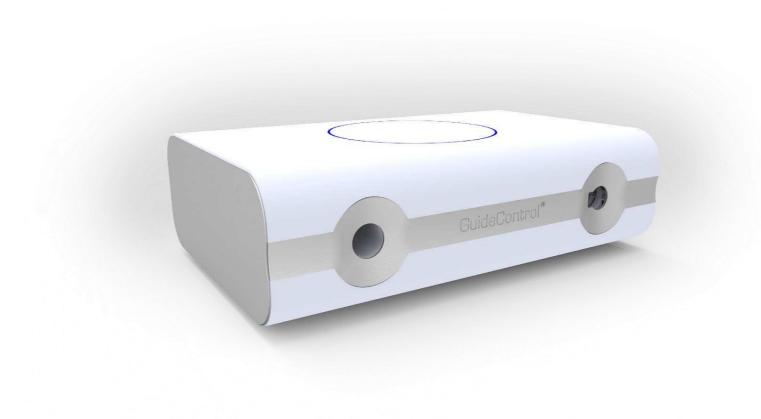


# **GuideControl**



**User manual** 

Date: 10/10/2022 Revision: v0.5



#### About this document

DOVIDEQ Medical Systems B.V. reserves the right to make changes to both this user manual the GuideControl and to the product that it describes. Product specifications are subject to change without notice. Nothing contained within this user manual the GuideControl is intended as any offer, warranty, promise, or contractual condition and must not be taken as such.

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This manual is written for the GuideControl operators and managers. This manual is periodically being updated to match new software releases. A release date of this manual is printed on the front page of this document. This ensures you that you always have the latest copy. Updates can be found at <a href="https://www.endoscopemanager.com">https://www.endoscopemanager.com</a>.



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# 1. Product description GuideControl

The *GuideControl* is designed and Assembled in the Netherlands. the *GuideControl* is a fully automatic testing device for light guide cables. It is designed to be fast, accurate and easy to operate. It can test light guides within 8 seconds after which the result is presented in a clear green or red on the LED indication ring on the top of the *GuideControl*. This enables (CSSD) employees to determine whether a light guide cable can be used at the OT or not. EndoscopeManager.com is the platform used to visualize the measurement data and allows you to manage your light guide cables.

The *GuideControl* can test all common light guide cables with instrument connectors like; Olympus, Storz, Stryker, and many more. The collected measurement data can be easily used for management reports and can benefit your purchasing and repair policy.

#### Important notice

A light guide cable consists of a bundle of glass fibres. Broken fibres, when aligned, can still transport light. When broken fibres are not aligned, less light will be transported, so less light is measured by the *GuideControl*. The accuracy of the *GuideControl* is very high. Fluctuations between measurements are possible due to the above mentioned. To avoid these fluctuations as much as possible, it is important you measure following the same routine.

# 2. Technical specifications

#### **General Specifications**

Power consumption Input: 100-240VAC

Output: DC 5V 6.0A

Frequency: 50-60 HzRating: 30 W (max)

Dimensions (L x W x H): 20cm x 30cm x 9cm

Weight: 3,2 Kg
Noise:  $\sim$  30 dB
Operating temperature: 5° to 35 °C

Humidity: Non-condensing (IEC 721)

**Connectivity** 

USB connection: USB 2.0

Ethernet connection: RJ45 / SSH & SSL

Speed: 100Mbps

Protocol: TCP
IP assignment: DHCP



#### 3. Disclaimer

This product was manufactured and assembled with the highest quality standards. The manufacturer reserves the right to change manuals. Future developments may result in changes in data and description. For this manual copyrights need to be respected. This manual contains specific manufacturer's information. It is forbidden to distribute partial or full copies of this manual without prior written consent from the manufacturer.

The manufacturer cannot be held liable for damages caused by molest or use of the device that is not according to the manual. If service is conducted by non-authorized personnel all claims regarding warranty, repair, service, liability and safety will be null and void. The purpose of the measuring results of the device is purely for screening. Binding legal conclusions cannot be made from the results of *GuideControl*.

# 4. Warranty

This product has full warranty for a period of 12 months. Excluded from warranty are use outside of the scope of this manual, molest, damage caused by external factors and modifications without written preapproved consent of the manufacturer.



## 5. Installation

## Placing the GuideControl

• Place the *GuideControl* always on a flat and stable surface.

# **Connecting the GuideControl**

- Connect the *GuideControl* to the internet with an Ethernet cable. Please make sure to read and follow the instruction below on 'internet & security'.
- Connect the power cable from the adapter to the 100/240V mains outlet and connect the 5V side of the adaptor to the *GuideControl*.
   The unit will now turn on and show a white LED ring on top. After a few seconds this will change into rainbow colors. Once the unit is fully started up the led ring will start to breath/glow in blue LED light. (The LED ring colors can be changed to your liking in endoscopemanager.com)





#### Go to the EndoscopeManager.com website

- Connect your PC to the internet and open your browser. (Preferably: Google Chrome)
- Go to <a href="https://www.endoscopemanager.com">https://www.endoscopemanager.com</a> and log in with your account information.

# Shutting down the GuideControl

To shut down the GuideControl, please disconnect the power cable.

#### **Internet & security**

- To allow the *GuideControl* to connect to our server, please make an outbound rule to connect to IP address 185.42.57.131.
- Data that is sent, only comprises the measurement results, images and GuideControl settings (LED colours eg). No patient-, nor private information is sent.
- Measurements and settings are sent encrypted via SSL (dest. port 443) and images are sent using the SSH protocol (SFTP, dest. Port 25, and next



software update port 22).

- The *GuideControl* does not connect directly to our database, but is routed through our cloud server, which connects to our database. The database is protected by our firewall, which allows only our cloud server to connect.
- Depending on the amount of measurements, data use can go up to 20 MB per day.

# 6. Test light guide cables with the GuideControl

The *GuideControl* is typically placed in the central sterile services department (CSSD). Cables are normally washed and disinfected before sterilization. These steps all occur in the CSSD. We therefore advise to test light guide cables after washing and disinfection, and before sterilization. This prevents failed cables to go through the sterilization process unnecessary.

To prevent that residue or water particles affect the test, you have to make sure that both sides of the cable are clean and dry before you start the test. To generate consistent and correct results, we advise to let the light guide cables acclimatize at least 30 minutes after washing and disinfection, before starting the test.

# Measuring procedure and routine

Measurements are either done with unrolled cables, or with rolled cables with a diameter no smaller than 20cm. Either way; always try to measure the same way, every time, to get the most concurrent results. Please push gently the light source side of the cable in the left hole. Now push gently the instrument side of the cable in the right hole. Make sure that the right side is centered correctly.

After 5-8 seconds the results are available. If a green ring on top is presented, the cable meets the quality standard, which is higher or equal to the set threshold. Red means that the measurement is below the threshold, and does not meet the quality standard.

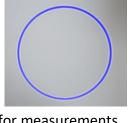








# Magic Ring colors and their meaning



Full blue "breathing" animation: the GuideControl is online and

ready for measurements.



Half blue circle filling counter-clockwise: insert animation for

the Light-sphere, or left side.



Half blue circle filling clockwise: insert animation for the

Camera-sphere, or right side.

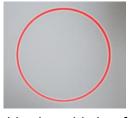


Full blue circle filling clockwise: the GuideControl is measuring.



Full green circle: the measurement meets the set thresholds,

your cable has passed the test.



Full red circle: the measurement does not meet the set

thresholds, the cable has failed the test.



#### Storing measurements

The *GuideControl* has the default option to save the last 500 measurements to its local storage. By connecting your *GuideControl* to the internet as described in chapter 5, the measurements are synced to EndoscopeManager.com. This means that the measured values can be viewed in EndoscopeManager.com after just a few seconds from your PC (see chapter 7).

EndocopeManager.com also provides the possibilities to change default settings of the *GuideControl* and to register light guide cables which are provided with UDI.

# **UDI** (unique device identification)

When your light guide cable has a unique identifier (Data Matrix or RFID) or the cable belongs to a specific tray with barcode, you can register the light guide cable on EndoscopeManager.com.

Connect the scanner to your PC and go to EndoscopeManager.com. Follow the add light guide wizard and scan the code when asked. After completing the wizard, the cable is added to your *GuideControl*, after a measurement or reboot took place.

To use the identification of the cable, make sure to connect the scanner to the **GuideControl**.

Start by scanning your cable. After recognizing the code, the left part of the circle animates to visualize that you have to insert the light source side of the cable in the left side of the *GuideControl*. Continue by inserting the instruments side of the cable to the right side of the *GuideControl*. After the measurement, the result is immediately displayed on the LED ring and the results are synced with the cloud. You can use the UDI feature to follow lifetime on EndoscopeManager.com. Here you can see how often a cable has been used and how fast the overall quality is deteriorating.



## No UDI (unique device identification)

When your light guide cable has no UDI, you can measure the cable without scanning. Follow the animation to insert the light source side on the left side, and the instrument side to the right side of the *GuideControl*. After the measurement you will see the results immediately, presented by the green or red ring on top of the *GuideControl*.

The cable will be presented as an unknown light guide cable in a grey color on EndoscopeManager.com. The values are shown for the light transmission, color correctness and percentage of fibers. In addition, a picture of the fibers is shown.

#### Master threshold value

This is the minimum value you accept for a certain cable type.

We advise to set the master threshold values at 70% for LT (field norm). You are free to determine your own threshold values for the Fibers and Color Correctness.

You can change the master threshold values in EndoscopeManager (see chapter 7).

#### **Validation**

The *GuideControl* can be validated with our special Validation tool. This is separately available. Please contact <u>sales@dovideqmedical.com</u> for more information.

The Validation tool is to be kept in a safe place. It is advised to be measured every 6 months. To perform the Validation process, first scan the first code to initiate validation mode, and then scan the second data matrix code for the serial number of the Validation tool. The values are stored and synced to the cloud. Please keep in mind that a tolerate of +/- 3% is considered okay. If the results transcend these values, please contact your distributor to recalibrate your *GuideControl*.







# **USB** to HDMI interface

A real-time readout of the *GuideControl*'s status is possible by connecting a monitor screen to one of the *GuideControl*'s USB ports.

# 7. EndoscopeManager.com

# EndoscopeManager dashboard

The coloured donut graph is showing the current status of your light guide cables. The outer rings shows the number of light guide cables per brand / diameter.

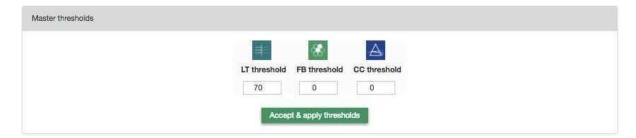
You can click on any part of the graphs and quickly review the data.



#### Set threshold values

Threshold values can be determined following these steps:

- -> Go to https://www.endoscopemanager.com
- -> Go to Administration
- -> Go to GuideControl
- -> Go to Master Thresholds
- -> Change your Master Threshold value
- -> Click on "Accept & Apply thresholds"



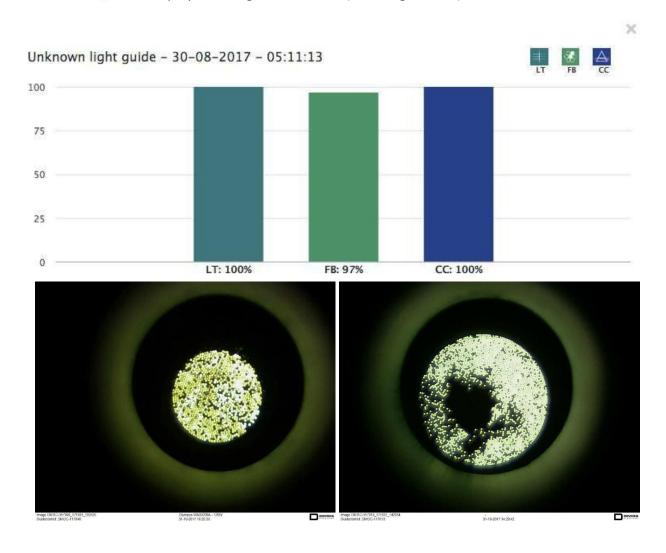
# Light guide cable information and settings

Go to the tabs for more information or to make adjustments. Please follow the next



#### steps:

- -> Go to www.endoscopemanager.com
- -> Go to Light Guide in the menu
- -> Click on the row that you would like to inspect
- -> All the information regarding this light guide cable will be shown (LT Light Transmission / FB Fibre Quality / CC Colour Correctness)
  - -> You can click at the symbol below the graph:
  - To add a comment on the measurement
  - To display the image of the fibers (see image below)



# 8. Cleaning and maintenance

The *GuideControl* is assembled with great care. Periodic maintenance and proper use of the device will extend its accuracy and lifespan. Handle the *GuideControl* with care. To disinfect the *GuideControl*, please be advised to first spray the fluids (70% alcohol) on a tissue, before cleaning the surface.



Please do not spray directly on the surface. The same applies for the 2 holes on the front.

Please pay extra care to the right side, where the Corning® Gorilla® Glass is to be cleaned with a dry spectacle cloth or cotton swab, to get the best possible images. This can be done every 2 weeks.

#### 9. Software

The *GuideControl* contains embedded software, which is prone to incremental updates.

# Software updates

Periodically, software updates will be released to improve or to add functionality. Whenever an update is available, an email will be send to the administrator to be advised to update the *GuideControl*.

Check out the latest changes on <a href="https://www.endoscopemanager.com">https://www.endoscopemanager.com</a>.

# Software copyright

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#### 10. Service contact

If you have an exchange service contract, please contact us before sending your *GuideControl* properly packed to the mentioned address below. We will send another *GuideControl* in exchange. If you have no exchange service contract, we will invoice time and material for the repair actions.

# **DOVIDEQ Medical Systems B.V.**

Munsterstraat 18, 7418 EV Deventer Netherlands

For maintenance and service requests: service@dovidegmedical.com

#### Commercial contact

For additional commercial questions you can contact our sales department: <a href="mailto:sales@dovideqmedical.com">sales@dovideqmedical.com</a> or +31570760800



#### 11. Maintenance

- GuideControl must be serviced at least once a year.
- Calibration and or repairs only be made by qualified personnel.
- Contact Dovideq for the possibilities

# Annual checkup

**Guidecontrol** must be checked annually on the following points:

- Check housing for damage and clean it.
- Check the power adapter and supply cable for damage.
- Perform an electrical safety test.

# 12. Spare parts

Description	Amount
Network cable (3m)	1
Main PWS adapter 5V - 6A	1

# 13. CE-compliance

**Guidecontrol** has been reviewed and compliance with the following guidelines:

- CE class 1
- Low voltage (2014/35/EU)
- RoHS(2011/65/EU)
- EMC (NEN-EN-IEC 61000-6- 3:2007/A1:2011/C11:2012)