



SPOT Imaging BlocDoc™ Paraffin Block Documentation

Integration and User Manual

Revision 1.0.1 (9-29-22)

PN: 8281

Diagnostic Instruments, Inc.

6540 Burroughs Ave.

Sterling Heights, MI, USA 48314

BlocDoc Notes:

[illegible]

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Revisions History

Manual Revision History

<u>Revision</u>	<u>Date</u>	<u>Changes</u>
1.0.000	9/29/2022	Initial Release

1.00 - Introduction

In this section we will cover general information about the BlocDoc system, the manufacturer, and this manual. The following topics will be covered: Purpose and Scope of this manual, Location of Manufacturer, Contact Information, All Rights Reserved, Trademarks, Restrictions and Liabilities, Abbreviations and Symbols, Warnings, Hazards, Precautions, Warranty, End User License, and Accessories for this system.

1.01 - Purpose and Scope of Manual

This manual has been written to provide:

- An overview of the operating principles of the BlocDoc System
- Discussion of Requirements for:
 - Specification of system components and modules
 - Specification of required customer infrastructure support
 - Installation and configuration of system components
- Brief explanation of each feature with small tutorial on its use
- Common troubleshooting procedures for service technicians.

1.02 - Location of Manufacture

Diagnostic Instruments, Inc.
6540 Burroughs Ave.
Sterling Heights, MI, USA 48314

1.03 - Contact Information

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Sterling Heights, MI, USA 48314-2133
Telephone: +1-586-731-6000
Fax: +1-586-731-6469
Email: info@spotimaging.com

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Please note that technical assistance from our specialists will only be available in one of three ways:

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- Via a pre-purchased service contract (note duration of contract and its coverage).
- Ad hoc purchase of service on a time and materials basis at the time of need via approved credit source.

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Email: info@spotimaging.com

General Inquiries:

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1.07 - Abbreviations and Symbols

	Alternating Current (AC)
	Direct Current (DC)
	Both Direct and Alternating Current
	Earth Ground
	Protective Conductor Terminal
	On (Supply Power)
	Off (Supply Power)
	Caution: Your actions can have detrimental impact to you or to associates and customers.
	Caution: Risk of electric shock

1.08 - Warnings

 **TO PREVENT FIRE OR SHOCK HAZARD, DO NOT EXPOSE THIS PRODUCT TO RAIN OR EXCESSIVE MOISTURE.**

Regulatory and Safety Compliance Notes


This equipment complies with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment.

The equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications.

Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interface at his own expense.

This product complies with the CE EN61326 and 61010-1 standards.

BlocDoc captures images of cassettes and slides or other sample containers during a scanning session and stores them to an internal database for authorized operator review. It does not discriminate PHI (Patient Private Health Information) from non-protected information, therefore it is the responsibility of the Administrators and Users to ensure that only HIPAA Qualified Users are allowed access to the BlocDoc instruments or its offline user interface which provides access to viewing scanned sample label or retrieved metadata which may exhibit patient PHI on their monitor.

 This instrument should only be serviced by personnel that are trained and certified on the appropriate precautions and procedures to avoid personal injury during the service work.

1.09 - Hazards



Warning! Power Rating:

The BlocDoc power cord must be connected to a power receptacle that provides voltage and current within the specified rating for the system. Use of an incompatible power receptacle may result in electric shock and fire hazards.



Warning! Electrical Grounding:

The BlocDoc power cord must **NOT** be replaced, plugged into a two-prong adapter or have its ground prong altered or removed. Any of these alterations defeats the utility ground, creating a severe shock hazard. The power cord must always be directly connected to a grounded three-prong receptacle with a functional ground.



Warning! Liquids:

Avoid spilling liquids into the rear ventilation holes on the Instrument, or into the monitor. Fluid spillage onto internal components creates a potential shock hazard. In the event of accidental liquid spillage, disconnect the power cord from the power source and take action to drain the liquid and allow the system to dry out and then conduct a system check for damage.

1.10 - Precautions

The following precautions are provided to help avoid damage to the instrument:



Caution-Service

The BlocDoc imaging system should be serviced by Diagnostic Instruments, Inc. authorized service personnel. Only qualified technical personnel should perform troubleshooting and service procedures on internal components.



Caution-Environmental Conditions

Do not expose the instrument to extreme temperatures during storage. For proper operation, ambient temperatures should remain between $0 - 40C$ ($32-104F$). Performance and reliability may be adversely affected if temperatures fluctuate above or below this range.



Caution-Cleaning

- It is recommended to use canned air, soft brush, or microscope cleaning hand pump to blow excess wax off the system before cleaning
- The computer monitor screen should only be cleaned with a cloth moistened with dish detergent.
 - Do **NOT** soak or overly wet these components as water infiltration may result.
 - Do **NOT** use harsh disinfectants or solvents on these components as this could cause hazing of the optical transmission surface.
- Mirror cleaning- Lens tissue saturated with Reagent-Grade Isopropyl Alcohol or Reagent-Grade Acetone is slowly dragged across the surface (recommended by Manufacturer).
- Working surfaces and structural components can be cleaned with standard lab disinfectants.

- Do not spray, pour or allow water or other cleaning solutions to be introduced into the cooling vents on the rear of the system.
- Washable Keyboard and Mouse can be washed in a dishwasher or sink using standard dish detergent and allowed to air dry overnight.

1.11 - Warranty

This Warranty is Limited and applies only to new products, except for computer-based software which is covered under a separate Warranty policy, manufactured by Diagnostic Instruments, Inc.. Diagnostic Instruments, Inc. makes no warranty whatsoever regarding the condition of used products unless a separate warranty or service contract is issued to cover the equipment.

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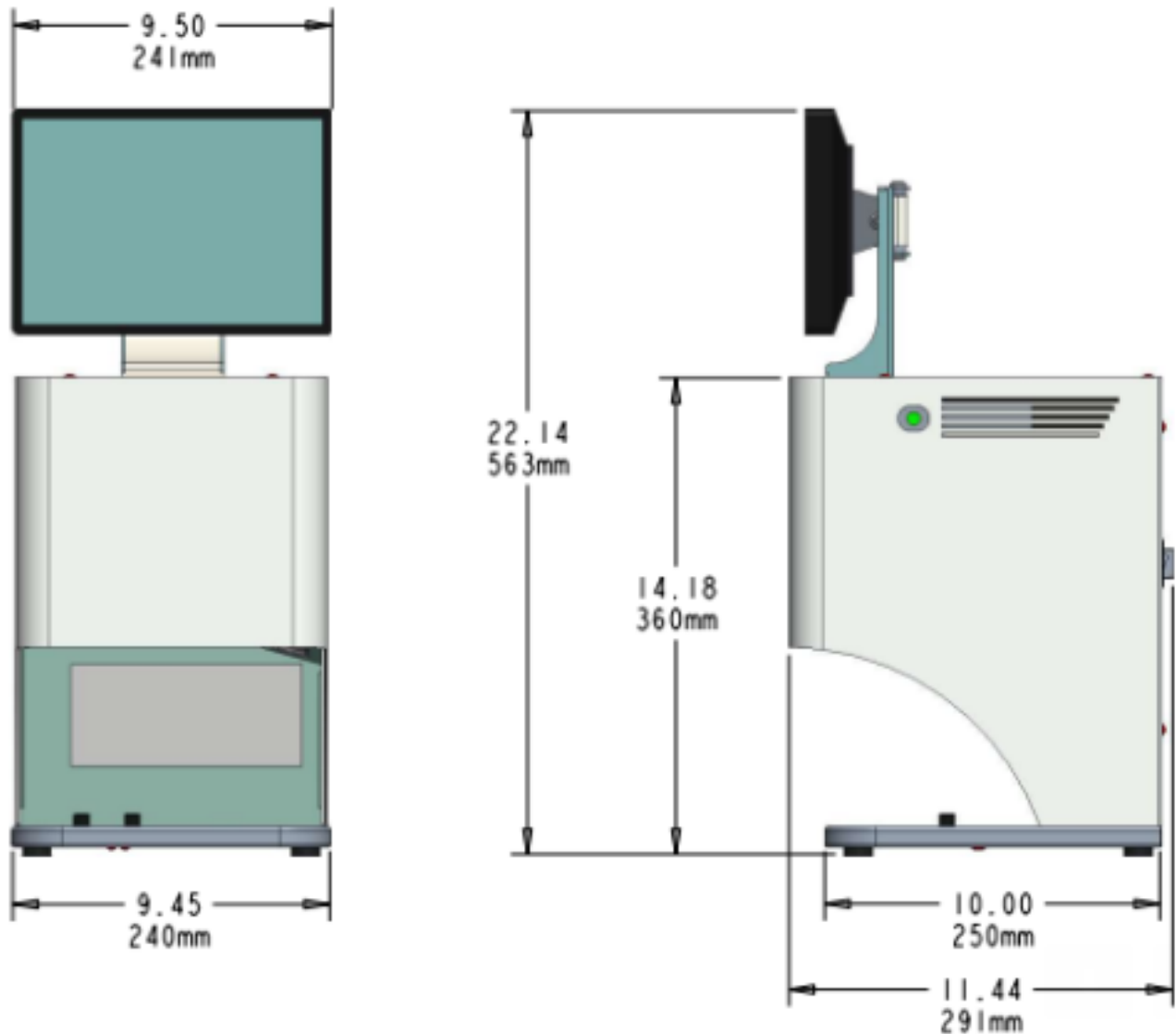
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2.00 - BlocDoc System Overview

This section provides background on the hardware and software network architecture, configuration and setup. We will go into detail about the BlocDoc system as well as the requirements for customer.

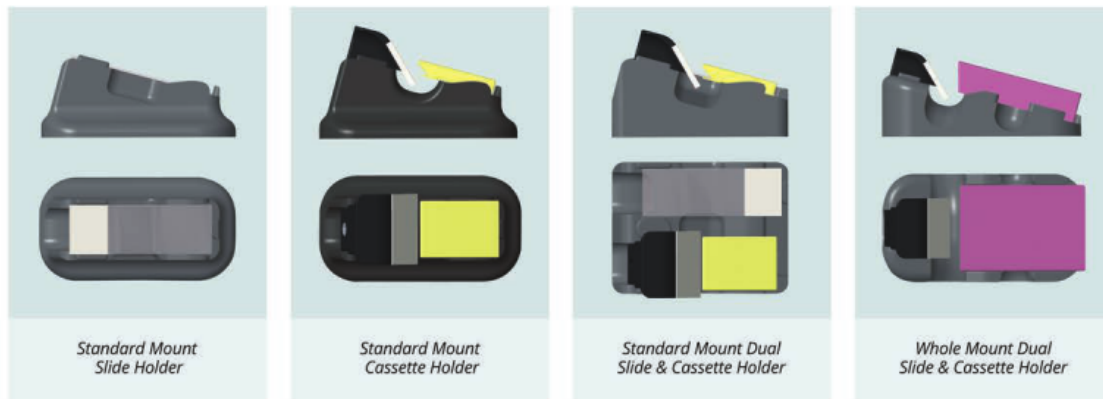


BlocDoc Specifications

BlocDoc Specifications		
Specification	Metric	SAE
Computer OS	Win 10 Pro	Win 10 Pro
USB 3.0 Ports	1	1
LAN Port	1	1
Keyboard and Mouse	Standard Wireless	Standard Wireless
Hand Held Barcode Reader	Optional	Optional
Display		
Touch screen	Standard	Standard
Size Diagonal	256.5 mm	10.1"
Resolution	1920 x 1080	1920 x 1080
Power / Environment		
Input	100-240VAC 2.5A 50/60Hz	
Fuse	5A 100-240VAC 5x20mm SloBlo	
Operating Temperature	0-40 C / 32-104 F	
Cautions	For Indoor use ONLY. For use with Diagnostic Instruments, Inc. BlocDoc Software.	
Certifications	CE, FCC Class A, RoHS	
Instrument Size		
Height	21.93"	557 mm
Width	9.50"	241 mm
Depth	10.94"	277 mm
Weight		
Instrument	35 lbs	15.8757 kg
Shipping	45 lbs	20.4117 kg
Sample Holders		
Standard Mt. Slide	For Std Slide Only Documentation	
Standard Mt. Cassette	For Std Cassette Only Documentation	
Standard Mt. Dual-Cassette & Slide	For Serial Std Slide & Cassette Documentation	
Whole Mt. Dual-Cassette & Slide	For All Whole Mount Sample Documentation	
Additional Cassette Barcode Mirrors	Spares for Quick 2 sec Swap When Dirty	

SPOT Sample Holder Units

Sample holders designed to hold standard and whole mount cassettes and slides.



2.01 - Intended Use

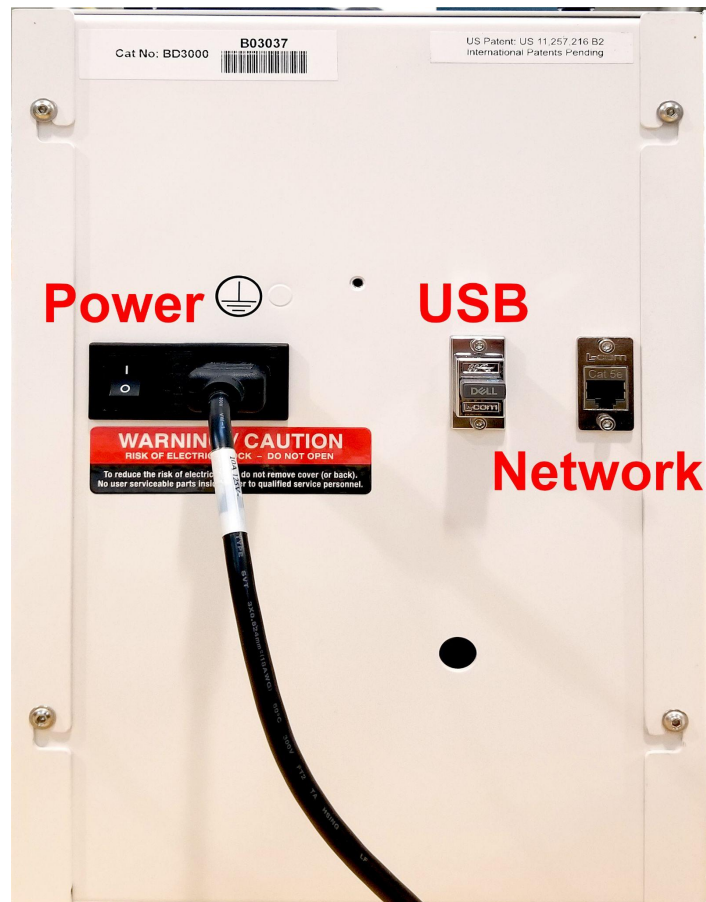
The BlocDoc system is designed for pathology labs to digitally document paraffin block tissue samples. It provides users the ability to clearly analyze wax-encased tissue samples with an extremely time efficient process. This information can be imaged and stored for further analysis by colleagues at a later time.

2.02 - Lifting & Carrying

The BlocDoc system weighs 32 lbs and can be lifted by one person with one hand firmly supporting the base and the other hand on the steel lip under the front body plate, under the camera ledge, stabilizing the device. The BlocDoc should only be lifted by the solid metal body or base plates, and never by the camera glass, plastic pieces, top screen or any exposed wires.

2.03 - Installation

The BlocDoc system should be placed on a flat surface which will preferably be its permanent home. A power supply cable is provided by the manufacturer which should be connected to the rear of the device. Connect a network cable to the input on the rear right edge of the device. The USB port can be used to connect a wireless receiver for a keyboard and mouse, or can be fitted with a USB hub if more USB ports are needed.



2.04 - LIS System Integration

System is designed to connect to customer LAN or WAN - Customer IT will be responsible to help set up the connection. Current implementation requires the user to maintain a sweep directory to which the system will save images. The LIS must sweep this directory for files on a regular basis. BlocDoc will save file names as the sample barcode plus the date.

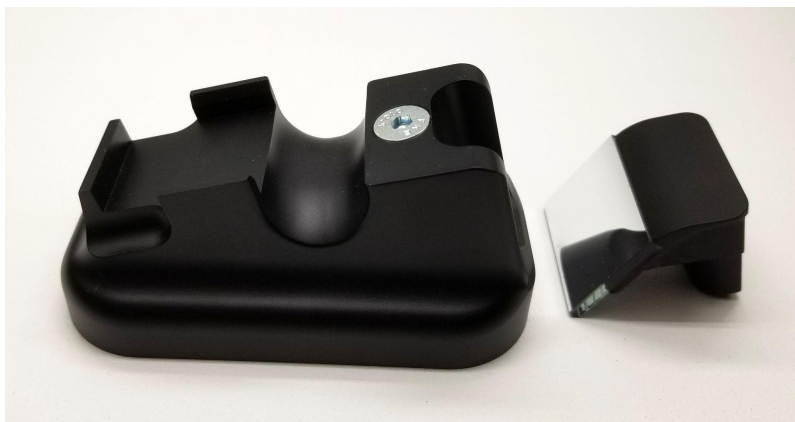
2.05 - Equipment Operation

Before the system can be used, the power supply cable must be plugged into the rear of the machine and the master power switch must be switched on. The master power switch is shown circled below and switched to the “on” position. The vertical line or “I” is the “on” position and the circle or “O” is the “off” position.



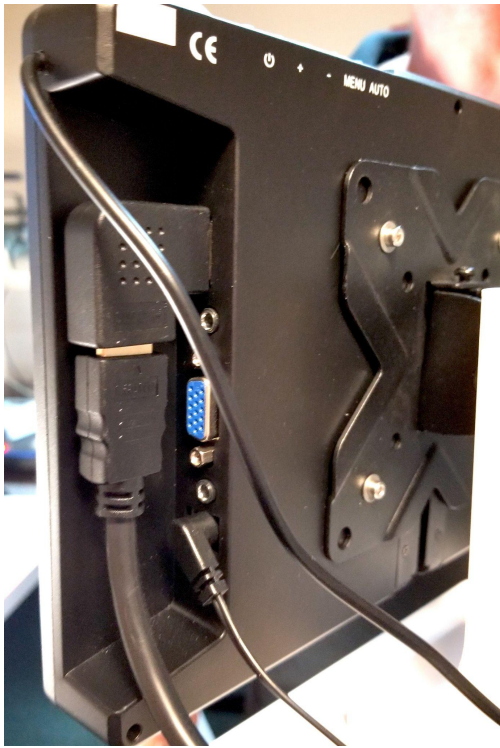
The system is activated by pressing the button found in the hole on the top right side of the device near the top.





The sample holders have a magnetic mirror attachment that must be attached. When mounting the mirror it is ideal to slide it to the rear as much as possible. The correct orientation is shown below with a green arrow. The incorrect orientation is shown with a red arrow.





This image shows the video and power cables connected to the BlocDoc monitor. The cable running from the top of the monitor is a USB cable that facilitates the touch screen interface for the BlocDoc system.

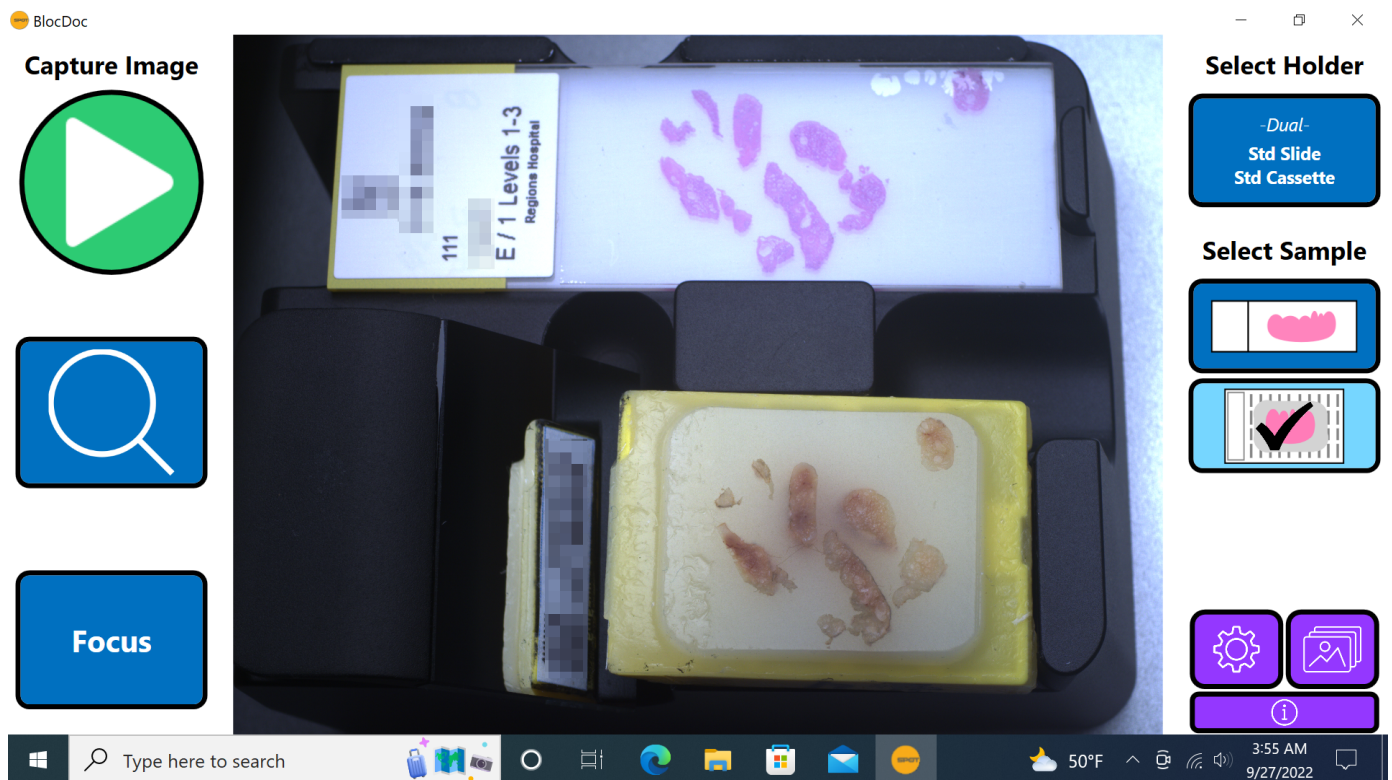
3.00 - Software Operation

This chapter will explain the use of the BlocDoc software.

3.01 - Live Screen

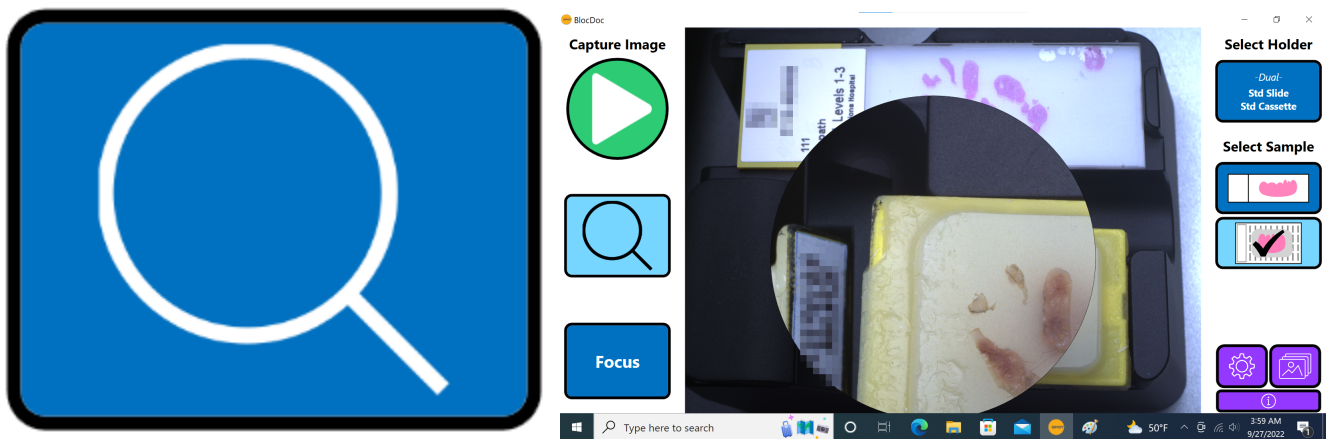
Once an operator has cut the top surface of the block and made a cassette and/or slide she will move the products to the BlocDoc system to set up and capture an image.

This is the screen that will appear when the BlocDoc software is opened, a standby mode awaiting a sample. A dual standard holder is shown below with both a cassette and a slide cut from the block.





Capture Image - The Capture Image button, shown above, will use the predefined settings to produce a digital image of the specimen in the viewing field and read the barcode.

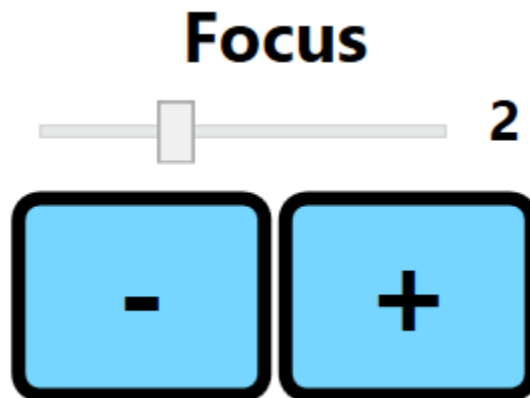


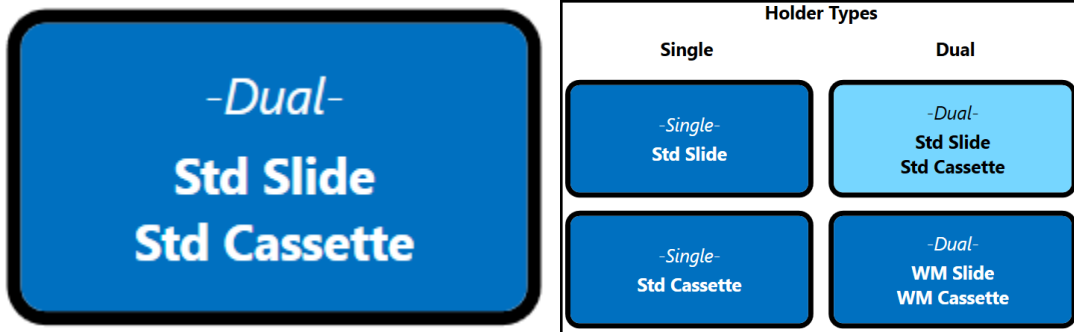
Magnifying Glass - Magnifying Glass button, shown above and to the left, will turn the cursor into a circle of magnified image while it is over the viewing field, as shown above and to the right. The button must be clicked again to toggle the feature off.



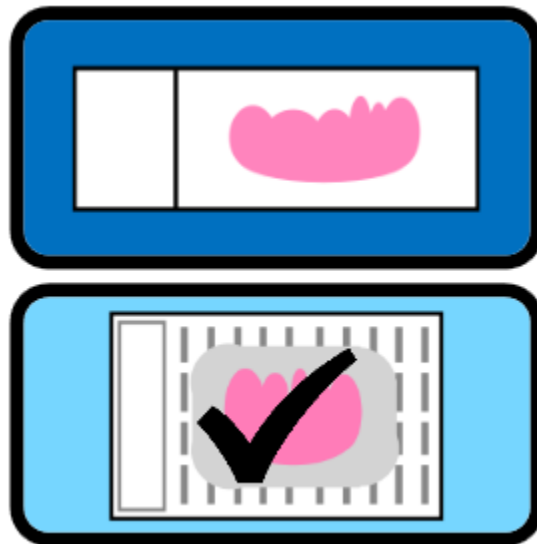
Focus - The Focus button causes the system to automatically refocus the camera.

NOTE: The Spot development team highly recommends the user have Autofocus engaged when imaging with the BlocDoc system. Users that need manual focus will see the below display instead of the above shown autofocus button when the appropriate settings are selected.





Select Holder - This button opens a pop-up menu that allows the user to select the type of slide holder or cassette holder that is being used to hold the specimen. Options include a single standard slide holder, a single standard cassette holder, a dual standard slide and cassette holder or a dual wide mount slide and cassette holder.



Sample Select - This prompts the user to define whether a slide or cassette is being imaged. The top button selects a slide and the bottom button selects cassette. A check mark appears over the selected mode.



Settings - Opens the BlocDoc system setting. These will be explored in further detail below.



Browse BlocDoc Images - Allows the user to open image files from the system hard drive or connected network. This should always point to the sweep directory that the LIS can take files from. Images are saved as a paged tiff file, third party image viewers must support paged tiff files if they are being used to view images produced by the BlocDoc system.

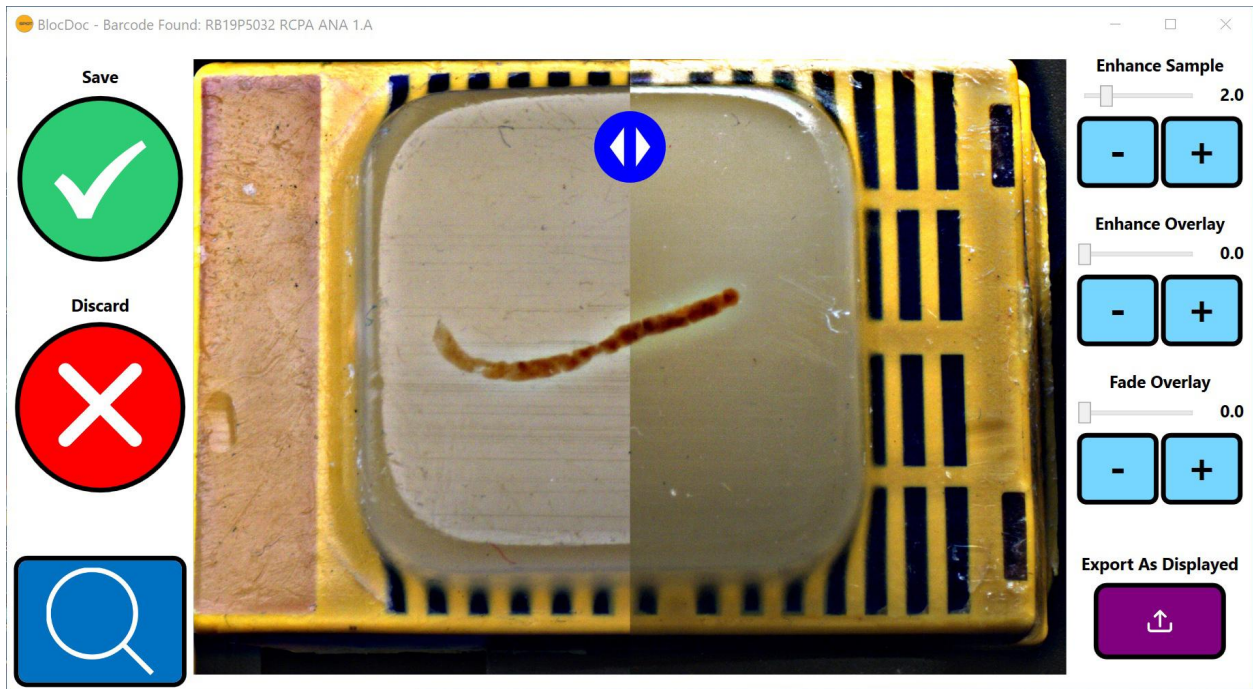


Information - This button opens the system information panel, showing the hardware revision and software version among other info.

3.02 - Capture Screen

Once a Cyto Tech has cut the top surface of the block and made a cassette and/or slide she will move the products to the BlocDoc system to set up and capture an image.

This is the screen that will appear after an image is captured. The left side shows the reflected light (surface) image and the right shows the polarized light (subsurface) image.



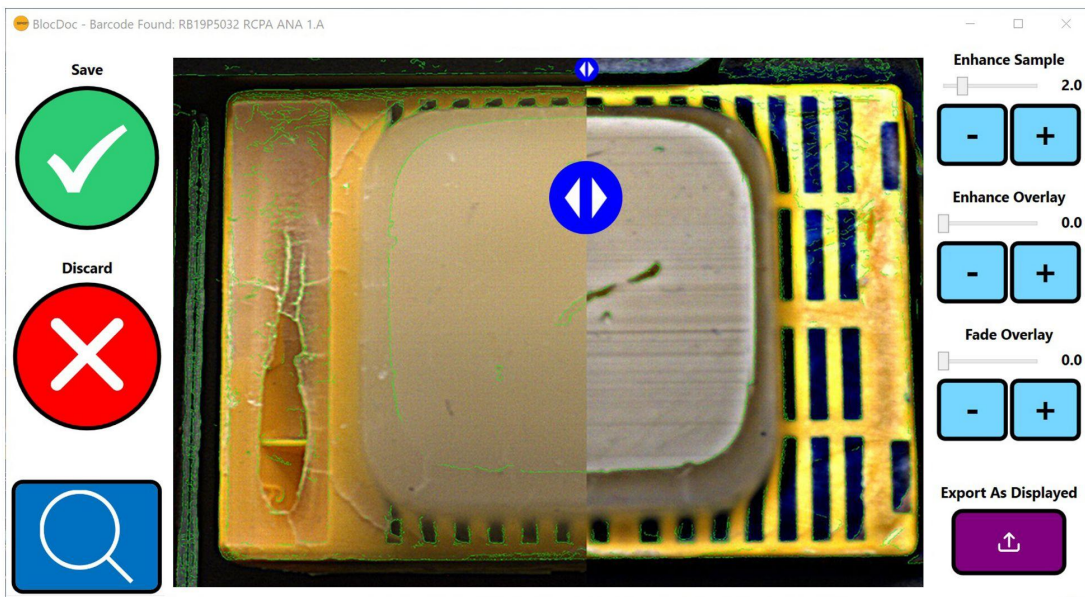
Enhance Sample - Adjusts the contrast of the whole image. Below is an example of the enhance sample setting dialed up to 3.5 (out of 10).



Enhance Overlay - Adjusts the sensitivity of the specimen detection outlines.

Fade Overlay - Adjusts the transparency of the tissue outlines.

The below image shows the settings adjusted to maximum tissue detection sensitivity and the most intense tissue outlines.





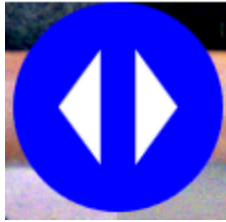
Save - Approves of the current image and saves them to the predefined file path on the network. These buttons will only appear if the user is hand approving each image capture instead of auto approving image captures.



Discard - Clicking this button deletes the current capture and reactivates the live view. These buttons will only appear if the user is hand approving each image capture instead of auto approving image captures.



Export as Displayed - Opens the save file dialog box. This image will be saved exactly as displayed on screen.

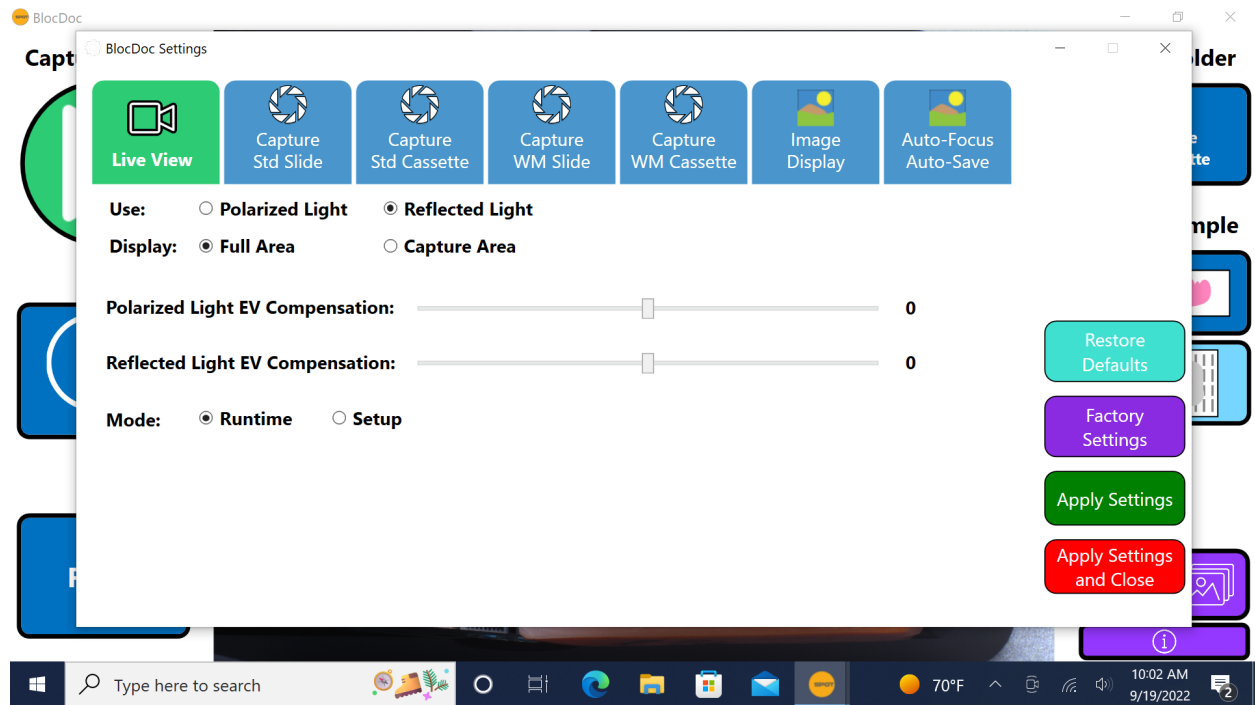


Split Image Controller - Slides left and right, showing polarized light on one side and reflected light on the other.

3.03 - Settings

The BlocDoc system has a host of options to precisely customize the user's experience.

Live View - Customize the live (pre-capture) viewing window.



Use - Allows the user to choose whether the light used in the live view is reflected or polarized. Polarized light is typically better for wax block cassettes while reflected light is typically used for slides.

Display - Allows the user to select how wide an angle is shown in the live view. Full area shows the whole tray and is more useful when setting up the holder, while capture will show only what will appear in the captured image.

Polarized Light EV Compensation - Allows the user to adjust the brightness of the image when using polarized light.

Reflected Light EV Compensation - Allows the user to adjust the brightness of the image when using reflected light.

Mode - Setup mode allows the user to adjust the scanning fields of the BlocDoc system. More information on using setup mode can be found below. Runtime mode is the operational standard for everyday workflow, using default or customized camera and lighting settings.

NOTE: Since the main window is used for both runtime and setup modes, make certain that you see the appropriate runtime icons before conducting workflow, you may need to change settings if something looks out of the ordinary.

Setup Mode - In setup mode three buttons can be found on the left side of the screen. With “Capture-Focus Area” selected, a green box will appear over the live image view showing the target area for image capture. This box can be moved or stretched to fit the user’s needs.



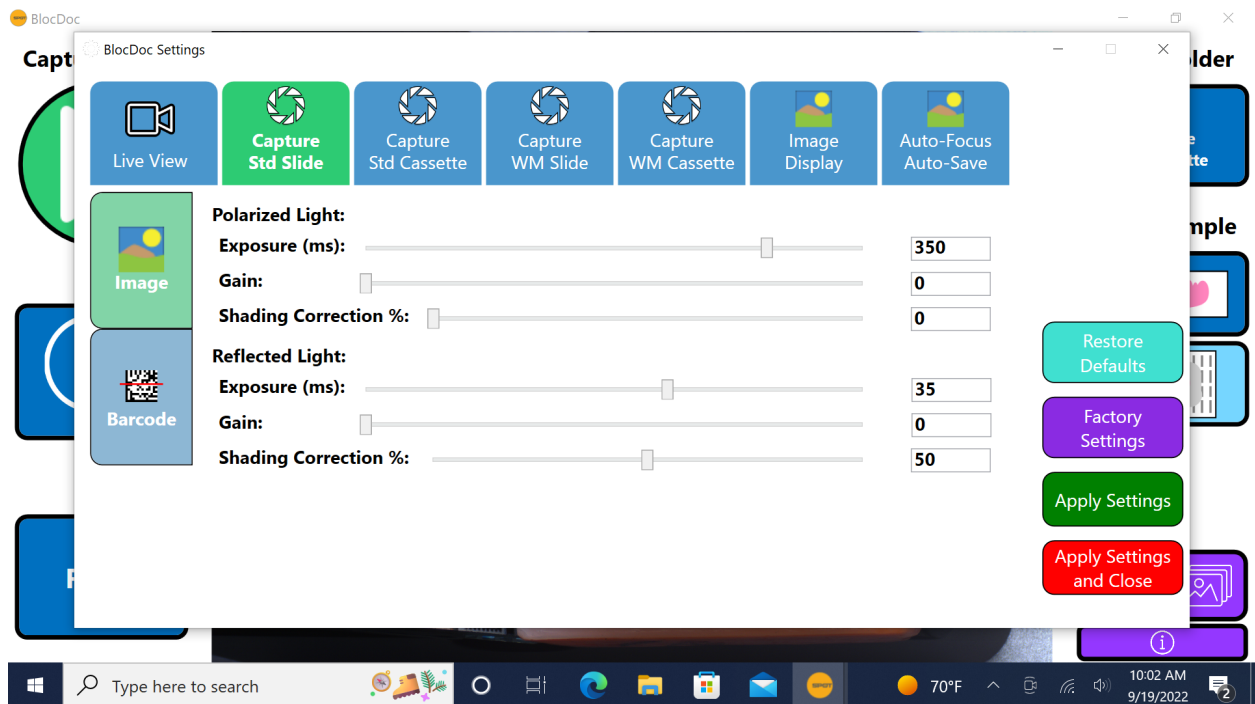
When the “Barcode Area” button is selected a similar blue box will appear to allow the user to select or adjust the area that will be scanned for barcode information. Likewise, this box can be moved or adjusted in size. If manual focus is being used, the barcode in a cassette must be focused 2 steps below the surface of the wax.



Selecting the third button, “Lens Focus” will give you a short dialogue explaining the setup for focus calibration. Follow these instructions and click continue. In some cases, when calibrating focus on a standard slide it may be useful to turn the slide 180 degrees as shown in the images above or to place a piece of paper with writing on the slide. The Cassette should be placed ***without a lid and without any wax*** (empty) so that the back surface can be used to calibrate focus.

These adjustments must be made for each sample and holder type. Selecting sample and holder types can be done normally using the buttons on the right side of the screen.

Capture Settings - Customize the image processing individually for each slide and cassette type with separate settings for both polarized and reflected light in each case.



Exposure - Allows the user to determine the shutter speed of the camera, this is measured in milliseconds.

Gain - Allows the user to set the degree to which the image is digitally amplified. As low a setting as possible while still capturing a valuable image is suggested.

Shading Correction % - This setting corrects for uneven lighting on the specimen. Reflected light is corrected at a 45 degree angle from the back left corner to the front right as the specimen as it lies in any standard holder. Polarized light is corrected at a 90 degree angle to the slide, from back to front.

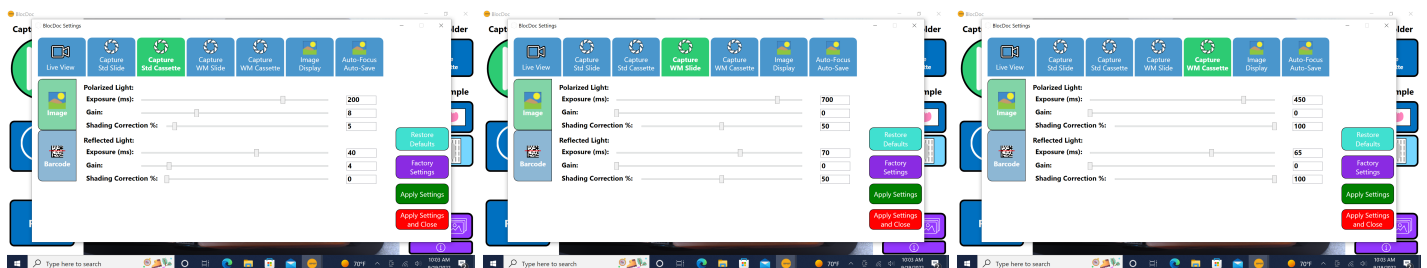
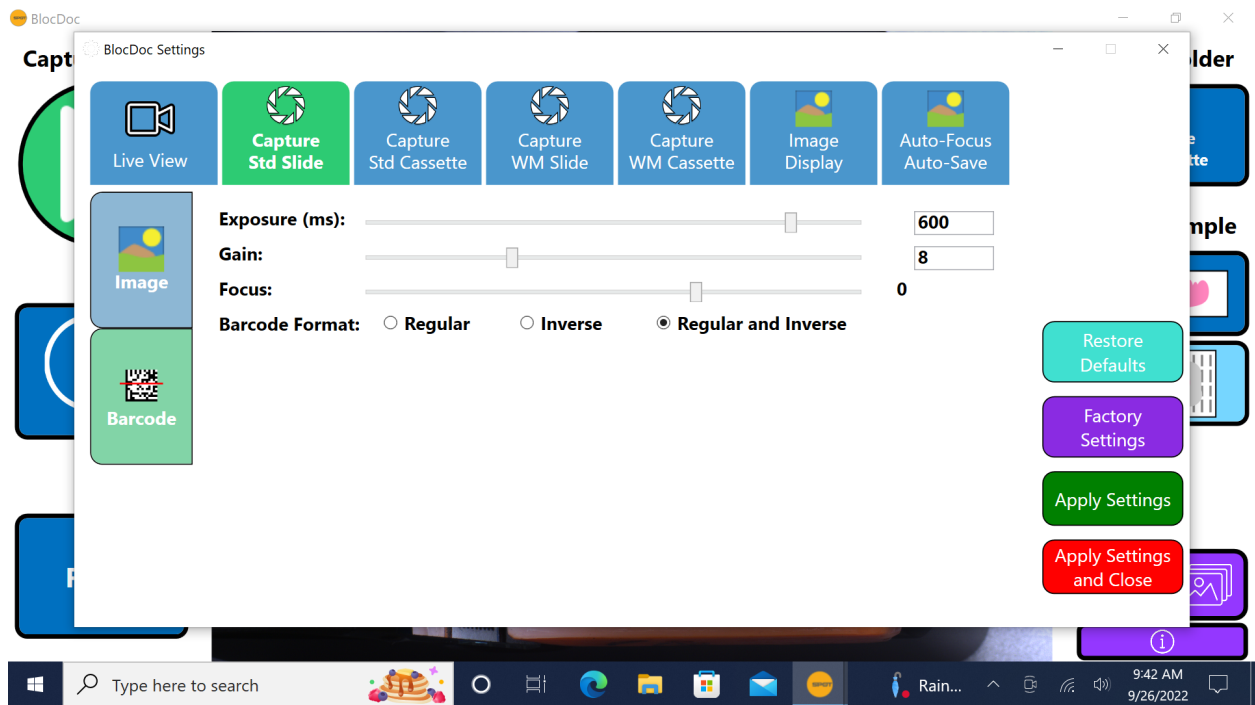


Image and Barcode Tab - These tabs allow the user to switch between the settings for imaging slides and cassettes or their barcodes IDs.



Exposure - Allows the user to determine the shutter speed of the camera, this is measured in milliseconds.

Gain - Allows the user to set the degree to which the image is digitally amplified. As low a setting as possible while still capturing a valuable image is suggested.

Focus - Allows the user to make fine adjustments to the focus of the barcode reader.

Barcode Format - Tells the system how barcodes will be oriented. If all of the barcodes are oriented the same way either regular or inverse should be selected, otherwise select both.

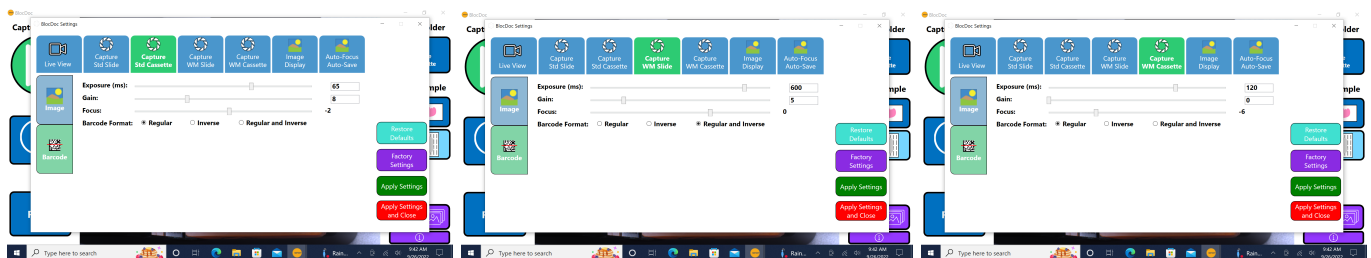


Image Display - Adjust the white balance and customize other functions of the system.

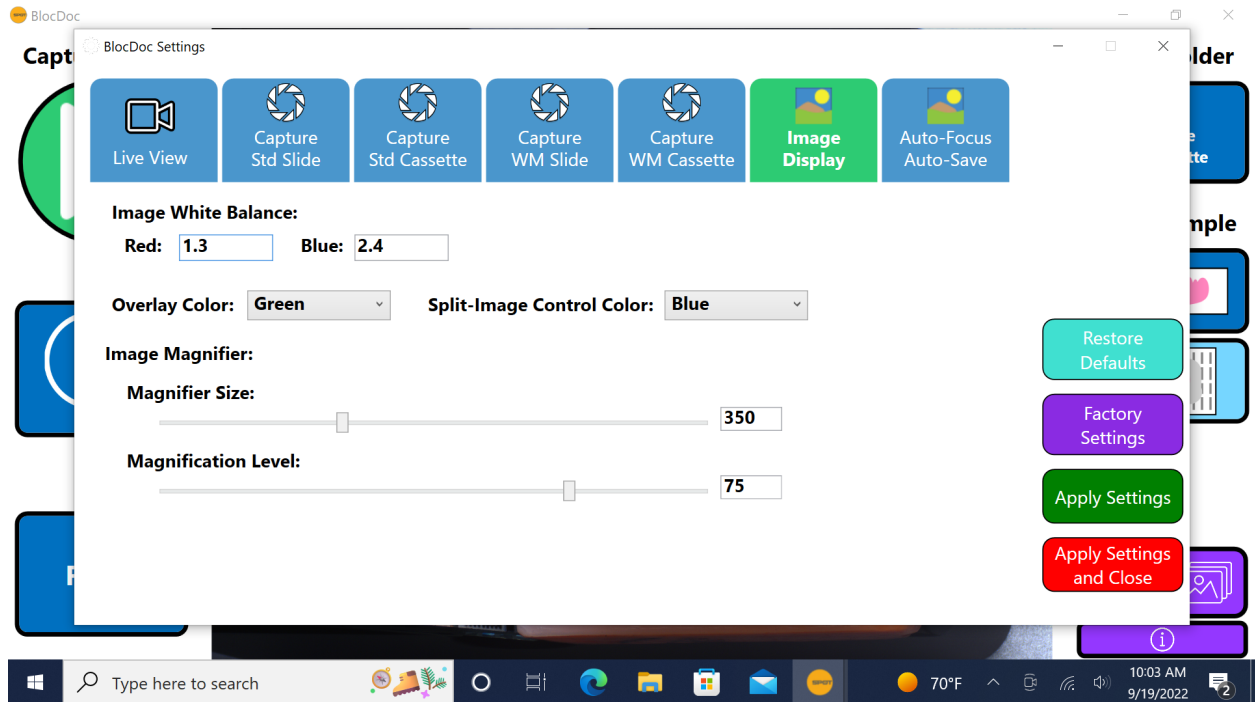


Image White Balance - Allows the user to correct the image color for the temperature of the light. The value found in each dialogue box is a multiplier by which the color channel is amplified. Factory default settings are Red at 1.3x and Blue at 2.4x as shown in the image above.

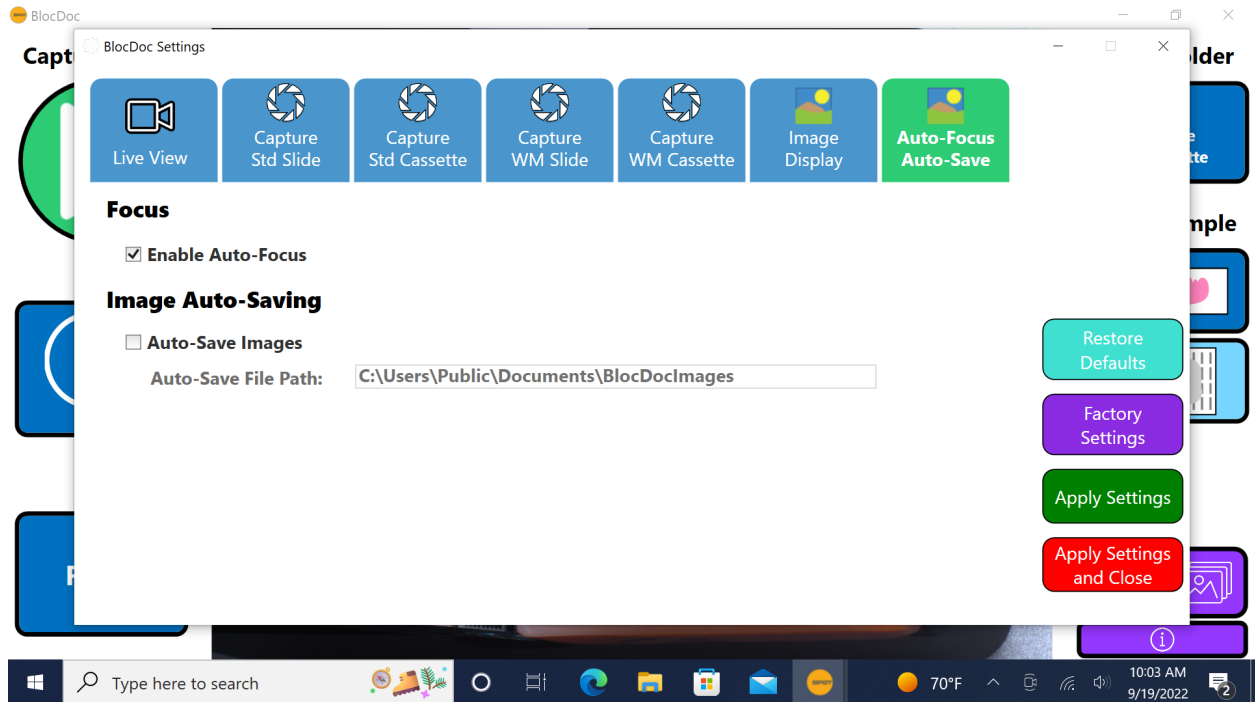
Overlay Color - Allows the user to determine color of the overlay box.

Split Image Control Color - Allows the user to customize the color of the split image control.

Magnifier Size - Allows the user to determine the diameter of the magnifier tool.

Magnification Level - Allows the user to determine how much magnification is gained using the magnifier tool.

Auto-Focus Auto-Save - Adjust the automated functions of the BlocDoc system.



Enable Auto-Focus - Allows the user to toggle whether or not the camera will automatically focus on specimens. It is highly recommended that Auto-Focus is used for all imaging.

Auto-Save Images - Allows the user to toggle automatic image saving. This setting allows the user to bypass the image approval stage of workflow if he/she is confident in the images being produced by the system.

Auto-Save File Path - Allows the user to choose where auto-saves are stored. This should point to the user's LIS if such a database exists.

Restore Defaults

Restore Defaults - Reverts settings to their default settings. This functions on a page by page basis.

Factory Settings

Factory Settings - Usually Locked. Opens a menu of proprietary hardware settings.

Apply Settings

Apply Settings - Activates the settings for use by the system.

Apply Settings and Close

Apply Settings and Close - Activates the settings and closes the settings menu.

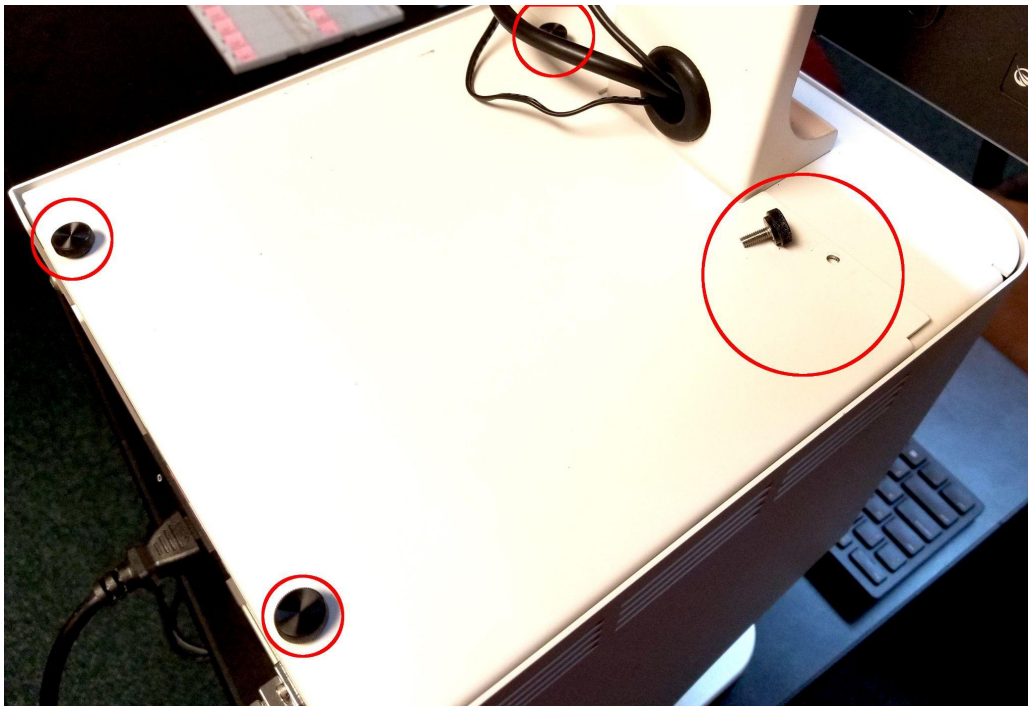
3.04 - Frequently Asked Questions

This section is dedicated to answering common user questions or concerns about the BlocDoc system.

Q: Why are my usual buttons not showing on the live screen?

A: *The system may be set to 'Setup' mode, this can be changed in settings under the 'Live View' menu at the 'Mode' heading.*

4.00 - Service and Maintenance



The BlocDoc system computer can be accessed by opening the top plate which is secured using thumb screws. Below the system computer is shown tucked into the top of the BlocDoc.



