

Vitegra[®]

Visual Integration System

User Manual



Fully integrated documentation and command system for versatile use – in one single device

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1 Legal Notes

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The manufacturer is grateful for information about any errors or inconsistencies in this document.

Due to continuous improvement of our products, we reserve the right to make technical changes that do not affect functionality and basic safety.

1.1 Liability

All procedures, notes and warnings described in this manual do not release the operator/user from his or her responsibilities regarding clinical judgment, experience, and best clinical practice.

2 General Description

The joimax® Vitegra® is a fully integrated documentation system. It enables recording and reviewing of video sequences including audio recordings and still images from endoscopic or other external camera devices.

It can be operated via tablet or touch monitor, voice control, camera head buttons or foot switch. The videos, including audio recordings and pictures, can be reviewed, and archived on external storage devices or in a network.

The Vitegra® also provides the hardware platform to operate the joimax® Vitegra® Command environment.

3 Signs and Symbols

	Please note!
	Warning!
	Separate collection of electrical and electronic devices (in accordance with directive 2012/19/EU, WEEE)
	CE mark of the manufacturer according to MDD 93/42/EEC
	Manufacturer
	Date of manufacture
	Follow Instructions for Use
	Item number
	Serial number
	Caution: U.S. federal law restricts this device to sale by or on the order of a physician.
	Non-ionizing electromagnetic radiation
	Equipotential (potential equalization)
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation
	Keep away from rain
	Keep away from sunlight
	Non-sterile
	Medical Device

3.1 Device Label

Vitegra® **joimax®**

REF ICS0401	Rated Voltage	100-240V~
SN XXXXXX	Rated frequency	60-50Hz
 YYYY-MM	Rated current	4-2A
	Line fuse	2x T 4A H, 250V
	Safety class	I
	EMC class	Group 1 - Class A

joimax® GmbH
Amalienbadstraße 41
RaumFabrik 61
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Germany

MD **CE** **R_x only**

 (01)04250337115281
(11)YYMMDD
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www.joimax.com Rev. 03_2018/001

Vitegra® Tablet joimax®

REF ICS0401T	SN XXXXXX
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R_x only

 (01)04250337116165
(21)XXXXXX

MD 

Rev. 03_2018/001

4 Intended Purpose and Characteristics

**Warning:**

The device must be used only for its intended purpose described in this manual!

4.1 Intended Purpose

The Vitegra® is intended to record videos and still images of multiple connected video sources in the medical field, especially during minimally invasive surgery.

The Vitegra® is intended for documentation purposes only and is not intended for diagnostic use or as image or video archive.

Indications for use

The device is intended to record videos, pictures and audio during surgery, especially during minimally invasive endoscopic procedures, e.g. at the spine.

Contraindications

There are no known contraindications.

Intended patient population

The Vitegra® is intended to be used on adult patients of all genders with appropriate indications (except pregnant women). The use of the Vitegra® is at the discretion of the respective user on the basis of his training and experience.

Intended users

The Vitegra® is intended for use by medical professionals (e.g. surgeons). It must be operated under the supervision of qualified and authorized personnel. Users are required to be trained and familiar with the basic principles, application rules, and risks of the device in order to reliably avoid a risk to the patient, user, and others.

Intended use environment

The Vitegra® is intended for use in operating rooms. The control unit is intended to be positioned stationary outside of the sterile patient environment, e.g. on a medical cart or table that is suitable in terms of tilting stability and weight of the device.

4.2 Characteristics

Performance Characteristics

The Vitegra® Documentation System is fully integrated into the joimax® endoscopy system. It enables simultaneous capturing of multiple analog (2x 4-pin Mini-DIN S-Video YC, 2x BNC composite) and digital (2x BNC 3G/HD-SDI, 2x DVI-I 24+5 HD) video signals of connected imaging devices up to Full HD (1080p60). The videos, including audio recordings and pictures, can be temporarily stored (512GB SSD), reviewed and archived on external storage devices (USB/CD/DVD/Blu-ray) or exported via Network or PACS (10/100/1000 Mbit/s Ethernet). It provides the hardware for the joimax® Command environment for remote status display or adjustment of the electronic devices of the joimax® endoscopic system.

Principles of Operation

Multiple analogue and digital video sources (e.g. camera systems, X-ray devices etc.) are connected to the Vitegra®. An integrated frame grabber digitizes analog incoming video signals and the Vitegra® processes the different digital video streams for display and recording purposes. A tablet or a touch monitor is used to display a graphical user interface and enable control of the software.

Key Components

Vitegra® Control Unit	Vitegra® Tablet
	
A control unit hosting the hardware for the documentation system as well as for the optional remote control interface system Vitegra® Command.	A tablet computer which serves as main display, control and potential remote-control device.

joimax® Touch Monitor

Optional display and input device permanently mounted to the endoscopic cart.

Vitegra® Foot Switch

For intraoperative initiation of basic commands (e.g., start/stop video).

Vitegra® Documentation Software

For basic functionality and unambiguous allocation of the acquired data to the corresponding patient.

Vitegra® Network/DICOM module

Optional software module providing import and export directly to a connected network and Worklist/PACS.

4.3 Clinical Benefits

The use of the fully integrated documentation system joimax® Vitegra® is favorable in terms of the following clinical benefits:

- Support of OR personnel in safe and efficient record keeping in the operating room:
 - Documentation of videos and still images
 - Connection of multiple different signal sources such as endoscopic camera, X-Ray, ultrasound, microscope, OR camera
 - Operation via tablet, touch monitor, voice control, camera head buttons and foot switch
 - Creation of customized reports
 - Safe export of all patient data via Blu-ray, USB, LAN, DICOM
 - User accounts with individual settings
- Support of OR personnel in safe and efficient post-operative record keeping:
 - Operation via tablet and touch monitor
 - Creation of customized reports
 - Safe export of all patient data via Blu-ray, USB, LAN, DICOM
 - User accounts with individual settings

5 Scope of Delivery

After delivery of the joimax® Vitegra®, the packaging must be checked for external damage. If any components are damaged or missing, please contact joimax® customer service.

Item number	Item description		
ICS0401S	joimax® Vitegra® Visual Integration System		
	List of components:		
	Item number	Item description	Quantity
	ICS0401	joimax® Vitegra® Control Unit	1
	ICS0401T	joimax® Vitegra® Tablet	1
	ICS0401TPS	USB Power Supply	1
	JDVI0020	joimax® DVI-D Cable	1
	JBNC0020	joimax® BNC Cable	1
	JSVHS020	joimax® S-Video Cable	1
	JTRS0010	joimax® Remote Cable	2
	JMUSBS128	joimax® USB Flash Drive 128 GB	1
	N/A	Instructions for Use for joimax® Vitegra®	2
	N/A	Instructions for Use for joimax® Vitegra®	2

6 Safety and Warning Notes

6.1 General Safety and Warning Notes

**Warning:**

This device must be used by trained professionals only!

Warning:

Never touch the patient and any signal input or output connectors on the device at the same time!

Warning:

Installation of the device on a medical trolley with multiple socket-outlet leads to the establishment of a medical electrical system and can lead to a reduced level of safety. The requirements of IEC 60601-1 regarding medical electrical systems must always be observed.

Warning:

The device is not intended for use in explosive areas (e.g. in the presence of anaesthetic gas).

Warning:

Keep these instructions for use within easy reach near the device!

Warning:

Read this manual carefully before first use. Protect yourself, patients, and third parties from damage by defective devices or improper operation!

Warning:

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

Warning:

Do not open any component of the joimax® Vitegra®. Opening leads to a reduced level of safety. Never use the device with the housing open.

Warning:

Always make sure blood circulation is not impaired when positioning and sedating the patient.

Warning:

Do not stare into the tablet camera LED. The intense light may cause temporary loss of vision.

6.2 Additional Notes regarding Electrosurgical Equipment

**Warning:**

If the device is used stacked in combination with electrosurgical devices, always position the device above the electrosurgical unit. Ensure that cables of active electrosurgical accessories are not positioned close to video cables.

6.3 Additional Notes regarding MRI (Magnetic Resonance Imaging) and CT (Computer Tomography)



Warning:

Do not use the Vitegra® during MRI or CT scans.

Due to energetic interactions of magnetic fields and X-rays with the material of the control unit and tablet, the electrical components of the Vitegra® may be damaged. Unforeseeable side effects and visual disturbances may occur.

6.4 IT Security Requirements



Warning:

Good physical security must be provided to prevent unauthorized physical access to the device.

Warning:

This device must only be used by trained and authorized professionals.

Warning:

Service activities must only be carried out by authorized service personnel.

Cybersecurity considerations were made in accordance with the nature of the device, including the device type and the use environment (operating room) during its lifetime.

Vitegra® is a networked product, designed to be used in secure and authorized non-internet connected healthcare device networks. As such its external network port is protected by a firewall and no incoming traffic is currently allowed and locked down. If configured to do so it can store data on network shares or access DICOM enabled endpoints. All those requests are outgoing in nature though.

The wireless network for using the Vitegra® Tablet is limited to only allow encrypted Wi-Fi protocols on a serial number related predefined network SSID.

The Vitegra® Control Unit has USB Port access to support accessing or writing data on such devices.

IT security measures include protection against unauthorised access, e.g., user authorization, enabling a switch for complex passwords for user logins and blocking users after 5 failed login attempts.

The healthcare provider is responsible to provide good physical security to prevent unauthorized physical access to the system. The following common best practice security controls ("security hygiene") in the operating environment are recommended to be followed:

- Ensure regulated and authenticated physical access via suitable technical measures (e.g., badges).
- Define roles and access rights, including those for physical access to medical devices.
- Provide security awareness training.
- Ensure that prescribed maintenance is done as required, including installation of security patches/updates.

Contact the joimax® technical support for further information provided on device cybersecurity.

Cybersecurity Vulnerability Reporting

If you detect a cybersecurity weakness or vulnerability of the device or if a cybersecurity incident takes place involving the device, contact joimax® technical support. Depending on the actual event, joimax® technical support will advise which steps to take.

Security Patches/Updates

Security patches/updates are provided by joimax® and may only be installed by authorized personnel. The *Vitegra*® does not allow additional software for malware detection or anti-virus.

6.5 Residual Risks and Undesirable Side-Effects

When using the product, residual risks exist and may lead to the following side-effects for patient, user or third parties: burns, electric shock, user is temporary blinded by the LED light of the tablet camera (seconds) , bacterial or viral infection, possible loss of medical image data, or recorded data assigned to the wrong patient.

7 Installation and Commissioning

**Warning:**

Examine the device, the accessories, and all electrical connections for function and damage prior to use! Defects in cables, connectors, housings, or loose parts can impair performance and safety and must be rectified immediately!

Warning:

This device must be installed and commissioned by authorized personnel only. Improper installation could cause damage to the user, the patient, or others, and might damage the device or other medical equipment.

Warning:

Place the device in a way that allows easy disconnection from the mains.

Warning:

The ambient temperature must not exceed 35° C (95° F) during operation.

Warning:

Place the control unit on a clean, flat surface. Ensure that you keep sufficient space behind the device for efficient airflow. Make sure that a minimum distance of 15 cm (6") is maintained between the back of the device and other objects. All ventilation openings must not be obstructed.



It is recommended to install the device in the joimax® endoscopic trolley.

Keep the original packaging for possible shipment of the device!

The device and all accessories must be checked immediately upon receipt for completeness and obvious damage. Damages may be claimed only if the manufacturer is notified immediately (within a 24-hour period).

7.1 Connection of the System

**Warning:**

To avoid the risk of electric shock, this equipment must always be connected to potential equalization and a power supply with protective earth!

Warning:

Only joimax® accessories (cables etc.) may be used for connection!

Warning:

Always keep cables out of passage areas in order to reduce the risk of stumbling.

Warning:

Make sure all connectors are free of coarse soiling before insertion.

Warning:

Before connecting and starting the system, all components must be visually inspected for integrity. Damaged parts must be replaced. This must be done by experts.

7.1.1 Connections on the Rear of the Device

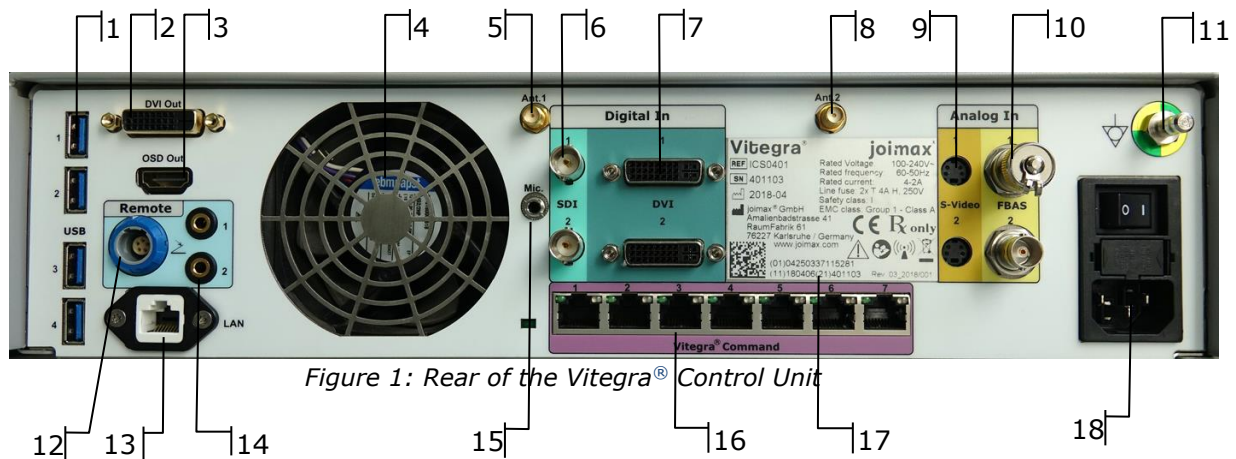


Figure 1: Rear of the Vitegra® Control Unit

1	4 x USB Type A ports	10	2 x BNC ports for Composite/FBAS video input
2	DVI-D 24+1 port for connection of the touchscreen monitor	11	Connector for potential equalization conductor
3	HDMI port for connection of the on screen display	12	Connector for foot switch
4	Fan	13	RJ45 port for connection of hospital network
5	RP-SMA connector for wireless antenna	14	2 x 3.5 mm TRS jack for connection of remote control
6	2 x BNC ports for HD-SDI/3G-SDI video input	15	3.5 mm TRS jack for connection of a microphone
7	2 x DVI-I 24+5 ports for DVI video input	16	7 x RJ45 port for connection of joimax® Command Interface
8	RP-SMA connector for wireless antenna	17	Device label
9	2 x 4-pin Mini-DIN port for S-Video input	18	Mains socket/Fuse holder

7.1.2 Connecting the Device to a Power Supply Network and Potential Equalization


Warning:

To avoid the risk of electric shock, the device must only be connected to a supply mains with protective earth.

Warning:

Always connect the device to a buffered power supply and make sure that the nominal voltage and power values are respected.
Check the power supply cable for damage prior to use!



Always respect the requirements of IEC 60601-1 regarding medical electrical systems.

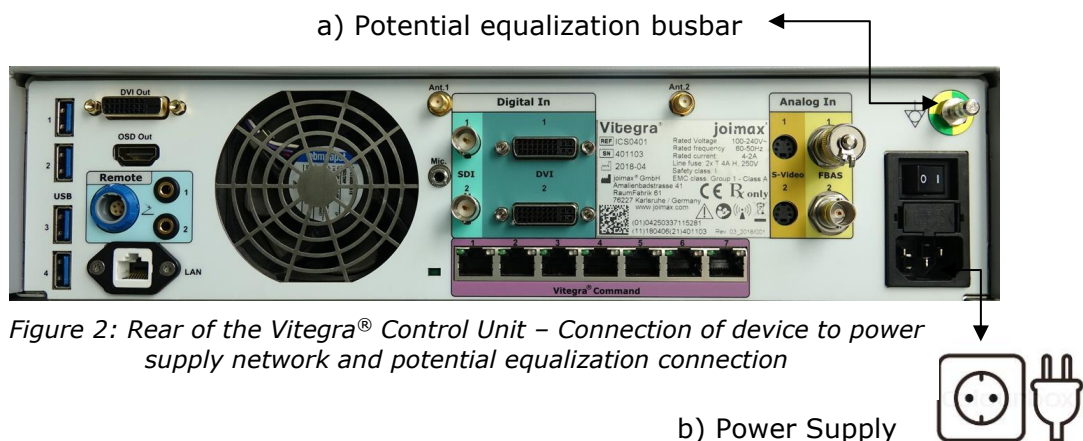


Figure 2: Rear of the Vitegra® Control Unit – Connection of device to power supply network and potential equalization connection

- Connect the potential equalization terminal to the potential equalization busbar of the electrical installation using a potential equalization conductor.
The potential equalization conductor creates electrical connections between conductive components, ensuring that they share the same electrical potential.
- Use the original power cord to connect the power inlet with the mains supply.

For safe disconnection of the device from mains power supply, set the power switch at the rear of the device to position "0" and unplug the power cord from the mains connection.

7.1.3 Connecting Video Input Sources to the Control Unit

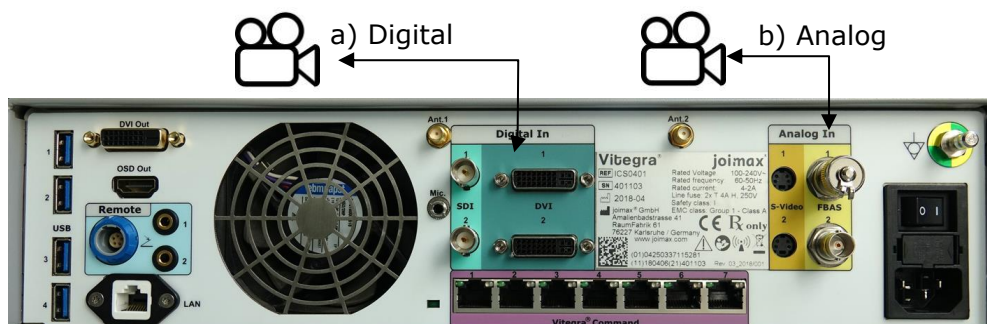


Figure 3: Rear of the Vitegra® Control Unit – Video Input Sources Connection

- Connect the digital output of the video device via a suitable video cable (DVI/SDI or different adapters) to the according "Digital In" connectors of the Vitegra® Control Unit.
- Connect the analog output of the appropriate video device via an appropriate video cable (S-Video/Composite or different adapters) to the respective "Analog In" connectors of the Vitegra® Control Unit.



Configure the input sources in the Vitegra® Settings after cabling, refer to Chapter 8.5.6 Settings Screen - Video Sources.

7.1.4 Network Connections

The Vitegra® software allows users to transfer patient data within an active hospital network. For the usage of the Network/DICOM module and export/import via network, ensure that a secure connection is used. The network information is displayed after a successful connection (see Chapter 8.5.6 – Settings Screen).



To activate the Network/DICOM module, please contact joimax® customer service.

Please connect the Vitegra® control unit only to a **secure** and **authorized** hospital network and never to unknown networks as this may cause the device to be vulnerable to malicious attacks. Please contact the hospital IT technician for further assistance.

In case of a suspected security threat or suspicious behavior of the software, please shut down the device immediately and contact the hospital IT technician.



Figure 4: Rear of the Vitegra® Control Unit – LAN Port

a) LAN Port

a) Connect an Ethernet cable from the LAN port to an active hospital network.

7.1.5 Connecting Accessories



Ensure that all connected external devices (e.g. USB storage device) are free from viruses or malware as this could cause potential damage to the device. It is recommended to connect only storage devices authorized from the hospital IT technician.

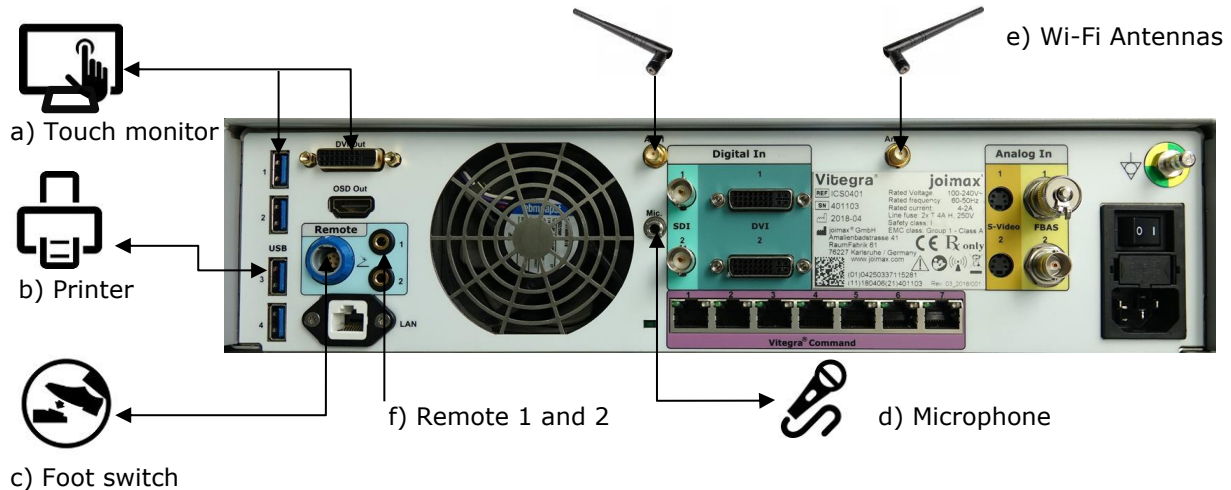


Figure 5: Rear of the Vitegra® Control Unit – Connection of Accessories

Optional: Connect the video input of the touch monitor to the "DVI Out" connector of the Vitegra® Control Unit and connect the USB cable with a USB slot.

- a) Optional: Connect the printer via USB.
- b) Optional: Connect the foot switch to the foot switch socket.
- c) Optional: Connect the receiver of the microphone (unbalanced input) via the provided TRS cable (ICWSR400KA) to the 3.5 mm jack.
Set up the microphone according to the manufacturer's instructions for use.
- d) Connect the two detachable external antennas to the RP-SMA connectors, positioning the antennas as shown above.
- e) Connect two remote cables (JTRS0010) to the 3.5 mm TRS jacks, e.g., for remote control via camera head buttons.

7.1.6 Adding a Printer

Please contact joimax® service for printer setup. The setup of a printer can only be done by joimax® service.

7.2 Functional Tests

After correct wiring, start all connected accessories according to their respective instructions for use, then start the Vitegra® system.

Connect the output of the video capture devices to the video input of the Vitegra® Control Unit and ensure that the Live Screen of the Vitegra® displays the connected video capture devices with a satisfactory image quality.

7.2.1 Behavior in the Event of Malfunctions



In the event of malfunction of the device or changes in its performance that may affect safety (e.g. deviations from the permissible operating conditions) have the faults corrected immediately.

The Vitegra® can be switched off at any time by using the power switch as an emergency stop switch.

Proceed as follows in case of malfunctions:

1. Inspect the Vitegra® and perform a functional test.
2. Contact the joimax® technical support.
3. Report any serious incident to joimax® GmbH and the competent authority having jurisdiction in your locale, see Chapter 18.

8 Operation

8.1 Control Elements

8.1.1 Vitegra® Control Unit



Figure 6: Glass Front of Vitegra® Control Unit

1	Standby button
2	Optical disc drawer (BR/DVD/CD)
3	USB 3.0 port

The Vitegra® is operated via the supplied tablet or the optional touch monitor by simply pressing the corresponding function field of the user interface displayed on the screen. A so-called double-click is not necessary for operation and causes no effect other than repeated execution of the selected function.



Ensure that all connected external devices (e.g., USB storage device) are free from viruses or malware as this could cause potential damage to the device. It is recommended to connect only storage devices authorized from the hospital IT technician.

8.1.2 Vitegra® Tablet

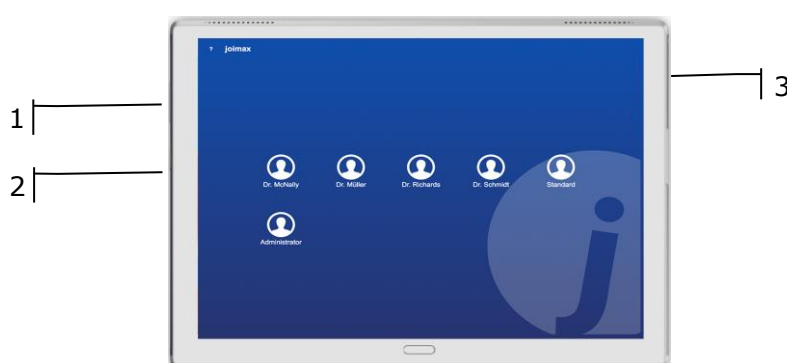


Figure 7: Vitegra® Tablet

1	Volume button
2	On/Off button
3	Charging port

8.2 Starting the Device



Warning:

Make sure that the device is turned on only after checking the power connector and after ensuring that the device is completely wired.



Make sure that the wireless antennas are connected to the control unit, in order to provide a wireless signal for the tablet connection!

Hold the "On/Off" button of the tablet for about 3 seconds to start the tablet.

If the tablet was not connected to a power supply for a longer time, it might be deeply discharged. In this case, connect a power supply to the tablet, wait until the tablet is charged for about 5 % and press the "On/Off" button for about 7 – 10 seconds until the logo appears.

1. Make sure that the device is wired correctly according to the connection instructions provided in Chapter 0.
2. Switch on any other connected devices or accessories, e.g., the optional touch monitor by pressing the "On/Off" button on the back of the monitor.
3. Switch the mains switch at the rear of the control unit to position "I".
4. Push the "Standby" button at the front panel of the control unit to boot the device.
5. Press and hold the "On/Off" button on the left side of the tablet until the logo appears to turn on the tablet.
6. Wait for 20 - 30 seconds until the Login Screen is displayed on the tablet and the optional touch monitor.

It is not necessary to switch off the tablet overnight during daily use. Pressing the "On/Off" button on the left side is enough to put the tablet into sleep mode.
To unlock the tablet screen, swipe upwards.

8.3 Shutting Down the Device



For full disconnection from the power supply, the mains switch at the rear of the device must be switched to position "0".

1. Shut down the control by pressing the "Standby" button on the device front.
2. Press and hold the "On/Off" button on the left side of the tablet for about 2 seconds until the shutdown dialog appears. Select "Power off" to turn off the tablet.

8.3.1 Rebooting the Device

1. Reboot the control unit by pressing the "Reboot" button  in the Vitegra® Settings (refer to Chapter 8.5.6 Settings Screen – System).
2. Press and hold the "On/Off" button on the left side of the tablet for about 2 seconds until the shutdown dialog appears. Select "Reboot" to reboot the tablet.

8.4 Tablet Storage and Charging

joimax® recommends storing the tablet in the optional Vitegra® tablet mount attached to the endoscopic trolley via a holding arm.

To store the tablet, insert it into the tablet mount with the display facing forward from the left, slide and lock it into place.

The tablet's battery is then automatically charged.

The battery needs to be charged before using the tablet. There are two options for charging:

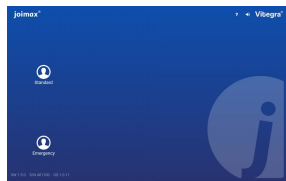
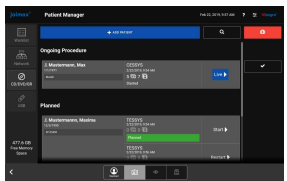
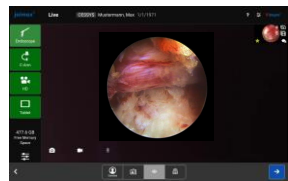
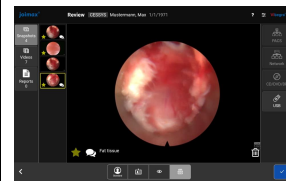
1. Connect the supplied USB cable to the charging port of the tablet. Now, connect the tablet to a power outlet using the USB cable and USB power adapter.
2. Use the optional tablet mount for charging. Insert the tablet into the tablet mount with the tablet display facing forward from the left, slide and lock it into place.

Charging is indicated by a charging battery logo on the tablet display.

8.5 Operation of the Software

8.5.1 General Notes

The Vitegra® software design follows a specific workflow with a corresponding screen set-up each:

			
1	2	3	4
Login Screen	Patient Manager Screen	Live Screen	Review Screen

Screen Layout

On each screen (except the Login Screen), the screen name, information to the actual patient (where applicable), the current date and time, the help question mark and the settings are shown at the top.

Buttons for switching between the different workflow steps and free memory space available are featured at the bottom of the screen.

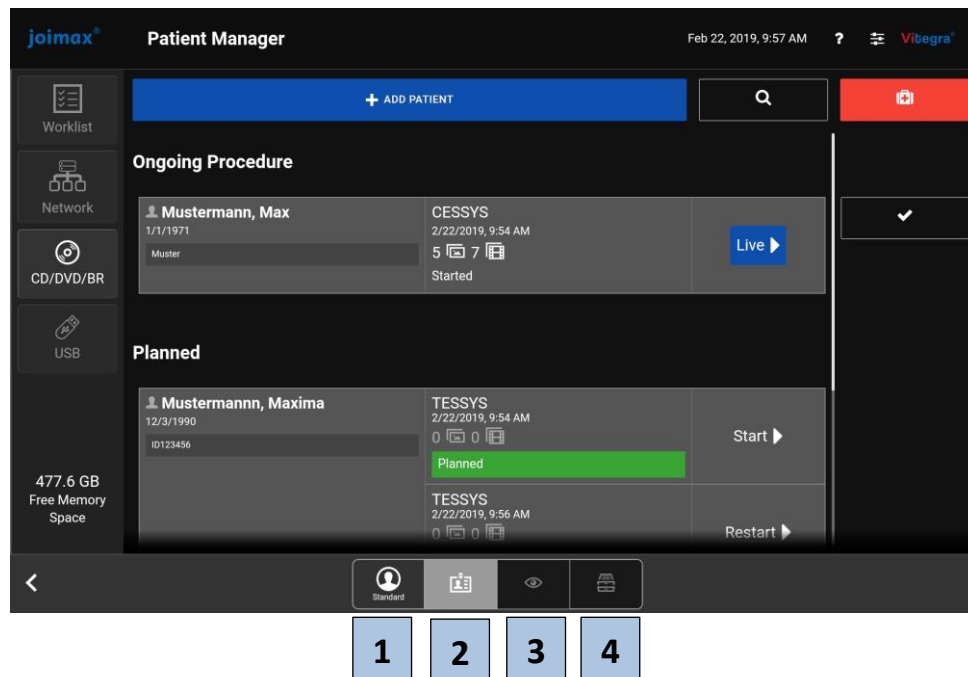


Figure 8: Vitegra® Patient Manager Screen

8.5.2 Login Screen

After starting the Vitegra®, the Login Screen is displayed. As per factory default, there are three users to choose from: *Administrator* (password protected), *Standard* (no password) and *Emergency* (no password).

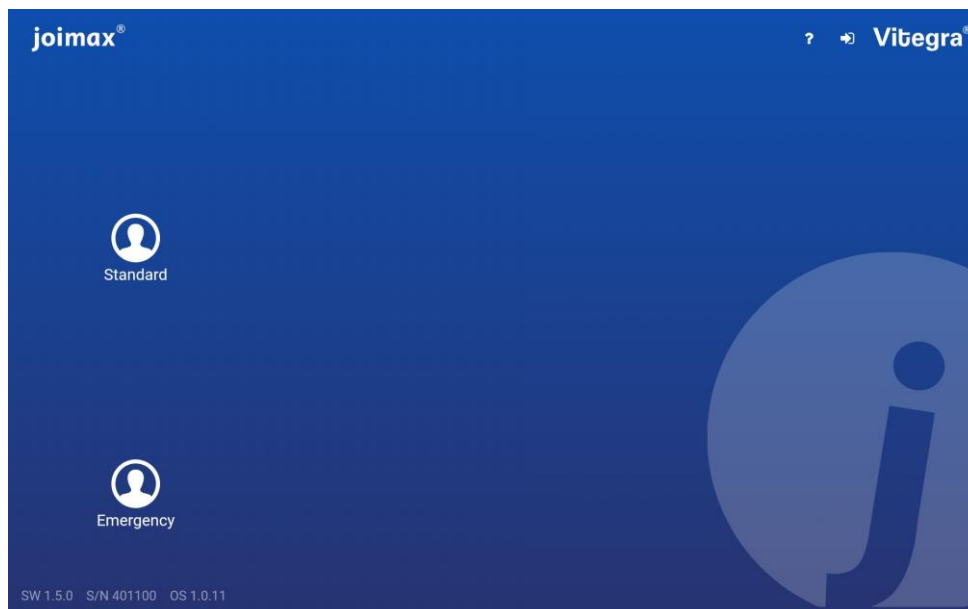


Figure 9: Vitegra® Login Screen

Standard Login

The password of the *Standard* user should be set immediately after first login via the Vitegra® Settings  (refer to Chapter 8.5.6 Settings Screen – Users).

Emergency Login

The *Emergency* user login shall only be used in emergencies.

When logged in as *Emergency* user, only emergency patients can be started, i.e., live recording of the procedure is started postponing the input of patient data until after the procedure.

The *Administrator* has the option to deactivate the *Emergency* user. After deactivation, the *Emergency* user icon in the Login Screen will not be displayed.

Administrator Login

To log in as *Administrator*, press  on the top right corner of the Login Screen. The *Administrator* has access to all available settings in the Vitegra® software.



The initial password for the Administrator login is provided by joimax® service. The password should be changed immediately after first login.

Additional Users

Additional users can be created via the Vitegra® Settings . To do this, log in as *Administrator*, refer to Chapter 8.5.6 Settings Screen – Users.

Security measurements

Entering an incorrect password multiple times locks a user for a certain period of time. After the 5th invalid attempt, the user is locked and no further login for this user is possible. Only the *Administrator* can unlock a locked user via the Vitegra® Settings .

Attempt 1	Warning
Attempt 2	Locked for 10 seconds
Attempt 3	Locked for 30 seconds
Attempt 4	Locked for 180 seconds
Attempt 5	User locked / For <i>Administrator</i> : locked for 1800s

Log Off



On the Patient Manager Screen, the logged in user is shown under the user logo. Press to log off and to return to the Login Screen. Current video recordings are stopped after logging out.

8.5.3 Patient Manager Screen

On the Patient Manager Screen, patient data can be entered manually by pressing . Furthermore, patient data can be imported from network, CD/DVD/Blu-ray or USB. An automatic import from the DICOM worklist is also supported when the Vitegra® Network/DICOM module is not activated.



The worklist icon in the Patient Manager Screen remains greyed out even if the DICOM Worklist is active. Patients from the worklist are automatically imported periodically according to the configured refresh interval as described in Vitegra® Settings  in Chapter 8.5.6 Settings Screen – Import.

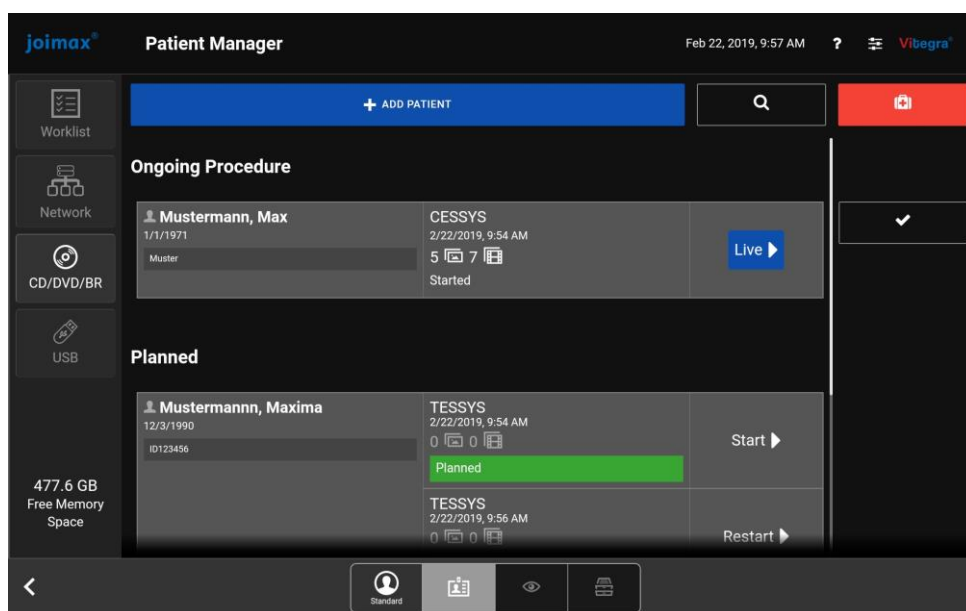


Figure 10: Vitegra® Patient Manager Screen



Existing patients and procedures can be searched by pressing . The search function can search for last name, first name, procedure description and patient ID. The search result for the patient ID is only displayed when the search term is entered completely.



The desired patient and the desired procedure can be selected for live recording or (if closed) for reviewing via .

Several treatments can be assigned to one patient. Further procedures of a patient can be planned by selecting the patient or a procedure in the patient list.

Disk space management

If the available disk space falls under a certain value, warnings appear to warn the user ahead of storage limitations. The user is advised to regularly backup patient data, clear the recycler and clean up old patient data. It is **strongly recommended** to use an external hard disk drive for this purpose. Ensure that the hard disk drive has sufficient space and is **empty** or does not contain any previous backups from the Vitegra®. If so, please remove previous backup data.

Free space available	Action
< 80GB	Warning message is displayed
< 10GB	Video recording is deactivated; button is greyed out
< 1GB	Image capture is deactivated; button is greyed out

Patient List

All patients are sorted by status and within the status by date (date furthest in the future first). The status of the procedures is shown as follows:

Status	Action	Description
Ongoing	Started	Live
		Treatment of the patient is in live recording mode. <i>Note: If a video recording has been started, a blinking REC icon is shown.</i>

Planned	Planned	Start	Procedure is scheduled for an appointment in the future and has not started yet.
Planned	Suspended	Restart	Recordings available but procedure not completed.
Closed	Closed	Review	Procedure with recordings completed.

For all existing procedures, the number of captured pictures and videos is displayed.

Emergency Patient



In case of emergencies, the manual input of patient data can be postponed until after the procedure by pressing . This activates the Live Screen immediately.

Patients and procedures that were created via the emergency function cannot be closed immediately and must be provided with the missing patient information by selecting the patient or the procedure in the patient list. To do this, log in as a standard user (not Emergency User) and remove the emergency flag. Emergency patients are visible to all users and are assigned to the currently logged in user who removed the emergency flag.

Multiple Selection



One or more patients can be selected for export or deletion via  in the Patient Manager Screen. When this function is activated, checkboxes are available next to the patient data. The desired patients can be selected and can then be either exported or deleted. The number of the selected patients and the total size file is shown at the bottom right corner of the Patient Management Screen.

Patient Input

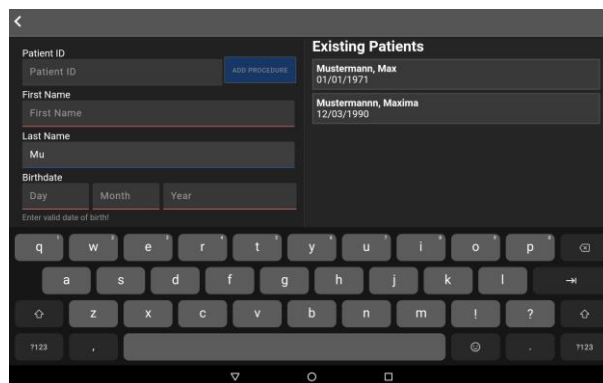


Figure 11: Vitegra® Patient Input screen

First name, last name and birthdate must be entered. When patient data is entered manually, the system automatically searches the saved existing patient data and suggests existing patients on the right-hand side those match the search criteria. The search result for the patient ID is only displayed when the search term is entered completely. If the desired patient already exists in the system, the new procedure can be added to the existing patient to avoid duplicates.



For each Vitegra® software entry, a country-specific virtual keyboard is displayed in the input fields. The language settings of the keyboard can be changed directly on the virtual keyboard (tablet: via space bar / touch monitor: via language icon at the bottom right corner). Language settings for the user interface itself can be changed via Vitegra® Settings  refer to Chapter 8.5.6 Settings Screen – System.

8.5.4 Live Screen

Input Sources



On the left side, the active video input sources are displayed and can be selected (by pressing the respective buttons) to switch between the input sources during live video recording. The recording continues without interruptions.

Additional sources can be added via Vitegra® Settings , refer to Chapter 8.5.6 Settings Screen – Video Sources.

Tap on the center of the displayed video stream to toggle between normal and full screen.

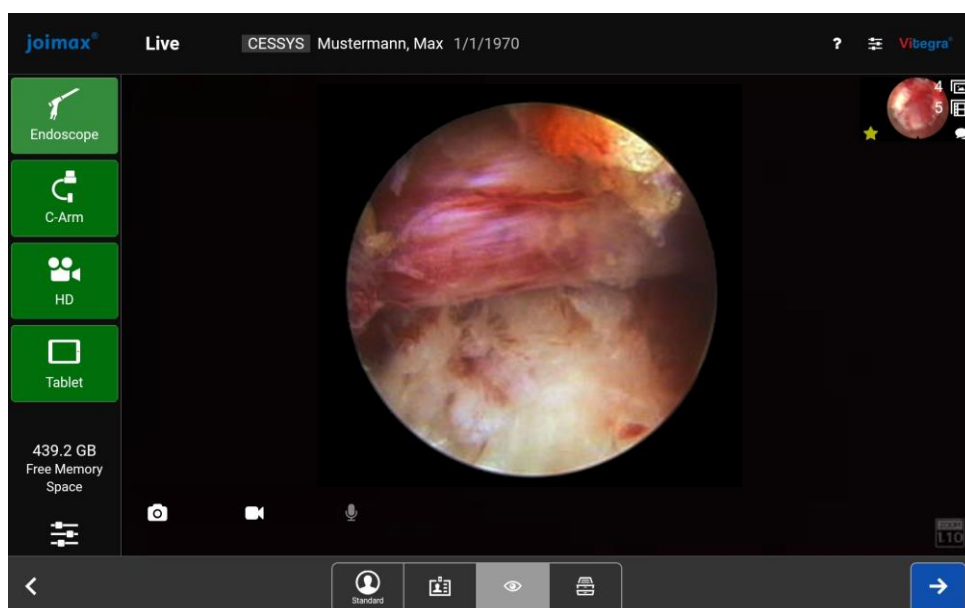


Figure 12: Vitegra® Live Screen

Snapshot, Video and Audio Acquisition



Press to capture a picture of the currently selected video stream.



Press to start or stop a recording of the video stream.



Press to activate or deactivate audio recording. If activated, audio recordings are taken during video recording. This function is only available if it is enabled in the Vitegra® Settings , refer to Chapter 8.5.6 Settings Screen– Recording Options.



If a long video has been recorded, it may take some time after recording stops for the REC icon and the recording icon to stop blinking.

If the file size of a video reaches 4 GB (approximately 45 minutes recording time), a new video file is automatically created. This feature can be activated by the user. This process is signaled by the video signal tone and can be switched on or off in the Vitegra® Settings , refer to Chapter 8.5.6 Settings Screen– Recording Options.

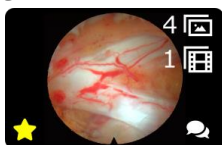
Tablet Camera



Press the tablet button on the tablet to start the tablet camera:

- Press the "Camera" icon to take a picture.
- Press the "Tick" icon to save the picture.
- Press the "Cross" icon to discard the picture.

Quick Review



The most recent image is shown in the upper right corner of the video stream. By clicking on it, the captured pictures can be previewed, commented, marked as favorite, and deleted while recording is in progress.

Remote Control

Besides remote control via the tablet and the optional touch monitor, the Vitegra® software can be operated via the following optional remote-control functions:

- Remote inputs, e.g., for camera head buttons
- Foot switch
- Voice Control

Remote: Input 1 and 2

Make sure that the two remote cables for remote control, e.g., via the camera head buttons, are connected as described in Chapter 7.1.4. Enable remote control and assign the remote commands via Vitegra® Settings . Refer to Chapter 8.5.6 Settings Screen – Remote.

The following commands can be assigned to the remote inputs:

Snapshot, Video Start, Video Stop, Video Toggle, Full Screen, Next Source, Previous Source and Disabled.



If remote control via the Camsource® LED camera head buttons is used, only set one command per input, e.g.:

Remote 1	Signal 1: Snapshot	Signal 2: Disabled
Remote 2	Signal 1: Video Toggle	Signal 2: Disabled

Remote: Foot switch

Make sure that the foot switch is connected as described in Chapter 7.1.5. Enable the foot switch control and assign the remote commands via Vitegra® Settings . Refer to Chapter 8.5.6 Settings Screen – Remote.

The following commands can be assigned to the foot switch buttons:
Snapshot, Video Start, Video Stop, Video Toggle, Full Screen, Next Source, Previous Source and Disabled.

Remote: Voice Control

Make sure that the wireless microphone for voice control is connected as described in Chapter 7.1.5. Enable the voice control and assign the remote commands via Vitegra® Settings . Refer to Chapter 8.5.6 Settings Screen– Remote.

The language of the voice control is automatically set via the system language.
Use the keyword "Vitegra" as trigger followed by a command, e.g "snapshot", to activate the automatic speech recognition. Say, e.g., "Vitegra Snapshot" to take a snapshot.

The following commands can be used:

Vitegra Snapshot, Vitegra Start, Vitegra Stop, Vitegra Source, Vitegra Full Screen, Vitegra Last Image, and Vitegra Live Screen.



The parameters of the speech and command trigger confidence can be adjusted to individual preference if voice control does not detect certain voice commands. Refer to Chapter 8.5.6 Settings Screen – Remote.

8.5.5 Review Screen

In this screen, the captured pictures and videos are shown on the left side and can be selected for editing and export. Treatment reports can be created.

Snapshots View

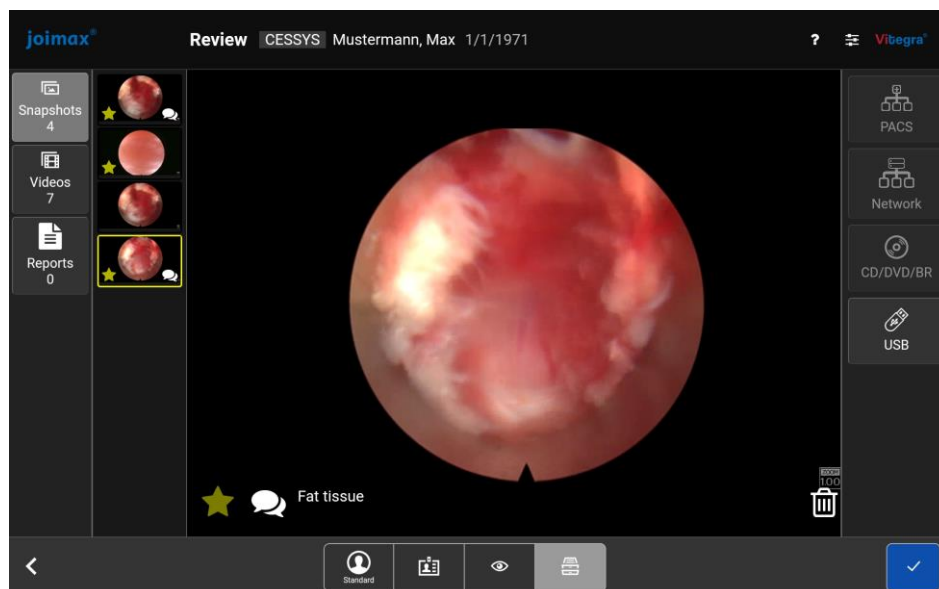


Figure 13: Vitegra® Review Screen – Snapshots View



Press to add comments to a snapshot.



Press to mark a snapshot as favorite. By marking a snapshot as favorite, it will be added to the automatically generated treatment report, and it is included in the export with selection "Favorites".



Press to delete snapshot.

Videos View

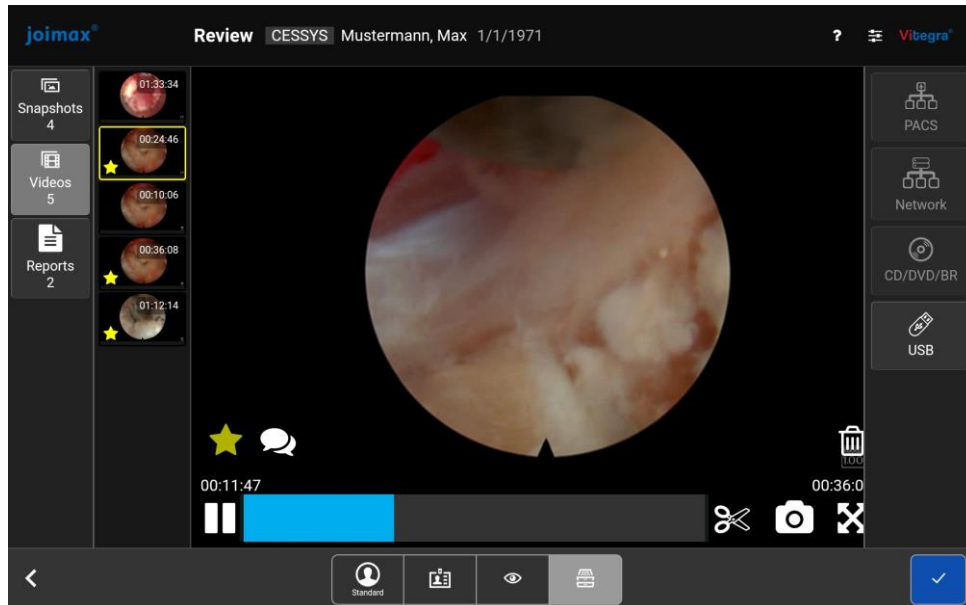


Figure 14: Vitegra® Review Screen – Videos View



Press to play videos.



Press to capture screenshots of the current frame of the video during playback.



Selected areas of a video can be duplicated as a new video. Select the starting point in the video and tap . Select the end point in the video and tap . The selected area of the video is then added to the list of videos as a new video. This can take several minutes depending on the length of the video. The cutting of a video can also be done during video playback.



Press to switch the screen to full screen.



By marking a video as favorite, it is automatically included in the export selection as "Favorites".



Press to add comments to video.



Press to delete video.



If a video recording has been started on the Live Screen, a blinking REC icon is shown on the Review Screen and the video playback of this video is deactivated.

Reports View

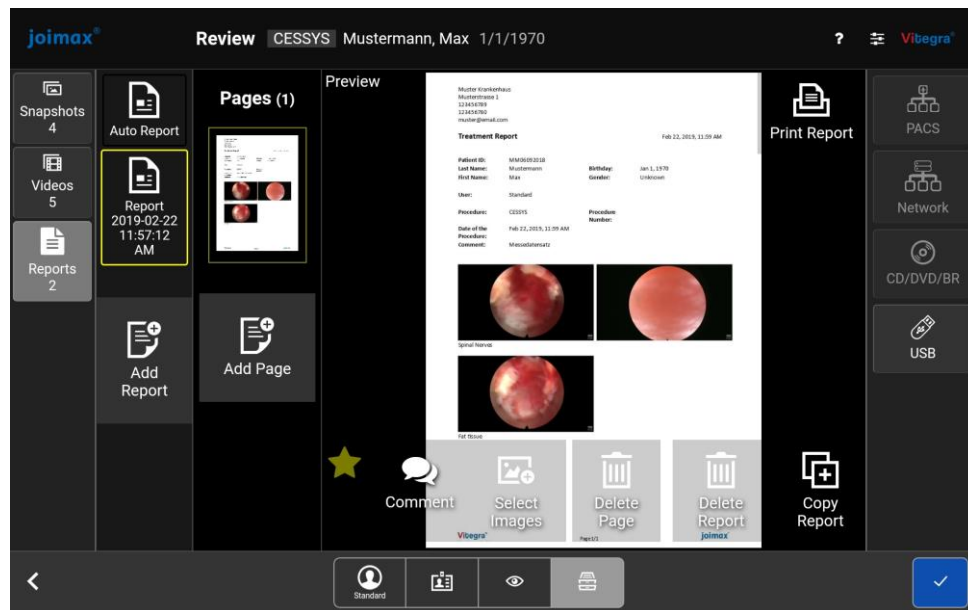


Figure 15: Vitegra® Review Screen – Reports View

Treatment reports can be created, edited and exported afterwards. An automatic treatment report is always created based on snapshots marked as favorites. The automatic treatment report is marked as favorite per default.



Add
Report

Press to create a manual report.



Copy
report

Press to create a copy of an existing report.



Add
Page

Press to add a new page to an existing report.



Select
layout

Snapshots can be included in the report via *Select Layout*. In the upcoming dialog, they can be selected and deselected by simply clicking them. Layouts of the reports can also be selected in the image selection screen. E.g., 2x3, 1x1.



By marking a report as favorite, it is automatically included in the export selection as "Favorites".



Press to add comments to reports or to edit the procedure comment as defined in the Patient Input Screen. To delete a previously written comment, set a space in the comment field.



Press to delete entire report or individual pages.



Press to print treatment reports.



If snapshots included in a manual report are deleted in the Snapshots View, the snapshots remain in the report.

Data Export

All data can be exported to different storage media (PACS, network, CD/DVD/Blu-ray, and USB) by clicking on the corresponding button on the right side of the Review Screen.



To export via Network/DICOM, an activation code is needed to unlock this module. Please contact joimax® customer service for further information.

The following export parameters can be selected:

- Selection: Favorites or All (default "All", can be changed via Vitegra® Settings )
- Format Images: Standard (.jpg) or DICOM (default "Standard")
- Format Videos: Standard (.mp4) or DICOM (default "Standard")
- Format Reports: PDF and/or Word (default "PDF and Word")



For exporting data via USB, it is recommended to use a USB 3.0 storage medium, e.g., the joimax® USB Flash Drive 128 GB.

For the export to USB and CD/DVD/Blu-ray, the size of the files to be copied (yellow bar) is displayed compared to the free memory space on the selected medium (blue bar). If a red bar is shown, there is not enough free space available.



Reading a CD/DVD/Blu-ray may take up to a minute.

A progress bar  is shown on the selected export icon during data transfer.

Export File Structure

The folder structure and naming of the exported files is as following:

Description	Format
<u>Patient folder:</u> Doe, John_1970-01-01_007	<Last name>, <Firstname>__<birthdate(YYYY-MM-DD)>__<patient ID>
<u>Procedure folder:</u>  2020-01-10T17_38_25.345+01_00_iLESSYS 22.01.2020 09:53  2020-01-10T17_38_25.345+01_00_iLESSYS.txt 22.01.2020 09:52  patient.dat 22.01.2020 09:54	<Procedure date(YYYY-MM-DD)> T(for Time) <Procedure time(hh_mm_ss_sss)> + <Time zone>__<Procedure type>.

Closing of a Procedure

Tap  to end the review and close the procedure. The Patient Manager Screen will then be displayed.

When a video recording has been started, it is stopped as soon as a procedure is closed.

8.5.6 Settings Screen

The settings menu can be entered via Vitegra® Settings . The settings are thematically divided into different screens, which can be selected via the navigation bar on the left side.

A distinction is made between settings that are valid for all users and user-specific settings (marked as *user-specific setting* in the following).

Vitegra

Vitegra



Turns off the Vitegra® Control Unit.



Reboots the Vitegra® Control Unit.



Ejects the optical disc drawer of the Vitegra® Control Unit.

Information on hardware, software, and operating system as well as manufacturer information are displayed.

Version The serial number of the Vitegra® Control Unit, the current software and operating system version number and MAC address of the external Ethernet port provided for the hospital connection (display depending on software version) are displayed.

The Vitegra® Tablet also displays the tablet version and tablet build.

Manufacturer The manufacturer name, address, website, and contact details are shown here.

Activation Code The serial number and activation code are entered here. The Network/DICOM module can be activated here.



The "Activation Code" tab is available depending on the software version.

Please contact joimax® customer service for the activation of the modules.

System

System

Date & Time The current date and time are displayed here.



Only the Administrator can change the date and time. Changing this setting may require up to a minute to take effect.

Language The language of the system (*user-specific setting*) can be changed here via a dropdown list: EN-US / DE / ZH-CN / FR / IT / ES / PT-BR / RU.



A reboot is required after changing the language for the change to take effect.

<i>Sound</i>	The device volume and microphone level can be adjusted here.
<i>Network</i>	The network information is displayed here (MAC-address, DHCP, Gateway, IP, and Mask).

Video Sources

Video Sources

The input sources have to be manually enabled and disabled. The user can select the signal input and add/change the name and the logo of the input source here.

Available input sources are:

- SDI 1 and SDI 2 (Digital)
- DVI 1 and DVI 2 (Digital)
- S-Video 1 and S-Video 2 (Analog)
- FBAS 1 and FBAS 2 (Analog)

Recording Options

Recording Options

The user can enable/disable the option to limit the recording duration and set the limit time (in minutes) of a video recording (0 minutes = no limit) (*user-specific setting*).

The user can enable/disable the option to limit the file size of a video recording to 4 GB (*user-specific setting*). If the file size of a video reaches 4 GB (e.g., approximately 45 minutes recording time using the Camsource® LED), a new video file is automatically created. This process is signaled by the video signal tone. This setting is available depending on the software version.

Audio recording (*user-specific setting*) additionally to video recording can be enabled/disabled here.

Remote

Remote

Remote Inputs The user can enable/disable the usage of remote inputs of a camera head with function buttons here (*user-specific setting*).

Make sure that the two remote cables for remote control, e.g., via the camera head buttons of the Camsource® LED, are connected as described in Chapter 7.1.5.

To use this function, the user must also activate the remote control in the remote device, e.g., Camsource® LED settings.

The following commands can be assigned to the remote inputs: Snapshot, Video Start, Video Stop, Video Toggle, Full Screen, Next Source, Previous Source and Disabled.



Ensure that the remote cables are connected correctly to the camera (e.g., Remote 1 of the Vitegra® to Remote 1 of the Camsource® LED) and that remote control is activated in the camera settings.

If the remote control via the Camsource® LED camera head buttons is used, only set one command per input, e.g.:

Remote 1, Signal 1: Snapshot, Signal 2: Disabled.

Remote 2, Signal 1: Video Toggle, Signal 2: Disabled.

Foot switch

The user can enable/disable the usage of a compatible foot switch here (*user-specific setting*).

Make sure that the foot switch is connected as described in Chapter 7.1.5.

The following commands can be assigned to the foot switch buttons:
Snapshot, Video Start, Video Stop, Video Toggle, Full Screen, Next Source, Previous Source, and Disabled.

Voice Control

The user can enable/disable the usage of voice control here (*user-specific setting*).

Make sure that the wireless microphone for voice control is connected as described in Chapter 7.1.5.

The language of the speech control is set to the system language.



A reboot is required after changing the language for the change to take effect.

Use the keyword "Vitegra" as trigger followed by a command e.g., "Snapshot" to activate the automatic speech recognition. Say, e.g., "Vitegra Snapshot" to take a snapshot.

The following commands can be set:

Command	Function	Description
Vitegra Snapshot	Disabled	Disabled
	Snapshot	Take a snapshot
Vitegra Start	Disabled	Disabled
	Video Start	Start video recording
Vitegra Stop	Disabled	Disabled
	Video Stop	Stop video recording
Vitegra Source	Disabled	Disabled
	Next Source	Select the next active video input source
	Previous Source	Select the previous active video input source
Vitegra Full Screen	Disabled	Disabled
	Full Screen	Toggle between normal screen and full screen
Vitegra Last Image	Disabled	Disabled
	Last Image	Show the last snapshot taken
Vitegra Live Screen	Disabled	Disabled
	Live Screen	Return to active Live Screen

The thresholds for speech trigger confidence and command confidence can be increased and decreased. The thresholds determine the sensitivity for the keyword or a command to be recognized. Increasing the value lowers the possibility to recognize a false keyword or command. Recommended values are 50 for speech trigger confidence and 30 for command confidence.



Adjust the speech trigger confidence threshold or command confidence threshold if speech control does not work reliably.

Lowering the command confidence threshold can trigger false commands which sound like the intended commands.

Procedures

Procedures

General

The user can enter procedure types and pre-formed comments in the text field. These procedures are available for selection in a dropdown list on the patient input screen (*user-specific setting*). The user can select pre-formed comments in a dropdown list when entering image, video, and report comments.



A new pre-formed comment can be added to the dropdown list by adding a new line to the text field.

Hospital

The hospital name, address, contact details, and logo can be entered here (*user-specific settings*). This information will then appear in the digital and printed treatment report.

To upload a hospital logo, connect a USB storage device with the image stored as .png or .jpg **directly in the root directory** of the USB storage device. Please ensure that there is only **one** image saved in the root directory.

Users

Users

The *Standard* user and each added user can modify its username and password. The *Standard* user can also choose to share patients with other users.

The *Emergency* user cannot modify its username. The patients created by the *Emergency* user are shared with all other users. The *Administrator* has the option to deactivate the *Emergency* user. After deactivation, the emergency user icon in the Login Screen will not be displayed.

The *Administrator* cannot modify its username but can modify its own password. Furthermore, the *Administrator* can add, edit, and delete users, toggle patient visibility and change passwords of all users.

When a new user is created, all current settings of the *Administrator* are used for the new user.

When a user is deleted, the patients of this user are still visible to the *Administrator*.

Complex passwords can be toggled on or off. Complex passwords require to be at least 8 characters long and must contain at least 3 criteria from the following: uppercase letter, lowercase letter, special characters, or numbers. By activating complex passwords, existing users with simple passwords are not affected unless the passwords are changed.



The Administrator can see all the patients of all other users even if patient sharing is disabled.

The Emergency user is not password protected.

The Administrator and Emergency user account cannot be deleted.

In case of forgotten passwords, the administrator can reset the user's password. If the Administrator account's password is forgotten or manipulated, please contact joimax® customer service.

Export

Export

Export Selection The user can enable/disable the option to limit the export only to images, videos and reports marked as favorites by default (*user-specific setting*).

DICOM Archive The user can configure DICOM related settings here. IP-address, port number, AE Titles must be entered correctly to enable export to PACS. The user can additionally choose to send PDF or MPEG-4 file formats depending on the PACS system used in the facility.



The export via DICOM is only available if the Vitegra® Control Unit is connected to the hospital network with the configured destination folder. Please contact the hospital's IT Department. Ensure that the Network/DICOM module is activated.

Network The user can activate/deactivate and define the data export to a shared network drive (*user-specific setting*).



The export via network is only available if the Vitegra® Control Unit is connected to the hospital network with the configured destination folder. Please contact the hospital's IT Department. Ensure that the Network/DICOM module is activated.

Import

Import

DICOM Worklist The user can configure Worklist related settings here. IP-address, port number, AE Titles must be entered correctly to enable import from the worklist. The user is additionally able to enter the desired refresh interval times. In the case of special characters, the user has the option to override the character set and select from a list of international character sets, if the worklist server does not use UTF8 encoding.



Ensure that the Network/DICOM module is activated.

Network The user can activate/deactivate and define the data import of a shared network drive (*user-specific setting*).



The import via Network is only available if the Vitegra® Control Unit is connected to the hospital network with the configured destination folder. Please contact the hospital's IT Department. Ensure that the Network/DICOM module is activated.

Service

Service

Operations



Update

Updates the Vitegra® software when a USB storage device with the update is inserted, refer to Chapter 12.2 Software Update (*Standard* user and *Administrator*).



Service

The password-protected service mode can be activated here via the *Administrator* login (*Administrator* only). Only the joimax® service has access to the service mode.



Backup

Creates a backup of all user and patient data and the current settings configuration (inclusive user-specific settings) when a USB storage device is inserted (*Administrator* only).



Restore

Restores user and patient data and settings configuration (inclusive user-specific settings) from a USB storage device from backup. All patient data and settings prior to the restoring process are overwritten (*Administrator* only).



Reset

Erases all user and patient data and settings configuration saved on the system and resets the whole system back to factory defaults (only *Administrator*).



Use **one** empty USB storage device for one backup file.

Ensure that sufficient free space is available on the external USB storage device before attempting a backup to prevent corruption of data. It is strongly recommended to use an external hard disk drive. Ensure that the hard disk drive is empty or does not contain any previous backups from the Vitegra®.

Use an exFAT or NTFS formatted USB storage device (formats with no file size limitation in comparison to FAT32) in order to allow copying files larger than 4 GB during the backup.

Do not use or turn off the Vitegra® Control Unit during backup and restore!

User and patient data as well as settings cannot be restored after reset!

During reset, the Vitegra® Control Unit is rebooted. Therefore, the tablet shows for a short time a lost connection before automatic reconnection.

The control unit will reboot after a successful restore process. If the control unit does not reboot, retry by selecting the restore button again, as this may indicate a failure of restoring data.

Recycler

Recycler

Here, the user can restore a patient/procedure after deletion from the patient list. Deleted patient/procedure data via the reset function cannot be restored.

The user can permanently delete all patients/procedures listed in the recycler or patients/procedures with a deletion date older than two weeks.

Only the creator of the patient can restore his/her patients from the recycler.



Deleted data will be automatically and permanently deleted from the system after 30 days.

9 Processing



Warning:

The Vitegra® Control Unit, the Vitegra® Tablet and the joimax® Touch Monitor must be cleaned and disinfected before first use.

Warning:

The Vitegra® Control Unit, the Vitegra® Tablet and the joimax® Touch are not suitable for sterilization and must not be sterilized.

Warning:

Check the device and all accessories after processing and prior to every use for damage and for proper operation.

Warning:

Before cleaning or disinfection, turn off the device and disconnect it from the power source. Also, disconnect it from all other devices connected to a power source.

Warning:

If the tablet is to be used within the sterile patient environment, a disposable sterile cover must always be used!



Always respect locally applicable regulations and hygiene procedures of the hospital.

9.1 Cleaning and Disinfection of the Control Unit



Warning:

Ensure no liquid enters the Vitegra® Control Unit during cleaning and disinfection.

Warning:

Before cleaning or disinfection, turn off the device and disconnect it from the power source. Also, disconnect the Vitegra® Control Unit from all other devices connected to a power source.

Warning:

In case of severe soiling, the front panel of the control unit can be carefully cleaned with a cotton swab soaked in alcohol. Do not use any sharp objects for cleaning!



For effective wipe disinfection of the Vitegra® Control Unit, use of Mikrozyd® sensitive wipes (Schülke & Mayr) is recommended by joimax® GmbH.

The surfaces of the Vitegra® Control Unit can be cleaned and disinfected with a suitable mild varnish- and plastic-friendly cleaning and disinfectant detergent using the following procedure:

1. Switch off the control unit and disconnect it from the power supply.
2. Seal the USB port at the device front with the enclosed plug.
3. Wipe the surface of the device with a clean, soft cloth, moistened with a mild, pH-neutral detergent or disinfectant.
4. Wipe the surface of the device again with a sponge or a soft cloth, moistened with clean water.
5. Dry the surface of the device with a clean and lint-free cloth.

9.2 Cleaning and Disinfection of the Tablet/Touch Monitor

**Warning:**

Ensure no liquid enters the Vitegra® Tablet and Vitegra® Touch Monitor during cleaning and disinfection.



For effective wipe disinfection of the Vitegra® Tablet and Touch Monitor, use of Mikrozyd® sensitive wipes (Schülke & Mayr) is recommended by joimax® GmbH.

The Vitegra® Tablet can alternatively be used with a sterile cover.

1. Switch off the tablet/touch monitor and disconnect the devices from the power supply.
2. Wipe the surface of the tablet/touch screen with a clean, soft cloth, moistened with a mild, pH-neutral detergent or disinfectant.
3. Wipe the surface of the tablet/touch screen again with a sponge or a soft cloth, moistened with clean water.
4. Dry the surface of the tablet/touch screen with a clean and lint-free cloth.

9.3 Cleaning and Disinfection of Accessories

Prepare the accessories as described in the corresponding processing instructions.

10 Technical Data

Vitegra® Control Unit	
General	
Processor	Intel CPU i5 64-bit processor with 4 cores, 3.5 to 4.1 GHz
Video capture	High Quality up to Full HD 1080p60 BNC 3G/HD-SDI, DVI, S-Video (YC), Composite Video
Integrated Data Storage	512 GB SSD data storage
Optical drive	Blu-ray disc drive supports: BD-R (SL 10x/DL 8x), DVD-R (16x), DVD+R (16x), CD-R (48x)
Network	Data transfer rate 10/100/1000 Mbit/s
Wireless communication	Antenna: 2x detachable external antennas Wireless standard: IEEE 802.11b/g/n Frequency: 2.4–2.4835 GHz Signal Rate: 300 Mbps at 2.4 GHz Wireless Mode: Ad-Hoc Security: encrypted connection to tablet Modulation: DBPSK, DQPSK, CCK, OFDM, 16-QAM, 64-QAM
Connectors	
Video input	2x BNC 3G/HD-SDI input 2x DVI-I 24+5 HD input 2x 4-pin Mini-DIN S-Video analog input 2x BNC composite analog input
Video output	1x DVI output – touch monitor 1x HDMI output - OSD
Audio	1x Audio IN (3.5 mm TRS connector)
Ethernet	1x RJ45 Gbit Ethernet network 7x RJ45 joimax® Command ports
Remote	1x connector for foot switch 2x 3.5 mm TRS connectors for e.g. camera remote control
Other	1x USB 3.0 front 4x USB 3.0 back 2x Ant.1 & Ant.2, RP-SMA female – WiFi antenna 1x Medical potential equalization
Technical Data	
Power Supply	100–240 V~ - 50/60 Hz
Input current	2–4 A
Fuse	2x T 4A H, 250 V
Weight	9.6 kg
Dimensions	90 mm x 374 mm x 440 mm (control unit)

Vitegra® Tablet	
General	
Type	Lenovo Tab4 10 Plus TB-X704-F
Processor	Qualcomm® Snapdragon™ 625
Battery	Li-ion Polymer 2-cell (7000 mAh)
Graphics	Integrated Qualcomm Adreno™ 506 GPU in processor
Memory	Max 4GB / LPDDR3, soldered to systemboard
Display	10.1" (257mm) FHD (1920x1200), color depth 16 million, color gamut 70%, 400 nits, 16:10 aspect ratio, IPS display
Multi-touch	Capacitive-type multi-touch, support 10 fingers
Integrated data storage	Up to 64GB eMCP (embedded Multi-Chip Package) flash memory on board
Wireless communication	WiFi 802.11 a/b/g/n/ac, Dualband (2.4 GHz /5 GHz)
Camera	Front camera: 5.0-megapixel, fixed focus Rear camera: 8.0-megapixel, auto focus
Connectors	
USB	1x Type-C USB 2.0
Audio	1x Dolby Atmos® audio, 3.5mm combo audio / microphone jack
Card slot	MicroSD card slot, support FAT32 up to 128GB
Technical Data	
AC adapter	5.2V/2A AC
Weight	0.475 kg
Dimensions	247 mm x 173 mm x 7 mm

joimax® Vitegra® System	
Operating Conditions	
Temperature	+10 °C to +35 °C / +50 °F to +95 °F
Relative humidity	30–75 %, non-condensing
Atmospheric Pressure	70 kPa to 106 kPa
Max. Altitude	3000 m
Transport/Storage Conditions	
Temperature	-40 °C to +70 °C / -40 °F to +158 °F
Relative humidity	10 % to 100 %, non-condensing
Atmospheric Pressure	50 kPa to 106 kPa
Special conditions	Keep the device dry and protected from sunlight.
Safety	
Protection class	I
Applied Standards	
IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 62304, IEC 62366-1	

11 EMC Notes

**Warning:**

The Vitegra® mandates special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided.

Warning:

The use of accessories and cables other than those specified or provided by the manufacturer of this equipment may result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning:

Use of this device adjacent to or stacked with other devices should be avoided, because it might result in improper operation. If the endoscopic camera must be used in a stacked configuration or adjacent with other electronic devices, this device and the other devices must be observed to ensure normal operation.

Warning:

This product may emit radio frequency energy and, if not installed and used according to the instructions, may cause harmful interferences to other devices in the vicinity. If this product interferes with other devices, the user is encouraged to try the following in order to correct the interference:

- Increase the distance between interfering components.
- Consult the manufacturer of the other device for help.

Warning:

Portable RF communications equipment should be used no closer than 30 cm (12") to any part of the Vitegra®. Otherwise, the performance of this equipment might be impaired.



This equipment has been tested and found to comply with the requirements regarding electromagnetic compatibility (EMC) according to IEC 60601-1-2. The customer or user of the Vitegra® has to ensure that it is operated in such environments.

The Vitegra® is suitable to be used in combination with RF surgical equipment. The device was tested according to IEC 60601-2-2, BB.4 and can withstand the emissions produced by such equipment.

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 group 1, class A). If it is used in a residential environment, (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

The Vitegra® is suitable for use in professional healthcare facility environments according to IEC 60601-1-2.

Phenomenon	Compliance	Electromagnetic environment – guidance
Conducted and radiated RF emissions	Group 1	The joimax® Vitegra® 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.
	Class A	The joimax® Vitegra® is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic distortion	Class A	
Voltage fluctuations and flickers	Compliant	

Phenomenon	Basic EMC standard or test method	Immunity test levels	Compliance levels	Electromagnetic environment – guidance
Enclosure Port				
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be made from wood, concrete or ceramic tiled. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF EM fields	IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the joimax® Vitegra® including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Proximity fields from RF wireless communication equipment	IEC 61000-4-3	See table "Enclosure port immunity to RF wireless communication equipment" below		Minimum distances between the joimax® Vitegra® and wireless communication equipment as specified in table "Enclosure port immunity to RF wireless communication equipment", must not be undercut.
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz	30 A/m 50 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Phenomenon	Basic EMC standard or test method	Immunity test levels	Compliance levels	Electromagnetic environment – guidance
Input AC power port				
Electrical fast transients / bursts	IEC 61000-4-4	±2 kV 100 kHz repetition frequency	±2 kV 100 kHz repetition frequency	The quality of the supply voltage must be that of a typical business or hospital environment.
Surges Line-to-line	IEC 61000-4-5	±0.5 kV, ±1 kV	±0.5 kV, ±1 kV	
Surges Line-to-ground	IEC 61000-4-5	±0.5 kV, ±1 kV, ±2kV	±0.5 kV, ±1 kV, ±2kV	
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the joimax® Vitegra® including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Voltage dips	IEC 61000-4-11	0 % U T ; 0.5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0 % U T ; 0.5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the joimax® Vitegra® requires continued operation during power mains interruptions, it is recommended that the joimax® Vitegra® be powered from an uninterruptible power supply or a battery.
Voltage interruptions	IEC 61000-4-11	0 % U T ; 250/300 cycles	0 % U T ; 250/300 cycles	

Signal input/output parts port				
Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be made from wood, concrete or ceramic tiled. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transients / bursts	IEC 61000-4-4	±1 kV 100 kHz repetition frequency	±1 kV 100 kHz repetition frequency	The quality of the supply voltage must be that of a typical business or hospital environment.
Surges Line-to-ground	IEC 61000-4-5	±2 kV	±2 kV	
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the joimax® Vitegra® including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

Enclosure port immunity to RF wireless communication equipment							
Test Frequency (MHz)	Band	Service	Modulation	Max. Power (W)	Distance (m)	Immunity Test Level (V/m)	Compliance Level (V/m)
385	380 – 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27	27
450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28	28
870							
930							
1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28	28
1845							
1970							
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9	9
5500							
5785							

12 Service/Maintenance Instructions


Warning:

Do not use the device during service activities.

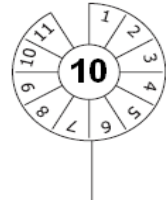


joimax® GmbH recommends performing a function and safety inspection at regular intervals according to EN 62353 or to other corresponding country-specific regulation.

The Vitegra® System is low maintenance. Regardless of the Vitegra® being low maintenance, regular service can contribute to early detection of defects and faults and, thus, extend the operating life of the device.

An operating life of 5 years is specified for the Vitegra®. Any use beyond this depends on the results of the safety inspections.

joimax® GmbH recommends an inspection to be performed at least once a year. The inspection should be documented with an inspection-label on the device.



12.1 Replacing the Fuse


Warning:

Always observe the specifications on the device label and follow the instructions below when replacing the fuse. Non-observance may result in malfunction of the device and possible injury.

Warning:

Always disconnect the device from the power supply when performing service activities.



Figure 16: Rear of Vitegra® Control Unit

- 1) Turn off the device via the power switch at the back side of the control unit.
- 2) Unplug the power cord from the control unit.
- 3) Open the fuse holder.
- 4) Check the type of replacement fuse on the device label and replace the defective fuses.
- 5) Plug the power cord into the control unit.
- 6) Turn on the device via the power switch at the back side of the device.

12.2 Software Update

Software updates can only be done either by joimax® service or by authorized joimax® service partners when required.

13 Troubleshooting

Problem	Possible Cause	Possible solution
No operation	No power supply	Check power supply connection
		Check main fuses
		Send the device to joimax® customer service
No image on the touch monitor or tablet at all	Device is not turned on	Switch on the device
	Low battery on the tablet	Charge the tablet's battery (see Chapter 8.4)
	Video cable from device to monitor is not properly plugged in	Check cable connections
		Check the monitor settings
	Video cable defective/broken	Replace video cable
	Defective control unit, monitor or tablet	Contact joimax® customer service for further steps
The image on the touch monitor is not shown in full after cabling	Loose DVI cable between monitor and control unit	Check DVI cable connection between monitor and control unit. Restart the control unit after cabling
Touch Monitor does not respond to touch	No communication between touch monitor and control unit	Check if the USB cable between touch monitor and control unit is connected
		Restart the Vitegra® Control Unit
No image on the Vitegra® software Live Screen / "No signal" is shown / No video recording possible	Signal source is not turned on	Turn on the signal source
	Signal source is not connected properly	Check the cable connections and make sure that all input cables are connected correctly
	Wrong signal	See technical data for suitable video signals
	The wrong input for the signal source is set in the Vitegra® settings	Check the input setting for the signal source in the Vitegra® Settings (e.g. check for mistaken assignments, DVI1 instead of DVI2)
	The wrong input for the signal source is selected in the Vitegra® Live Screen	Check the selection of the signal source in the Vitegra® Live Screen
Tablet shows the following icons: 	The tablet has no Wi-Fi connection to the control unit	Check if the two Wi-Fi antennas are connected at the back of the control unit
	The tablet has no connection to the Vitegra® software	Check that the control unit is turned on and the Vitegra® software has started
		Check that the airplane mode is off
		Restart the Vitegra® application on the tablet by pressing "Restart App" in the upper right corner of the tablet

Problem	Possible Cause	Possible solution
		If the above points are fulfilled, reboot the control unit by turning it off and on again
	Defective control unit or tablet	Contact joimax® customer service for further steps
Tablet shows "No Connection"	The tablet has temporarily no Wi-Fi connection to the control unit / The tablet has lost the connection to the control unit	Check that the control unit is turned on and the Vitegra® software is started
		Swipe down from the upper edge of the tablet screen and select the 'refresh' icon
		Ensure that the tablet is within Wi-Fi range of the control unit
		Ensure that the connection between the tablet and the control unit is not disturbed, e.g. by objects
	Defective control unit or tablet	Contact joimax® customer service for further steps
Remote control via camera head buttons, e.g. of Camsource® LED, does not work Camera head commands do not work	Remote cables are connected wrongly	Check that the two remote cables for remote control, e.g. via the camera head buttons of Camsource® LED, are connected correctly at the Vitegra® Control Unit and at the Camsource® LED Control Unit; i.e. Remote 1 connected to Remote1
	Remote control is not assigned to the camera head buttons in the Camsource® LED settings	Check that the remote-control inputs are correctly assigned to the camera head buttons in the Camsource® LED settings
	Remote control is wrongly configured in the Vitegra® settings	Check if the assignment of functions is correct
		If the remote control via the Camsource® LED camera head buttons is used, only set one command per input, e.g.: Remote 1, Signal 1: Snapshot, Signal 2: Disabled Remote 2, Signal 1: Video Toggle, Signal 2: Disabled
Voice control does not work	The wireless microphone for voice control is not connected correctly	Check that the wireless microphone for voice control is connected correctly
	The wireless microphone is not set up properly	Check the setup, refer to user instructions of joimax® wireless microphone set
	The microphone is not sitting right on the head; it is too far away from the mouth	Adjust microphone to fit on head properly

Problem	Possible Cause	Possible solution
	Voice command not detected by software	Adjust the speech trigger confidence threshold or command confidence threshold
	Battery of bodypack transmitter is empty.	Replace the battery (AA).
Unable to find patient using patient ID search	Patient ID not entered completely	Enter the complete patient ID (case insensitive)
Data cannot be exported/imported	No external USB storage device connected	Connect an external USB storage device
	No CD/DVD/BR inserted	Insert an optical disc (check technical data for suitable medium)
	CD/DVD/BR is not readable	Make sure the CD/DVD/BR is empty/unused
	Network cable to hospital network is not connected	Connect network cable to hospital network
	Network path is not defined in the Vitegra® settings	Define the network path in the Vitegra® settings
	DICOM worklist not reachable (if the Vitegra® Network/DICOM module is available)	Check connection to DICOM worklist and configuration in Vitegra® Settings (if the Vitegra® Network/DICOM module is available)
Data cannot be exported via USB	Video files larger than 4 GB cannot be saved on a USB storage medium formatted in FAT32	Make sure that the setting "File size of a video recording limited to 4 GB" in the Vitegra® Settings is enabled; so that a new video file is automatically created if the file size of a video reaches 4 GB (approximately 45 minutes recording time)
		Use an exFAT or NTFS formatted USB storage medium (no size file limitation)
Data export via USB is too slow	A USB 2.0 or lower storage medium is used	Use a USB 3.0 storage medium, e.g. the joimax® USB Flash Drive 128 GB
After restore/import: image/video thumbnail not available in Review Screen	Data is corrupt as the data transfer is incomplete, e.g. due to removal of external storage device before data backup/restore transfer has been finished.	Retry Import/restore patient again. Wait until data transfer has been finished
Not able to print report	Printer is not setup.	Check that the printer is setup and set to default printer. Therefore, contact joimax® service
	Printer is not set to default printer	
	Connection is not established	Check if a connection is established
Backup/Restore failed	USB storage device storage device does not have sufficient storage	Make sure a USB storage device with sufficient free space is inserted

Problem	Possible Cause	Possible solution
	No USB storage device inserted	Check if the USB Button on the Patient Manager Screen is white before doing a backup/restore
	USB storage device is removed before backup/restore is complete	The backup/restore process will be indicated by a bar. Wait until the bar disappears before removing the USB storage device to avoid possibly corrupting the data
	The system was used during the backup/restore process	The user should refrain from operating the Vitegra® system on the control unit and tablet once the backup or restore process has begun. It is advised not to exit the screen until the progress bar disappears (for export) and until the control unit reboots (for restore)
Unable to take images and videos/buttons are greyed out	The hard disk is almost full	Hard disk space is less than 10GB: Video recording is deactivated; button is greyed out
		Hard disk space is less than 1GB: Image capture is deactivated; button is greyed out
Others (not listed)	N/A	Contact joimax® customer service for further steps

14 Warranty

**Warning:**

Do not open the Vitegra®. Unauthorized opening, repair, or modification of the device releases joimax® GmbH from any liability for the operating safety of the device and results in any claims becoming void, even during the warranty period.

Warning:

In case of return of equipment or accessories, original packaging material must always be used!

Warning:

To protect your staff and the joimax® GmbH employees, please clean the unit and its accessories and disinfect it before sending it.

Should this be impossible due to temporal constraints, please prepare the unit as much as possible and label it accordingly.



joimax® does not assume any liability for the consequences resulting from additionally installed third party software or consequent updates performed by the user themselves.

The warranty period for the Vitegra® depends on the legal regulations of the specific country and on agreements in the purchase contract.

In addition, the details in our general terms and conditions apply.

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

- Model/Item number (REF)
- Serial number (SN)
- A description of the error as accurate as possible
- Invoice of the device if available
- Contact person for questions

15 Accessories


Warning:

Only the accessories from joimax® GmbH listed below are to be used with the Vitegra®. Use of accessories and cables other than those specified or provided by the manufacturer may result in improper operation.

Warning:

Make sure to follow the instructions for use of accessories to be used with the device (e.g. monitors, recording systems etc.).

Item number	Item description
JFMST215S	 joimax® Touch Screen 21,5" TFT
ICWSR400S	 joimax® Wireless Microphone Set
JVFS0001	 joimax® Vitegra® Foot switch
JESTTHS	joimax® Vitegra® Tablet Mount Set, incl. charging station
JESTTA	Mounting Arm for joimax® Vitegra® Tablet
ICS0401D	joimax® Vitegra® DICOM module
JDVI0020	joimax® DVI Cable
JBNC0020	joimax® BNC Cable
JSVHS020	joimax® S-Video Cable
JEC0010	joimax® Ethernet Cable
JTRS0010	joimax® Remote cable for Camsource® LED
JDVIHDMI020	joimax® HDMI-to-DVI Cable
JMUSBS128	joimax® USB Flash Drive 128 GB
ICBR025	joimax® Blu-ray disc, 25 GB

15.1 Spare Parts

Item number	Item description
ICS0401TPS	Power supply for ICS0401T
JESTTHU	USB Type-C cable for ICS0401T
JFMST215PS	Power supply for JFMST215
JFMST215U	USB cable for JFMST215
ICS0401WA	WiFi antenna for ICS0401

16 Compatibility

Any video source (e.g camera, PC, C-arm etc.) with a compatible video signal can be connected to the Vitegra® via appropriate video connection cables.

DVI-I Connector

- DVI 1.0
- HDMI 1.4a (via breakout cable)
- VGA (via DVI2VGA connector)
- Component (via breakout cable)

4-pin Mini-DIN Connector

- YC (S-Video)
- Composite video
- Analog audio (L+R)
- Component video

BNC Connector

- SD/HD/3G SDI

Video capture formats

- Support for capture image resolutions up to 2048x2048 pixels
- Support for capture frame rates up to 144fps
- Support for 4:2:0 8-bit capture formats: NV12, I420, YV12
- Support for 4:2:2 8-bit capture formats: YUY2, YUYV, UYVY
- Support for 4:4:4 8-bit capture formats: V308, IYU2, V408, BGR24, BGR32
- Support for 4:4:4 10-bit capture formats: V410, Y410



Avoid converting signals to different video interfaces (e.g DVI to Composite Video) via active adapters, as this might reduce video quality.

Detailed information regarding joimax® endoscopic cameras and accessories can be found in the joimax® product catalog.

For further information and new products directly contact the joimax® customer service or your joimax® representative.

17 Disposal of the Device



Warning:

This symbol indicates that medical devices must be disposed of separately from household waste. Dispose of electrical waste in accordance with the applicable national and local regulations.



Warning:

This symbol must be affixed to the waste container or the device when discarding it.



Dispose of packing material, unless it is contaminated, in accordance with national and local regulations.



According to the implementation of European law into national laws and regulations, the user is obliged to properly dispose of medical devices.

Discard used and contaminated medical devices at a collection point of an appropriate disposal carrier. "Medical waste" is classified according to dangerous goods law (for transportation) by UN number UN 3291.

18 Emergency Number/Incident Reporting

In emergencies, contact joimax® at the following telephone number:

For the US	+1 949-859-3472	(24-hour availability)
For all other countries	+49 (0)721 25514 – 999	(24-hour availability)

Any serious incident that has occurred in relation to the device should be reported to joimax® GmbH and the competent authority having jurisdiction in your locale.
Thank you for your support!



REF IFUVIDOEN

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joined minimal access



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