

IndiMag 48s

User Manual

Magnetic bead-based nucleic acid extractor



IN943048s



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Contents

- Safety and warning symbols..... 4
- Safety information..... 5
 - Proper use 5
 - Transport precautions 6
 - Environment..... 7
 - Electrical safety..... 8
 - Biological safety 9
 - Chemicals 11
 - Waste disposal 11
 - Mechanical hazards..... 12
 - Magnetic hazards 12
 - UV irradiation hazard 12
- Introduction 13
- Principle 14
- Installing the IndiMag 48s 15
 - Unpacking the instrument 15
 - Site requirements..... 15
 - Installation 16
 - Repackaging the instrument for transport 19
- Operating the instrument 20
 - Preparing a nucleic acid extraction..... 20
 - Starting and completing a protocol 23
 - Barcode Data Input..... 31
 - UV sterilization 36

Maintenance 39

 Cleaning the instrument..... 39

 Replacing the UV lamp 40

Appendix 41

 Technical specifications 41

 WEEE 42

 Ordering information 43

 Change index..... 44

Declaration of Conformity 45

Safety and warning symbols

The following symbols are used on the IndiMag 48s instrument.



Legal manufacturer



Handbook



Catalog number



Serial number



Warning: Risk of electric shock



Warning: Biohazard risk



Warning: Risk of injury to the user



Caution: Risk of damage to the instrument or other equipment



WEEE mark for Europe



CE marking for European Conformity

Safety information

This user manual is written for end users. Read this user manual carefully and pay particular attention to the safety information before operating the IndiMag 48s. The instructions and safety information in the user manual must be followed to ensure safe operation of the instrument and to maintain the instrument in a safe condition.

The advice provided in this user manual is intended to supplement, not supersede, the normal safety requirements prevailing in the user's country.

Proper use

Only use the IndiMag 48s according to this manual. Read this user manual entirely and in detail before using the instrument.

- Follow all safety instructions printed on or attached to the instrument.
- Improper use may cause personal injuries or damage to the instrument.
- Only qualified personnel who have been appropriately trained should use the instrument.
- Instrument servicing must only be performed by specialists authorized by INDICAL BIOSCIENCE GmbH.
- Do not use the instrument in hazardous environments for which it has not been designed.



Warning/Caution: Risk of personal injury or material damage

Do not open the housing of the IndiMag 48s instrument. The housing is designed to protect the operator and to ensure proper operation of the instrument. Using the instrument without the housing leads to electrical hazards and instrument malfunction.

Transport precautions



Warning/Caution: Risk of personal injury or material damage

The IndiMag 48s instrument weighs approximately 25 kg. To avoid personal injury or damage to the instrument, only lift the IndiMag 48s with two people. Take care when lifting it and use appropriate lifting methods.

Environment

The IndiMag 48s should only be operated in an environment that is free of excessive drafts, moisture, and dust, as well as protected from direct sunlight, large temperature fluctuations, heat sources, vibration and electrical interference. The instrument requires sufficient clearance on all sides for proper ventilation.



Caution: Impeded ventilation

To ensure proper ventilation, maintain a minimum clearance of 10 cm at the rear of the IndiMag 48s and do not block airflow under the unit. Slits and openings that ensure instrument ventilation must not be covered.

The IndiMag 48s fulfills the emission and immunity requirements in EN 61326. It is recommended to evaluate the electromagnetic environment prior to operating the device.



Caution: Electromagnetic interference

Do not place or use the IndiMag 48s in close proximity of sources of strong electromagnetic radiation (e.g., unshielded intentional RF sources), as these can interfere with proper operation.

Electrical safety

Observe all general safety precautions that apply to electrical instruments.

Disconnect the line power cord from the power outlet before servicing.



Warning/Caution: Electrical hazard

Lethal voltages inside the IndiMag 48s. Do not open the housing of the instrument.

The line power cord must be connected to a line power outlet that has a protective conductor (earth/ground).

Do not touch any switches or power cords with wet hands.

Do not use the instrument outside of the specified power conditions.

Biological safety

The IndiMag 48s instrument and associated purification kits do not contain biohazardous materials. Handle and dispose of samples and reagents containing biological materials as potentially biohazardous. Always follow safe laboratory procedures as detailed in publications such as Biosafety in Microbiological and Biomedical Laboratories, from the Centers for Disease Control and Prevention and the National Institutes of Health (www.cdc.gov/od/ohs/biosfty/biosfty.htm).

Samples processed on the IndiMag 48s may contain infectious agents. Users should be aware of the health hazard presented by such agents and use, store and dispose of samples according to the required safety regulations. Wear personal protective equipment and disposable powder-free gloves when handling reagents or samples, and wash hands thoroughly thereafter.

Observe safety precautions as outlined in relevant guidelines, such as the Clinical and Laboratory Standards Institute (CLSI) Protection of Laboratory Workers from Occupationally Acquired Infections, Approved Guidelines M29, or other appropriate documents.

Handle samples with care to avoid contaminating the IndiMag 48s and workspace. In the event of contamination, clean and decontaminate the affected area and the instrument.



Warning: Biological hazard

Use caution when loading or removing infectious samples into or from the IndiMag 48s.

Handle biological samples as if they may contain potentially infectious agents.



Warning: Risk of contamination

Contain and clean contamination from spilled samples immediately.

Chemicals

Material safety data sheets for the INDICAL extraction kit materials are available and can be requested from **compliance@indical.com**.

Used consumables must be disposed of in accordance with all national, state and local health and safety regulations and laws.



Warning: Hazardous chemicals

Some chemicals used in the associated extraction kits may be hazardous or may become hazardous. Always wear eye protection, gloves and a lab coat.



Caution: Risk of damage to the instrument

Avoid spilling chemicals or other liquids onto or into the IndiMag 48s. Damage caused by liquid spillage will void the warranty.

Waste disposal

Follow laboratory and country-specific procedures for the disposal of biohazardous waste. Refer to local regulations for the disposal of infectious material.



Warning: Samples can be potentially infectious

Dispose all used plates, disposable gloves, syringes, disposable tips, and so on as biohazardous waste. Disposal of infectious material according to GLP.

Mechanical hazards



Caution: Moving parts

An electronic lid sensor ensures that the instrument lid must be closed for operation of the IndiMag 48s. Do not under any circumstances disable this lid sensor.

Magnetic hazards



Caution: Electromagnetic interference

Do not place or use the IndiMag 48s in close proximity of sources of strong electromagnetic radiation (e.g., unshielded intentional RF sources), as these can interfere with proper operation.

UV irradiation hazard



Caution: UV irradiation

An electronic lid sensor ensures that the instrument lid must be closed for operation of the UV lamp. Do not under any circumstances disable this lid sensor.

Introduction

The IndiMag 48s is an automatic extraction system for the isolation of high-quality nucleic acids from biological samples. The IndiMag 48s operates with no liquid aspiration or dispensation.

The IndiMag 48s is an open platform, designed for use with specifically developed and validated purification kits from INDICAL. Refer to the instructions for use for the particular extraction kit in use for more details.

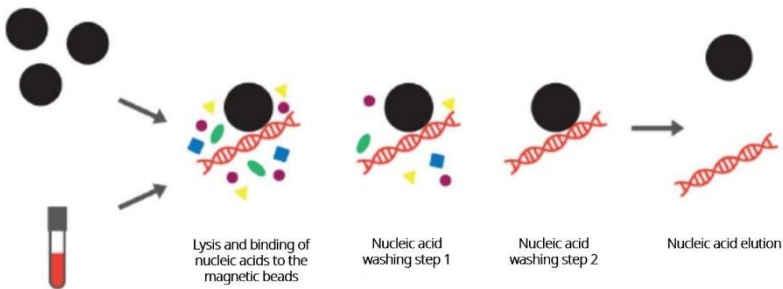


Figure 1. Magnetic bead-based purification of nucleic acids.

Principle

The IndiMag 48s automates isolation of high-quality nucleic acids from up to 48 samples per run.

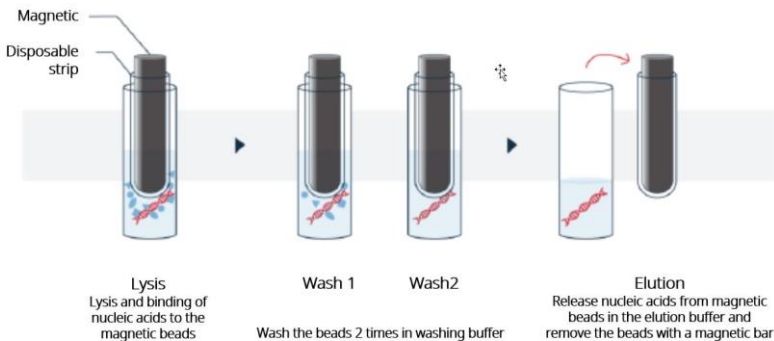


Figure 2. Overview of the IndiMag 48s nucleic acid purification steps.

Instrument front lid

The instrument lid incorporates magnetic sensors that determines whether the lid is open or closed. The instrument lid must be closed for the software and hardware to initialize and for a run to proceed.

Opening the front lid while the IndiMag 48s is performing a run will cause the instrument to pause.

UV lamp

The instrument contains a UV lamp, which provides efficient decontamination and helps prevent sample contamination. For increased safety, electronic lid sensors ensure that the UV lamp only operates when the front lid is closed.

Installing the IndiMag 48s

This section provides instructions for unpacking and installing the IndiMag 48s.

Unpacking the instrument

Before unpacking the IndiMag 48s, move the package containing the instrument to the installation site. Ensure that the arrow on the package points upwards. Leave the instrument in its protective, antistatic plastic wrapping until it reaches ambient temperature to prevent condensation. Remove the instrument from the package and place it on a clean level surface. We recommend two people lift the instrument together, taking proper precautions to avoid injury as the net weight of the entire system is approximately 25 kg (55 lbs). When lifting the IndiMag 48s, put your fingers under the bottom on either sides and lift it with your knees, maintaining a back straight.

Site requirements

The installation site should be free of vibrations, strong magnetic fields, direct sunlight or UV light, drafts, excessive moisture, excessive dust and large temperature fluctuations. The instrument is for indoor use only.

The IndiMag 48s is not designed for use in an explosive atmosphere.

The width of the instrument is 36.4 cm (14.3 in.), the depth is 42 cm (16.5 in), and the height is 38.6 cm (15.2 in). Place the instrument onto a laboratory bench that is large enough to allow at least 10 cm (3.9 in.) on both sides and the back of the instrument to allow adequate air circulation.

The instrument operates at voltages of 100–240 VAC and a frequency range of 50/60 Hz.

Installation

Before operating the IndiMag 48s remove the transport inserts, connect the power cord and perform an operational check.

Removing the transport inserts

Remove the transport inserts in the order as illustrated in the Figure 3. Order of removal is important as removing inserts incorrectly may damage the machine.

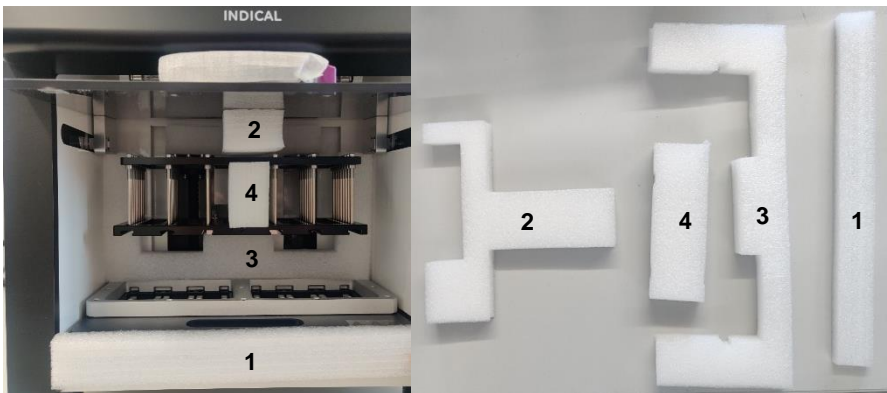


Figure 3. Removal of the transport inserts.

Number and store the transport inserts in a safe location, as it will be needed for future transport of the IndiMag 48s.

Connecting the power supply cable

Ensure the power switch is set to position '0' before connecting the supply cables. Connect the mains supply cable to the mains power connector at the bottom left of the back of the chassis. Connect the instrument to a properly grounded outlet.



Figure 4. Switch and power supply.

Operational check

After connecting the power supply, ensure the IndiMag 48s operates properly before extracting samples.

Press the power switch 'On' the back panel to the 'I' position to power on the IndiMag 48s. The IM48s performs initialization tests, adjustments, and a loading screen will display (see figure 5).

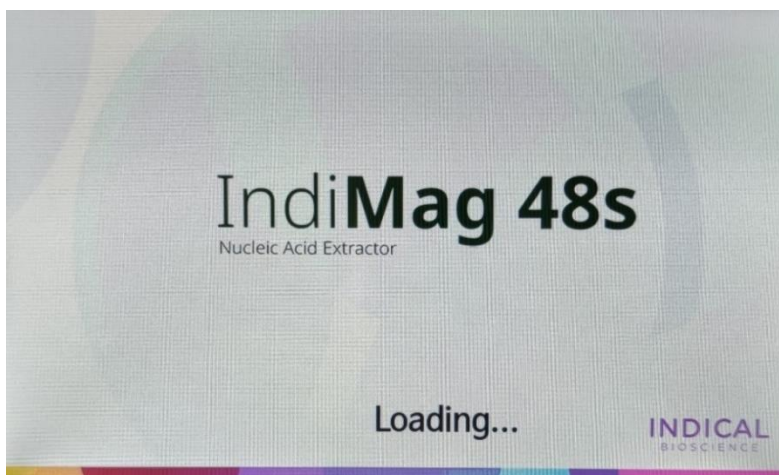


Figure 5. Loading Screen

When these tests are complete, the touchscreen of the IndiMag 48s will open the main menu (See Figure 10 below for image).

We recommend performing a test run using a protocol to verify proper instrument operation. Select Protocol "Pathogen" or Protocol "Mastitis" under the 'Run' menu. Follow the Operating the Instrument section of the manual for details.

Repackaging the instrument for transport

Prior to transporting of the IndiMag 48s, the instrument must be prepared as follows:

Switch 'Off' the power and unplug the power cord.

Reinstall the transport inserts by placing it in the position shown below from Figure 6.

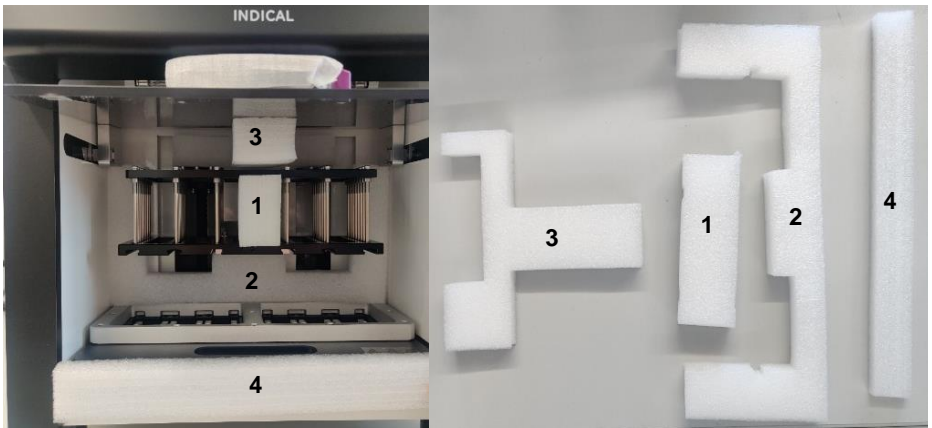


Figure 6. Reinsertion of the transport inserts.

Operating the instrument

Preparing a nucleic acid extraction

1. Prepare the samples and reagents in appropriate well plates (4-, 32-, or 96-well plates) according to the corresponding kit instructions.

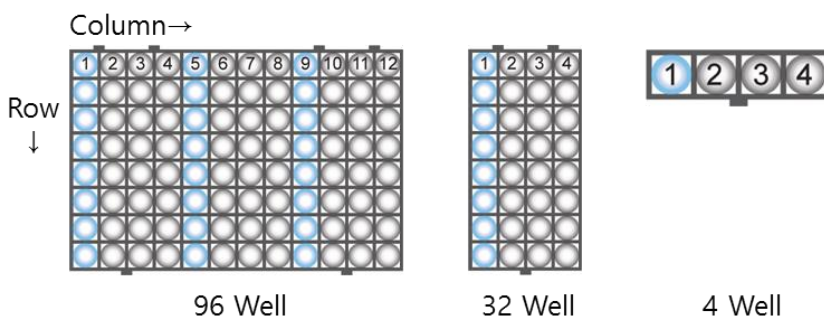


Figure 7. 96-well plate for 24 samples, 32-well plate for 8 samples and 4-Well plate for 1 sample.

2. Open the front lid of the instrument and slide out the plate loader.
3. Fully insert magnet a rod cover strip into one of the strip holders as illustrated below:

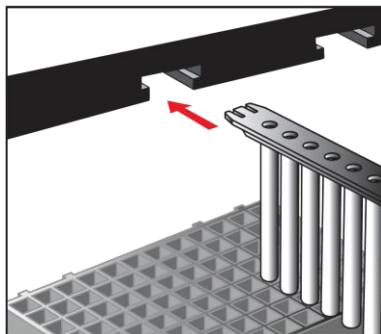


Figure 8. Insertion of a magnetic rod cover strip into the strip holder.

The IndiMag 48s uses one magnet rod cover per row. The instrument will operate with 1 to 6 magnet rod covers, depending on the number of samples to be processed and the type of well plate. Ensure the rods are fully inserted as it may damage the magnetic rods if they are not.

4. Place the well plate onto the plate loader, lining up the notches as shown in the figure below.

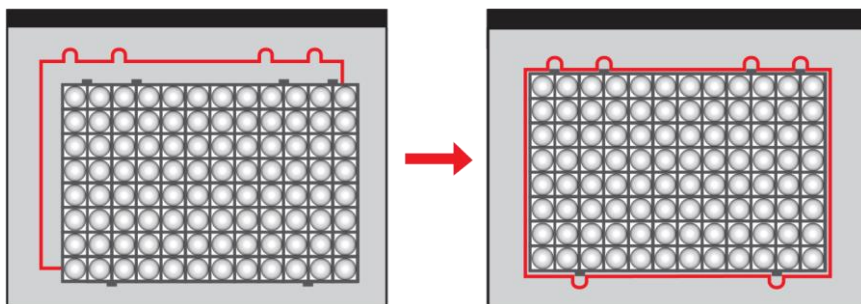


Figure 9. Correct positioning of a 96-well plate (for 24 samples) onto the plate loader.

Note: If using a 1-sample block, first place it onto the dedicated plate holder, and then place this assembly onto the plate loader.

5. Slide the plate loader fully back in position.
6. Close the front lid.
7. Proceed with “Starting a protocol”, see the next section listed below.

Starting and completing a protocol

1. Tap 'Extraction' in the main menu to open the Protocol Settings.

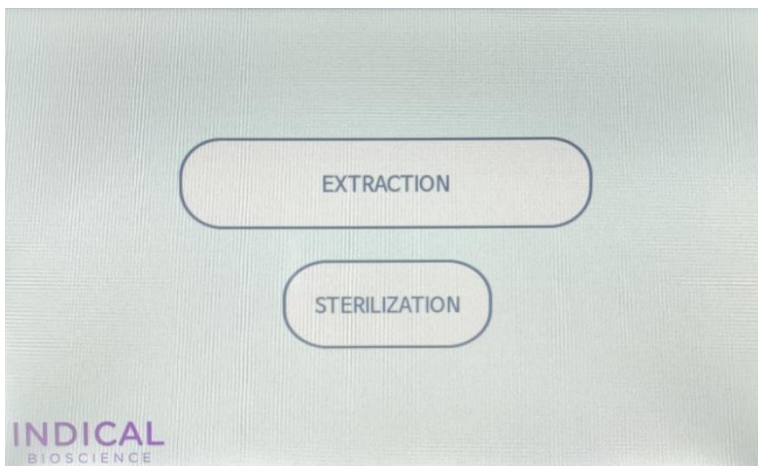


Figure 10. Main menu of the IndiMag48s touchscreen interface – to access protocols or UV light to run.

The buttons described below appear in the Main menu



Tap 'Extraction' to run saved protocols



Tap 'Sterilization' to start decontamination by UV Light

2. Select plate type by ensuring the U-well strip type is selected. Do not adjust the Gap. Tap 'Select Protocol' to open Protocol Selection Menu. See figure 11 below for details.

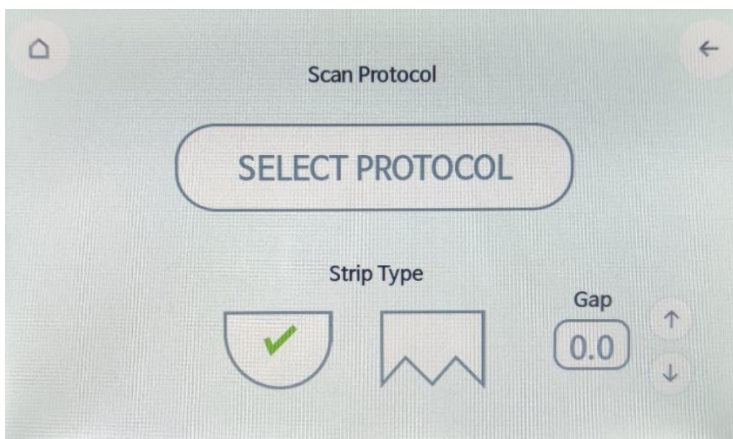


Figure 11. Plate Selection Menu of the IndiMag48s touchscreen interface – for the selection of plasticware used.

The buttons described below appear in the Plate Selection menu:



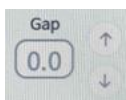
Tap 'SELECT PROTOCOL' to select desired saved protocol to run



Tap to use for U-well plates – **TO BE USED FOR INDIMAG KITS**



Tap to use V-well plates (**IMPORTANT: not to be used with IndiMag kits**)



Only to be used for adjustment during calibration of machine by authorised personnel

3. Tap the button corresponding to the desired protocol (see Figure 12 for reference). The Heater Setting menu will open.

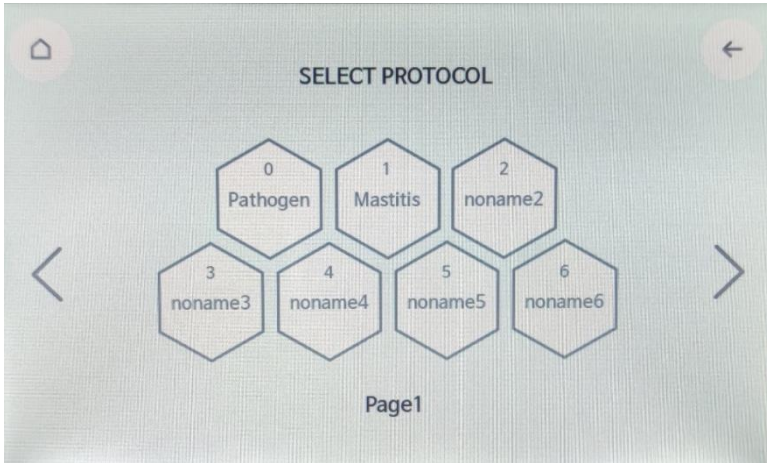


Figure 12. Protocol Selection Menu of the IndiMag 48s touchscreen interface. List of protocols programmed into the machine.

The following protocols are provided by INDICAL BIOSCIENCE and are preinstalled in the system



Default protocol for IndiMag Pathogen Kit, IndiMag Pathogen Kit w/o plastics, and IndiMag Pathogen IM48 Cartridges



Default protocol for IndiMag Mastitis Kit



and

Tap the side-to-side arrow buttons to scroll to the next group of 7 protocols. Total of 56 protocols available (2 pre-programmed by Indical).



Tap the back-arrow button to go back to the previous screen



Tap the Main button to return to the Main menu

4. In the Heater Settings Menu, **ensure all heating elements are turned off**. The elements in the plate loader should be greyed out. (See Figure 13 below for reference). Tap 'Set' to open Run Menu.

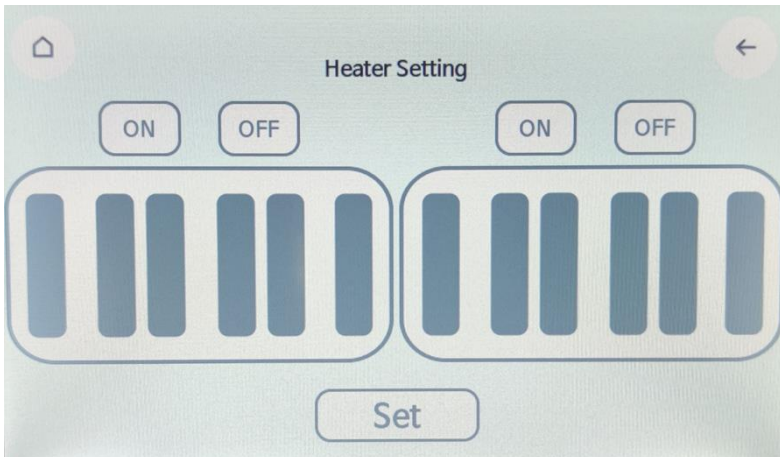


Figure 13. Heater Settings Menu of the IndiMag 48s touchscreen interface.



Tap to set heater 'ON' or 'OFF' – **IMPORTANT: all heating elements should be 'off' for indical pathogen and mastitis kits**



Tap 'SET' to proceed to the 'Run' Menu

5. Tap 'Start' located bottom left of the screen (see Figure 14).

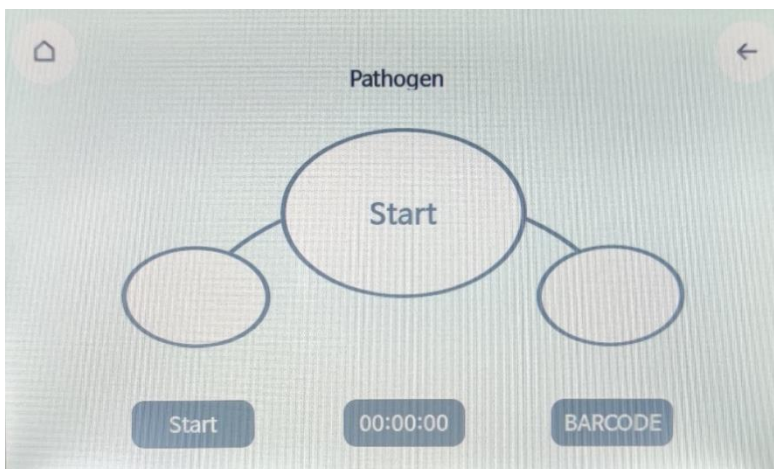


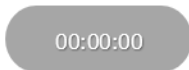
Figure 14. Run Menu of the IndiMag 48s touchscreen interface.



Tap to start run



Tap to pause run



Time display left for the run



Tap 'BARCODE' button to use barcode reader option

Screen will change and display stages of the protocol (refer to Figure 15 below as an example).

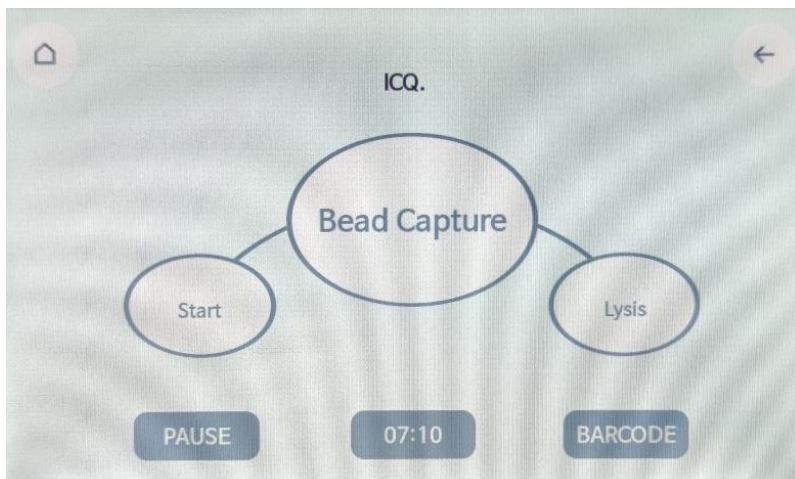


Figure 15. Protocol display example.

Opening the front lid or tapping 'Pause' will stop the IndiMag 48s while extraction nucleic acid from samples. Close the front lid and tapping 'Ok' (see Figure 16 below) or tapping 'Resume' will continue the extraction process from the stopping point.

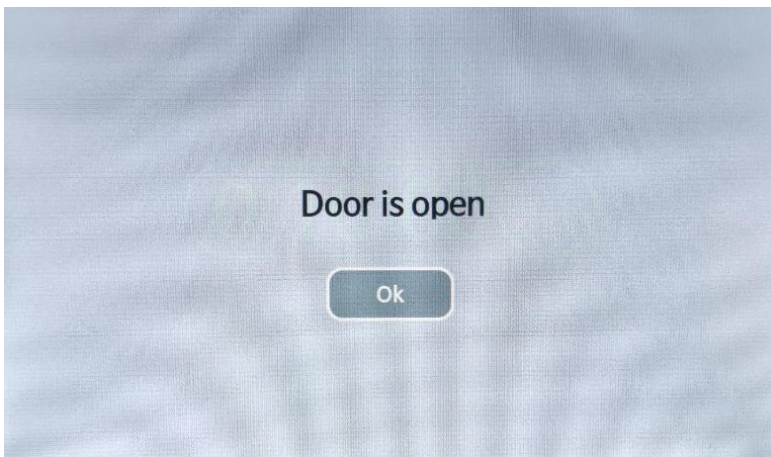


Figure 16. Door Open Alert

6. After a run has completed successfully, the Completion screen will appear (See Figure 17).

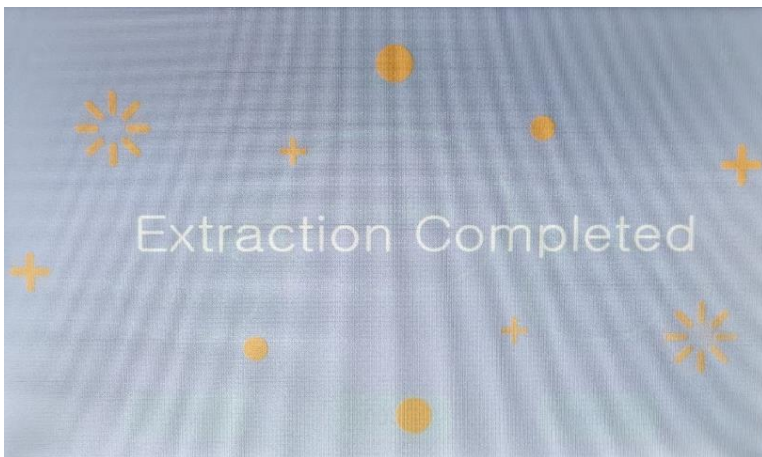


Figure 17. Run completion screen of the IndiMag 48s touchscreen interface

7. Touch the screen to return to Main menu.
8. Open the front lid and slide out the plate loader.
9. Remove the plate(s) and transfer the eluates into other tubes for long-term storage.

Barcode Data Input

- 1. Follow 'Starting a Protocol' procedure above to step 4.
- 2. Tap 'BARCODE' to access Barcode menu (See Figure 14 for Run Menu). The Barcode Menu will display (See Figure 18).

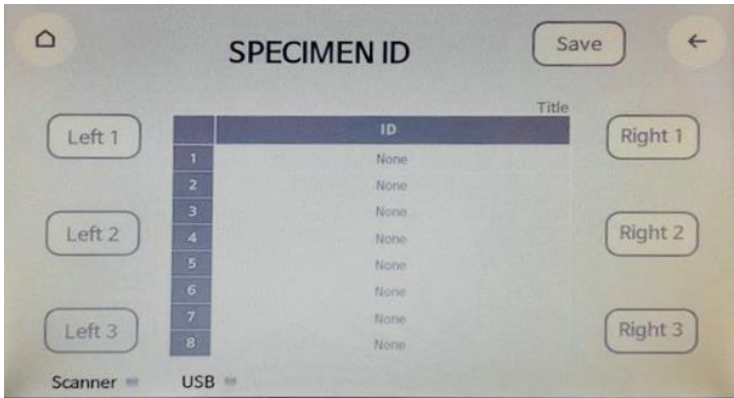


Figure 18. Barcode ID Menu of the IndiMag48s touchscreen interface for data input.

'Title '

Tap to assign title to sample ID set

SAVE

Tap to save barcode details to USB



Tap to select location of sample set in plate loader

3. Insert USB into 'USB' port and barcode reader into 'BARCODE' port in the back of the machine (see Figure 19 below for reference).



Figure 19. Data Update, USB and Barcode reader port location at the back of the machine.

Blue light will show on screen for scanner and USB option when plugged in (See Figure 20).

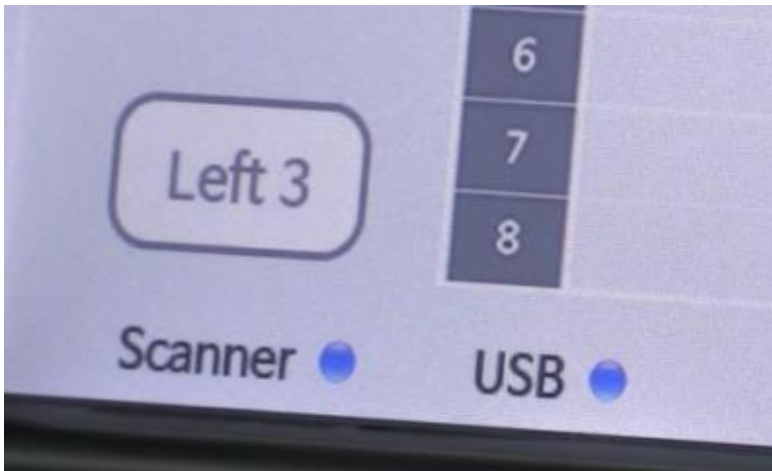


Figure 20. Scanner and USB plugged indicators.

4. Tap 'Title' on screen and give name to file (See Figures 21-22).

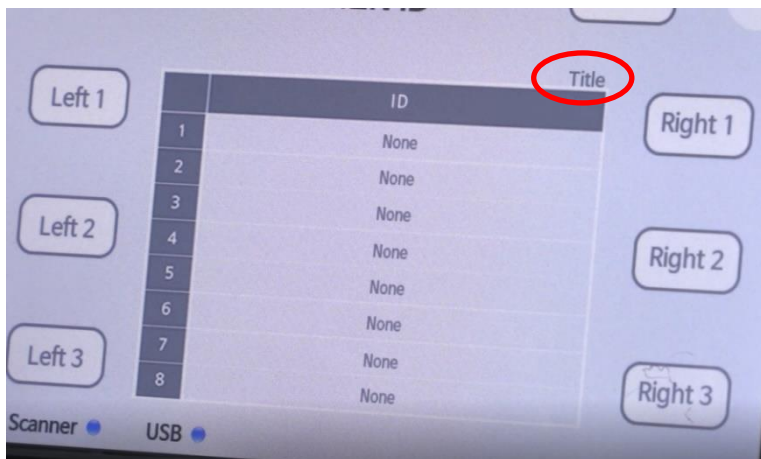


Figure 21. Location of of 'Title'



Figure 22. Inputting Title

5. Select location of sample set in plate loader by tapping Left 1-3 or Right 1-3 option in the 'Barcode Menu' (See Figure 23 as an example).

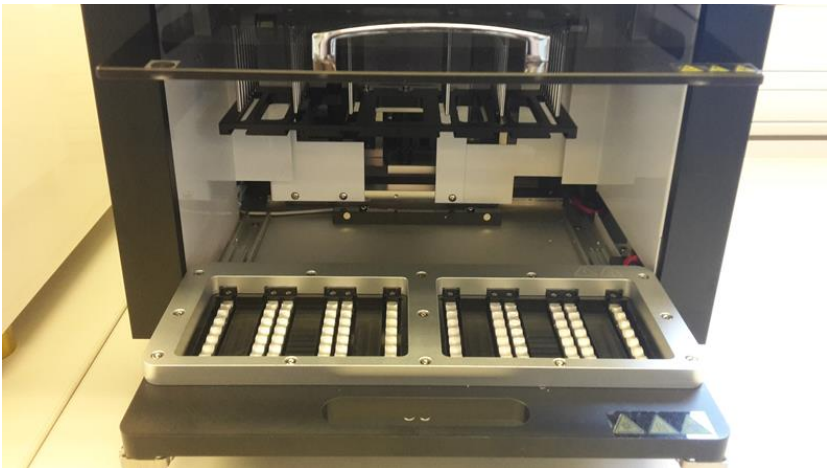


Figure 23. Plate loader locations example.

6. Tap desired location of sample (1-8) to import barcode data (see figure 24 below). Scan the sample's barcode with barcode reader until sample's barcode data displays on screen. Repeat steps 4 and 5 until all the sample data is recorded.

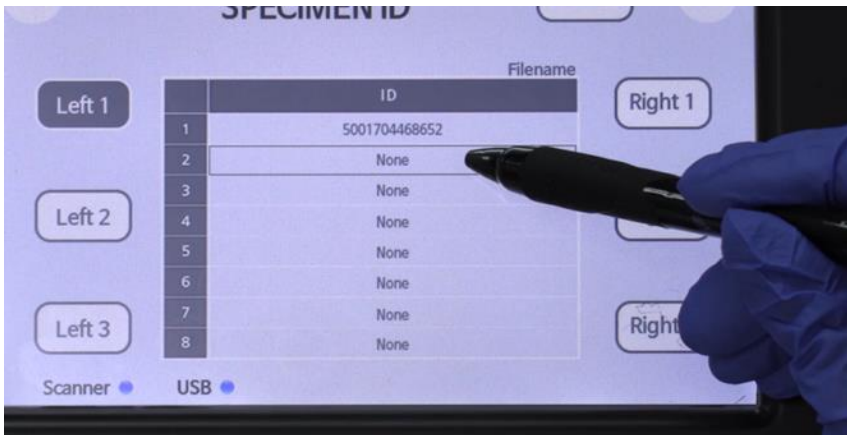



Figure 24. Sample location option.

7. When complete tap 'SAVE' located at top of the screen (see figure 18). File will be exported to USB.
8. Tap  Arrow button to go back to the 'Run' menu.
9. Tap 'START' button to run protocol.

UV sterilization

1. Tap 'Sterilization' in the Main menu to start decontamination.

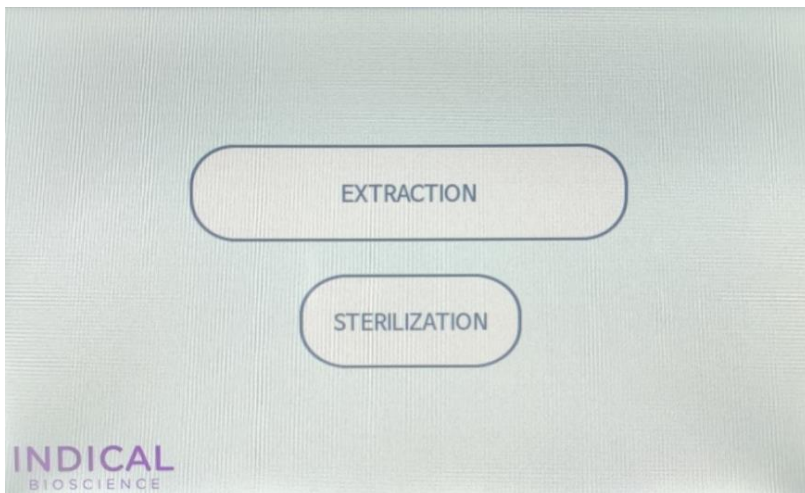


Figure 25. Main menu of the IndiMag 48s touchscreen interface.

2. Set the desired time using the set minute buttons (see Figure 26 for details).



Figure 26. Sterilization menu of the IndiMag 48s touchscreen interface.



Tap to start UV Light



Tap to select time desired for UV light

3. Make sure that the front lid of the instrument is securely closed.
4. Tap 'Start' to switch the UV lamp on for the indicated time.

For increased safety, electronic lid sensors ensure that the UV lamp only operates when the front lid is closed.

If the front lid is opened during the decontamination process, the UV lamp will turn off, but the timer will continue. Closing the front lid will switch the UV lamp back on and continue the decontamination process.

Maintenance

Cleaning the instrument

Clean the instrument regularly depending on the operating grade, but ideally daily, by following the steps below. In case you need further assistance please contact us under **support@indical.com**.

Switch the IndiMag 48s power off by moving the power switch at the bottom left of the back of the chassis into the off position.

Wipe the plate loader surface and the adjacent instrument surface with a **soft cloth or tissue paper** moistened with distilled water, a mild detergent such as SDS (sodium dodecyl sulfate) or soap solution. **Note:** Avoid spraying directly into the device. Do not use bleach to wipe the device on the inside.

Turn on the UV lamp to initiate sterilisation process when decontamination is needed.

Replacing the UV lamp

It is necessary to change the UV lamp regularly, depending on the operating grade. To replace the UV lamp, follow the steps below. In case you need further assistance please contact us under **support@indical.com**.

1. Ensure that the power is switched OFF.
2. Open the front lid of the instrument. Do not slide the door in completely in order to give space to access the lamp.
3. Rotate the installed UV lamp bulb by 90° and disconnect it from the UV plug.
4. Connect the new UV lamp bulb into the UV plug and rotate it by 90°.



Figure 27. UV lamp replacement

5. Switch the instrument ON.
6. Tap 'UV Lamp ON' in the Main menu to start decontamination.

Appendix

Technical specifications

Description	Details
Power Requirements	100-240 VAC 50-60 Hz
Operating Conditions	Temperature: 15-30°C (59-86°F) Humidity conditions: 20~80% relative, non-condensing Altitude 0-2200 m
Shipping Conditions	Temperature: -20°C to +55°C (-4 to +131°F), maximum 85% relative humidity, non-condensing
Weight	25 kg

WEEE

This section provides information about disposal of waste electrical and electronic equipment by users.

The crossed-out wheeled bin symbol (see below) indicates that this product must not be disposed of with other waste; it must be taken to an approved treatment facility or to a designated collection point for recycling, according to local laws and regulations.

The separate collection and recycling of waste electronic equipment at the time of disposal helps to conserve natural resources and ensures that the product is recycled in a manner that protects human health and the environment.



Ordering information

Product	Description	Cat no
IndiMag Pathogen IM48 Cartridge	For automated purification of viral RNA and DNA and bacterial DNA from animal samples using	SP947654P224; SP947654P608
IndiMag Pathogen Kit (384) formerly: <i>MagAttract® 96 cador® Pathogen Kit</i>	For rapid and automated purification of viral RNA/DNA and bacterial DNA from animal samples, incl. all plastics	SP947457
IndiMag Pathogen Kit w/o plastics (384) formerly: <i>MagAttract 96 cador Pathogen Kit w/o Plastics</i>	For rapid and automated purification of viral RNA/DNA and bacterial DNA from animal samples, excl. plastics	SP947257
IndiMag Mastitis Kit (384) formerly: <i>MagAttract Mastitis Kit</i>	For rapid and automated purification of bacterial DNA from milk	SP947757
IndiMag 48 PW 1-Sample Block	Plasticware (4-well blocks) for 368 x 1 sample on IndiMag 48	PW940123
IndiMag 48 PW 8-Sample Blocks	Plasticware (32-well blocks) for 70 x 8 samples on IndiMag 48	PW940166
IndiMag 48 PW 24-Sample Blocks	Plasticware (96-well blocks) for 28 x 24 samples on IndiMag 48	PW940187
IndiMag 48 PW Rod Cover	Rod cover (8-strips) for 84 x 8 samples on IndiMag 48	PW940237

Change index

Handbook	Version	Change
HB-2556-EN-002	March 2021	Document revision
HB-2556-EN-001	August 2020	Product Launch

Declaration of Conformity

INDICAL
BIOSCIENCE

Declaration of Conformity

We, **INDICAL BIOSCIENCE GmbH**
Deutscher Platz 5b
04103 Leipzig, Germany

declare under our sole responsibility that the product

Product name: **IndiMag 48s**
Catalogue numbers: **IN943048S; DM-IN943048S**

has been tested and is in conformity with the following standards:

- RoHS EN 50581 : 2012
IEC 62321 series (EN 62321 series)
- EMC IEC 61326-1 : 2012
- Safety IEC 61010-1 : 2010
IEC 61010-2-010 : 2014
IEC 61010-2-051 : 2015
IEC 61010-2-101 : 2015

Detailed specification of the tested product is shown in the following test reports:

- RoHS Test Report: ETLRD191010.0130
- CB Test Report (EMC): OT-18D-REC-001
- CB Test Report (Safety): OT-201-RHC-001

This EC-Declaration of Conformity is following the provisions of RoHS DIRECTIVE 2011/65/EU, Low Voltage DIRECTIVE 2014/35/EU, DIRECTIVE on electromagnetic compatibility (EMC) 2014/30/EU and Safety Requirements.

Place and date of issue: Leipzig, 23.06.2020
Authorized by:


Dr Fredrik Ullman, CEO



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Ordering: www.indical.com/contact
Technical Support: support@indical.com
Website: www.indical.com