CapsoVision

CapsoAccess®

INSTRUCTIONS FOR USE

CapsoAccess®

Capsule Data Access System

Catalog Number: CDAS3

CE

English

Table of Contents

Symbol	Meaning	Symbol	Meaning
REF	Manufacturer's Catalog Designation or Number		Warning: Dangerous Voltage
	Use Caution	EC REP	Contact/European Representative of Manufacturer
CE	Product Meets European Standards for Safety and Quality		Special Disposal for Electronic Waste Required
	Instructions Are Included and Must Be Followed		Manufacturer
LOT	Lot Number		Product Meets US and Canada Standards for Safety and Quality

1. Warnings and Safety Precautions

The CapsoAccess® Capsule Data Access System (CDAS3) has been constructed in accordance with US (FDA), Canada (CSA) 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 and follow these operating instructions carefully before using the system. Keep these instructions in a safe place.

Do not modify this equipment without authorization of the manufacturer.

Operators should always wear gloves when handling the capsules and system.

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

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

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

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

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

Use only the supplied medical grade power supply. 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 CapsoAccess® system, 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.

It should not be used with life-support systems.

2. General

2.1 Device Description

The CapsoAccess® Capsule Data Access System enables trained medical personnel to extract *in-vivo* data from the CapsoCam Plus® capsule. The system transfers the data to a computer running the CapsoView® 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 CapsoAccess® Capsule Data Access System is intended for accessing data from the CapsoCam Plus® capsule endoscopes. The

system may be used in hospitals, outpatient clinics, and physician offices.

2.3 Contraindications
The CapsoAccess® Capsule Data Access System has no known contraindications.

2.4 Intended User Profile
The CapsoAccess® Capsule Data Access System is intended for use by trained medical personnel.

2.5 Adverse Events
The CapsoAccess® Capsule Data Access System has no adverse events.

2.6 Warranty
CapsoVision warrants that the system is free from defects in both materials and workmanship. Suitability for use of the system for any procedure shall be determined by the user. CapsoVision shall not be liable for incidental or consequential damages of any kind. The above warranties are in lieu of all other warranties either expressed or implied including any warranty of any merchantability or fitness for use.

2.7 Related Documents
CapsoView® Software Instructions for Use (IFU)

CapsoCam Plus® Instructions for Use (IFU)

3. Principle of Operation

3.1 CapsoAccess® Capsule Data Access System
The CapsoAccess® Capsule Data Access System 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 CapsoVision 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. CapsoAccess® Capsule Data Access System
2. AC adapter
3. Power cable
4. USB cable
5. Instructions for Use

5. Installation

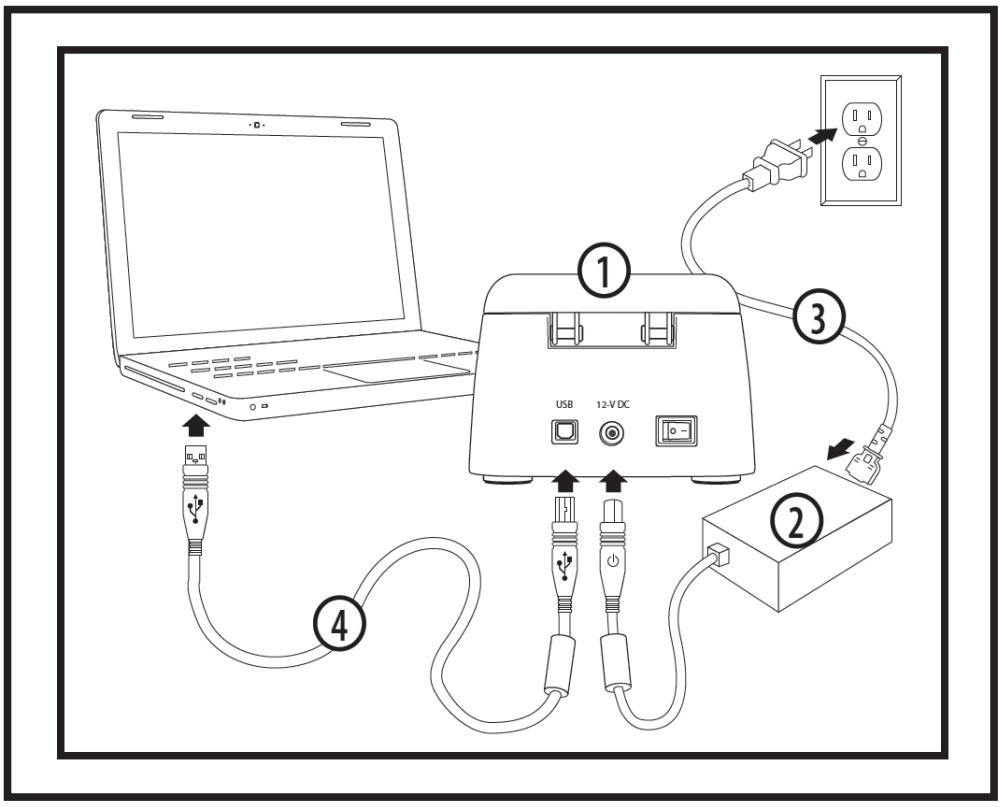
Connect the power cable (3) to the supplied AC adapter (2).

Connect the AC adapter (2) to the 12V DC input of the CapsoAccess® Capsule Data Access System (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 CapsoAccess® Capsule Data Access System (1).

Connect the other end of the USB cable (4) to the computer with the CapsoView® software and the required USB driver installed.

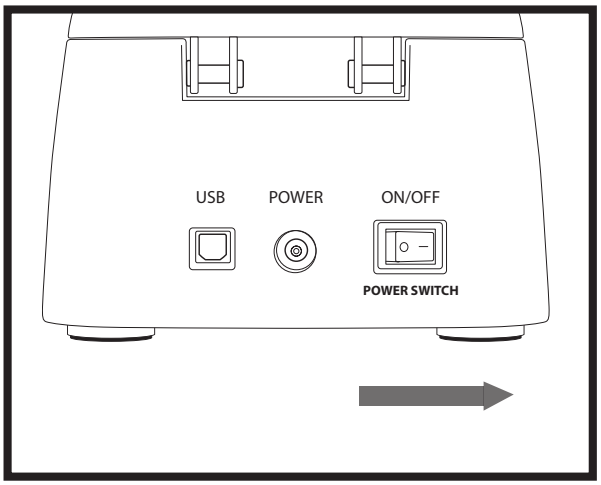


6. Operation

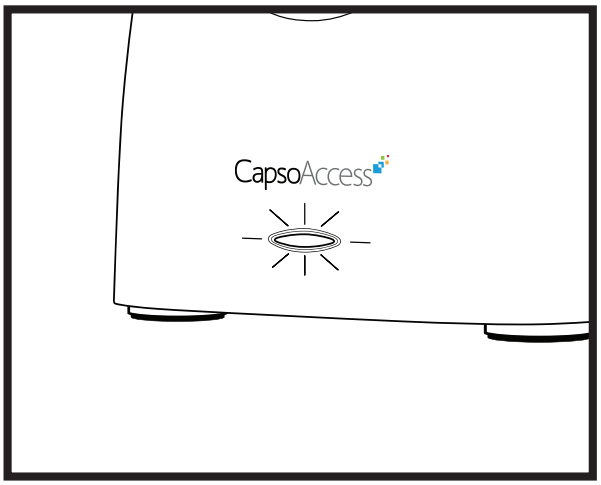
Verify that the capsule has been cleaned and disinfected and is completely dry.

Inspect the inside of the CapsoAccess® Capsule Data Access System receptacle and remove any obstructions.

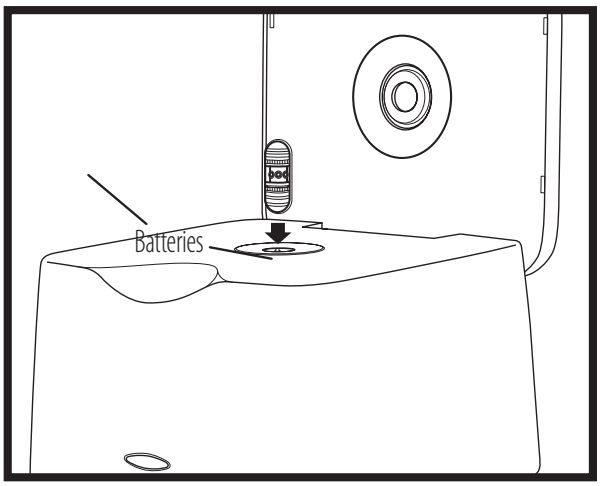
Turn ON the system power switch.



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. The download operation will fail with an incorrectly oriented capsule.



Start the CapsoView® software. Refer to the CapsoView® Instructions for Use.

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

Select the destination where you would like to save the file and click Next. 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. CapsoAccess® System 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 CapsoVision or your local distributor of CapsoVision devices.

Symptom	Possible Solutions
CapsoView® menu item "Download → Download Images" is not enabled (it is in gray font and not black)	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 CapsoView® software application. 6. Reboot the computer.
After selecting "Download Images" a system data transfer error message appears	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, 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	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 CapsoAccess® system indicator light is not illuminated	1. Verify that the power switch is turned to ON. 2. Verify that the power cable is fully inserted into the outlet and 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, Maintenance and Disposal

The CapsoAccess® Capsule Data Access System is typically used in an office environment with clean, disinfected, dry capsules. The system should be cleaned only as needed. 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.

Disposal: After its useful life or after sustaining unrepairable damage, the CapsoAccess® Capsule Data Access System 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.

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

10. Specifications and Ratings

Class I medical (Grounded) device

The CapsoAccess® Capsule Data Access System is classified as NO APPLIED PARTS EQUIPMENT.

The CapsoAccess® Capsule Data Access System 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.

The CapsoAccess® system needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.

Portable and mobile RF communications equipment can affect the CapsoAccess® system.

The use of accessories, transducers and cables other than those specified by CapsoVision, Inc. may result in increased EMISSIONS or decreased IMMUNITY of the CapsoAccess® system.

This CapsoAccess® system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the CapsoAccess® system should be observed to verify normal operation in the configuration in which it will be used.

Essential Performance: Data integrity during video download is considered to be the essential performance of the CapsoAccess® system. If the essential performance is lost or degraded due to EM disturbances, the video data may be

incomplete or corrupted which will require redownload.

11. Federal Communication Commission (FCC) Compliance

The CapsoAccess® system (CDAS3) complies with Part 15 of the United States FCC rules and with international standards for electromagnetic compatibility regarding its use.

Table 1 — Guidance and manufacturer's declaration – electromagnetic emissions

The CapsoAccess® system is intended for use in the electromagnetic environment specified below. The customer or the user of the CapsoAccess® system should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The CapsoAccess® system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The CapsoAccess® system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2 — Guidance and manufacturer's declaration – electromagnetic immunity

The CapsoAccess® system is intended for use in the electromagnetic environment specified below. The customer or the user of the CapsoAccess® system should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0% UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase: at 0° Voltage interruptions: 0% UT; 250/300 cycles	Voltage dips: 0% UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase: at 0° Voltage interruptions: 0% UT; 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CapsoAccess® system requires continued operation during power mains interruptions, it is recommended that the CapsoAccess® system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic, commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Table 3 — Guidance and manufacturer's declaration – electromagnetic immunity

The CapsoAccess® system is intended for use in the electromagnetic environment specified below.
The customer or the user of the CapsoAccess® system should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
IEC 61000-4-6 Conducted RF	3 Vrms 150 KHz to 80 MHz 6 Vrms in ISM bands between 150 KHz and 80 MHz	3 Vrms 6 Vrms in ISM bands	Portable and mobile RF communications equipment should be used no closer to any part of the EQUIPMENT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended distance $d = 1.2\sqrt{P}$ 150 KHz to 80 MHz $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CapsoAccess® system is used exceeds the applicable RF compliance level above, the CapsoAccess® system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the CapsoAccess® system.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4 — Recommended separation distances between portable and mobile RF communications equipment and the CapsoAccess® system (CDAS3)

The CapsoAccess® system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CapsoAccess® system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CapsoAccess® system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the ransmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

Environmental conditions
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 3000 m
Storage / Transportation ..... 0 to 12,000 m

The CapsoAccess® Capsule Data Access System (CDAS3) is intended for general use in hospital environment for data collection for reference

Electrical Ratings:

Adapter: HiTron Electronics Corp./ HEMG24-S120200-7
Adapter Input Voltage: 100-240 V AC, 60/50 Hz, 0.46-0.25 A
Adapter Output Voltage: 12 V DC, 2 A, max 24W
CapsoAccess® Input Voltage: 12 V DC
CapsoAccess® Input Current: 2 A

Contact Information

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