Operating Manual

Your guide to the StatLab

PiSmart Single Hopper **Laser Cassette Printer**

PISMART-CL1

Company Information

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CE

This instrument conforms to the essential requirements of

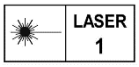
- Low Voltage Directive 2014/35/EU
- Safety of Laser Products EN 60825-1

Symbols

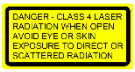
The following symbols and conventions may be used throughout this document and on the instrument:

This symbol is used on the equipment, or in a document, to indicate that instructions must be followed for safe and correct operation. If this symbol appears on the instrument, always refer to the operator guide.

This symbol is used on the equipment, or in a document, to warn of the potential hazard of Laser Radiation.



This marking is used on the equipment, it indicates that it is a CLASS 1 Laser product



This marking is used on the equipment, located on the protective shield covering the laser marking area. It warns of radiation if the cover is removed.

Manufacturer

A WARNING or CAUTION is provided with appropriate instruction if there is a danger of personal injury or damage to the equipment or samples.

Notes provide additional information about a job or instruction, but do not form part of the instruction.

Purchase and Service Contact

StatLab Medical Products

2090 Commerce Drive

McKinney, TX 75069

Telephone 1-800-442-3573

www.StatLab.com

Contents

Safety Information

EMC Statement

This equipment complies with the emissions and immunity requirements of EN61326-1:2013.

This equipment has been designed and tested to CISPR 11 Class A Group 1.

This equipment is intended for use in a laboratory environment, by a trained and qualified professional. In a domestic environment, it may cause radio interference, in which case it may be necessary to take measures to mitigate the interference.

Do not use this instrument in close proximity to strong electromagnetic radiation as these may interfere with the proper operation. The electromagnetic environment should be evaluated prior to operation of this device.

Introduction

Pyramid Innovation Ltd instruments are designed for convenient and reliable service; however, improper use or handling by a user may damage the instrument or cause a hazard to health.

The following sections contain important information for the safe setup and use of the instrument and should be read and understood by the user before using the instrument.

Laser Safety

This is a CLASS 1 Laser product, as supplied, conforms to IEC60825-1 issue 2014

Complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No.50 dated June 24, 2007.

The product incorporates a CLASS 4 embedded Laser, located inside the protective housing.

WARNING – Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

Do not operate the product without the enclosure covers fitted to avoid the risk of CLASS 4 invisible laser radiation exposure.

General Safety

This instrument, as supplied, conforms to IEC61010-1 issue 2010; however, the addition of chemicals introduces potential hazards. Good laboratory practice must be employed and consideration must be given to the potential for hazard when dealing with chemicals.

Do not remove any panels or access covers unless specifically instructed to do so. The instrument does not have any user serviceable parts. Potential lethal voltages are present inside the instrument.

The instrument is only connected to the mains power supply using the supplied power adaptor and detachable mains lead. For replacement power adaptor or mains lead see the Consumables and accessories list or ask your local distributor.

The instrument must be properly connected to a good earth (ground) via the Mains input supply and positioned such that it is possible to interrupt the Mains supply at the source by removing the plug from the socket.

Use only factory approved accessories or replacement parts within the instrument.

If the equipment is used in a manner not specified by Pyramid Innovation Ltd, the protection offered by the equipment may be impaired.

Any problems should be reported to your Pyramid Innovation Ltd supplier.

Correct maintenance procedures are essential for consistent performance. It is recommended that a Maintenance Contract is taken out with the service department.

Any maintenance or service work required may only be carried out by trained personnel.

The instrument should be placed on a suitable level surface and not in direct sunlight.

Only use cleaning agents recommended in the Operator Guide.

Chemical Safety

The introduction of chemicals creates potential hazards. Pyramid Innovation Ltd has adopted the following position with regard to the subject of volatile chemicals used in laboratories:

Do not use harmful chemicals or solvents to clean the instrument.

The operator is fully aware of the contents of the specification documents detailing the properties of the chemicals they are using.

The operator has carried out any legally required assessments of chemicals used and is using good laboratory practice.

Environment

This instrument is required to comply with the European Union's Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU. It is marked with the following symbol:

At the end of the product life, it must be recycled in accordance with local regulations. It can be returned to a Municipal Collection Facility or to the retailer when a replacement is purchased. Where applicable this facility will be offered by the Product dealer.

Further information on Pyramid Innovation Ltd's compliance with these directives, the recyclers in your country, and information on Pyramid Innovation products which may assist the detection of substances subject to the RoHS Directive are available from your distributor.

www.PyramidInnovation.com

Warranty Statement

Pyramid Innovation Ltd are proud of our quality, reliability and of our after-sales service. We continuously strive to improve our service to our customers.

Please ask your distributor representative about service contracts which can help maintain your instrument in an optimal operating condition.

Warranty provisions necessarily vary to comply with differences in national and regional legislation. Specific details can be found in the delivery documentation or from your dealer or representative.

Please note that your warranty may be invalidated if:

- This instrument is modified in any way, or not used as intended by Pyramid Innovation Ltd.
- Accessories and reagents which have not been approved by Pyramid Innovation Ltd are used.
- The instrument is not operated or maintained in accordance with the instructions in the Operator Guide.

Product Return Safety

In the event that the instrument has to be returned to the factory, the Product Return Safety Declaration form must be completed and included with the instrument. Contact your supplier or see Appendix B.

Operator Guide

How To Use This Guide

Introduction

The printer is designed to print directly onto laboratory tissue cassettes. The operator is responsible for ensuring the accuracy of the information printed onto the cassette.

Using Cassettes other than the ones recommended may cause irrevocable damage to the instrument. Please see Appendix A for a list of recommended Cassettes.

Recommended cleaning method

This section provides guidance on cleaning the Cassette printer

Getting Started

This takes you through from opening the box to printing a test Cassette.

Printer Operation

This takes you through general printer operation.

Parts of the Printer

A. Removable Hopper

B. Touchscreen Display

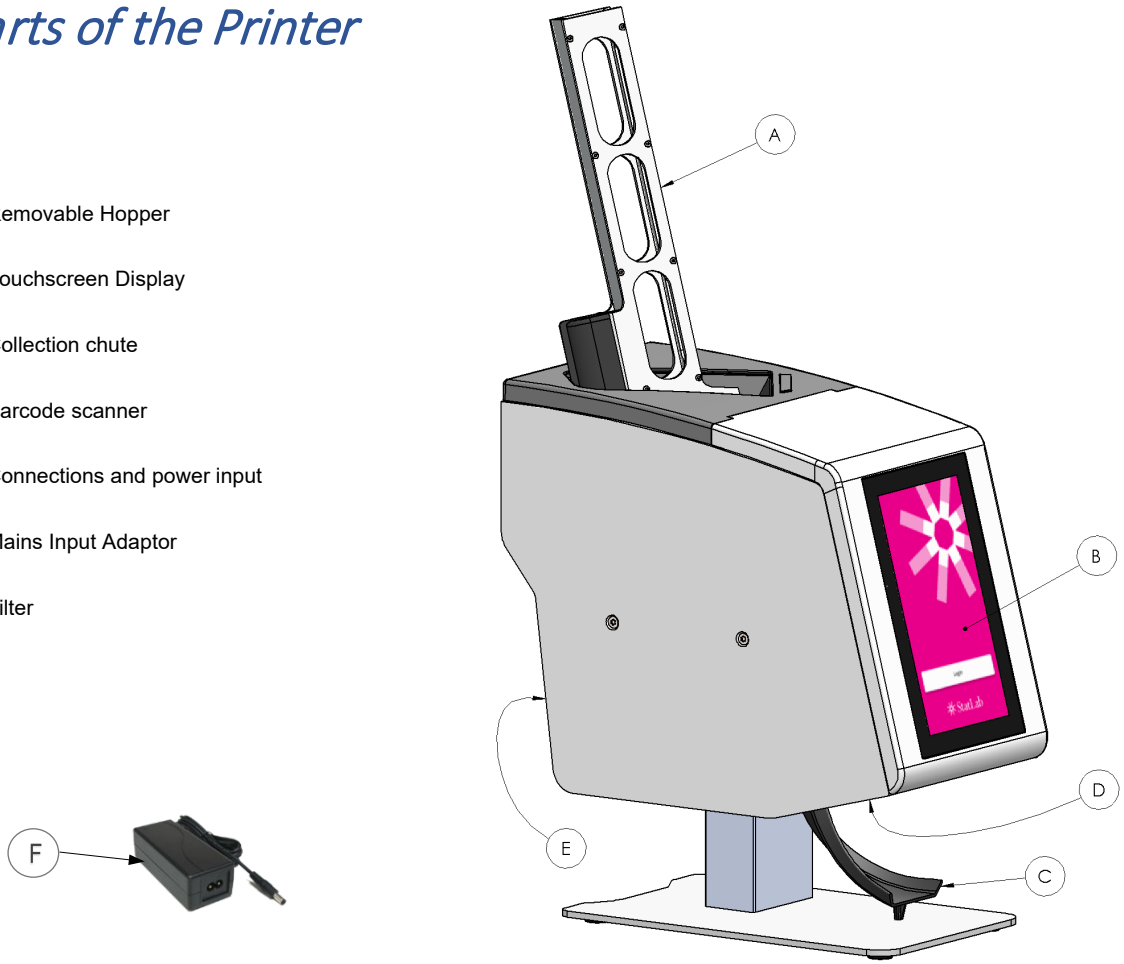
C. Collection chute

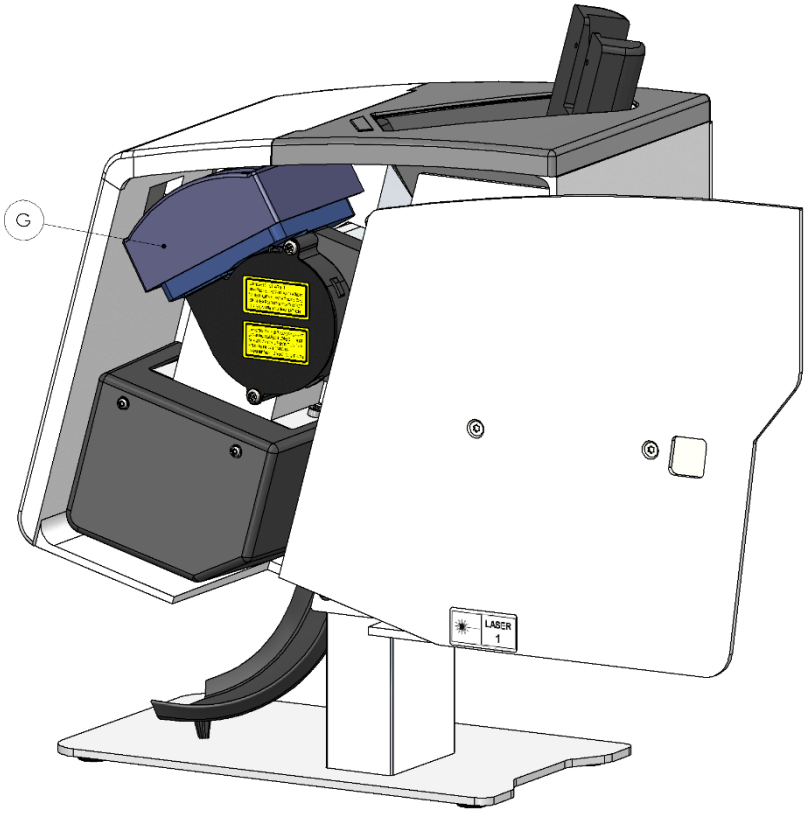
D. Barcode scanner

E. Connections and power input

F. Mains Input Adaptor

G. Filter





Back panel and connections

At the back of the printer there are a number of connections including the 24v DC power adaptor.

Signal connections suitable only for connection to equipment meeting the requirements of clause 6.3 of IEC 61010-1 or the SELV requirements of IEC 60950-1, 2014.

On / Off button	Press the right side in to turn power on. Press the left side to turn the printer off.
24V DC	Only connect the supplied or specified 24v power adaptor.
2 x USB	USB 2 ports used to connect external keyboard or USB drive.
Accessory interface	Used to connect to printer-controlled accessories.
USB to PC	Used to connect the printer to a PC running the Windows driver.
Network	Used to connect the printer to a PC running Windows driver or the Hub (printer manager).

Scanner

The barcode scanner mounted under the left front edge of the Cassette printer uses an LED light source requiring no special eye protection. The scanner has a motion sensor that activates the scanner function and illumination. If the sensor sees no motion for a period of time, the illumination will cycle off – the area under the scanner will remain dark. When in standby mode, the motion sensor continues to monitor the area and will come out of standby mode as needed when motion is detected.

The scanner is programmed to read the Data matrix code, QR code and Code 128 barcodes by default. Additional codes can be activated, contact your local distributor for details.

Filter

The Printer incorporates a replaceable filter which should be periodically replaced to maintain best performance. The life of the Filter will be affected by several factors, the most significant being the number of cassettes printed. We recommend changing the filter every 10,000 cassettes printed.

The Filter is located behind the Sliding Door on the right-hand side of the unit.

See section: Maintenance/ Filter Replacement

Recommended Cleaning Method

The printer power should be turned off prior to cleaning.

The outer case can be cleaned using a soft cloth dampened with a mild detergent, Alcohol or a glass or multi-surface cleaning product.

The touch screen can be cleaned with commercial glass cleaning solution. Dampen a soft cloth or paper towel or spray directly onto the touchscreen, wipe immediately.

The dispense mechanism and outlet can be cleaned using a brush. (similar to a small paint brush) The power should be turned off prior to cleaning the unit.

Getting started

Remove packaging.

Turning on the printer for the first time

Connect the appropriate mains power lead to the power adaptor.

Plug the round 24V plug into the power socket at the back of the printer.

Plug the mains lead into the wall socket

To turn the printer on or off, press the power button on the back of the printer.

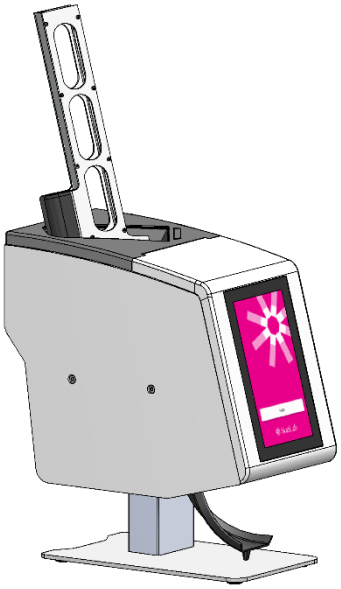
Wait for the printer to run through its initialisation process which checks that the internal mechanism is operating correctly.

Printer Operation

The printer is designed to print the label image that is currently displayed on the printer display. The front of the unit is a high-definition, touchscreen display. To operate the unit, press specific areas of the screen to activate buttons and functions; these functions are intended to be obvious.

A barcode scanner is built into the front left-hand corner of the printer. The scanner is motion activated and will project a thin green bar onto the table surface. This bar is an LED aimer that will indicate the area where barcodes should be placed in order to read the data from the barcode into the printer software. Barcodes printed on paper or other objects can be placed under the scanner for decoding.

The built-in software enables you to:



- Print individual label images.
- Create and print sequences.
- Create and print protocols.
- Edit printable data.
- Change the Template used to print.

Design your own Templates using different fonts and barcode types.

- Set Items to automatically increment.
- Setup Templates to accept data from scanned barcodes or LIS input.
- Edit and delete label images within a sequence.

The printer can create label images using the following input methods:

- Text file import.
- Using the scanner to capture required data.
- Internal designed label images using data files from LIS or other external source.

Loading Cassettes

The printer can select between six on-board hoppers. Prior to use, the hoppers should be loaded with Cassettes, please refer to Chapter 6 for a full list of accessories and consumables.

The hoppers have a capacity of approximately 40 Cassettes. The Cassettes should never be stacked above the top of the hopper as they could fall from the top if stacked too high. The hopper will need to be attached to the printer.

The cassette must be loaded with the writing surface to the left and the cassette opening to the top. Cassettes should not be loaded while the printer is in operation.

To load Cassettes into the hopper:

1. Place a thread of cassettes into the hopper.
2. While pressing downward on the top of the stack, firmly pull upward to remove the plastic thread.
3. Add Cassettes as necessary until the hopper is full. A partial thread can be loaded.

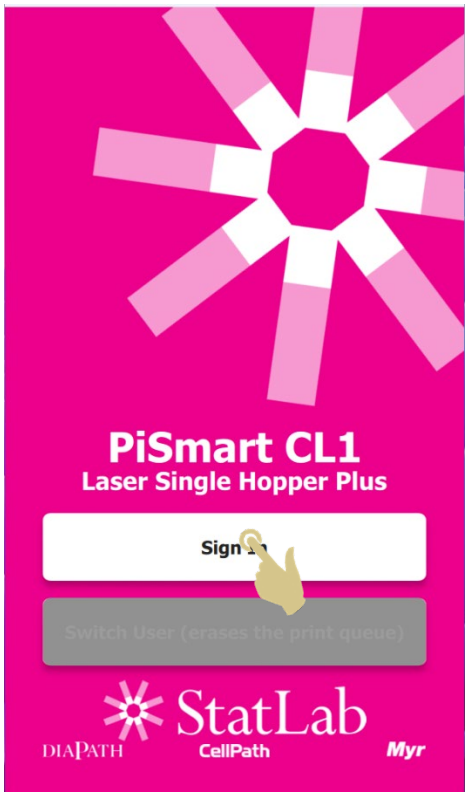
Image shown is the Single Hopper Cassette Printer. Filling the Hopper is the same

Cassette Selection

It is critical that the Pyramid Innovation cassettes are used in the Cassette printer, these cassettes are specially designed for best operation in the printer. Using other cassettes, can cause damage to the printer or affect print quality or print chemical resistance.

This operator guide includes a list of Cassettes which have been tested and are approved for use in the Single Hopper Cassette printer.

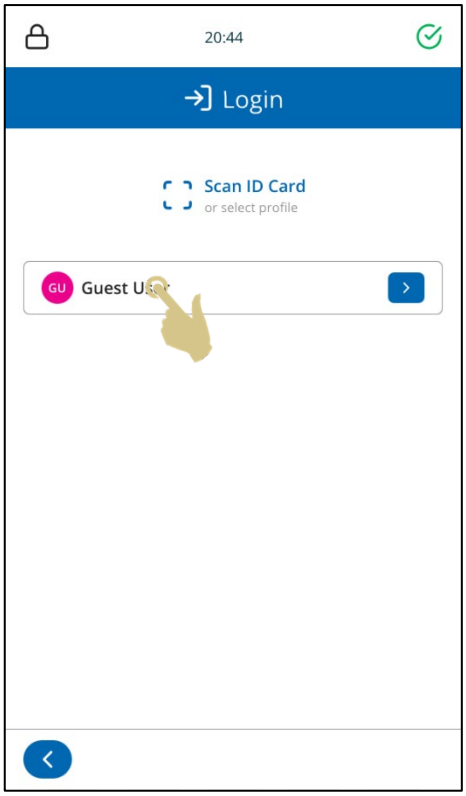
Cassette Printer Operation



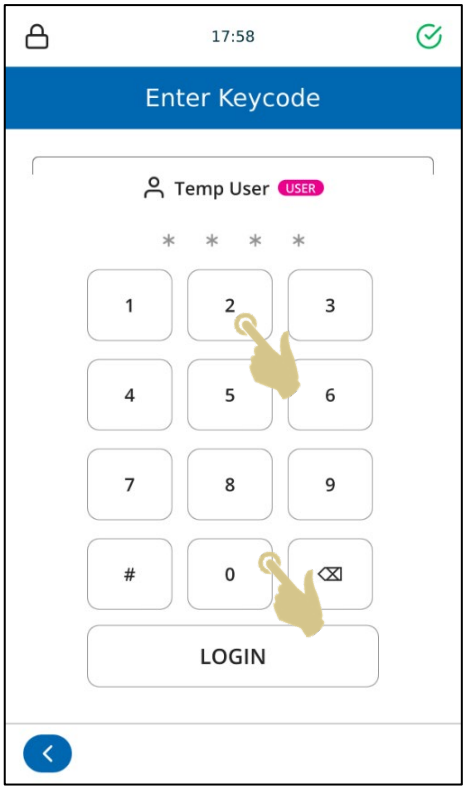
To begin using the Cassette Printer, press the Sign In button.

Main User Interface

To log into the system



1. Select the correct user.



2. Enter the correct passcode (1234)
3. Press the LOGIN button
4. Once the correct code is entered, the home screen will be displayed. If the incorrect code is entered, the user screen will be displayed.

Home Screen

The home screen is used to display the status of the Cassette printer.

Scan barcodes on specimens to enter them into the Cassette printer.

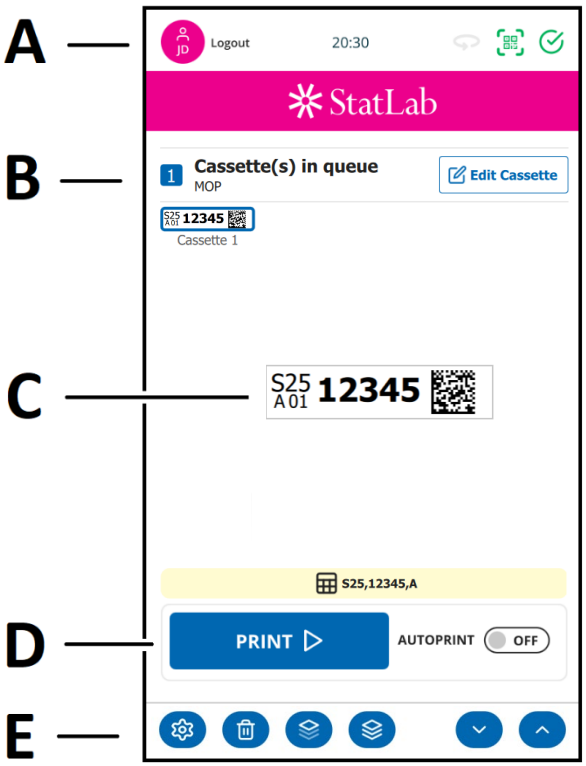
To log out, press the user button.

Home Screen

The home screen is used to display the status of the Cassette printer, create Cassette labels and control printing.

A. Printer Status Bar

- The top bar of the display shows the printers status.
- Current Time
- Current User



B. Scanner Bar

The scanner bar displays data scanned using the integrated scanner or typed into the on-screen keyboard.

Special Note: if the scanner box contains data, any data transfer from a windows printer will be paused.

C. Template

Shows the data that will be printed on the Cassette. To edit the label, touch the middle of the template.

D. Play Button

Pressing the PRINT button will start the print process

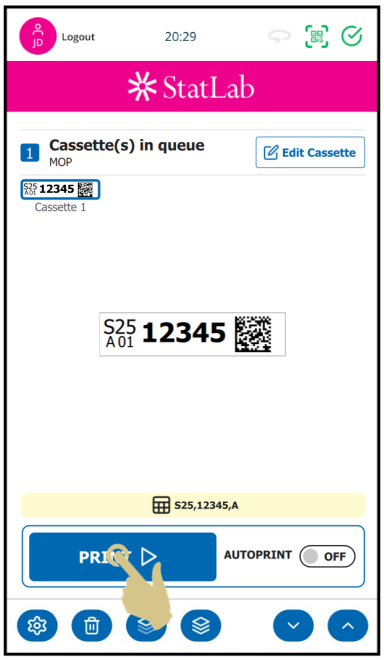
E. Settings Bar

Buttons on the settings bar will change based on the functions available. Buttons will be added or removed automatically as the screen or information changes to allow or disallow operations. The buttons will be explained further throughout the operator manual, however common buttons are:

Printing Cassettes

The Single Hopper Cassette printer is designed to print Cassettes on-demand. The displayed label shows what will be printed on the Cassette. This section applies to printing Cassettes regardless of the method in which the Cassettes were placed into the print queue.

To print a Cassette, press the print button.



Settings Menu

Settings Button

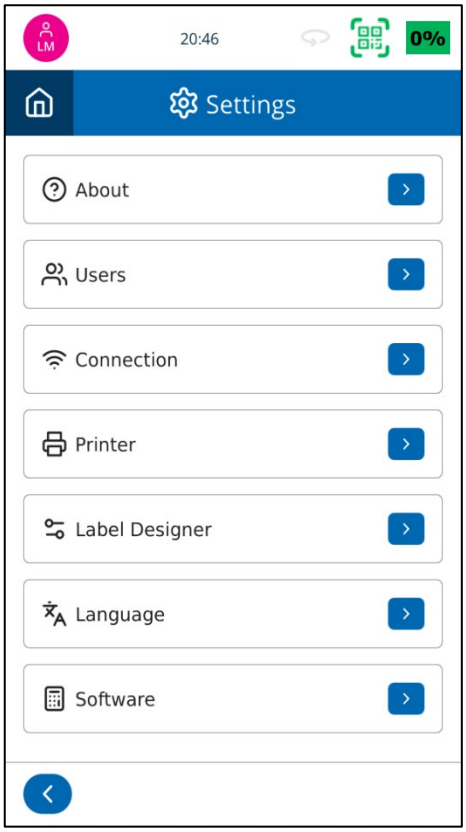
From the home screen, press the settings button to enter the settings menu.

Back Button

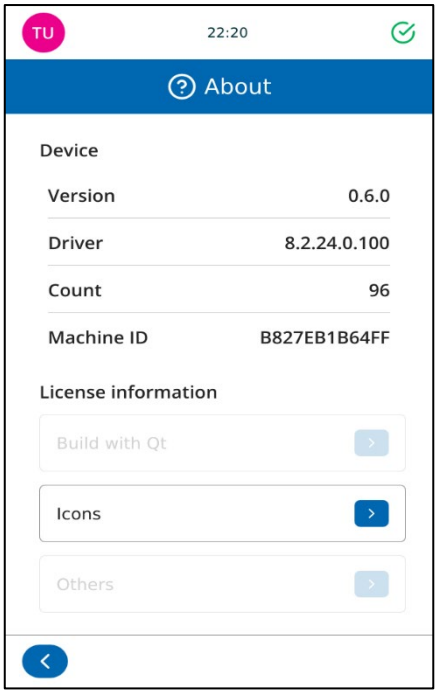
When pressed, any changes will be saved and the previous software menu will be displayed.

Up and Down Arrow Buttons

The up and down arrow buttons will scroll the menu items up and down.



About Menu

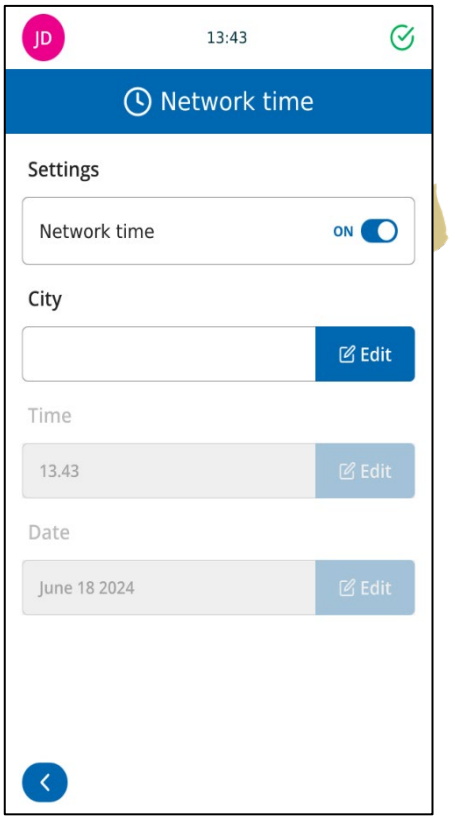


Provides information regarding the device's software and general information.

Shows:

- Software version
- Firmware version (Driver)
- Count of total Cassettes printed
- Machine ID (Mac Address)

Network Time Menu



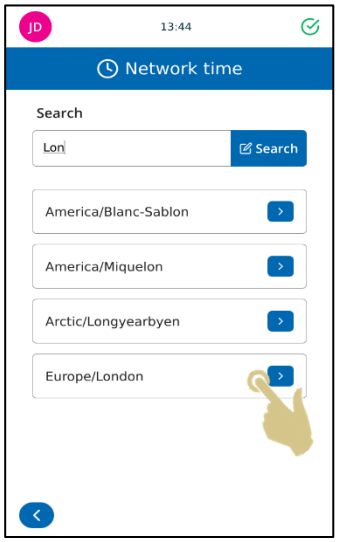
When the device is connected to a network it is recommended that the NETWORK TIME setting is used. This will ensure the device is synchronized with other systems in the laboratory.

To use the network time:

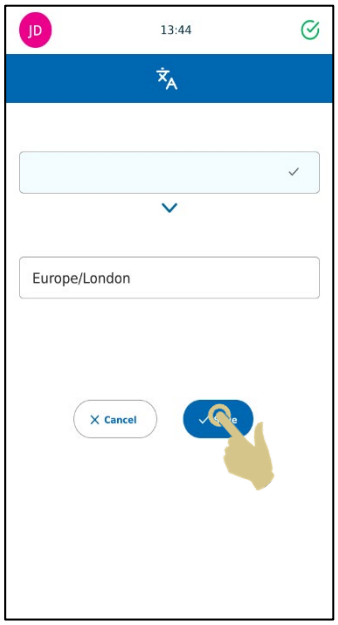
1. Slide the button next to Network Time.
2. Set the City by pressing the Edit button

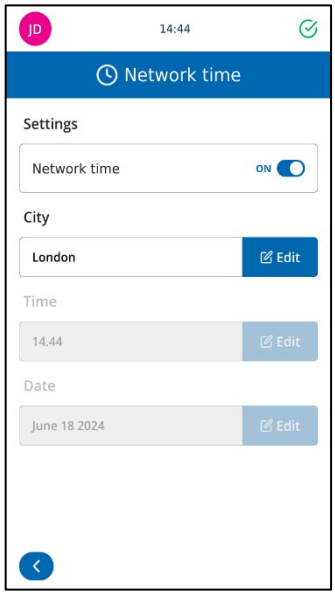
3. Select a city in your same time zone, you may use the search box to fine your city faster.

4. Press the City button

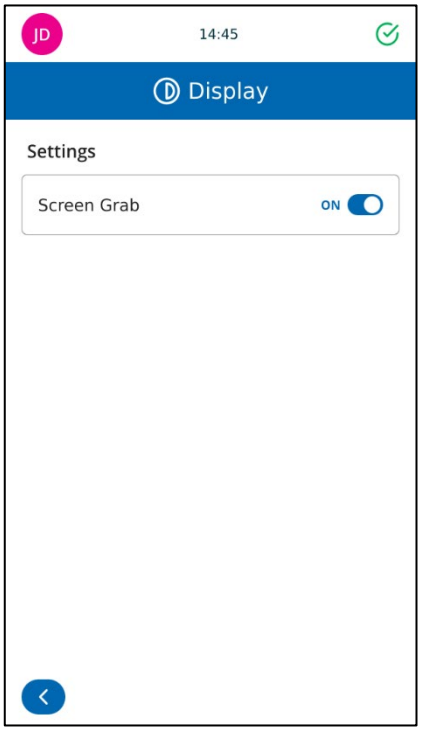


5. ONCE THE INFORMATION IS CORRECT, PRESS THE SAVE BUTTON





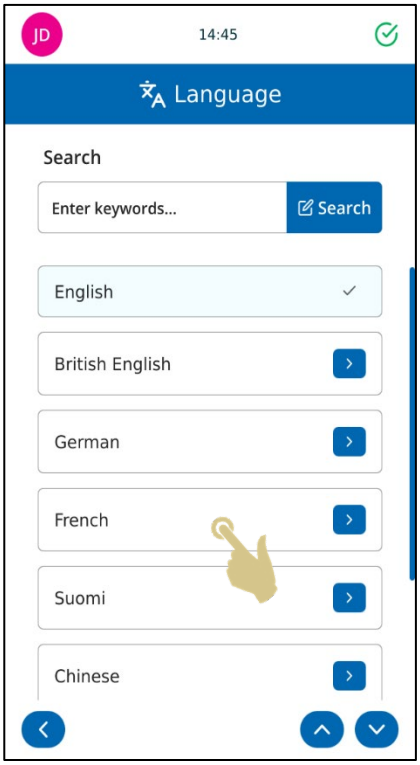
Display Menu



Screen grab

If this is ON, the screen image can be saved to a USB stick by touching the area of the display the time is shown. This can be done from any software menu.

Language Menu



Languages

Changes the displayed language.

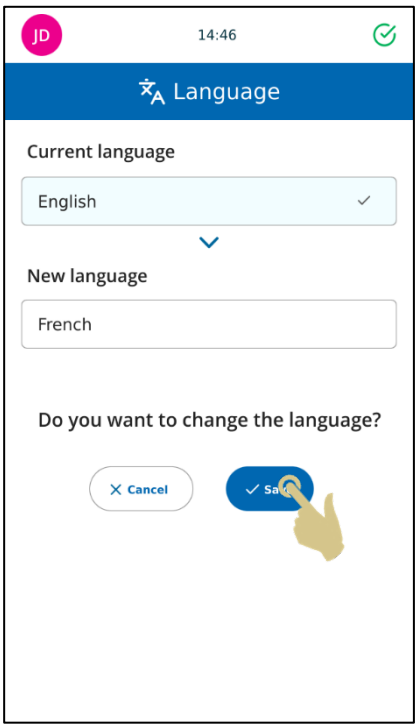
The default language is English, all devices ship set to English language.

To select a different language:

1. PRESS SETTINGS
2. PRESS THE LANGUAGE BUTTON

   SELECT THE REQUIRED LANGUAGE

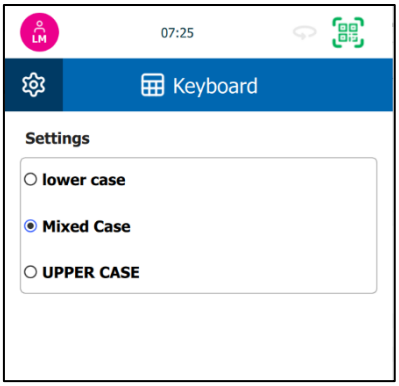
3. PRESS THE SAVE BUTTON
4. THE NEW LANGUAGE WILL BE DISPLAYED



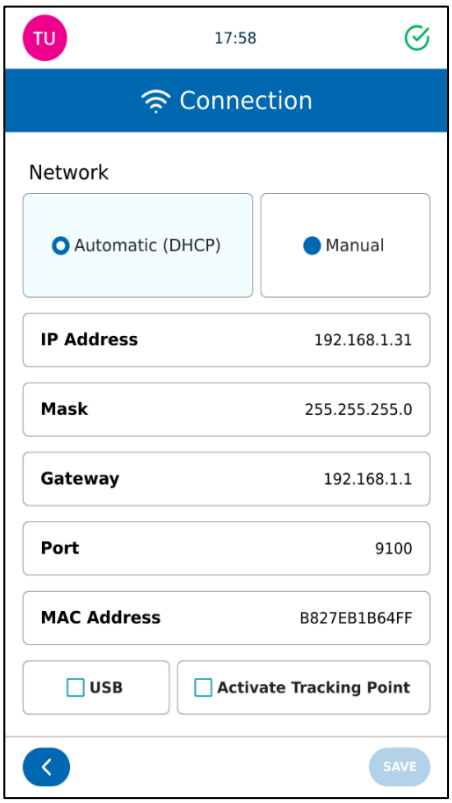
Keyboard Menu

If selected the first character typed will be uppercase and then automatically switch to lower case.

If unselected, the type will remain in uppercase.



Connection Menu

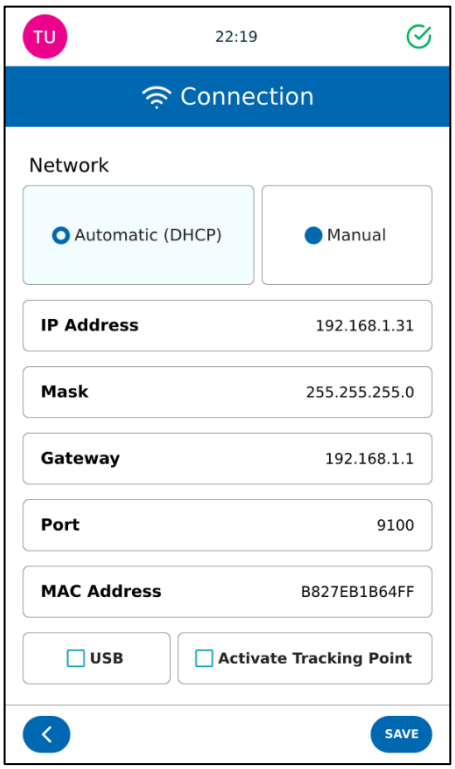


Network settings is used to connect the device to networks and network services. The device can be connected to networks via an RJ45 connector located at the back of the device.

To establish this connection, with the power off, insert a standard network cable into the RJ45 connection on the back of the device.

Plug the other end of the cable into a local network connection.

Power the device on. Once the device is powered and initialized, press the settings button, then the Network button, a network IP Address should be displayed.



IP Address

To connect to a network, select IP Address and select IP Type

Automatic (DHCP) the IP address is assigned by Network. or Manual (IP address selected by user)

Port

Port used for connection

MAC Address

Displays the MAC Address of the device

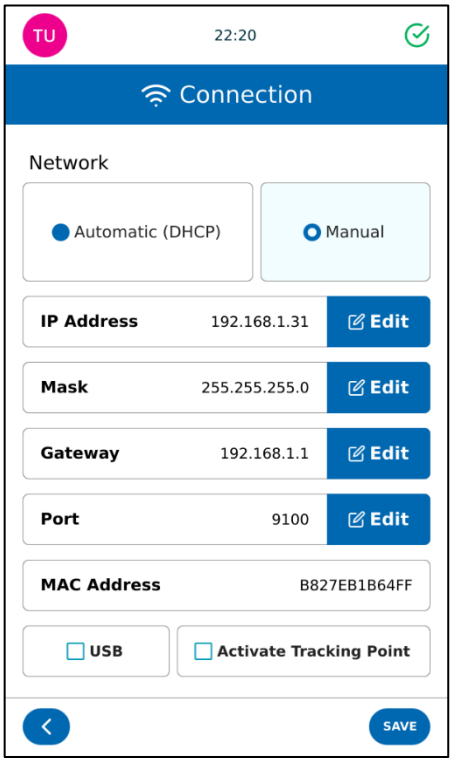
USB

Used to connect to the device using USB connection.

Activate Tracking Point

Used to connect to PathSmart Tracking software.

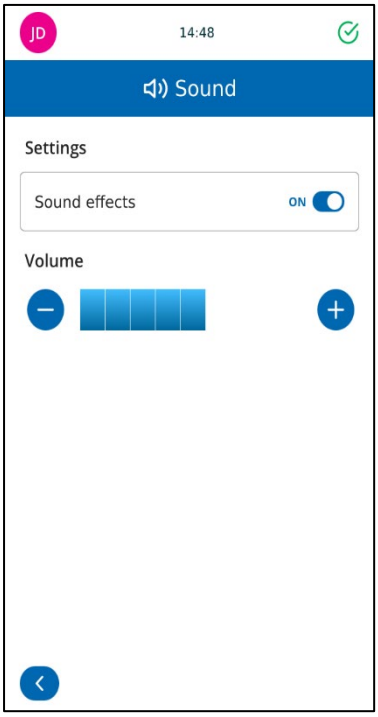
To set a fixed IP Address from the Network menu:



1. PRESS MANUAL BUTTON

2. PRESS THE EDIT BUTTON NEXT TO EACH SETTING AND ENTER THE CORRECT INFORMATION.

Sound Menu



Sound can be switched off by sliding sound effects to off.

Volume can be adjusted using the + and – buttons. When finished, press the back button.

Maintenance

How To replace the Filter

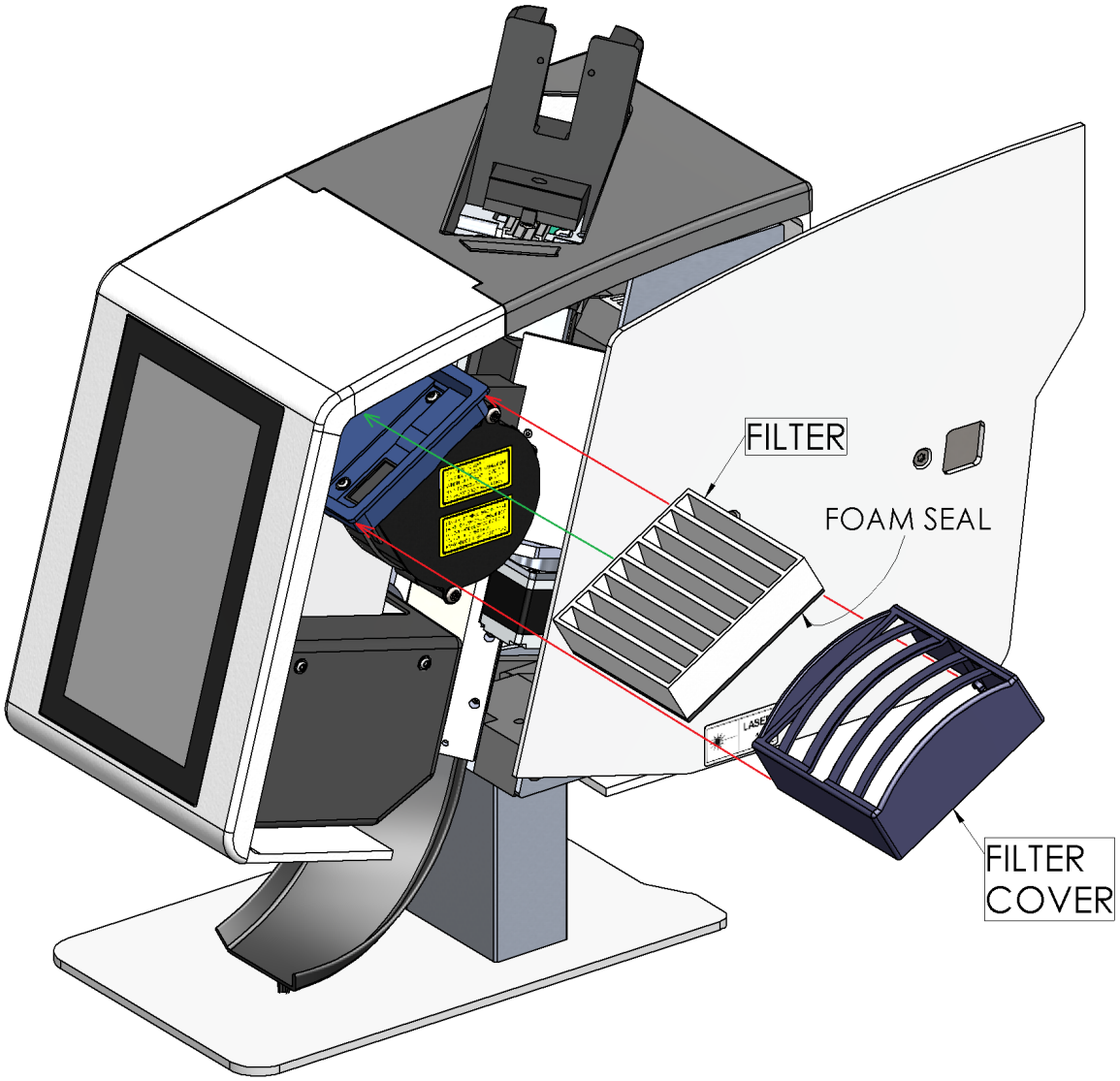
Turn off the Printer and disconnect the Power connection

Open the sliding Door on the R side of the Printer

Grip the sides of the Filter Cover and pull outwards to release it. The Filter can be removed and discarded.

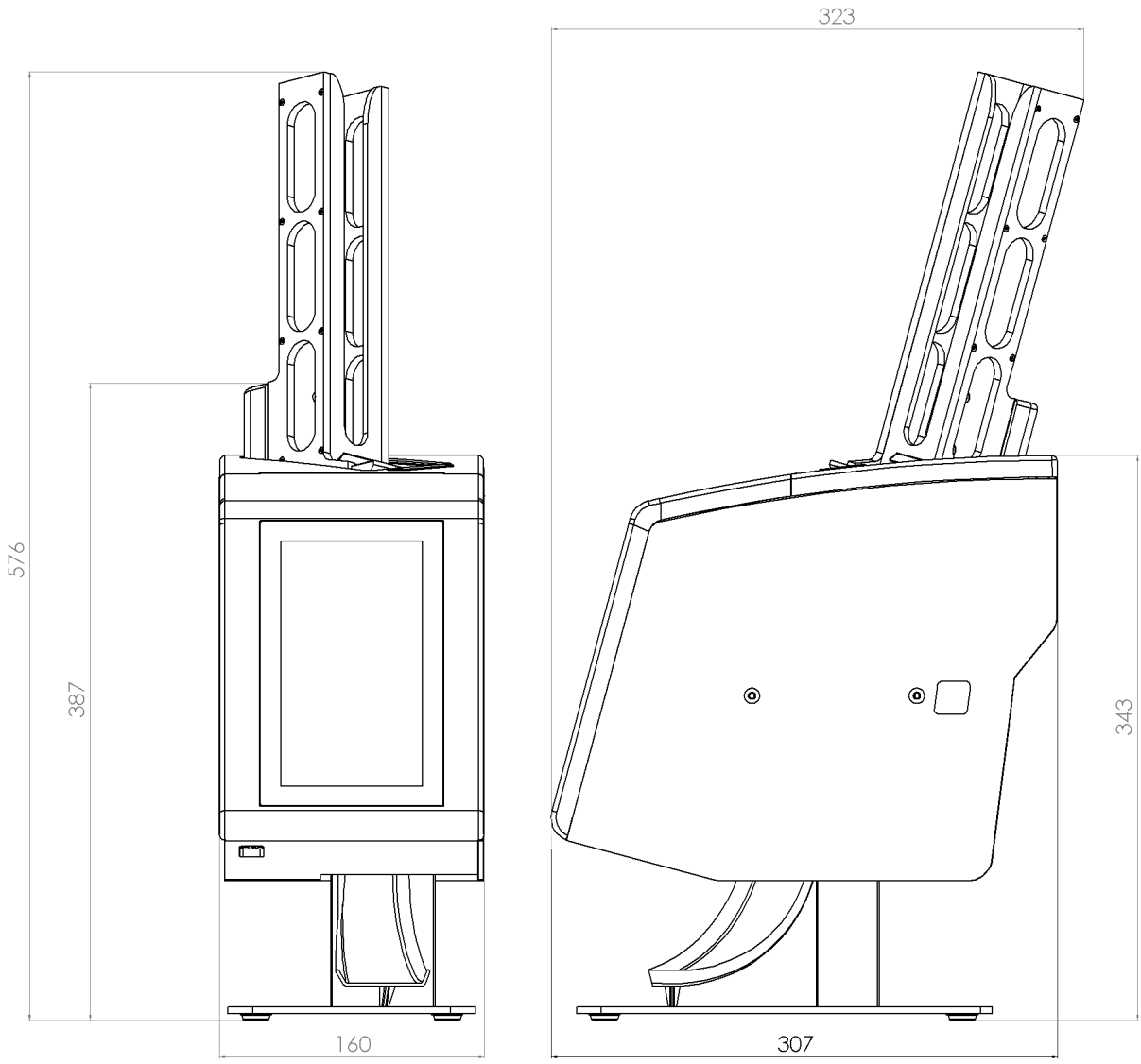
Place the new filter with the foam surface downwards.

Slide back the Filter Cover engaging the two pegs on the underside of the base.



Printer Specifications

Dimensions



Instrument	
Weight	Printer 7.6Kg (excluding hopper); Hopper 0.4kg
Input Voltage	24V DC
Current	2.7A
Print resolution	600 dpi
Print speed	3-5 seconds typical (full area print)
Cassettes	Only approved cassettes listed in Appendix A can be used in the Pyramid Innovation Cassette Printers
Hoppers	1
Environment	Altitude up to 2,000m Temperature 5 ˚C to 40 C **Recommended** +15˚C to +30 ˚C (+59 ˚F to +86 ˚F) Performance may deteriorate if operated outside recommended range.
Storage environment	-25 ˚C to +45 ˚C (-13 ˚F to 113 ˚F) Short period only
Relative Humidity	Max. 80% RH up to 31°C Decreasing linearly to 50% RH at 40°C
Pollution	Level 2
Over voltage category	II

Embedded Laser Specifications

Embedded Laser Category	CLASS 4
Wavelength	1064nm
Beam divergence	35mrad
Modulation frequency (nominal)	40kHz
Pulse width (nominal)	3nsec
Max Power (nominal)	2.0W

Consumables and Accessories

Description	Part Ref
Mains lead USA	SP50007
Power adaptor for Laser Printer 24V 2.7A	CP50006
Mains lead UK	SP50009
Mains lead EU	SP50010
Mains lead, China	SP50015
Mains lead, Japan	SP50016
Cassette Dispense Hopper	P52001-E
Hopper Rack, 2 position	P52002-E
Collection Tray	P52003-E
Cassette Hopper Stand	P52004-E
Extraction Filter (pack of 4)	CP50009

Appendix A

Recommended Cassette Types

Manufacturer / Brand
StatLab / Pathflow PiSmart Laser Cassette - Slotted
StatLab / Pathflow PiSmart Laser Cassette - Biopsy
StatLab / Pathflow PiSmart Laser Cassette - MicroBiopsy
StatLab / Pathflow PiSmart Laser, Slotted, Attached Lid Front Hinge Cassette
StatLab / Pathflow PiSmart Laser, Biopsy, Attached Lid Front Hinge Cassette
StatLab / Pathflow PiSmart Laser, MicroBiopsy, Attached Lid Front Hinge Cassette
CellPath / BioMesh Cellsafe One Laser Cassette
CellPath / System II Hex Laser Cassette
CellPath / System II+ Slotted Laser Threaded Cassettes
CellPath / System II+ Biopsy Laser Threaded Cassettes
CellPath / System II+ MicroBiopsy Laser Threaded Cassettes
Sakura / Tissue-Tek® Paraform® Sectionable Laser Cassette

Appendix B

Product return Safety Declaration Form

Part1 **Decontamination Certificate**

Any instrument or part of any instrument must be clean before being returned, and where necessary accompanied by a completed Decontamination Certificate. Should the instrument or any part of it be received in an unclean condition, or Pyramid Innovation Ltd consider it to be a hazard, the instrument or part will be returned unrepaired at the expense of the customer.

It is important that the certificate is forwarded by post or fax, and a copy attached to the exterior of the container. Containers will not be opened until the company is in possession of the required certificate.

This form MUST be completed by the customer and NOT by a Distributor or distributor employee.

If an instrument or part is to be returned to Pyramid Innovation Ltd, please note the following.

1. If the instrument or any part of it has been exposed to or been in contact with potential pathogenic or radioactive material, it is essential that it is decontaminated.
2. Set procedures are laid down in the European Health and Safety Directives for decontamination. To avoid any misunderstanding, we request that all instruments or parts returned to us must be accompanied by a certificate stating the following:

We certify that this (Model) ……..

Serial No ……..

- Has not been exposed to pathogenic, radioactive or other hazardous material and has been cleaned.
  OR
- Has been decontaminated and cleaned (if exposed to the above) according to approved procedures following exposure to:

Has the instrument been used for work with human or animal Transmissible Spociform Encephalopathies, e.g. Creutzfeld-Jacob disease, Scrapie or BSE?
YES / NO
If yes, please contact Pyramid Innovation service before taking any further action.

Signed ……. Position ……

Name (Block Capitals) ……..

Company or Organization ……

Full Address……..

……

Part 2 **Guidelines for Returning Instruments**

Please use the checklist below to ensure that the instrument being returned is ready for collection.

All reagents / wax removed from instrument, including vapour traps (if applicable)…… ☐

Accessories are secured / itemised …… ☐

Instrument is packed in original packaging…… YES / NO

RMA No …… Carrier ……..

For Attention of ……..