



CP-201 Visualisation Laptop

Laptop Video System for medical Endoscopy consisting of: TFT-Flatscreen Monitor 10,4", 1-CCD-Chip-Camera, LED-Lightsource, USB Image Capture



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2. Legal advice

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Due to constant development of our products, we reserve us the right to change technical details without announcement

Authorized retailer

Manufacturer:



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CE



3. Key to the Symbols



Please note!

- **Warning:** To call attention a potentially hazardous situation / hazard alert. The Failure to comply can result in death or serious injury.
- Attention: To call attention of a potentially hazardous situation / hazard alert. The Failure to comply can cause injury and / or cause damage to the product.



Marking for safety instruction - Warning



Please observe instructions for use

CE

CE-mark according guideline 93/42/EWG

CE-Label

The CE-label certifies that the product corresponds to the regulations ISO 60601-1 respectively SAFTY and ISO 60601-1-2 respectively EMC.

With regard to medical devices the CE-label certifies, that the product corresponds to the Medical Device Directive 93/42/EEC respectively to the Medical Device Law.



4. Introduction

Dear customer,

We congratulate you on your purchase Blazejewski MEDI-TECH CP-201 laptop visualization system.

Endoscopic visualization systems are medical devices that are manufactured to the highest technical level and need the careful handling, maintenance and storage.

Under these circumstances they meet the high demands that are placed on them and stay usable for a long time period in order to satisfy you completely.



Blazejewski MEDI-TECH GmbH endoscopic visualization systems are sensitive to electrically operated medical devices!



Please treat your endoscopic system always with the utmost care!



All adapted equipment or accessories shall comply with the ISO standard for medical devices!



Read this tutorial carefully before first use. Protect yourself, patients and third parties from damages which can be caused by incorrect connection, damage or improper operation!



5. Safty Notes

This manual does not contain a detailed description of endoscopy and is not suitable for a beginner to introduce into this surgical technique!

This device shall be taken in operation by technically competent persons only, which furthermore have been introduced in the kind of operation of this device.

Improper use can cause damages to you, the patient or third parties or lead to damages of the endoscopic system itself.

Take advantage that the endoscopic system is used for the purposes described in this guide only!

These instructions should be kept in a conspicuous place near the device!

Examine the device, the accessories and all electrical connections on function and damage! Defects in cables, connectors, housings and further parts or loose parts can degrade the performance and security and must be removed immediately!

There should be nothing on the connectors.

Always install all the cables in a way that there exists no risk of stumbling.

Regarding the adaptation to other devices or accessories, please assure yourself that the manufacturer security hints of these devices have been taken into account (f.ex. endoscopes, TV adapters, monitors, printers, video recorders, storage systems, pumps, shavers, insufflators, RF devices, laser devices, etc.).

The device is not intended for use in explosion-prone areas!

Protective measures against combustion and high concentration of light, RF applications, including laser application high-energy applications have not been integrated. Pay attention to the fact that devices which are approved by ISO for medical purposes should be adapted only!

Mechanical stress, such as by falling, can damage or destroy the device!

Failure of the device can lead to hazards. Therefore you should have a functioning replacement device available.



Attention:

Remember that light is an energy source that can heat up any endoscope. The application period is limited by the selection of endoscopes and light intensity.

The fiber optic port on the endoscope can reach temperatures that can cause burns. Please never touch the exit surface of the light source and the entrance and exit surfaces of endoscopes, it threatens danger of burning.

In addition light of high radiation energy can lead to a temperature increase in the tissue. In invasive applications with tissue contact temperatures above +41°C at the distal end should be avoided, otherwise you may experience tissue damage!

Therefore avoid direct tissue contact and pay attention to sufficient irrigation of the operative field, if applicable. Furthermore please pay attention to the respective device-specific instruction manuals and safety instructions.

Place the light source never onto non heat-proof components, it threatens to fire. Never use the device with open housing.

We accept no liability for damages incurred by false application or misuse of the device!

Do you have any questions, we will answer you this very much.

You can reach us daily on weekdays from 8:00 to 16:30.

6. Intended use and operation

To display endoscopic images and video signals in medicine, endoscopic imaging procedures are required.

The CP-201 visualization system is a combined light source, camera and display unit.

It consists of a color video camera with remote camera head, a remote LED light source, integrated flatscreen monitor and USB memory unit. It is intended specifically for use in medical endoscopy and diagnostics.

The endoscopic image can also use the analog output as composite signal to be connected to an external monitor / display or recording system.

The LED light source, the cold light, is connected directly to the fiber optic connector of the endoscope. This leads to a more homogeneous and intense illumination of the medical examination area.

Endoscopic images can be saved directly to a connected USB flash drive by a high performance graphics processor.

Endoscopic surgery performed both diagnostic and therapeutic nature are far less stressful for the patient than traditional methods.

Indications: The use of the device is indicated for endoscopic procedures and other procedures of surgery.

Contraindications: The use of the device is contraindicated if endoscopic procedures and surgery procedures are contraindicated.



Please read this manual carefully before operating.

These instructions should be kept in a conspicuous place nearby the device.

7. First start / Installation

Take out the Blazejewski MEDI-TECH CP-201 visualization system from its packaging and remove all packaging components.

Warning: Store, the package and packaging components, out of reach of children.

The CP-201 consists of the control unit, the camera head, the LED light source and the power cord.

The delivery includes:	1 piece	Control unit
	1 piece	camera head
	1 piece	power cord
	1 piece	LED light source
	1 piece	User manual
	1 piece	Testreport
Optional Accessories:	1 piece 1 piece 10 piece	TV-Adaptor (optional) USB flash drive Fuses

The device and its accessories should be checked immediately upon receipt for completeness and obvious damage. Damage can only be claimed if the vendor is notified immediately (within a 24-hour period).

In case of return of equipment or accessories please always use the original packaging. Describe the error or the failure and tell us the name of a contact person for any questions. Read **Chapter 16 Warranty, Service and Repair**

The endoscopic system must be cleaned and disinfected before first use according to the cleaning instructions. Use the appropriate cleaning agents and disinfectants. Avoid ingress of fluids and objects in the device. The control unit cannot be sterilized. Refer to **Chapter 10 Cleaning, disinfection, sterilization**

Place the device on a clean, flat surface. Ensure that you keep enough distance on the back for an efficient air flow. Make sure that a minimum distance of 15 cm is maintained between the rear wall and other objects. All ventilation openings should be free.

The ambient temperature shall be not higher than 40° C.



Connect the included LED light source to the front of the control unit.

Please note that the plug is in the correct position (red dot on plug and socket) and the locking sleeve snaps forward.

To resolve the plug locking sleeve must be drawn backward (Release the lock).

Connect the cable of the camera head to the front page of the control unit.

Please note that the plug is in the correct position (red dot on plug and socket) and the locking sleeve snaps forward.

To resolve the plug locking sleeve must be drawn backward (Release the lock).

Possibly connect the optional composite FBAS (or BNC) cable plug to the correspondingly labeled output of the control unit and connect to an additional external monitor, if available.

Connect the POAG equipotential grounding pin with the appropriate link.

Check network connection, make sure that the nominal voltage and power values are respected.

Connect the endoscopic system with the supplied power cord to the power connector.

Turn on the device. The power switch is located on the back.

To operate, please read Chapter 9 Operating.

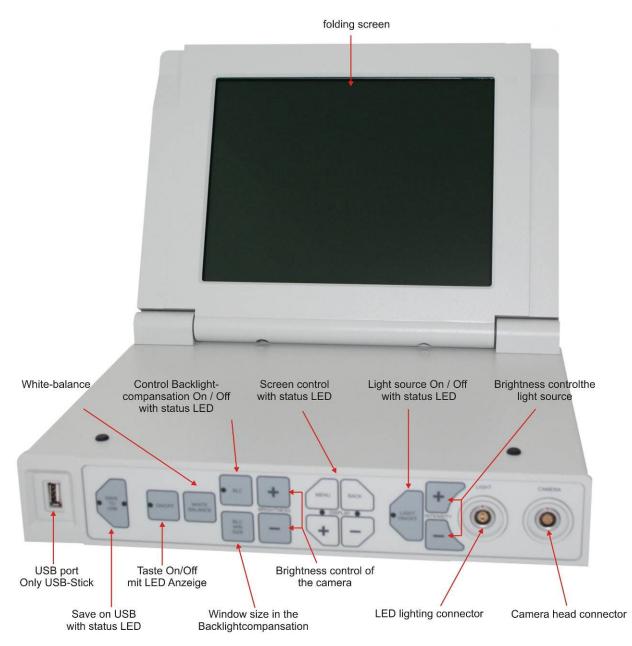
! Attention!

Please make sure that the device is turned on only after checking the power connector and after checking if the device is completely wired.



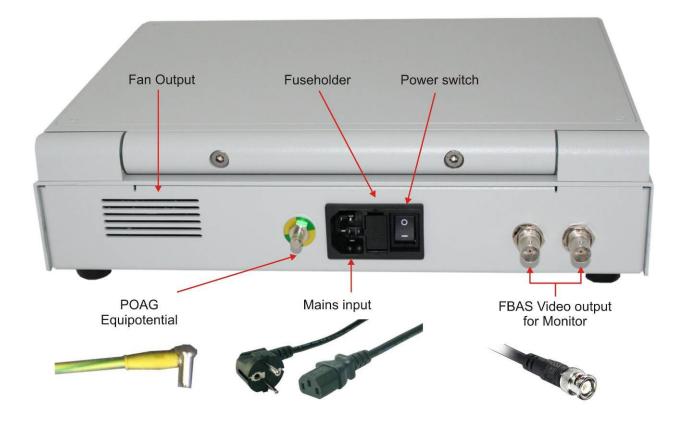
8. Overview of the device

8.1 Front view of the device





8.2 Rear view of the device





9. Operating

9.1 **Possible adaptions**

9.1.1 Endoscope connector (optional)

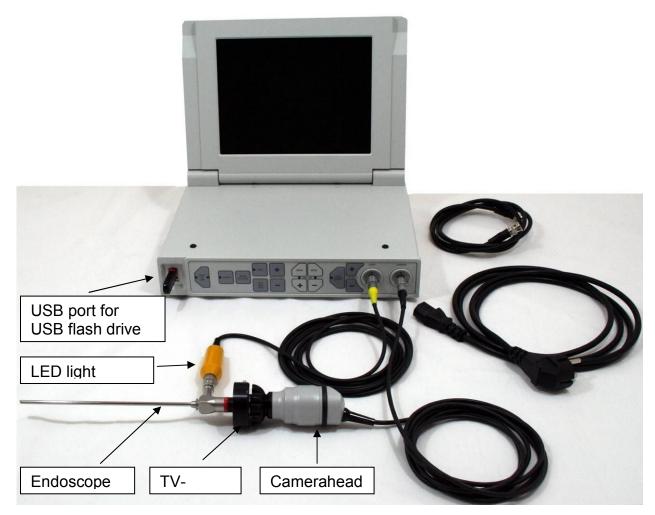
An optional TV adapter and the LED light source can be connected to an endoscope.

Please pay attention to the compatibility here.

By default the light source is supplied with Wolf® compatible light connector.

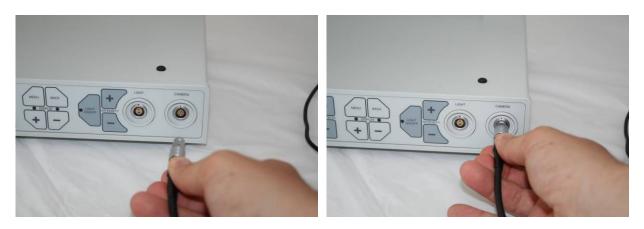
Basic configuration of an endoscopy system:

(which can vary through different combinations of devices)



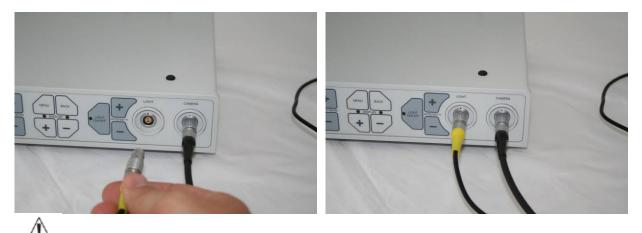


Connect the camera head to the camera connector !



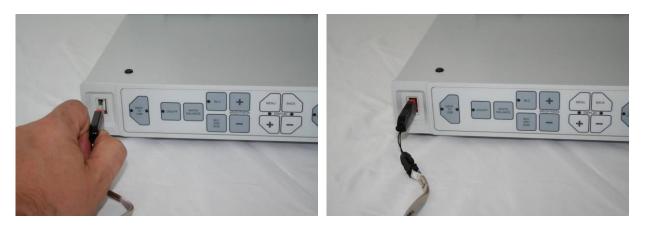
A Pay attention to the locking mechanism of the plug!

Put the light source to the light source connector!



igtriangleup Pay attention to the locking mechanism of the plug!

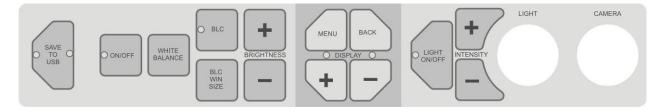
Plug the USB flah drive into the USB port!





Look for the arrest of the USB flash drive!

9.2 Operation of the control unit



9.2.1 Turn on

After plugging in the power cord and turn on the power switch on the back the device is in standby mode, a green status LED in the power button blinks.

By pressing the button "ON / OFF, the device is switched on (the status LED lights now permanently green), by again pressing the power button the device goes back to standby mode.





Note:

In short succession, followed by starting the lamps reduces the lamp life considerably. Please avoid this if possible.

9.2.2 White balance

At the front of the control unit is the button for the application-specific semi-automatic white balance. This white balance is necessary to ensure a lifelike color reproduction in case of different lighting conditions, varying optical circumstances and generally after changing endoscopes.



The semi-automatic white balance is performed as follows:

- Ready for operation (turn on unit and light)
- Adapt endoscope to TV adapter
- Endoscope image blurry set on a white object, while meeting a distance of about 2 to 5 cm between the distal end of the endoscope and a white surface.
 Then press the "WHITE BALANCE" to temporarily operate the LED. On the monitor one can watch how the color of the original increasingly color (white) is adjusted.
 After about 4 seconds, the white balance is completed. The so-chosen color reproduction is maintained up to a re-calibration.

! Important!

To achieve an optimum color fidelity, a white balance after every change of endoscopes is required.

Notice!

To find the optimal white point, it may be helpful to vary the distance between the distal end of the endoscope and the white object while the white balance is made. The white object or the white surface should not reflect or shine. The more matt the better the result. We recommend you to use a piece of white paper (or something similar).



9.2.3 Back Light Compensation BLC

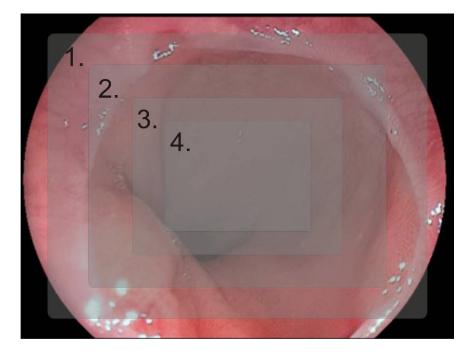
To ensure optimum brightness control and to avoid possibly glare it is possible to activate a socalled viewing window through the BLC button (the Status-LED lights solid green when BLC is turned on).



You can use the button BLC WIN SIZE to choose between four window sizes. This allows your application to obtain an optimal image result.



The size of the set window is presented to you on the display.





9.2.4 Brightness

To adjust the image brightness to your personal feelings, you can adjust brightness with the buttons" +" and " -".



The setting range is from 0 (dark)) to 60 (light).

You can change the values by pressing briefly in individual steps or incremental by prolonged pressure in big steps.

The final values are signaled by a long high note.

9.2.5 Function of the light source

By pressing the button light ON / OFF the light source is turned on. (the Status-LED lights solid green when the light is on)



If the lamp is switched off, the status LED blinks.

Note:

In short succession, followed by starting the lamps reduces the lamp life considerably. Please avoid this if possible.



9.2.5.1 Regulation of light source

The LED light source has an electronic light adjustment system which allows you to manually adjust the required light intensity. The adjustment of light intensity is important: for endoscopes with different diameters (or possibly use of various TV adapters) the integrated camera needs different light intensity to provide a perfect endoscopic picture. Note: Less light is often more image quality!

To approximate the general surgical field illumination according to your personal feelings you can adjust with the buttons INTENSITY "+" and "–" the amount of light.



! Warning !

If it is turned on, do not stare into the outlet of the light source: This could damage your eyes.

! Warning !

Remember that light is a source of energy and due to construction conditions light sources can be very hot.

Please avoid temperatures above + 41° C strictly, otherwise tissue damage may occur!

! Warning !

Remember that light is an energy source that can heat up any endoscope. The application period is limited by the setting the amount of light of the light source. In invasive application temperatures above +41° C at the distal end of endoscopes should be avoided, otherwise you may experience tissue damage!

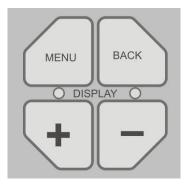


9.2.6 Setting the display

! Inportant!

The display is factory set. Please change settings only by consulting the manufacturer.

Individual adjustment of the display can be set with the display keys Menu, Back, "+" and "-".



(the Status-LED's are orange in standby mode, and solid green when the display is switched on).

In factory defaults the TFT Flatscreen always starts automatically when the whole unit is turned on. It is therefore unnecessary to turn on/off the TFT display separately.



9.2.7 Change the fuses



- 1. Turn the unit off
- 2. Unplug the power cord
- 3. Open the fuse holder
- 4. Replace the defective fuse
- 5. Check the type of backup on the nameplate
- 6. Plug the power cord
- 7. Turn on the unit



10. Cleaning, disinfection, sterilization

! Attention !

Before cleaning or disinfection turn off the device and disconnect from the power source.

Disconnect the unit also from all other devices which are connected to a power source.

10.1.1 Cleaning of control unit

The device is so designed that the smooth surface and the front panel of the control unit can be cleaned gently with a suitable enamelled-friendly detergent in combination with a soft cloth. In case of heavy pollution the keyboard layer can be carefully cleaned for excessive dirt with cotton swabs soaked in alcohol. Sharp-edged objects should not be used for cleaning!

!! Warning !! !! Control unit should not be placed in liquid. !! !! Control unit should not be placed in a cleaning machine. !! !! Avoid getting any liquid inside the Control unit. !! !! Control unit must not be cleaned in an ultrasonic bath. !!

10.1.2 Cleaning of cable with integrated light source

Clean the light source separately from the control unit. Light source can be cleaned with endoscopy approved cleaning fluid. In case of heavy pollution the glass surface within the light source can be gently cleaned with cotton swabs soaked in alcohol. Sharp-edged objects should not be used for cleaning!

10.1.3 Cleaned by cable with integrated camera head and the optional TV adapter

To clean the camera cable disconnect it from the control unit. The camera head can be cleaned in cleaning fluid which is approved for endoscopy. In case of heavy pollution the glass surfaces of the camera and the TV adapter can be carefully cleaned for excessive dirt with cotton swabs soaked in alcohol. Sharp-edged objects should not be used for cleaning!

10.1.4 Drying

The CP-201, the light source, the camera head and the TV adapter must be completely dried after cleaning and then disinfected.



10.2.1 Disinfection of the control unit

The device is so designed that the smooth surface and the front panel of the control unit can be disinfected gently with a suitable enamelled-friendly detergent in combination with a soft cloth.

!! Warning !! !! Control unit should not be placed in liquid. !! !! Control unit should not be placed in a cleaning machine. !! !! Avoid getting any liquid inside the control unit. !! !! Control unit must not be disinfected in an ultrasonic bath. !!

10.2.2 Disinfection of the cable with integrated light source

Disinfect the light source separately from the control unit. Light source can be disinfected in an approved disinfecting liquid for endoscopy.

10.2.3 Disinfection of cable with integrated camera head and optional TV-adapter

To disinfect the camera cable disconnect it from the control unit. The camera head can be disinfected in an approved disinfecting liquid for endoscopy.

10.2.4 Drying

The CP-201, the light source, the camera head and the TV adapter must be completely dry after disinfecting.

10.2.4 Storage

CP-201 must be dried completely.

Disinfected devices should always be stored in a closed sterile area or cabinet and protected against heat, radiation, dust, moisture, temperature changes and contamination.



10.3.1 Sterilization of the control unit

!! Warning !!

!! The control unit is not designed to be sterilized. !!

!! Control unit can not be sterilized in an autoclave, with plasma or other sterilization methode **!!**

10.3.2 Sterilization of the cable with integrated light source

!! Warning !!

!! The light source is not designed to be sterilized. !!

!! The light source can not be sterilized in an autoclave, with plasma or other sterilization methode **!!**

10.3.2 Sterilization of the cable with integrated camera head and a optional TV adapter

!! Warning !!

!! The camera head and a TV adapter is not designed to be sterilized. !! !! The camera head and a TV adapter can not be sterilized in an autoclave, with plasma or other sterilization methode !!

10.3.3 Drying

The CP-201, the light source, the camera head and the TV adapter must be completely dry after disinfecting.

10.3.4 Storage

CP-201 must be dried completely.

Disinfected devices should always be stored in a closed sterile area or cabinet and protected against heat, radiation, dust, moisture, temperature changes and contamination.



11. Maintenance



Regard!

All Blazejewski MEDI-TECH GmbH products include lighting and accessories are supplied non-sterile!

The original packaging includes:

1 pieceCarton1 pieceUpper damping foam1 pieceLower damping foam4 pieceCorner protection foam

In case of a return of the CP-201, or accessories, please always use the original packaging.

Make sure that only clean and disinfected equipment be sent back.

Please protect the CP-201 always from heat, radiation, dust, humidity and temperature fluctuations in storage.



12. Trouble shooting

Problem	Possible Cause	Possible solution
No operation	- No electrical voltage	- Check power supply
		- Check the main fuses
		- Back to the nearest service point
No image	- Device not turned on	- Switch on the device?
	- Cable from the camera is not	- Check connections
	properly plugged	 Check the monitor settings
	- Cable from the camera defective	 Camera head plugged in
	/ broken	correctly?
	- Defective camera	- Check cable connection camera
	- Defective display	head to control unit
		- Check the attached optic
		- Back to the nearest service point
Image is too dark	- Cable from the light source is	- Cable from light source plugged in
	not properly plugged	correctly?
	- Cable of light source is defective	- Check cable connection from light
	/ broken	source
	- Brightness adjustment camera is	 Increase the brightness of the
	too dark	camera with "+"
	- Light source brightness setting is	- To increase the brightness of the
	too dark	light source with "+"
	- Display brightness setting is too	- To increase the brightness of the
	dark	display with a "+"
		- Check the attached optic
		- Replace the light source
		- Back to the nearest service point
Image blur	- Endoscope, TV adapter or	- Check the attached optic
	camera head dirty or fogged	- Check the connected TV Adapter
	- TV adapter is not properly	- Refocus connected TV Adapter
	focused	- Check the camera head
		- Back to the nearest service point
Picture shows an unnatural color	- White balance of the camera not	- Perform white balance
	performed	- Adjust colors on display again
	- Adjust colors on the display	- Check the attached optic
	- Endoscope, TV adapter or	- Check the connected TV Adapter
	camera head damage	- Back to the nearest service point
Others		- Back to the nearest service point

! Important!

The display has a factory set. Please consult the manufacturer befor you change the display settings.



13. Technical data

TV-System	NTSC	PAL	
Display:		-	
Туре	SVGA TFT LCD		
Active screen size	10,4 inches(264mm) diagonal		
Pixel pitch	0.26 mm x 0.26 mm		
Pixel format	800 horiz. By 60	0 vert. pixels	
Luminance,White	250 cd/m ²	² (typ)	
Camera:			
Image Sensor	High resolution Interline transfer 1-CCD-1/3"		
Active Pixel	758 (H) x 492 (V)	752 (H) x 582 (V)	
Active Image Area	4,8 (H) x 3,7 (V) mm (equivalent to 1/3")		
Scanning Lines	525	625	
Scanning System	2:1 Interlaced		
Sync System	Internal		
Scanning Frequency (H)	15.743 kHz	15.625 kHz	
Scanning Frequency (V)	59,94 Hz	50 Hz	
Aspect Ratio	4:3		
Illumination	Standard : 2.500 lux F8 (3.000K) Minimum : 3 lux / F 1.4 (AGC on)		
Video output	2 x FBAS		
Resolution (H)	470	470	
Resolution (V)	350	430	
Signal / Noise Ratio	> 46 dBp-p		
High-Speed-Shutter	Automatic Shutter Control max. Shutter Speed is 1/100.000 sec.		
White balance	semi-automatic, storable		
BLC	ON / OFF with different window sizes		



Features	White Balance, BLC Window-Size, Brightness, Head soakable		
Cable length	3m		
Light source:			
Туре	newest LED Light technology		
Lamp Power	effective 3W		
Color temperature	> 5000K / bright white		
Live time	> 5000 Hours		
Features	Adaptation on standard Endoscope Light guide connector, Brightness control, Head soakable		
Cable length	3m		
USB Capture:			
Storage system	PNG Format (ISO/IEC 15948:2003) License free		
Sorage type	USB Flash Drive (STICK from 16 MB up to 4 GB)		
Triggering	Camerahead- or Frontpanel- switch		



Generally:			
Power Supply	100-250 V AC / 50 - 60 Hz		
Power consumption	Max. 50 W		
Fuse	2 x T 3,15A – 250V		
Weight	Control unit:4 kgCamera head:100g /250g (with cable and connector)LED head:100g /200g (with cable and connector)		
Dimensions	Control unit : (BxHxD) 320 x 250 x 85 mm closed (290mm opened) Camera head : (ØxL) 36 x 70 mm LED head : (ØxL) 30 x 70 mm		
Operating Temperature	+4°C to + 40 °C		
Storage Temperature	-20°C to + 45 °C		
Relative humidity	30% to 90%		
Security:			
Protection class			
Classification	BF without function group with 1 Patient circuit		
Test standard	DIN EN 60601-1, DIN EN 60601-1-2, MPG		



14. Spare Parts

Use only original Spare parts!

Mainfuses	:	T3.15A/250V
Power cord	:	4.503.001.001.2500
	:	

15. Classification

Class1, BF without functionsgroup with 1 patient circuit (resp. EN 60601-1)



16. Warranty, Service and Repair

The Blazejewski MEDI-TECH GmbH grants 12 months on the function of the unit. The validity of this warranty is limited to claims that are submitted within the specified warranty period from date of purchase of the unit, possibly related to repairs, stating the invoice number. This warranty covers only defects are not due to normal wear and tear, misuse, improper handling, inadequate or incorrect treatment, or force majeure.

This warranty excludes wear items.

In cases of maintenance or repair, please contact the Blazejewski MEDI-TECH Service or an authorized repair specialist:

Blazejewski MEDI-TECH GmbH Elzstraße 2 79350 Sexau / Germany Tel.:+49 (0) 7641 / 93067 – 0 Fax.: +49 (0) 7641 / 93067 – 29 www.Blazejewski.de E-mail: info@Blazejewski.de

To facilitate rapid processing of service requests, we ask you to send the product with the following information:

- Model /Articlenumber (REF)
- Serial number (SN)
- the most accurate description of the error



Marning: To protect your staff and the Blazejewski MEDI-TECH employees please clean the unit and its accessories and disinfect it before sending it.

Should this be impossible for urgent reasons, please prepare the unit as much as possible and label it accordingly.

Due to security reasons our service will not repair dirty or contaminated products.

All warranty will be lost if the user performs himself or any unauthorized person or repair shop maintenance and repairs.

Unauthorized opening, repairing and modifications to the device manufacturer exempt from any liability for the safe operation of the plant. During the warranty period expires by any warranty.

In case of any inquiery or sparepartorder always give the Type- und Serialnumber.

Authorized retailer:

Service adress:



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17. Waste disposal

According to the implementation of European law into national laws and regulations you are obliged to proper disposal of medical devices.

The symbol below indicates that medical devices should be disposed of separately from household waste. Please dispose of medical waste in accordance with national and local regulations.



Discard used and contaminated medical devices at a collection point of an appropriate disposal carrier.

"Medical waste" is classified acc. to dangerous goods law (for transportation) by UN number UN 3291.

Please fix the symbol at the bottom to the waste container. Please dispose of medical waste in accordance with national and local regulations.



Packing material, unless contaminated, please dispose of in accordance with national and local regulations.





18. Appendix I Service schedule

Service	Comment	Date	Person