

▶ Importing an assay or protocol

1. Select the *Import Assay or Protocol* button. An *Import Assay or Protocol* dialog is shown.

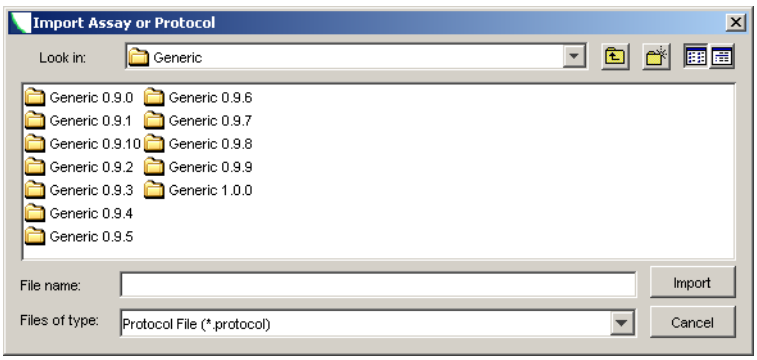


Figure 5-13: Import Assay/Protocol Dialog

2. Locate and select the assay definition or extraction protocol. Protocol files are always of the file type ‘protocol’ (*.protocol) or ‘assay‘ (*.assay).
3. Press the *Import* button. The *Import Assay or Protocol* dialog is closed.

   The imported assay or protocol is shown in the assay/protocol list and the information of the assay/protocol will be displayed in the detailed information window.

   The newly imported assay definition will be defined as active.

When an assay protocol is imported, the corresponding/referenced extraction protocol(s) will be imported automatically. If the corresponding extraction protocols are already present, they will not be installed.

Activating a protocol

Above the protocols list a filter button is shown. Clicking this button will change the list contents from ‘All Protocols’ to ‘Active Protocols’ and vice-versa.

1. Set the filter of the protocol list to ‘All protocols’. Select an inactive assay definition or protocol (with a red ‘✗’ in front of it) in the Protocol list.

2. Select the *Activate* action button. A confirmation dialog is displayed.
3. Press the *OK* button on the confirmation dialog. The confirmation dialog closes.
4. The assay definition or protocol is now set to active and a check mark ‘✓’ is shown in front of it.

An activated protocol can be used for manual extraction request definition. Activated assay protocol with state ‘Trial’ and ‘Released’ can also receive extraction requests via ***NucliSENtral****.*

De-activating a protocol

1. Select an active assay definition or protocol (with a ‘✓’ in front of it) in the Protocol list.

2. Select the *De-activate* action button. A confirmation dialog is displayed.
3. Press the *OK* button on the confirmation dialog. The confirmation dialog closes.
4. The assay definition or protocol is now set to’ inactive’ and has a red ‘✗’ shown in front of it. When the filter on the protocol list is set to active protocols, this protocol no longer appears in the list.

A deactivated protocol cannot be used for manual extraction request definition.

Deleting a protocol

1. Select a protocol to delete in the Protocol list.
2. Select the *Delete* action button. A confirmation dialog is displayed.
3. Press either the *Yes* button on the confirmation dialog to confirm deletion or *No* to cancel the action. The confirmation dialog closes.

*When a 'Trial' and 'Released' assay protocol is deleted, this change in protocol configuration is automatically communicated to **NucliSENtral**.*

Enable sending data to *NucliSENtral* for a protocol

1. Select an assay protocol from the protocol list.
2. Click on the *Enable **NucliSENtral** connectivity* button to make this assay protocol available for transfer via the ***NucliSENtral*** network. A confirmation dialog is displayed.
3. Click either *Yes* to apply or *No* to cancel the action.

*Extraction results corresponding to the enabled protocol can be sent through **NucliSENtral**. This change in protocol configuration is automatically communicated to **NucliSENtral**.*

Disable sending data to *NucliSENtral* for a protocol

1. Select an assay protocol from the protocol list.
2. Click on the *Disable **NucliSENtral** connectivity* button to disable this assay protocol for transfer via the ***NucliSENtral*** network. A confirmation dialog is displayed.
3. Click either *Yes* to apply or *No* to cancel the action.

*Extraction results corresponding to the disabled protocol cannot be sent through **NucliSENtral**. This change in protocol configuration is automatically communicated to **NucliSENtral**.*

Creating Assay Protocols

The ***NucliSENS easyMAG*** software enables assay protocol creation.

Assay development is needed for ***NucliSENS easyMAG*** to be able to recognize LIS orders related to a specific sample and assay, and to be able to pass the extraction information to ***NucliSENS EasyQ*** including the sample/ assay combination.

The *Assay Development* work area is available in the *Maintenance* menu.

Refer to "Assay Development Work Area" on page D-43 for a detailed description of the elements in the 'Assay Development' work area.

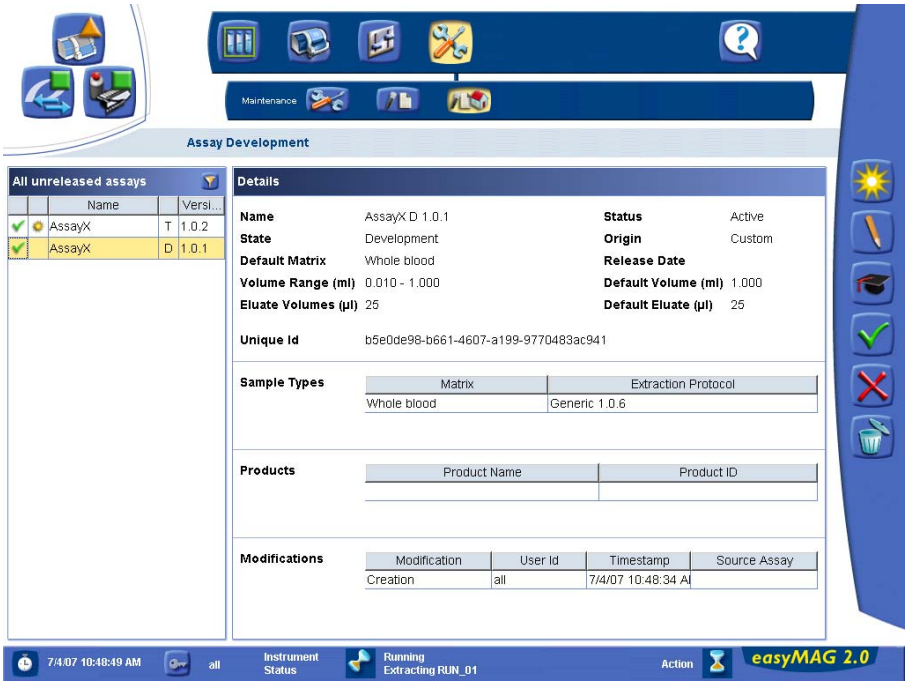


Figure 5-14: Assay Development work area

Create New Assay

Follow the procedure below to create a new assay.

1. Open the *Assay Development* work area in the *Maintenance* menu.
2. Click the *Create new assay* action button to open the *Create new assay* dialog box.

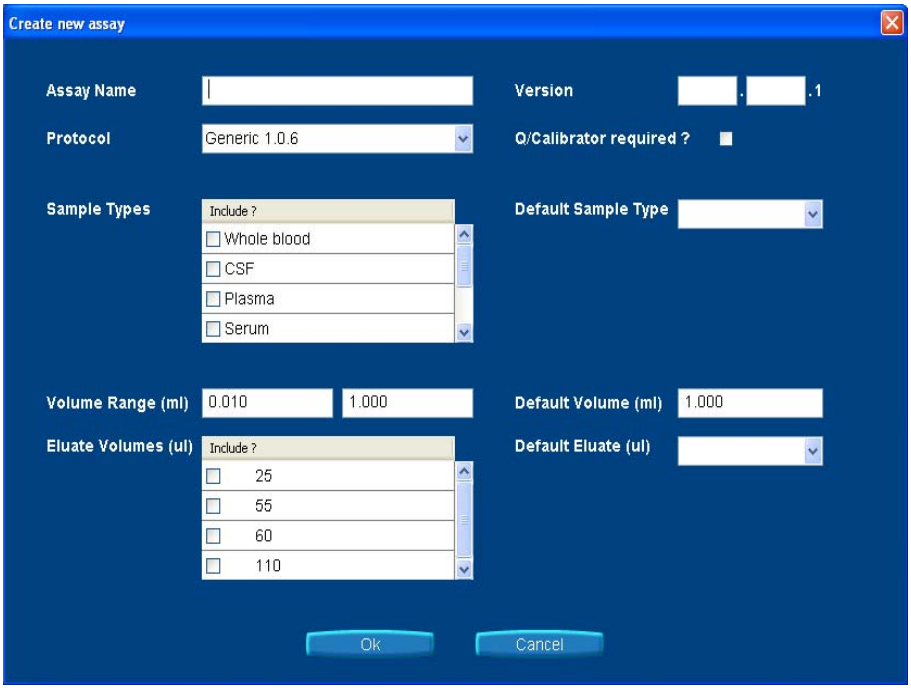


Figure 5-15: Create new assay dialog box

3. Enter or select assay information in the corresponding fields:

Assay Name	Enter the name of the new assay protocol.	
Version	Enter a numeric value in the two corresponding text fields to identify the assay protocol version number. The third digit is automatically added by the system.	
Protocol	Select an extraction protocol as basis for the new assay protocol	
Internal control/ Calibrator required	Enabled	A control or calibrator is required for running this assay protocol.
	Disabled	A control or calibrator is not required for running this assay protocol.
Sample Types	Select one or more the sample type(s) that can be used for the assay protocol.	
Default Sample Type	Select the default sample type for the assay protocol from the drop-down list.	
Volume Range (ml)	Enter the range of permitted input volumes for this protocol.	
Default Volume (ml)	Enter the default input volume for this assay protocol.	
Eluate Volumes (µl)	Select one ore more possible eluate volume(s) for this assay protocol.	
Default Eluate (µl)	Select the default eluate volume for the assay protocol from the drop-down list.	

4. Click *OK* to save the assay protocol settings and close the *Create new assay* dialog box.

The new assay protocol is displayed in the *All unreleased assays* list in the *Assay Development* work area.

Edit Assay

Follow the procedure below to edit an existing assay.

1. Open the *Assay Development* work area in the *Maintenance* menu.
2. Select an assay protocol to be edited in the *All unreleased assays* list.
3. Click the *Edit assay* action button. The *Edit assay* dialog box opens.

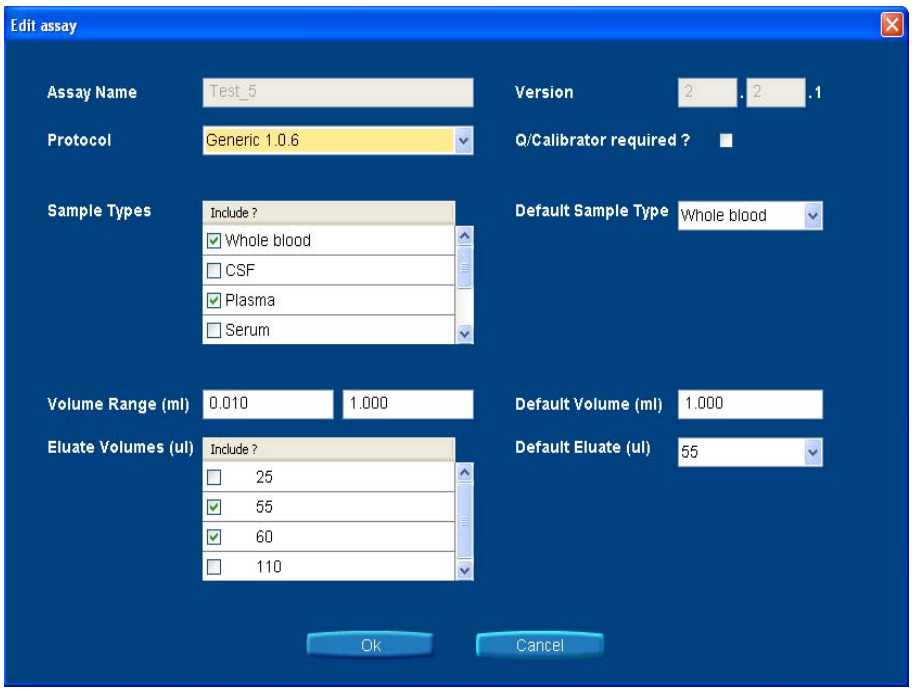


Figure 5-16: Edit assay dialog box

4. Edit the desired assay protocol parameters.

The Edit assay dialog box is identical with the Create new assay dialog box, only the parameters for assay name and version cannot be edited.

5. Click *OK* to save the changes.

Promote Assay

Follow the procedure below to promote an existing assay.

1. Open the *Assay Development* work area in the *Maintenance* menu.
2. Select a ‘Development’ or ‘Trial’ status assay protocol to be promoted in the *All assays* list.
3. Click the *Promote assay* action button. A confirmation dialog box opens.
4. Click *Yes* to promote a ‘Development’ assay to ‘Trial’ or a ‘Trial’ assay to ‘Released’ status.

*Assay protocols with status ‘Trial’ and ‘Released’ assigned are also displayed in the Protocol Inventory work area and can be used for **NucliSENtral**.*

The meaning of ’Development’ and ’Trial’ is to use these assays only within the development environment of your laboratory. The assay display names contain an indication that you have a ‘Development’ or ‘Trial’ assay (i.e. 'D' or a 'T' in the assay display name).
‘Released’ assays can be used within the routine environment of a laboratory. ‘Released’ assay protocols will always increase the version ID up by one, while all other information remains unchanged. ‘Released’ assay protocols cannot be edited any more.

It is the responsibility of the lab technicians to validate assay protocols before promoting an assay protocol to ‘Released’ status.

Activate/Deactivate Assay

Follow the procedure below to activate/deactivate an existing assay.

1. Open the *Assay Development* work area in the *Maintenance* menu.
2. Select an assay protocol to be activated/deactivated in the *All assays* list.
3. Click the *Activate assay* action button to activate the assay protocol, if deactivated before. A confirmation dialog box opens.
4. Click *Yes* to confirm the action.

   Or:
5. Click the *Deactivate assay* action button to deactivate the assay protocol, if activated before. A confirmation dialog box opens.
6. Click *Yes* to confirm the action.

Activating/Deactivating assay protocols in the 'Assay Development' work area will also be adapted in the 'Protocol Inventory' work area.

Activated assay protocols can be used for manual extraction request definition, deactivated assay protocols cannot be used for manual extraction request definition.

Application Settings

The ***NucliSENS easyMAG*** application environment can be set to support specific needs for a certain lab or customer situation.

The following application settings can be changed:

- Workflow preferences related to executing a run according to a predefined workflow
- Barcode reader settings
- Instrument communication settings
- ***NucliSENtral*** communication settings
- Sounds

*Do not change Application settings for the Barcode Reader, Instrument and **NucliSENtral** Communication without prior consent of the local bioMérieux representative.*

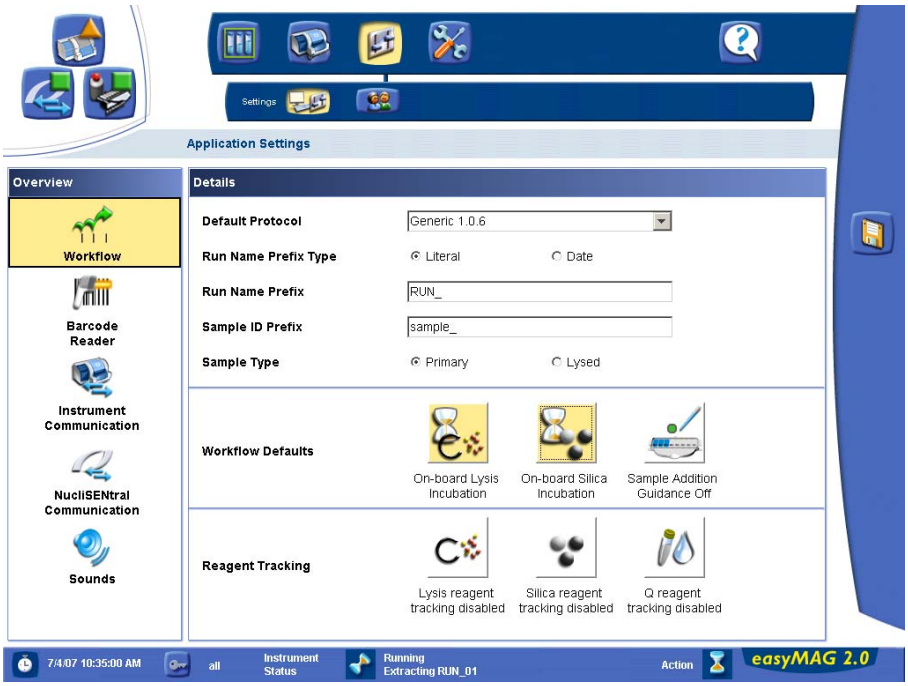


Figure 5-17: Application Settings work area

Workflow Settings

Select the *Workflow* icon from the *Overview* column on the left side of the screen to display the workflow details in the work area.
The user can set the following preferences to adjust the software workflow settings to match typical procedures used in their laboratory:

- **Default Assay/Protocol**:

  The protocol or assay that is selected here will always be shown as the default in the *Define extraction request* work area.
- **Run Name prefix type**:

  Define which type of prefix should be added to identify a run. Select ‘Literal’ if you want to enter your own prefix under *Run Name Prefix* or select ’Date’ to let the program automatically add the current date to the run name when a new run is created.
- **Run name prefix**:

  Define a prefix that will be presented as the first part of the run name when the user defines a new run. This prefix can be overwritten when a new run is created.

When ’Date’ is selected, the run name is displayed as date and a sequential number.

- **Sample ID prefix**:

  Define a prefix that will be presented as the first part of a sample identification when the user defines a new extraction request. The prefix is only used when extraction requests are generated using the auto number option; the prefix is not used when defining extraction requests within the *Define Extraction Request* work area. This prefix can be overwritten when a new extraction request is created.
- **Sample Type (primary or lysed)**:

  Define a default for the sample types to be processed by the ***NucliSENS easyMAG***. Select ‘Lysed’ if the samples are generally already lysed; select ‘Primary’ otherwise.

- **Default on board lysis addition (On/Off)**:

  When lysis addition is to be performed by the ***NucliSENS easyMAG*** instrument, click on the *On-board Lysis Incubation* button. This setting is a default that can be overruled when new runs are defined.

- **Default on board silica incubation (On/Off)**:
  When lysis incubation is to be performed by the ***NucliSENS easyMAG*** instrument, click on the *On-board Silica Incubation* button. This setting is a default that can be overruled when new runs are defined.

- **Sample addition guidance (On/Off)**:
  Click on the *Sample Addition Guidance* button for guidance when adding samples to the samples strips.
  When scanning the sample ID, the instrument will light the LED at the position where the sample is expected according to the predefined run layout. Click on the same button again to turn off the guidance.

- **Lysis reagent tracking (On/Off)**:
  Click on the *Lysis reagent tracking* button to force the operator to enter the lot numbers of lysis reagents before a run can be started. Click on the same button again to disable lysis reagent tracking.

- **Silica reagent tracking (On/Off)**:
  Click on the *Silica reagent tracking* button to force the operator to enter the lot numbers of magnetic silica reagents before a run can be started. Click on the same button to appear again to disable silica reagent tracking.

- **Internal control reagent tracking (On/Off)**:
  Click on the *Internal control reagent tracking* button to force the operator to enter the lot numbers of internal control reagents before a run can be started. Click on the same button again to disable internal control reagent tracking.

Barcode Reader Communication Settings

Select the *Barcode Reader* icon from the *Overview* column on the left side of the screen to display the barcode reader details in the work area.

The following barcode reader communication settings can be defined:

- Scanner Port (active COM ports)
- Communication Speed
- Communication Parity
- Data bits
- Stop bits

For each of these settings the user can select a value from a selection box; values other than those presented in the selection boxes are not possible.

To reset the barcode reader to its factory settings, refer to “Barcode Reader Configuration” on page B-1.

Instrument Communication Settings

Select the *Instrument Communication* icon from the *Overview* column on the left side of the screen to display the instrument communication details in the work area.

Define the following instrument communication settings:

- Instrument Port:

  This value needs to be in the range between 1024 and 65535
- IP address for instrument communication:

  The required syntax for this value is xxx.xxx.xxx.xxx, where xxx needs to be in the range 0 – 255

NucliSENtral Communication Settings

Select the ***NucliSENtral*** *Communication* icon from the *Overview* column on the left side of the screen to display the ***NucliSENtral*** communication details in the work area.

Define the following ***NucliSENtral*** communication settings:

- Enable ***NucliSENtral***:

  Check to activate communication via ***NucliSENtral***.
- Application ID:

  Enter a unique identification of ***NucliSENS easyMAG*** to be able to participate in ***NucliSENtral*** data communication.

The Application Id entered here must be the same as entered in the Administrator software of ***NucliSENtral****.*

- Port:

  Enter the port of the ***NucliSENtral*** network. This value needs to be in the range between 1024 and 65535.
- Address:

  Enter the IP address of the ***NucliSENtral*** network.
  The required syntax for this value is xxx.xxx.xxx.xxx, where xxx needs to be in the range 0 – 255.

Sound Settings

Select the *Sounds* icon from the *Overview* column on the left side of the screen to display the sound notification details in the work area.

Select On or Off for the following types of sound:

- Alarm Sound

  Played when an alarm occurs.
- Protocol Finished Sound

  Played when an extraction protocol has successfully completed. Note that when it cannot successfully complete an alarm shall occur.
- Dialog Sound

  Played when a warning, error or confirmation dialog window is displayed.

Saving Application Settings

To save the changed settings, press the *Save* action button.

- The Workflow application settings will become active immediately after the changes have been saved. There is no need to restart the application.
- When the user taps the Save button the software will attempt to connect to the barcode reader using the given settings. The user will be informed as to whether or not this connection was made successfully.
- The Instrument Communication settings will become active on the next connection attempt. To activate the settings either disconnect and reconnect the instrument in the *Device Status* work area, or restart the application.
- The ***NucliSENtral*** settings can only be changed when NOT connected to ***NucliSENtral***.
- The Sound settings will become active immediately after the changes have been saved.

If settings in the 'Details' work area have been changed and not saved, a confirmation dialog box is displayed. The user has to confirm if the changed settings should be saved before accessing another program window.

Maintenance

The ***NucliSENS easyMAG*** system requires regular maintenance. Some maintenance activities must be performed by the instrument. For this purpose ‘maintenance protocols’ are available; refer to “Cleaning And Maintenance” on page 8-1 for further details.

Execute routine maintenance protocols from within the *Maintenance* work area. This work area shows a list of available maintenance protocols, and detailed information of the selected protocol. The detailed information contains a list of reagents that need to be installed on the instrument before the instrument can perform the selected protocol.

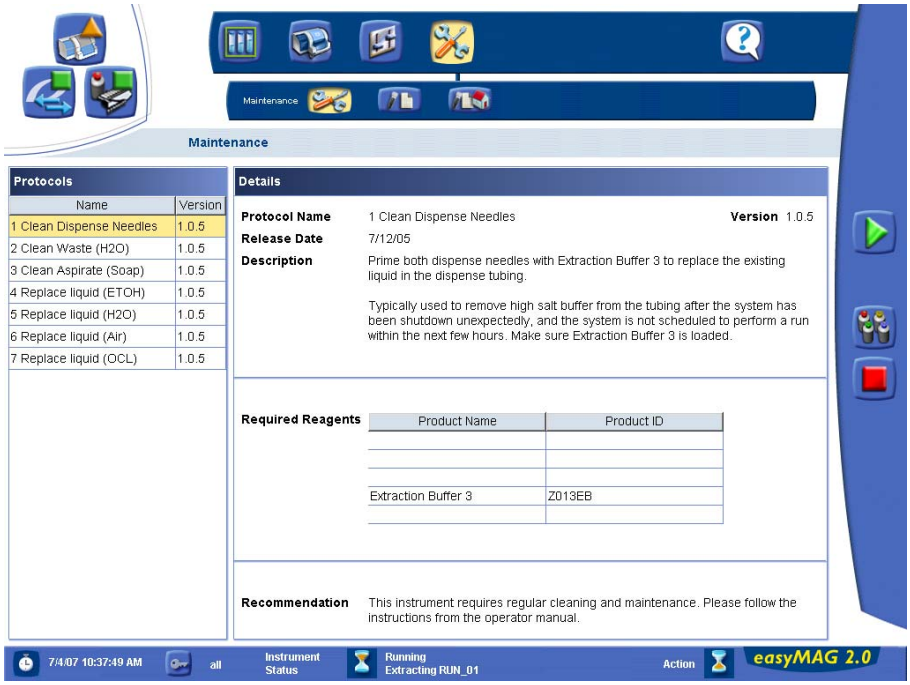


Figure 5-18: Maintenance work area

Installing Maintenance Reagents

Specific reagents must be installed before a maintenance protocol can be started.

▶ To install maintenance reagents

1. Select the required protocol in the protocol list. Detailed information of the protocol is shown in the detail window. When reagents are required for the selected protocol, they will be presented in the required reagents list.

2. Press the *Install Maintenance Reagents* button. The window will switch to the *Reagent Inventory* work area.
3. The *Reagent Inventory* work area will show what reagents need to be installed on which reagent positions. For further information on how to install the required reagents see “Step 2: Install On Board Reagents” on page 6-15 and “Cleaning And Maintenance” on page 8-1.
4. When reagents are installed as required, press the *Back* button in the *Reagent Inventory* work area.

Install Maintenance Disposables

Before a maintenance protocol can be started, three aspirator disposables and three empty sample strips must be installed.

Start Maintenance Protocol

When all preconditions are met to start the maintenance protocol, the *Start* button will activate the execution of the selected maintenance protocol. The status bar will display ‘running maintenance protocol xxxx’. When the maintenance protocol is finished, the status bar will indicate the instrument status as ‘idle’. When an error has occurred, the status bar will indicate the status as ‘error executing maintenance protocol xxxx’.

Stop Maintenance Protocol

When a maintenance protocol is running, it can be stopped by selecting the *Stop* button. The instrument will initiate stopping the protocol, and will indicate this by the status bar information ‘aborting ….’. When the protocol has stopped the status bar will display ‘idle’.

6 Operating Procedures

This chapter directs the user through the procedures that are required to operate the ***NucliSENS easyMAG*** system. The main procedure that the user will encounter is known as a *Routine Extraction*.

Preparing For Operation

Unpacking and re-packing, as well as installing and uninstalling the system should be performed by qualified bioMérieux personnel.

*Ensure that no other software applications are running before launching the **NucliSENS easyMAG** user software.*
*Running other software applications alongside the **NucliSENS easyMAG** user software may hamper performance of the **NucliSENS easyMAG** system.*
*It is allowed to run the **NucliSENtral** administrator application next to the **NucliSENS easyMAG** software.*

Starting Up The System

To start both the ***NucliSENS easyMAG*** instrument and software, proceed as follows:

1. Power up the computer and the touch screen.
2. Power up the instrument.The instrument LED turns orange to indicate that the instrument is initializing. Wait until the LED turns either green or red.
3. Login to the system by entering user name and password. Note that the password is case-sensitive.
4. The software will show the *Device Status* work area

The software may already be running while the instrument is powered down. This may happen for example when the instrument was not powered down under software control.

To start the system under this circumstance, proceed as follows:

1. Power up the instrument.The instrument LED turns orange to indicate that the instrument is initializing. Wait until the LED turns either green or red.
2. Login to the system by entering user name and password. Note that the password is case-sensitive.
3. The software will show the *Device Status* work area (see chapter 7).
4. To connect the computer and the instrument, tap the *Connect* button (See also chapter 7).

General Laboratory Procedures

Please consult the procedural precautions described in “Safety Precautions” on page 1-3.

Routine Extraction

Before samples can be processed, information needs to be entered to prepare an extraction or is received through ***NucliSENtral***. The *Daily Use* menu guides the user through the steps that need to be performed. It offers 5 sub-menus that represent, from left to right, the subsequent steps necessary to perform a run.

*Extraction requests which already have been received through **NucliSENtral** may disappear from the list due to processing ot this request on another **NucliSENS easyMAG**.*

Click *Daily Use* on the main menu bar to display the sub-menu items. The preparation is divided into three steps:

1. **Define Extraction Requests**…
2. **Organize Runs**…
3. **Loading the Run**…
   - (i) Install sample strips and aspirator disposables
   - (ii) Install on board reagents
   - (iii) Load samples
   - (iv) Add lysis (when necessary)
   - (v) Perform lysis Incubation (when necessary)
   - (vi) Add pre-mix

   or:

   - (vii) Add internal control
   - (viii) Add Magnetic Silica

The following sections describe the actions necessary to complete these steps.

Define Extraction Request

Requesting extractions for samples is the first task in the routine extraction workflow. This involves entering sample information into the system and ordering extractions for the samples. The user enters sample information in the *Define Extraction Requests* work area, either by manual entry (typing or scanning) or by using the *Auto-generate new extraction requests* function.

In this working area also the requests received from LIS via ***NucliSENtral*** are displayed.

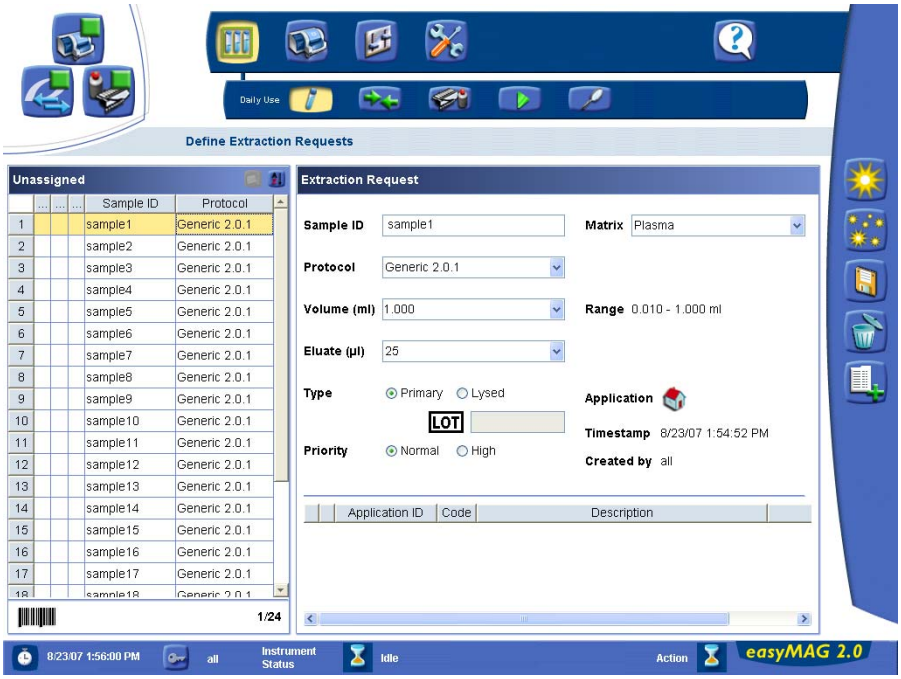


Figure 6-1: Define Extraction Request work area

1. Click the *Define Extraction Requests* button on the sub-menu bar. The *Define Extraction Requests* work area appears. The default settings are displayed.

*When a test request is received from **NucliSENtral**, the lysis buffer lot number may not be supplied. It is possible to indicate the lysis buffer lot number by editing each received request or by selecting several received test requests and adding a remark containing this lot number.*

*When a test request is received from **NucliSENtral**, the defaults have values which are configured in **NucliSENtral** software. When the defaults are not configured in **NucliSENtral** software, the defaults are filled by **NucliSENS easyMAG** like in case of locally created extraction requests.*

2. Modify the default settings for extraction *Protocol*, sample input *Volume*, *Eluate* volume, sample *Matrix*, *Type* and *Priority* as required.

*When a test request is received from **NucliSENtral**, some extraction request properties are read-only in order to provide the integrity of information across the **NucliSENtral** system.*

3. Enter the sample ID in the *Sample ID* field, either by keyboard or barcode reader. When entering the sample ID using the keyboard the input must be confirmed using the <Enter> key on the keyboard or by clicking on the *Save* button.

   Validity of information is checked. If the entered sample ID in combination with the selected (assay) protocol is already in the system, a warning dialog box will appear. The dialog box will prompt the user to confirm entry of a duplicate extraction request.

   When the entered extraction request information is invalid, the system will inform the user about the cause and allow adjustment of the information.

   The system generates an extraction request from valid information; the extraction request will appear in the unassigned extraction request list. The valid extraction request information is saved in the system's database. In the unassigned extraction request list the order of extraction requests is determined by the order of sample login if no sorting is applied.

Repeat the above procedure to login additional samples.

The following features exist to facilitate fast data entry:

When an extraction request is saved, the settings of that request are remembered. These settings will be used when a new extraction request is created. The 'Enter' key on the Sample ID field will save the current values and create a new extraction request (with the settings copied from the previously saved test request).
Scanning a barcode will first do a save of any previous edits and then create and save the scanned barcode using the remembered settings.

When the user enters a sample ID in combination with a(n) (assay) protocol that is already in the system, the program prompts for confirmation. If the user confirms to allow duplicate test requests, the duplicate will be created.

The following action buttons are available in this sub-menu.

Auto-Generate New Extraction Requests

Clicking the *Auto-generate new extraction requests* button allows the user to generate several new extraction requests at once, based on the settings in the *Extraction Request* area.

1. Use the *Auto-generate new extraction requests* function by clicking the corresponding button in the *Action* bar. The *Auto generate* dialog box opens.

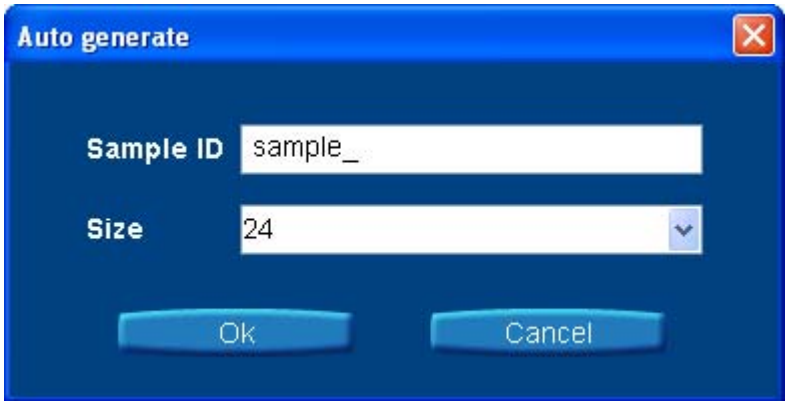


Figure 6-2: Define Extraction Request work area

2. Enter a prefix for the extraction request name in the *Sample ID* text field. The extraction request name will be extended by a unique number after auto-generation.
3. Select a predefined number of extraction requests to be auto-generated from the Size drop-down list. You can also enter a custom number by editing the text field directly.
4. Click *OK* to start auto-generation.

If auto-generated extraction requests have an identical sample ID (assay) protocol combination as existing requests in the system, the program prompts for confirmation, if duplicate test requests should be generated.

Enter New Extraction Request

Clicking the *Enter New Extraction Request* button allows the user to quickly enter a new extraction request. It clears the Sample ID field and fills the other fields with values from the last entered extraction request. If the user has modified but not yet saved the current extraction request when the *Enter new extraction request* button is pressed, the software saves the current request first.

Edit Extraction Requests

In the *Define Extraction Requests* work area the user can change extraction request information.
Follow the procedure below to edit previously submitted information.

1. Select the desired extraction request to be edited in the *Unassigned* extraction request list.
2. Alter the information in the detail extraction request panel.

3. Click the *Save* button. The validity of the altered information is checked and saved in the system's database when valid.

When test requests are received, some data of the test request information cannot be edited. Any editing will be logged with the test request.

Delete Extraction Requests

In the *Define Extraction Requests* work area, the user can delete one or more extraction requests.
Follow the procedure below to delete extraction requests.

1. From the extraction requests list, select the desired extraction requests to be deleted.

2. Click the *Delete* button. A dialog box appears prompting the user to confirm the deletion.

'Multi-select' is enabled here to facilitate the selection of multiple extraction requests.

3. Click *Yes* to confirm. The extraction requests are removed from the system's database.

Add Remark

In the *Define Extraction Requests* work area, the user can add a free-text remark to an extraction request. Remarks remain associated with the extraction request as long as it is in the system.
Follow the procedure below to add a remark.

1. From the extraction requests list, select the desired extraction request.

2. Click the *Add Remark* button. A dialog box appears in which the remark can be typed.
3. Click *Yes* to couple the remark to the extraction request. The remark will then be added to the remarks table.

Select The Relevant Protocol

For specific sample types, different choices in protocols for the ***NucliSENS easyMAG*** are available. Make sure that the correct protocol is selected for the sample type which is in the extraction request.

New protocols are available through your local bioMérieux representative.

For installation of a new protocol, see “Protocol Inventory” on page 5-22.

Organizing Runs

The second task in the routine extraction workflow is the organization of the run. First select the *Organize Runs* sub-menu item; the *Organize Runs* work area will then be displayed:

Figure 6-3: Organize Runs work area

The different steps involved in organizing the run are as follows:

1. Create or Select a run.
2. Select extraction requests in the unassigned extraction request panel or scan the sample ID barcode.
3. In case the extraction request is manually selected, move the selected extraction requests to the selected run.
4. Check the assigned positions of the extraction requests.
5. Add remarks to a run or selected samples in the run layout when applicable.

Creating A New Run

If no runs are ready to be processed, a new one needs to be created. Follow the procedure below to create a new run.

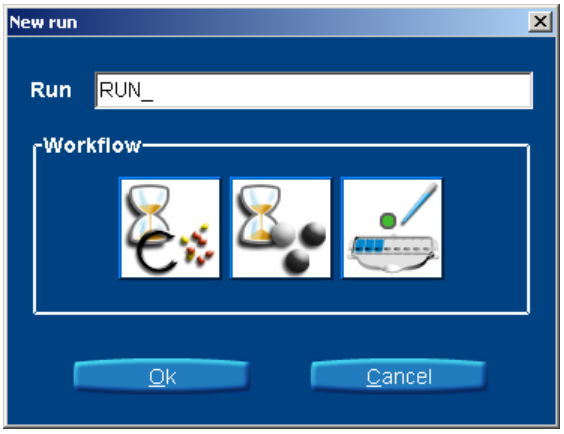


Figure 6-4: The New Run dialog

1. Click the *New Run* button. The *New Run* dialog box appears. The run name (prefix) is automatically generated by the system, as defined in Application Settings.
2. Complete or edit the generated run name as required.
3. Accept or change the default workflow settings for lysis incubation, silica incubation and sample guidance by clicking on the corresponding button in the *Workflow* area.
4. Click *OK*. The run is created and appears in the Run list.

When performing the silica incubation off-board, it is the responsibility of the lab technician to take the 10 minutes incubation into account. When incubation is less then 10 minutes this can influence the performance of the extraction output.

Silica incubation setting off-board is only available when the extraction protocol supports this.

Moving Extraction Requests To A Run

Follow the procedures below to move extraction requests to a run.

1. To quickly assign extraction requests to a run, click the *Auto fill run* button. All compatible extraction requests from the list will be moved to the run layout (maximum 24 extraction requests).

All extraction requests are moved to the run that are compatible with the first one selected in the list, starting with the next compatible extraction request in the list order.

Or:

1. From the Run list, select the run to which the extraction requests are to be moved. The selected run is shown in the selection box, and its run details (Protocol and Workflow) are displayed.
2. Select the extraction requests in the correct order.
3. 'Multi-Select' is enabled here to facilitate the selection of multiple extraction requests.

   Only compatible extraction requests can be assigned to the same run. The assay of the first extraction request in the selection or in the run sets the reference parameters. To be compatible the requests must refer by their assay to the same extraction protocol, i.e. requests which are primary and lysed can be assigned to one run.

4. Click the *Move to Run* button.

   The Run layout will display the sample positions to which the extraction requests are assigned. Extraction requests are automatically assigned to a sample strip position according to the order in which they are listed in the unassigned extraction request list.

Or:

1. From the Run list, select the run to which the extraction requests are to be moved. The selected run is shown in the selection box, and its run details (Protocol and Workflow) are displayed.
2. Scan the sample ID barcode, automatically related extraction request will be selected and moved to the run.

   The Run layout will display the sample positions to which the extraction requests are assigned. Extraction requests are automatically assigned to a sample strip position according to the order in which they are listed in the unassigned extraction request list.

It is possible to move requests to a run by scanning sample's barcode. When unassigned test request list contains one test request regarding scanned sample, this request will be highlighted and automatically moved to the run.The compatibility check is also performed.
When unassigned test request list contains more than one test request regarding scanned sample, these requests will be highlighted and a message will be given.
When unassigned test request list doesn't contain any compatible test requests regarding scanned sample, a message will be given.

Removing Extraction Requests From A Run

The user may need to remove extraction requests from a run.
Follow the procedure below to remove the extraction requests from a run.

1. From the Run list, select the run to be edited. The selected run is displayed.
2. Select the extraction requests to be removed from the run.
3. Click the *Remove from run* button.
4. The extraction request is removed from the run and moved to the unassigned extraction request list.

Editing A Run

Run information that can be modified includes the run's name and workflow options.

Follow the procedure below to edit a run.

1. From the Run list, select the run to be edited.

2. Click the *Edit Run* button. The *Edit Run* dialog appears. This is identical to the *New Run* dialog described above.
3. Modify the run name if desired. It is not possible to modify the run name into one that has already been used for another run.
4. Modify the workflow options if desired. Note that the workflow options are restricted to those options that are compatible with the extraction requests already in the run.
5. Press *OK* when finished. The software will now carry out the modifications. Should the user have attempted to make an illegal change, the software will display an error message.

Moving Extraction Requests Up / Down Within A Run

Extraction requests can be moved to another position in the run. This is useful if the user wishes to place certain extraction requests on the same sample strip.

Follow the procedure below to move extraction requests within a run

1. From the Run list, select the required extraction request. ‘Multi-select’ is available here.

2. To move the extraction request(s) upwards (in the direction of smaller position numbers) click the *Move Up* button.
3. To move the extraction request(s) downwards (increasing position numbers) press the *Move Down* button.

Deleting A Run

Follow the procedure below to delete a run.

1. From the Run list, select the run to be deleted. The selected run is displayed in the selection box.

2. Click the *Delete Run* button.
3. Click *Yes* to confirm the deletion of the selected run. Upon deleting the run, any extraction requests in the run are moved back to the unassigned extraction request list. The run is deleted.

If you need to delete an unprocessed run but it is not listed in the Run list in the ‘Organize Run’ work area, the run probably is already 'in process' as far as the software is concerned. First stop the run by selecting the run in the Run list in the ‘Load Run’ work area and press the Stop button. The run now should be listed in the Run list in the ‘View Results’ work area where it can be deleted.

Load A Run

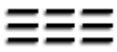
Before executing an extraction run the samples need to be prepared and loaded on the instrument. This task is handled in the *Load Run* work area.

Figure 6-5: Load Run work area

The *Load Run* work area's main window has four tabs, visible in the upper right-hand side corner.

Progress view - the user uses this view to determine what remains to be done before the run can be started.

Assign Kit reagents view - the user can assign different kit reagents to extraction requests if applicable.



Layout view - the three columns show the IDs of the samples that belong to the corresponding three sample strips.

Incidents view - any errors or warnings that occurred so far are listed here.

In addition to the buttons on the *Action* bar, there is a group of five small buttons in the barcode Input window in the lower left part of the *Load Run* work area. These buttons indicate whether a scanned barcode represents a sample strip, a sample, internal control, silica or diluent.

Scan-Look-Fill

The preferred way of loading a run is to first pipette the sample and then the pre-mix of internal control and silica on the instrument. The software and the instrument provide guidance by illuminating LEDs at those positions where the user needs to pipette the sample. The user scans a sample tube barcode, looks at the lit LED and fills the sample at the indicated position. Lysis buffer dispensing and incubation can be taken care of by the instrument.

In some circumstances, the user may want to carry out sampling, lysing and incubation away from the instrument, for example in a bio-safety cabinet. The software can produce a printed work list to support off board pipetting. The user can select their way of working on a per-run basis.

Tracking Reagents

The user may also decide to pipette the pre-mix of internal control and/or silica in a protective environment away from the instrument. Regardless of whether the user pipettes on or away from the instrument, the system can track such data as product and lot numbers. When the system is configured for Reagent Tracking the software shall require the user to identify the silica by scanning its barcodes and the internal control by entering its lot information.

Attention Indicators

Only after all required tasks have been completed a run can be started. This includes having inserted and identified new sample strips, having added all samples and silica, as well as having identified the on board reagents. Tasks that are completed show a green square, whereas tasks that require attention indicate this with an orange warning triangle or a red error circle. A run can only be started when there are no red circles left.

Step 1: Install Sample Strips And Aspirator Disposables

Follow the procedure below to install the sample strips and aspirator disposables on the instrument.

1. From the Run list, select the run for which the samples will be prepared and loaded. The selected run is displayed.
2. Open the instrument process door and install the required number of clean aspirator tips. The software will display the slot that the aspirator disposable has been loaded in.
3. Install the required number of sample strips in the strip slots. The software will display where the strip has been loaded.
4. Scan first the position barcode and then scan the sample strip barcode, in this order. The software displays the scanned strip ID and a green square to indicate that the strip has been properly identified at that position. Repeat this for all sample strips.

Step 2: Install On Board Reagents

Reagents need to be present in the ***NucliSENS easyMAG*** system before starting a run. When run(s) have been organized, the system indicates whether the required reagents are present or need to be loaded onto the system.

Whenever a new reagent bottle is installed, the user is asked to write the date of first opening on the bottle label. Reagents are designed for single use; they are to be left on the system until they are fully consumed.

Reagents have to be re-identified whenever the software has been shut down.

If the reagent batch has passed the expiry date, a warning message will be displayed when the bioMérieux barcode is entered or read.

Follow the procedure below to install the on board reagents.

1. Tap the *Reagent Inventory* button on the *Action* bar to navigate to the *Reagent Inventory* work area.
2. The *Reagent Inventory* work area will be displayed with the run and the protocol already selected. The software indicates which reagents are required for a particular run.

It is not necessary to have runs organized to be able to install reagents.

3. Place the reagent bottles at the indicated positions with the barcode labels pointed toward the user. The reagent bottles have color-coded caps that correspond with the colors on the reagent tube holders in the reagent bay and the colors shown on the *Load Reagents* screen of the software. Connect the tubing to the bottles.
4. For each bottle, scan the position barcode label first, followed by the barcode on the bottle label. The software will indicate the reagent volumes and further information extracted from the reagent barcode; e.g. reagent name, product ID, lot-number and expiry date.
5. Navigate back to the *Load Run* work area using the *Back* button.

Figure 6-6: Reagent Inventory work area

The bar to the left of each bottle indicates the volume of that particular bottle.

*The **NucliSENS easyMAG** reagents have an on board stability of 1 month. Do not remove the bottles at the end of a work shift; leave them in place to ensure the liquid system remains 'closed'. Disconnection can cause bacterial contamination.*

Emptying The Waste Container

Waste contains a mixture of biological and chemical components.
It is important that the waste container is emptied regularly with the appropriate degree of caution (see below).

To empty the waste container, always start by selecting the *Empty out waste container* action button from the *Reagent Inventory* work area. Tap the *Empty out waste container* button to initiate controlled waste disposal.

The *Waste Disposal* dialog box will then be displayed:

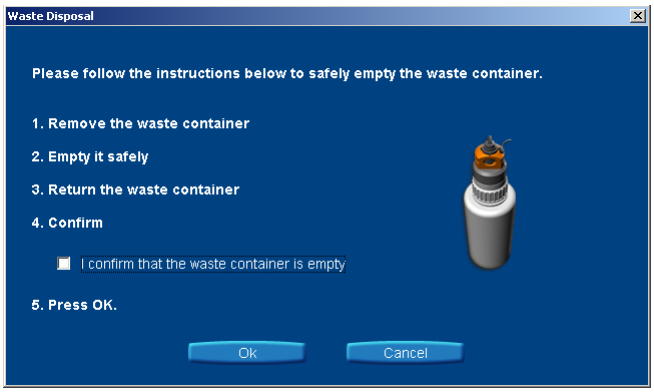


Figure 6-7: Waste Disposal dialog

To empty the waste container continue with the procedure below:

1. Disconnect the waste container from the instrument.
2. Safely remove the contents of the waste container (see “To empty the waste container” on page 4-18 for details on how to do this).
3. Replace and reconnect the empty waste container to the instrument.
4. Select the confirmation check box on the *Waste Disposal* dialog, to confirm that container is empty.

Select the confirmation check box only when the waste is indeed emptied.

5. Press the *OK* button. The *Waste Disposal* dialog will be removed and the system will record that the waste container is empty.

The waste container must always be emptied under software control. If the waste container is emptied without using software control the software will not be aware that the container has been emptied.

Waste

Dispose of chemical and biological waste in compliance with corresponding local laws and regulations. We recommend contacting either the authorities in charge, or approved waste disposal companies, who will advise on how to dispose of this type of waste.

Occupational Health And Safety

Cleaning and disinfecting agents and the corresponding waste should be handled with the care usual when dealing with chemicals, and in compliance with the installation site's occupational health and safety procedures. Avoid contact with skin and eyes. Wear suitable protective clothing, suitable eye/face protection and suitable gloves. Activities should be performed in a well-ventilated room. Wash hands and/or face before taking a break or leaving work.

Assign Kit Reagents

Every test request can have defined kit reagents assigned, like internal controls or silica.

If several kit reagents are introduced via barcode-scanning or manual entry, the user has to assign these reagents to the extraction requests.

Figure 6-8: The Assign Kit Reagents work area

▶ To assign kit reagents to extraction requests

1. Select the *Assign Kit reagents* tab in the *Load run* work area. In the top columns of the *Kit Reagents* all reagents that have been introduced to the run are listed. The run layout of *Assigned Kit Reagents* can show all samples of the selected run, or the added silica, the added internal control or the added diluent per sample.
2. From the Kit Reagents list, select the desired reagent to assign to one or more sample(s).
3. Select one or more sample(s) in the Assigned Kit Reagents list that you want the reagent to be assigned to.
4. Click the *Add* button to assign the kit reagent to the selected extraction requests.

▶ To remove assigned kit reagents from extraction requests

1. Select the *Assign Kit reagents* tab in the *Load run* work area.
2. Select the correct layout and one or more kit reagents assigned to extraction requests, which should be removed.
3. Click on the *Remove* button to remove the assigned reagents.

Print Work List

It is possible to use the work list printout to help position the samples correctly when sampling is performed away from the instrument.

▶ To print the work list

1. Navigate to the *Load Run* work area.
2. From the Run list select the run to be printed.
3. Click on the *Print* button in the *Action* bar. The *Print* dialog box appears.
4. Click the *OK* button. A work list for the selected run is printed.

Add Remark

In the *Load Run* work area, the user can add a free-text remark to a run. Remarks remain associated with the run and/or test request as long as it is in the system.

▶ **To add a remark**

1. From the Run list, select the desired run.
2. Click the *Add Remark* button. A dialog box appears in which the remark can be typed.
3. Click the *Yes* button to couple the remark to the run. The remark will then be added to the Incidents table.

Remarks can be added to a selected extraction request or to a run.

Step 3: Load Samples

Dispensing samples into the Sample strips can be done either off-board or on-board. When dispensing samples off-board the *print work list* printout can be used for guidance. When dispensing samples on-board the proper location of the sample can be determined by looking at the sample layout tab available in the *Load Run* work area. The system can also be configured for sampling guidance in the *Settings* work area.

▶ **To do this**

1. Make sure that sample tracking is activated in the configuration screen.
2. Make sure the sample button is pressed in the enter barcode section in the bottom left corner of the *Load Run* work area.
3. Scan or enter a sample tube identification. The software will highlight its ID and the corresponding LED will light up. When the sample ID does not belong to the run, the user will be asked whether to add the sample to the active run (if possible).
4. Repeat step 2 until all samples have been loaded.

Step 4: Add Lysis (when necessary)

When the run is configured for on board lysis dispensing follow the procedure below to add lysis buffer to the primary samples:

▶ **To add lysis buffer to the primary samples**

1. Install the lysis buffer according to the procedure “Step 2: Install On Board Reagents” on page 6-15.
2. Close the process door of the ***NucliSENS easyMAG*** instrument.
3. Select the *Dispense Lysis* action button and the addition of the lysis buffer will start for all installed strip positions that contain primary samples.

Step 5: Perform Lysis Incubation (when necessary)

In the case of lysis buffer addition performed by the instrument, the lysis incubation step starts automatically with the incubation time set by the extraction protocol.

Step 6: Add Internal Control

▶ To add an internal control

1. Press the *Internal Control input* button and enter the internal control lot number (by keyboard or barcode reader) present on the sachet label.
2. Pipette the internal control to the sample in the sample strip.
3. Assign the internal control lot number to the sample strip position.
4. The software shall indicate that it registered the internal control lot numbers by displaying them at the corresponding test request.

Step 7: Add Magnetic Silica

▶ To add magnetic silica

1. Press the *Magnetic Silica input* button and enter the silica lot number.
2. Pipette the Magnetic Silica to the sample in the sample strip.
3. Assign the magnetic silica lot number to the sample strip position.
4. The software shall indicate that it registered the magnetic silica lot numbers by displaying them at the corresponding test request.

Addition of an internal control and silica can be done simultaneously using the pre-mix option and an electronic multichannel pipette. See “Using The System” on page 3-4 for further details.

During Operation

Starting A Run

Reagent tracking can be enabled for internal control, silica and lysis buffer. When tracking is enabled but the reagent information is not entered, the software will log a warning incident to the run.

1. Select the run to be extracted.
   A selected run is displayed in the run selection box.
2. Click the *Start* button.
   The instrument starts processing the run.
3. The operator is reminded to add control/silica or premix.

Do not take out or replace any reagent bottles while the run is being executed. Before the run is being executed the software has already checked that the reagent bottle levels are sufficient to complete the run.

*Do not open the process door when the **NucliSENS easyMAG** is in operation. If the process door is raised, processing will pause. If this happens in the first 20 minutes of the run for longer than 20 seconds, the aspirator needles may clog. In the worst case extraction cannot continue. Close the door to continue processing.*

Execute A Run

After the run has been started in the *Load Run* work area, the system automatically moves on to the *Execute Run* work area *Progress* view. The user can monitor run progress here.

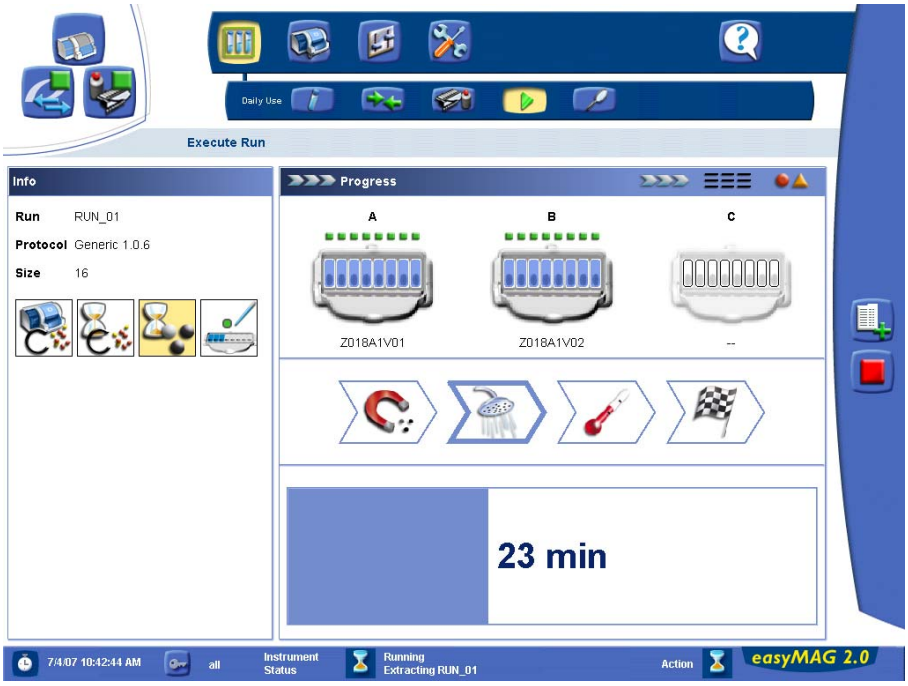


Figure 6-9: Execute Run Progress work area

The *Execute Run* work area's main window has three tabs, visible in the upper right-hand side corner.

Progress view - the user uses this view to monitor the progress of the run. Both the step that is currently being performed and the remaining time are displayed.

Layout view - the layout of the currently processed run is displayed here.

Incidents view - any errors or warnings that occurred so far are listed here.

Stopping A Run

Tap the *Stop* button to stop the execution of the run. The software will ask for confirmation before actually stopping the run. When a run is interrupted in this manner it will be marked as 'aborted'.

Add Remark

In the *Progress* work area, the user can add a free-text remark to the currently processed run. Remarks remain associated with the run as long as it is in the system.

▶ **To add a remark**

1. Click the *Add Remark* button. A dialog box appears in which the remark can be typed.
2. Click the *Yes* button to couple the remark to the run. The remark will then be added to the remarks table.

Remarks can be added to a selected extraction request or to a run.

Unloading Samples

When the run has finished, and the ***NucliSENS easyMAG*** is idle, the extracted samples should be unloaded within 30 minutes from the ***NucliSENS easyMAG***.

Wait until the instrument is idle before opening the hood and removing the sample strips.

Transfer the extracted nucleic acid from the strip into a fresh tube, using a multichannel or single channel pipette. Take care not to transfer any silica particles, since they might interfere with subsequent procedures.

Before transferring the eluates, make sure that the immobilized silica is visible in each of the wells used. If a well does not contain silica the extraction was not successful and the eluate can not be used for downstream applications.

Ensure that tubes are labeled appropriately to be able to correctly identify each sample.

Samples are now ready for further processing. If samples are not to be used immediately in subsequent procedures, they should be stored as soon as possible.

Nucleic Acid Extracts Storage

The user is responsible for validation of the storage procedures and conditions used in their laboratory. Eluates can typically be stored at room temperature (± 22 °C) for 2 hours, at 2 to 8 °C for 8 hours and 1 month at -20 °C to -70 °C. Storage of small quantities of nucleic acid extract (i.e. 5 µl) is not recommended.

It is the responsibility of the user to establish and validate suitable elute storage conditions for each laboratory procedure.

Consult individual instructions for use for further details when using these reagents in conjunction with other bioMérieux products.

View Run Progress

Select the *Execute Run progress* view to get an overview of the status of the sample strips and their related positions. When a sample is present, its position in the strip is colored blue.

View Run Layout

The run layout can be displayed in the *Layout* work area. Information is shown about the order of samples on the corresponding strips and carriers and also more sample-related details can be shown by selecting individual samples. (Note that the *Load Run* work area also has a *Layout* view.)

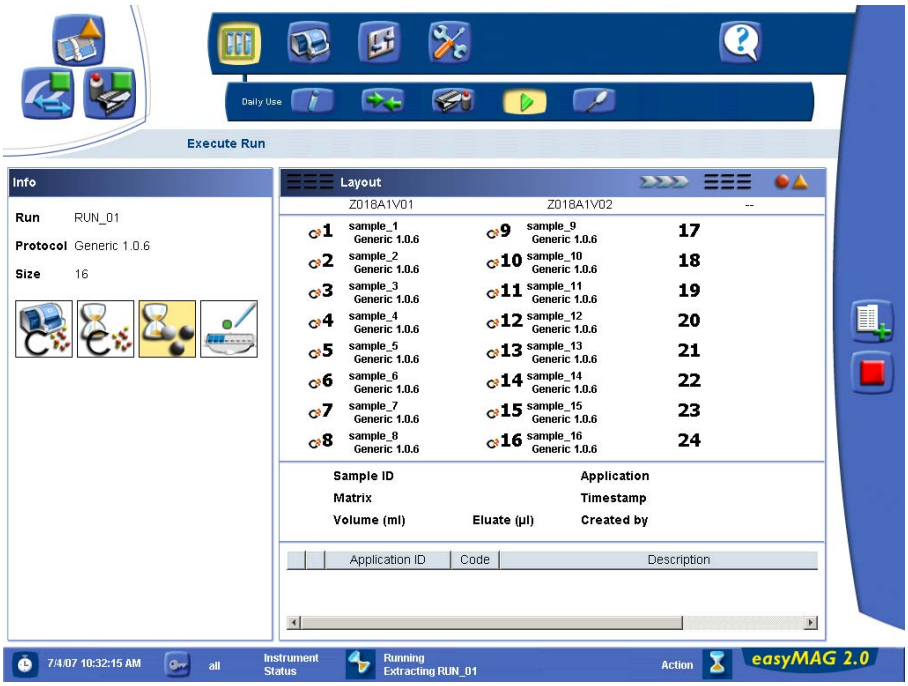


Figure 6-10: Execute Run Layout work area

▶ To view the run layout of the current run

1. Select the *Execute Run Layout* view to get an overview of the status of the sample strips and the samples they contain.
2. Click on an individual sample to display sample and system related information right below the *Layout* view:
   Sample ID, Volume, Eluate, Matrix, Application, User, Timestamp
   If a remark or an incident is related to the selected sample, it is displayed in a table below the sample details.

View Incidents

The software issues errors and warnings when, during the extraction, a situation occurs that should be brought to the attention of the user. All such incidents are recorded in the *Incidents* view of the *Execute Run* work area, along with any remarks. (Note that the *Load Run* work area and *View Results* work area also have *Incidents* views.)

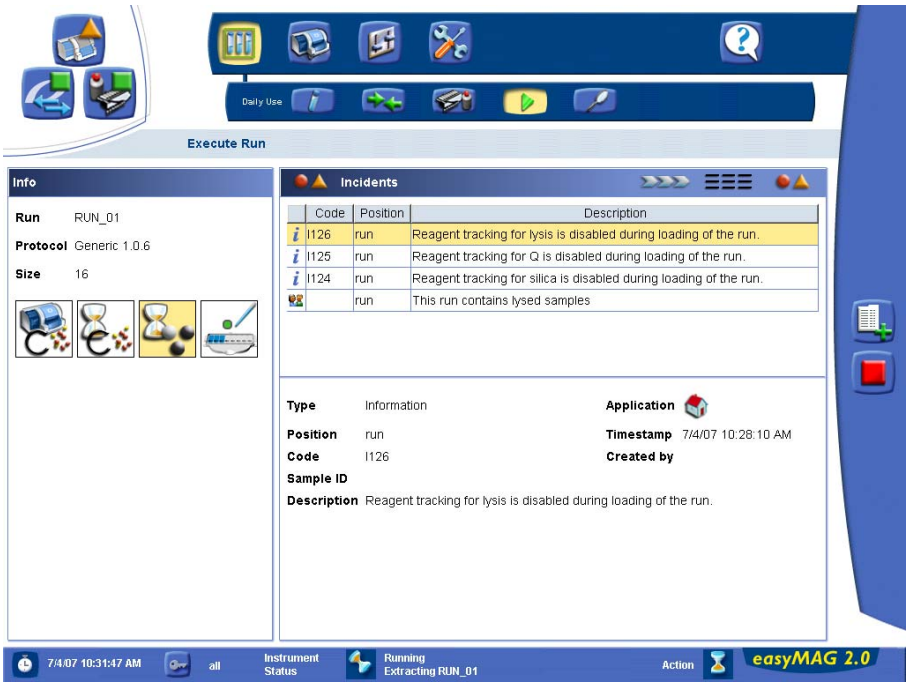


Figure 6-11: Execute Run Incidents work area

▶ To view incidents that occur during the extraction process

1. Select the *Execute Run Incidents* view to get the overview of all incidents and remarks in chronological order for that run.
2. The software displays a short description of the incident or remark, along with the position in the sample strip to which the incident or remark applies. When the incident is related to the entire sample strip, the software displays the appropriate sample strip A, B or C in the position field.

The incident can have three severity states: error, warning, information. The severity states are indicated by an icon.


Error - Something occurred that led to failure of the extraction process for either a single sample strip position, for a complete sample strip or even for an entire run.


Warning - Additional information regarding a run or sample is given.


Remark - A remark created by the user.


Informational - Some information regarding a run that is neither an error nor a warning.

3. Select an incident in the table to view details that can help interpret and resolve the incident.

Run Status

The following set of rules is applied to determine whether individual extraction requests or even the entire run shall be set to failed. Note that only errors can actually lead to failure, not warnings:

- When an error has occurred for one of the eight vessels in a sample strip, the extraction request assigned to that vessel will be set to failed.
- When an error has occurred for all vessels of all sample strips to which an extraction request is assigned, further processing is not worthwhile. The entire run shall therefore be set to failed.
- When an error has occurred for a complete sample strip, all extraction requests assigned to that sample strip are set to failed.
- When an error has occurred that pertains to the entire run, the run shall be stopped. The run and all of its extraction requests shall be set to failed.


The software issues an error when the elution temperature is out of range. When no error is present on the reports it is implicit that the elution temperature has been in the defined range all of the time, implicitly validating the elution temperature.

View Extraction Results

A run is finished when the extraction was performed successfully, when the run was failed by the system, or when the run was aborted by the user. The results of all finished runs can be inspected in the *View Results* work area. Run results can be assessed, printed, exported, deleted and transferred to the ***NucliSENtral*** network. Remarks can be entered and repeat extractions initiated.

*The extraction results related to **NucliSENtral** enabled assays are automatically sent to **NucliSENtral** after assessment.*

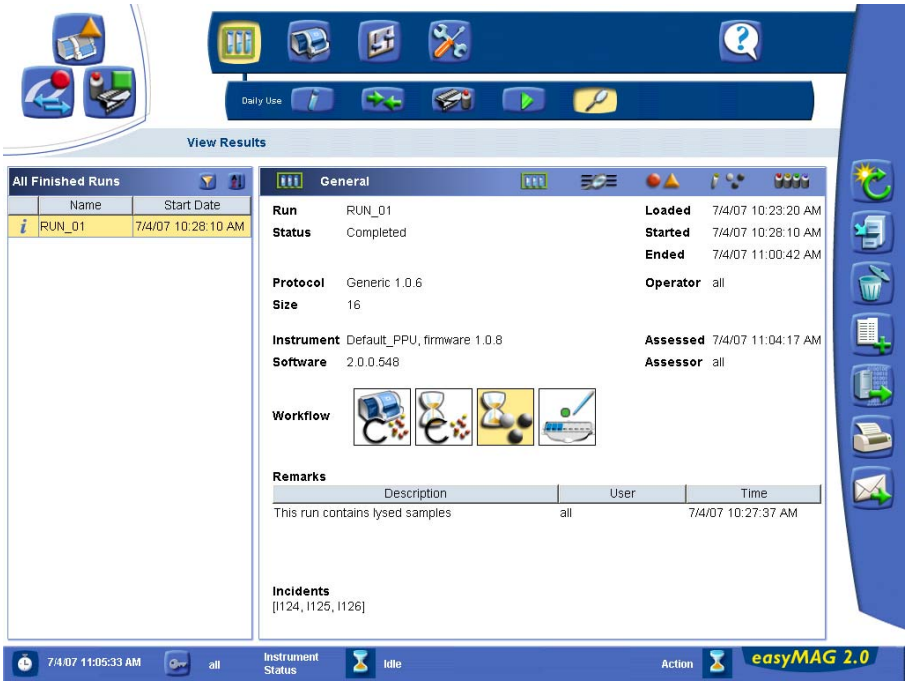


Figure 6-12: View Results work area

The *View Results* work area's main window has five tabs, visible in the upper right-hand side corner.

Run view - the user uses this view to determine whether or not the run has completed successfully. This view also displays when the run was performed, by whom and on what instrument.

Result layout view - the user uses this view to view the results for individual extraction requests.

Incidents view - any incidents or remarks present are listed here.

Assigned Kit Reagents view - If kit reagents have been assigned to samples in the *Load Run* work area, these off-board reagents are displayed here.

On-board Reagents view - lists the product and lot numbers of the on-board reagents that were used in the run.

Assessing A Run

Assessing a run is a means of indicating that the run is fully finished and can be ‘archived’. Assessing a run does not delete it from the system but does remove it from the active (‘unassessed’) list.

After a run has finished executing, the execution status can be one of the following:

- **Completed** - the entire protocol was executed. Typically, all extraction requests were processed without problems. However, individual extraction requests may have warnings or errors. The run as a whole may have warnings but no errors.
- **Failed** - the protocol may not have finished execution all the way to the end. An error has occurred for the run itself, an error has occurred for every sample strip, or errors have occurred for every extraction request. Further processing was not worthwhile and the run was stopped by the system.
- **Aborted** - the user stopped the run.

▶ To view the run related information

1. In the runs list tap the filter button to view unassessed runs or all runs.
2. Select a run to view. The most recently started run is shown at the top of the run list. The run related information will be shown in the five dedicated tab windows:
   - General tab: displays run name, protocol, date and execution status
   - Results tab: displays extraction requests assigned to this run
   - Incidents tab: displays run and sample strip related errors, warnings and remarks
   - Reagents tab: displays all run related on board reagents information. For software version 1.0 (if entered) the internal control lot information is displayed here.
   - Kit Inventory tab: Displays the entered off board reagent information (silica, control, lysis and diluent).

3. Select the *Mark this run Assessed* action button to mark the run as assessed. The run will no longer be displayed when the filter is set to unassessed runs.

*When the run is assessed, all results related to the **NucliSENtral** enabled assay protocols are automatically sent through **NucliSENtral**.*

Printing Run Information

▶ **To print the run related information**

1. Select the filter option to view all unassessed runs or all runs.
2. Select a run to be printed.
3. Select the *Print* action button. Press *OK* to print the run.

When a run is printed the operator is asked to mark the run assessed.

Exporting Run Information

Run information can be stored as a PDF file or in tab-delimited format. Invalid runs cannot be exported to tab-delimited format.

▶ **To export the run related information**

1. Select a run to be exported.
2. Select the *Export* action button. The *Export to* dialog will appear.
3. Select the file type, i.e. PDF format or tab-delimited.
4. Select the destination where the file shall be stored and select the *OK* button. The file will be stored in the selected format at the selected destination.

When a run is exported the operator is asked to mark the run assessed.

Issuing A Repeat Extraction

When a sample needs to be retested a repeat extraction can be initiated. An identical extraction request will be automatically generated and can be assigned to be processed.

▶ **To initiate a repeat extraction**

Only for samples in unassessed runs a repeat extraction can be initiated.

1. Select the *Results* tab in the *View Results* work area. The extraction request related information is shown.
2. Select the extraction requests for which a repeat extraction shall be initiated.

'Multi-select' is enabled here to facilitate the selection of multiple extraction requests.

3. Select the *Repeat extraction* action button. A message will ask for confirmation before the extraction requests are created.
4. Confirm the message. Duplicate extraction requests will be created for all selected extraction requests. The created duplicate extraction requests will appear in the unassigned extraction request list, recognizable by the repeat extraction request icon.

When duplicate requests are present in the unassigned request list, the software will indicate in a confirmation message that for sample with <sample id> already a request is present.

*Repeat extractions are also sent via **NucliSENtral** to other **NucliSENS easyMAG** systems.*

Add Remark

Additional text information can be added to a run.

▶ **To add additional information to a run**

1. Select the filter option to view all unassessed run or all runs.
2. Select the runs to which the additional information shall be added.
3. Select the *Add remark* action button. A dialog will appear in which run or extraction request related remarks can be posted.
4. Select the run check box and enter the information text and select the *OK* button. Additional information will be stored to all selected run requests.

Remarks can be added to a selected extraction request or to a run.

Deleting Runs

Runs may be deleted when they are no longer required. Once deleted it is not possible to recover a run. All extraction results associated with that run will be deleted.

A record of a run can be made by printing or exporting it to a pdf file before deleting.

▶ **To delete run information**

1. Select the filter option to view all unassessed runs or all runs.
2. Select the runs for which the information should be deleted.
3. Select the *Delete Run* action button. A confirmation dialog will appear asking whether to proceed with the delete action.
4. Click *Confirm* and the selected run will be removed.

Send Run Results Manually

Assessed Run results with assay protocols assigned to at least one sample can be resent to the ***NucliSENtral*** network.

▶ **To resend results**

1. Select the filter option to view all runs.
2. Select the run(s) with at least one sample having an assay protocol assigned, which results should be resend to the ***NucliSENtral*** network.
3. Click the *Send* button to send the results to the ***NucliSENtral*** network. A dialog box opens.
4. Click *Yes* to confirm sending of the run results.

*If the results are not sent through **NucliSENtral** automatically, the user can send these results manually. There is a visual indication (an icon next to each sample) whether the results have been sent or not.*

Shutting Down The System

After each working day the system (instrument + computer) must be shutdown. The system is always flushed before and after one run - no flushing is necessary. Shutdown the software first, include the instrument. Then shutdown the computer and switch off the instrument, by using the Switch Off button on the instrument.

7 Device Status

The *Device Status* work area presents a graphical overview of the ***NucliSENS easyMAG*** system and the status of each of the system modules. By means of the alarm icons, the occurrence of system related incidents will be brought to the attention of the user. There are two ways to navigate to the *Device Status* work area: via the alarm icons in the event that an incident has occurred or via the sub-menu item *Device Status*.

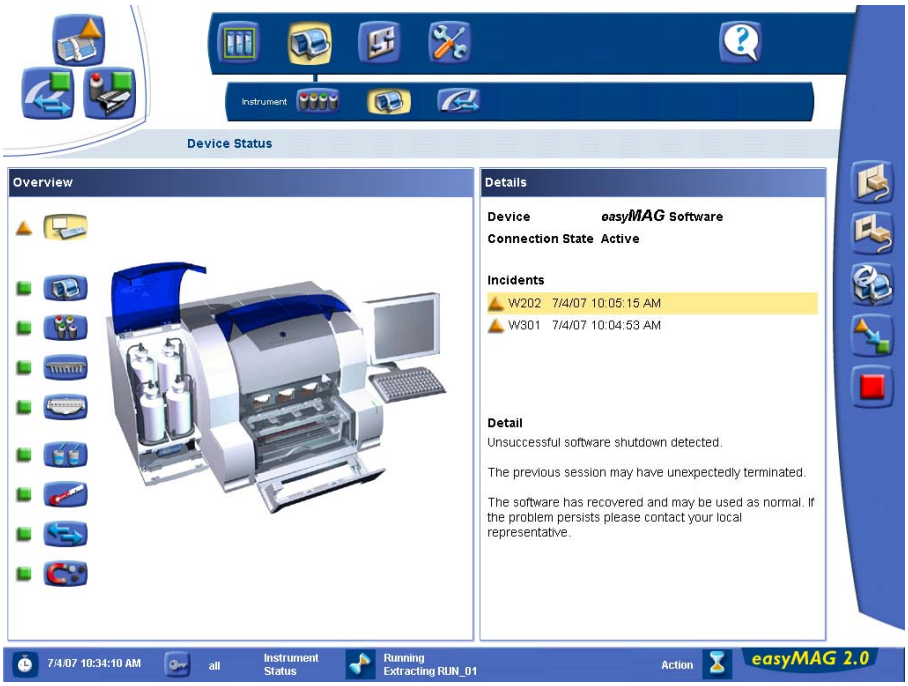


Figure 7-1: Device Status work area

The *Device Status* work area displays details of the following devices, each of which is accessed by its own button:


Software


Instrument


Reagent Bay


Aspirator


Sample


Dispenser


Heater


Mixer


Magnetic Silica Capture

For each of the devices, a device button is available on the left side of the work area. In front of the device buttons an alarm icon is shown:

- **Green square**: No incidents for this device
- **Orange triangle**: Warnings occurred for this device
- **Red circle**: Errors occurred for this device

When the user selects a device button, the part of the instrument image that represents the selected device will be highlighted and the application software shall display the corresponding detailed device status information:

Device name, status, and possible incidents.

When an incident is selected, more detailed information on this incident will be shown.

Connect / Disconnect Instrument

When the connection to the instrument is not active and the instrument device button is selected, the detail panel for the instrument shall display state ‘Disconnected’.

To activate the connection, press the *Connect instrument* action button.

To be able to connect to the instrument, the instrument has to be powered on, the power indicator must be green, a physical connection must be available, and instrument connection settings must be valid. See “Application Settings Work Area – Instrument Communication” on page D-35.

When the instrument state displays ‘Connected’, pressing the *Disconnect instrument* action button will disconnect the instrument.

Initialize Instrument

When the instrument has the status ‘Error’, initializing the instrument may solve the problem.To clear warnings, the instrument does not require an initialization cycle. Please use the *Clear Incidents* button to get rid of warnings (see below).

To initialize the instrument press the *Initialize Instrument* action button. The software checks that an initialization is allowed and asks for confirmation. Completing an initialization cycle may take some time. The *Status* bar reads ‘Idle’ to indicate that initialization has completed successfully.

Initializing the instrument also resets the instrument alarm if it was set.

When the barcode reader is attached but not working, initialization of the instrument will not help. The barcode reader must be attached before the application is started. An application restart is required only when the reader is attached after the application has been started. The barcode reader settings should then be properly configured in the ‘Application Settings’ work area. Once the barcode reader is working, the related warning can be cleared using the Clear Incidents button.

Clear Incidents

When the instrument has observed a warning (alarm control of the device shows an orange triangle), the warning usually can be fixed by the user without having to reinitialize the instrument.

Errors can not be cleared with the *Clear incidents* button. To clear errors, please use the *Initialize instrument* button

To clear the incidents, select a device, then select the clear incident button.

When the device is in an error state (alarm control of the device shows a red circle), the clear incidents action cannot be used to clear the error.

When the incidents have been cleared and no other errors have occurred, the alarm control of the selected device will show a green square (device is OK).

If no other devices are in the warning or error state the instrument alarm will be reset.

Stop Instrument

If required the user can stop the instrument by pressing the *Stop Instrument* button.

When the instrument is dispensing lysis buffer, performing an extraction run or a maintenance run, it cannot be stopped with this button. Should the user desire to stop the instrument this can be done in the *Load Run*, *Execute Run* or *Maintenance* work areas, respectively.

When the instrument is disconnected, the *Stop Instrument* action cannot be performed.

Connect/Disconnect *NucliSENtral*

The ***NucliSENtral*** *Status* work area presents an illustration of a typical ***NucliSENtral*** configuration and provides the ***NucliSENtral*** connection status as well as an overview of ***NucliSENtral*** alarms. By means of the alarm icons, the occurrence of system related incidents will be brought to the attention of the user. There are two ways to navigate to the ***NucliSENtral*** *Status* work area: via the alarm icons in the event that an incident has occurred or via the sub-menu item ***NucliSENtral*** *Status*.

Figure 7-2: ***NucliSENtral*** *Status work area*

The application software displays detailed ***NucliSENtral*** status information in the *Details* area.

When an incident is selected, more detailed information on this incident will be shown.

Normally connection to and disconnection from ***NucliSENtral*** *is performed automatically during startup and shutdown.*

Connect / Disconnect *NucliSENtral*

When the connection to the ***NucliSENtral*** is not active and the *Connection Alarm* button is selected, the detail panel for the ***NucliSENtral*** status shall display state ‘Disconnected’.

To activate the connection, press the *Connect* ***NucliSENtral*** action button.

To be able to connect to the ***NucliSENtral*** network, the ***NucliSENtral*** network settings have to be entered in the *Application Settings* work area under ***NucliSENtral*** communication.

When the Connection state displays ‘Connected’, pressing the *Disconnect* ***NucliSENtral*** action button will disconnect the ***NucliSENtral*** connection.

Clear Alarms

When the software has observed an ***NucliSENtral*** status warning, the warning usually can be fixed by the user without having to reinitialize the instrument.

NucliSENtral status Errors can also be cleared with the *Clear alarms* button.

To clear the incidents, select an incident, then select the *Clear alarms* button.

When the incidents have been cleared and no other errors have occurred, the alarm control of the Connection alarm icon will show a green square (device is OK).

8 Cleaning And Maintenance

Before undertaking electrical safety or other compliance testing on the instrument, contact bioMérieux.

Treat all equipment, samples, blood-based internal controls and quality control (QC) products assayed on this system, as well as all waste in the waste containers, as potentially biohazardous material. Handle all materials and mechanical components according to the installation site's biohazard procedure. Use the personal protective equipment recommended by the installation site when handling any of these components, including gloves, safety goggles, and protective laboratory wear.

It is possible to pierce through protective gloves. Therefore use extra caution when working in the sampling and reagent areas.

Do not use cleaning or decontamination agents that will react with parts of the equipment or materials.
Consult bioMérieux if there is any doubt about compatibility with decontamination or cleaning agents and parts of the equipment or material contained in it.
Ensure that acidic substances are not used around the equipment.

Before performing any maintenance or cleaning tasks, with the exception of the automatic maintenance protocols, make sure to switch of the Instrument, Computer and Touch screen to avoid damaging the system or harm the user.

The separation magnets are protected against corrosion by a coating of silicon oil. After cleaning the magnets, it is imperative that a new coating of silicon oil is applied. The silicon oil is supplied as part of the instrument spare parts kit, and is also available as a commercial product.

Introduction

The ***NucliSENS easyMAG*** system is designed to limit the required amount of maintenance by the user. Liquid Level Sensing and extraction protocols that include fluidic system rinse procedures, ensure that the system is kept clean automatically. Routine maintenance is limited to keeping the work areas clean on a weekly basis. The user is also responsible for the inspection (and replacement if required) of some filters.

The maintenance strategy for the ***NucliSENS easyMAG*** system includes a number of on board maintenance protocols that were designed to assist the user in cleaning the system for the purpose of Service, Transport or Template Decontamination.

For the convenience of the user the maintenance strategy and the related maintenance protocols are summarized in “Maintenance and decontamination flow chart” on page 8-18.

Repeat failure to perform the required maintenance procedures might reduce the performance of the system resulting in, for instance, fluid spills, longer extraction times and decreased extraction efficiency. Also note that special considerations should be given to maintaining a clean work area and ensuring that all equipment is left clean and not used in other areas of the laboratory.

Schedule

Item	Frequency	Page
Cleaning Inspection	Daily	8-6
Routine Maintenance	Weekly	8-6
Clean aspirator nozzle O-rings	As Required	8-8
Carbon filter	Inspect weekly	8-15
Reagent bottle filter	Inspect weekly	8-16
Waste bottle filter	Inspect weekly	8-16
NucliSENS easyMAG service	Every six months	8-9
Decontamination procedures	As required	8-10

The following solutions are used in the maintenance procedures:

- Pyrogen-free sterile water
- 70% ethanol, REF: 284048
- Cleaning solution (5% detergent solution; e.g. Decon 90 (Decon Laboratories Limited) or Extran®)
- 0.1% sodium hypochlorite

Spills

Lysis Buffer Spill

Do not allow the lysis buffer or waste from the instrument to contact acidic materials. Lysis buffer can potentially release cyanide gas on contact with acid. The quantities that may be released depend on the volume of both the buffer and the acidic material in contact. Refer to the MSDS for the lysis buffer for further information.

Avoid contact with skin, eyes and clothing.

If lysis buffer is spilled, isolate spill area. Do not allow lysis buffer to enter drains or watercourses. Absorb using absorbent material (for example, tissue), and clean affected area with copious amounts of water.

Other Spills

Crystallized drops

The potential for exposure of the respiratory tract may occur in case of cleaning crystallized lysis buffer; extraction buffer 1; Guanidine thiocyanate containing waste drops, and dusts may be generated.

Avoid generation of dusts.
Harmful by inhalation.
Do not breathe dust.
Avoid contact with skin, eyes and clothing.
Wear protective gloves (nitrile rubber), a lab coat, safety glasses or goggles.

Wipe up GuSCN drops immediately. Remove crystallized drops carefully with distilled water and clean the area with a fiber free towel containing a 5% Extran solution. After cleaning with the 5% Extran solution, clean the affected area with 70% Ethanol. Then wipe the area clean using a fiber-free towel containing a small amount of silicon oil. This to prevent any GuSCN crystals to re-occur.

Crystallized spills

The potential for exposure of the respiratory tract may occur in case of cleaning crystallized lysis buffer; extraction buffer 1; Guanidine thiocyanate containing waste spills, and dusts may be generated.

Avoid generation of dusts.
Harmful by inhalation.
Do not breathe dust.
Avoid contact with skin, eyes and clothing.
Wear protective gloves (nitrile rubber), a lab coat, safety glasses or goggles.
Respiratory protection required when dusts are generated (Filter FFP2, according to EN149).

Remove crystallized spills carefully. Spray the area carefully with water and absorb using absorbent material (for example fiber free tissue), clean the affected area with copious amounts of water. Then clean the area with a fiber free towel containing a 5% Extran solution. Then clean the area with the 5% Extran solution, and clean the affected area with 70% Ethanol. Finally wipe the area clean using a fiber-free towel containing a small amount of silicon oil. This to prevent any GuSCN crystals to re-occur.

Routine Maintenance

Daily Cleaning

The ***NucliSENS easyMAG*** should be cleaned and inspected after each day of use as follows:

- Empty and dispose the contents of the waste bottle into the chemical waste system according to the local waste procedure, the waste contains guanidine thiocyanate. Rinse the waste bottle with water after emptying.
- Wipe up any spillage according to the procedure described above.

Weekly Maintenance And Inspection

Performing these routine cleaning tasks is recommended at least once per week or when required.

Surfaces

Clean the instrument with a cleaning solution (5% solution of a detergent like Decon 90 or Extran). Wipe the area with paper towels and then clean the area with 70% ethanol. Wipe dry using fiber-free paper toweling.

Ensure that the following areas are properly decontaminated:

- External covers
- Internal work surfaces (reagent bay, drip tray, drawer, sample strip loading bay)
- Dispense probe and dispense probe clean station (when required)
- Clean reagent caps and reagent bottle connector fittings with tissues wetted with water. Avoid wetting the reagent cap vent filters.

Clean the sample strip carriage when required using a cloth and cleaning solution or water. Wipe the carriage dry using fiber-free paper toweling.

Clean the magnet arrays only when required. Switch off the instrument, open the sample strip loading bay by loosening the two screws at the front and push the sample strip carriage, gently, all the way to the back.
Use a cloth or cotton tips moistened with de-ionized water to clean the array taking care not to damage the magnet arrays or the neighboring dispense needle station. Use the drip tray to collect the water. Apply a coat of silicone oil on the magnet arrays afterwards which will help to protect them. Do not apply silicone oil to other parts of the system. Remember to also clean the drip tray.

Inspect Filters

- Inspect the reagent cap vent filters, they should be dry and free of crystals. Replace the filters as required. An indication for a blocked filter is the fact that the bottle builds up a slight under-pressure.

▶ **The reagent cap vent filters should be replaced as follows**

1. On the top of each reagent bottle cap is a small white filter that filters air that enters the reagent bottle as the liquid is consumed.
2. To remove the filter, insert a pair of pliers into the top of the filter and pull it out of the mounting hole.
3. To install a filter, gently push the new filter into the mounting hole. The filter will seal along the wall of the mounting hole.

- Inspect the carbon filter in the front, underneath the reagent bay. The filter should be free of visible condensation. Replace the filter when required.
- Inspect the waste bottle filter whenever emptying the bottle. It should be dry and free of crystals. An indication for a blocked filter is the fact that the bottle builds up a slight over-pressure

Keyboard

The keypads can be cleaned by wiping with toweling soaked with cleaning solution and then with 70% ethanol.

Touchscreen

Gently wipe the monitor with a tissue or soft towel moistened with a mild cleaning solution or commercially available LCD screen cleaning solution. Use very light pressure on the display window and never allow liquid to pool on the display. Repeat this step with ethanol 70% and then wipe clean with a dry tissue or soft towel.

Sample Vessel Carrier

The sample vessel carrier can be cleaned by wiping with toweling soaked with cleaning solution and then with 70% ethanol, or immersed in cleaning solution and then 70% ethanol.

Barcode Reader

The window of the reader is sensitive. While cleaning the reader observe the following precautions:

- Do not allow any abrasive material to touch the window
- Do not spray water or other cleaning liquids directly into the window
- Do not remove the reader's rubber nose.

▶ To clean the barcode reader

1. Disconnect the barcode reader.
2. Remove dirt particles with a damp, lint-free cloth.
3. Wipe the window using a tissue moistened with distilled water.

Aspirator Disposable O-rings

When required (salt build-up), the O-rings of the aspirator nozzle should be cleaned, using a cotton-tip dipped in pyrogen-free sterile water. Use clean materials for each nozzle.

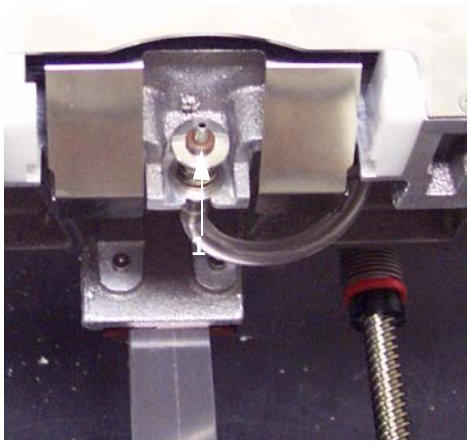


Figure 8-1: Aspirating nozzle assembly (viewed from underneath), showing O-ring (1)

Clean Dispense Needle

If the user feels the need to clean the dispense needles and tubings, they can manually clean the outside of the needles and/or execute the ‘Clean Dispense needles’ maintenance protocol.

To manually clean the dispense needles use a soft cloth or a cotton tip moistened with pyrogen-free sterile water. Make sure to use a clean cloth or cotton tip for each needle. Wipe the needles clean from top to bottom taking care not to put physical stress on the needles. The top of the needle wash station can be cleaned using the same type of cleaning materials.

Take care not to damage the dispense needles and bot to get liquid on the Liquid Level Sensing system located in the vicinity of the needle wash station.

To clean the tubing execute the ‘Clean Dispense needles’ maintenance protocol that performs a rinse of both the macro and micro dispense circuit using ***NucliSENS easyMAG*** extraction buffer 3.

To execute the protocol, navigate to the *Maintenance* work area and select the ‘Clean Dispense needles’ maintenance protocol. Follow the instructions on the screen and press the start button when ready.

Every Six Months

Performed during preventive maintenance by a bioMérieux representative.

- Replace the exhaust air filter of the vacuum pump.
- Replace the vent filter on the waste bottle.

Decontamination Procedures

Overview

Due to environmental contamination in the laboratory invisible or unexpected hazards from biological and chemical materials may exist in the ***NucliSENS easyMAG*** and its replaceable assemblies and components. Disinfection is done to protect users, field service personnel, factory repair personnel, and any others who may come in contact with the ***NucliSENS easyMAG*** or its replaceable assemblies and components.

Disclaimer:
The cleaning and decontamination procedures described here have been designed with care. However, bioMérieux can accept no responsibility for the status of the instrument after cleaning and decontamination activities have been carried out.

It is always the responsibility of the user to clean and decontaminate the instrument. The instrument must always be thoroughly cleaned and decontaminated before any service activities by a bioMérieux representative.

The system offers a number of maintenance protocols that perform many of the decontamination procedures semi-automatically. Executing maintenance protocols involves loading the system with reagent bottles containing water, cleaning solution, ethanol, air or hypochlorite. Keep the first sets of empty reagent bottles aside for this purpose.

The maintenance protocols make use of reagents exactly like the normal extraction protocols do. This means the reagents need to be identified with their unique barcode. An example of the maintenance protocol reagents barcodes can be found at the end of this chapter.

Always use caution when handling or discarding biological and hazardous waste material. See SAFETY INFORMATION at the beginning of this manual.

Preparing The System For Service

Whenever the system needs to be serviced it must be cleaned properly first to protect the service engineer. Cleaning the system for service involves some manual cleaning actions and executing 4 maintenance protocols.

These protocols were designed to first remove all traces of the reagents from the system and than clean the system with Cleaning solution and Ethanol followed by a rinse with Water. Perform the maintenance protocols by navigating to the *Maintenance* work area and selecting the proper maintenance protocol.Make sure to follow the flowchart as shown in Figure 8-5. For each protocol follow the instructions on the screen and press the start button when ready.

▶ Clean instrument

Figure 8-5 shows that the first step in the Service clean process is cleaning the instrument according to the Weekly maintenance - Surfaces procedure, described above followed by 4 automated maintenance protocols which are listed and explained below:

▶ Instrument Clean Waste (H_2O)

1. Select and run the ‘Clean Waste (H_2O)’ protocol from the *Maintenance* work area. Make sure 4 reagent bottles containing pyrogen-free sterile water are loaded and identified.
2. Empty and rinse the waste bottle before proceeding to remove all traces of guanidine thiocyanate from the system.

The waste contains guanidine thiocyanate.
Make sure to empty and dispose of the contents of the waste bottle into the chemical waste system according to the local waste procedure.

▶ Clean Aspirate (Soap)

1. Load 3 empty sample strips containing 3ml of Cleaning solution and load 3 aspirator disposables.
2. Select and run the ‘Clean Aspirate (Soap)’ protocol from the *Maintenance* work area.

▶ Replace liquid (EtOH)

1. Clean the cover of the dispense needles wash station with cleaning solution. Be careful not to damage the dispense needles.
2. Load 3 empty sample strips and 3 aspiration disposables onto the instrument.
3. Select and run the ‘Replace Liquid (EtOH)’ protocol from the maintenance screen. Make sure 4 reagent bottles containing 70% ethanol (REF: 284048) are loaded and identified.
4. Clean the cover of the dispense needles wash station with 70% Ethanol. Be careful not to damage the dispense needles.

▶ Replace Liquid (H_2O)

1. Load 3 empty sample strips and 3 aspiration disposables onto the instrument.
2. Select and run the ‘Replace Liquid (H2O)’ protocol from the maintenance screen. Make sure 4 reagent bottles containing pyrogen-free sterile water are loaded and identified.

Preparing The System For Transport

When the system needs to be transported it should be cleaned to remove any chemical and biological contamination. The cleaning procedure for Transport is identical to the procedure for service cleaning with the exception that the last protocol, rinsing with water, is replaced by a protocol that bleeds the system of all liquid. This prevents leaking during transport and damage to the system caused by freeze/thawing.

Refer to Figure 8-5 and chapter “Preparing The System For Service” on page 8-11 above.

Remember to finish the proceeding by executing the 6. Replace liquid (AIR) maintenance protocol.

Template Decontamination

*Avoid contamination of the **NucliSENS easyMAG** by following good laboratory practices. See “Safety Precautions” on page 1-3.*

*The **NucliSENS easyMAG** instrument is a relatively closed system that uses reagents that are replaced regularly and single-use disposables. This should help in keeping the system clean. A suspected template contamination of the reagents can be resolved by following the procedures described below.*

This procedure should only be used if nucleic acid contamination of the internal fluid paths of the instrument is suspected. Such instrument contamination can occur if reagents or reagent bottles become contaminated.

Always use caution when handling or discarding biological and hazardous waste material. See SAFETY INFORMATION at the beginning of this manual.

▶ Initial decontamination procedure

1. Rinse all instrument tubing with ***NucliSENS easyMAG Extraction Buffer 3*** or pyrogen-free sterile water.
2. Clean the surfaces and work areas using a 0.1% sodium hypochlorite solution followed by cleaning with de-ionized water.

If persisting contamination is suspected follow the instrument decontamination procedure described below.

▶ Instrument template decontamination

1. Remove all disposables. Clean off any spills or crystallization that may have occurred using cleaning solution, see instructions on page 8-4. Thoroughly clean the exterior of the instrument first using a mild sodium hypochlorite solution (0.1% sodium hypochlorite), then with cleaning solution. Repeat this step with Ethanol 70% and then wipe clean with a dry tissue or soft towel.
2. Empty and dispose the contents of the waste bottle into the chemical waste system according to the local waste procedure, the waste contains guanidine thiocyanate. Rinse the Waste bottle with water after emptying.
3. Remove the ***NucliSENS easyMAG*** buffer bottles and discard them. Remove the filters from the caps. Clean the caps using hypochlorite, Cleaning solution, Ethanol and Water and place a new filter.
4. First execute the ’Clean Waste (H2O)’ protocol to remove any residue of Lysis buffer. Make sure the empty the waste container before proceeding.
5. Replace the fluid in empty reagent bottles with 0.1% sodium hypochlorite (use the first set of empty reagent bottles for this purpose).
6. Load 3 empty sample strips onto the instrument and make sure that the 3 corresponding aspiration disposables are in place.

7. Select and run the ‘Replace liquid (OCL)’ protocol from the *Maintenance* work area to flush with mild sodium hypochlorite.
8. Remove the 4 reagent bottles and empty its content. Rinse the bottles thoroughly with pyrogen-free sterile water.
9. Empty the waste bottle.
10. Load 4 reagent bottles with pyrogen-free sterile water and run the ‘Clean Waste (H2O)’ protocol from the maintenance screen.
11. Empty the waste bottle.

▶ **Bulk waste bottle decontamination**

1. Empty the waste bottle and rinse it with water.
2. Add 500 ml of cleaning solution to the bottle and leave to soak for 15 minutes with intermittent mixing. Empty the cleaning solution from the waste container into the chemical waste system according to the local waste procedure.
3. Repeat this step wit 70% ethanol.
4. Clean the outside of the waste bottle with cleaning solution and 70% ethanol and rinse off. Flush out the waste bottle 3 times with approximately 500 ml of pyrogen-free sterile water. Drain out excess water and allow drying.

Decontamination of the equipment at the end of its life cycle

Refer to the instructions for use in the "General safety and regulatory information" booklet and follow the instructions described in the chapters “Preparing The System For Service” on page 8-11, “Preparing The System For Transport” on page 8-12 and “Template Decontamination” on page 8-13.

Replacing Filters And Fuses

Some filters and fuses might need replacement at some point. Often this will be done as part of the preventive maintenance procedure. The following paragraphs offer some guidance should the user be confronted with the necessity to replace an item.

Filter Replacement

Special attention should be taken into account handling the reagent caps. Use a new set of gloves during cleaning and/or replacement of sinker filter and suction pipes per bottle position.

Carbon Filter

There is a carbon filter located beneath the reagent bottle platforms. Access is via a hinged door.

Figure 8-2: Carbon filter with flow direction indicator circled

To replace the filter, press the release buttons at each end of the filter and remove the filter. When replacing the filter, ensure the flow direction marked on the filter points to the right. Replacement carbon filters must be obtained through bioMérieux.

Reagent Filter

This is the filter that is placed on the end of the reagent bottle straw.

Figure 8-3: Picture showing the reagent filter

To replace this filter, pull it out of the straw and push in a new filter. Replacement reagent filters must be obtained through bioMérieux.

Waste Bottle Filter

The waste bottle filter must be replaced if it becomes moist.

To replace the filter, unscrew it counter clockwise from the cap of the waste bottle and screw a new one in its place. Replacement wash bottle filters must be obtained through bioMérieux.

Fuse Replacement

High voltages are present in the instrument.
Before replacing fuses, shut down the instrument, turn off the main power switch, and remove the main lead.

A fuse can be replaced by turning the slot in the fuse holder 45° counter clockwise. The holder can now be removed and the fuse replaced. Push the fuse and holder into the socket and turn the holder clockwise to lock it into place.

Fuse	Function	Rating
1	Incoming power	5 Amp
2	Incoming power	5 Amp
3	LCD monitor power	0.5 Amp

Figure 8-4: Fuses

Replacement fuses must be obtained through the instrument manufacturer. Do not substitute fuses.

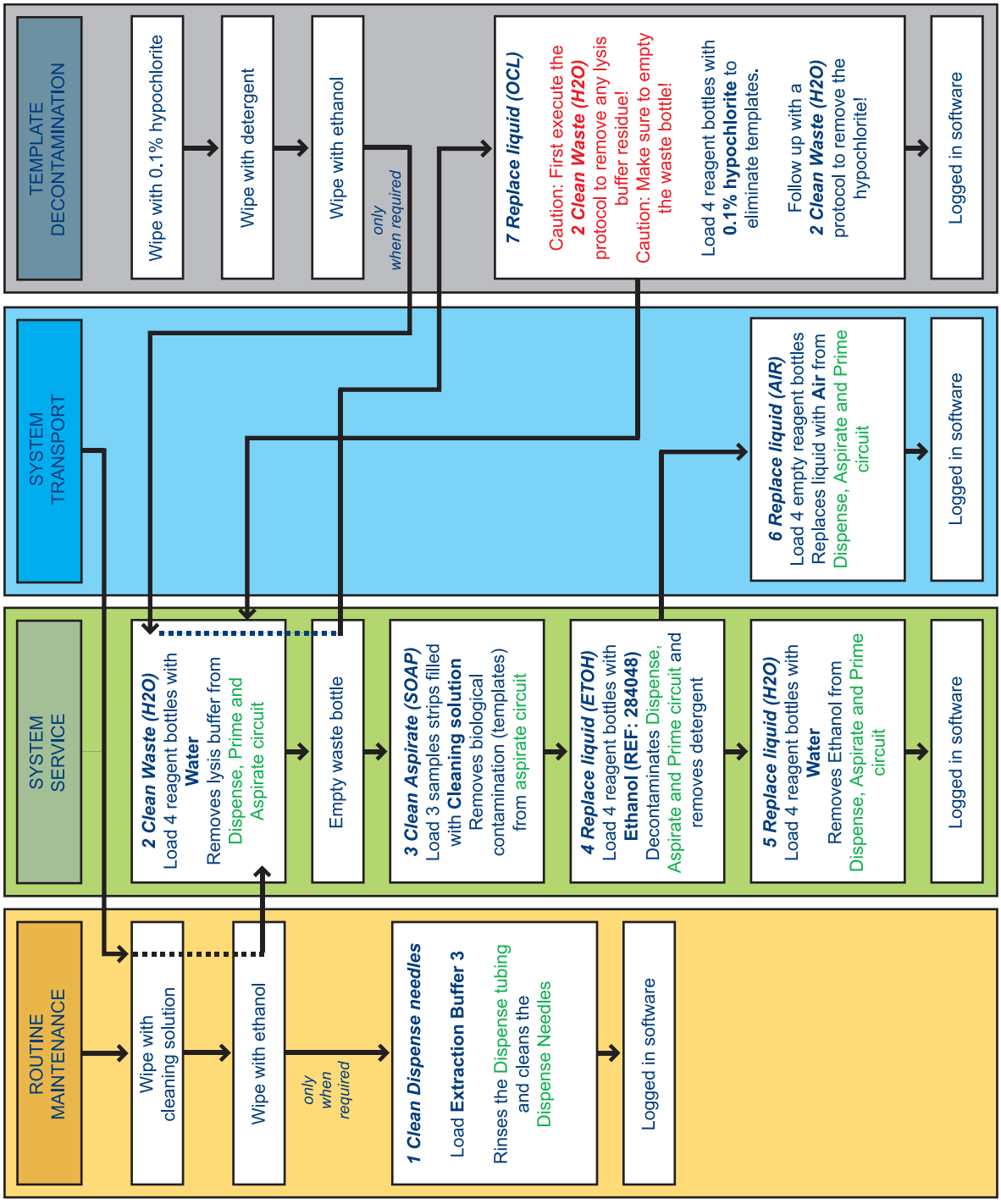


Figure 8-5: Maintenance and decontamination flow chart

Pyrogen-free sterile water

Maintenance protocols: ‘Clean Waste (H2O)’, ‘Replace liquid (H2O)’

70% ethanol, REF: 284048

Maintenance protocol: ‘Replace liquid (ETOH)’

Hypochlorite

Maintenance protocol: ‘Replace liquid (OCL)’

Cleaning solution

Figure 8-6: Maintenance protocol reagent barcodes

Data Maintenance

Good housekeeping of instrument data is strongly recommended.

Assess runs each day and delete finished runs on a monthly basis. This will maintain optimal performance.

The application software is capable of storing the results from many runs should the user wish to do this. However at some point a reduction in software response times is to be expected. If it is suspected that there is a reduction in software response time it is recommended to delete finished runs from the database.

Please note that the size of the database will not influence the ability of the instrument to perform runs or to retrieve data reliably.

Backups

To prevent loss of valuable data, for example, due to a crashed hard disk, it is advised to make regular backups of the computer. In particular the database containing extraction requests and run results should be backed up, and the 'Logs' folder where the instrument history is logged. For a full backup of the entire computer please refer to the Windows XP backup procedure.

The backup and restore procedures described below require a certain degree of familiarity with Windows XP. In case the user feels not confident to carry out the procedure below please contact your local bioMérieux representative.

The procedure below describes how to make a backup of the database. Backing up the Logs folder works in the exact same way. Where the procedure refers to the folder named 'Database', please use the folder 'Logs' instead.

Preparation

The ***NucliSENS easyMAG*** computer comes with a CD RW drive and Ahead Nero's InCD pre-installed. Writing a CD is a safe way of preserving a backup should the harddisk of the application PC fail. Please format a rewritable CD for use with InCD (packet writing protocol) before attempting to write backups to the CD RW.

The user may also choose to store backups on the hard-drive only. Store the backups in a dedicated folder (e.g. D:\backups) so they can be easily located when needed.

Backing Up The Database

▶ To create a backup of the database

1. Close the ***NucliSENS easyMAG*** user software.
   To close the software tap the *Key* button in the *Status* bar, then tap *Quit*. Make sure the *Shutdown operating system* option is deselected and tap *OK*. The computer shall close the software and display the Windows XP desktop.
2. Open Windows Explorer.
3. Navigate to the drive and folder where the ***NucliSENS easyMAG*** user software is installed.Typically, the software is installed in D:\bioMérieux\easyMAG.
4. In the folder, select the folder named ‘Database’ and compress the entire folder using ‘Send To - Compressed (zipped) folder’ - a function that is available by right-clicking the mouse.
5. Rename the compressed folder to a suitable name.

*Tip: Rename the compressed folder to ‘Database + software version + date’, for example Database 1.0.50.0_2004_12_20. This way the backup can easily be identified which is helpful when the backup needs to be restored. The version of the software can be found in the Title bar when the **NucliSENS easyMAG** user software is running.*

6. Write the compressed folder to the CD RW using ‘Send To - CD RW’ - a function that is available by right-clicking the mouse. Follow the instructions provided by Windows to complete the writing process. Alternatively, move the compressed folder to the backups folder.
7. Open the compressed folder to view its contents.The folder should contain at least the following items if the backup was successful:
   - a folder named ‘schema’
   - a file named ‘objects.dat’
   - a file named ‘objects.idx’
8. Close the folder to finish the backup procedure.

Restoring The Database

Restoring a backup will irrevocably delete all extraction requests and runs that are currently in the database. Only restore a backup of the database when it is certain there is no other way to solve the problem.
Backup the current database before attempting to restore a previously backed up database. To backup the current database follow the procedure described in “Backing Up The Database” on page 8-21.
If unsure about how to restore the database please do not proceed but contact your local bioMérieux representative instead.

▶ **To restore a backup of the database**

1. Close the ***NucliSENS easyMAG User Software***.
2. Open Windows Explorer.
3. In the installation folder, select the folder named ‘Database’ and press *Delete*. Press *Yes* to confirm.This will delete the current (corrupted) database.
   Typically, the software is installed in D:\bioMérieux\easyMAG.
4. Navigate to the backups folder on the CD-RW. Alternatively, navigate to the backup storage folder on the hard-drive.
5. Select the compressed backup to restore.
   Expand the backup into the folder where the ***NucliSENS easyMAG User Software*** is installed.
6. Make sure the installation folder now contains a folder named Database. Additionally, make sure the folder contains at least the following items:
   – a folder named ‘schema’
   – a file named ‘objects.dat’
   – a file named ‘objects.idx’
7. To restart the software, double tap the icon named ***NucliSENS easyMAG*** software on the desktop. The unprocessed extraction requests, runs and finished runs should now be identical to the point in time when this backup was created. When the software does not behave as expected, please contact your local bioMérieux representative.

Restoring the instrument history (‘Logs‘ folder) is done in a similar fashion. Expand the appropriate backed up ‘Logs‘ folder into the folder where the ***NucliSENS easyMAG User Software*** is installed. The folder should then contain a number of log files.

User Maintenance Check List

On the next page you find a check list for the user maintenance procedures. Copy or print this page and keep it in the vicinity of the ***NucliSENS easyMAG***.

NucliSENS easyMAG™ USER MAINTENANCE CHECKLIST REVISION 3

INSTRUMENT #:	MONTH:	YEAR:

DAY OF MONTH:		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
easyMAG																																
Shutdown Instrument and PC	Daily																															
Wipe instrument (except the touchscreen) with 5% Extran followed by 70% EtOH. Wipe clean with paper towel	Daily																															
Check drip tray	Daily																															
Check waste bottle	Daily																															
Empty waste bottle	As required																															
Clean reagent bottle caps	Weekly																															
Check reagent bottle vent filter	Daily																															
Replace reagent vent filter	As required																															
Check reagent bottle sinker filters	Weekly																															
Check o-rings for crystals	Daily																															
Clean o-rings*	Weekly																															
Run 1-Clean Dispense Needles	Weekly																															
Check Carbon filter	Weekly																															
Initals																																

*When cleaning the o-rings, use a cotton tip dipped in nuclease free water. Use clean materials for each nozzle.

Note: Please run the Clean Waste Protocol (Maintenance Protocol #2) prior to using instrument, if instrument has not run within 30 days.

System Service to be performed prior to Field Service Engineer Visit

	DATE PERFORMED	INITIALS
1-Clean Dispense		
2-Clean Waste (H20)		
3-Clean Aspirate		
4-Replace liquid (ETOH)		
5-Replace liquid (H20)		

A Instrument Specifications

General

Dimensions	1000 mm wide by 650 mm deep by 530 mm high (excluding computer, LCD monitor & keyboard)
Weight	128 kg (dry instrument including LCD monitor & keyboard) 8 kg (computer)

Operating Conditions

Temperature	15 ºC to 30 ºC
Humidity	Maximum 80% RH non-condensing at 30 ºC DB
Power Supply	100 – 240 VAC, 50/60 Hz
Power rating	400 W
Altitude	Up to 2500 meters above sea level

Shipping Conditions

Shipping Temperature	-20 ºC to +60 ºC
Humidity	Maximum of 100% RH, non condensing

System Input Requirements

Run size	1-24 samples per run.

Processing

Heating	62.5 to 85 ºC, 10 minutes maximum
Magnetic Silica flushing frequency	0.2 Hz to 1.4 Hz

Barcode Reader

Formats	Code 128, Code 39, Interleave 2 of 5, Codabar, and others
Minimum size	Capable of reading Code 128 barcodes with a minimum X dimension 0.167 mm (0.0066 inch)

Equipment Identification

Computer	Minimal configuration: Pentium® IV processor (2.6 GHz), 512 Mb RDRAM, hard drive (>=10 Gb), floppy disk drive, CD-RW drive, internal speaker, keyboard, mouse, two IEEE 802.3u 10/100 BASE-T Fast Ethernet ports, Microsoft® Windows XP® Professional, parallel port for printing, serial port, 2 x USB 2.0 ports. Only the bioMérieux supplied ***NucliSENS easyMAG*** computer is to be used with this instrument.
Monitor / Touch-screen	Minimal configuration: 15" SVGA LCD Touch screen Monitor, 1024 x 768 pixels, 60 Hz, true colors. Only the bioMérieux supplied ***NucliSENS easyMAG*** monitor / touch-screen is to be used with this instrument.
Barcode reader	Datalogic 'Gryphon' D130. Only the bioMérieux supplied ***NucliSENS easyMAG*** barcode reader is to be used with this instrument.

B Barcode Reader Configuration

This appendix provides instructions for re-configuring the barcode reader to its bioMérieux factory settings.

Before changing the barcode reader configuration please ensure that the reader communication settings in the 'Application Settings' work area are correct.

Factory Supported Barcode Symbologies

The following barcode symbologies are supported in the factory settings for barcode reader:

- EAN 8/EAN 13 / UPC A/UPC E without ADD ON (check digit transmitted, no conversions)
- Interleaved 2 of 5 (check digit control and transmission, variable length code; 4-99 characters)
- Standard Code 39 (no check digit control, variable length code; 1-99 characters)
- Code 128 (variable length code; 1-99 characters)
- Codabar (no start/stop character equality control nor transmission)

Barcode Reader Configuration

The Gryphon D120 barcode reader can be configured by scanning a series of barcodes. Perform the following steps in the given order to re-configure the barcode reader.

USB-Com Interface Selection

Serial emulation mode is required for the ***NucliSENS easyMAG*** system. Scan the barcode below to configure the reader for serial emulation mode:

Gryphon Defaults

Scan the barcode below to re-configure the Gryphon barcode reader to factory defaults:

BioMérieux *NucliSENS easyMAG* Defaults

The bioMérieux ***NucliSENS easyMAG*** default barcode settings are defined as variations to the Gryphon D120 default settings. The bioMérieux settings enable the codabar symbology, and enable the automatic reading of barcodes when the reader is in its holder. Scan the barcode below to enable the bioMérieux ***NucliSENS easyMAG*** settings:

Installation Procedure And Configuration Of The Gryphon D130 Barcode Reader

Configuring the barcode reader (USB-COM interface)

Scan the barcode below to configure the barcode to USB-COM interface.

USB-COM*

S+UA02S-

Additional barcodes were provided to configure the D120 barcode reader. These should not be used to setup the D130 barcode scanner as it will not operate in the auto-detect mode (in the holder). If these barcodes are used, restore the default configuration as described in the next section.

Restoring Default Setting

The D130 barcode reader is supplied with correct settings to use on ***NucliSENS easyMAG***. This procedure is only required if the settings are changed (as described in section above). However, this procedure can be used to ensure the correct settings are used.

Scan the following barcode to restore the default setting.

Restore Default

S+S*

Scan the following barcode to exit and save settings.

Exit and Save Settings

S-

This procedure does not restore the barcode reader to the original serial interface. The SB-COM interface is retained after restoring the default settings.

CODABAR Barcode Decoding

Codabar barcode decoding is not enabled by default in the D130 reader. If CODABAR encoding is required then the barcodes below can be scanned to enable that mode in the reader.

Enter Configuration

Standard Codabar

no transmission

Exit and Save Configuration

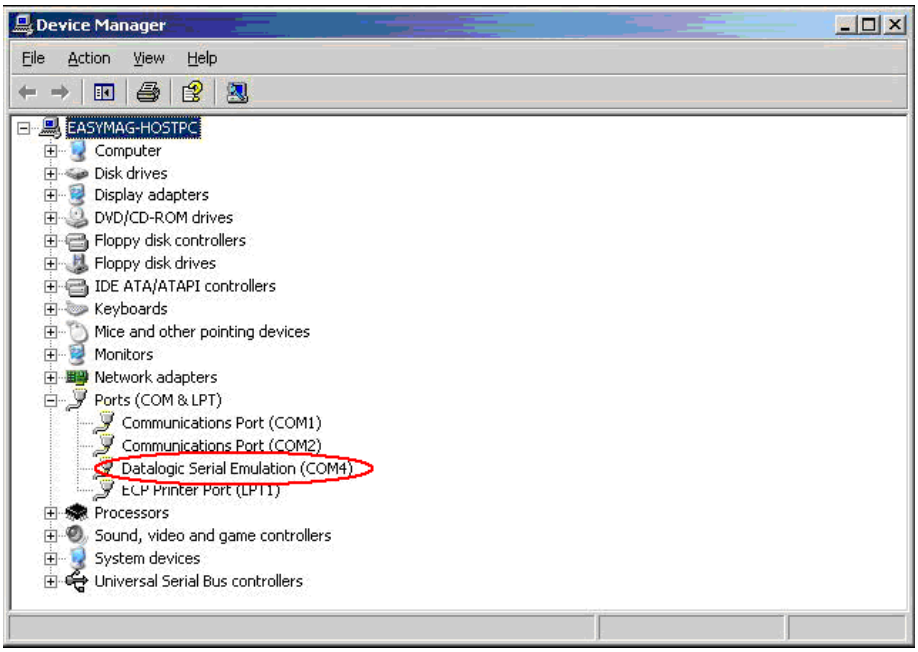
*In the **NucliSENS easyMAG** user manual a section Barcode reader is adapted (Appendix B). In this section it is stated that the barcode reader can be configured by scanning the shown barcodes. This procedure is for the Gryphon D120 only. If by mistake these barcodes are canned with the D130 barcode scanner, the scanner will stay in the configuration mode. To get out of this mode scan the above barcode and select 'Exit and save configuration'.*

Assign Barcode To COM4 Port

The following procedure assigns the barcode reader to the COM port setting used by the ***NucliSENS easyMAG*** software.

▶ **Assign the barcode reader to COM port setting**

1. On the bottom left of the screen click on *Start* then click on *Control Panel*.
2. Click on *System*, then on the *Hardware* tab and then click *Device Manager*.
3. Expand Ports (COM & LPT) by clicking on the '+' sign.



4. The barcode scanner (Datalogic Serial Emulation) is not usually set to COM4 by default. If the barcode scanner is already set to COM4, proceed to step 7 to complete the installation. Otherwise continue on to step 5 to assign the correct COM port.
5. Right click on the barcode reader port (Datalogic Serial Emulation), select *Properties* then click on the *Port Settings* tab. Select *Advanced*, then change the Com Port Number to COM4.

If a barcode reader has previously been installed and assigned to COM4, you will need to remove this assignment. To do this, expand Universal Serial Bus controllers and uninstall the USB2 Enhanced Host Controller. The installed USB devices will be detected immediately and the USB2 Enhanced Host Controller will be reinstalled for these devices. The barcode reader can now be assigned to COM4 as above.

6. Select the *Action* menu and then scan for hardware changes to confirm the barcode reader has been assigned to COM4.
7. Click *OK* twice to exit then close the *Device Manager* window. Click *OK* to close the *System Properties* window.

The barcode reader is now installed and functional.

C Touch Screen Re-calibration

Re-Calibrating The Touch-Screen

This appendix provides instructions for re-calibrating the touch screen.

This procedure requires that the touch screen be operating at least to some degree. If however the touch screen is not operating sufficiently well to follow this procedure, then it will need to be re-installed, repaired or replaced. In these situations, please contact your local bioMérieux representative.

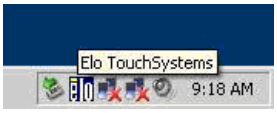
Please verify which touchscreen is present.

For the ELO touchscreen calibration follow the actions as described in the following procedure

For the NEC touchscreen please follow the actions as described in “To re-calibrate the touch screen (NEC)” on page C-5.

▶ To calibrate the touch screen (ELO)

1. Three point calibration for the Elo touchscreen will be automatically launched once the calibration software is installed. If the calibration needs to be performed again, double click the button on the desktop for ‘ELO touchscreen’ calibration. Proceed with step 3.
2. If the Desktop button is not present move the mouse to the down right corner of the Quick start buttons.
3. Double-click on the ELO icon.



4. The following screen will pop up where you select the *Align* button in the *General* tab.

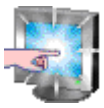
Figure C-1: ELO Touchscreen Properties dialog box

5. The calibration screen will appear. Follow the instructions on screen to perform a three-point calibration. Press each time the calibration point in the allowed timeframe for about one second. This has to be performed for all three points.

6. Check the calibration and press the green tick if it is OK (otherwise repeat the calibration by selecting the blue repeat arrow)

Figure C-2: Calibration confirmation dialog box

To re-calibrate the touch screen (NEC)



1. Minimize or terminate the ***NucliSENS easyMAG*** application software. In the case of termination, do not shut down the operating system.
2. On the desk top, click the *TouchWare* icon. The *TouchWare Properties* screen should then be displayed:

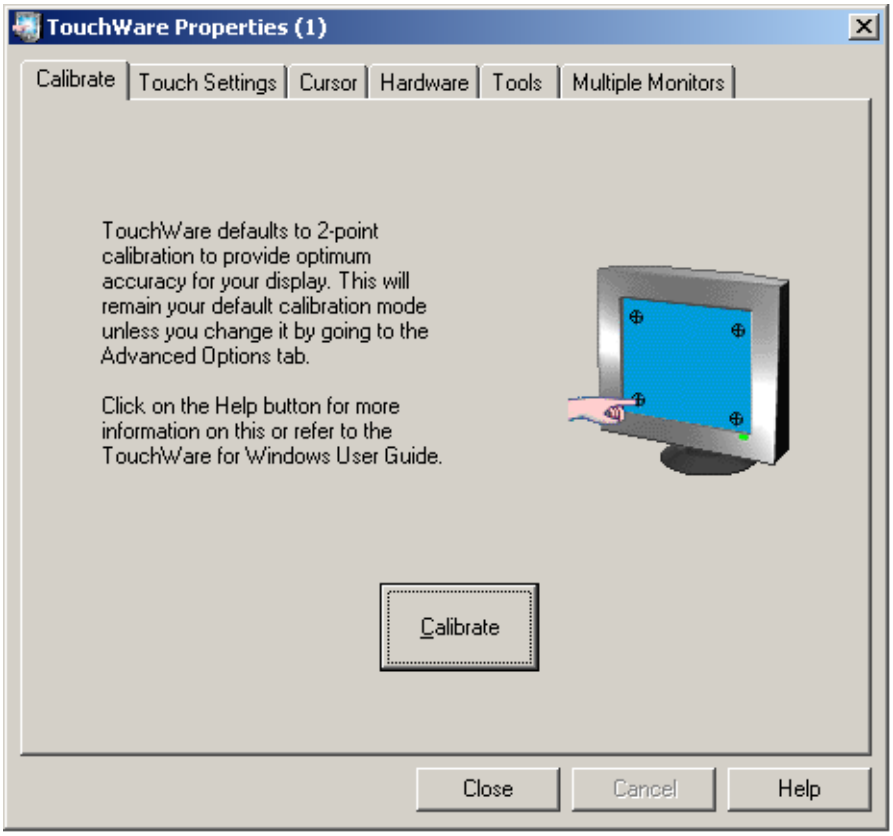


Figure C-3: TouchWare properties screen

3. Click the *Calibrate* button. The *calibration* screen should then be displayed:

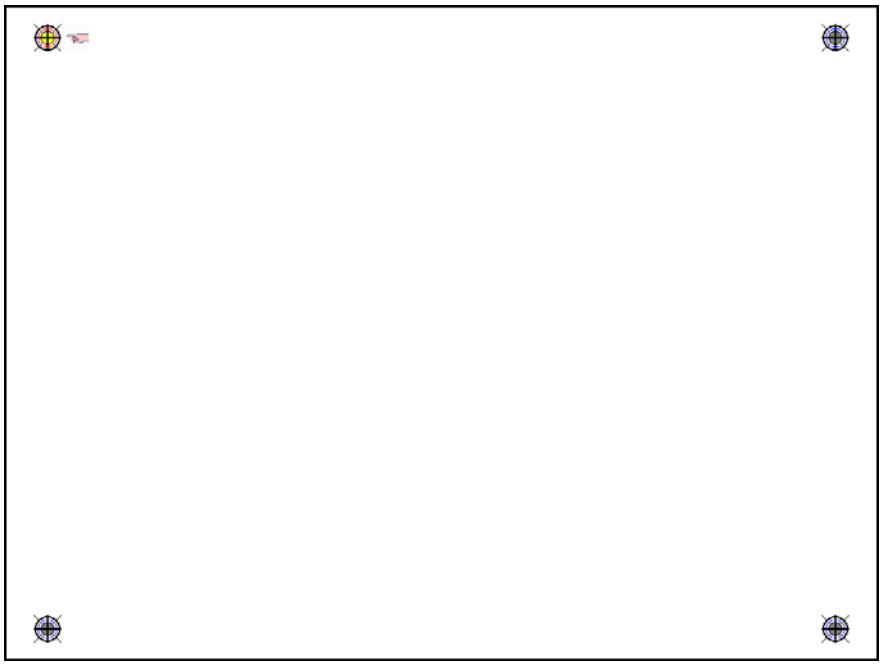


Figure C-4: TouchWare calibration screen.

4. Touch each of the 4 targets when prompted by the software.
5. After a short delay, the *Calibration Complete* dialog should be displayed:

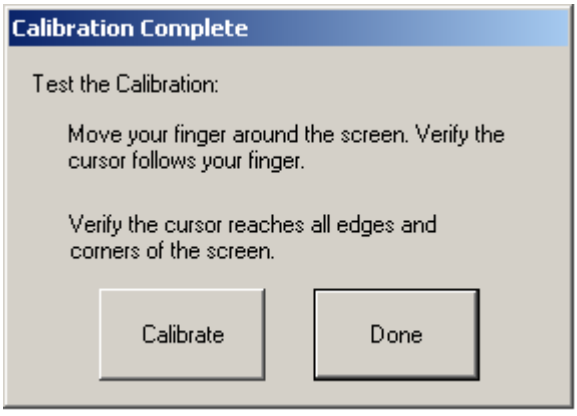


Figure C-5: TouchWare done screen

6. Test the touch screen as per the software's instructions. If all is well, click the *Done* button. If however, the touch screen needs to be re-calibrated, then click the *Calibrate* button.
7. When the *TouchWare Properties* screen is re-displayed, exit the program by clicking the *Close* button.
8. Maximize or restart the ***NucliSENS easyMAG*** application software.

D Software Reference

This appendix provides a summary of all software screens and their associated controls.

Daily Use Menu

Define Extraction Requests Work Area

The *Define Extraction Requests* work area is the work area where the user creates extraction requests. The user identifies the primary or lysed sample, and selects the requested extraction type.

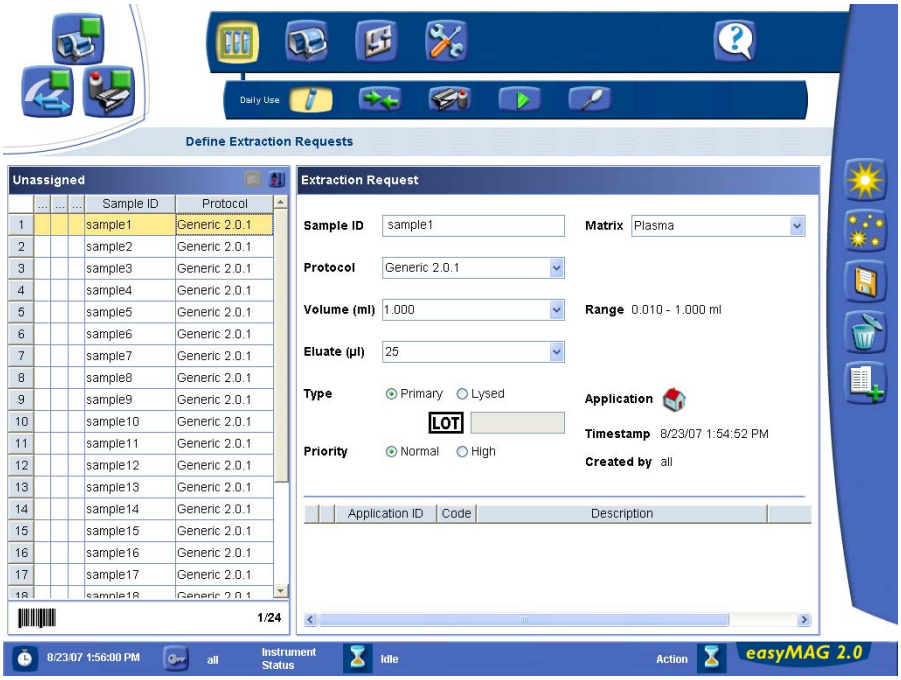


Figure D-1: Define Extraction Requests work area

Unassigned		
Unassigned	List of extraction requests that have not yet been assigned to a run.	
	 	Refresh the list of unassigned samples for requests sent by ***NucliSENtral*** (coloured symbol = enabled, grey symbol = disabled).
		Reset the sorting of the samples according to their creation date.
Column 1		Indicates that the sample is pre-lysed.
Column 2		Indicates that the sample is marked as ‘High Priority‘.
Column 3		Indicates that an extraction request is a repeat request.

Sample ID	Identification of sample, for example sample barcode.	
Protocol	Extraction protocol or assay protocol.	
1/4	Selected number of samples/Total number of samples in the list.	
Extraction Request		
Sample ID	Identification of sample, for example sample barcode.	
Matrix	Sample type, for example plasma or whole blood.	
Protocols	Extraction protocol or assay protocol.	
Volume (ml)	Input volume of sample, must be in the indicated Range.	
Range	Permitted input volumes.	
Eluate (ml)	Volume of eluate to be produced. Select one.	
Type	Primary	The sample is not lysed.
	Lysed	The sample is lysed. Enter the Lysis Lot ID in the adjacent text field, if applicable
Priority	Normal	The extraction request has normal priority.
	High	The extraction request has high priority.
Application	Indicates on which application the extraction request was created. Contains application type and application Id when not created on this ***NucliSENS easyMAG***, otherwise it contains a 'locally created' indication.	
Timestamp	Creation date of the extraction request.	
Created by	Login or user name of the user who created the extraction request.	
Incidents and Remarks		
Column 1	A symbol is displayed for the origin of the entry. A remark is always user-created, whereas an incident is indicated by an error status icon.	
Column 2	This column indicates by a symbol, if the remark/incident was created on the local system or has been derived from ***NucliSENtral***.	
Application	Indicates on which application the incident was created. Contains application type and application Id when not created on this ***NucliSENS easyMAG***, otherwise it contains a 'locally created' indication.	
Code	Unique code for the incident, if applicable.	
Description	Incident description or text of the remark.	
Timestamp	Creation date of the incident or remark.	
Created by	Login or user name of the user who created the incident or remark.	

Organize Runs Work Area

The *Organize Runs* work area is where the user combines extraction requests that are to be processed together into runs. A run can be created by selecting extraction requests from the *Unassigned* list and moved into the run, either manually or by means of scanning the sample ID barcodes. Both methods can be combined.

Figure D-2: Organize Runs work area

Unassigned		
Unassigned	List of extraction requests that have not yet been assigned to a run.	
	 	Refresh the list of unassigned samples for requests sent by ***NucliSENtral*** (coloured symbol = enabled, grey symbol = disabled).
		Reset the sorting of the samples according to their creation date.
Column 1		Indicates that the sample is pre-lysed.
Column 2		Indicates that the sample is marked as 'High Priority'.
Column 3		Indicates that an extraction request has been marked for re-testing in the *View Results* work area.
Sample ID	Identification of sample, typically the sample barcode.	
Protocol	Extraction protocol or assay protocol.	
1/4	Selected number of samples/Total number of samples in the list.	

Layout		
Layout	Part of the screen displaying the placement of extraction requests on sample strips.	
Run	Unique name of the run, defined when the run was created. Can be modified.	
Size	Number of extraction requests assigned to the run.	
Protocol	Extraction/Assay protocol for this run.	
Version	Extraction/Assay protocol version.	
Workflow	On-board lysis addition	Indicates whether on-board lysis addition is enabled or disabled.
	On-board lysis buffer incubation	Indicates whether on-board lysis incubation is enabled or disabled.
	On-board silica incubation	Indicates whether on-board silica incubation is enabled or disabled.
	Sample guidance	Indicates whether on-board sample addition is enabled or disabled.
1...24	Each number represents a single vessel in a sample strip.	
		This symbol in front of a number indicates a pre-lysed sample.
Incidents		
Column 1	A symbol is displayed for the origin of the entry. A remark is always user-created, whereas an incident is indicated by an error status icon.	
Code	Unique code for the incident, if applicable.	
Position	Vessel number of the test request	
Description	Incident description or text of the remark.	
Details		
Type	Type of the incident, e.g. warning or remark.	
Position	Sample strip position (1-24)	
Code	Unique code for the incident, if applicable.	
Sample ID	Identification of sample, typically the sample barcode.	
Description	Incident description or text of the remark.	
Application	Indicates on which application the incident was created. Contains application type and application Id when not created on this ***NucliSENS easyMAG***, otherwise it contains a 'locally created' indication.	
Timestamp	Creation date of the incident or remark.	
Created by	Login or user name of the user who created the incident or remark.	

Load Run Work Area

The *Load Run* work area is where the user actually loads disposables and samples. The run can be started when all status indicators are ok, indicated with a green square. Please select what kind of information will be scanned or typed in the Barcode Input area. Select sample strip, samples, internal control or silica.

Load Run Work Area – Progress View

This view shows the user how far the loading process has progressed.

The arrow-like images represent the steps that are to be taken: load samples, dispense lysis buffer (when required), incubate lysis buffer, load internal control and finally, load silica.

Sample strips and aspirator disposables are displayed solidly when they are actually placed in their holders on the instrument. The sample strip ID is displayed immediately below the sample strip image.

Figure D-3: Load Run work area - Progress view

Info		
Info	This area identifies the run that is being loaded.	
Run	Unique name of the run, defined when the run was created.	
Protocol	Extraction protocol and version number for this run.	
Size	Number of extraction requests assigned to the selected run.	
Workflow icons	On-board lysis addition	Indicates whether on-board lysis addition is enabled (yellow) or disabled (white).
	On-board lysis buffer incubation	Indicates whether on-board lysis incubation is enabled (yellow) or disabled (white).
	On-board silica incubation	Indicates whether on-board silica incubation is enabled (yellow) or disabled (white).
	Sample guidance	Indicates whether on-board sample addition is enabled (yellow) or disabled (white).
Barcode Input		
Barcode Input	This area is where the user scans barcodes. Select the type first.	
Type		Click this button to scan or type in a sample strip barcode.
		Click this button to scan or type in a sample barcode.
		Click this button to scan or type in an internal control barcode.
		Click this button to scan or type in a silica barcode.
		Click this button to scan or type in a diluent barcode.
Position	A, B or C	Sample strip position from left (A) via center (B) to right (C).
		Displays the scanned barcode. When not using the barcode scanner, please type the barcode in this field.

Load Run Work Area – Assign Kit Reagents View

The *Assign Kit Reagents* view displays the installed kit reagent lots and sample IDs of the extraction request run that is being loaded.

If more than one kit reagent should be used in one run they have to be assigned to the extraction requests. This view comprises three layout views with all installed kit reagents (silica, internal control, diluent) and one layout view with all extraction requests.

Figure D-4: Load Run work area - Assign Kit Reagents view

Kit Reagents		
Kit Reagents	This table lists all kit reagent lots available for a run.	
Silica	bioMérieux product ID / lot ID for Silica	
Internal Control	bioMérieux product ID / lot ID for Internal Control	
Diluent	bioMérieux product ID / lot ID for Diluent	
Assigned Kit Reagents		
Assigned Kit Reagents	This table lists all extraction requests of the currently selected run and the assigned kit reagents. The table consists of four tabs for Samples, Silica, Internal Control and Diluent.	
1 - 24	Each number represents a single vessel in a sample strip.	
Column 2		This symbol indicates a pre-lysed sample.
Sample tab	Sample ID, protocol and protocol version number of the extraction request.	
Silica tab	Product ID and Lot ID of the assigned silica reagent.	
Internal control tab	Product ID and Lot ID of the assigned internal control reagent.	
Diluent tab	Product ID and Lot ID of the assigned diluent.	

Load Run Work Area – Layout View

The *Layout* view displays the sample IDs of the extraction request run that is being loaded.

Sample strips and aspirator disposables are displayed solidly when they are actually placed in their holders on the instrument. The sample strip ID is displayed immediately below the sample strip image.

Figure D-5: Load Run work area - Layout view

Barcode Input		
Barcode Input	This area is where the user scans barcodes. Select the type first.	
Type		Click this button to scan or type in a sample strip barcode.
		Click this button to scan or type in a sample barcode.
		Click this button to scan or type in an internal control barcode.
		Click this button to scan or type in a silica barcode.
		Click this button to scan or type in a diluent.
Position	A, B or C	Sample strip position from left (A) via center (B) to right (C).
		Displays the scanned barcode. When not using the barcode scanner, please type the barcode in this field.
Layout		
A	Aspirator disposable A	Status of aspirator disposable A.
	Sample strip A	Status of sample strip A. A blue vessel indicates a sample in the corresponding place, white indicates an empty vessel. The scanned or entered barcode is displayed below the sample strip.
1-8	Each number represents a single vessel in sample strip A.	
B	Aspirator disposable B	Status of aspirator disposable B.
	Sample strip B	Status of sample strip B. A blue vessel indicates a sample in the corresponding place, white indicates an empty vessel. The scanned or entered barcode is displayed below the sample strip.
9-16	Each number represents a single vessel in sample strip B.	
C	Aspirator disposable C	Status of aspirator disposable C.
	Sample strip C	Status of sample strip C. A blue vessel indicates a sample in the corresponding place, white indicates an empty vessel. The scanned or entered barcode is displayed below the sample strip.
17-24	Each number represents a single vessel in sample strip C.	

Load Run Work Area – Incidents View

When the user loads a run, several errors and warnings can occur. The *Incidents* view allows the user to view detail information about such incidents. In addition this view lists user remarks.

To view details, select an incident or remark in the upper list. Details about the selected item are displayed in the lower part of the screen.

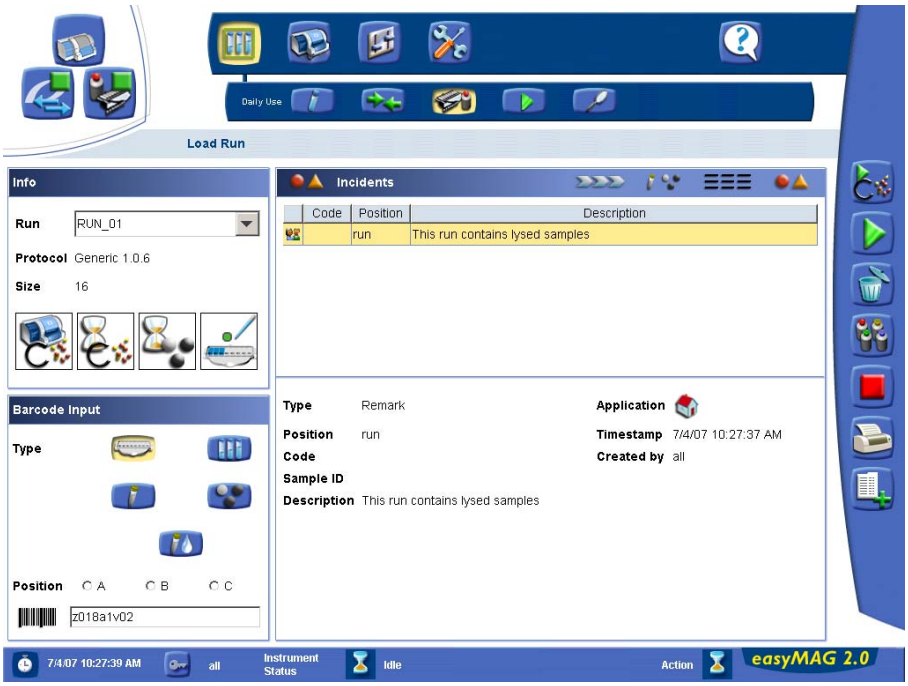


Figure D-6: Load Run work area - Incidents view

Barcode Input		
Barcode Input	This area is where the user scans barcodes. Select the type first.	
Type		Click this button to scan or type in a sample strip barcode.
		Click this button to scan or type in a sample barcode.
		Click this button to scan or type in an internal control barcode.
		Click this button to scan or type in a silica barcode.
		Click this button to scan or type in a diluent.
Position	A, B or C	Sample strip position from left (A) via center (B) to right (C).
		Displays the scanned barcode. When not using the barcode scanner, please type the barcode in this field.
Incidents		
Column 1	A symbol is displayed for the origin of the entry. A remark is always user-created, whereas an incident is indicated by an error status icon.	
Code	Unique code for the incident, if applicable.	
Position	Vessel number of the test request	
Description	Incident description or text of the remark.	
Details		
Type	Type of the incident, e.g. warning or remark.	
Position	Sample strip position (1-24)	
Code	Unique code for the incident, if applicable.	
Sample ID	Identification of sample, typically the sample barcode.	
Description	Incident description or text of the remark.	
Application	Indicates on which application the incident was created. Contains application type and application Id when not created on this ***NucliSENS easyMAG***, otherwise it contains a 'locally created' indication.	
Timestamp	Creation date of the incident or remark.	
Created by	Login or user name of the user who created the incident or remark.	

Execute Run Work Area

The *Execute Run* work area is automatically displayed when the user starts the run from the *Load Run* work area.

Execute Run Work Area – Progress View

The *Progress* view displays the expected amount of time to complete the run.

Similar to the *Load Run* work area the arrow-like images represent the steps that are to be taken: capture, wash, elution and finish.

The indicators above the vessels show the status of the extraction request in that vessel.

Figure D-7: Execute Run work area - Progress view

Info	This area identifies the run that is being loaded.	
Run	Unique name of the run, defined when the run was created.	
Protocol	Extraction protocol and version number for this run.	
Size	Number of extraction requests assigned to the selected run.	
Workflow icons	On-board lysis addition	Indicates whether on-board lysis addition is enabled or disabled.
	On-board lysis buffer incubation	Indicates whether on-board lysis incubation is enabled or disabled.
	On-board silica incubation	Indicates whether on-board silica incubation is enabled or disabled.
	Sample guidance	Indicates whether on-board sample addition is enabled or disabled.

Execute Run Work Area – Layout View

The *Layout* view displays information about the assignment of vessels on the sample strips. Detailed information about every sample can be displayed.

Figure D-8: Execute Run work area - Layout view

Layout	
Column 1	Displays the barcode and vessels of sample strip A with sample ID, protocol name and version number.
1-8	Each number represents a single vessel in sample strip A.
Column 2	Displays the barcode and vessels of sample strip B with sample ID, protocol name and version number.
9-16	Each number represents a single vessel in sample strip B.
Column 3	Displays the barcode and vessels of sample strip C with sample ID, protocol name and version number.
17-24	Each number represents a single vessel in sample strip C.

Sample Details	
Sample ID	Identification of sample, typically the sample barcode.
Volume (ml)	Input volume of sample.
Eluate (ml)	Volume of produced eluate.
Matrix	Sample type, for example plasma or whole blood.
Application	Indicates on which application the extraction request was created. Contains application type and application Id when not created on this ***NucliSENS easyMAG***, otherwise it contains a 'locally created' indication.
Created by	Identification of the user who originated the extraction request.
Timestamp	Time when the extraction request was created/received.
Incidents	
Column 1	A symbol is displayed for the origin of the entry. A remark is always user-created, whereas an incident is indicated by an error status icon.
Column 2	This column indicates by a symbol, if the remark/incident was created on the local system or has been derived from ***NucliSENtral***.
Application ID	ID of the application which originated the incident, if applicable.
Code	Unique code for the incident, if applicable.
Description	Description of the incident or the user remark text.
Time	Time when the extraction request was created/received.

Execute Run Work Area – Incidents View

When a run is being executed, several errors and warnings can occur. The *Incidents* view allows the user to view detail information about such incidents. In addition this view lists user remarks.

To view details, select an incident or remark in the upper list. Details about the selected item will be displayed in the lower part of the screen.

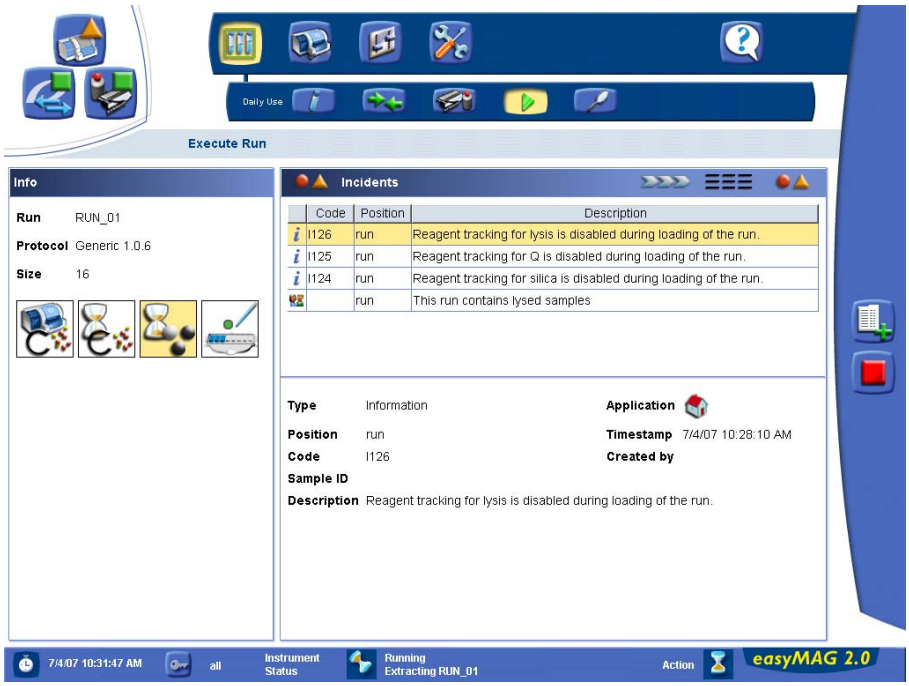


Figure D-9: Execute Run work area - Incidents view

Incidents	
Column 1	A symbol is displayed for the origin of the entry. A remark is always user-created, whereas an incident is indicated by an error status icon.
Code	Unique code for the incident, if applicable.
Position	Sample strip position (1-24)
Description	Incident description or text of the remark.
Details	
Type	Type of the incident, e.g. warning or remark.
Position	Sample strip position (1-24)
Code	Unique code for the incident, if applicable.
Sample ID	Identification of sample, typically the sample barcode.
Description	Incident description or text of the remark.
Application	Indicates on which application the incident was created. Contains application type and application Id when not created on this ***NucliSENS easyMAG***, otherwise it contains a 'locally created' indication.
Timestamp	Creation date of the incident or remark.
Created by	User who created the incident or remark.

View Results Work Area

The user inspects the results of completed runs in the *View Results* work area. The *View Results* work area lists both successful runs and runs that have failed due to errors.

Four different views allow the user to focus on different aspects of a completed run:

General view – Identifies the run, when it was executed and what its result was.

Results view – Lists the run's extraction requests.

Incidents view – Lists all errors, warnings and remarks pertaining to the run.

Assigned Kit Reagents view – Lists the reagent lots used in the run that have been assigned to extractions.

On-board Reagents view – Identifies the reagents used in processing the run.

View Results Work Area – General View

The *General* view shows detailed run information.

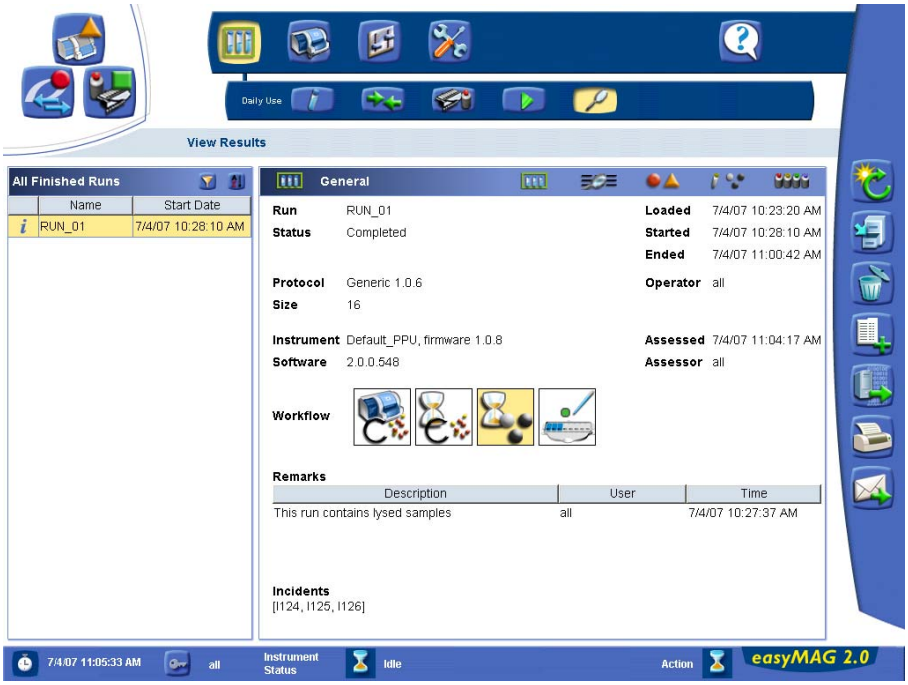


Figure D-10: View Results work area - General view

Run List		
Unassessed runs only	Lists the runs that have not yet been assessed.	
		Click the funnel button to show all runs, assessed and unassessed.
		Reset the sorting of the runs according to their start date.
Column 1	Displays a symbol if errors, warnings and remarks pertain to the run.	
Name	Unique name of the run, defined when the run was created.	
Start Date	Date and time the run was started.	
General		
Run	Unique name of the run, defined at run creation.	
Loaded	Date and time the run was loaded.	
Status	Indicates whether or not the run was completed, has failed or was aborted. Note that a run that was completed may have errors for one or more individual extraction requests, but not all. Refer to the *Results* view for details.	
Started	Date and time the run was started.	
Ended	Date and time the run finished.	
Protocol	Extraction protocol for this run, includes version.	
Operator	User that loaded the run.	
Size	Number of extraction requests assigned to the run.	
Instrument	Identifies the instrument on which the run was executed. Includes instrument firmware version.	
Assessed	Date and time the run was assessed.	
Software	Software version with which the run was executed.	
Assessor	User that assessed the run.	
Workflow icons	On-board lysis addition	Indicates whether on-board lysis addition is enabled (yellow) or disabled (white).
	On-board lysis buffer incubation	Indicates whether on-board lysis incubation is enabled (yellow) or disabled (white).
	On-board silica incubation	Indicates whether on-board silica incubation is enabled (yellow) or disabled (white).
	Sample guidance	Indicates whether on-board sample addition is enabled (yellow) or disabled (white).
Remarks	Table listing user remarks.	
Description	User remark text.	
User	Identifies the user that created the remark.	
Time	Time when the remark was added.	
Incidents	List of error and warning codes that have occurred. When the list is not empty, please refer to the *Incidents* view for details.	

View Results Work Area – Results View

The *Results* view shows result data for all samples and related information.

Figure D-11: View Results work area - Results view

Samples		
1...24	Each number represents a single vessel in a sample strip. Vessels where a sample is loaded display the sample ID and the used protocol. Symbols in front of the number indicate various status information.	
	Incident/ Remark	A symbol is displayed for the origin of the entry. A remark is always user-created, whereas an incident is indicated by a status icon.
		This sample was lysed outside the instrument.
		Indication that the sample has been sent.
		Indication that the sample is currently sent.
		Indication that the sample has not been sent.

Sample details		
Sample ID	Identification of sample, typically the sample barcode. Symbols in front of the sample ID indicate various status information.	
		This sample was lysed outside the instrument.
		Indicates that the sample is marked as ‘High Priority‘.
		Indicates that this sample has been marked for re-testing in the *View Results* work area.
Volume (ml)	Input volume of sample.	
Eluate (ml)	Volume of eluate produced.	
Matrix	Sample type, for example plasma or whole blood.	
Application	Indicates on which application the extraction request was created. Contains application type and application Id when not created on this ***NucliSENS easyMAG***, otherwise it contains a 'locally created' indication.	
Created by	User that created the extraction request	
Timestamp	Creation date of the extraction request.	
Sample Incidents		
Positional Incidents and Remarks	Section that lists the incidents and remarks pertaining to the vessel position 1-24 selected in the above list. Note: This section does not list incidents and remarks for sample strips or the entire run. (Please refer to the *Incidents* view.)	
Column 1	Incident/ Remark	A symbol is displayed for the origin of the entry. A remark is always user-created, whereas an incident is indicated by a status icon.
Column 2	Displays a symbol for the application which originated the incident.	
Application ID	ID of the application which originated the incident.	
Code	Error or warning code. Remarks do not have a code.	
Description	Description of the incident or the user remark text.	
Time	Time when the incident occurred or the remark was added.	

View Results Work Area – Incidents View

The *Incidents* view shows incidents and remarks assigned to the selected run.

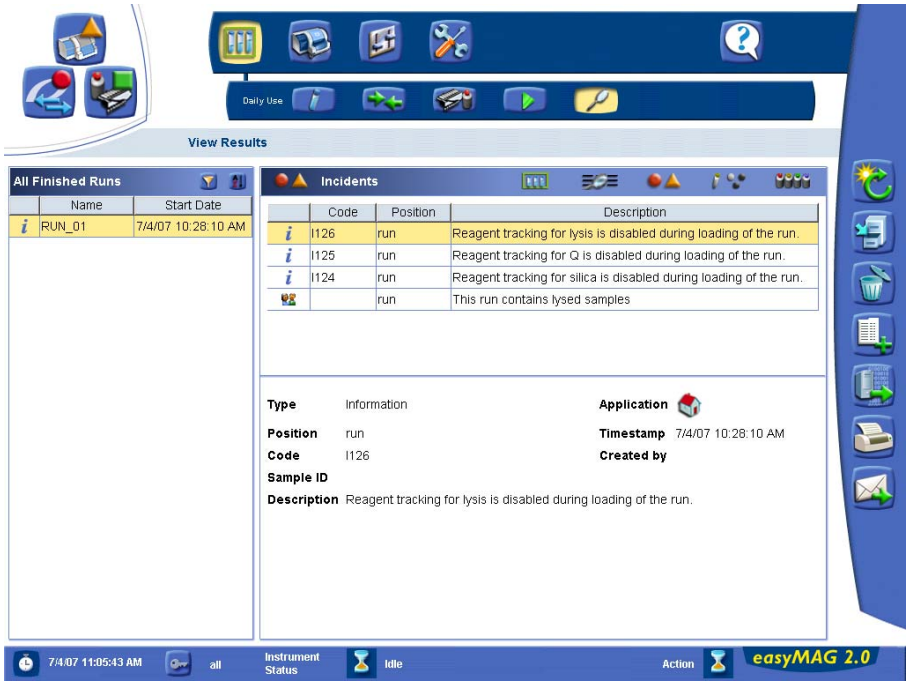


Figure D-12: View Results work area - Incidents view

Incidents		
Column 1	Incident/ Remark	A symbol is displayed for the origin of the entry. A remark is always user-created, whereas an incident is indicated by a status icon.
Code	Error or warning code. Remarks do not have a code.	
Position	1-24	The incident applies to the given vessel only.
	A, B or C	The incident applies to the sample strip at position A, B or C
	run	The incident applies to the entire run.
Description	Description of the incident or the user remark text.	
Incident Details		
Type	Error, warning, information or remark.	
Position	1-24	The incident applies to the given vessel only.
	A, B or C	The incident applies to the sample strip at position A, B or C
	run	The incident applies to the entire run.
Code	Error, warning or information code. Remarks do not have a code.	
Sample ID	Identification of sample, typically the sample barcode.	
Description	Description of the incident or the user remark text.	
Application	Indicates on which application the incident was created. Contains application type and application Id when not created on this ***NucliSENS easyMAG***, otherwise it contains a 'locally created' indication.	
Timestamp	Time when the incident occurred or the remark was added.	
Created by	User that created the extraction incident.	

View Results Work Area – Assigned Kit Reagents View

The *Assigned Kit Reagents* view shows the kit reagents that have been assigned to the samples and were used during the extraction process.

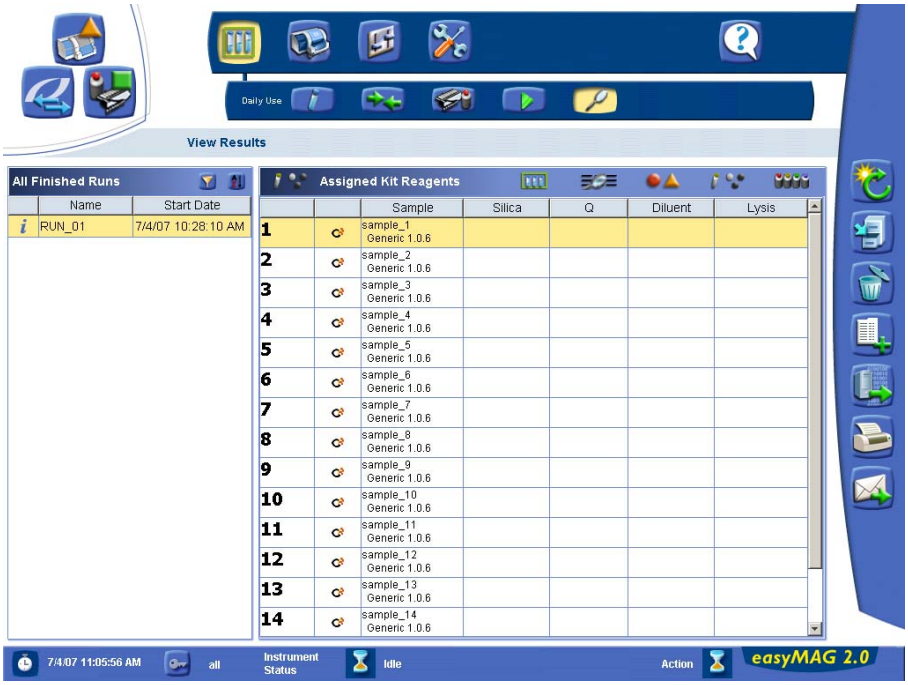


Figure D-13: View Results work area - Assigned Kit Reagents view

Assigned Kit Reagents		
1-24	Sample position.	
Column 2		Indicates if the sample has been lysed outside the instrument.
Sample	Sample ID and protocol version number.	
Silica	Used Silica reagent lot used for the sample.	
Internal control	Used internal control reagent lot used for the sample.	
Lysis	Used Lysis reagent lot used for the sample, when lysis has not been performed on the instrument.	

View Results Work Area – Reagents View

The *Reagents* view shows the product and lot numbers of the reagents that were used during the extraction process.

The bottles are displayed on the screen exactly as they are placed on the instrument. Calibrator/control and silica lot numbers are displayed below the bottles.

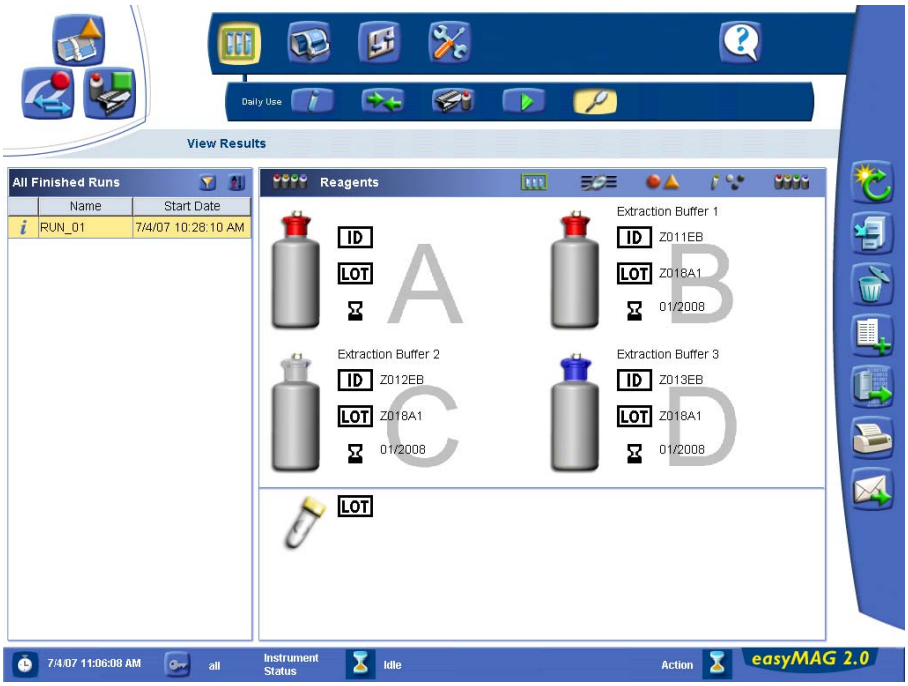


Figure D-14: View Results work area - Reagents view

Reagents	
ID	Reagent product identification.
LOT	Reagent lot number.
⧗	Reagent expiry date.

Instrument Menu

Reagent Inventory Work Area

The *Reagent Inventory* work area displays the type and volume of bottled reagent installed on the instrument. This work area supports the user in installing and identifying the right reagents.

The *Reagent Inventory* work area is displayed when the *Reagent Inventory* sub-menu is chosen from the *Instrument* menu. Alternatively, the *Reagent Inventory* work area is shown when the user presses the *Reagent Inventory* action button in the *Load Run* work area.

When the *Reagent Inventory* work area is invoked from within the *Load Run* work area, the information shown shall be related to the run that the user is currently loading. For example, each bottle will list what type of reagent is required for that run when no bottle or the wrong bottle is currently placed.

Error indicators above the bottles indicate whether the reagent installed for that position is correct for the selected run.

Figure D-15: Reagent Inventory work area

Info		
Info	This area identifies the run that is being loaded.	
Run	Unique name of the run, defined when the run was created. All unassessed runs can be selected from the drop-down box.	
Protocol	Extraction protocol and version number for this run.	
Size	Number of extraction requests assigned to the selected run.	
Workflow icons	On-board lysis addition	Indicates whether on-board lysis addition is enabled (yellow) or disabled (white).
	On-board lysis buffer incubation	Indicates whether on-board lysis incubation is enabled (yellow) or disabled (white).
	On-board silica incubation	Indicates whether on-board silica incubation is enabled (yellow) or disabled (white).
	Sample guidance	Indicates whether on-board sample addition is enabled (yellow) or disabled (white).
Barcode Input		
Barcode Input	This area is where the user scans barcodes. Select the bottle position first.	
Position	Bottle position upper left (A), upper right (B), lower left (C) or lower right (D).	
	Displays the scanned barcode. When not using the barcode scanner, please type the barcode in this field.	
Name	Reagent name.	
	Reagent product identification.	
	Reagent lot number.	
	Reagent expiry date.	

Device Status Work Area

The *Device Status* work area shows detailed information about the status of each of the devices that the system is made up of.

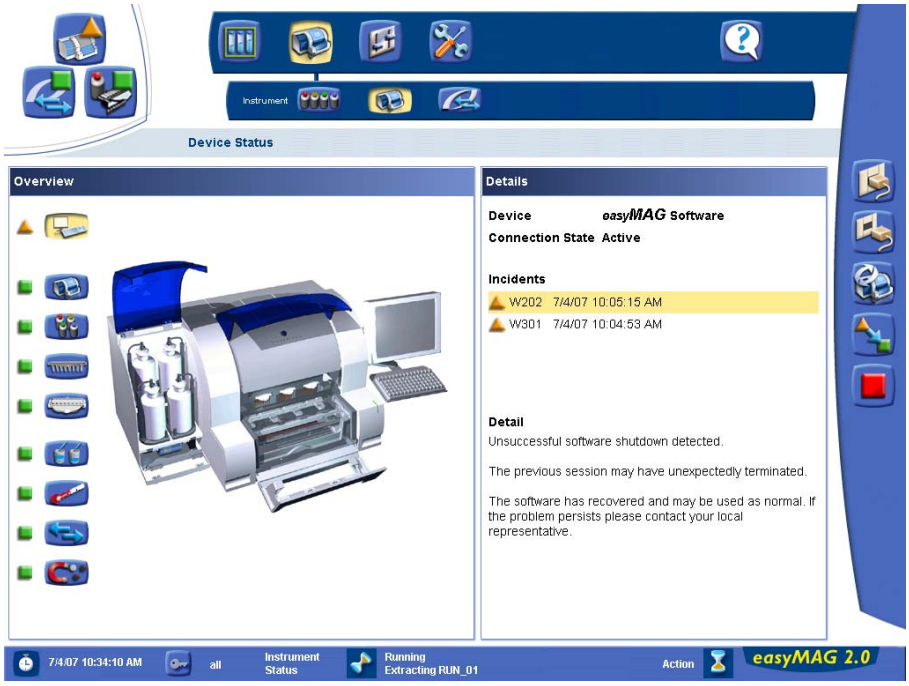


Figure D-16: Device Status work area

Overview	
Overview	Click a button to view detailed status information about an instrument device (sub-system.)
	View the status of the software.
	View the status of the instrument.
	View the status of the reagent bay.
	View the status of the aspiration device.
	View the status of the sample device.
	View the status of the dispenser.
	View the status of the heater.
	View the status of the mixer.
	View the status of the silica capture device.
Device	Name of the device selected in the Overview area.
Connection State	Status of the selected device.
Incidents	Lists incidents pertaining to the selected device. Select one to view details.
Detail	Details about the selected incident if any.

NucliSENtral Status Work Area

The ***NucliSENtral*** *Status* work area shows detailed information about the connection status of the ***NucliSENtral*** network.

The example below illustrates the situation in which the ***NucliSENtral*** network is disabled.

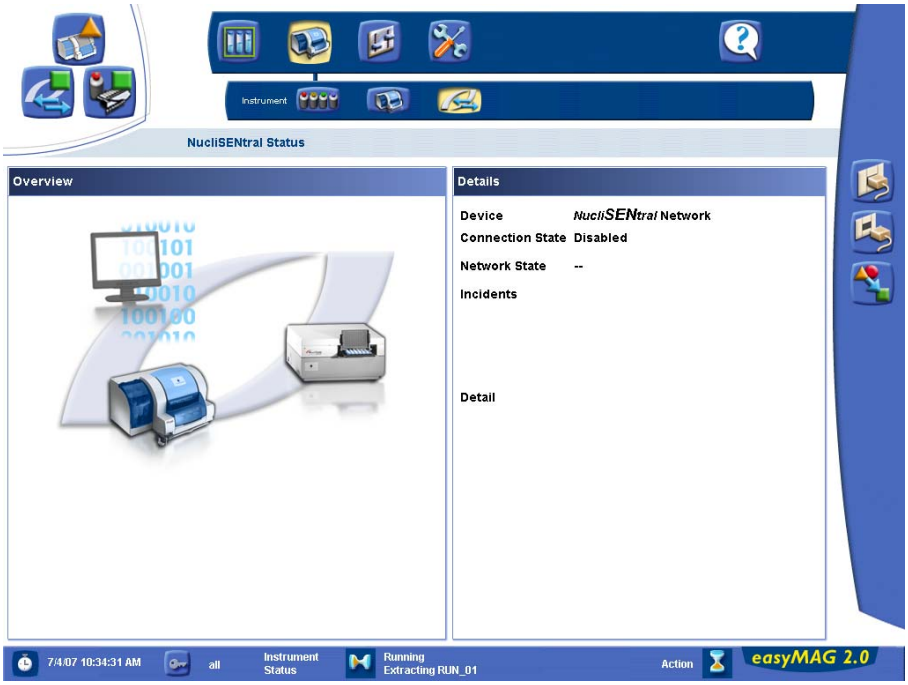


Figure D-17: ***NucliSENtral*** *Status work area*

Overview	
Overview	Illustration of a typical ***NucliSENtral*** configuration.
Details	
Device	Name of the ***NucliSENtral*** network.
Connection State	Status of ***NucliSENS easyMAG*** connection to ***NucliSENtral***.
Network State	Status of the ***NucliSENtral*** network.
Incidents	Lists incidents concerning the data communication through ***NucliSENtral***. Select one to view details.
Detail	Details about the selected incident if any.

Settings Menu

The *Settings* menu contains work areas in which the user or system administrator can configure several aspects of the system.

Application Settings Work Area

The *Application Settings* work area contains five categories. Select a category in the left part of the work area in order to view or modify application settings belonging to that category.

Overview	Select one of the categories to view or modify settings pertaining to the workflow, the barcode reader, instrument communication or sounds.	
	Workflow	Select this category to customize the system to local needs.
	Barcode Reader	Select this category to modify the barcode reader settings.
	Instrument Communication	Select this category to modify the way the software communicates with the instrument.
	NucliSENtral Communication	Select this category to define the settings for communication with the ***NucliSENtral*** network.
	Sounds	Select this category to turn on or mute system sounds.

Application Settings Work Area – Workflow

In the example below, the workflow is configured for the Generic 1.0.6 protocol using primary samples and on-board lysis buffer dispensing and incubation as well as silica incubation. Sample tracking and reagents tracking are disabled. Auto-generated extraction requests shall be named ‘sample_##’, where ‘##’ shall be replaced by an ascending number.

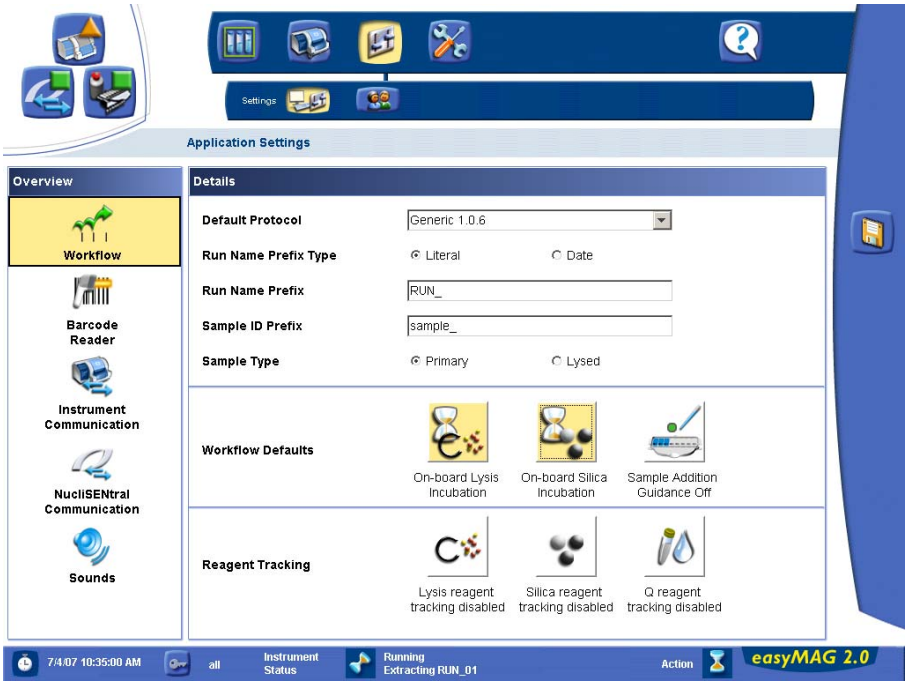


Figure D-18: Application Settings work area - Workflow details

Details		
Default Protocol	Select the protocol that shall be used for new extraction requests as default.	
Run Name Prefix Type	Literal	The default run name prefix is used for new run names.
	Date	The current date is used for new run names. If ‘Date‘ is selected, the option ‘Run Name Prefix‘ is disabled.
Run Name Prefix	Default prefix for new runs, if ‘Literal‘ is selected as run name prefix type.	
Sample ID Prefix	Default sample ID prefix for auto-generated extraction requests. See the *Organize Runs* work area for details on auto-generating extraction requests (section Organize Runs Work Area).	
Sample Type	Primary	Select this option when working with primary samples.
	Lysed	Select this option when working with lysed samples.

Workflow Defaults	On-board Lysis Incubation	Enable this option (yellow) to have the instrument incubate the samples in lysis buffer. Disable this option (white) to incubate the samples in lysis buffer off-board, for example in a protective cabinet.
	On-board Silica Incubation	Enable this option (yellow) to have the instrument incubate the silica reaction. Disable this option (white) to incubate the silica reaction off-board, for example in a protective cabinet.
	Sample Addition Guidance	Enable this option (yellow) to turn on sample tracking. When loading the run the user shall need to identify individual samples. The system LED's shall light to indicate where the identified sample should be pipetted. Disable this option (white) to turn off sample tracking.
Reagent Tracking	Lysis Reagent Tracking	Enable this option (yellow) to turn on lysis reagent tracking. The user must identify the lysis reagent before a run can be started. Disable this option (white) to turn off lysis reagent tracking.
	Silica Reagent Tracking	Enable this option (yellow) to turn on silica reagent tracking. The user must identify the silica reagent before a run can be started. Disable this option (white) to turn off silica reagent tracking.
	Internal control Reagent Tracking	Enable this option (yellow) to turn on internal control reagent tracking. The user must identify the internal control reagent before a run can be started. Disable this option (white) to turn off internal control reagent tracking.

Application Settings Work Area – Barcode Reader

The *Barcode Reader* category is used to view or modify communication settings pertaining to the barcode reader.

When the barcode reader is not connected, please connect it first and then re-start the software. After the software has been re-started try scanning bar-codes in one of the system's barcode input areas, for example in the 'Reagent Inventory' work area. Only when the barcode reader does not appear to be working, try changing settings as described in this section.

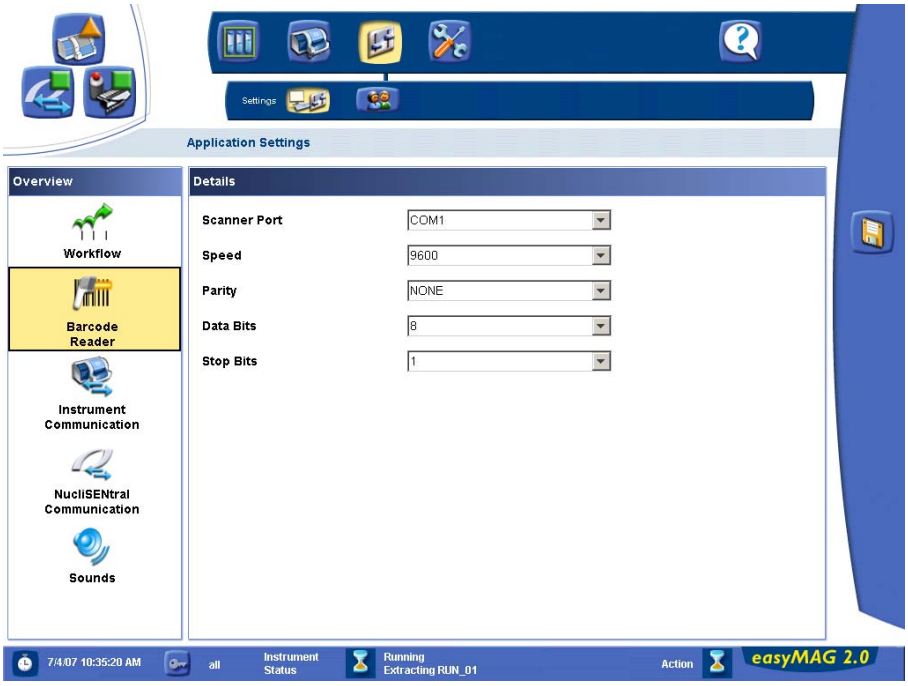


Figure D-19: Application Settings work area - Barcode reader details

Details	
Scanner Port	Select the COM port to which the barcode reader is connected.
Speed	Transmission speed.
Parity	Parity used.
Data Bits	Number of data bits in a packet.
Stop Bits	Number of stop bits in a packet.

Application Settings Work Area – Instrument Communication

Changing these settings may cause the communication between the instrument and the software to be lost

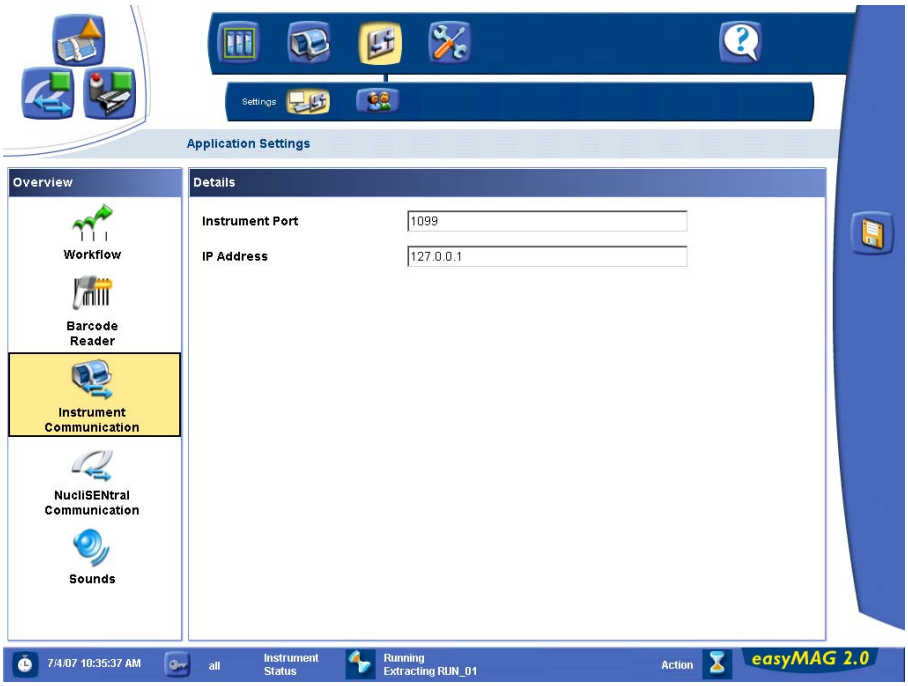


Figure D-20: Application Settings work area - Instrument Communication

Details	
Instrument Port	Port number used by the instrument connection.
IP Address	IP address of the instrument.

Application Settings Work Area – *NucliSENtral* Communication

*Changing these settings may cause the communication between the software and the **NucliSENtral** network to be lost!*

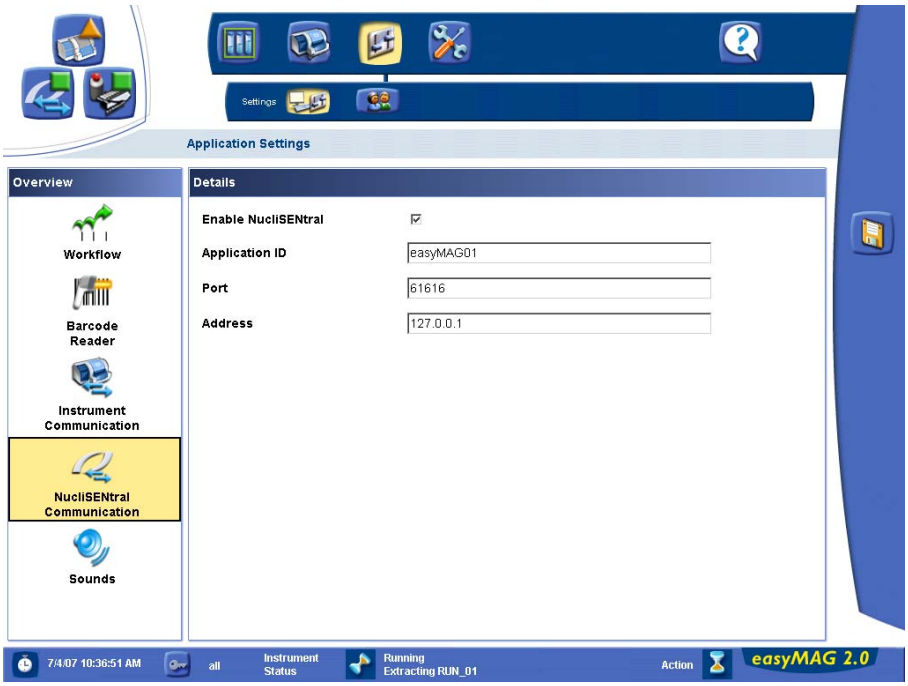


*Figure D-21: Application Settings work area - **NucliSENtral** Communication*

Details	
Enable ***NucliSENtral***	Enable this option to activate ***NucliSENtral*** communication and to enter the ***NucliSENtral*** network settings.
Application ID	Enter a unique identification of ***NucliSENS easyMAG*** to be able to participate in ***NucliSENtral*** data communication.
Port	Enter the port of the ***NucliSENtral*** network.
Address	Enter the IP address of the ***NucliSENtral*** network.

Application Settings Work Area – Sounds

In the example below a beep or short tune shall sound when a protocol finishes execution or when a dialog is displayed. The occurrence of an alarm shall also be signalled by a beep.

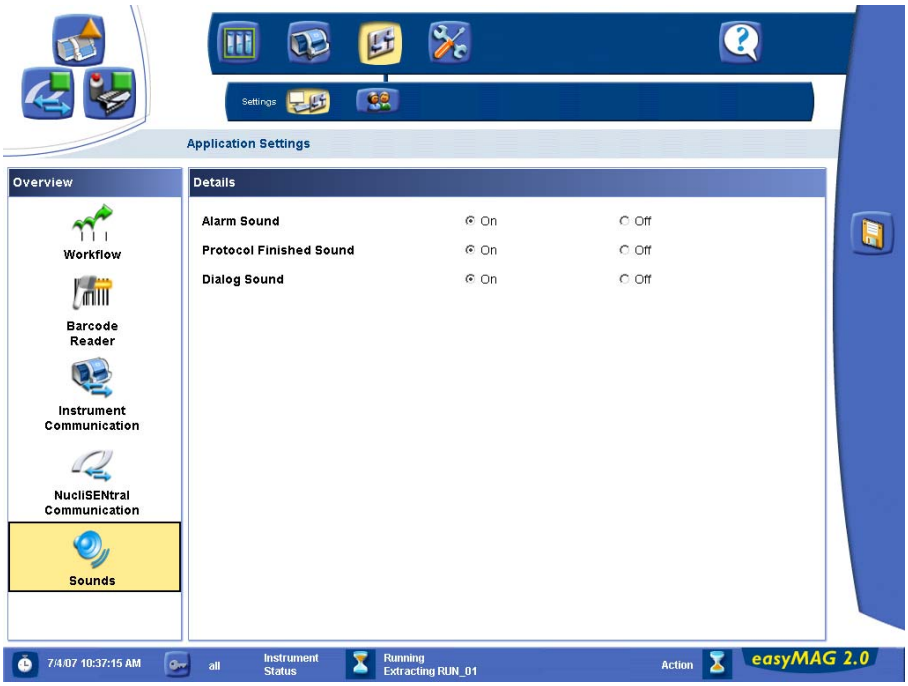


Figure D-22: Application Settings - Sound Details

Alarm sound	On	Sound a beep whenever an alarm occurs.
	Off	Mute the alarm sound.
Protocol Finished Sound	On	Sound a beep when an extraction protocol has finished execution.
	Off	Mute the protocol sound.
Dialog Sound	On	Sound a beep whenever a confirmation, error or other dialog is displayed.
	Off	Mute the dialog sound.

User Administration Work Area

The *User Administration* work area is for adding or removing user accounts. Users are members of pre-defined security groups. Being a member of one or more security groups determines what functionality a user has access to.

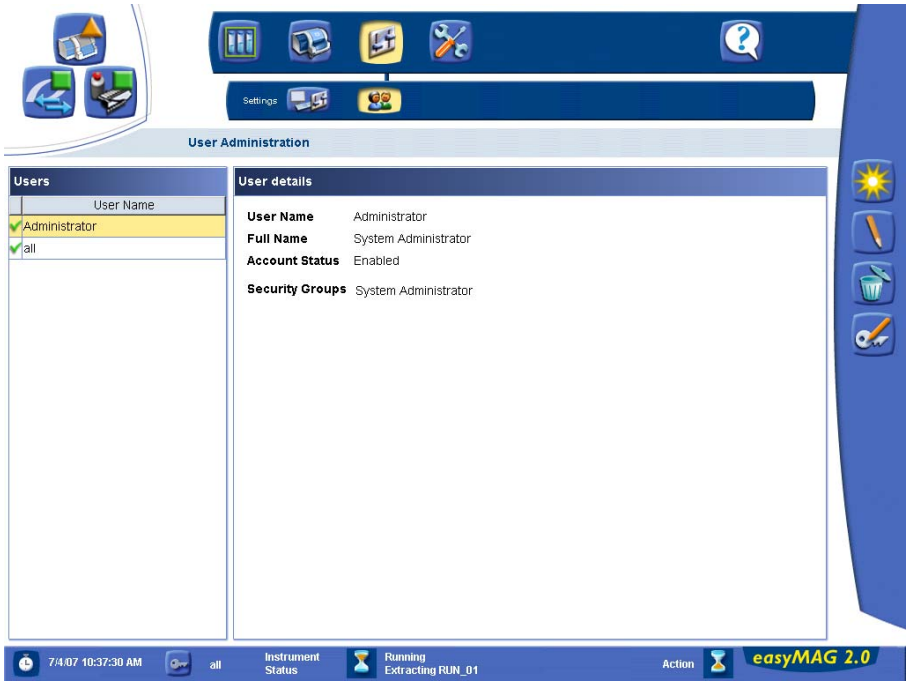


Figure D-23: User Administration work area

Users		
Users	Lists the user accounts that are known to the system. Select a user to view details.	
Column 1	✔	User account enabled.
	✘	User account disabled.
User Details		
User Name	Login name of the user.	
Full name	Full name of the user	
Account Status	Enabled	The user is allowed to login and use the system.
	Disabled	The user is not allowed to login and use the system.
Security Groups	Security groups to which the selected user is assigned. Being part of a certain group allows a user access to functionality of that group. To use the system, a user must be a member of at least one security group. A user may belong to more than one group.	

Maintenance Menu

Maintenance Work Area

The *Maintenance* work area is where the user performs routine maintenance protocols. Similar to the *Load Run* work area, the user must make sure that all reagents required for a certain maintenance protocol are installed.

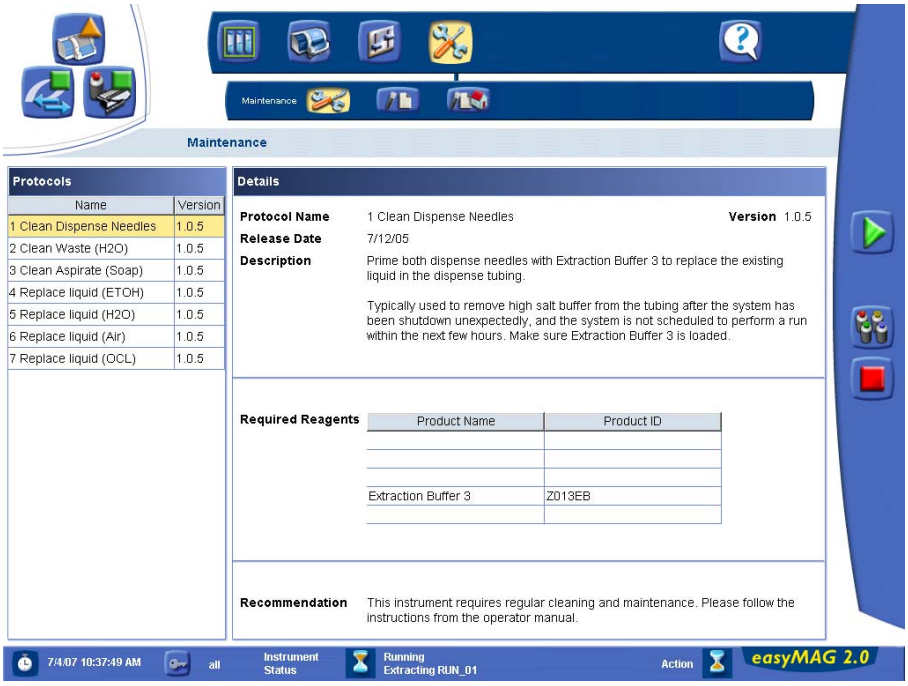


Figure D-24: Maintenance work area

Protocols	
Protocols	Lists the available maintenance protocols. Select one to view details.
Name	Name of the maintenance protocol.
Version	Version of the maintenance protocol.
Details	
Protocol Name	Name of the maintenance protocol.
Version	Version of the maintenance protocol.
Release Date	Release date of the maintenance protocol.
Description	Description of the maintenance protocol.
Required Reagents	Lists the reagents that are to be installed on the instrument in order to execute the selected maintenance protocol.
Product Name	Reagent product name.
Product ID	Reagent product identification.
Recommen-dation	Recommendations for proper execution of the maintenance protocol.

Protocol Inventory Work Area

The *Protocol Inventory* work area is where all protocols are maintained. When a new assay, extraction protocol or maintenance protocol becomes available, it can be imported here.

Protocols can be activated and deactivated to govern which protocols can actually be executed.

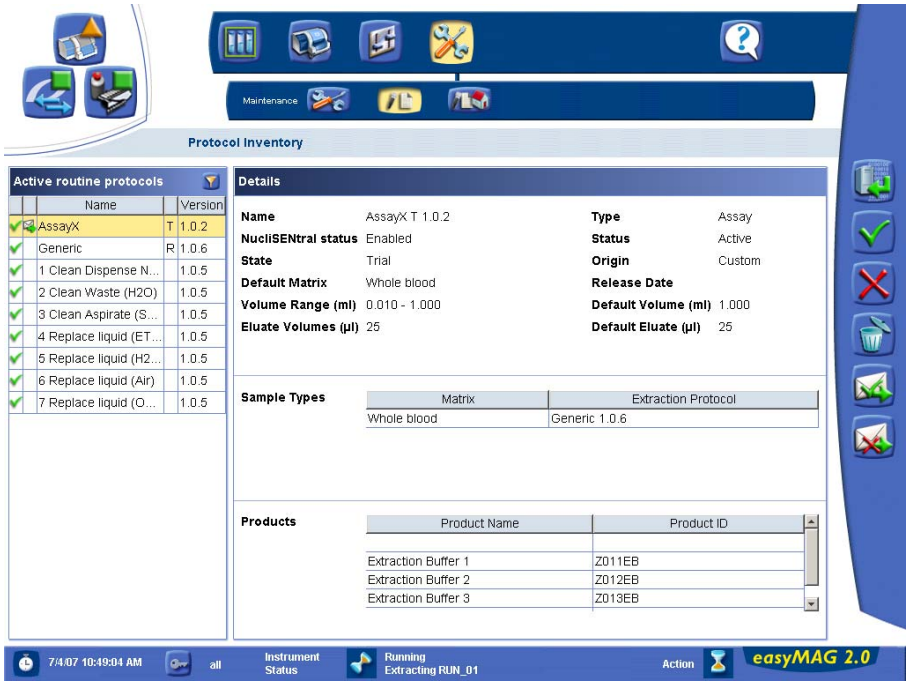


Figure D-25: Protocol Inventory work area

Active routine protocols		
Active routine protocols	Lists the active extraction and maintenance protocols. Select one to view details. Click the funnel button to view both active and inactive protocols.	
Column 1	✔	Active protocol.
	✘	Inactive protocol.
Column 2		Protocol enabled for sending to ***NucliSENtral***
Name	Name of the protocol.	
Column 3	R	‘Released’ protocol
	T	‘Trial’ protocol

Details		
Name	Name and version of the protocol.	
Type	Assay	The selected protocol is an assay protocol. An assay protocol uses an extraction protocol to perform the actual extraction.
	Extraction	The selected protocol is an extraction protocol
	Maintenance	The selected protocol is a maintenance protocol.
Nucli-SENtral Status	Enabled	The selected protocol is enabled for sending to ***NucliSENtral***.
	Disabled	The selected protocol is disabled for sending to ***NucliSENtral***.
Status	Active	The protocol can be executed.
	Inactive	The protocol cannot be executed.
State	Trial	The protocol has status ‘Trial‘ assigned.
	Released	The protocol has status ‘Released‘ assigned.
Origin	Custom	Customer-created protocol.
	BioMérieux	Protocol created by bioMérieux.
Default Matrix	Default matrix for this protocol.	
Release Date	Date the protocol was released.	
Volume Range (ml)	Range of permitted input volumes for this protocol.	
Default Volume (ml)	Default input volume required for this protocol.	
Eluate Volumes (ml)	Set of possible eluate volumes for this protocol.	
Default Eluate (ml)	Default eluate volume produced by this protocol.	
Sample Types	Lists the sample types to which the protocol applies.	
Matrix	Matrix for which the protocol is suitable.	
Extraction Protocol	Displays the extraction protocol and version number used by the selected assay protocol.	
Products	Lists the reagents that are to be installed on the instrument in order to execute the selected maintenance protocol. Use the *Reagents Inventory* work area to install reagents.	
Product Name	Reagent product name.	
Product ID	Reagent product identification.	

Assay Development Work Area

The *Assay Development* work displays all customer-created assay protocols with details. New assay protocols can be created or existing assay protocols be edited.
Assay protocols can be activated and deactivated to govern which protocols are currently displayed in the list. Assay protocols can also be promoted from 'Development' to 'Trial' and from 'Trial' to 'Released' state to be available in the *Protocol Inventory* work area.
The example below displays details about a customer-created assay protocol.

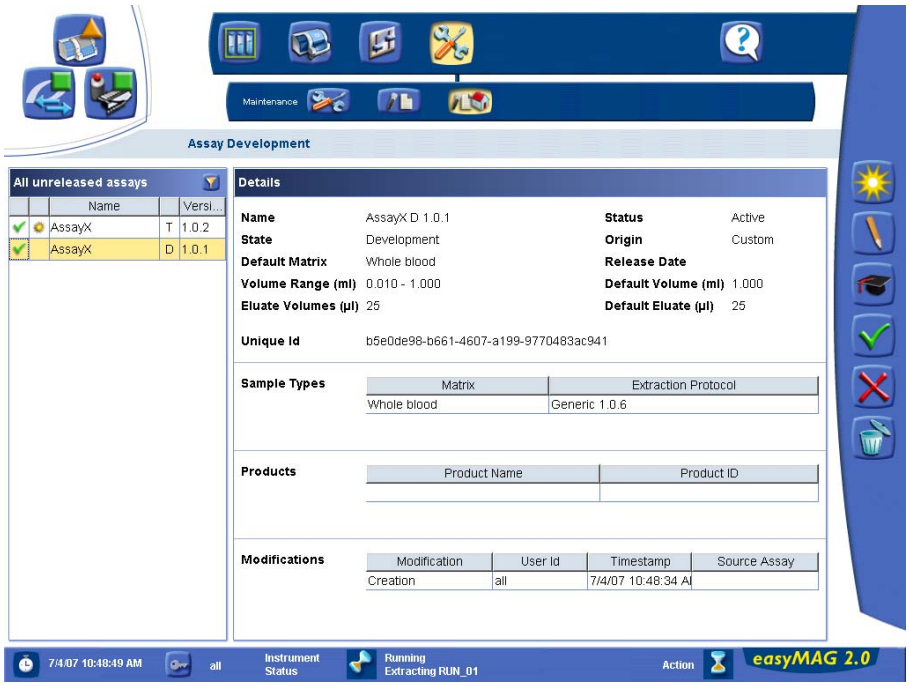


Figure D-26: Assay Development work area

All unreleased assays		
All unreleased assays	Lists unreleased assay protocols. Click the funnel button to view both released and unreleased assay protocols.	
Column 1	✔	Active assay protocol.
	✘	Inactive assay protocol.
Column 2	☼	The most recent version of the assay in this development tree.
Name	Name of the assay protocol.	

Column 3	R	'Released' assay protocol
	T	'Trial' assay protocol
	D	'Development' assay protocol.
Version	Version of the assay protocol.	
Details		
Name	Name and version number of the selected assay protocol.	
Status	Active	The assay protocol can be executed.
	Inactive	The assay protocol cannot be executed.
State	Development	The assay protocol has status 'Development' assigned.
	Trial	The assay protocol has been promoted to 'Trial' status.
	Released	The assay protocol has been promoted to 'Released' status.
Origin	Custom	Customer-created assay protocol.
Default Matrix	Default matrix for this protocol.	
Release Date	Date the protocol was released, if applicable.	
Volume Range (ml)	Range of permitted input volumes for this protocol.	
Default Volume (ml)	Default input volume required for this protocol.	
Eluate Volumes (ml)	Set of possible eluate volumes for this protocol.	
Default Eluate (ml)	Default eluate volume produced by this protocol.	
Unique ID	Every assay protocol has a unique ID assigned.	
Sample Types	Lists the sample types to which the assay protocol applies.	
Matrix	Matrix for which the assay protocol is suitable.	
Extraction Protocol	Displays the extraction protocol and version number used by the selected assay protocol.	
Products	Lists the reagents that are to be installed on the instrument in order to execute the selected assay protocol. Use the *Reagents Inventory* work area to install reagents.	
Product Name	Reagent product name.	
Product ID	Reagent product identification.	
Modifications	Modifications of the assay protocol since creation date.	
Modification	Type of modification (creation, promotion, edit...).	
User ID	User that made the modification.	
Timestamp	Date of modification.	
Source Assay	Assay protocol version the selected assay protocol is based on.	

Help Menu

About Work Area

The *About* work area contains three categories. Select a category in the left part of the work area in order to display information belonging to that category.

Overview	Select one of the categories to display information about the application, system or third-party software.	
	Application Info	Select this category to display information about the current application software.
	System Info	Select this category to display system related information.
	Credits	Select this category to display licensing information about third-party software.

About Work Area – Application Info

Here information about the application software is displayed.

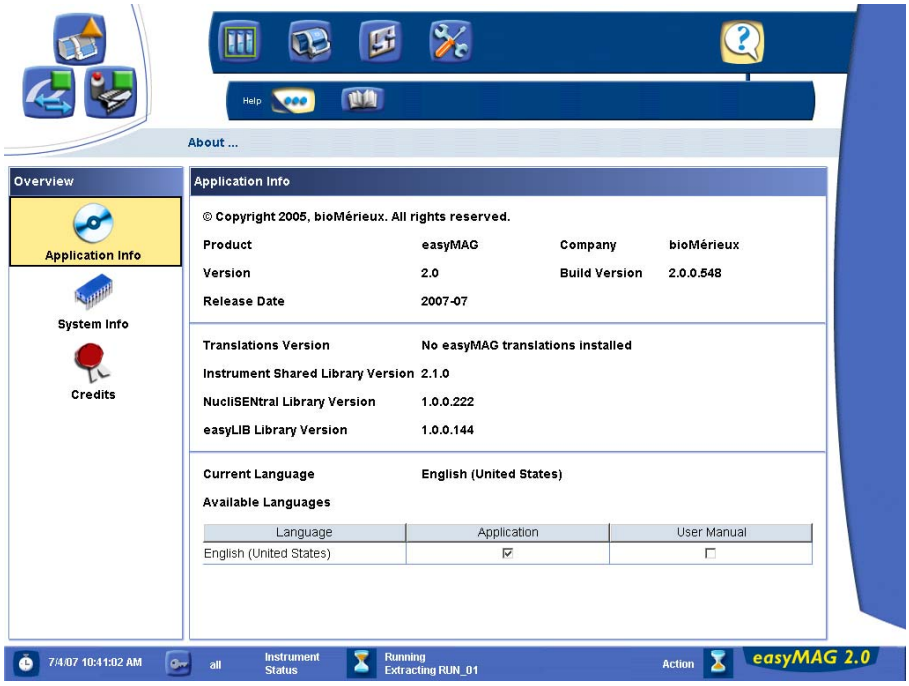


Figure D-27: About work area - Application Info

Application Info	
Product	Name of the application software.
Company	Manufacturer of the application software.
Version	Version number of the application software.
Build Version	Detailed version number of the application software.
Release Date	Release date of the application software.
Transla-tions Ver-sion	Installed languages of the application software.
Instrument Shared Library Version	Version number of the instrument shared library.
Nucli-SENtral Library Version	Version number of the ***NucliSENtral*** library.
easyLIB Library Version	Version number of the easyLIB library.
Current Language	Current language of the application software.
Available Languages	Lists all installed languages for the application software.
Language	Installed language.
Application	Language available for the application software.
User Manual	User manual available in selected language.

About Work Area – System Info

Here information about the system is displayed.

Figure D-28: About work area - System Info

System Info	
Memory Usage	Information about memory usage of the system.
Free Memory	Amount of currently free memory (kb).
Used Memory	Amount of used memory by the system (kb).
Total memory	Amount of total system memory (kb).
System Properties	Lists various system configuration and settings details.
Name	Name of the system setting or system configuration.
Value	Type or value of the system setting or system configuration.

About Work Area – Credits

Here licensing information about third-party software is displayed.

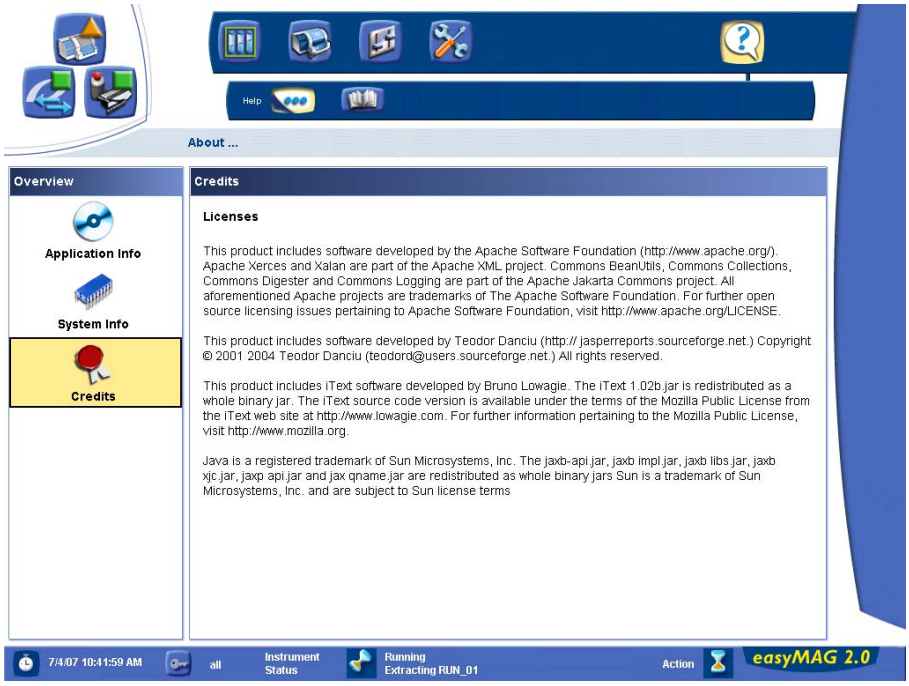


Figure D-29: About work area - Credits

Credits	
Licenses	Statement about third-party software used by the application software.

User Manual Work Area

If the *User Manual* work area is opened, the user manual file opens and is displayed in a separate window. The user can browse for information in this electronic user manual.

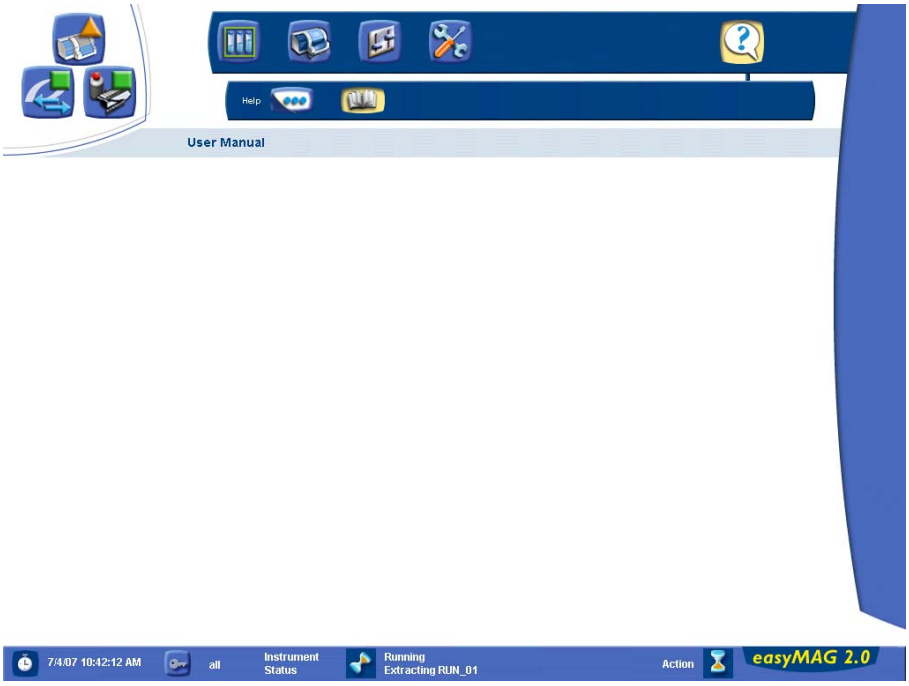
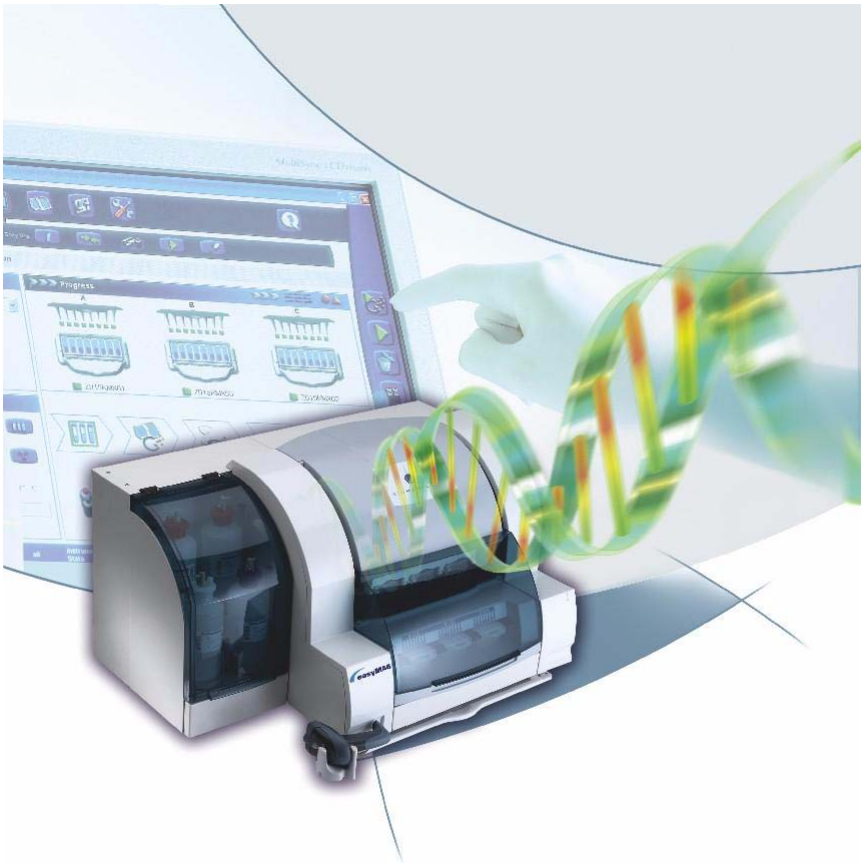


Figure D-30: User Manual work area

E Addendum

Generic Extraction, Additional Information



Intended Use

The ***NucliSENS easyMAG*** platform is intended for the automated isolation (purification and concentration) of total nucleic acids (RNA/DNA) from biological specimens. For in vitro diagnostic use.

Summary And Explanation

This supplement is intended to be used in combination with the ***NucliSENS easyMAG User Manual*** to provide the user with the information required to develop and process 'home-made' nucleic acid analysis and detection solutions. After the ***NucliSENS easyMAG*** platform has been properly validated by the user, the nucleic acids prepared by the ***NucliSENS easyMAG*** platform are suitable for a variety of nucleic acid analysis and detection methods. Always consult individual instructions for use for further details when using the ***NucliSENS easyMAG*** platform in conjunction with downstream analysis and detection platforms.

Principle Of The Method

The ***NucliSENS easyMAG*** nucleic acid extraction method is based on Boom chemistry[1] using magnetic silica particles. Briefly, under high salt conditions, nucleic acid will bind to the silica particles. These silica particles act as solid phase and non-nucleic acid components are removed by several washing steps performed in the ***NucliSENS easyMAG*** instrument. Next, nucleic acids are eluted from silica particles and the silica particles are removed from the extracted specimens by the ***NucliSENS easyMAG*** instrument. The resulting eluate contains purified and concentrated total nucleic acids.

NucliSENS easyMAG Platform

NucliSENS easyMAG extraction products

REF 200292	48x 2 ml	***NucliSENS Lysis Buffer***	⚠
REF 280134	4x 1000 ml	***NucliSENS easyMAG Lysis Buffer***	⚠
REF 280133	48x 0.6 ml	***NucliSENS easyMAG Magnetic Silica***	
REF 280130	4x 1000 ml	***NucliSENS easyMAG Extraction buffer 1***	⚠
REF 280131	4x 1000 ml	***NucliSENS easyMAG Extraction buffer 2***	
REF 280132	4x 1000 ml	***NucliSENS easyMAG Extraction buffer 3***	
REF 280135	48x	***NucliSENS easyMAG Disposables***	

For detailed instructions on the use of these products, consult the ***NucliSENS easyMAG User Manual*** (REF 280163, Chapter 3, *System basics* and Chapter 6, *Operating procedures*).

1. Boom R, Sol CJA, van der Noordaa J, et al. (1990). Rapid and simple method for purification of nucleic acids. J.Clin.Microbiol.28, 495-503.

Warnings And Precautions

Certain reagents contain guanidine thiocyanate
***R21/22**: Harmful in contact with skin and if swallowed.*
***R32**: Contact with acid liberates very toxic gas.*
***S26**: In case of contact with eyes rinse immediately with plenty of water and seek medical advice.*
***S36/37/39**: Wear suitable protective clothing, gloves and eye/face protection*

Buffers containing guanidine thiocyanate should not be mixed with cleaning solutions containing bleach. Liquid waste from extraction and isolation procedures containing guanidine thiocyanate must not be mixed with other laboratory waste. This will prevent harmful chemical reactions from occurring.

*Storage of **NucliSENS easyMAG Lysis Buffer** and **NucliSENS easyMAG Extraction Buffer 1** may give rise to the appearance of crystals due to the high salt concentration. These crystals must be dissolved during reagent preparation. Consult the **NucliSENS easyMAG User Manual** (REF 280163).*

Specimen Types

The ***NucliSENS easyMAG*** platform has been validated for plasma, serum, CSF, blood, sputum and stool specimen. Some specimen types (sputum and stool) require preparation steps prior to the use on the ***NucliSENS easyMAG*** platform. Consult your local bioMérieux representative for detailed instructions on these procedures.

Procedure

Refer to ***NucliSENS easyMAG User Manual*** (REF 280163, Chapter 6, *Operating procedures*) for detailed instructions on the ***NucliSENS easyMAG*** operating procedures.

Limitations Of The Procedure

Refer to the ***NucliSENS easyMAG User Manual*** (REF 280163, Chapter 3, *System basics*) for limitations of the procedure.

Performance Characteristics

Performance characteristics are based on limited studies.

Specimen Types

*The user is responsible for validating the **NucliSENS easyMAG** platform in their local setting in accordance to local regulations and to determine whether the performance of the platform meet their needs.*

*The **NucliSENS easyMAG** platform supports the use of internal controls/calibrators which may be required for downstream specific nucleic acid analysis and detection. The use of internal controls could be beneficial when establishing or monitoring the performance of the extraction process.*

Viral Nucleic Acid Recovery

In order to detect and analyze rare nucleic acids from microorganisms, such as viruses, the ***NucliSENS easyMAG*** platform has been used to extract viral nucleic acids from different specimen types. Viral recovery of nucleic acid was measured by spiking a fixed amount of intact viral particles to primary specimens. The viral nucleic acid was detected in all extracted specimens by using real-time PCR. Based on the measured threshold cycles[1] (Ct values), the amount of viral nucleic acid present in the extracted specimens was estimated as + (10-35%), ++ (35-70%), or +++ (>70%). The NucliSENS® miniMAG™ was used as reference extraction method.

1. The threshold cycle (Ct value) is defined as the cycle number of the PCR at which the signal passes the baseline (threshold) and is statistically significant above the background signal.

Recovery Of Viral Nucleic Acid In Different Specimen Types

			Nucleic acid recovery		
Specimen	n=	Specimen volume	***NucliSENS easyMAG*** [on board]	***NucliSENS easyMAG*** [off board]	***NucliSENS miniMAG***
Plasma	20	1 ml	✓+++	✓+++	✓+++
Serum	20	1 ml	✓+++	✓+++	✓+++
Blood	20	0.1 ml	✓++ *	✓+++	✓+++
CSF	20	0.25 ml	✓+++	✓+++	✓+++
Sputum **	40	0.25 ml	✓+ ***	✓+ ***	✓+
Stool **	20	100-400 mg	+ *	+++	+++
Urine	20	1.5 ml	+ *	+++	+++

✓: Viral nucleic acids detected.

* Optimal sensitivity for whole blood, stool and urine is accomplished by off board workflow.

** Pre-processing of sputum and stool specimens is mandatory in order to obtain a consistency that can be handled by the instrument. Details about the recommended pre-process procedure can be obtained from your local bioMérieux representative.

*** For sputum and stool specimens less viral nucleic acid was recovered as compared to the other specimen types due to the fact that sputum and stool specimen contain large amounts of background nucleic acids. Note that the total amount of nucleic acid recovered from sputum and stool specimen is higher as compared to the other specimen types.

Removal Of Downstream Application Inhibitors

Removal of inhibitors was verified by analysis of ***NucliSENS easyMAG*** extracts from different specimen types (plasma, serum, blood, CSF, sputum and stool), spiked with fixed amounts of intact viral particles. Diluted and undiluted extracts were assayed in real time PCR to obtain Ct values. With the exception of stool specimen, the difference in Ct values between undiluted and diluted extracts corresponded with the dilution factor indicating that any inhibitory component present in primary specimens was adequately removed/inactivated by the ***NucliSENS easyMAG*** extraction procedure.

For stool specimens some down stream applications might experience a degree of inhibition. To reduce the inhibition it is recommended to dilute the extracted specimens prior to detection and/or reduce the amount of stool specimen processed. The user is responsible for validating the ***NucliSENS easyMAG*** platform in their local setting and in accordance to local legislation to determine whether the performance of the ***NucliSENS easyMAG*** platform meets their needs.

Reliability Characteristics

Reproducibility

The variation between ***NucliSENS easyMAG*** extraction runs was assessed by processing viral particles spiked in water in 11 independent extraction runs. The coefficient of variance (CV%) calculated for Ct values obtained in real-time PCR with the extracts was <2%. Similar results were found when viral particles were directly applied (without extraction) to the real-time PCR amplification reaction (CV <2%). This indicated that the extraction process did not significantly attribute to the variations observed in down stream applications.

Specimen To Specimen Contamination

The degree of specimen-to-specimen contamination was measured by processing high positive viral specimens (>10^8 copies/ml) and negative specimens alternating in the same run. Low positive specimens (0.5*10^3 copies/ml) were included in each run to monitor the sensitivity of detection. Extracted specimens were analyzed with real-time NASBA. The measured carry over rate was <0.1ppm based on the detection limit of the assay used.

Platform Characteristics

Throughput

Workflow	Time / Run	No. of specimen / Run
On-board workflow	60 min.	24
Off-board workflow	40 min.	24

Flexibility

Depending on the down stream application needs, both the input volume (0.1 to 1 ml) and the output volume (25 to 110 µl) can be varied, however, it is the responsibility of the user to validate different input and output volumes in their own laboratory setting.

Generic Extraction Protocol

The ***NucliSENS easyMAG*** platform uses one generic extraction protocol based on Boom chemistry for total nucleic acid extraction for all specimen types tested.

Reagents And Disposables

The ***NucliSENS easyMAG*** platform uses one set of reagents to perform generic extraction. Using the platform with reagents and disposables not released by bioMérieux for the purpose of processing specimens on the ***NucliSENS easyMAG*** instrument may result in damage or harm to the platform, the user or the patient.

Troubleshooting

Error Code	Priority	Description Instrument	Error Trigger Condition	Solution
2231	FATAL	Waste Trap Error on Initialization	The waste trap sensors are in an erroneous combination - the high sensor is inactive, the full sensor is active. The sensors are most likely faulty and should be checked.	Contact your local bioMérieux representative.
2232	WARNING	Waste Trap Full on Initialization	The waste trap full sensor is active when going through the initialization procedure. The waste trap will attempt to recover by purging. Failing this, error 2242 will result.	Wait for the instrument to attempt to recover.
2233	WARNING	Waste trap calculated full	The waste trap has been calculated as being full when going through the initialization procedure. The waste trap will attempt to recover by purging. Failing this, error 2243 will result.	Wait for the instrument to attempt to recover.
2234	WARNING	Waste trap High on initialization	The waste trap high sensor is active when going through the initialization procedure. The waste trap will attempt to recover by purging. Failing this, error 2244 will result.	Wait for the instrument to attempt to recover.
2241	FATAL	Waste Trap Error on Initialization	The waste trap sensors are in an erroneous combination after attempting recovery - the high sensor is inactive, the full sensor is active. The sensors are most likely faulty and should be checked.	Contact your local bioMérieux representative.
2242	FATAL	Waste Trap Full after Initialization	The waste trap full sensor is still active after the Initialization procedure has attempted to recover by draining the waste trap. The sensor may be faulty or there may be a problem draining the waste trap.	Contact your local bioMérieux representative.
2243	FATAL	Waste trap Calculated Full after Initialization	The waste trap has been calculated as being full after attempting a recovery in initialization. The sensor may be faulty.	Contact your local bioMérieux representative.

Error Code	Priority	Description Instrument	Error Trigger Condition	Solution
2244	FATAL	Waste trap High after initialization	The waste trap high sensor is still active after the initialization procedure has attempted to drain the waste trap. The sensor may be faulty or there may be a problem draining the waste trap.	Contact your local bioMérieux representative.
2251	WARNING	Waste trap error in run	The waste trap sensors are in an erroneous combination - the high sensor is inactive, the full sensor is active. The sensors are most likely faulty and should be checked.	Contact your local bioMérieux representative.
2252	FATAL	Waste trap full in run	The Instrument Firmware has detected that the waste trap is full or nearly full.	Check the connections of the waste bottle containers or empty the waste bottle when possible.
2253	FATAL	Waste trap calculated full in run	The waste trap has been calculated as being full but the full sensor has not triggered yet. The sensor may be faulty.	Contact your local bioMérieux representative.
2254	WARNING	Waste trap high in run	The waste trap high sensor has been toggled active. Fluid purging to the waste bottle may not be taking place.	Check the connections of the waste bottle containers or empty the waste bottle when possible.
2305	WARNING	IPC fan failed	The fan in the Instrument PC has been detected as stopped or disconnected.	The system will continue functioning but your local bioMérieux representative should be contacted to solve the problem. It is not advised to load new runs when the cool fans are faulty.
2306	WARNING	Electronics fan failed	The fan in the electronics area has been detected as stopped or disconnected.	The system will continue functioning but your local bioMérieux representative should be contacted to solve the problem. It is not advised to load new runs when the cool fans are faulty.
2307	WARNING	Process area fan failed	The fan in the process area has been detected as stopped or disconnected.	The system will continue functioning but your local bioMérieux representative should be contacted to solve the problem. It is not advised to load new runs when the cool fans are faulty.

Error Code	Priority	Description Instrument	Error Trigger Condition	Solution
2308	WARNING	Fluidics fan failed	The fan in the fluidics area has been detected as stopped or disconnected.	The system will continue functioning but your local bioMérieux representative should be contacted to solve the problem. It is not advised to load new runs when the cool fans are faulty.
2401	WARNING	Pressure switch toggled active	The pressure has built up in the waste bottle. The peri pump will not run, and hence waste will not be flushed from the waste trap bottle.	Check the waste bottle connections at the back of the instrument.
2402	WARNING	Pressure switch toggled inactive	The pressure in the waste bottle has been reduced to a level that the peri pump will be able to run, flushing waste from the waste trap to the waste bottle.	The over pressure issue has been resolved.

Problem	Possible cause	Recommendation
Inhibition in down stream application.	(1) Remains of lysis buffer in eluate due to wrong addition of the lysed specimen into the sample vessel when using the off board workflow.	(1) Be sure not to introduce any foam when adding the specimen to the vessel; do not add more then 3 ml of specimen-lysis mixture.
	(2) Magnetic silica particles introduced in the down stream application.	(2) Be sure not to touch the immobilized magnetic silica particles when taking the extracted specimen. Silica particles can be removed from the extracted specimen by centrifugation/magnetic separation.
	(3) Total nucleic acid content too high for the specimen type / individual specimen processed.	(3) Reduce the amount of specimen volume or dilute the extracted specimen prior to analysis.
Internal RNA/DNA control not (optimal) detected in down stream application.	(1) Inhibition in down stream application.	(1) See above.
	(2) Amount of spiked internal control too low for the specimen tested.	(2) Increase the amount of internal control RNA/DNA for the specimen.

Low target RNA/ DNA recovery.	(1) Nucleases contamination.	(1) Confirm that nucleases are present in the extracted specimen by spiking RNA/DNA; perform decontamination procedure as described in the user manual before continuing with specimen extraction. For certain downstream applications it might be beneficial to use internal controls when establishing or monitoring the performance of the extraction process. Also the routine use of positive and negative controls can be beneficial.
	(2) Inefficient lysis step.	(2) Optimize the lysis step for your application.
	(3) Operating temperature too high resulting in a premature elution during the last wash step.	(3) Lower the environmental temperature in which the ***NucliSENS easyMAG*** platform is operating.
	(4) High nucleic acid background.	(4) In some cases (e.g. sputum/ stool) the eluate may contain a very high amount of total nucleic acid resulting in impaired specific RNA/DNA recovery. To recover from this, dilute the eluate or add less primary sample to the extraction process.
Cross contamination.	(1) Aspirators not replaced.	(1) Do not re-use disposables.
	(2) Manual steps (loading specimen/addition of silica particles) not performed accurately.	(2) Be sure not to introduce any foam when adding the specimen / silica particles to the vessel, do not add more then 3 ml of specimen-lysis mixture.
	(3) Laboratory area/ instrument contaminated due to post-amplification handling.	(3) Clean area and follow the decontamination procedure described in the user manual.
Spillage	(1) Viscosity of specimen/ lysis mixture is too high for the aspirate module to effectively aspirate liquid from the ***NucliSENS easyMAG*** sample strips.	(1) Remove the specimen from the ***NucliSENS easyMAG*** sample strips before starting the extraction run.

Symbols

REF	Catalog number
⚠	Caution, see instructions for use

Availability

For The *NucliSENS easyMAG* Platform

Article	Catalog number	Sufficient for
NucliSENS Lysis Buffer (2 ml/tube)	200292	48 extractions
NucliSENS easyMAG Lysis Buffer	280134	384 extractions
NucliSENS easyMAG Extraction Buffer 1 (4x 1000 ml/bottle)	280130	384 extractions
NucliSENS easyMAG Extraction Buffer 2 (4x 1000 ml/bottle)	280131	384 extractions
NucliSENS easyMAG Extraction Buffer 3 (4x 1000 ml/bottle)	280132	384 extractions
NucliSENS easyMAG Magnetic Silica (48x 0.6 ml/vial)	280133	384 extractions
NucliSENS easyMAG Disposables (48 pieces)	280135	384 extractions
NucliSENS easyMAG Instrument starter pack	280140	

For The *NucliSENS miniMAG* Platform

Article	Catalog number	Sufficient for
NucliSENS Magnetic Extraction Reagents	200293	48 extractions
NucliSENS miniMAG	200305	

NucliSENS EasyQ Products

Article	Catalog number	Sufficient for
NucliSENS EasyQ Basic Kit	280104	48 extractions
NucliSENS EasyQ Analyzer	200276	

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