

# User Manual

## Endoscopic Camera System

- Ackermann Fusion™ FullHD 3CMOS NTSC/PAL Camera #16-2091



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## 1. PREFACE

We thank you for your purchase of the Ackermann Fusion™ Endoscopic Camera System.

In order to make the best use of it while having all the necessary precautions at your disposal, it is essential for you to become acquainted with this manual.

The sentences displaying the symbol  correspond to points requiring special attention.

The sentences displaying the  symbol represent items of information.

To facilitate installation and use of the device, we have attempted to make the device manual more practical. Consequently, references to the product presentation page on the inside cover (like C1 ) for example) will be provided for easier viewing of the relevant product parts.

This user manual is an integral part of the device. It must be made available to the user. Proper use and correct handling of the device entail following these instructions. The user alone shall be responsible for any damage that may result from improper use.

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## 2. INTRODUCTION OF THE UNIT

This is a 3CMOS FULLHD medical camera.

Its ergonomically designed sensor, automatic shutter, good sensitivity, excellent resolution and faithful color-rendering make it ideal as a medical tool for rigid or flexible endoscopy.

This camera comes with:

- A control unit
- A camera head with integrated 15-35 mm zoom lens
- Video cables
- A power cable
- A peripheral cable
- Two communication cables
- A set of 6 Fusion Cards
- A user manual
- A Quickstart guide


 For the United States and Canada, the "hospital grade" power cord supplied and the connector must be used with a "hospital grade" mains socket.

 This equipment has been delivered to you in packaging to be retained for use if transporting the device


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## 3. SAFETY INSTRUCTIONS


 Read the User Manual.

 This user manual is an integral part of the device. It must be made available to the user. Proper use and correct handling of the device entail following these instructions. The user alone shall be responsible for any damage that may result from improper use.


- Comply with the conditions of use and storage
- Do not expose the device to excessive dust
- The device should be opened only by a competent technician authorized by the manufacturer
- Do not insert metal objects into the device. This is to avoid any risk of electrical shock, fire, shortcircuit or hazardous emissions
- Do not expose the device to splashed water or to damp
- Use only the accessories supplied with the device or recommended as options by the manufacturer
- This camera is not a flame-proof device. Therefore, it must not be used in the presence of flammable anaesthetics
- This device was not designed to be used in an ionising environment
- This device is not sterile
- The surface temperature of the camera can reach 41°C (after a few minutes' use). Therefore, avoid any contact with this area
- The camera is intended for use by qualified, trained professionals, in an operating theatre
- Prior to plugging in the device, check that the mains voltage and mains frequency indicated on the device correspond to the power system values
- Prior to activation, ensure that neither the device nor the power cable is damaged. Deteriorated cables and connectors must be replaced immediately
- Do not drop the device. If the device falls, do not reconnect the device but send it back to your authorised distributor or directly to the Ackermann after-sales service department
- No additional multiple-socket outlets or extension cords must be connected to the EM system

 To avoid any risk of electrical shock, this device must be connected only to a power system equipped with protective grounding


 Devices connecting to the input/output ports must comply with the IEC 60950-1 standard

 Any modification of this device without authorisation from the manufacturer is prohibited. If the medical device is modified, an inspection and a test must be carried out to ensure that the medical device complies with the safety regulations

 Check with the manufacturer regarding the compatibility of your endoscope and your light source, prior to use

 It is advisable to have a second surgical camera in the operating theatre so that action can be taken if the device fails to perform or if a deterioration in performance is noticed

This device is to be used on individuals (patients) fit to undergo an endoscopic procedure

 The potential equalization plug located at the back of the medical device can be used to equalize the grounding potential of the medical device with that of all the devices plugged into the power main in the environment. Use the shared grounding system in the hospital or the building

 Device connecting to the input/output ports must comply with the IEC 60950-1 standard

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## **4. REGULATORY ADVICE**

### **4.1. COMPLIANCE**

This product was designed and manufactured by a company with a certified quality system. It meets the requirements of European directive 93/42/CEE, on medical devices. Consequently, it particularly meets the standards of electrical safety (IEC) and electromagnetic compatibility (CEM) ad hoc.

## 4.2. ELECTROMAGNETIC INTERFERENCES AND ELECTROSTATIC DISCHARGE

Although this product complies with CEM standards, it may in very special circumstances interfere with other devices, or itself be the object of interference from other devices or an unfavourable electromagnetic environment.

Image transfers from the camera to a monitor may be susceptible to electromagnetic disturbances and electric system disturbances.

In order to avoid these situations, it is advisable to:


- Ensure of the quality of the electric power system (especially the grounding of all devices and medical carts)
- Keep the device away from electromagnetic sources (e.g. compressors, motors, transformers, HF generators, etc.)

## 4.3. MEDICAL DEVICE VIGILANCE

Like any medical device, this device is subject to the stipulations governing medical device vigilance, and therefore any serious malfunction must be reported to the competent authorities and to the manufacturer as quickly and as accurately as possible. For manufacturer contact details, refer to the last page of the manual.

## 4.4. END OF LIFECYCLE

This device carries the recycling symbol in compliance with European directive 2002/96/ CEE on Waste Electrical and Electronic Equipment (DEEE or WEEE). By correctly disposing of this device you are helping to prevent harmful effects on the environment and on human health.

The  symbol displayed on the device and on the accompanying documentation indicates that this product cannot under any circumstances be treated as household waste. It must therefore be delivered to a waste collection centre for the recycling of electrical and electronic equipment.

In disposing of it, please comply with the waste elimination norms in effect in the country where it is installed.

For further details on the treatment, recovery and recycling of this device, kindly contact your nearest retailer who will advise you on the procedure to follow.

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## 5. INSTALLING THE UNIT

This medical device is intended for use by a qualified surgeon during endoscopic exploration. No special training is required to install it. Kindly refer to the instructions in this manual.

Place the control unit on its base and have to hand the various accessories required to operate it.

### 5.1. CONNECTIONS

- Connect the power cord to the mains socket of the camera C2 and a video lead to one of the video output ports: We recommend selecting the DVI output C6 for connecting the main surgical monitor
- Connect the second end of the video lead to the video input port on the monitor
- If you wish to control certain functionalities of the Ackermann insufflator or the Ackermann lightsource, connect these to the AckermannCOM socket on the camera's control unit C9 intended for this purpose, using the two cables provided


Connecting the endoscope to the sensor:

- Turn the ring on the endoscope-holder on the camera head clockwise
- Once the endoscope is inserted, release the ring
- If the sensor has to be locked into position on the endoscope, the ring should be turned in the opposite direction
- Connect the potential equalization cable to the equipotential plug C13 at the back of the device

**5.2. ACTIVATION**

To optimize the quality of the images obtained with this product, always be sure to connect the camera head before turning on the control unit

- Connect the power cable to the plug C2 at the back of the camera
- Connect the DVI-D cable to the corresponding output port C6 at the back of the product and to the corresponding input port on the monitor
  - The HDSI output produces a progressive 1080 signal
- If needed, connect other monitors or peripherals, preferably using the HDSI output ports C8
  - HDSI output ports produce an interleaved 1080 signal
  - HDSI output ports are preferred when a very long cable is necessary
- Turn the activation switch S2 to position "1"
  - The camera takes about 30 seconds to come on. The Ackermann logo is displayed on the screen during this interval
  - The flashing LED standby button, and the appearance of "standby" on the screen indicate that the camera is properly activated
- Connect the camera head to the control unit via the dedicated connector C1
- Touch the screen, OR press the Standby button to access the main menu
- Select a surgical speciality from Laparoscopy, Cystoscopy, Hysteroscopy, ENT, Arthroscopy and Flexible Endoscopy, by clicking the associated symbol
  - Once the selection is made, the camera is in surgery mode
- After connecting the light cable and the endoscope, film a white surface and launch the White Balance by pressing the dedicated button on the touch screen interface, or the camera head's pre-programmed button
  - When the surgical monitor appears indicating "AWB OK" and the chronometer starts, this signals that the white balance has successfully been set
  - The chronometer shows the operating time by default (the starting point being when the white balance is set). However, this chronometer can be set beforehand if necessary, independently of the white balance
- The video settings have been defined for each surgical speciality. However, they can be modified, if necessary, during surgery
  - 3 of these (Brightness, Sharpness and Red Gain) can be directly accessed from the main screen. All the others (Gamma, Blue Gain, Color, Red Phase, Gain, Noise Reduction, and Aperture) can be accessed by clicking the "More Settings" button. This is a drop-down list. To scroll through the parameters, touch the left section (the parameter headings) with your finger
- Press "Close settings" to exit and return to the main screen
- You can at any time during surgery to return to the factory settings for the surgical speciality by clicking the "Specialities presets" button.
- Press the "STOP" button at the end of the surgery
  - You can at this stage:
  - Return to the main menu by clicking the "Completed" button
  - OR
  - Create a user profile from the settings used during the operation
  - OR
  - Log in if you wish to add this set of settings to your profile

 Before connecting an endoscope (or fibroscopes) to the camera lens, check the condition of this endoscope (clean distal lens, setup if necessary)

## 5.3. ACTIVATION OF THE UNIT WITH A FUSION CARD

Scan a Fusion Card on the read area provided on the lexan housing (next to the Ackermann logo)

- Scanning a standard Fusion Card:

- Activate the camera directly on the surgical screen, in the surgical application corresponding to the Fusion Card scanned

- Scanning a personal Fusion Card:

- Activate the camera directly on the surgical screen, in the surgical preset corresponding to the Fusion Card scanned. If the user profile associated with the Fusion Card scanned shows more than one preset, then an intermediate stage for selecting the desired preset will be necessary

- Scanning an administrator Fusion Card:

- Activate the camera in the administrator menu

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## 6. OPERATING GUIDELINES

### 6.1. SELECTING THE SURGICAL SPECIALITY

This camera can be used in various mini-invasive surgical operations.

Select the speciality from the pre-entered list. This loads the video parameters for the application accordingly:

- LAPAROSCOPY
- HYSTEROSCOPY
- CYSTOSCOPY
- ENT
- ARTHROSCOPY
- FLEXIBLE ENDOSCOPY

**Note 1:** Each of these specialities can be accessed by scanning the Fusion Card on its dedicated area Z1 on the control unit. This can be done at any time. If the Fusion Card is scanned while a surgical operation is in progress, then confirmation will be requested

**Note 2:** If you have entered customized parameters into a user profile beforehand, then you can select this user profile either by using the "Log in" button, or by scanning your personal Fusion Card on the dedicated area Z1 of the control unit if the control unit is linked to your personal profile

### 6.2. CONFIGURATION OF THE FUNCTIONS OF THE CAMERA HEAD BUTTONS

This operation is performed on the corresponding page of the menu interface, which can be accessed from the dedicated "Camera head" button:

Click the button you wish to configure (B1, B2 or B3).

Select the type of press (short press or long press) and the corresponding function desired, and confirm.

Repeat this procedure for each of the three buttons.

The configuration selected for each of the three buttons will be entered into the user's personal profile.

Below is the comprehensive list of the configurable functions:

Short press	Long press
No action	No action
Brightness +	Brightness +
Brightness -	Brightness -
Light source - Intensity +	Light source - Intensity +
Peripheral 1	Peripheral 1
Peripheral 2	Peripheral 2
Mirror	Mirror
Freeze frame	Freeze frame
Recording images on the camera (if equipped with an integrated recorder)	AWB
Record / Stop video recording on the camera (if equipped with an integrated recorder)	Insufflators (RUN/High Flow Rate/STOP)
	Lightsource (ON/OFF)
(a) Recording images on the PC	Recording images on the camera (if equipped with an integrated recorder)
(b) Record / Stop video recording on the PC	Record / Stop video recording on the camera (if equipped with an integrated recorder)
	(a) Recording images on the PC
	(b) Record / Stop video recording on the PC

By default, the following configuration is applied (factory setting):

B1 (short press / long press): Brightness - / Light source

B2 (short press / long press): Brightness - / Insufflator

B3 (short press / long press): No action / AWB

Mirror mode: An "M" is displayed on the monitor to indicate that the mirror mode (inverted image) is active, and disappears when it is deactivated.

Freeze mode: an «F» is displayed on the monitor to indicate that the freeze mode is active, and disappears with it is deactivated.

### 6.3. WHITE BALANCE

The white balance can be set in 2 ways:

- From the touch screen interface, click the white balance button
- From one of the camera head buttons, depending on your programming (only possible with long press)

You should proceed as follow:


- Once the camera is paired with the endoscope, the ambient light reduced to a minimum and the light source active, film a white surface



- Set the white balance; the BALANCING IN PROGRESS message is displayed on the screen
- Continue to film the white surface until the BALANCE OK message is displayed on the screen


**Note 1:** Setting the white balance causes the chronometer to be activated, signalling the start of the surgery and therefore the availability of additional functionalities, particularly those linked to the image quality settings

**Note 2:** If the Ackermann light source is connected to the Ackermann camera by the communication cable supplied, then setting the white balance will cause the LED to light up if it was previously off

 In the event that the white balance is set during an operation, i.e. inside the patient, the endoscope must be pulled out of the trocar and the white balance must be set again using gauze

## 6.4. FOCUSING

Once the endoscope is connected and the light source is activated, slowly turn the lens focus ring to find a position where the objects being observed are sharp.

 Focusing on a fairly distant point helps obtain adequate field depth for the operation and therefore avoids having to do retouching too regularly

## 6.5. FUNCTIONALITIES

### 6.5.1. VIDEO SETTINGS

Once the white balance is set, or the "Start" button has been pressed, access to the video settings is authorised. In this way, it is possible to work directly on brightness, sharpness and red gain. Additional settings are available by clicking the "More settings" button.

The following parameters can be modified:

Brightness	This parameter varies the general brightness of the image
Blue gain	Colorimetry shift from white to blue
Red gain	Colorimetry shift from white to red
Color	Modifies color saturation
Noise reduction	Reduces the noise in an image
Window	Shutter window analysis: surface of the image on which the camera analyses the quantity of light received, in order to adjust the speed of the shutter to obtain a right exposure time. Use the automatic mode or change it according to the scope size
Gamma	Modifies the dynamics of the dark areas: +1 reduces the difference between the light portions and the dark portions, therefore making these dark areas appear less so. -1 does the opposite: the dark portions are made even darker.
Sharpness	Modifies the sharpness of the image to obtain a 3D effect or on the other hand, softens the image with the anti-moiré filter for flexible endoscopes.
Gain	Modifies the brightness level in cases of mediocre lighting conditions



Red phase

Colorimetry phase shift from Orange to Magenta

Click the “Close settings” button once to return to the previous menu.

### 6.5.2. OTHER PARAMETERS

#### HD Recording:

If your camera is equipped with an integrated HD recorder, you can set HD image / video recording from the interface menu using the corresponding buttons or from the buttons on the camera head if these have been programmed accordingly.

#### Insufflators:

If your camera is connected to the Fusion insufflator via the communication cable provided, you can select from the parameters menu whether or not to display information about the operating status of the insufflators on the surgical monitor's OSD.

#### In particular:

Feedback on instantaneous pressure in the pneumoperitoneum;

Feedback on warning messages from the insufflators.

In addition, one of the buttons on the camera head can be configured (long press only) to control the Fusion insufflators according to the following sequence: Start insufflation in low flow / Change to high flow / Stop insufflation.

### 6.6. COMPLETION

Once the operation is completed, press the “STOP” button. You will be given the option:

- To create a user profile
- To log in, if you have not already done so
- To save any modifications to the settings in your personal profile, if you have not already done so
- To exit

**Note:** If you are already logged in, you can opt to save the modifications to your personal profile.

#### In particular you will be able to save:

- Modifications to the video settings
- Modifications to the Ackermann light source intensity setting (last setting used)
- Modifications to the Ackermann insufflator pressure setpoint (last setting used, with 15 mm Hg limitation, and mode)
- Modifications to the settings on the surgical monitor supported models only)

Once the selection has been made, you can overwrite the existing preset, or create another one

### 6.7. GENERAL SETTINGS MENU

The general settings menu is used to:

- Set the light intensity on the touch screen
- Select the display messages and the display of the instantaneous pressure in the pneumoperitoneum from the Fusion insufflator
- Select the language
- Pause the live video when a photo is taken to verify its quality

### 6.8. INFORMATION MENU

The information menu is used to access a rapid start-up product guide.

## 6.9. CONNECTIONS MENU

The connections menu is used to obtain the connection status of all of the system's devices.

In particular, the camera head, the Ackermann light source, the Ackermann insufflators, the Ackermann PC Panel and the Surgical Monitor.

**Note:** The icon for this menu changes to orange when at least one of the products on the system is disconnected.

## 6.10. CREATING USER PROFILES

- Click the "Log in or create a profile" button
- Click the "Create a profile" button
  - Activating the camera with a blank Fusion Card gives direct access to the following stage
- Click the text field and enter the desired profile name
- Click the "Return" button
- Select a surgical speciality. This will form the basis for the video parameters
- Click the "Create a profile" button OR scan a blank Fusion Card on the area provided for this purpose on the lexan housing (next to the Ackermann logo)
- A message is displayed for a few seconds indicating that the device supports the creation of a profile
- You can then:
  - Rename the profile and/or the preset by clicking the "Manage" button
  - Delete one (of the) profile preset(s) by clicking "Manage"
  - Use the preset created by clicking on it
  - Log out by clicking the "Log out" button

**Notes:** If a blank Fusion Card has been scanned at least once (during activation and/or while saving a created profile), then the profile (and the presets) created will be automatically linked to this Fusion Card. A padlock icon will be displayed on this profile. This means that:

- The presets locked in this profile cannot be modified without the corresponding Fusion Card
- The names of the presets and the profile name cannot be modified without the corresponding Fusion Card

## 7. DESCRIPTION OF FRONT & BACK PANELS

### 7.1. MAINS SOCKET

The camera receives electrical power by means of the mains plug located on the back panel C2, which must be connected to the mains power supply by the lead supplied with the camera. This plug carries a fuse trap as well as a master switch for turning on the device.

The camera uses T2.5AL - 250V fuses.

When replacing a fuse, the camera must be unplugged and the same type of fuse must be used.

The T in "T2.5A" means "time-delay". Only use fuses marked UL/CSA.

### 7.2. VIDEO OUTPUTS

The following video output ports are available on this camera: DVI C6, HD-SDI C8, RGBS C5, Y/C C10 and composite C11.

**i** The DVI output port provides the best image quality in 1080p format over short distances.

**i** HD-SDI output ports are used to transport the video signal over long distances (screen at a distance of up to 50 m).

### 7.3. PERIPHERAL OUTPUTS

Two (2) peripheral output ports are available C12 and these are used with a 3.5 mm jack lead for managing two peripherals (for example: a printer and a video recorder) from the buttons on the camera head.

 The devices connecting to the “VIDEO OUT” and “PERIPHERAL” ports must be compliant with standard IEC 60950.

### 7.4. KEYS & SYMBOLS ON THE FRONT & BACK PANELS

The keys and symbols on the back panel are for identifying the camera in accordance with international standards IEC 60601-1, IEC 60601-2-18, IEC 60417 and EN 980 (See Appendix 1)

The table below describes the back and front components:

<b>C1</b>	Connector for the camera head
<b>C2</b>	Main power socket
<b>C3</b>	RS232 output
<b>C4</b>	Service line
<b>C5</b>	RGBS video output
<b>C6</b>	DVI-D video output
<b>C7</b>	Ethernet output
<b>C8</b>	SDI output
<b>C9</b>	Connections to Ackermann product (lightsource and insufflator)
<b>C10</b>	Y / C video output
<b>C11</b>	Composite video output
<b>C12</b>	Peripheral connections
<b>C13</b>	Equipotential plug
<b>C14</b>	USB storage device port
<b>L1</b>	Touchscreen
<b>S1</b>	Standby button
<b>S2</b>	Power button
<b>Z1</b>	Read area of Fusion Card

## 8. SUGGESTED DECONTAMINATION PROCEDURES

### Disinfecting the camera control unit

- ⚠ The camera control unit is a non-heat-resistant medical device and does not withstand immersion; consequently, it should be disinfected using a non-woven medium saturated with a disinfectant detergent
- ⚠ This device is not drip-proof. Do not splash liquid on this product
- ⚠ As decontamination is linked to the products, methods and/or tools used, decontamination is the sole responsibility of the staff concerned
- ⚠ The device must always be disconnected before any cleaning procedure is carried out
- ⚠ This device is not autoclavable
- ⚠ Existing alkaline solutions for the disinfection of certain medical devices are NOT RECOMMENDED for disinfecting this device

### Disinfecting the camera head

Pre-disinfection cleaning	Disinfection	Sterilization
Immersion in an enzymatic cleaning solution (Aniosyme DD1, Hexanios G + R or surface cleaning ((Anios wipes)).	Immersion in a glutaraldehyde solution (Anios Laboratory - Steranios 2%)	Low-temperature sterilisation with hydrogen peroxide or oxide


- ⚠ Any other disinfection methods are prohibited, and the manufacturer accepts no liability for any damage caused by using such methods
- ⚠ It is advisable to use a disposable, sterile, protective cover on the camera regardless of the sterilisation procedure followed and throughout the surgical operation
- ⚠ The camera is not autoclavable
- ⚠ The camera is not compatible with automatic washer-disinfectors
- ⚠ Existing alkaline solutions for the pre-disinfection of certain medical devices are NOT RECOMMENDED for pre-disinfecting our cameras
- ⚠ It is essential for the parts coming into contact with the disinfectant to be thoroughly rinsed
- ⚠ Use soft non-woven cloths for wiping the lenses dry so as not to scratch them
- ⚠ The procedures described in this section are given as guidance, and cannot under any circumstances be substituted for official recommendations or directives
- ⚠ The connector on the camera equipped with its sealing cap can be immersed. Traces of water are visible just as the connector seal is removed (runoff and condensation). It is therefore essential to dry the inside of the cap well before reusing it

### **Disinfecting the lens surfaces**

A dirty lens surface can interfere with observation. The lens surface must not have any marks or smudges. To avoid scratching the lens surface, never use abrasive cloths or sponges to clean it

To remove dust, dirt and other impurities not originating from the patient, wipe clean with a soft, lint-free cloth moistened with ethanol or 70% iAckermannpyl alcohol. When cleaning, wear gloves for protection from chemical products.

Ensure that the equipment is completely dry before use.

 Use soft non-woven cloths to clean the lenses so as to avoid scratching them.

**Please read the cleaning, disinfection and sterilization instructions given in the “General Reprocessing Instructions” procedure**

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## **9. AFTER-SALES SERVICE & MAINTENANCE**

This device does not require any special maintenance operations.

 **Note:** Misuse of the device is not covered by the warranty.

If a fault persists and the device has to be returned to the after-sales service department, ensure that it is shipped in its original packaging.

Similarly, it is advisable to return the device in its entirety (control unit, power cables).

 Kindly attach to the shipping order a short explanatory note about the fault noted. The equipment must be disinfected before it is returned for repair. When returning the equipment, check its condition and note any exceptions on the shipping order if necessary, and confirm these with the shipper by registered mail within 48 hours. If any equipment shipped by us suffers damage during transport, the total amount for repairs will be charged either to the shipper if notification of the exceptions has been given within the deadline, or failing such, to the recipient. In the event of an incident, kindly contact our customer service department or your nearest sales representative.

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## **10. TROUBLESHOOTING**

### **The indicator light on the standby switch S1 does not light up on start-up:**

- Check that the mains socket at the back of the camera is properly connected to the power supply and that the general switch at the back of the camera is in the operating position (“I”)
- Check that the fuses are in good condition (only use the fuses specified on the back panel).


### **The indicator light on the standby button S1 comes on but no image appears on the screen:**

- Check that the sensor is properly connected to the control unit (if not, a color bar will be displayed), and that it is filming a workable image
- Check that the control unit on the camera is correctly connected to the monitor (cable in good condition, plugs correctly pushed in)
- If the video channel has several components, connect the camera directly to the monitor to verify that the problem is not with one of the peripherals
- Check that the monitor is in fact switched on, wired to the correct video input and that the image settings are at the mid-point position (color, light and contrast)
- Check the light source, the light cable and the endoscope

### **The image is blurred and white all over:**

- Check that there is no condensation on the lens
- Check that the sensor is not aimed at an object that is too bright

- Check the lens setup

 If there is no image or if the image is not displayed, unplug and re-plug your device or reset the camera to the factory settings

### **The image is extremely light or dark:**

- Check that the BRIGHTNESS parameter is not at the maximum or minimum setting
- Check that the APERTURE used is not too wide or too narrow
- Check that the camera head is correctly connected to the control unit
- Check that the light intensity from the light source is not too low or too high
- Turn off and turn back on the control unit

If the fault persists and it becomes necessary to return the camera to the after-sales service department, be sure to ship it in its original packaging after disinfecting it. Similarly, it is advisable to return the camera in its entirety (control unit, sensor, lens, cables). Kindly attach to the shipping order an explanation concerning the fault noted.

 The equipment must be disinfected before it is returned for repair.

When returning the equipment, check its condition and note any exceptions on the shipping order if necessary, and confirm these with the shipper by registered mail within 48 hours. If any equipment shipped by us suffers damage during transport, the total amount for repairs will be charged to the shipper if notification of the exceptions has been given within the deadline, or otherwise to the recipient.

## **11. TECHNICAL SPECIFICATIONS**

### **Control unit**

#### Main functions:

- Class 1 device, CF-type applied part
- 3 programmable buttons
- Application and user MENUS
- Automatic compensation function for defective pixels
- RF transmitter:
  - Type : RFID
  - Frequency : 13,56 MHz
  - Modulation feature : OOK
  - Transmitter power : 70mW (+18 dBm)

#### Video output:

- CVBS: 1.0 V [P-P] / 75 ohms Negative Sync,
- Y/C: Y: 1.0 V [P-P] / 75 ohms, C: 0.286 V [P-P] (NTSC), C: 300 Vp-p V [P-P] (PAL) / 75 ohms Negative Sync,
- RGB: 3x0.7 V [P-P] & 0.3 V [P-P] / 75 ohms
- HD-SDI: 0.8 V [P-P] / 75 ohms SMPTE292M
- DVI-D 3x0.7Vcc/& 0.3Vcc/75Ω)

#### Environment:

- Operating temperature: +10°C / +40°C
- Operating humidity: 30% to 75 %
- Transport and storage temperature: -10°C / +45°C
- Transport and storage humidity: 20 to 85 %
- Operating, storage and transport atmospheric pressure: 700hPa to 1060hPa
- Control unit is not drip-proof (IPX0)
- Not suitable for use in presence of flammable gas. Recommendation of use in an operating room in accordance with applicable regulations
- Compliant with European directive 93/42/CEE.

- Compliant with international standards IEC 60601-1; IEC 601-2-18; IEC 60417 and EN 980
- Dimensions (W x H x D): 310 x 136 x 385 mm
- Control unit weight: 4300g
- Electric power supply: 100 – 230 VAC @ 50 Hz-60 Hz
- Electricity consumption: 38-50 VA
- Two T2.5AL – 250V fuses (Marked UL/CSA only)
- Continuous operation

### **Camera head**

- CF-type applied part
  - Sensor: 3 CMOS
  - Acquisition in native 16:9 format
  - Progressive scan technology
  - Resolution: HDTV 1080p format: 1920x1080 pixels
  - Definition: 1080 lines
  - Sensitivity: 5 lux
  - Signal/Noise ratio: 54dB
  - Cable length: 3m
  - Sensor dimensions (D x H): 149 x 53 mm
  - Sensor weight: 270g
- 

## **12. ELECTROMAGNETIC COMPATIBILITY**

All the information below is based on the requirements of standards to which the manufacturers of electrical medical devices must adhere (as stated in standard IEC60601-1 Ed4).

The medical device complies with the electromagnetic compatibility standards in force. However, the user must make sure that any electromagnetic interference does not create an additional risk, such as radiofrequency transmitters, or other electronic devices.

This chapter contains the information required for you to install and use your medical device in optimum conditions in terms of electromagnetic compatibility. The different medical device cords must be kept away from each other.

Some types of mobile telecommunication devices such as mobile phones may interfere with the medical device. The separation distances recommended in this chapter **MUST** be complied with. The medical device must not be used near another device or placed on top of it. If this cannot be avoided, correct operation of the device in operating conditions must be checked prior to use.

The use of accessories other than those specified or sold by Ackermann as replacement parts may increase the emission or reduce the immunity of the medical device.



## 12.1. CABLE LENGTH

Cables and accessories	Maximum length	Test type	In compliance with
Video cables Mains cable Mains boundary cable Communication cable	< 3 meters	RF emission CISPR 11, Class B	CISPR 11, Class B
		Harmonic current emission	IEC 61000-3-2
		Voltage changes and flicker	IEC 61000-3-3
		Electrostatic discharge immunity	IEC 61000-4-2
		Transient electromagnetic immunity	IEC 61000-4-3
		Electrical fast transient/burst immunity	IEC 61000-4-4
		Surge immunity	IEC 61000-4-5
		Immunity to conducted disturbances, induced by radio-frequency fields	IEC 61000-4-6
		Radiated immunity – magnetic fields	IEC 61000-4-8
		Voltage dips, short interruptions and voltage variation immunity	IEC 61000-4-11

## 12.2. RECOMMENDED SEPARATION DISTANCES

The medical device is designed to be used in an electromagnetic environment in which interferences caused by RF radiation are controlled.

The user or installer of the medical device may help to prevent electromagnetic interference by maintaining a minimum distance, depending on the maximum power of the radiofrequency transmission equipment.

RF mobile communication devices (including peripherals such as antenna cables and external antennas) should not be used nearer than 30 cm (12 inches) from any part of the medical device, including the cables specified by the manufacturer. If this is not respected, the performance of these devices may be impaired.

## 12.3. ELECTROMAGNETIC EMISSIONS

The medical device is designed for use in the electromagnetic environment described in the table below. The user and/or installer must ensure that the medical device is used in the environment described below.

Emission test	Conformity	Electromagnetic environment – comments
Electromagnetic radiation disturbance (radiated emissions) (CISPR 11)	Group 1	The medical device uses RF energy for its internal operation.



Disrupting voltage on the power terminals (Conducted emissions) (CISPR 11)	Class B	<p>The EMISSIONS characteristics of this device allow it to be used in industrial areas and in hospital environments (class A defined in CISPR 11). When it is used in a residential environment (for which class B defined in CISPR 11 is normally required), this device may not offer adequate protection for radio frequency communication services.</p> <p>The user may need to take corrective actions, such as relocating or redirecting the device.</p> <p>A professional healthcare environment.</p>
Harmonic current emission (IEC 61000-3-2)	Conforming	
Voltage variations, voltage fluctuations and flicker (IEC 61000-3-3)	Conforming	

## 12.4. MAGNETIC & ELECTROMAGNETIC IMMUNITY

The medical device is designed for use in the magnetic and electromagnetic environment described in the table below. The user and/or installer must ensure conformity of the electromagnetic environment.

Immunity test	Test level according to IEC 60601	Conformity level	Electromagnetic environment / comments
Electrostatic discharge (ESD) (IEC 61000-4-2)	± 8 kV contact ± 15 kV in the air	± 8 kV contact ± 15 kV in the air	A professional healthcare environment
Electrical fast transient bursts (IEC 61000-4-4)	± 2 kV for electricity supply lines	± 2 kV for electricity supply lines ± 1 kV for signal ports A professional healthcare environment	A professional healthcare environment
Shock waves (IEC 61000-4-5)	± 1 kV in differential mode ± 2 kV in common mode	± 1 kV in differential mode ± 2 kV in common mode	A professional healthcare environment
Magnetic field at assigned industrial frequency (IEC 61000-4-8)	30 A/m	30 A/m	A professional healthcare environment
Voltage dips, short interruptions and voltage variations (IEC 61000-4-11)	0% UT for 0.5 cycles A 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT for 1 cycle 70% UT for 25 cycles at 50 Hz For 30 cycles at 60 Hz Single-phase: at 0	0% UT for 0.5 cycles A 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT for 1 cycle 70% UT for 25 cycles at 50 Hz For 30 cycles at 60 Hz Single-phase: at 0	A professional healthcare environment  If the use of the system requires continuous operation during mains power outages, it is advisable to supply the medical device using a separate current source (UPS, etc.).

## 12.5. ELECTROMAGNETIC IMMUNITY, RADIOFREQUENCIES

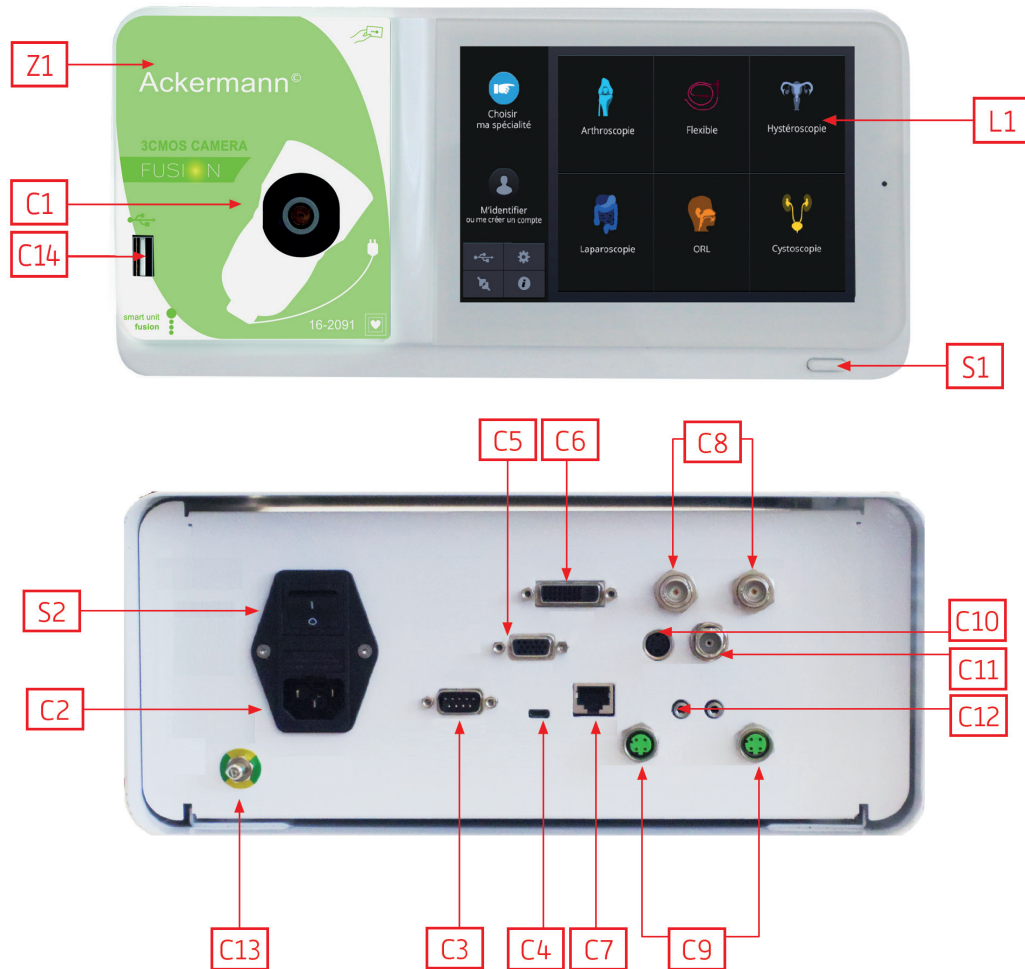
The medical device is designed for use in the magnetic and electromagnetic environment described in the table below. The user and/or installer must ensure conformity of the electromagnetic environment.

Immunity test	Test level	Conformity level	Electromagnetic environment / comments
CAUTION: RF mobile communication devices (including peripherals such as antenna cables and external antennas) should not be used nearer than 30 cm (12 inches) from any part of the medical device, including the cables specified by the manufacturer. If this is not respected, the performance of these devices may be impaired.			
Radiated radiofrequency electromagnetic field (IEC61000-4-3)	10 V/m 80 MHz at 2.7 GHz 80 % MA at 1 kHz	10 V/m 80 MHz at 2.7 GHz 80 % MA at 1 kHz	A professional healthcare environment
Near fields emitted by wireless RF communication devices (IEC 61000-4-3 provisional method)	9 V/m 710 MHz, 745 MHz, 780 MHz, 5240 MHz, 5550 MHz, 5785 MHz	9 V/m 710 MHz, 745 MHz, 780 MHz, 5240 MHz, 5550 MHz, 5785 MHz	A professional healthcare environment
	27 V/m 385 MHz	27 V/m 385 MHz	
	28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	
Conducted disturbances, induced by RF fields (IEC61000-4-6)	3 V 150KHz at 80MHz	3 V 150KHz at 80MHz	A professional healthcare environment
	6 V in ISM frequency band and band between 0.15 MHz and 80 MHz,	6 V in ISM frequency band and band between 0.15 MHz and 80 MHz,	
	80% MA at 1 KHz	80% MA at 1 KHz	



## 13. SYMBOLS

Symbol	Description
S L C I	Button Screen Socket Label (rear panel of the unit)
	For medical devices, this symbol is associated with the year of manufacture. The latter is denoted by four figures
	For medical devices, this symbol is associated with the name and address of the manufacturer
	Protective grounding
<b>Class 1</b>	Class 1 product
	Compliant with European directive 93/42/CEE
	An equipotential grounding socket conductor other than protective grounding or a neutral conductor, for direct connection between the electrical equipment and the potential equalisation busbar. Kindly refer to standard IEC 60601-1, 3rd edition
	T UL/CSA time-delay fuses
	Video output ports and peripheral control output port
	Data input and peripheral output
	CF-type device
	Electronic and electrical equipment marketed after 13/08/2005. This symbol indicates that this product is not to be treated with household waste.
	Read the user manual
	RF transmitter
	Upper and lower temperature limit of the medical device
	Humidity range within which the medical device can be safely exposed
	Atmospheric pressure limit. Indicates the range of atmospheric pressure within which the medical device can be safely exposed
<b>REF</b>	Catalogue number
<b>SN</b>	Serial number



## 14. APPENDIX

All product codes covered by these instructions are listed below:

- Ackermann Fusion™ FullHD 3CMOS NTSC/PAL Camera incl. CCU, USB Recording/Archive and 15-35 mm Coupler **#16-2091**

## 15. CONTACT DETAILS



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