MagNA Pure

MagNA Pure Compact Instrument Addendum 5 to Operator's Manual, Version 1.3

Software Version 1.1 **July 2016**

For general laboratory use.

Updated Information about the MagNA Pure Compact System

Dear Valued User of the MagNA Pure Compact System,

Please be informed that Section III, Declaration of Conformity is replaced by the following section:

Approvals

The MagNA Pure Compact System meets the requirements laid down in:

Directive 2014/30/EU of the European Parliament and Council of 26 February 2014 relating to electromagnetic compatibility (EMC).

Directive 2014/35/EU of the European Parliament and Council of 26 February 2014 relating to electrical equipment designed for use within certain voltage limits.

Compliance with the applicable directive(s) is provided by means of the Declaration of Conformity.

The following marks demonstrate compliance:

CE	Complies with the provisions of the applicable EU directives.
c UL us	Issued by Underwriters Laboratories, Inc. (UL) for Canada and the US.
Equipment de Laboratoire / Laboratory Equipment	'Laboratory Equipment' is the product identifier as shown on the type plate.

If you have any questions regarding the MagNA Pure Compact System Instrument, please contact your Roche Diagnostics representative.

Published by
Roche Diagnostics GmbH
Sandhofer Straße 116
68305 Mannheim
Germany

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For general laboratory use.

MagNA Pure

MagNA Pure Compact Instrument Addendum 4 to Operator's Manual, Version 1.3

Software Version 1.1 **November 2013**

For general laboratory use.

Updated Information for the MagNA Pure Compact Instrument

Dear Valued User of the MagNA Pure Compact Instrument,

This addendum is to inform you that the floppy disk drive for the MagNA Pure Compact Instruments has been removed for serial numbers starting with MPCC1550.

If you have any questions regarding the MagNA Pure Compact System, please contact your Roche Diagnostics representative. To call, write, fax, or email us, visit the Roche Applied Science homepage at www.roche-applied-science.com and select your home country. Country-specific contact information will be displayed.

Please note the following correction to the **MagNA Pure Compact Operator's Manual**:

The floppy disk drive on the MagNA Pure Compact Instruments starting with serial number **MPCC1550** has been removed.

Old Version	**New Version without Floppy Disk Drive**
	

The **MagNA Pure Compact Operator's Manual** is corrected as shown below:

Section	Current Version	Changes
A 3.3.1 8 Disk Drive (p 24)	8 Disk Drive The disk drive allows the operator to store the data generated as well as transfer it easily to other instruments or computers (*e.g.*, for sample tracking, documentation, or troubleshooting). In addition, new MagNA Pure Compact purification protocols can be uploaded from commercially available disks.	Section 8 Disk Drive no longer valid.
A 3.3.4 Sides of the Instrument (p 29)	9 USB Ports There are two USB ports. USB 1 and USB 2 ports can be used for any accessories that are not included with the MagNA Pure Compact Instrument.	9 USB Ports There are two USB ports. USB 1 and USB 2 ports can be used for any accessories that are not included with the MagNA Pure Compact Instrument. A USB memory stick allows the operator to store the data generated or transfer it easily to other instruments or computers (*e.g.*, for sample tracking, documentation, or troubleshooting). In addition, new MagNA Pure Compact purification protocols can be uploaded.
B 4 Data Transfer to or from the MagNA Pure Compact Instrument (p 67)	The data from the result screen can be saved to a disk. In future applications with the LightCycler® System and the COBAS TaqMan® 48 Analyzer, these data files can be transferred to the respective instruments.	To save data from the result screen, use a USB storage device.

Section	Current Version	Changes
B 4.2 Upload of New Updated Purification Protocols (p 67)	As new or updated purification protocols are created, they may be added to the MagNA Pure Compact Instrument via external data carrier disks (*e.g.*, software update disk) during program startup. Additional protocols will be available for download from www. magnapure. com. Follow the download instructions on this webpage.	To upload new protocols, use a USB storage device.
	Update disks will automatically be checked for viruses by the instrument software.	No longer valid.
	Workflow: 1. MagNA Pure Compact Instrument must be shut down. 2. Insert update disk. 3. Switch on instrument. 4. Software is automatically updated. 5. After Main Screen is displayed, remove update disk. 6. Update complete. 7. The instrument is ready for use.	Workflow: 1. MagNA Pure Compact Instrument must be shut down. 2. Insert USB. 3. Switch on instrument. 4. Software is automatically updated. 5. After Main Screen is displayed, shut down the MagNA Pure Compact Software, remove USB, and start the MagNA Pure Compact Software again. 6. Update complete. 7. The instrument is ready for use.
C 5 Documentation (p 97)	The result screen of the respective run will be displayed and can be printed or saved to a disk or LIMS.	To save data from the result screen, use a USB storage device or save them directly to a LIMS.

Published by
Published by
Roche Diagnostics GmbH
Sandhofer Straße 116
68305 Mannheim
Germany

① 1113

For general laboratory use.

MagNA Pure

MagNA Pure Compact Instrument

Addendum 3 to
Operator's Manual, Version 1.3

Software Version 1.1

August 2012

Information regarding MagNA Pure Compact Instrument

Dear Valued User of the MagNA Pure Compact Instrument,

Roche Diagnostics Ltd. has merged into Roche Diagnostics International Ltd and therefore the company name has changed to

Roche Diagnostics International Ltd

In order to harmonize and improve our support, the legal manufacturer changes as follows:

Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim
Germany

If you have any further questions regarding this matter, please do not hesitate to contact your Roche Diagnostics representative. To call, write, fax, or email us, visit the Roche Applied Science home page, http://www.roche-applied-science.com and select your home country. Country-specific contact information will be displayed.

The address of the legal manufacturer in section "Prologue/Contact Addresses" changes as follows:

Old adress	New adress
Roche Diagnostics Ltd. Forrenstrasse CH-6343 Rotkreuz Switzerland	Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim Germany

06845070001 ① 0812

Information regarding the MagNA Pure Compact Instrument Operator's Manual Version 1.3

Versatile Nucleic Acid Purification –
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Dear valued user of the MagNA Pure Compact Instrument,

With this document Roche Applied Science releases information on safety standards to provide a maximum of health and environment assurance. Please read the following information carefully, which updates information given in the MagNA Compact Instrument Operator's Manual.

If you have any further questions regarding this matter, please do not hesitate to contact our Technical Services Department at your best convenience. To call, write, fax, or email us, visit the Roche Applied Science home page, **http://www.roche-applied-science.com** and select your home country. Country-specific contact information will be displayed.

New Prologue Chapters:

Warnings and Precautions

In an emergency, immediately turn the power switch off and unplug the Instrument.

This Instrument is an electromechanical device, that could cause electrical shock or injury if not operated according to the procedures in this Operator's Manual.

Disposal Recommendations

All electrical and electronic products should be disposed off separately from the municipal waste system. Proper disposal of your old appliance prevents potential negative consequences for the environment and human health.

The Instrument must be treated as biologically contaminated-hazardous waste. Decontamination (*i.e.*, a combination of processes, including cleaning, disinfection and/or sterilization) is required before reuse, recycling, or disposal.

Dispose of the Instrument according to local and/or labor regulations.

For more information, contact your local Roche representative.

Components of your Control Unit, such as the computer, monitor, keyboard *etc.*, which are marked with the crossed-out wheeled bin symbol are covered by the European Directive 2002/96/EC on waste electrical and electronic equipment (WEEE) of the European Parliament and the Council of 27 January 2003.

These items must be disposed of via designated collection facilities appointed by government or local authorities.

For more information about disposal of your old product, please contact your city office, waste disposal service or your local Roche representative.

Constraint

It is left to the responsible laboratory organization to determine whether control unit components are contaminated or not. If contaminated, treat in the same way as the Instrument.

Symbols used in the Manual, *page 8*

Current Version

Symbol	Heading	Description
	WARNING RISK OF DANGER	This symbol is used to indicate that noncompliance with instructions or procedures may lead to physical injury or even death or could cause damage to the instrument.
	HOT SURFACE	This symbol is used to label potentially hot instrument surfaces.
	BIOHAZARD	This symbol is used to indicate that certain precautions must be taken when working with potentially infectious material.
	IMPORTANT NOTE	This symbol is used to bring your attention to an important annotation.
	INFORMATION NOTE	Designates a note that provides additional information concerning the current topic or procedure.

Additional Information:

Symbol	Heading	Description
	WEE	Electrical and electronic equipment marked with this symbol are covered by the European directive WEEE. The symbol denotes that the equipment must not be disposed off in the municipal waste system.

General Information, *page 11*

	Current Version	Additional Information
Electrical Safety	General Information: Protection Class I	*The MagNA Pure Compact Instrument is designed in accordance with Protection Class I (IEC). The chassis/housing of the Instrument is connected to protection earth (PE) by means of a cable. For protection against electrical shock hazards, the Instrument must be directly connected to an approved power source, such as a three-wire grounded receptacle for the 230V line. Where an ungrounded receptacle is encountered, a qualified electrician must replace it with a properly (PE) grounded receptacle, in accordance with the local electrical code. An extension must not be used. Any break in the electrical ground path, whether inside or outside the Instrument, could create a hazardous condition. Under no circumstances should the user attempt to modify or deliberately defeat the safety features of this Instrument. If the power cord becomes cracked, frayed, broken, or otherwise damaged, it must be replaced immediately with the equivalent part from Roche Diagnostics.* *All peripheral devices that are connected to the MagNA Pure Compact Instrument must comply with safety standard IEC 60950 for information technology equipment, or with IEC 61010-1, UL 61010-1 for laboratory instruments.*

Setup, *page 16*

	Current Version	Additional Information
Selecting a Location	The MagNA Pure Compact Instrument requires very little setup. Choose for the MagNA Pure Compact Instrument a clean, dry, level, stable surface within 3 m of a compatible electrical outlet. To ensure proper ventilation, leave 10 cm of space behind the instrument and 15 cm at each side of the instrument. No space is needed at the back of the instrument.	To carry the instrument, place your hands under the base of the instrument. For this purpose, the instrument base plate provides four recessed carrier grips. The weight of the MagNA Pure Compact Instrument is approx. 60 kg, ensure that enough manpower is available for transportation.

Description of the Instrument, *page 22*

	Current Version	Additional Information
UV Light Protection	The door permits a good view of the interior of the instrument. During the decontamination cycle, the door prevents escape of UV light from the interior.	The Front Door is impervious to UV light from inside the Instrument, in case the decontamination function is activated, but permits good view to the inside of the Instrument. However do not look at the UV source directly. Locking of the door is controlled by the software. Movement of the Robotic Arm is only possible after the Instrument Door is closed and locked.

Description of the Instrument, *page 29*

	Current Version	Additional Information
Socket for power cable	This is the plug-in for the power cable. There are two power cables included in the instrument package, one for US and one for German wall outlets.	Always connect the Instrument to a grounded wall outlet.

Performing a Purification Run, *page 43*

	Current Version	Additional Information
	For kit specific details regarding the handling of Reagent Cartridges, please see the corresponding pack insert of the kit.	Reagents might be flammable. For kit specific details regarding the handling of Reagent Cartridges, please consult the package insert of the respective reagent kit for further information.

Cleaning, *page 81*

	Current Version	Additional Information
	The surface of the MagNA Pure Compact Instrument as well as removable internal parts should be cleaned on a weekly basis with a lint free cloth moistened with deonized water. If a spill of reagents occurs, the instrument should be cleaned with a 70% ethanol solution or any acceptable PCR laboratory cleaner. Turn the instrument power Off and disconnect or unplug the power cord before cleaning the instrument.	⚠ *Mixtures of water and ethanol, that contain 70% ethanol, are highly flammable.*

Information regarding the MagNA Pure Compact Software Update 1.1.2

Versatile Nucleic Acid Purification –
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Information regarding the MagNA Pure Compact Software Update 1.1.2

Please read the following information, which updates information given in the MagNA Pure Compact Instrument Operator's Manual!

Dear valued user of the MagNA Pure Compact Instrument,

In March 2009, Roche Applied Science introduced an updated version of the MagNA Pure Compact Software: Version 1.1.2.

This latest version:

- fixes some bugs, found in previous versions
- improves some of the text messages
- updates the start up functions of the instrument, including the Plausibility Check
- improves tip handling
- includes updated and improved protocols; a list of installed protocols has also been implemented in the Maintenance Menu
- improves Sample Ordering
- includes a Create Problem Report function

If you have any further questions regarding this matter, please do not hesitate to contact our Technical Services Department at your best convenience. To call, write, fax, or email us, visit the Roche Applied Science home page, **http://www.roche-applied-science.com** and select your home country. Country-specific contact information will be displayed.

Important Information regarding the MagNA Pure Compact Instrument Operator's Manual

Versatile Nucleic Acid Purification –
Smart. Small. Simple

Important Information regarding the MagNA Pure Compact Instrument Operator's Manual

Please read the following information, which updates information given in the MagNA Pure Compact Instrument Operator's Manual!

Prologue

Contact Addresses, *page 5*

	Current Version	Changes
Manufactured by	Roche Instrument Center AG Forrenstrasse CH-6343 Rotkreuz Switzerland	Roche Diagnostics Ltd. Forrenstrasse CH-6343 Rotkreuz Switzerland

Marks of Conformity, *page 6*

	Current Version	Changes
The MagNA Pure Compact Instrument has been investigated according to:	EN 61326:1997 + A1:1998 + A2:2001 Class B ("Electrical equipment for measurement, control and laboratory use – EMC requirements")	EN 61326:2006 Class B ("Electrical equipment for measurement, control and laboratory use – EMC requirements")
	CAN/CSA C22.2 No. 1010.1-92	CAN/CSA C22.2 CSA C22.2.61010.1
CE – Testing Information	The instrument conforms to following directives as issued by the European Union according to the Council Directive 89/336/EEC (Electromagnetic Compatibility) and 73/23/EEC (Electrical equipment for use within certain voltage limits).	The instrument conforms to the following directives as issued by the European Union according to the Council Directive 2004/108/EC (Electromagnetic Compatibility) and 2006/95/EC (Electrical equipment for use within certain voltage limits).

Please Note: *the sentence "Equipment to be connected must fulfill the standards set by IEC 950 (Information security in technical equipment, including electronic business machines).", should be disregarded.*

Chapter A:

2. Installation of the Instrument

2.4 Setup, *page 16*

	Current Version	Changes
2.4.1 Selecting a Location	The MagNA Pure Compact Instrument requires very little setup. Choose for the MagNA Pure Compact Instrument a clean, dry, level, stable surface within 3 m of a compatible electrical outlet. To ensure proper ventilation, leave 10 cm of space behind the instrument and 15 cm at each side of the instrument. No space is needed at the back of the instrument.	The MagNA Pure Compact Instrument requires very little setup. Choose for the MagNA Pure Compact Instrument a clean, dry, level, stable surface within 3 m of a compatible electrical outlet. To ensure proper ventilation, leave 10 cm of space behind the instrument and 15 cm at each side of the instrument.

3. Description of the Instrument

3.3.5 MagNA Pure Compact Accessories

7 Barcode Scanner – Scanner Specifications, *page 33*

	Current Version	Changes
Drop Resistance	IEC 68-2-32 Test ED; withstands repeated drops from 1.8 m onto a concrete surface	DIN EN 60068-2-32 Test ED; withstands repeated drops from 1.8 m onto a concrete surface

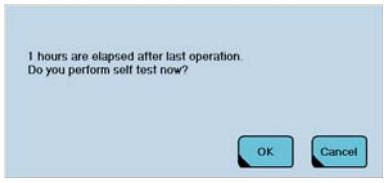
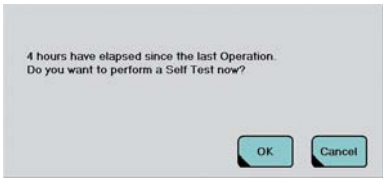
Chapter B:

1. Handling the MagNA Pure Compact Software

1.1 Starting the MagNA Pure Compact Instrument, *page 37*

	Current Version	Changes
New Screenshot		

1.1 Starting the MagNA Pure Compact Instrument, *page 38*

	Current Version	Changes
New Screenshot		

1.2 Overview of Main Menu Screen

Table 4: Overview of menu and submenu structure, *page 41*

	Current Version	Changes
Maintenance: Detailed Actions	Maintaining: ▶ Leakage Test ▶ Counter and Reminder ▶ Error Log ▶ O-ring Exchange ▶ Liquid Waste Discard ▶ UV Decontamination	Maintaining: ▶ Leakage Test ▶ Counter and Reminder ▶ Error Log ▶ O-ring Exchange ▶ Liquid Waste Discard ▶ UV Decontamination ▶ Create Problem Report

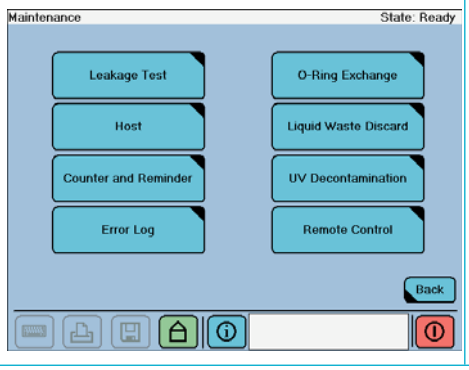
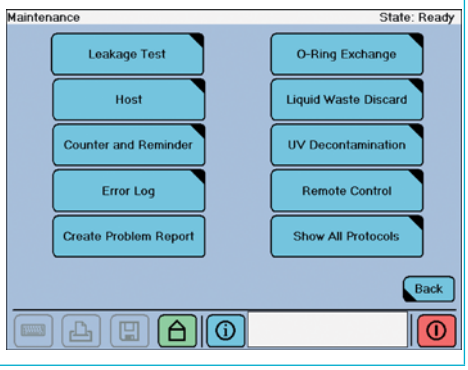
2. Performing a Purification Run, *page 45*

	Current Version	Changes
For the MagNA Pure Compact RNA Isolation Kit:	The selection of an appropriate endogenous IC is of high importance when developing a quantitative RT-PCR assay. The IC is co-amplified with the target of interest and serves as a control for several factors: differences in initial template concentrations between different samples, sample-to-sample variations in the PCR, presence of PCR inhibitors or the extent of any RNA degradation. The advantage of using an endogenous IC is that both internal control mRNA and target mRNA is extracted from cells or tissue and reverse transcribed together. Commonly used endogenous ICs include so-called housekeeping gene mRNAs. (Note that Roche Applied Science offers several LightCycler® Housekeeping Gene Sets for the detection of human housekeeping genes, incl. G6PDH, HPRT, ALAS, and _2-microglobulin.) The level of expression of an appropriate endogenous IC should not vary with the experimental conditions or treatments to be compared.	The selection of an appropriate endogenous IC is of high importance when developing a quantitative RT-PCR assay. The IC is co-amplified with the target of interest and serves as a control for several factors: differences in initial template concentrations between different samples, sample-to-sample variations in the PCR, presence of PCR inhibitors or the extent of any RNA degradation. The advantage of using an endogenous IC is that both internal control mRNA and target mRNA is extracted from cells or tissue and reverse transcribed together. Commonly used endogenous ICs include so-called housekeeping gene mRNAs. The level of expression of an appropriate endogenous IC should not vary with the experimental conditions or treatments to be compared.

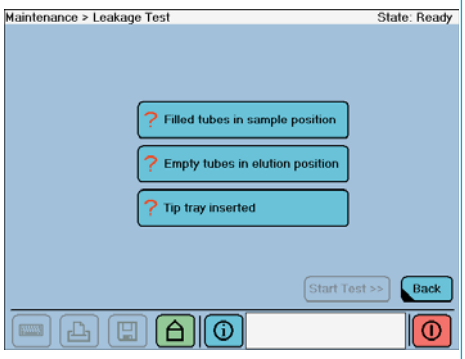
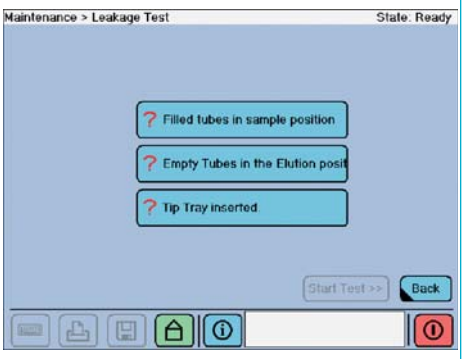
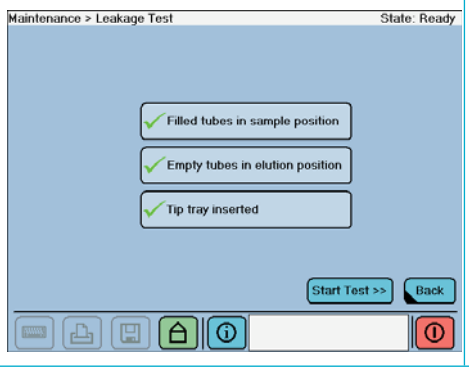
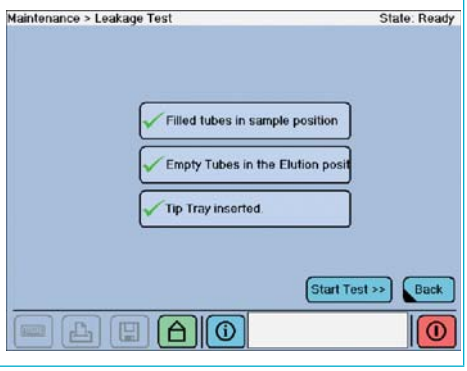
Chapter C:

1. User Maintenance

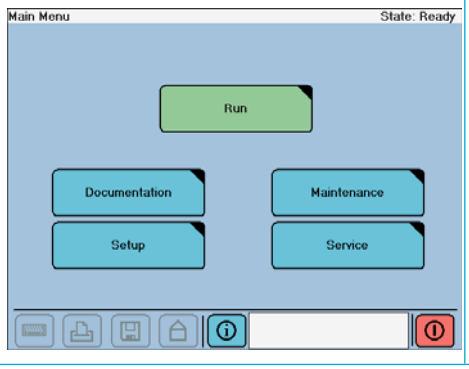
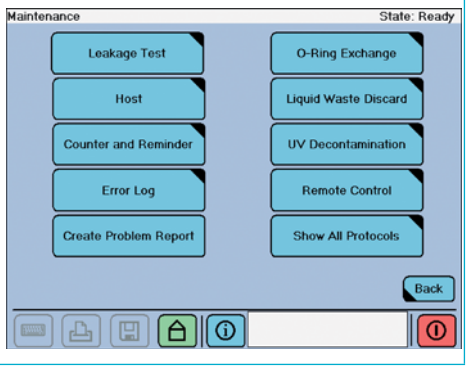
1.1 Leakage Test, *page 72*

	Current Version	Changes
New Screenshot		

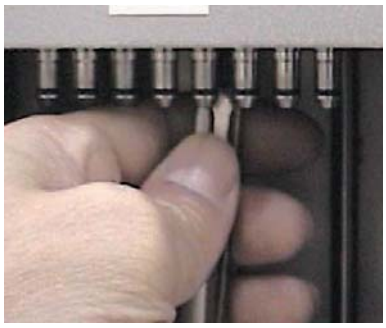
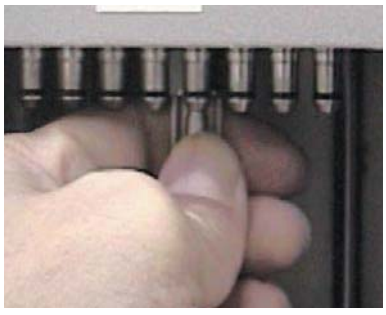
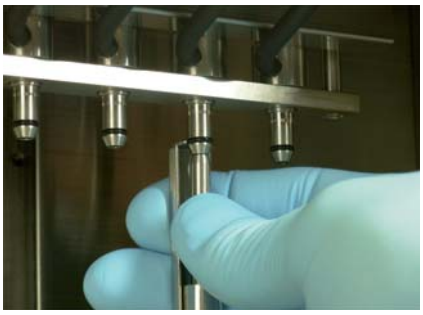
1.1 Leakage Test, *page 73*

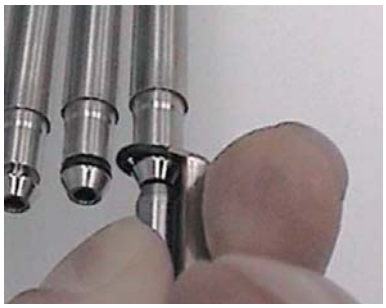
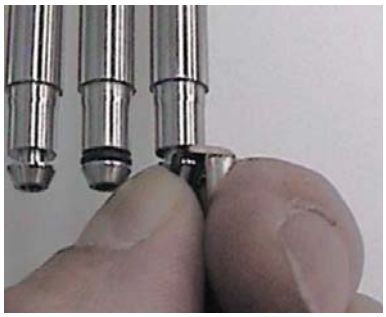
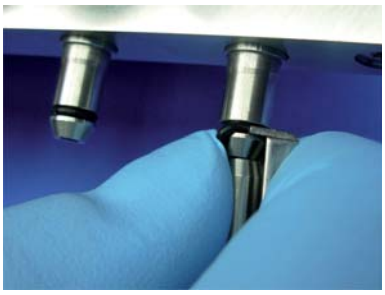
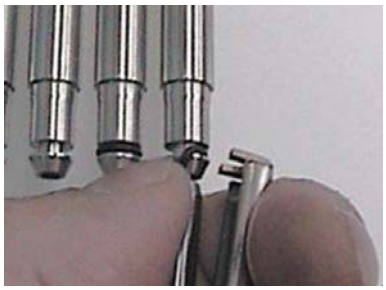
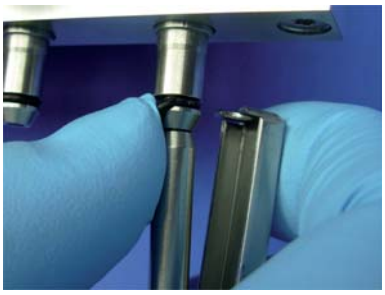
	Current Version	Changes
New Screenshot		
New Screenshot		

1.2.2 O-Ring Exchange, *page 77*

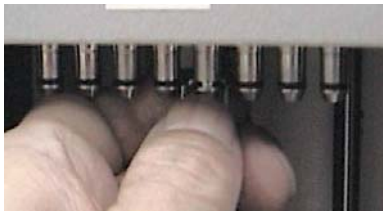
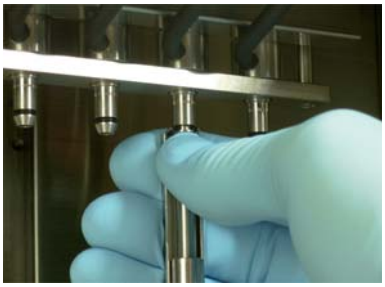
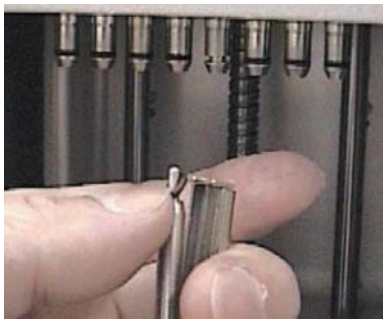
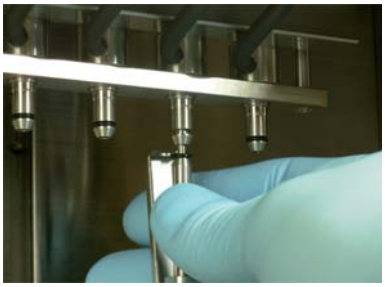
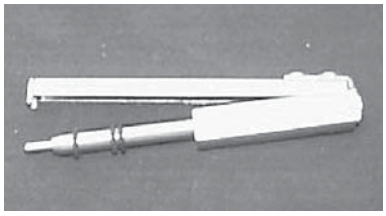
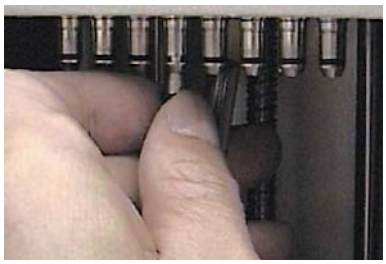
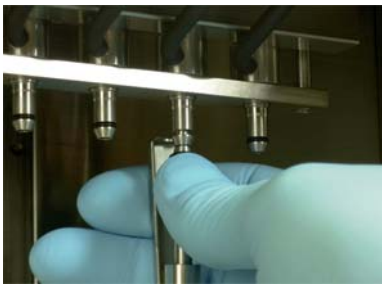
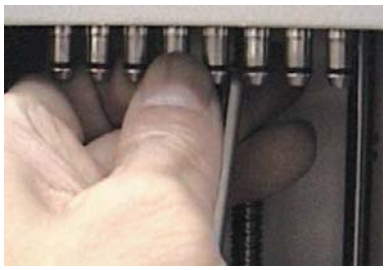
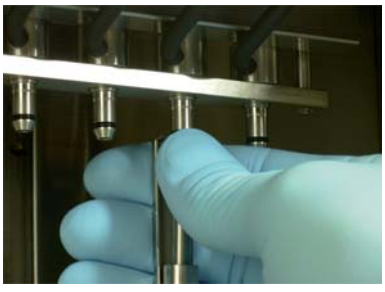
	Current Version	Changes
New Screenshot		

1.2.2 O-Ring Exchange, *page 78*

	Current Version	Changes
New Pictures		
New Pictures		
New Pictures		

	Current Version	Changes
New Pictures		
New Pictures		
New Pictures		

1.2.2 O-Ring Exchange, *page 79*

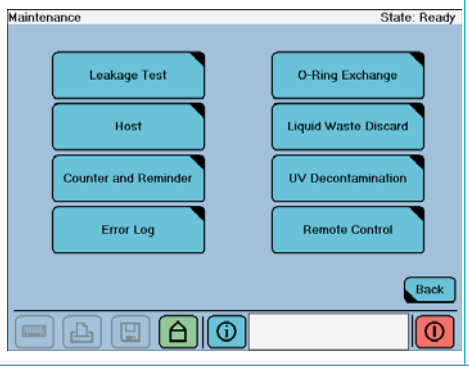
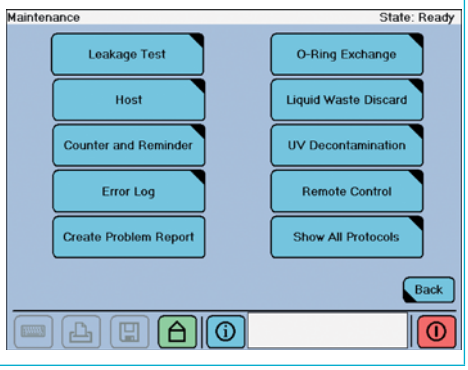
	Current Version	Changes
New Pictures		
New Pictures		
New Pictures		
New Pictures		
New Pictures		

2. Service Maintenance, *page 81*

	Current Version	Changes
Note:	Service Maintenance may only be performed by a Roche Diagnostics service engineer. Contact your local Roche representant for maintenance assistance and for more details on country-specific service contracts.	Service Maintenance may only be performed by a Roche Diagnostics service engineer. Contact your local Roche representative for maintenance assistance and for more details on country-specific service contracts.
2. Exchange:	Hepa Filter	HEPA Filter

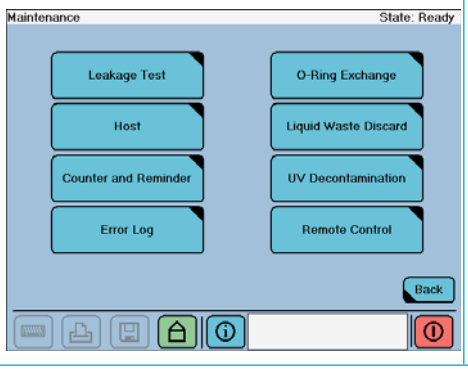
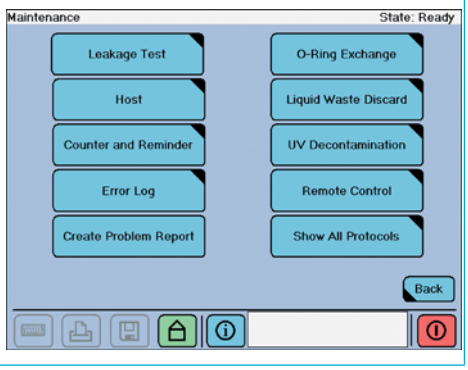
3. Cleaning Instructions and UV Decontamination

3.2 UV Decontamination, *page 85*

	Current Version	Changes
New Screenshot		

4. Error Codes and Trouble Shooting Guide

4.1 Error Log, *page 86*

	Current Version	Changes
Important Note:	In case you want to trouble shoot an error together with a local Roche representant, have these informations ready or make sure the remote service option is enabled.	In the event that you want to trouble shoot an error, together with a local Roche representative, have this information ready, or ensure that the remote service option is enabled.
New Screenshot		

6. Administrator Authorization, *page 98*

	Current Version	Changes
	Your local Roche Diagnostics representant will define an administrator authorization during instrument installation. The administrator rights are secured with a password and enable to define additional operators. During the administrator authorization the password will be displayed hidden, to guarantee confidentiality. In case you should forget the administrator password, contact your local Roche Diagnostics representant and you will receive a new one.	Your local Roche Diagnostics representative will define an administrator authorization during installation of the Instrument. The administrator rights are secured with a password and enable the ability to define additional operators. During the administrator authorization the password will be displayed hidden, to guarantee confidentiality. In the event that you forget the administrator password, contact your local Roche Diagnostics representative and you will receive a new one.

7. Ordering Guide

7.1 Related Products, *page 99*

	Current Version	Changes
Recommended Printer for Use with the MagNA Pure Compact Instrument:	Hewlett Packard Laserjet 1015	Please contact your local Roche representative for details.
	For installation with the MagNA Pure Compact Instrument, please contact your local Roche representantative.	For installation with the MagNA Pure Compact Instrument, please contact your local Roche representative.

7.3 MagNA Pure Compact Accessories, *page 100*

	Current Version	Changes
Waste Tank	03 788 270 001	03 788 300 001
Drop Catcher	03 788 300 001	03 788 270 001
Trademarks	MAGNA PURE, LIGHTCYCLER, COBAS, and TAQMAN are trademarks of Roche.	MAGNA PURE, LIGHTCYCLER, LC, HYBPROBE, COBAS and TAQMAN are trademarks of Roche.

Additional Information

Chapter C:

1. User Maintenance

1.3 Create a Problem Report

For troubleshooting by a Roche representative, error messages and configuration files can be exported to a Problem Report.

The Problem Report is a zipped file containing log, configuration and version files.

To create a Problem Report:

1. Insert an empty USB Memory Stick on the right side of the Instrument. On the "Main Menu" screen, press the 'Maintenance' button. Press the 'Create Problem Report' button and select "OK" in the pop-up window.
2. The Problem Report is created and stored on the attached USB Memory Stick. A pop-up window will open when the Problem Report has been saved.

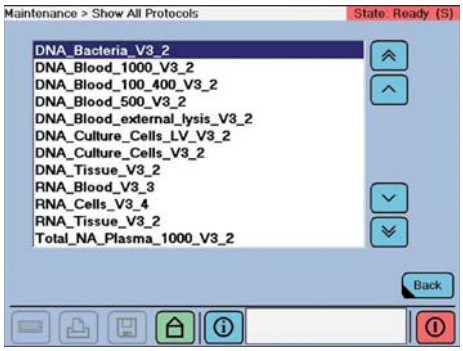
1. User Maintenance

1.3 Show All Protocols

The "Show All Protocols" option lists all the protocols which are installed on the MagNA Pure Compact Instrument.

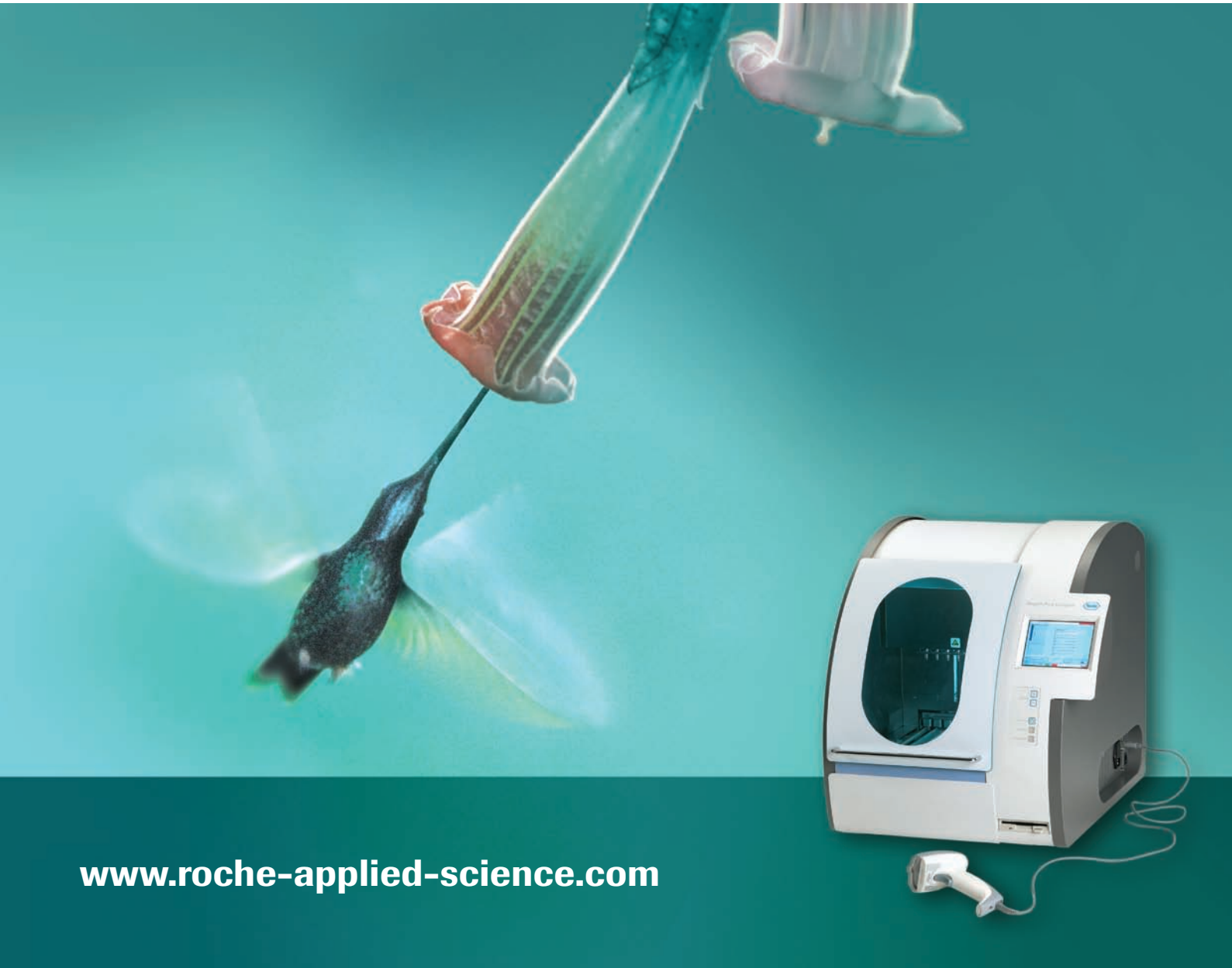
To "Show All Protocols"

1. On the "Main Menu" screen, press the 'Maintenance' button. Select the "Show All Protocols" button.
2. All protocols that are installed on the Instrument will be displayed, as shown in the screenshot below.



MagNA Pure Compact Operator's Manual

Instrument Version 1.0
Software Version 1.1



www.roche-applied-science.com

Table of Contents

Table of Contents

Prologue

Prologue

Intended Use of the Instrument

The MagNA Pure Compact Instrument is a robotic workstation for the automated preparation of nucleic acids from a broad variety of sample materials (*e.g.*, mammalian blood, serum, plasma, or blood cells; cultured cells; tissue) with the assistance of specially designed MagNA Pure Compact reagent kits. The isolated high-quality nucleic acids are suitable for PCR and RT-PCR reactions on the LightCycler System, as well as on standard block cyclers, and for many other downstream applications.

The instrument is intended for nucleic acid preparation in general laboratory use by trained professionals.

Contact Addresses

Manufactured by	Roche Instrument Center AG Forrenstrasse CH-6343 Rotkreuz Switzerland
for	Roche Diagnostics GmbH Sandhofer Straße 116 D-68305 Mannheim Germany
Distribution in USA	Roche Diagnostics Corporation 9115 Hague Road PO Box 50457 Indianapolis, IN 46250 USA

Revision History

Manual Version	Instrument Version	Software Version	Revision Date
1.1	1.0	1.0	December 2003
1.2	1.0	1.1	August 2004
1.3	1.0	1.1	February 2006

Marks of Conformity

The MagNA Pure Compact Instrument had been investigated according to:

- IEC 61010-1, 2nd Edition ("Safety requirements for electrical equipment for measurement, control and laboratory use; Part 1: General requirements")
- EN 61326:1997 + A1:1998 + A2:2001 Class B ("Electrical equipment for measurement, control and laboratory use - EMC requirements")
- UL 61010A-1
- CAN/CSA C22.2 No. 1010.1-92

The instrument has been manufactured and checked in accordance with all relevant safety standards prior to leaving the factory. The instrument has been approved for use by recognized testing institutions. This is confirmed by the following conformity symbols:

Acronym	Test Symbol	Testing Information
CE	CE	The instrument conforms to following directives as issued by the European Union according to the Council Directive 89/336/EEC (Electromagnetic Compatibility) and 73/23/EEC (Electrical equipment for use within certain voltage limits).
CUL	c UL US LISTED	Certified by the Underwriters Laboratories Inc.

Equipment to be connected must fulfill the standards set by IEC 950 (Information-security in technical equipment, including electronic business machines).

Classification

The Instrument is classified as:

- Designed for stationary operation.
- Intended for worldwide use.
- Intended for evaluating preprocessed biological material.

Note on Use with Infectious Material

- The Instrument may not be used to analyze infectious materials unless additional safety measures to ensure safe sample handling are taken beforehand.

How to Use this Manual

Important: Before operating the MagNA Pure Compact Instrument, be sure to read and understand the warnings, cautions and safety requirements in this manual. Failure to follow the instructions contained in this manual may have hazardous consequences.

Chapter A	**General Overview describes**

- contents of the MagNA Pure Compact system package
- design of the instrument
- accessories and disposable plastics required for instrument operation
- isolation method of the MagNA Pure Compact Instrument

Chapter B	**How To Operate the MagNA Pure Compact Instrument describes how to**

- use the MagNA Pure Compact Software
- prepare the instrument for a purification run
- perform a purification run

Chapter C	**Presents additional information on maintenance of the instrument and troubleshooting**

- User Maintenance
- Service Maintenance by the Roche service
- Cleaning of the instrument
- Troubleshooting

Symbols used in this Manual

Symbol	Heading	Description
	WARNING RISK OF DANGER	This symbol is used to indicate that non-compliance with instructions or procedures may lead to physical injury or even death or could cause damage to the instrument.
	HOT SURFACE	This symbol is used to label potentially hot instrument surfaces.
	BIOHAZARD	This symbol is used to indicate that certain precautions must be taken when working with potentially infectious material.
	IMPORTANT NOTE	This symbol is used to bring your attention to an important annotation.
	INFORMATION NOTE	Designates a note that provides additional information concerning the current topic or procedure.

General Overview

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General Overview

1 Specifications of the Instrument

Do not use the equipment in a manner not specified by the manufacturer. Otherwise, the protection provided by the equipment might be impaired.

1.1 General Information

Cat. No.	03 731 146 001
Dimensions	W 540 mm; D 610 mm; H 570 mm
Weight	approx. 60 kg
Power supply	100 - 240 V AC +/- 10%
Frequency	50/60 Hz +/- 5%
Power consumption	Max. 400 VA
Fuses	4.0 AT, 2 pieces
Heat emission	1440 kJ/h (max.) 860 kJ/h (average value during operation)
Protection Class	I
Installation Category	II
Electromagnetic Emission: **Terminal disturbances voltage**	Class B
Electromagnetic radiation disturbances	Class B

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1.2 Operating Environment

Temperatures allowed during transportation/storage/packaging	-25°C to +70°C
Temperatures allowed during operation	+18°C to +30°C
Pollution Degree: 2	Indoor use
Maximum relative humidity	80% (for operating temperatures up to 31°C); decreases linearly to 50% for operating temperatures up to 40°C
Altitude	up to 2000 m

1.3 Operating Parameters

Note: Exact values depend on the purification protocol used.

Processing capability	1 to 8 samples per batch
Processing time	20 to 45 min (depending on protocol)
Pipetting Accuracy	25 µl to 100 µl: ≤5% >100 µl ≤2%
Sample Volume	100 – 1000 µl
Elution Volume	50 – 200 µl
Internal Control Volume	5 – 20 µl

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2 Installation of the Instrument

2.1 Shipping

The MagNA Pure Compact Instrument is shipped in a styrofoam container surrounded by a cardboard box. Before opening it, inspect the container carefully for damage. Report any damage to your local Roche Diagnostics office before accepting the unit.

2.2 Unpacking

Note: The following steps will be done by your local Roche Diagnostics representative.

Standard Component List

- 1 MagNA Pure Compact Instrument body

Individual parts:

- 1 Cartridge Rack
- 1 Tube Rack
- 1 Elution Tube Rack
- 1 Waste Tank
- 1 Drop Catcher
- 1 Drip Tray
- 1 Barcode Scanner and cable
- US power cable
- German power cable
- 1 package High Vacuum Grease
- 1 package O-rings (8 pieces)
- 2 fuses for line filter
- Operator's Manual

The MagNA Pure Compact Instrument is a standalone instrument, which needs no additional computer. The computer is already included in the instrument housing and and may be operated via a touch-screen.

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2.3 Additional Items Required for Operation and Maintenance

2.3.1 Operating Reagents

Before operating the MagNA Pure Compact Instrument for the first time, you must have one of the following reagent kits:

Cat. No.	Purification Kit	For Preparation Of
03 730 964 001	MagNA Pure Compact Nucleic Acid Isolation Kit I	Genomic DNA from mammalian whole blood, plasma and culture cells. Total nucleic acids from mammalian plasma and whole blood.
03 730 972 001	MagNA Pure Compact Nucleic Acid Isolation Kit I - Large Volume	Genomic DNA from mammalian whole blood, plasma and culture cells. Total nucleic acids from mammalian plasma and whole blood.
04 802 993 001	MagNA Pure Compact RNA Isolation Kit	Total RNA from mammalian whole blood, blood cells, cultured cells, and tissue.

These three kits for the purification of genomic DNA, viral total nucleic acid (DNA and RNA) or total RNA are currently available from Roche Diagnostics. The instrument software already contains operating protocols that can be used with the MagNA Pure Compact Nucleic Acid Isolation Kits. Purification protocols for the MagNA Pure Compact RNA Isolation Kit are available for download from http://www.roche-applied-science.com/sis/magnapure/magna_compact_protocols.htm. Please contact your local Roche representative or visit www.magnapure.com for the latest information on additional purification kits and protocols. See section 4.2 for details on how to install new purification protocols into the MagNA Pure Compact software.

Each purification kit includes the reagents and disposables needed for a standard purification run. If you need additional tubes, e.g. for an internal control or maintenance activities (leakage test), you must order them from Sarstedt. (See the Appendix for detailed ordering information.)

Note: The actual amount of reagents and disposables may vary between the different available MagNA Pure Compact purification kits.

Kit content:

- Prefilled Reagent Cartridges (individually packed in a sealed foil pouch, with barcode)

- Sample Tubes (35 tubes per package, 2.0 ml each, with stand, without barcode)

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Kit content:
▶ Elution Tubes (35 tubes per package, 2.0 ml each, with stand, with barcode) 
▶ Caps for Elution Tubes (35 caps per caps) 
▶ Tip Trays (including Piercing Tool and tips). The tips are placed in the following order into the Tip Tray: one Piercing Tool, one small tip, two large tips. 

2.3.2 Maintenance Items

Cat. No.	Purification Kit	Contents
03 561 429 001	MagNA Pure LC O-Ring Maintenance Kit	O-rings (12 x 8), High Vacuum Grease (1)
03 753 166 001	MagNA Pure Compact Tip Tray Kit	10 Tip Trays

Note:

▶ To ensure that they work correctly, you must grease the O-rings once per week (or after every 20 purification runs). If the O-rings malfunction, the instrument nozzles may leak. For details, please see the Maintenance section in Chapter C.

▶ Perform a leakage test every two months (or after every 50 purification runs) to determine whether the O-rings should be changed. For details please see the Maintenance section in Chapter C.

There is an O-Ring Exchange Tool available, which simplifies the O-ring changing process. Please contact your local Roche Diagnostics representative if you need O-rings changed or want one of these tools.

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2.4 Setup

2.4.1 Selecting a Location

The MagNA Pure Compact Instrument requires very little setup. Choose for the MagNA Pure Compact Instrument a clean, dry, level, stable surface within 3 m of a compatible electrical outlet. To ensure proper ventilation, leave 10 cm of space behind the instrument and 15 cm at each side of the instrument. No space is needed at the back of the instrument.

Protect the MagNA Pure Compact Instrument from heat and excessive sunlight and always ventilate the room well. The instrument is for „indoor use only“ and should not be operated in areas of excessive humidity or extremes of temperature. Do not use the instrument where there is a risk of explosion.

2.4.2 Easy Teaching Procedure

The software has been preinstalled by the manufacturer. The installer (service user) must perform an adjustment procedure, called Easy Teaching, before the instrument can be used. Only a service operator, not a regular operator, can access the menu for the Easy Teaching procedure. This is done by your local Roche Diagnostics representative.

Note: The Easy Teaching Procedure must be performed before the instrument will work correctly. If the adjustment is not done properly, either the instrument could be damaged or the instrument performance could be affected (*e.g.* pipetting accuracy, yield in nucleic acids, etc.).

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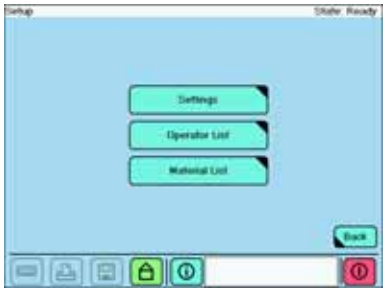
2.4.3 Software Setup

Either a service operator or a regular operator can access the menu for software setup. This menu enables the operator to

- set the time and date
- preset the location (folder) where all generated data will be saved
- enter a laboratory name
- choose the types (and loudness) of alarm sounds the instrument will generate
- manage the list of operators that have access to the instrument
- specify the types of sample materials to be handled with the instrument

Note: The type of sample material used for a purification run can be selected later on during Sample Ordering 2 (see chapter B for details). It is used for documentation purposes only and does not influence the purification protocol.

Action	Software Screen
1	Turn on the MagNA Pure Compact Instrument by pressing the Power On button on the front of the instrument.
2	During initialisation/self test of the system components the start-up screen appears.
3	The MAIN MENU Screen appears 
4	Touch the SETUP Button on the touch-screen
5	The SETUP Screen appears ***Note:*** Touch the Back button (at the lower right corner of the SETUP Screen) to return to the MAIN MENU Screen. 
6	Touch the SETTINGS Button
7	The SETTINGS Screen appears. ***Note:*** Touch the Back button (at the lower right corner of the SETTINGS Screen) to return to the SETUP Screen without changing any of the current settings.

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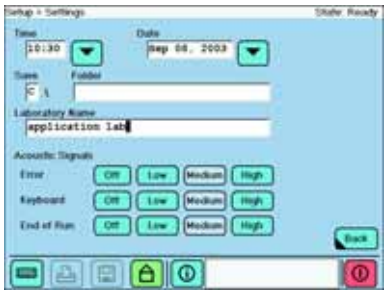
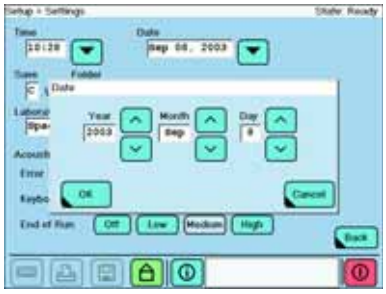
Action	Software Screen
8	**Basic Settings**  Program the actual time and date by pressing the ▼ buttons next to the time and date displays. A pop up window opens to allow you to set the correct values.
8a	Touch the Up and Down buttons (to the right of each number) to change the values for hours and minutes (see figure). The Up button increases values by one unit, the Down button decreases values by one unit. Touch the OK button to confirm the changes and return to the SETTINGS Screen. Touch the Cancel button to return to the Settings Screen without changing any settings. ***Note:*** The hour setting uses a 24-hour clock, where 11:00 PM is hour 23, and midnight is hour 0. The hour and minute values can be set independently; that is, you can change from minute 59 to minute 0 (or vice versa) without causing the hour setting to change. 
8b	Touch the Up and Down buttons (to the right of each number) to change the values for year, month and day (see figure). The Up button increases values; the Down button decreases values. Touch the OK button to confirm the changes and return to the SETTINGS Screen. Touch the Cancel button to return to the SETTINGS Screen without changing any settings. ***Note:*** These values can be set independently. You can change from December to January (or vice versa), without causing the year to change. You can change from day 30 (or 31) to day 1 (or vice versa) without causing the month to change. 
8c	To specify the default folder where all generated data will be saved, touch the Folder field, then use the pop-up virtual keyboard to type the name of the folder into the field . 

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Action	Software Screen
8d	To specify the default laboratory name that will be mentioned with all generated data, touch the Laboratory Name field, then use the pop-up virtual keyboard to type the laboratory name into the field. 
8e	**Alarm Settings** To specify the types of alarm that the instrument software should give, as well as the loudness of each alarm, touch appropriate buttons on the "Acoustic Signals" panel.  Note: You can choose to sound an alarm each time an error message is displayed (Error), each time a button has been touched on the virtual keyboard (Keyboard), and each time the purification run has ended (End of the run). If you don't want one of these alarms, just select Off for that particular alarm. For each alarm you want, choose whether the alarm sound should be given at low, medium or high volume.
9	Select Back to return to the Settings Menu without modification.
10	Select the Operator List button from the Setup menu.  To enter a new operator type a new name into the entry field below the Operator List and select the Add button. ***Note:*** Only an administrator can define a new user. The administrator is asked for his admin password when this button is used. If no administrator should be defined, set the first time the Return key. 

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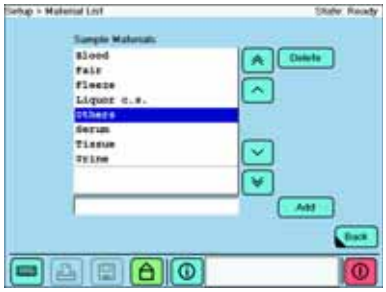
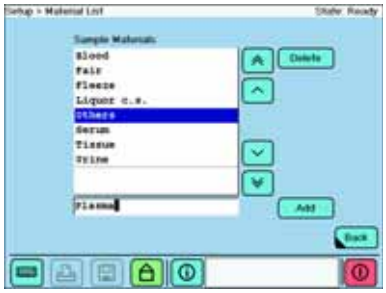
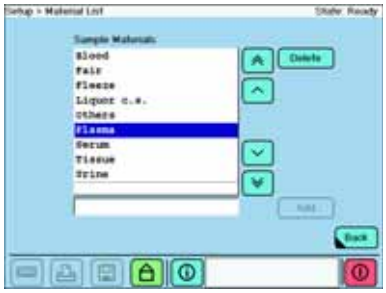
Action	Software Screen
11	Select the Material List button from the Setup menu.  To enter a new type of sample material type a new name into the entry field below the material list.  Select the Add button to add the new name to the Material List. 
12	The MagNA Pure Compact Instrument is now ready for use.

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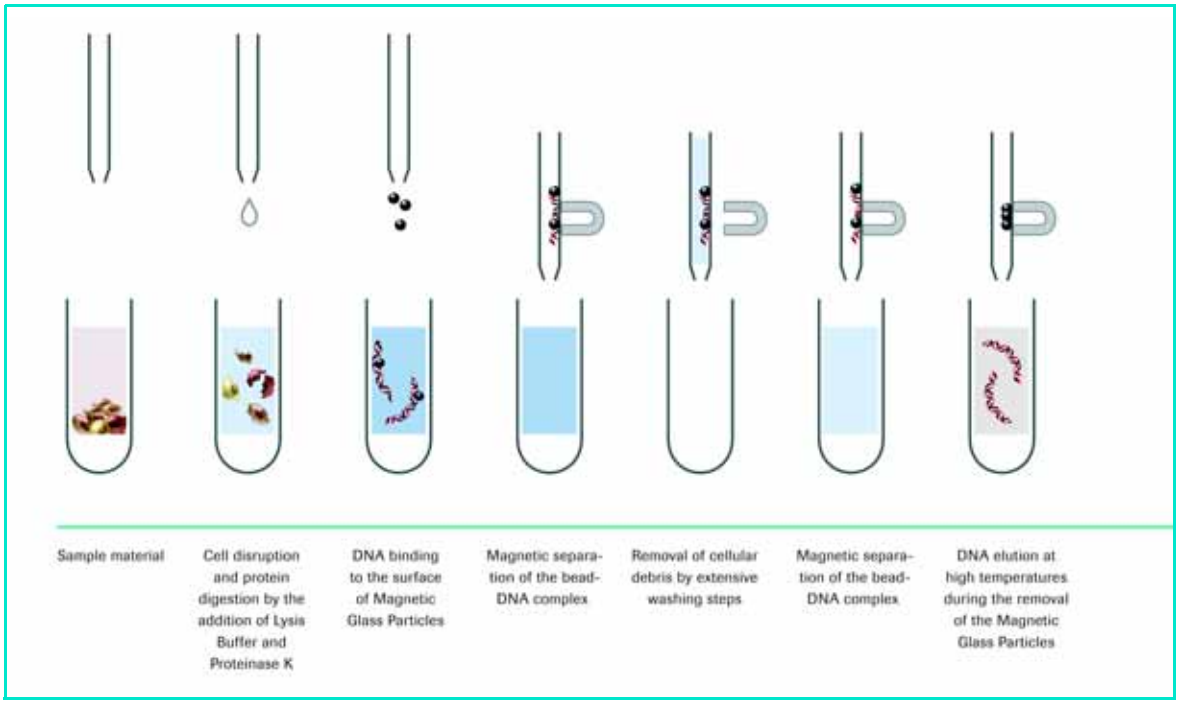
3 Description of the Instrument

3.1 General Description

The MagNA Pure Compact Instrument is a robotic workstation that can automatically isolate nucleic acids from crude sample material. It is a compact benchtop instrument with an integral touch-screen computer. The central processing unit of the instrument is a robotic arm with an 8-nozzle pipette head. This pipette head can process 1–8 samples per run. In addition, this pipette head has a specialized sensor unit, which can detect clots in sample material and loss of reaction tips.

3.2 Function Principle

When it is purifying DNA, the basic operations of the instrument are:



For details on the purification kits (provided in prefilled cartridges) please refer to their pack inserts. All kit pack inserts can be obtained at the Roche home page: http://www.roche-applied-science.com

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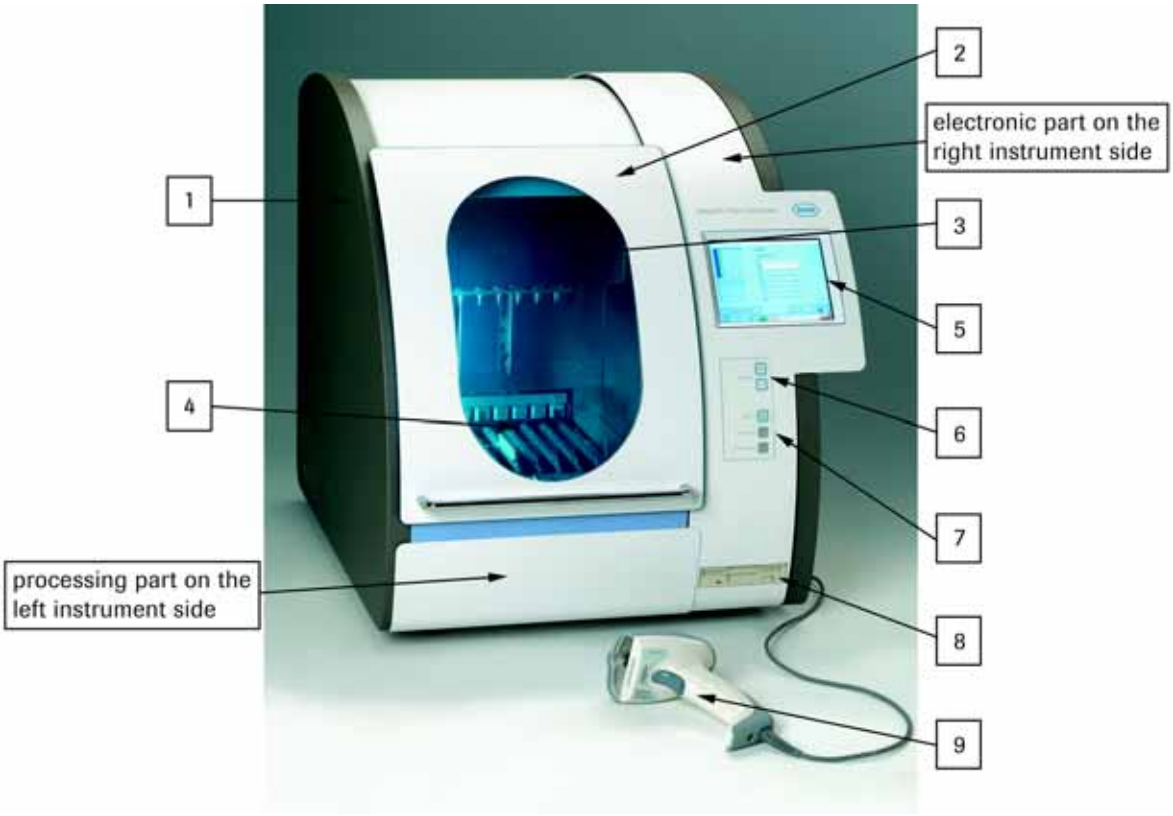
3.3 Description of the Instrument

3.3.1 Front View of the Instrument



1 Housing

Painted sheet metal housing contains the main body of the instrument and protects it from electromagnetic influences, chemicals, and UV-light.

2 Front Door

The nozzle head can only be moved after the instrument door is closed and locked. This door lock is controlled by the software. This prevents anyone from reaching inside the instrument during the purification, which might lead to injuries.

The door permits a good view of the interior of the instrument. During the decontamination cycle, the door prevents escape of UV light from the interior. It also protects reagents, disposable plastics and samples from environmental contamination.

The front door has to be opened to get access to the liquid waste tank and drip tray.

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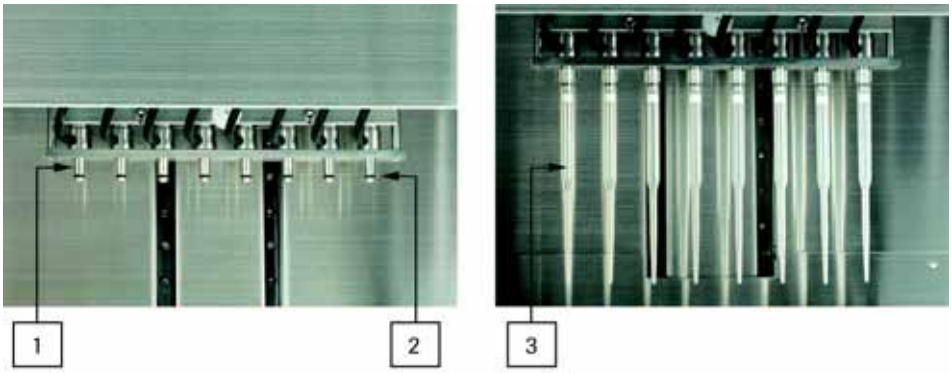
3 Nozzle Head

The nozzle head moves over the processing stage up and down (vertically along the z-axis). It carries the pipetting unit, the sensor unit and the magnet unit. The pipetting unit consists of 8 independent working air-filled plungers, each connected to a nozzle (1) which takes up the Reaction Tip. The Reaction Tip (3) is held by the O-ring (2) on the nozzle. A specially designed sensor unit checks all 8 channels indiviually for clots in the sample material, correct position of the reagent cartridge and piercing tool, loss of reaction tips, as well as for the presence of sample tube and internal control tube (if appropriate).



4 Processing Stage

The processing stage holds the cartridge rack with the reagent cartridges, the tip trays, the tube rack with elution tube rack, the heating units and the waste tank. It moves back and forth (horizontally along the y-axis), thereby moving the cartridge rack with the prefilled reagent cartridges into position so they can be processed. It contains a loading mechanics that lifts the cartridge rack to the top position for easy insertion and removal of the cartridge rack or the cartridges. The equipped cartridge rack is then manually pushed down to the low position of the loading mechanics inserting the respective cartridge wells into the heating unit.

5 Touch-screen

From the touch-screen, you can operate all instrument features. E.g., you can program a run, install a new protocol, maintain the instrument or search for accumulated data. You can activate the functions on the touch-screen either with your fingertips or with a PDM pencil.

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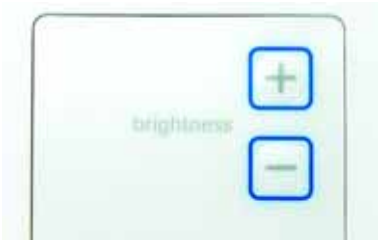
6 Buttons for Setting Screen Contrast

By pressing the + and – buttons, you can set the brightness of the touch screen.



7 Status Indicator LEDs and Power On Button

The instrument is turned on pressing the "power on" button.
Three LEDs indicate the current status of the instrument:

- The green LED of the "power on" button indicates that the instrument is powered on
- the red "processing" LED indicates the status of processing
- the yellow "run completed" LED signalizes that the run is completed.

8 Disk Drive

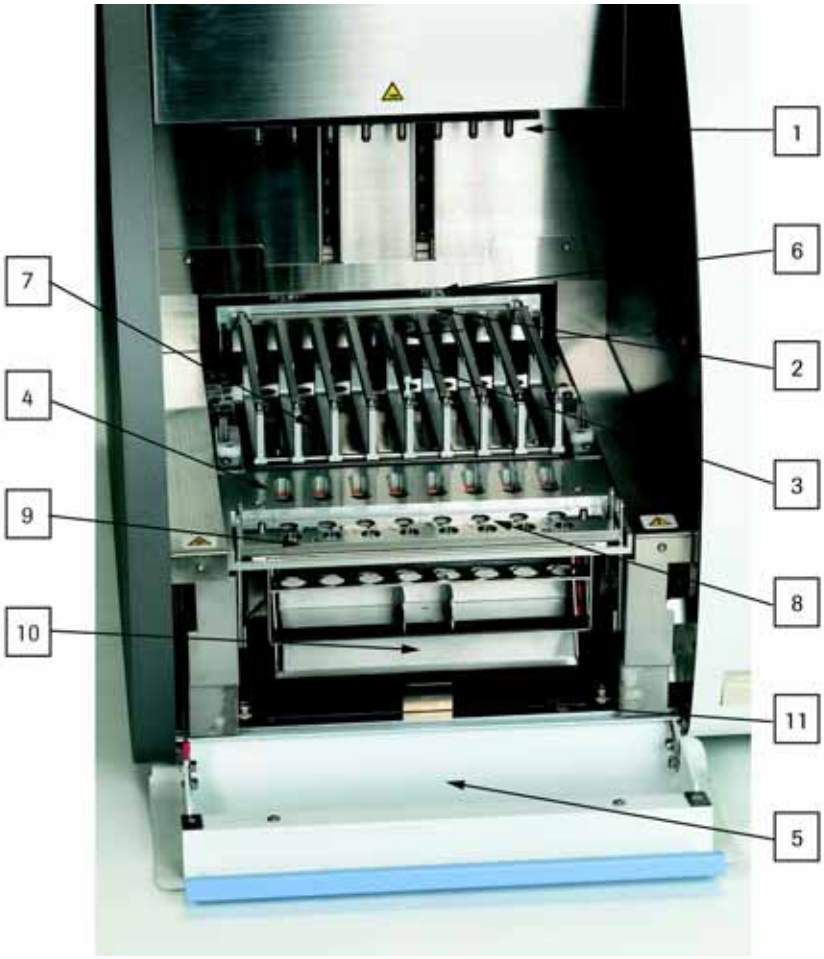
The disk drive allows the operator to store the data generated as well as transfer it easily to other instruments or computers, e.g for sample tracking, documentation or trouble-shooting. In addition, new MagNA Pure Compact Purification protocols can be uploaded from commercially available disks.

9 Barcode Scanner

The barcode scanner enables the use of barcodes to track samples through the entire purification process as well as prior (sample preparation) and subsequent steps (e.g. PCR, storage of the eluate). Moreover, when you scan the cartridge barcode, the touch-screen will display the name of the correct MagNA Pure Compact Purification Kit and the instrument will automatically load the appropriate purification protocol.

A

3.3.2 Detailed view



1 Nozzle Head

The nozzle head performs all pipetting steps. Its 8 nozzles can hold up to 8 reaction tips per time. It also contains the tip-loss & clot-detection system (pressure sensor).

2 Magnet Unit

The magnet unit contains permanent magnets and can move forward and backward from the rear of the chamber. For separation of magnetic beads from the buffers, the magnetic plate moves closer to the reaction tips, thereby immobilizing the magnetic beads on the inner surfaces of the reaction tips. The distance between magnet and reaction tips is controlled by the software. The magnet unit also holds the drop catcher.

A

3 Heating Block

The heating block has two independantly working units for two dedicated wells (for the lysis and elution step) per one reagent cartridge. These wells are separated from each other and from the wells with ambient temperature by a little distance.

4 Tip Rack

The tip rack holds up to 8 Tip Trays, each carrying 2 large tips, 1 small tip, and a disposable piercing tool, which pierces the aluminum foil on every cartridge well before purification starts. After it uses them, the instrument places the tips back into their original positions on the tip tray for easy disposal.

5 Front Door

The front door can be opened for maintenance purposes or to remove the trays, the liquid waste tank, or the drip tray. It is opened by moving the lever at the right door side to the left.

Instrument parts 6-11 are accessories and are described in detail under section 3.3.5 MagNA Pure Compact Accessories.

6 Drop Catcher

7 Cartridge Rack

8 Tube Rack

9 Elution Tube Rack

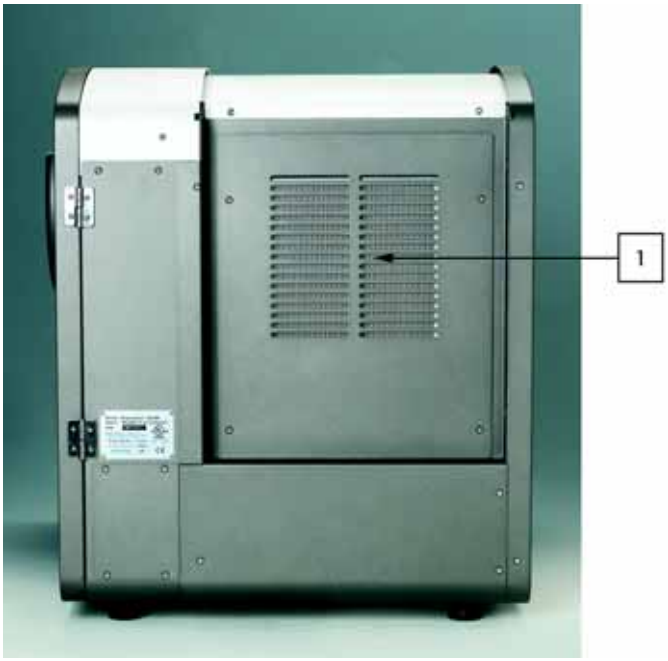
10 Waste Tank

11 Drip Tray

A

3.3.3 Back View of the Instrument

Description of Instrument Back



1 Exhaust fans with HEPA filter

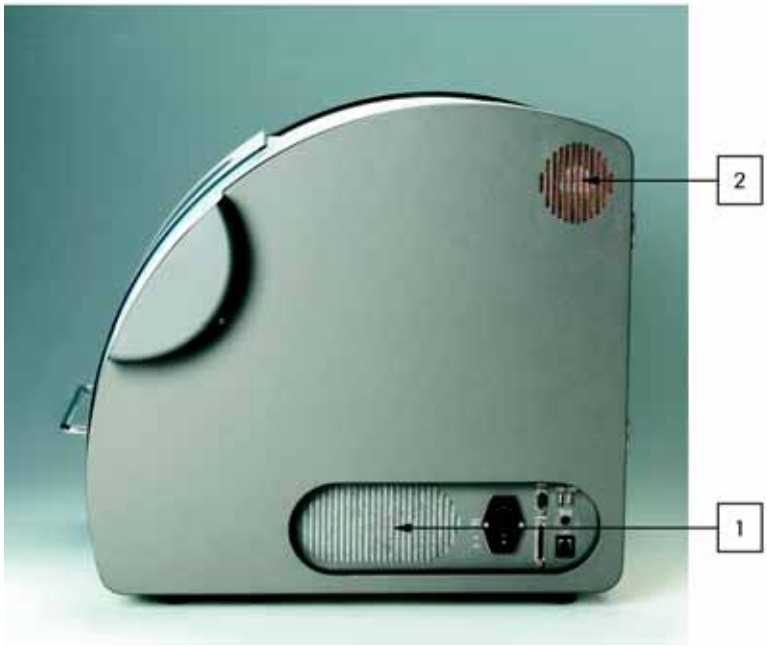
The housing is cooled by air. The instrument has air inlets with dust filters on both sides of the instrument. An exhaust fan expels this air from the back of the instrument through a HEPA (glass fiber) filter.

Note: This HEPA filter retains some aerosols. However, the MagNA Pure Compact Instrument is not guaranteed to be fully air-tight. Although the total air flow from the platform goes through the HEPA filter, air does flow under the platform as well as over it. Thus, there is a possibility that some of the air surrounding the platform will escape from the instrument without HEPA filtration.

A

3.3.4 Sides of the Instrument

Description of Right Side of Instrument

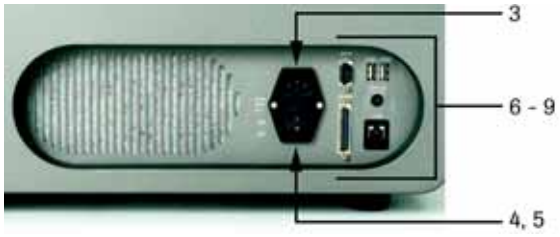


1 Air Inlet

Air inlet for electronic compartment, with dust filter.

2 Air Outlet

Air outlet for electronic compartment.



3 Main Switch

Use the Main Switch to turn the instrument on and off, e.g. in case of an emergency or if the instrument is not in use for longer time periods. In routine daily use the instrument should be turned off via the software button on the touch-screen as described in chapter B.

A

4 Socket for power cable

This is the plug-in for the power cable. There are two power cables included in the instrument package, one for US and one for German wall outlets.

5 Fuse

Next to the power inlet is a socket for the 2 main fuses. In case the fuses need to be replaced, make sure to first unplug the instrument from electrical power. A set of spare fuses is enclosed with the instrument.

6 Barcode Scanner port

The PS/2 port marked „Barcode Scanner“ is to be used for the barcode scanner.

7 Parallel Port

The parallel port is intended to be used for the connection with a local printer.

8 Serial Port (RS232)

The serial port might be used for additional external devices for LIMS.

9 USB Ports

There are two USB ports, USB 1 and USB 2 port, can be used for any accessories that are not included with the MagNA Pure Compact Instrument.

Description of Left Side of Instrument

1 Air Inlet

Air Inlet for the processing area with dust filter. Dust filters keep dust particles away from the inside of the instrument. Air is expelled by a fan through the HEPA filter on the back-side of the instrument.

A

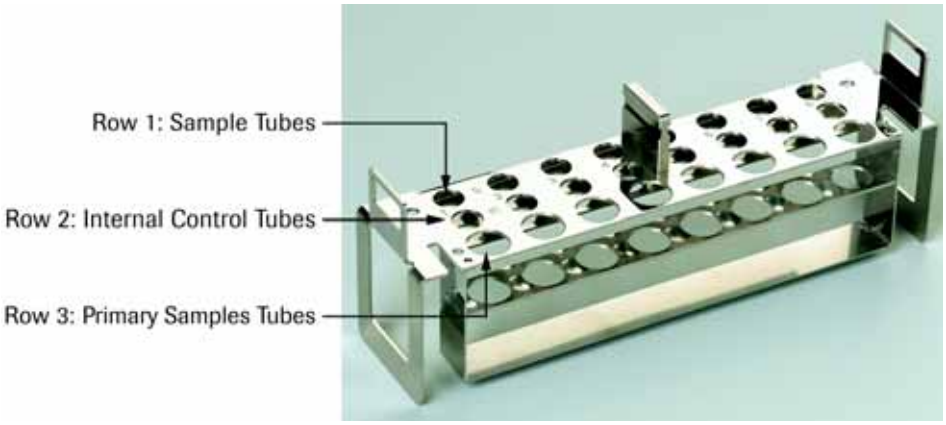
3.3.5 MagNA Pure Compact Accessories

All MagNA Pure Compact Accessories described below can be ordered separately. For ordering information see chapter C, Ordering Guide.

1 Cartridge Rack

The cartridge stage holds the cartridge rack, where the individual prefilled reagent/processing cartridges (up to 8 per purification run) are inserted. The Cartridge Rack can be equipped in and outside of the instrument.

2 Tube Rack



In row 1, the Tube Rack holds up to 8 sample tubes (capacity 2.0 ml), which are provided with the purification kits. If you are running an Internal Control, you can purchase up to 8 additional sample tubes (capacity 2.0 or 1.5 ml) from Sarstedt and place them in row 2 (the Internal Control Tube Rack). (For details see the Related Products section in Chapter C). In row 3, primary sample tubes (not provided) may be placed prior to starting the purification process. To discriminate it from row 1 and 2 the positions of row 3 have a wider diameter.

The rack has numbered positions (1-8) and can stand upright on e.g. a bench. The tubes can be screwed down with one hand, as they are secured against turning by a mechanical anti-twist device.

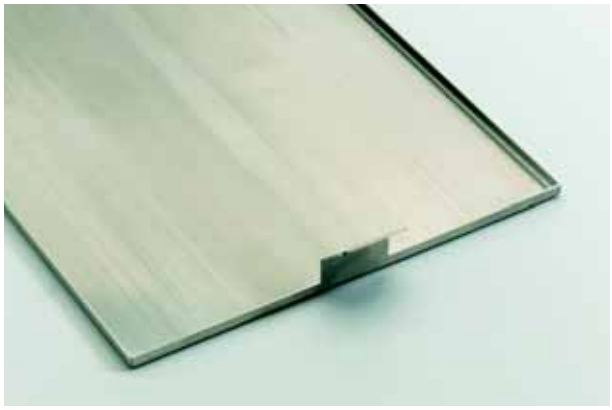
Note: To ensure correct pipetting, use only these recommended types of tubes for the Internal Control: 2.0 ml Sarstedt Tubes (without cap: Sarstedt #72.608; with cap: Sarstedt #72.693).

A

3 Elution Tube Rack

The Tube Rack also contains a separate rack for elution tubes. The Elution Tube Rack will sit on the tube rack, after both have been equipped. The two holes of the Elution Tube Rack match with the two pins of the tube rack. After assembly the elution tube rack hides the row for primary sample tubes. The elution tube rack holds up to 8 tubes (capacity 2.0 ml), each labelled with an individual barcode. These tubes are provided with the reagent kits. The rack has numbered positions (1-8) and can stand upright on e.g. a bench.

4 Drip Tray



The Drip Tray keeps any accidentally spilled liquid away from the interior of the instrument housing, especially from the electrical components of the instrument which are located below the Processing Stage. It can be removed for cleaning. (For details see the Maintenance section in chapter C.) See chapter C for details on cleaning the drip tray.

A

5 Waste Tank

The instrument contains an integral waste tank, where liquid waste accumulates during each purification run. It can hold all the liquid waste from one purification run.

Note: To avoid contamination, always remember to empty the waste tank after every purification run. The tank is located beneath the tube racks, which must be removed before you can reach the tank. The waste tank sensor will determine whether the tank is inserted correctly or not. See chapter C for details on emptying the liquid waste tank.

6 Drop catcher

The drop catcher is carried by the upper side of the magnet unit and is placed directly below the nozzle head each time it moves anywhere except from one well to the next. If a drop should leave the pipet, it is caught by the drop catcher.

The drop catcher can be removed from its place for cleaning purposes. See chapter C for details on possible causes and how to avoid.

7 Barcode Scanner

The barcode scanner is intended for protocol selection (automatically when the kit cartridge is scanned) and positive sample tracking.

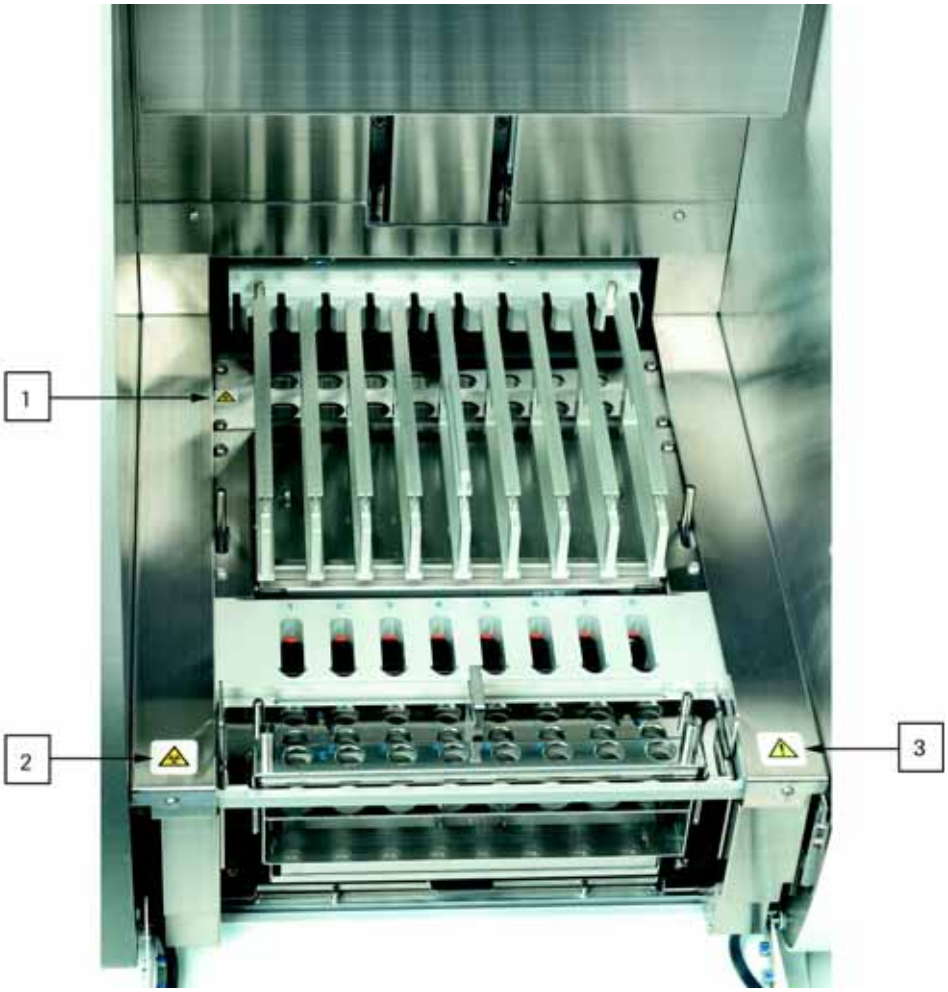
A

Scanner Specifications

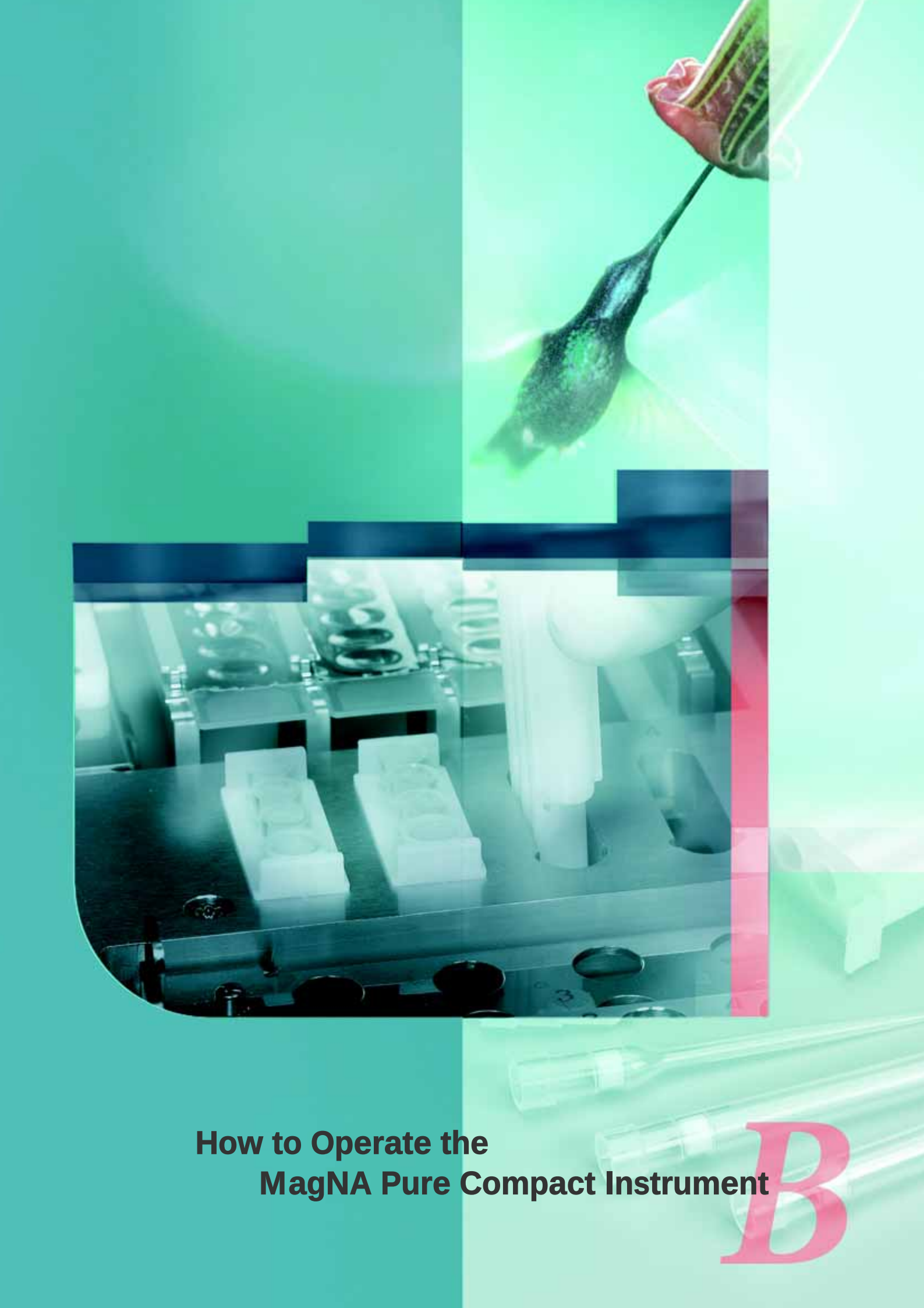
Power Supply	5 VDC ±5%
Consumption	250 mA operating, 330 mA max.; 250 µA sleep mode
Max. Resolution	0.076 mm (3 mils)
Scan Rate	270 scans/sec.
Min. Print Contrast Ratio	15%
Reading Angle	Skew: ±80°, Pitch: 65°, Tilt ±35° (EAN13, M=0.8, PCS=0.9)
Reading Indicators	Good Read LED, „green spot“ on the code, adjustable tone „beeper“
Readable Barcodes	2/5 family, Code 39 (plus Code 32, Cip 39), EAN/UPC, EAN 128, Code 128, Code 93, CODABAR, TELEPEN, PLESSEY, Code 49, Code MSI, Code Delta IBM, Code 11, CODABLOCK, and Code 16K, PDF 417
Enhanced Features	Puzzle Solver™, data editing and data concatenation
Weight	(approx.) 200 g
Case Material	ABS and Polycarbonate
Cable Length	2 m (6.1 ft.) linear or coiled
Ambient Light Conditions	Up to 100.000 lux
MTBF	>240,000 hours (MIL-HDBK-217F ground benign)
Operating Temperatures	0 to 55 °C
Storage Temperature	-20 to 70 °C
Humidity	90% non-condensing
Drop Resistance	IEC 68-2-32 Test ED; withstands repeated drops from 1.8 m onto a concrete surface
ESD Protection	16 kV
Environmental Protection	IP30

A

3.3.6 Position and Meaning of Warning Labels



No.	Symbol	Location	Meaning
1		Heating Block	The heating block reaches temperaturs of 100°C. Do not touch the block during and directly after purification. If you touch the block, it may burn you.
2		Housing	Biological hazardous material is processed inside the instrument.
3		Warning	Read the Operator's Manual before using the instrument.



How to Operate the MagNA Pure Compact Instrument

B

B

How to Operate the MagNA Pure Compact Instrument

B

1. Handling the MagNA Pure Compact Software

Once the MagNA Pure Compact Instrument is turned on, the integral computer controls all instrument operations. The instrument is operated by the touch-screen and the bar-code scanner only. The menus on the instrument touch-screen will guide you through instrument set up and operation.

Note: If you need additional information about a particular function, touch the Information button to see a more complete description of the function.

1.1 Starting the MagNA Pure Compact Instrument

To start the MagNA Pure Compact Instrument, push the Power On button on the front of the instrument

Note: The Power On button is only used for starting the instrument. To shut down the instrument, always use the Exit button on the computer touch-screen. (See below for location of this button.)

On start up, the program displays a START UP Screen while it loads the program and runs a start up self-test. The startup usually takes about one-minute.

B

Table 1 below shows the systems examined during the self-test. If any test is not passed, the screen will display an error message. (For an overview of error messages, please see chapter C.)

Function	Test
Instrument communication	Check for correct communication between hardware and software.
Door sensor	Function test of sensor for locked front door.
Magnetic sensor	ON/OFF status must correspond to its position
Home sensor	Function test of sensor for robotic arm in home position.
Waste tank sensor	Check for presence of waste tank.
Housing fan sensor	Check for presence of housing fan.

Table 1: Overview of self-test

Note: If the self-test is not passed and the remedy as described in the section about errors and troubleshooting does not help, please contact your local Roche representative.

Note: Besides the start up self-test, the instrument will automatically perform a self-test after a certain period of instrument inactivity. You must confirm execution of this self-test on a message window.

1.2 Overview of Main Menu Screen

After the self-test is complete, the MAIN MENU screen appears (figure 1). From this menu, you can easily access all the software submenus by touching the appropriate buttons.

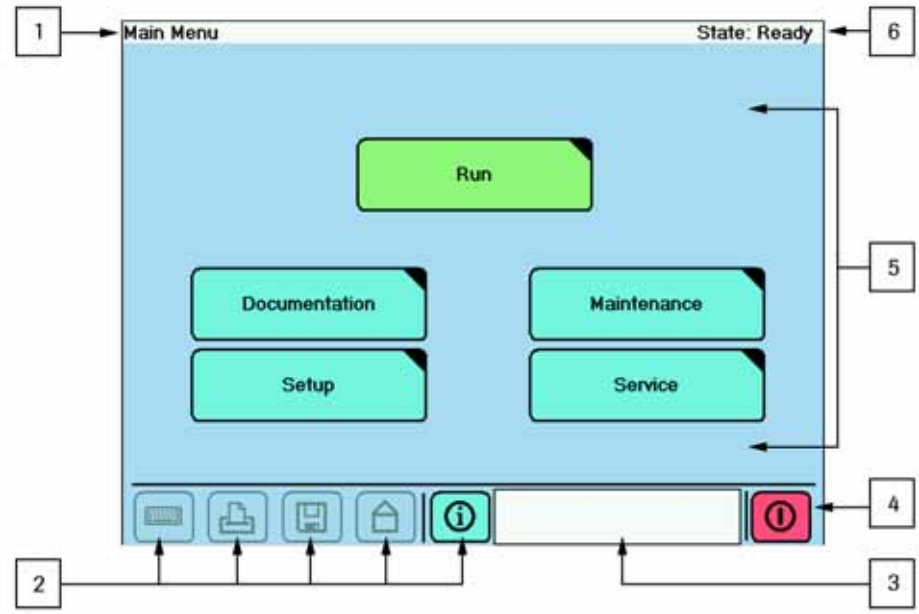


Figure 1: Parts of the Main Menu Screen

1. Title of current menu/submenu

The left portion of the title bar lists the name of the menu or submenu currently displayed on the screen. Table 4 on page 41 shows an overview over menu and submenu structures.

2. Global Action Buttons

Touching one of the global action buttons will activate/execute the corresponding function. Table 2 at the end of this section gives an overview of the function buttons.

Note: If a function button appears in the background (i.e., is displayed in the background color), it cannot be activated at this time.

3. Display field for error codes/information

A short error code is displayed here, if an error occurs. For an overview about instrument errors, please see chapter 4.2 Instrument Error Codes. An information window with a long information message pops up, if the appropriate global action button is activated.

4. Button for Instrument Shutdown

Solely shut down the instrument by touching this button.

5. Buttons for Submenus

You can access any submenu by touching one of the submenu buttons on the MAIN MENU screen. Table 4 at the end of this section describes the functions of the main menu and submenus. An overview of the maintenance submenu is given in chapter C, sections 1 and 2.

6. Status Indicator

The right portion of the Title Bar shows the current status of the instrument. For a list of possible statuses, see table 3 at the end of this section.

B

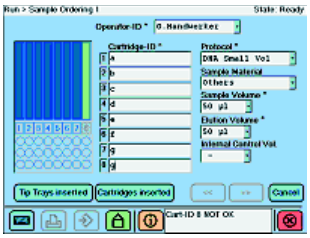
Symbol	Name	Function
	Keyboard	Brings up a virtual keyboard. Only active when a text box that allows typed entries is highlighted. Regular set of symbols (mostly lower case) for virtual keyboard (shift off):  Alternate set of symbols (mostly upper case) for virtual keyboard (shift on): 
	Print	Prints current screen information, if a printer is connected locally.
	Save	Saves current screen information to the folder defined in the Setup submenu.
	Home	Returns to main screen. Inactive during processes that cannot be interrupted (*e.g.*: purification runs)
	Information	Errors, warnings and additional informations are displayed in the display for error codes/information.  To obtain more detailed information about the current software function or about the error history, select the information button; a pop-up window will open.  According to the type of message displayed, the Information button changes its color: Red — Error — Urgent information, act immediately. Yellow — Warning — Information needs attention soon. Green — Information — Supplementary information, instrument is running OK.
	Exit	Exits the software program and switches the instrument off. When you touch this button, a dialog box will appear to ask you to confirm the Shut Down command, 

Table 2: Global action buttons

State	Description, instrument action
Ready	Self-tests OK, instrument is ready for operation, maintenance, or service functions.
Error	Instrument is shut down by fatal error or awaiting user intervention after error
Running	Protocol is beeing processed
Run completed	Run is completed, result screen is displayed.
Leaky	If the last leakage test has not been successful (state remains until next O-ring change or next successful leakage test). Performing a purification run is not possible.

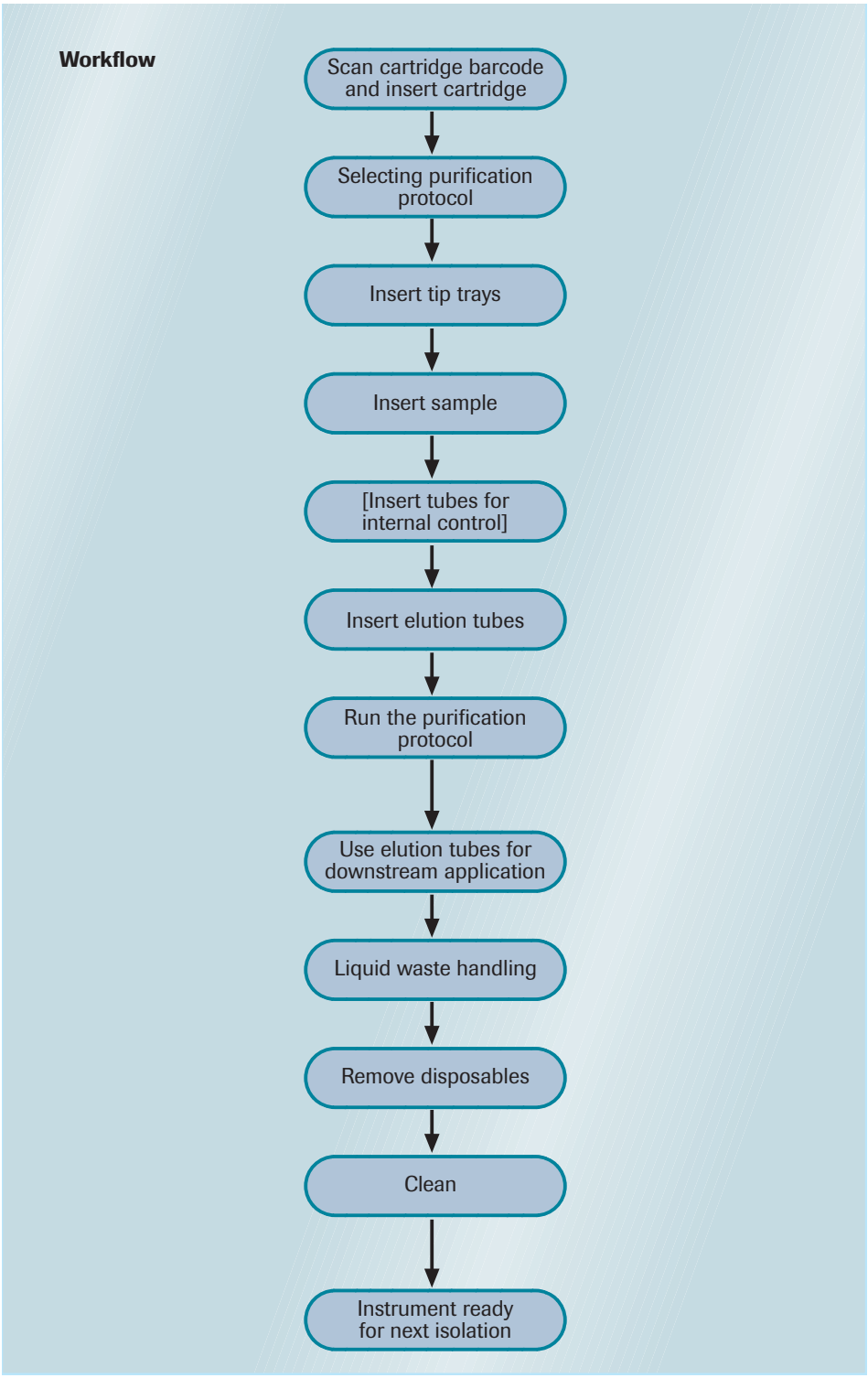
Table 3: Overview of Instrument Statuses

Submenu	Function	Described in	Detailed Actions
Run	Performing a purification run	Chapter B	Perform the sequence of steps on the Sample Ordering Screens: ▶ Operator Authorization ▶ Sample Ordering 1 ▶ Sample Ordering 2 ▶ Sample Ordering 3 ▶ Sample Ordering 4 [available with IC] ▶ Sample Ordering 5 ▶ Confirmation
Setup	Setting basic information	Chapter A	Setting: ▶ Time and Date ▶ Operator administration ▶ Laboratory name ▶ Folder where results are saved ▶ Sample material
Documentation	Organizing documentation	Chapter B	Documentation via: ▶ Printouts ▶ Saved result files
Maintenance	Performing instrument maintenance	Chapter C	Maintaining: ▶ Leakage Test ▶ Counter and Reminder ▶ Error Log ▶ O-ring Exchange ▶ Liquid Waste Discard ▶ UV Decontamination
Service	Performing specialized service functions	Not described in this Operator's Manual.	Used by Roche service operators only

Table 4: Overview of menu and submenu structure

B

1.3 Flow Diagram for Preparation of a Purification Run:



2. Performing a Purification Run

Do not use the equipment in a manner not specified by the manufacturer (see pages 11-12). Otherwise, the protection provided by the equipment might be impaired.

For kit specific details regarding the handling of Reagent Cartridges, please see the corresponding pack insert of the kit.

Warnings and Precautions when handling the Reagent Cartridges:

- Wear protective disposable gloves, laboratory coats and eye protection when handling samples and kit reagents, and follow usual safety precautions during handling. Avoid contact of the reagents from the kit with skin, eyes, or mucous membranes. If contact does occur, immediately wash with large amounts of water. Burns can occur if left untreated. If reagents are spilled, dilute with water before wiping dry.
- Handle each Reagent Cartridge prior to use as follows:
  - Always adapt the Reagent Cartridge to room temperature (30 min). If you use the reagents at temperatures outside the recommended range, the kit may not work well.
  - Check the cartridge sealing foil for any possible damage and the cartridge for correct filling. Do not use a cartridge that does not appear as specified.
  - Always wear gloves when handling the MagNA Pure Compact reagent cartridge.
  - Hold the cartridge at the barcode imprinted area and the opposite side only.
  - Avoid touching the sealing foil covering the cartridge wells.
  - Avoid touching the two single open wells and do not use them as handles.
  - Mix the content of the cartridge wells by turning the whole cartridge upside down several times.
  - Avoid any foam formation.
  - Let the fluid within the cartridge wells settle again completely. If fluid or magnetic glass particles remain under the sealing foil, knock the cartridge bottom gently on a flat lab bench surface. Note: Small drops may remain at the sealing foil (up to 30 µl).
- Wash hands thoroughly after handling samples and test reagents.
- Do not eat, drink, or smoke in the laboratory work area and do not pipet by mouth.
- Some buffers contain the hazardous compounds guanidine thiocyanate and guanidine hydrochloride. Do not allow reagents containing guanidine thiocyanate to contact sodium hypochlorite (bleach) solution or acids. These mixtures produce a highly toxic gas.
- All mammalian (especially human) material and all resulting waste is potentially infectious. Thoroughly clean and disinfect all work surfaces with disinfectants recommended by the local authorities.
- Dispose of unused reagents and waste in accordance with country, federal, state, and local regulations.
- Material Safety Data Sheets (MSDS) are available upon request from the local Roche office.
- Use sterile, disposable, nuclease-free pipette tips to avoid microbial and nuclease contamination.
- Do not use sharp or pointed objects near the reagent cartridge in order to prevent damage of the sealing foil and loss of reagent.
- Do not use a kit after its expiration date.

B

Warnings and Precautions when handling the Tip Trays:

- Check that piercing tool and reaction tips are placed correctly in the Tip Trays before use.
- Handle Tip Trays with care to prevent tips or piercing tool from falling out of the tray. Should this happen, discard the respective tip tray and tips. Use the Tip Tray Kit to replace missing Tip Trays.

Note: To ensure that you have entered all essential information before starting the purification run, the software screens will guide you through the steps for programming a purification run. At each screen, you must enter values in all parameter fields that are marked with a "*“ and press all confirmation buttons that are marked with a "?“ before you can go to the next screen. All fields that are not marked with a "*“ are for documentation only; you do not have to fill these in. Nevertheless, we recommend that you enter values in these fields, since this information may later help with troubleshooting.

Controls

Always run appropriate controls with the samples, especially if you want to perform quantification analyses of the eluted DNA samples (*e.g.*, by LightCycler® 2.0 System PCR assays). In order to control the complete process starting from sample preparation to quantification analysis, perform the following controls:

- Positive Control, by using a sample material positive for your target.
- Negative Control, by using a sample material negative for your target.
- Internal Control, by adding a defined amount of a control template (*e.g.*, plasmid DNA) to all samples to be purified or by analyzing an endogenous nucleic acid sequence present in all your samples.

For the MagNA Pure Compact Nucleic Acid Isolation Kit and MagNA Pure Compact Nucleic Acid Isolation Kit - Large Volume:

The Internal Control (IC) is added prior to the purification step, then co-purified, and amplified with your target of interest from the specimen in the same PCR reaction. The IC concept is especially useful for enzyme-based amplification processes such as PCR, because inhibitors present in the purified sample material might reduce efficiency of the PCR process. In addition, the Internal Control is used to compensate for possible losses of your target during purification.

For LightCycler® 2.0 System quantification assays use a synthetic double-stranded DNA molecule with primer-binding sites identical to those of your target sequence, but having a unique probe-binding region that differentiates the IC from the target-specific amplicon. Discriminate the signals derived from your target and the IC by performing a dual-color HybProbe assay. For detailed information regarding the IC concept in combination with the LightCycler® 2.0 System, read LightCycler® Technical Note 12/2000 “Absolute Quantification with External Standards and an Internal Control” available at http://www.lightcycler-online.com.

For the MagNA Pure Compact RNA Isolation Kit:

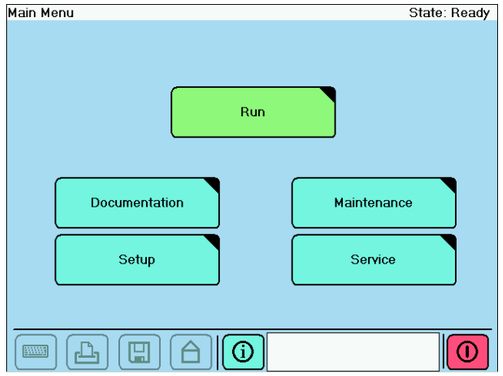
The selection of an appropriate endogenous IC is of high importance when developing a quantitative RT-PCR assay. The IC is co-amplified with the target of interest and serves as a control for several factors: differences in initial template concentrations between different samples, sample-to-sample variations in the PCR, presence of PCR inhibitors or the extent of any RNA degradation. The advantage of using an endogenous IC is that both internal control mRNA and target mRNA is extracted from cells or tissue and reverse transcribed together. Commonly used endogenous ICs include so-called housekeeping gene mRNAs. (Note that Roche Applied Science offers several LightCycler® Housekeeping Gene Sets for the detection of human housekeeping genes, incl. G6PDH, HPRT, ALAS, and β2-microglobulin.) The level of expression of an appropriate endogenous IC should not vary with the experimental conditions or treatments to be compared.

2.1 Purification

Action	Handling
1	
2	

Software programming

Please select the Run button from the Main Menu Screen to get to the following screen.



The OPERATOR AUTHORIZATION Screen appears. While at this screen, do the following:

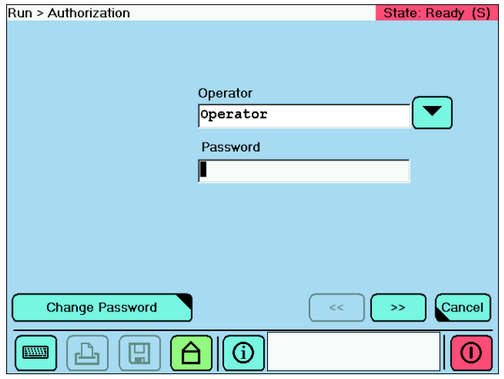
a. Either accept the User name that appears in the Operator field or select a different name from the drop-down menu (accessed by touching the Down button beside the field).

b. Enter the password

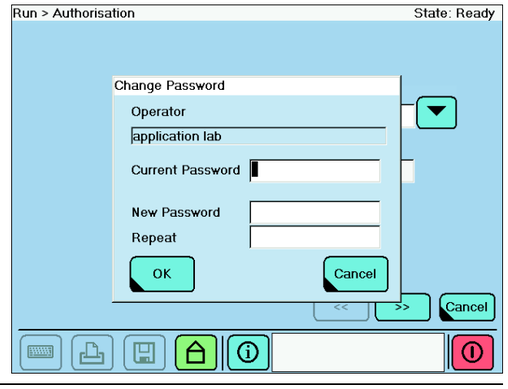
c. *Cancel* leeds back to the Main Menu.

d. Confirm your choices by touching the *Next* >> button (which will be active only if the Operator and Password fields are filled in and the password is correct).

Note: You cannot add new operator names from this screen; these must be added from the SETUP Screen (as described in chapter A 3.4.3).



To change the password associated with a particular operator name, touch the Change Password button. A pop-up window will open to allow you to enter the new password.



B

Action	Handling
3	
4	

B

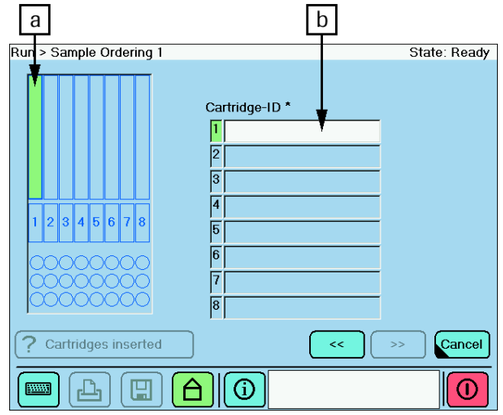
Software programming

Open the front door of the MagNA Pure Compact Instrument and remove all the racks you will need for the run:

a. Cartridge Rack
Pull the handle towards you to lift the Processing Stage. Pull the stage towards the front of the instrument to move the pin on the front of the stage to the top (wide part) of the keyhole in the Cartridge Rack. Now you can remove the Cartridge Rack.

b. Tube Racks
Remove the Tube Rack (which also holds the Elution Tube Rack) and place it on the laboratory bench, so you can easily insert the samples and (if appropriate) the internal controls according to the instructions that will appear on the touch-screen.

SAMPLE ORDERING SCREEN 1 appears. While at this screen, do either of the following:

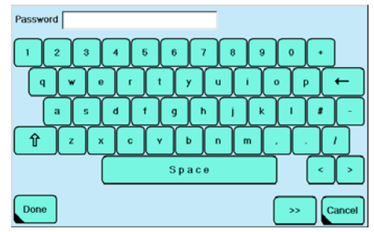


- Use the barcode scanner to scan the barcode of the first prefilled Reagent Cartridge.
  Note: In case you experience difficulties in scanning the barcode:
  - try to scan holding the barcode scanner in different angles
  - wipe the barcode surface carefully before scanning

Result:

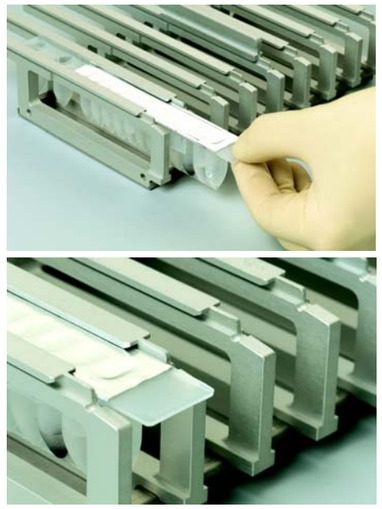
- The instrument will display the name of the appropriate purification kit.
- On the overview diagram (upper left corner of screen), cartridge position 1 (a) changes from the background color to green (indicating position 1 is "active").
- The scanned barcode (b) appears in the first text field (Cartridge ID 1).

Alternatively, you may use the virtual keyboard to enter the barcode in the Cartridge ID field:



- Touch the field to highlight it.
- Type the Barcode number in the keyboard text field.
- Touch the Return key to transfer the number to the Cartridge ID 1 field (on SAMPLE ORDERING SCREEN 1).

B

Action	Handling
5	
6	
7	 

B

Software programming

For best results, grab the flap that is on the opposite end of the cartridge from the two isolated wells. Then, with the two isolated wells pointing away from you, insert all the wells on the plastic cartridge into the holes in the cartridge rack. Use the guide slots on the rack to help position the cartridge.

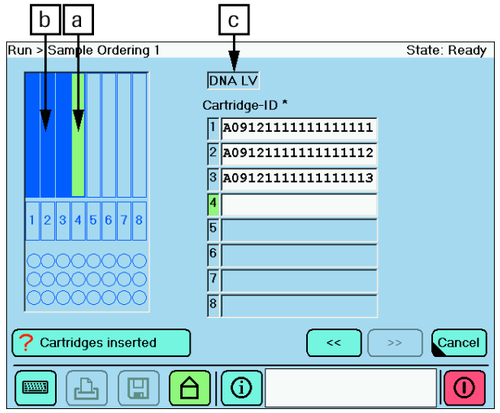
Note: Make sure the cartridge fits all the way into the rack. Do not simply lay the cartridge on top of the rack, since, if it sticks up, it may move during the run and cause the instrument to malfunction.

If you are going to process more than one sample during the current purification run:

Repeat the above cartridge identification and placement steps 4-5 for each prefilled cartridge until all (up to 8) cartridges are recorded on screen and inserted in the cartridge rack.

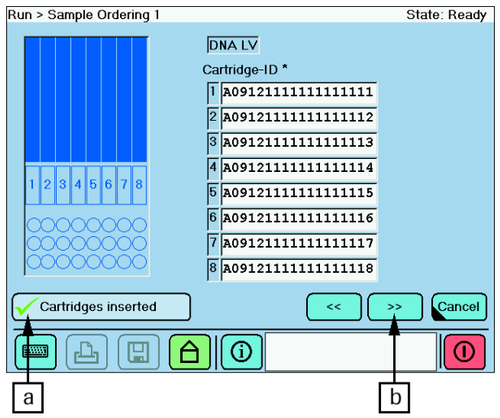
Result: On the overview diagram, the last added cartridge position will be green (a), and the previously added positions will be dark blue (b). The name of the appropriate purification kit will also be displayed (c).

Note: It is not possible to enter barcodes of the same type (catalogue number). Barcodes from identical or expired cartridges are rejected.



When all cartridges have been programmed and inserted into the cartridge rack, do the following:

- Reinsert the Cartridge Rack into the MagNA Pure Compact Instrument. To reinsert the Cartridge Rack, fit the pin on the stage into the wide part of the keyhole on the rack, then push the rack back, which will also immobilize the pin in the narrow part of the keyhole. Now you can lower the stage by moving the handle away from you.
- On SAMPLE ORDERING SCREEN 1, touch the Cartridge Insertion confirmation button (a). After you touch the confirmation button, the symbol on the button changes from "?" to a checkmark.
- The Next [>>] button (b) will now be active. Touch this button to confirm the information on this screen and go to the next programming screen.



B

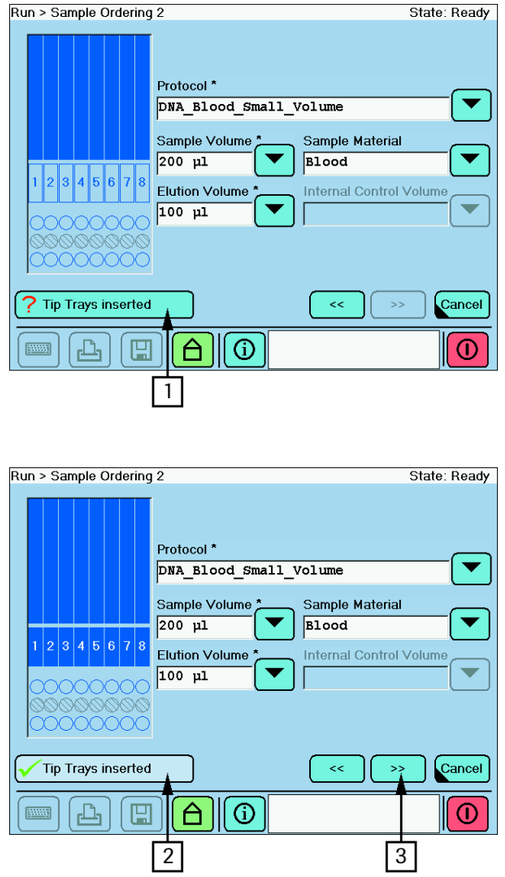
Action	Handling
8	

B

Software programming

SAMPLE ORDERING SCREEN 2 appears. While at this screen, do the following:

- In the Protocol field, either accept the protocol (from the last run) that appears in the field or select another purification protocol from the adjacent pull-down menu. (Touch the Down arrow to the right of the field to access this menu.)
- In the Sample Volume field, select a value from the adjacent pull-down menu.
- In the Sampe Material field, select your sample material from the adjacent pull-down menu.
- In the Elution Volume field, select a volume from the adjacent pull-down menu.



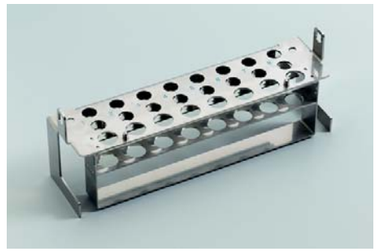
Note: For an overview about the possible combinations of different sample and elution volumes, please refer to the respective pack insert of the purification kit. Combining of non recommended volumes may leed to suboptimal results (*e.g.* processing performance, yield, etc.)

- (optional) If you are using an internal control, select a control volume from the pull-down menu adjacent to the Internal Control Volume field: You can choose between 5, 10, or 20 µl. Default setting is None. Note, that some purification protocols do not allow an optional internal control.
- Insert the appropriate number of Tip Trays (one per purification) in the instrument Tip Rack.
- On SAMPLE ORDERING SCREEN 2, touch the "Tip Trays inserted" confirmation button (1).

Result:

- After you touch the "Tip Trays inserted" confirmation button, the symbol on the button changes from "?" to a checkmark (2). Also, the reagent layout diagram shows the tip trays inserted (in dark blue).
- The Next button [>>] will now be active. Touch this button to confirm the information on this screen and go to the next programming screen.

B

Action	Handling
9	  

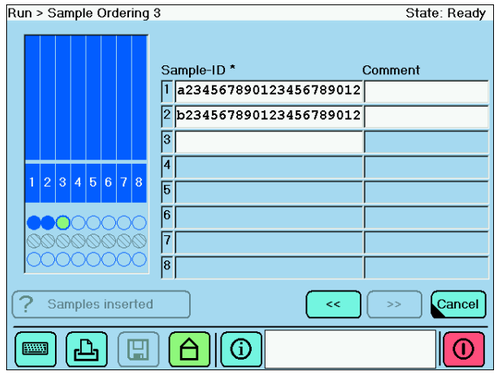
Do one of the following:

If ...	Then ...
You are not using internal controls (i.e., you selected a protocol with no internal control on SAMPLE ORDERING SCREEN 2) (Action 8 above)	▶ Insert the tube rack into the MagNA Pure Compact Instrument. ▶ Touch the "Samples inserted" confirmation button (a). ▶ The Next button (b) will now be active. Touch this button to confirm the information on this screen and go to the next programming screen (SAMPLE ORDERING SCREEN 5). ▶ Go to Action 11 below.
You are using internal controls (i.e., you selected a protocol with internal control on SAMPLE ORDERING SCREEN 2)	▶ Touch the "Sample inserted" confirmation button (a). ▶ The Next button (b) will now be active. Touch this button to confirm the information on this screen and go to the next programming screen (SAMPLE ORDERING SCREEN 4). ▶ Go to Action 10 below.

B

Software programming

SAMPLE ORDERING SCREEN 3 appears. While at this screen, do the following:

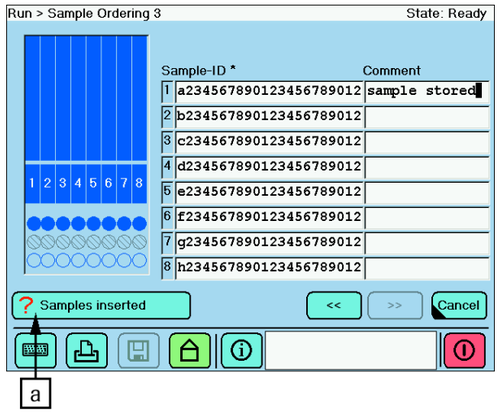


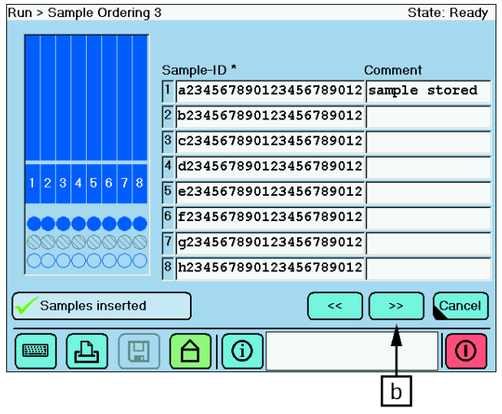
- Pipet the correct type and amount of sample material (as chosen on Sample Ordering Screen 2) into a sample tube (tube without barcode label, from the reagent kit).
- Identify the tube by attaching your own barcode label or writing a number on the tube with a permanent marker.
- Put the filled sample tube in position 1 on row 1 of the Tube Rack.

Note: It is recommended to use the appropriate row in the tube rack for original sample tubes, if suitable for these tubes (e.g. max. 15 ml Falcon tubes).

- On SAMPLE ORDERING SCREEN 3, touch Sample ID field 1. In that field, enter the ID of Sample 1 (i.e., the one you just put in the rack) by either scanning the (self-attached) barcode or using the virtual keyboard to type the ID number. (Touch the Keyboard button to access the keyboard.)
- (optional) In the Comment field, you may enter additional information about Sample 1. (Touch the field to highlight it, then use the virtual keyboard.)
- Repeat the above sample placement and identification steps for each sample to be purified (e.g., for Sample position 2, 3, …, 8).

Result: As you fill in the "Sample-ID" field for each sample, the corresponding position in the reagent layout will change from green (active) to dark blue (installed in instrument).





B

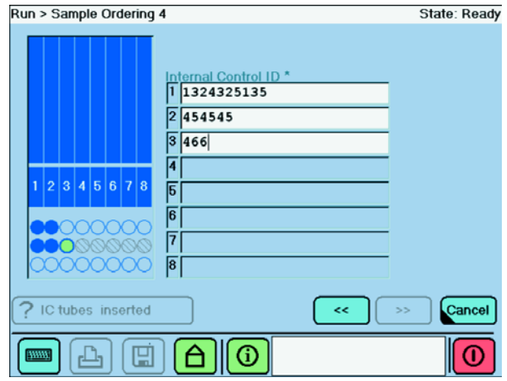
Action	Handling
10	 
11	  

B

Software programming

SAMPLE ORDERING SCREEN 4 appears.

Note: This screen only appears and accepts information about Internal Control Tubes if you selected a protocol with internal controls on SAMPLE ORDERING SCREEN 2. (See Action 8 above). The program will skip this screen if you selected a protocol with no internal control.



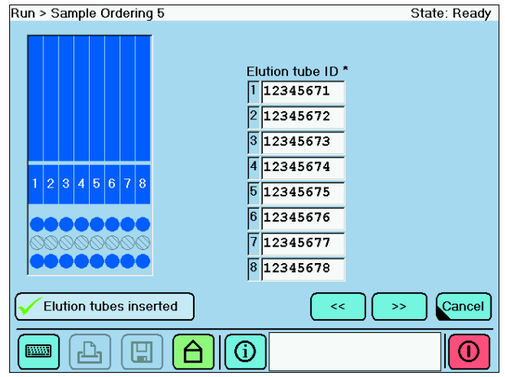
Note: Pipette the lysed sample into the Internal Control Tube before you place the tube in the cartridge. It is essential for this action to have an Internal Control Tube inserted!

- Pipet the proper amount of internal control (as specified on Sample Ordering Screen 2) into one of the Internal Control Tubes (not provided in kit; for purchase information, see chapter C).
- Identify the tube by attaching your own barcode label or writing an ID number on the tube with a permanent marker.
- Put the filled control tube in position 1 on row 2 of the Tube Rack.
- On SAMPLE ORDERING SCREEN 4, touch IC Sample ID field 1. In that field, enter the ID of Control 1 (i.e., the one you just put in the rack) by either scanning the (self-attached) barcode or using the virtual keyboard to type the ID number. (Touch the Keyboard button to access the keyboard.)
- Repeat the above control placement and identification steps for each control used (*e.g.*, for Control position 2, 3, …, 8).

Result: As you fill in the "Internal Control ID" field for each control, the corresponding position in the reagent layout will change from green (active) to dark blue (installed in instrument).

- Insert the Tube Rack with sample and internal controls into the MagNA Pure Compact Instrument.
- Touch the "IC Tubes inserted" confirmation button.
- The Next button [>>] will now be active. Touch this button to confirm the information on this screen and go to the next programming screen.

SAMPLE ORDERING SCREEN 5 appears. While at this screen, do the following:



- Put the appropriate number of Elution Tubes (supplied in the purification kit, with barcode labels) into the Elution Tube Rack.

Note: Elution Tubes will contain the final purified nucleic acid after it is eluted from the magnetic beads with elution buffer.

- Either scan the barcode on each elution tube into one Elution Tube ID field on SAMPLE ORDERING SCREEN 5 or type the tube ID into the field manually with the virtual keyboard.

For convenience you may insert all the tubes in the rack, then scan all their barcodes into the ORDERING screen at the same time (see picture). Alternatively, you may scan the barcode from each tube first, then insert it into the rack.

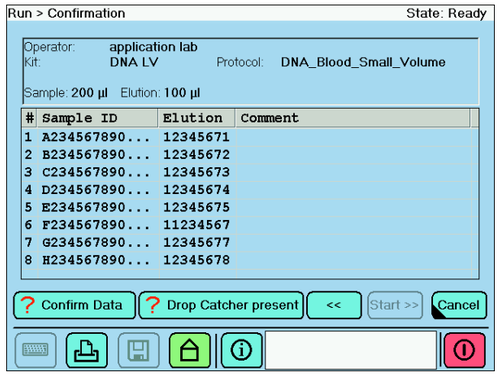
Result: As you fill the Elution tube ID field for each elution tube, the corresponding position in the reagent layout will change from green (active) to dark blue (installed in instrument).

- Insert the filled Elution Tube Rack into the MagNA Pure Compact Instrument.
- Touch the "Elution tubes inserted" confirmation button.
- The Next button [>>] will now be active. Touch this button to confirm the information on this screen and go to the next programming screen.

Action	Handling
12	
13	

Software programming

The CONFIRMATION Screen appears. While at this screen, do the following:



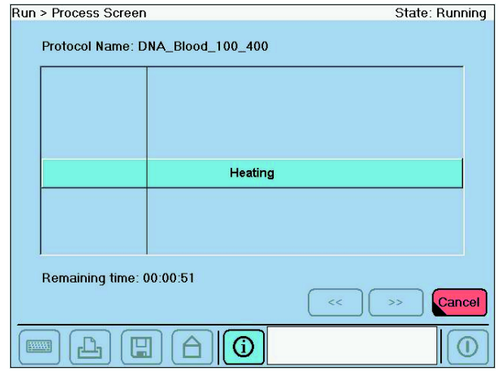
- Check the information display and:
  - if the information is correct, confirm it by touching the "Confirm Data" button, or
  - if the information is not correct, touch the Previous button [<<] as many times as necessary to go back to one of the earlier screens and change the erroneous information. Once the information is correct, touch the Next button [>>] (repeatedly) to return to the CONFIRMATION screen, then touch the "Confirm Data" button.
- Make sure the Drop Catcher is present on the Preparation Stage, then touch the "Drop Catcher present" confirmation button.
- Now the Start button will be active. Start the purification by touching this button.

The HEATING Screen will appear displaying the time needed for heating of the heating units.

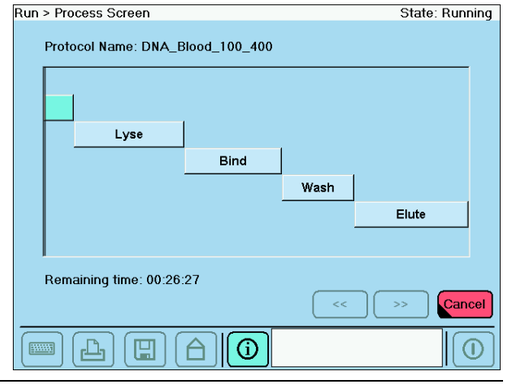
When heating is completed, the PROCESS Screen will appear and remain throughout the entire purification run.

- As the run progresses, this screen will display the actual step being performed and the time remaining.

Note: If you need to interrupt the run before it is complete, you can execute an emergency stop by touching the Cancel button. (Before the instrument actually stops the run, you will need to confirm the request twice by replying to dialog boxes that appear.)



- The instrument will sound an alarm when the run is finished. (See Chapter A for information on setting this alarm.).



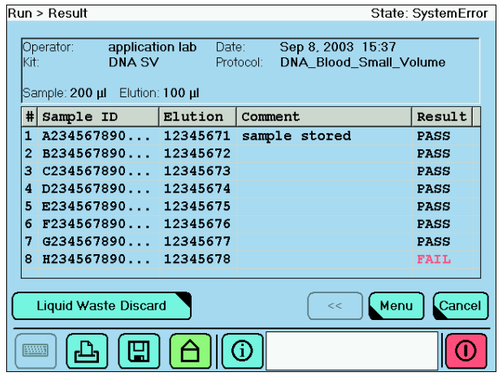
B

Action	Handling
14	
15	  
16	

B

Software programming

After the purification run has ended, the RESULT screen appears.



- The RESULT screen shows the result of the isolation process for each channel:
  - The result will be PASS if the isolation run was completed without any warning or error.
  - The result will be FAIL if any interruption of the process or error occurred during the run. For each FAIL result, the result screen will show a brief error or warning messages (in the scrollable Result list or the Information text box) to help you decide whether the error or warning can be ignored.

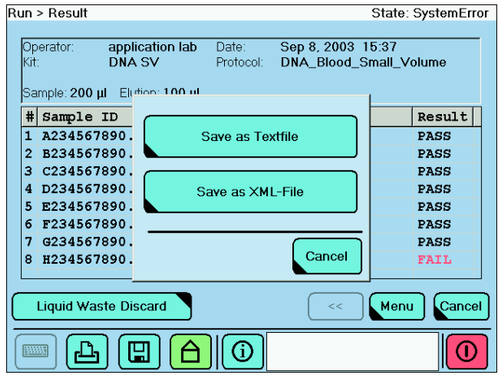
Note: To investigate a potential error cause either touch the Information button or use the Errorlog function from the Maintenance menu.

- To set up for the next run, you must empty liquid waste from the Drip Tray, then touch the Liquid Waste confirmation button on the RESULT screen.

Note: See chapter C for details on discarding liquid waste.

You can print and/or save the result by touching the appropriate function buttons (icons) at the bottom of the RESULT Screen.

Note: If you touch the Save button, a pop-up window will open to allow you to specify the export format (plain text or XML) of the Result file. The export file is saved to the Save Folder defined under basic software settings (see Chapter A, Software setup for details). The file name is equal to the Run ID.



Take out the Elution Rack with the Elution Tubes for further use.

Close the Elution Tubes with the screw caps provided.

Note: The tubes can be screwed down with one hand, as they are secured against turning by a mechanical anti-twist device.

Perform Liquid Waste Discard. Either discard all disposables containing liquid waste according to the relevant country specific regulations. Or use the automated function, which is accessible

a. via the Liquid Waste Discard button displayed on the RESULT screen

b. via the Maintenance Menue as described on the following pages in chapter B. 2.2

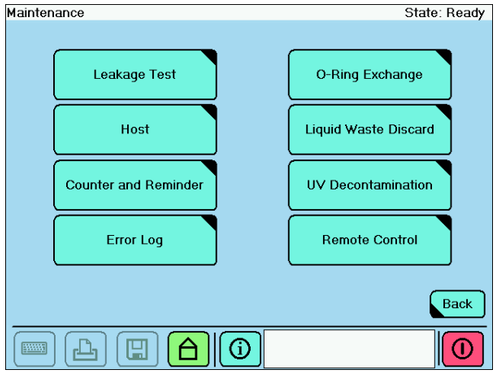
2.2 Liquid Waste Discard

Remove, empty and clean waste tank after each liquid waste discard.

Action	Handling
1	
2	
3	

Software programming

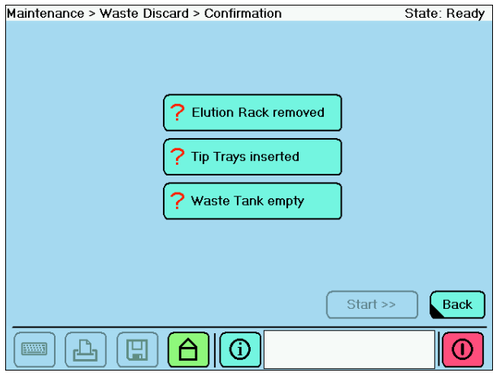
Use the in-built liquid waste discard function of the MagNA Pure Compact Instrument to collect the reagents of one purification into the Waste Tank. Thereafter, you can discard the liquid waste following relevant country-specific saftey rules. The instrument will prompt the operator to empty the Waste Tank after every purification run.



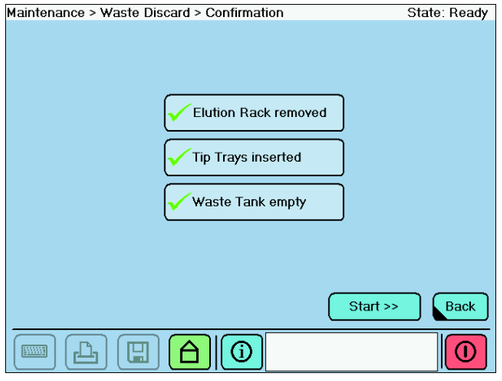
- On the Main Menu Screen touch the Maintenance button. The Maintenance screen appears.
- Touch the Liquid Waste Discard button.

Result: The Waste Discard Confirmation screen appears.

- Before performing the test, do the following in the instrument:
  - First, remove the Sample and Elution Tube Racks.
  - Make sure the Tip Trays are still inserted.
  - Make sure the Waste Tank is empty (but still in the instrument).



- After you perform each of the actions in Step 2, touch the appropriate button on the WASTE DISCARD CONFIRMATION Screen:
  - Elution Rack removed confirmation button
  - Tip Trays inserted confirmation button
  - Waste Tank empty confirmation button



- After you touch the three confirmation buttons, the Start button will become active. Touch this button to make the instrument start transferrring liquid waste from the cartridges to the Waste Tank.

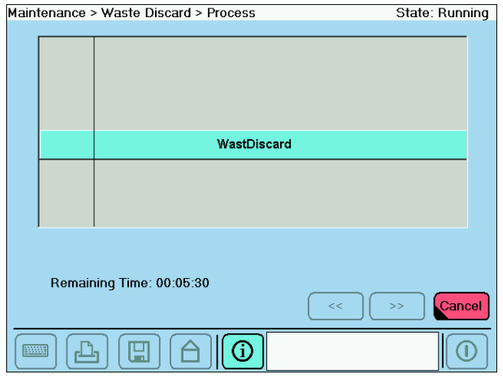
Action	Handling
4	
5	 

Software programming

After having touched the Start button,

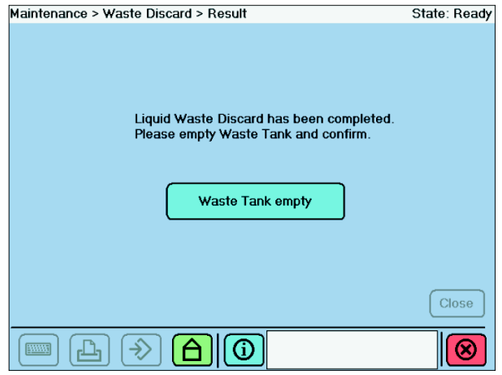
- the Nozzle Head will take up one tip from each of the tip trays, aspirate the liquid from each individual well in the cartridge, and ejects it into the Waste Tank.
- During the discard procedure, the screen will display the time remaining in the procedure.

Note: You may interrupt the Liquid Waste Discard procedure at any time by touching the Cancel button



- After the Liquid Waste Discard procedure is complete, the following message appears on the screen:

Note: The MagNA Pure Compact Instrument does not automatically check the liquid level inside the waste tank. Always ensure that there is enough volume for uptake of liquid waste of one purification run. If the Waste Tank is too full, overflowing liquid will pour into the Drip Tray. However, if the overflow is too great, liquid waste will flow into into the instrument housing and even onto the lab bench. This will lead tp potential contamination and damage of the instrument.



Always empty the Waste Tank after each purification run, when asked by the instrument's software to do so, or the instrument might be severely damaged! Treat the liquid waste as biohazardous material. Emtpy and clean waste tank as described in chapter C 3.1 Cleaning.
If the Waste Tank should overflow, it is essential to clean the instrument according to the local regulations.

- Open the instrument's front door by moving the lever at the right door side to the left.
- Remove the Waste Tank and empty.
- After confirmation the Close button appears.
- Touch the Close button to return to the MAIN MENU or MAINTENANCE Screen.

B

3. Use of Internal Controls

3.1 Function of Internal Control

If you are going to perform PCR on the purified nucleic acid and want to have an Internal Control (IC) for that PCR, we recommend that you add the IC to the sample before you purify it on the MagNA Pure Compact Instrument. Adding the IC at this stage allows you not only to estimate the efficiency of the PCR, but also the efficiency of the purification.

Note: For your convenience, many of the LightCycler® reagent kits already contain such an IC. (See the pack inserts of these reagent kits for details).

3.2 How to program the instrument for an internal control

The IC may be added to the run of the MagNA Pure Compact Instrument in either of two ways:

1	Add the internal control directly to the sample: When you program a run with an IC in the sample, do the following: On SAMPLE ORDERING Screen 2, choose a protocol „without IC“ in the Protocol field and specify „none“ in the Internal Control Volume field. In the Comment field, note that IC was added directly to the sample. ***Note:*** Do not use this method if the IC is naked DNA (e.g. plasmid) or RNA, because the control may be degraded by nucleases present in the sample.
2	Add the IC to one of the assigned IC positions in the Sample Tube Rack. Pipet the IC (5, 10 or 20 µl) into a separate tube. (Use only the tubes specified in chapter C, since only they meet the instrument specifications.) Place the control tube in the IC row (row 2) of the Sample Tube Rack. When you program the run with separate ICs, do the following: On SAMPLE ORDERING Screen 2, choose the protocol „with IC“ in the Protocol field and specify the correct volume of IC in the Internal Control Volume field. The instrument will automatically include the IC tubes in the purification process. ***Note:*** The IC will be directly mixed with the Lyis Buffer at the beginning of the run and will thus be protected from nucleases. Therefore, choose this method if your control is naked DNA or RNA.

As soon as one of the samples within a purification run is using IC, an IC tube has to be inserted in all channels that contain sample material (as indicated on the schematic on the screen).

Note: If you program a run with an IC, but do not place any tubes in the IC positions of the Sample Tube Rack, the instrument will pipet Lysis Buffer through the empty IC tube postion directly onto the instrument stage. This spilled liquid may harm the operator as well as the instrument. If this happens, you should immediately clean the instrument (as described in chapter C) to prevent corrosion of the instrument stage. Always use gloves when you touch the instrument or reagents, and observe the instructions on the Material Safety Data Sheet that accompanies the reagents.

4. Data Transfer to or from the MagNA Pure Compact Instrument

The data from the result screen can be saved to a disk. In future applications with the LightCycler System and COBAS TaqMan 48 Analyzer these data files can be transferred to the respective instruments.

4.1 Data Transfer to other Instruments

- Data transfer to the LightCycler® System
  You may create a text file of MagNA Pure Compact Run information and results that may be used on the LightCycler® System.
  Note: Details on the creation of this file are contained in a separate document.

- Data transfer to COBAS TaqMan 48 Analyzer
  You may create a text file of the purification run of the MagNA Pure Compact Instrument containing information and results that may be used on the COBAS TaqMan 48 Analyzer.
  Note: Details on the creation of this file are contained in a separate document.

4.2 Upload of New or Updated Purification Protocols

As new or updated purification protocols are created, they may be added to the MagNA Pure Compact Instrument via external data carrier disks (e.g. software update disk) during program start up.
Additional protocols will be available for download from http://www. magnapure.com. Follow the download instructions on this web site. Always save the downloaded protocol files onto a newly formatted floppy disk.

Note:
- Update disks will automatically be checked for viruses by the instrument software.
- Each protocol file contains information on which reagent kits may be used with the protocol. The instrument will use this information [kit name and kit number (included as a barcode on kit cartridges)] to verify and decode the scanned cartridge barcodes when you scan them into the SAMPLE ORDERING Screens. (See section B.2 for details.)

Workflow:

1. MagNA Pure Compact Instrument must be shut down.
2. Insert update disk.
3. Switch on instrument.
4. Software is automatically updated.
5. After Main Screen is displayed, remove update disk.
6. Update complete.
7. The instrument is ready for use.

B

Maintenance and Trouble Shooting

C

C

Maintenance and Trouble Shooting

1. User Maintenance

User Maintenance consists beside regular cleaning mostly of a regular check of the Nozzle Head function. Other regular activities for the operator are mentioned throughout this manual. In order to check the proper function the following routine checks are recommended and explained in the course of this chapter.

Leakage Test:	every 50 purification runs or every second month or if the Nozzle Head seems to show leakage
O-ring maintenance:	Greasing of O-rings: every 20 purification runs or once a week Exchange of O-rings: If the Leakage Test indicates

It is recommended to start a ring-binder with the new instrument, where all operator maintenance, cleaning and service engineer maintenance is documented. There should be documented also regular checks of the system performance. If you need assistance in creating such ring-binder, please contact your local Roche representative.

As well it is advisable to document there or in the MagNA Pure Software documentation all operators and used reagent kit lot no.s in order to be able to perform an optimal trouble shooting, if needed.

1.1 Leakage Test

Purpose

The Leakage Test will detect any leakage of air into the reaction tips, which might eventually lead to loss of liquid. If there is a leak, the most probable cause is deteriorated or damaged O-rings (on the Nozzle Head).

Use

We recommend that you perform a Leakage Test after two months or after 50 purifications. You should also perform a Leakage Test any time you suspect that the pipet tips are leaking.

Note: Although wear and tear-on the O-rings is related to the number of isolations performed, it is also influenced by maintenance (e.g. if the O-rings are not greased often enough) and environmental conditions (e.g. light, chemicals). Because of this, we recommend that you regularly test for leakage, even if the instrument is not used regularly.

After each Leakage Test, do one of the following:

If the Leakage Test shows that the O-rings...	Then ...
are leaking and need to be changed	▶change the O-rings (as described in Section C.1.2.2). ▶perform the Leakage Test again, to make sure the new O-rings are working correctly.
are O.K.	do nothing now, but repeat the test after another two months or 50 purification runs.

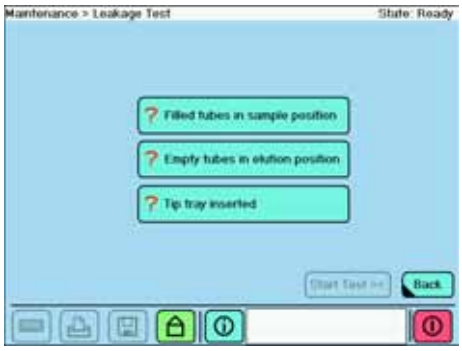
Performing of the Leakage Test

Disposables needed:

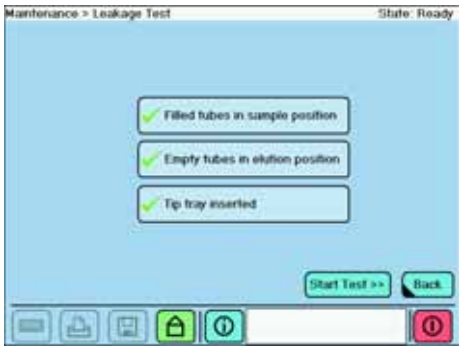
Cat. No.	Product	Content
03 561 429 001	MagNA Pure LC O-Ring Maintenance Kit	O-rings (12 x 8), Grease (1)
03 753 166 001	MagNA Pure Compact Tip Tray Kit	10 Tip Trays
Sarstedt	Tubes as recommended in chapter C.5.1 Related Products	

- Launch the MagNA Pure Compact software.
- On the MAIN MENU Screen that appears, touch the Maintenance button.
- On the MAINTENANCE Screen that appears, touch the Leakage Test button.

- Put 8 new Tip Trays (from the Roche Tip Tray Kit) into the Tip Tray Rack.
- Pipet 1 ml water into each of 8 Sarstedt tubes, then insert the tubes into row 1 (Sample Tube row) of the Tube Rack.
- Place 8 empty Sarstedt tubes into the Elution Tube Rack.
- After doing each of the above steps, touch the correct confirmation button on the touch-screen:
  - "Filled tubes in sample position" confirmation button
  - "Empty tubes in elution position" confirmation button
  - "Tip trays inserted" confirmation button



- As you touch each confirmation button, the "?" symbol on the button changes to a checkmark.
- After you touch the three buttons, the Start Test button will become active. Touch it to start the test.



As the instrument performs the Leakage Test described below, the screen will display the time remaining.

Note: To cancel the test at any time, touch the Cancel button.

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Instrument actions during the Leakage Test:

1	At the beginning of the test, the robotic arm picks up the tips and moves to the Sample/Internal Control Tube Rack. The arm aspirates 1 ml of water plus an additional 100 µl of air from the sample tubes.
2	The stage moves the empty Elution Tubes under the Nozzle Head.
3	The Nozzle Head moves to a position directly in front of the Magnetic Plate and raises the nozzles until the water meniscuses in the Reaction Tips are even with the upper rim of the Magnetic Plate.
4	The Nozzle Head holds this position for 10 min. While the Nozzle Head is holding position, open the instrument door, so you can more easily observe the Nozzle Head.
5	Watch the water level within the Reaction Tips. If the water level remains the same in all tips, none of the tips is leaking. If you observe different water levels in different tips or drops of liquid falling into the sample tubes, one or more nozzles is leaking. As a final check, visually inspect the empty Elution Tubes for liquid, as well as the Nozzle Head. If there has been leakage, change the O-rings as described in Section C.1.2.2. ***Note:*** Some leakage can be tolerated. If, after 10 minutes, the difference in water levels between tips is less than 4 mm, you do not need to change the O-rings.
6	After 10 min, close the instrument door. Result: The instrument will eject the water back into the Sample Tubes and the Reaction Tips are placed back in the Tip Tray. After the Leakage Test is complete, the Leakage Test Result screen is displayed. ▶Touch the appropriate button to document the test results. ▶Touch the Close button to return to the MAINTENANCE Screen. 

Note: As soon as *Leakage* has been confirmed, the State indicator will permanently show LEAKY until the O-rings are changed and *No Leakage* has been confirmed.

1.2 O-ring Maintenance

Purpose of O-rings: The O-rings hold the reaction tips on the nozzles of the Nozzle Head. They also form an airtight seal around the top of the reaction tips to prevent leakage and ensure accurate pipetting. After a time, O-rings may wear out and cause the reaction tips to either leak or be poorly attached to the nozzles. Therefore, worn O-rings can eventually lead to pipetting errors.

1.2.1 Greasing the O-rings

Lubricating the O-rings prevents them from deteriorating (e.g. cracking) and allowing the reaction tips to leak.

The O-rings should be greased regularly, whether the instrument is in use or not. You should grease the O-rings once a week or after each 20 purification runs. Also, to ensure correct reaction tip function, you must lubricate new O-rings before placing them on the pipet nozzles (as in Section C.1.1.2 below).

Procedure for correctly lubricating the O-ring:

1	Apply a small bit of vacuum grease to index finger, then rub it between thumb and index finger. ***Note:*** We recommend that you use special High Vacuum Grease. A tube of this grease is supplied with the instrument. To order replacement tubes, see the Recommended Products section in chapter C.
2	Rub the O-ring with your greased fingers.
3	Remove excess vacuum grease from the O-ring with a cloth (*e.g.* Kimwipe™).

Note:
We advise checking O-ring lubrication periodically and adding small amounts of vacuum grease as needed.

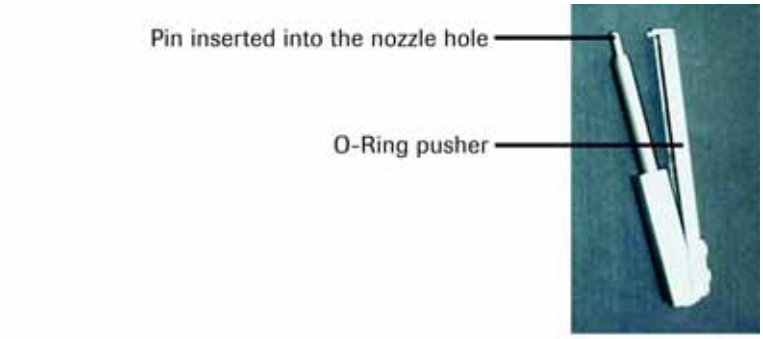
Never use bleach or ethanol to clean the Nozzle Head. These reagents will remove grease from the O-rings and probably even accelerate the deterioration of the O-rings themselves. We do not recommend ever using these reagents to clean the Nozzle Head.

In case the Nozzle Head has to be cleaned, remove the O-rings beforehand. Having cleaned the Nozzle head, apply bi-distilled water and put the greased O-rings back to their proper position.

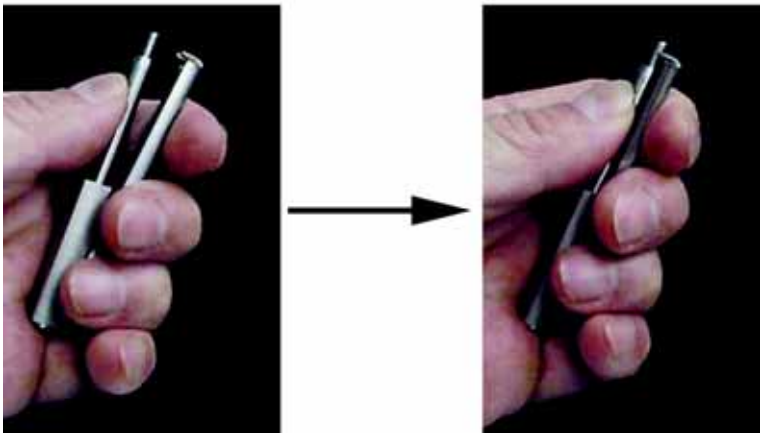
1.2.2 O-ring Exchange

If you believe (or a Leakage Test [see above] indicates) that the O-rings are damaged or worn out, use the O-ring exchange tool to replace them with new ones.

Description of the O-ring Exchange Tool



The O-Ring Exchange Tool can be closed and opened like forceps:



Execution of the O-ring Exchange

- On the touch-screen, access the MAIN MENU Screen.

- Touch the Maintenance button.
  Result: The MAINTENANCE Screen appears.

- Touch the O-Ring Exchange button.
  Result: The O-RING EXCHANGE Screen appears.

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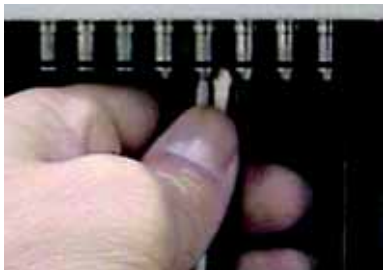
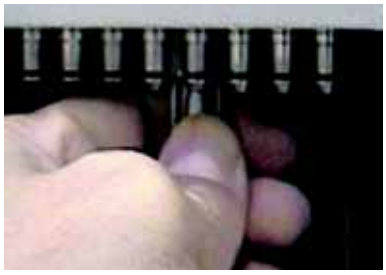
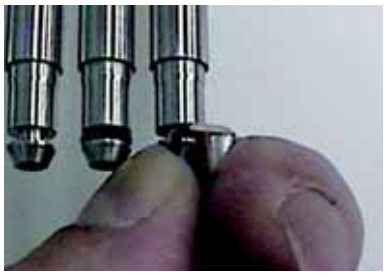
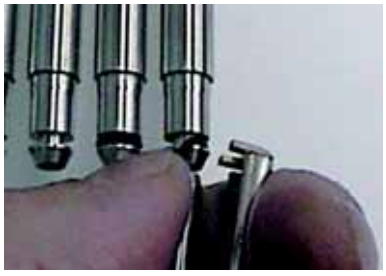
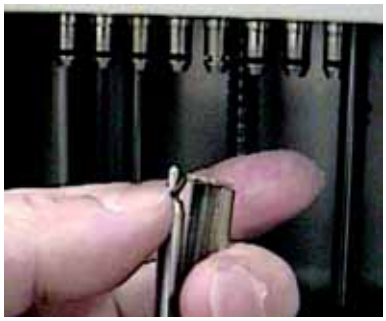
▶ With the O-Ring Exchange Tool, remove the O-rings as shown below:

1	Place the pin of the O-Ring Exchange Tool into the hole of a nozzle:	
2	Insert the pin into the nozzle as deeply as possible.	
3	While maintaining the position of the pin, move the O-ring pusher toward the pin until it is inserted into the groove in the nozzle.	
4	Move the O-ring pusher closer to the pin until it displaces the O-ring from the groove.	
5	Use your thumb to pull down the part of the O-ring that now sticks out of the groove. Roll the O-ring down around the shaft of the Exchange Tool.	
6	Relax your forefinger until the O-ring pusher pops out of the nozzle groove.	

7. While holding the O-ring on the Exchange Tool with your thumb, pull the entire O-ring changer downward, away from the nozzle.

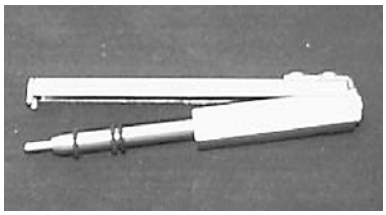
8. The O-ring is now removed from the nozzle:



Grease the new O-rings as described in Section C.1.2.1 above.
Note: Lubricating the O-rings before placing them on the nozzles is important to ensure correct reaction tip uptake and alignment.

► Install new O-rings as shown below:

1. Place a new, greased O-ring on the shaft of the O-Ring Exchange Tool. Make sure the O-ring is well below the pin.



2. Insert the pin of the O-Ring Exchange Tool as deep as possible into the nozzle hole:

3. Use your thumb and forefinger to push the O-ring up the shaft onto the nozzle. Continue pushing until the O-ring is seated in the nozzle groove.
Slowly withdraw the Exchange Tool from the nozzle.

▶ Press *Back* to go back to the MAINTENANCE Menue

▶ On the O-RING EXCHANGE Screen, do one of the following:

If ...	Then ...
you have successfully changed the O-rings	▶touch the OK button to confirm the O-ring exchange.
the O-ring exchange was not successful	▶touch the Cancel button (for documentation purposes).

▶ Touch the Back button to return to the MAINTENANCE Screen.

▶ Perform the Leakage Test, as described in Section C.1.3 below.

2. Service Maintenance

We recommend that a Roche Diagnostics service engineer perform the first Service Maintenance of the instrument one year after the instrument is installed. Subsequently, this Service Maintenance should be performed annually.

Note: Service Maintenance may only be performed by a Roche Diagnostics service engineer. Contact your local Roche representant for maintenance assistance and for more details on country-specific service contracts.

During Service Maintenance, the Roche service engineer will do the following:

1. Check and (if necessary) adjust:

- ► Easy Teaching procedure
- ► Clot sensor signals
- ► Temperature settings on Heating Unit
- ► Leakage test
- ► Tip alignement
- ► Belt tension

2. Exchange:

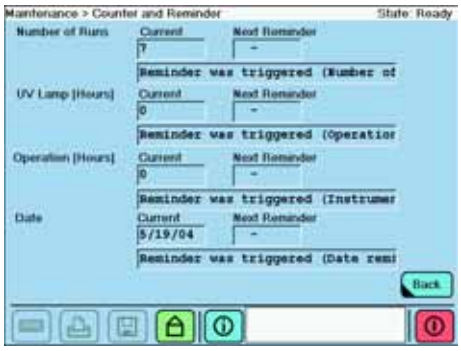
- ► O-Rings
- ► Hepa filter
- ► UV lamp
- ► Air filter

3. Clean and/or grease:

- ► Clot sensor
- ► LM Guide
- ► Z-axis thread bar/slide shafts
- ► Z-plunger

2.1 Counter and Reminder

The MagNA Pure Compact Instrument Software has a Counter and Reminder function which counts the number of runs, number of hours of UV lamp usage, and number of hours of operation.



Your Roche Diagnostics service representative is able to set reminders based on these individual counters or on a fixed date e.g. to be reminded for the regular O-ring or UV lamp exchange. If the counter reaches the set "Next Reminder" value the reminder text defined is displayed on the screen.

To view the current counter and set reminder values, you can access the Counter and Reminder Screen via the respective button on the Maintenance Menu Screen. Reminder values can changed by the service representative only.

2.2 Remote Control and Host

Your Roche service representative is able to perform some of the service and trouble-shooting via the remote control function. For this purpose there are two buttons Remote Control and Host available in the Maintenance Menu. In order to get support via remote control, please contact directly your local service representative for enabling this option.

3. Cleaning Instructions and UV Decontamination

Never clean the MagNA Pure Compact Instrument without turning the instrument power switch off (using the Exit button on the touch-screen) and disconnecting the power cable.

Never pour liquids into the instrument housing.

As with all potentially biohazardous specimens, use universal safety precautions when handling and processing samples. For example, immediately clean up spills with an appropriate disinfectant solution to avoid contaminating laboratory personnel or equipment. Handle and dispose of infectious material according to local safety guidelines.

3.1 Cleaning

The surface of the MagNA Pure Compact Instrument as well as removable internal parts should be cleaned on a weekly basis with a lint free cloth moistened with deonized water. If a spill of reagents occurs, the instrument should be cleaned with a 70% ethanol solution or any acceptable PCR laboratory cleaner. Turn the instrument power Off and disconnect or unplug the power cord before cleaning the instrument.

Removable internal parts of the instrument, such as the racks, drop catcher or drip tray should be wiped clean with a lint free cloth moistened with a 70% ethanol solution or any acceptable PCR laboratory cleaner. The waste tank has to be cleaned each time it was emptied, to avoid contamination. After the liquid waste has been disposed according to the MSDS (Material Data Safety Sheet) and local regulations, the waste tank should be incubated with a compatible laboratory cleaning agent.

To get access to the removable internal parts, first open the front door by moving the lever on its right side to the left.

Now you can remove both the Liquid Waste Tank and the Drip Tray.

To remove and place the Liquid Drop Catcher on the magnet unit, first remove the Cartridge Rack:

The area around the instrument should be periodically checked to ensure that air flow around the instrument is unrestricted and that books, papers or other items do not interfere with air flow.

If a sample or other biohazardous materials is spilled on the system or any of the system racks, the area or racks should be cleaned with a 10% (v/v) bleach solution (0.5% sodium hypochlorite) followed by thorough cleaning with 70% ethanol.

Commercial liquid household bleach typically contains sodium hypochlorite at a concentration of 5.25%. A 1:10 dilution of household bleach will produce a 0.5% sodium hypochlorite solution.

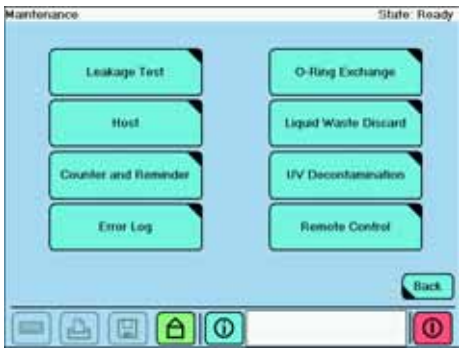
After using bleach, ventilate the instrument for at least 1 hour.

Never clean the cartridge rack in a diswasher. All other removeable accessories are dishwasher proof. Always use only detergents that are compatible with the instrument's surface. If in doubt, please contact your local Roche representative!

3.2 UV Decontamination

After cleaning the Reagent/Sample Stage with bleach and water/ethanol, sterilize the instrument with UV light, as follows:

- Close the instrument door and touch the UV Decontamination button on the MAINTENANCE Screen.

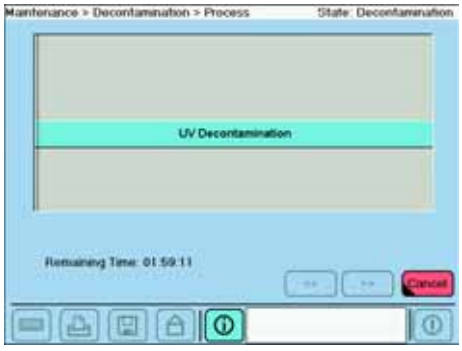


- On the DECONTAMINATION SETUP Screen that appears, use the Up and Down buttons to set the decontamination time. The recommended setting is 6 hours.

Note: In the Time field, one unit is 15 minutes.

- Touch the Start button.
- The screen will display the time remaining in the decontamination procedure.

Note: You can stop the decontamination procedure at any time by touching the Cancel button.



- After the decontamination procedure is finished, either return to the MAIN MENU Screen to perform a purification run (*e.g.* when the decontamination has been run overnight) or shut the instrument down.

For safety reasons it is recommended to decontaminate the surface of the workstation and the accessories additionally by wiping it with decontaminating reagents that destroy any nucleic acids or DNases/RNases. Also decontaminate the work area where the manual handling steps are performed.

For decontamination either bleach or the following commercially available reagents may be used (follow the working procedures given by the respective manufacturer): LTK-008^{TM} (Biodelta GmbH, Germany; www.biodelta.de) DNAZap^{TM} or RNase Zap^{TM} (Ambion Inc., Texas, USA; www.ambion.com).

4. Error Codes and Trouble Shooting Guide

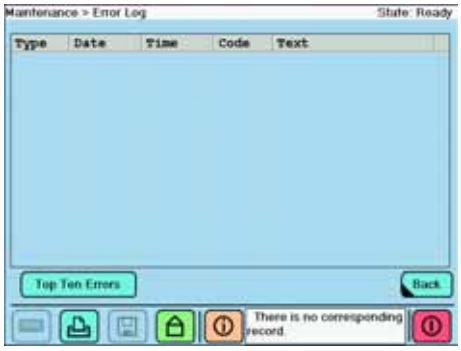
4.1 Error Log

Beside the indication during the purification run it is possible to get an overview about occurred errors. This option can be accessed via the button Error Log in the Maintenance Menu.

In case you want to trouble shoot an error together with a local Roche representant, have these informations ready or make sure the remote service option is enabled.

The Error Log shows the following information about the errors:

- Type
- Date
- Time
- Code
- Text



By using the button Top Ten Errors it is possible to set a selection filter for the ten types of error that have occurred most frequently.

4.2 Instrument Error Codes

Valid for Software Version 1.1 and higher

Error Code ID	Error Message	Error Information (displayed on information screen)	Explanation	Action
1 to 99	[diverse messages]	-	Internal error	Shut down instrument at main switch and restart system. If problem persists, contact Technical Service.
3502	Barcode ID x is invalid	The entered barcode ID is not valid. Repeat entering of the barcode ID, or type in barcode manually. If problem persists, contact Technical Service.	The entered barcode ID is not valid.	Repeat entering of the barcode ID, or type in barcode manually. If problem persists, contact Technical Service.
3504	Liquid Waste Discard aborted.	Liquid Waste Discard run was aborted.	Liquid Waste Discard run was aborted by Operator.	Restart Liquid Waste Discard.
3505	Front door is open.	Front door is not properly closed. Check front door.	Front door is not properly closed. Check front door.	Check front door. Open and close dront door again. If problem persists, contact Technical Service.
3506	Invalid kit code.	The entered kit name coded in the cartridge ID barcode is invalid. Repeat entering of the barcode ID, or type in barcode manually. If problem persists, contact Technical Service.	The entered kit name coded in the cartridge ID barcode is invalid.	Repeat entering of the barcode ID, or type in barcode manually. If problem persists, contact Technical Service.
3507	Invalid cartridge expiry date format.	The entered cartridge expiry date coded in the cartridge ID barcode is invalid. Repeat entering of the barcode ID, or type in barcode manually. If problem persists, contact Technical Service.	The entered cartridge expiry date coded in the cartridge ID barcode is invalid.	Repeat entering of the barcode ID, or type in barcode manually. If problem persists, contact Technical Service.
3508	Reagent Cartridge expired.	The cartridge expiry date coded in the cartridge ID barcode is exceeded. Repeat entering of the barcode ID, or type in barcode manually. If problem persists, contact Technical Service.	The cartridge expiry date coded in the cartridge ID barcode is exceeded.	It is recommended to discard the cartridge. If you decide to use the expired cartridge the appropriate channel will be flagged FAIL on the result screen. Note: the function of expired cartridges cannot be guaranteed.

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Error Code ID	Error Message	Error Information (displayed on information screen)	Explanation	Action
3509	Different kit types mixed.	Mixing up of different kit types is not possible.	Mixing up of different kit types is not possible.	Make sure that only one kit type is used per run. Repeat entering of the barcode ID, or type in barcode manually. If problem persists, contact Technical Service.
3510	Too many data found.	The search found too many data. Search more specific.	More than 1.000 data sets were found.	Search more specific.
3511	Unable to save to folder.	Unable to save to folder. Check folder name in settings.	Unable to save to folder.	Check folder name in settings. If problem persists, contact Technical Service.
3512	Front door is open.	Front door is open and should be closed.	Front door should be closed during initialization of instrument and during purification run.	Close front door and press OK.
3513	Front door cannot be lokked.	Front door cannot be locked.	Failure of front door lock or door lock sensor.	Open and close front door again. If problem persists, contact Technical Service.
3514	Z crash sensor test failed.	Z crash sensor malfunction.	Z crash sensor is not working properly.	Restart system. If problem persists, contact Technical Service.
3515	Pressure sensor test failed.	Pressure sensor malfunction.	Pressure sensor is not working properly.	Restart system. If problem persists, contact Technical Service.
3516	Magnet home position sensor failed.	Magnet home position sensor malfunction.	Magnet home position sensor is not working properly.	Restart system. If problem persists, contact Technical Service.
3517	Magnet ON sensor failed.	Magnet ON sensor malfunction.	Magnet ON sensor is not working properly.	Restart system. If problem persists, contact Technical Service.
3518	Z axis home position sensor failed.	Z axis home position sensor malfunction.	Z axis home position sensor is not working properly.	Restart system. If problem persists, contact Technical Service.
3519	Y axis limit sensor failed.	y axis limit sensor malfunction.	Y axis limit sensor is not working properly.	Restart system. If problem persists, contact Technical Service.
3520	Y axis home position sensor failed.	Y axis home position sensor malfunction.	Y axis home position sensor is not working properly.	Restart system. If problem persists, contact Technical Service.
3521	P axis home position sensor failed.	P axis home position sensor malfunction.	P axis home position sensor is not working properly.	Restart system. If problem persists, contact Technical Service.
3522	Waste tank sensor failed.	Waste tank sensor malfunction.	Waste tank sensor is not working properly.	Restart system. If problem persists, contact Technical Service.

Error Code ID	Error Message	Error Information (displayed on information screen)	Explanation	Action
3523	Hepa filter fan sensor failed.	Hepa filter fan sensor malfunction.	Hepa filter fan sensor is not working properly.	Restart system. If problem persists, contact Technical Service.
3524	Heater unit 1 sensor failed.	Heater unit 1 sensor malfunction.	Heater unit 1 sensor is not working properly.	Restart system. If problem persists, contact Technical Service.
3525	Heater unit 2 sensor failed.	Heater unit 2 sensor malfunction.	Heater unit 2 sensor is not working properly.	Restart system. If problem persists, contact Technical Service.
3526	Database access error.	Connection to database could not be established.	Connection to database could not be established.	Restart system. If problem persists, contact Technical Service.
3534	Changes cannot be saved.	Changed list cannot be saved.	Changes in the sample material or operators list cannot be saved.	Restart system. If problem persists, contact Technical Service.
3546	File Access Error	Unable to save data of result screen, teaching log or run log.	Unable to save data of result screen, teaching log or run log.	
3547	New database was created.	New database was created. Original database was not found or not functioning properly.	New database was created. Original database was not found or not functioning properly.	
3549	Insufficient Sample volume. [Ch_X]	Smaller volume than selected was detected in the sample tube in referenced channel number. Check and add sample volume in respective channel, if needed.	Smaller volume than selected was detected in the sample tube in referenced channel number.	Check and add sample volume in respective channel, if needed, and restart run.
3550	Sample missing. [Ch_X]	No sample was detected in referenced channel number. Check if sample tube has been inserted and contains the sample.	No sample was detected in referenced channel number.	Check if sample tube has been inserted and contains the sample. Then restart run.
3551	Sample clot.[Ch_X]	A clot has been detected in the sample of the referenced channel number. Check the sample for clots, follow the pack insert recommendation for characteristics of sample.	A clot has been detected in the sample of the referenced channel number.	Check the sample for clots, follow the pack insert recommendation for characteristics of sample. Then restart run.
3552	Moving range error	The range of possible movements of the axis was exceeded.	The range of possible movements of the axis was exceeded.	Restart system. If problem persists, contact Technical Service.
3553	There is no corresponding record	No data found in database corresponding to entered parameters.	No data found corresponding to entered parameters.	Check search parameter entries. If problem persists, contact Technical Service.

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Error Code ID	Error Message	Error Information (displayed on information screen)	Explanation	Action
3555	No protocol files found	No valid protocol for the entered cartridge ID found.	No valid protocol for the entered cartridge ID found.	Restart sample ordering and enter cartridge ID again. Install appropriate protocol, if available. If problem persists, contact Technical Service.
3556	Exe file could not be found	The file that was specified by the ini file does not exist.	When remote access button was pressed: The executable file that was configured for remote access could not be found.	If remote access is desired: Restart system. If problem persists, contact Technical Service.
3557	Empty waste tank	Waste tank has not been emptied after Liquid Waste Discard.	After Liquid Waste discard process the waste tank has to be emptied. This is controlled by a waste tank sensor.	Empty waste tank.
3558	Folder does not exist	The specified folder be found. Files can not be saved.	The save folder that is set in [Setup>Settings] could not be found.	Confirm existence of folder in the [Setup>Settings] screen.
3559	Could not create folder	The save folder was not existent and could not be created. Files can not be saved.	The save folder that is set in [Setup>Settings] could not be found and could not be created.	Confirm existence of folder or drive in the [Setup>Settings] screen.
3560	New folder was created	The save folder was not existent and was created.	The save folder did not exist and was created.	
3561	No Cartridge [Ch_X]	Ordered cartridge was not found.	A cartridge that was ordered during sample ordering was not found.	Check stage setup.
3562	Temperature Error [Ch_X]	Temperature that was called for by the chosen protocol could not be reached.	Temperature that was called for by the chosen protocol could not be reached.	Restart system. If problem persists, contact Technical Service.
3563	Unexpected Error [Ch_X]	An unexpected error has occured.	An unexpected error has occured.	Restart system. If problem persists, contact Technical Service.
3564	Waste tank is not inserted	The waste is not inserted into the instrument.	The waste is not inserted into the instrument. The instrument will not perform Liquid Waste Discard without a waste tank.	Insert waste tank.
3566	Hepa Filter Fan stopped	Hepa fan does not work. The Run function is suspended.	Hepa filter fan does not work. The Run function is suspended	Restart system. If problem persists, contact Technical Service.
3568	Plausibility test failed	The plausibility test of axes and sensors failed. Check stage and restart the system. If problem persists contact Technical Service.	The instrument tests axes and sensors with a plausibility test which failed.	Check stage and restart the system. If problem persists contact Technical Service.

Error Code ID	Error Message	Error Information (displayed on information screen)	Explanation	Action
3572	Large Tip missing	No large Tip was detected in referenced channel number. Check if tip tray has been inserted and contains large tip.	No large Tip was detected in referenced channel number.	Check if tip tray has been inserted and contains large tip.
3573	Too much sample	Larger volume than selected was detected in the sample tube in referenced channel number. Check and correct sample volume in respective channel, if needed.	Larger volume than selected was detected in the sample tube in referenced channel number.	Check and correct sample volume in respective channel, if needed, and restart run.
3580	Run aborted.	Run was aborted by operator.	Run was stopped during purification, liquid waste discard or leakage test due to operator interaction, obstacles in the movement path or incorrect heating temperature.	Repeat run. If problem persists, contact Technical Service.
3581	Run aborted by error.	Run was aborted by an error.	Run was aborted by an error.	Repeat run. If problem persists, contact Technical Service.
3582	Obstacles on stage.	Run was aborted due to obstacles on the stage.	Run was aborted due to obstacles on the stage.	Repeat run. If problem persists, contact Technical Service.
3583	Temperature timeout error.	Process aborted due to time-out error of heating unit temperatures.	Process aborted due to timeout error of heating unit temperatures.	Restart system. If problem persists, contact Technical Service.
3584	New database was created frequently.	New database was created frequently. Original database was not found or not functioning properly.	New database was created. Original database was not found or not functioning properly.	If problem persists, contact Technical Service.
3585	Unspecific database error.	Unspecific database error.	Unspecific database error.	Restart system. If problem persists, contact Technical Service.
3587	ID entry missing in Ch. X	Cartridge ID input is missing. Check correct position of the cursor. Insert barcode ID and proceed sample ordering	ID input for cartridge is missing.	Check correct position of the cursor. Insert barcode ID and proceed sample ordering.
3588	IC ID entry missing in Ch. X	Cartridge ID input is missing. Check correct position of the cursor. Insert barcode ID and proceed sample ordering	ID input for Internal Control is missing.	Check correct position of the cursor. Insert barcode ID and proceed sample ordering.

Error Code ID	Error Message	Error Information (displayed on information screen)	Explanation	Action
3589	Sample ID missing in Ch. X	Cartridge ID input is missing. Check correct position of the cursor. Insert barcode ID and proceed sample ordering	ID input for sample tube is missing.	Check correct position of the cursor. Insert barcode ID and proceed sample ordering.
3590	Elution ID missing in Ch. X	Cartridge ID input is missing. Check correct position of the cursor. Insert barcode ID and proceed sample ordering	ID input for elution tube is missing.	Check correct position of the cursor. Insert barcode ID and proceed sample ordering.
3607	Small Tip missing	No small Tip was detected in referenced channel number. Check if tip tray has been inserted and contains small tip.	No small Tip was detected in referenced channel number.	Check if tip tray has been inserted and contains small tip.
3608	Piercing Tool missing	No Piercing Tool was detected in referenced channel number. Check if tip tray has been inserted and contains a Piercing Tool.	No Piercing Tool was detected in referenced channel number.	Check if tip tray has been inserted and contains a Piercing Tool.

Error Code ID	Error Message	Error Information (displayed on information screen)	Explanation	Action
Errors during Self Test (in pop-up windows)				
5601	Door is open (5601). Retry?	_	Instrument Door was open during initial self test. Door must be shut.	Close Door tightly and press OK in message box.
5602	Door cannot be lokked (5602). Retry?	_	Instrument door cannot be locked during self test of instrument. Door must be locked during nozzle head movement.	Close Door tightly and press OK in message box.
5603	Crash sensor failed (5603). Retry?	_	Internal error regarding crash sensor. Sensor failed during self test.	Press OK for retry. If that fails restart system. If problem persists, contact Technical Service.
5604	Pressure sensor failed (5604). Retry?	_	Internal error regarding pressure sensor. Sensor failed during self test.	Press OK for retry. If that fails restart system. If problem persists, contact Technical Service.
5605	Magnetic home sensor failed (5605). Retry?	_	Internal error regarding magnetic home sensor. Sensor failed during self test.	Press OK for retry. If that fails restart system. If problem persists, contact Technical Service.
5606	Magnetic sensor failed (5606). Retry?	_	Internal error regarding magnetic sensor. Sensor failed during self test.	Press OK for retry. If that fails restart system. If problem persists, contact Technical Service.
5607	Z axis sensor failed (5607). Retry?	_	Internal error regarding Z axis sensor. Sensor failed during self test.	Press OK for retry. If that fails restart system. If problem persists, contact Technical Service.
5608	M axis sensor failed (5608). Retry?	_	Internal error regarding M axis sensor. Sensor failed during self test.	Press OK for retry. If that fails restart system. If problem persists, contact Technical Service.
5609	Y axis sensor failed (5609). Retry?	_	Internal error regarding Y axis sensor. Sensor failed during self test.	Press OK for retry. If that fails restart system. If problem persists, contact Technical Service.

4.3 Trouble Shooting Guide

Problem	Possible cause	Recommendation
Drops of liquid on the dropcatcher or the stage.	Leakage of reaction tips due to damaged or worn nozzle O-rings	Check O-rings and exchange, if necessary
Run stopped due to head crash sensor activation	Disposables were not inserted correctly or any other obstacle is in the way of the nozzle head	▶ Follow the instructions about placement of accessories and disposables ▶ Check reaction tips ▶ Check even alignment of reaction tips when attached to the nozzles.
Pipetting of wrong liquid volumes	▶ Reagent Rection Tips might be bent. ▶ Reaction tips not attached correctly to the nozzles ▶ Instrument misadjusted.	▶ Check reaction tips ▶ Check O-rings of nozzle head ▶ Call Roche service for Easy Teaching
Clumping of beads or beads in eluate	Too much sample material was used	Reduce amount of sample material to the values recommended in the pack insert.
	Magnetic glass particles (MGPs) were magnetized prior to use	Avoid contact of the MGPs with magnets prior to use.
Degraded nucleic acid	Inappropriate storage of samples	Use fresh or frozen samples; avoid using samples that were stored at room temperature for extended periods of time.
	Incorrect storage of eluate	Do not store eluates at room temperature; do not perform overnight runs.
	Nuclease contamination due to improper handling	Keep instrument clean and use nuclease-free pipettes and tips. Wear gloves.
Poor DNA yield	Sample does not contain enough cells	Cultured cells: Count cells before use. Optimal results are obtained with 10^5-10^6 cells. Blood: Do not use clotted or sedimented blood.Use anticoagulated fresh or frozen blood. Mix tubes before use. Count cells before use.
	Storage of samples was not optimal	Use fresh or frozen samples; avoid using samples that were stored at room temperature for extended periods of time.
Poor DNA purity (low ratio OD 260/280 nm)	Too much sample material	Reduce amount of sample material to the values recommended in the pack insert.
	Storage of samples was not optimal	Use fresh or frozen samples; avoid using samples that were stored at room temperature for extended periods of time.

Problem	Possible cause	Recommendation
Poor (RT-) PCR performance / poor sensitivity	Too much nucleic acid in PCR	Check nucleic acid concentration in the eluted samples and adjust amount of eluate per PCR. Optimum: e.g. for DNA 10-100 ng/PCR.
		Use less starting material. Refer to the respective pack insert of the reagent kit.
	Not enough nucleic acid in PCR	Check nucleic acid concentration in the eluted samples and adjust amount of eluate per PCR. Optimum: e.g. for DNA 10–100 ng/PCR.
		Use more starting material, refer to the respective pack insert of the reagent kit.
	Poor purity of nucleic acid	Too much sample material, refer to the respective pack insert of the reagent kit.
	Storage of samples was not optimal	Use fresh or frozen samples; avoid using samples that were stored at room temperature for extended periods of time.
	Improper storage of eluate	Do not store eluates at room temperature; do not perform overnight runs.
	Incorrect anticoagulant was used	Use EDTA or citrated blood or plasma. Do not use heparinized blood or plasma.
	(RT-) PCR reagents and protocols are not optimal	Check (RT-) PCR reagents and protocols with a positive DNA or RNA control (*e.g.*, Human Genomic DNA, Cat. No. 1 691 112) or use an internal control.

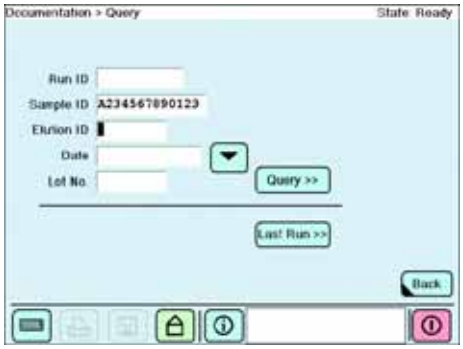
5. Documentation

Touch the Documentation button on the Main Menu screen to search for certain parameters of a purification run:

You can search for

- Run ID
- Sample ID
- Elution ID
- Date
- Lot. No.

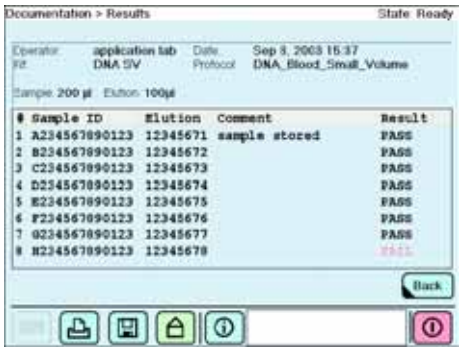
or you can call up the data from the previous run by using the Last Run button.



The runs which are matching with the search parameter are displayed as a list.

For viewing details of this run, select it on the touch-screen and touch the Select button.

The result screen of the respective run will be displayed and can be printed or saved to a disk or LIMS.



6. Administrator Authorization

Your local Roche Diagnostics representant will define an administrator authorization during instrument installation. The administrator rights are secured with a password and enable to define additional operators. During the administrator authorization the password will be displayed hidden, to guarantee confidentiality. In case you should forget the administrator password, contact your local Roche Diagnostics representant and you will receive a new one.

7. Ordering Guide

7.1 Related Products

These products are not available from Roche Applied Science, but recommended for use with the MagNA Pure Compact Instrument.

- Tubes for Maintenance and Internal Control

If needed, we recommend the following Sarstedt Tubes for use with MagNA Pure Compact Instrument only. They have the appropriate specifications to ensure the correct functioning of the instrument (pipetting, etc.).

Note: In case, tubes with caps are chosen, it is important to remove the caps before the purification protocol begins. Failure to remove caps could result in damage to the instrument and leads to an abortion of the respective action performed by the instrument (e.g. purification run).

2.0 ml tubes without screw cap	Sarstedt-ID-No. 72.608
2.0 ml tubes screw cap enclosed	Sarstedt-ID-No. 72.693

Recommended Printer for the Use with MagNA Pure Compact Instrument:

Hewlett Packard Laserjet 1015

Specifications:	
Performance (print speed; time to first page out)	14 ppm; 10s
Media Format	370x230x208 mm
Max. Resolution	1200 dpi effective output
Interfaces	USB, parallel and ext. Networking
Memory	16 Mb
Paper Feed	150 sheets; 10 sheet priority
Network	yes; external
Operating Systems	WIN 98, Me, 2000, XP
	WIN 95 and NT 4.0
	Mac OS 9.1 and later
	Mac OS X10.1 and later

For installation with the MagNA Pure Compact Instrument, please contact your local Roche representantative.

7.2 MagNA Pure Compact System Products

Product	Pack size	Cat. No.
MagNA Pure Compact Instrument	1 Instrument	03 731 146 001
MagNA Pure Compact Nucleic Acid Isolation Kit I‡	1 Kit 32 reactions	03 730 964 001
MagNA Pure Compact Nucleic Acid Isolation Kit I - Large Volume‡	1 Kit 32 reactions	03 730 972 001
MagNA Pure Compact RNA Isolation Kit‡	1 Kit 32 reactions	04 802 993 001
MagNA Pure Compact Tip Tray Kit (for replacement and leakage test)	1 Kit 10 Tip Trays	03 753166 001

7.3 MagNA Pure Compact Accessories

Cat. number	Accessory
03788237001	Cartridge Rack
03788296001	Tube Rack
03788288001	Elution Tube Rack
03788270001	Waste Tank
03788300001	Drop Catcher
04347005001	Drip Tray

Notice To Purchaser

‡The purchase of this product does not convey any licenses or other rights for the performance of PCR.

8. Index

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