










INSTRUCTIONS FOR USE
ALICAM™
Reader
English

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Symbol	Meaning	Symbol	Meaning
	Manufacturer's Catalog Designation or Number		Warning: Dangerous Voltage
	Use Caution		Special Disposal for Electronic Waste Required
	Instructions Are Included and Must Be Followed		Manufacturer
	Lot Number		

1. Warnings and Safety Precautions

The ALICAM™ Reader has been constructed in accordance with US (FDA) and international (European MDD) regulations and standards for operation of electrical equipment, electromagnetic compatibility, and stipulated safety requirements.

To prevent accidental damage to the equipment, and to ensure safe, trouble-free operation, please read these operating instructions carefully before using the system. Keep these instructions in a safe place. Follow the instructions below to ensure safe and trouble-free operation of your system.

To avoid risk of electric shock, this equipment must only be connected to grounded electrical outlets.

Do not modify this equipment without authorization of the manufacturer.

After its useful life or after sustaining unrepairable damage, the ALICAM™ Reader and its power supply should be disposed of in an environmentally sound

manner. Please consult and obey national, state, and local laws and ordinances governing the safe disposal of electronic equipment.



CAUTION! Do not open AC adapter. Risk of electric shock.

Keep liquids out of the system interior. Do not submerge or autoclave.

Clean exterior surfaces with a cloth and swab moistened with disinfectant.

Insert the capsule into the system with the battery end of the capsule facing upward. The download operation will fail with an incorrectly oriented capsule.

Clean, disinfect and completely dry the capsule prior to inserting it into the system.

Use only the medical grade power supply, supplied. A medical grade power supply is required for use in devices intended for medical applications.

This unit only complies to regulatory standards if used with the supplied medical grade power cord.

Before unplugging the ALICAM™ Reader, make sure the unit is powered OFF.

Power cord is used as a disconnection device. To de-energize equipment, disconnect the power cord.

Per manufacturer's declaration all USB ports are for exclusive connection to IEC 60601-1 certified equipment when it is placed within a patient environment.

2. General

2.1 Device Description

The ALICAM™ Reader enables trained medical personnel to extract *in-vivo* data from the ALICAM™ capsule after retrieval. The system transfers the data to a computer running the ALICAM™ Software.

The system is not intended for use by patients or on patients and is not intended to interact with any part of the body or any type of body tissue.

2.2 Indications for Use

This ALICAM™ Reader is intended for accessing data from the ALICAM™ capsule. The system may be used in hospitals, veterinary clinics, and veterinarian offices.

2.3 Contraindications

The ALICAM™ Reader has no known contraindications.

2.4 Intended User Profile

The ALICAM™ Reader is intended for use by trained medical personnel.

2.5 Adverse Events

The ALICAM™ Reader has no adverse events.

2.6 Warranty

Limited Warranty. Ininiti Medical warrants solely that this product is free from defects in materials and workmanship for a limited period of time. Ininiti Medical shall, at no charge, replace any product that fails due to a defect in material or workmanship that is discovered and reported to Ininiti Medical by the user for one year after the date of receipt by the user. All product returns for product replacement under this warranty must have prior authorization from Ininiti Medical. If you believe that you have received a defective product, please contact your Ininiti Medical representative for information. If your representative determines that the product is defective and such defect is covered under this warranty, your representative will make arrangements to replace the product under this

warranty at no charge. The replacement product shall have the same limited warranty as the original product. Ininiti Medical makes no warranty or representation concerning the suitability of the product for any procedure. The veterinarian who has selected the product for use shall be solely responsible for determining the suitability of the product for any procedure. THERE ARE NO REPRESENTATIONS OR WARRANTIES OTHER THAN THE REPRESENTATIONS AND WARRANTIES IN THIS SECTION APPLICABLE TO THE PRODUCT, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL ININITI MEDICAL OR ITS SUPPLIERS BE LIABLE FOR ANY CONSEQUENTIAL, INDIRECT, EXEMPLARY, SPECIAL, OR INCIDENTAL DAMAGES (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF BUSINESS PROFITS, BUSINESS INTERRUPTION, OR ANY OTHER PECUNIARY LOSS) ARISING FROM OR RELATING TO THE PRODUCT, EVEN IF ININITI MEDICAL OR ITS SUPPLIERS HAVE BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. THE

PROVISIONS CONTAINED IN THIS PARAGRAPH LIMITING WARRANTIES AND LIMITING INFINITI MEDICAL'S AND ITS SUPPLIERS' LIABILITY SHALL APPLY TO THE FULL EXTENT PERMITTED BY LAW AND REGARDLESS OF FAULT.

2.7 Related Documents

ALICAM™ Software Instructions for Use (IFU)
ALICAM™ Instructions for Use (IFU)

3. Principle of Operation

3.1 ALICAM™ Reader

The ALICAM™ Reader provides power inductively to the capsule. It can be used either with capsules that have depleted batteries or ones with still-active batteries and flashing LEDs. The magnet on the lid of the system opens the switch inside the capsule, disconnecting the batteries from the inductive power.

The system and capsule communicate via a bidirectional optical link, and the capsule transfers the clinical data to the system.

4. Getting Started

4.1 Unpacking and Inspection

Upon receipt of the system, carefully remove the contents from the box and check for visible damage to components. If you see damage, contact your local Infiti Medical representative. Save the shipping box and packaging until you have successfully installed and verified correct operation of the system. The original packaging provides the best protection for return shipment, if necessary.

4.2 Equipment supplied

The equipment supplied includes the components listed below:

1. ALICAM™ Reader
2. AC adapter
3. Power cable
4. USB cable
5. Instructions for Use

5. Installation

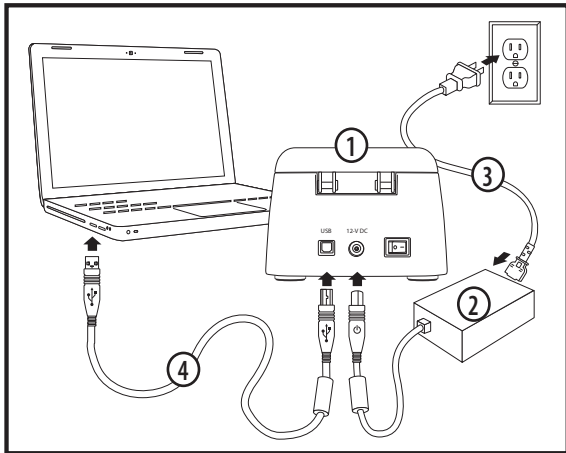
Connect the power cable (3) to the supplied AC adapter (2).

Connect the AC adapter (2) to the 12V DC input of the ALICAM™ Reader (1).

Connect the power cable (3) to an outlet rated for a voltage between 110 and 240V AC.

Attach the USB cable (4) to the USB input of the ALICAM™ Reader (1).

Connect the other end of the USB cable (1) to the computer with the ALICAM™ Software and the required USB driver installed.

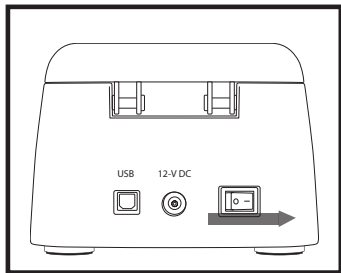


6. Operation

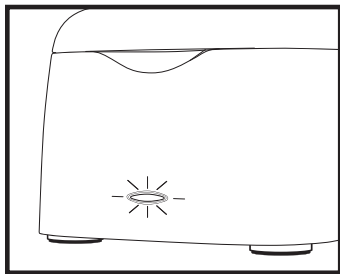
Verify that the capsule has been cleaned and disinfected and is completely dry.

Inspect the inside of the ALICAM™ Reader receptacle and remove any obstructions.

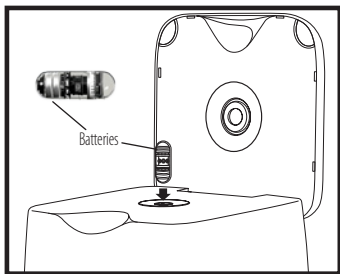
Turn ON the system power switch.



The light on the front of the system should illuminate.



Place the capsule into the system receptacle battery-end up and close the lid of the system.



Start the ALICAM™ Software. Refer to the ALICAM™ Software Instructions for Use.

To begin the download process, click Download on the ALICAM menu bar.

A window should appear where procedure-specific information must be entered before beginning the download. Click Next after the information has been entered.

Review the information in the window and click Yes to begin the download of data from the capsule.

After all capsule downloads are completed, the system may be turned OFF.

7. ALICAM™ Reader Indicator Lights

Light	Status
Solid Yellow	Unit is idle and lid is open
Solid Green	Ready for download or download is complete
Flashing Green	Data transfer in progress
Flashing Yellow	Error status
No light	Power is off

8. Troubleshooting

In case of any issues with the system, refer to this guide for possible solutions. If the problem persists, contact Infiti Medical or your local distributor of Infiti Medical devices.

Symptom	Possible Solutions
ALICAM menu item "Download → Download Images" is not enabled (it is in gray font and not black)	<ol style="list-style-type: none">1. Verify that the USB cable is connected between the system and the computer that the system power is ON and that system indicator light is illuminated.2. Verify that the computer has been configured for downloading capsule data and confirm that the system USB driver is installed.3. Turn system OFF, wait a few seconds, and turn it back ON.4. Disconnect and reattach the USB cable.5. Close and restart the ALICAM™ Software application.6. Reboot the computer.
After selecting "Download Images" a system data transfer error message appears	<ol style="list-style-type: none">1. Turn the system OFF, wait a few seconds, and turn it back ON to reset the USB connection. Try downloading again.2. Try docking a known, good capsule, such as a capsule with data previously downloaded. If the error message reappears, repeat step 2. If the error reappears again, the system may be malfunctioning. On the other hand, if this known-good capsule docks successfully (the Procedure Information window appears), the original capsule may be damaged or malfunctioning. In this case, click "Cancel" in the Procedure Information window.
After selecting "Download Images" an error message appears indicating that no capsule is detected	<ol style="list-style-type: none">1. Verify that the capsule is in the receptacle and in the correct orientation with the battery-end facing upwards.2. Ensure that the capsule dimple and system receptacle are clean.3. Rotate the capsule approximately 180° and retry.
The ALICAM™ Reader indicator light is not illuminated	<ol style="list-style-type: none">1. Verify that the power switch is turned to ON.2. Verify that the power cable is fully inserted into the outlet and that the cord is plugged into the power supply and that the light on the power supply is illuminated.3. Verify that the power supply is plugged into the system.

9. Care and Maintenance

The ALICAM™ Reader is typically used in an office environment with clean, disinfected, dry capsules. The system should be cleaned only as needed to maintain a good appearance. More extensive cleaning may be required if the system is accidentally soiled or contaminated. Follow the recommendations herein.

Cleaning: Disconnect the power and USB cables prior to cleaning. The system chassis contains electronics. Keep liquids from entering the chassis. Avoid submerging the system in liquid or sterilizing it in an autoclave. All exposed surfaces may be wiped with a swab or cloth moistened in isopropyl alcohol or other disinfectant. Clean the receptacle with a swab including the underside of the rubber gasket that comes in contact with the capsule.

General: Contact your local distributor or Ininiti Medical representative if capsule docking becomes unreliable.

10. Specifications and Ratings

Class I medical (Grounded) device

The ALICAM™ Reader is classified as NO APPLIED PARTS EQUIPMENT.

The ALICAM™ Reader shall be classified as ORDINARY EQUIPMENT, not intended or evaluated for use in the presence of flammable anesthetic mixture with air, oxygen, or nitrous oxide.

Protection against harmful ingress of water: INGRESS PROTECTION (IP21)

Environmental conditions for transport and storage

Temp.

Operating 10°C to 30°C

Storage / Transportation 10°C to 35°C

Humidity (non-condensing)

Operating 20% to 80%

Storage / Transportation 10% to 90%

Altitude

Operating 0 to 3000m

Storage / Transportation 0 to 12,000m

The ALICAM™ Reader is intended for general use in hospital environment for data collection for reference. It is not be used with life-support systems.

Electrical Ratings:

Adapter: HiTron Electronics Corp./HEMG24-S120200-7

Adapter Input Voltage: 100-240 V AC, 60/50 Hz,
0.46-0.25A

Adapter Output Voltage: 12V DC, 2A, max 24W

ALICAM™ Reader Input Voltage: 12V DC

ALICAM™ Reader Input Current: 2 A

Contact Information



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