

# Installation and User Manual



# LightControl

**Automated Endoscope Tester** 

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# 1. Preface

#### 1.1 Description of the User

### **A WARNING**

These instructions are intended for the end user of the product. The product's end user is a person who has read and understood these user instructions, is an experienced user of similar equipment, is aware of all possible dangers, and is capable of acting accordingly.

The LightControl system is designed for professionals involved in the quality control, maintenance, and manufacturing of straight (non-angled) rigid endoscopes.

The primary users include hospital staff, Central Sterile Services Departments (CSSD), Biomedical Engineering Departments, endoscope repair companies, and endoscope manufacturers.

All users should have a basic understanding of endoscope design and optical performance. This document is intended for all primary users, including LightControl operators and managers.

#### 1.2 Explanation of Safety Warnings

### **A** DANGER

Danger indicates a hazard with a high level of risk, which, if not avoided, will result in death or serious injury.

### **A**WARNING

Warning indicates a hazard with a medium level of risk, which, if not avoided, could result in death or serious injury.

### **A** CAUTION

Caution indicates a hazard with a low level of risk, which, if not avoided, could result in minor or moderate injury.

#### NOTICE

Indicates information considered important but not hazard-related.

#### 1.3 How to Use These Instructions

Ensure that each person using the product has read and understood this manual and its safety instructions before using it. Failure to do so can result in serious injury or death.

When this manual refers to the *product*, *appliance*, or *device*, it refers to the LightControl, possibly connected to a scanner, monitor, and the EndoscopeManager platform.

Take note of all warnings, safety precautions, and instructions to avoid potential fires, explosions, electric shocks, or other hazards that may damage property or cause severe or fatal injuries. Keep all safety information and instructions for future reference and pass them on to subsequent product users.

The manufacturer is not liable for cases of material damage or personal injury caused by incorrect handling or non-compliance with the safety instructions. In such cases, the warranty will be voided.

This manual is periodically updated to match new software releases. The release date is printed on the front page of this document, ensuring that you always have the latest copy. Updates can be found at www.dovidegmedical.com.

Unauthorized copying of this publication may not only infringe copyright laws but may also reduce DOVIDEQ Medical Systems B.V.'s ability to provide accurate and current information to users. The latest version of the documentation is available at www.dovidegmedical.com.

DOVIDEQ Medical Systems B.V. reserves the right to change the LightControl and this user manual. Product specifications are subject to change without notice. Nothing contained within this user manual is intended as an offer, warranty, promise, or contractual condition and must not be taken as such.

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

Hassinkweg 10 **Telephone:** +31 (0)570 760 800

7556 BV Hengelo **Email**: info@dovideqmedical.com

The Netherlands



#### 1.4 Declaration of Conformity

This device complies with all relevant European Directives. The Declaration of Conformity is available upon request.

#### 1.5 Warranty

The manufacturer provides a full 12-month warranty on this product. Excluded from warranty are the use outside the scope of this manual, intentional damage, damage caused by external factors, and modifications without the written, pre-approved consent of the manufacturer.

#### 1.6 Service

For maintenance and service requests, contact Dovideq Medical Services by emailing service@dovideqmedical.com.

Contact our sales department at info@dovideqmedical.com or +31 (0)570 760 800 for commercial inquiries.

If you have a service contract, please contact Dovideq before sending your LightControl to the address below. We will then send you another LightControl in exchange. If you do not have an exchange service contract, Dovideq will charge for the time and materials needed for the repair.

Always make sure the device is properly and securely packaged.

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

Hassinkweg 10 7556 BV Hengelo The Netherlands

#### 1.7 Disclaimer

This product is manufactured and assembled to the highest quality standards. The manufacturer reserves the right to change manuals. Future developments may lead to changes in data and description.

Copyrights must be respected for this manual. This manual contains specific information from the manufacturer. Distribution of partial or complete copies of this manual without prior written permission from the manufacturer is prohibited. The manufacturer cannot be held liable for damage caused by misuse or use of the device that is not in accordance with the manual. If maintenance is performed by unauthorized personnel, all warranty, repair, service, liability, and safety claims will be voided. The device's measurement results are purely for screening purposes.

No binding legal conclusions can be drawn from the results of LightControl.

The LightControl is designed as a tool to give the end user additional visual information about the internals of a rigid endoscope. It allows them to set certain thresholds and parameter boundaries. The user should refer to the instructions for use (IFU) provided by the endoscope manufacturers while using the visual output on the screen.

#### 1.8 Software

#### 1.8.1 Software Copyright

Software copyright ©2014-2055 DOVIDEQ Medical Systems B.V. All rights are reserved. All other product names are the property of their respective owners. Reproduction in whole or in part in any form or by any means is prohibited without the written consent of the copyright holder.

#### 1.8.2 Software Updates

Periodically, software updates will be released to improve or add functionality to LightControl. Check out the latest changes at https://www.endoscopemanager.com.

Neither this software nor the device holds or transmits privileged patient data. This device, nor any software provided as an accessory to its use, should in no way be used to hold privileged patent data requiring adherence to confidentiality rules and regulations.



# 2. About the LightControl

#### 2.1 Intended Use

The LightControl is an optoelectronic testing device for rigid endoscopes intended to measure and convey data to end users for decision making.

The LightControl is a manually operated device, and its optics are fixed. The sphere unit must be moved manually on the slider to the correct position indicated by the device in accordance with the length of the endoscope. This allows for testing of a wide variety of rigid endoscope types.

Within use, a light source and camera assembly captures and displays imaging of rigid endoscope optics from which measurement parameters can be determined and analyzed. It provides measured and analyzed values to the user within a digital interface for verification and validation and compares them against user-configured thresholds and parameter boundary settings per scope unit or type.

Measured data of a rigid scope's light and fiber transmission, color correctness, and focus for screening purposes are provided for analysis. In advance of scheduled service analysis, automated analysis in the detection of particles and/or lens fracture is also provided for decision-making on the need for advanced interim unit servicing.

By maintaining user-configuration data and comparing measured results, LightControl is intended to assist in creating streamlined, consistent, and efficient processes for users in their validated processes.

### 2.2 Reasonably Foreseeable Misuse

### **NOTICE**

Use the product, accessories, tools, software, etc., in accordance with these instructions, taking into account the working conditions and the work to be performed. Using the product for operations different from those intended could result in a hazardous situation and void the warranty.

The LightControl System aims to objectively determine and record the optical parameters of straight, non-angled, rigid endoscopes. The endoscopes should be equipped with an eyepiece that falls within the length range of 13 to 67 cm and is 1.7 to 10 mm thick.

This system is specifically designed to be used during quality control processes at hospitals, endoscope repair shops, and manufacturing facilities. The system measures and provides data on the following critical optical parameters.

- ▶ **Light Transmission.** Measures the light transmission of the rod lenses of the endoscope and compares it with the reference value of the selected type.
- ▶ **Fiber Transmission.** Measures the light transmission of the fiber package and compares it with the reference value of the selected type.
- ▶ Color Correctness. Measures the color correctness of the image transmitted through the endoscope based on the HSV model and compares it with the reference value of the selected type.
- ▶ **Focus.** Measures if the endoscope is in focus based on the Haar Wavelet transformation and compares it with the reference value of the selected type.

The following automated analysis is also provided for decision-making on the need for advanced interim unit servicing.

- ▶ Particle Detection. Checks the rod lenses of the endoscope for particles with an Al algorithm based on the camera image output.
- ▶ Lens Fracture Detection. Checks for damage to rod lenses with an AI algorithm based on the camera image output.

The LightControl System shall not be used as follows.

- ▶ Application Beyond Design Specs. Using the system with endoscopes outside specified parameters may cause damage or yield inaccurate results.
- ▶ Operation by Untrained Individuals. Use by untrained individuals may lead to erroneous data analysis, compromising endoscope safety and effectiveness.
- ▶ Usage in Unsuitable Environments. Use only in suitable environments to prevent damage to the system and maintain accuracy.
- ▶ Adaptation for Non-Intended Devices. Use only straight, non-angled, rigid endoscopes to avoid incorrect assessments and damage to the system.
- ▶ **Neglecting System Care.** Maintenance and calibration are essential to prevent a decrease in accuracy over time.
- ► Circumventing Safety Protocols. Modifying or disabling safety mechanisms may pose risks to the user and compromise data quality.



The LightControl shall be used with the following software, original accessories, and components only:

- ▶ DoviScan data matrix code scanner\*
- ► EndoscopeManager cloud platform
- ▶ Straight, non-angled rigid endoscopes
- ► Compatible HDMI display monitor
- ▶ Other compatible 3rd party equipment that is supported by Dovideq. Go to www.dovideqmedical.com for more information.

The product shall only be used in accordance with the instructions described in this manual. Any use other than those described in this manual is considered non-intended use. This will also invalidate the warranty.

#### 2.3 System Description

The DoviScan data matrix code scanner, attached to the LightControl, scans an endoscope's UDI. After scanning, the user moves the sphere unit to the correct position indicated by the device. Once the sphere unit is in position, LightControl automatically starts testing. After the test, LightControl gives instant feedback through images of the rod lenses and LightControl sphere on a connected HDMI screen. This feedback shows whether the scope has passed or failed according to the user's set thresholds in EndoscopeManager regarding specific parameters.

The system compares the measurement values with the scope type's reference values fetched from the EndoscopeManager cloud platform and creates a normalized output value between 0 and 100 percent for the different parameters. Based on the threshold values defined by the end user, each parameter will "pass" or "fail". The system is also responsible for recording the measurements and corresponding results on the same platform. This approach ensures that quality control is standardized and that the accuracy and traceability of the process are improved by leveraging cloud technology.

# 2.4 Product Specifications

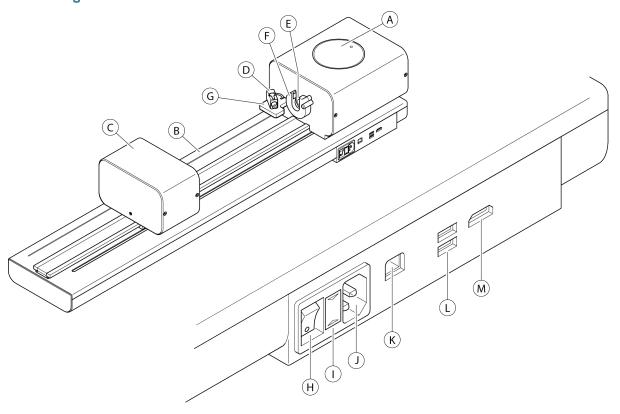
Parameter	Unit
Device	
Device name	LightControl
Model / Type	DMLC-24XXX
Protection ration	IP20
Protection class	Class 1
Dimension (LxWxH)	1061 x 200 x 200 mm
Weight	19.9 kg
Input	100-240 VAC
Fuse	T10A (2x)
Max power	100 W
Main power supply	C13 Power cable
Frequency	50-60 Hz
Sound level	~60 db
Operation temperature	15° to 35 °C (59° to 95 °F)
Storage temperature	5° to 50 °C (41° to 122 °F)
Relative humidity	0 - 85% / Non-condensing (IEC 721)
Technical life span	5 years
Connections and communication	
Parameter	Unit
Operating system	Linux (embedded, Yocto based)
USB connection	USB 2.0 (2x)
Ethernet connection	RJ-45 Ethernet port
Video out	HDMI A



Parameter	Unit
Protocol	HTTPS
Ports	443 TCP 123 UDP (for NTP time synchronization) 53 UDP (for DNS name resolving)
Encryption	SSH/TLS
IP	DHCP/Static
LC Animations version	1.0 / 20240221

### 2.5 Product Elements

# 2.5.1 LightControl

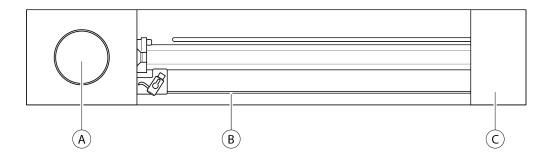


Α	DoviCircle	Н	Power switch
В	DoviStrip	I	Fuse holder
С	Sphere compartment	J	Mains power inlet

D	Camera compartment	K	Ethernet socket
E	Light fiber sensor	L	USB 2.0 sockets
F	Ocular clamping mechanism	М	HDMI output
G	Fiber sensor support		

#### 2.5.2 Visual and Audio Signals

The **DoviCircle** (a) indicates whether the LightControl is turned on, the status of a test procedure, and whether an endoscope has been placed correctly in the LightControl.



The **DoviStrip** 8 uses colors, pulse frequency, and partial illumination to indicate the status of LightControl and the desired movement direction of the **sphere compartment** 0.

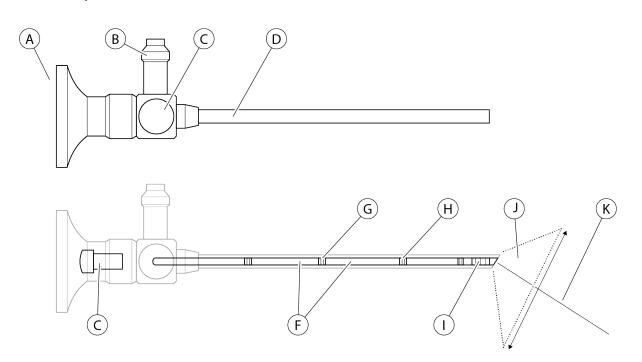
Status	DoviCircle	DoviStrip	Sound	HDMI output
Booting	White; then all colors	White	N/A	Dovideq logo / Booting screen
Ilde; connected	Blue (breathing)	Off	N/A	Scan UDI
Ilde; disconnected	White (breathing)	Off	N/A	No connection
After the scan; scan successful	Green (shortly); then blue	Green (shortly); then off	N/A	Move slider
After the scan; scan not successful	Red (shortly); then blue	Red (shortly); then off	N/A	Scope not recognized. Add the scope to EndoscopeManager.



Status	DoviCircle	DoviStrip	Sound	HDMI output
After moving the slider	Blue (flashing)	Blue (moving to the left)	N/A	Move slider
After hitting the barrier	Blue (flashing)	Blue (moving to the left)	N/A	Move slider
In position	Green (flashing)	Green; square around slider (flashing)	N/A	In position, do not touch.
Beyond position	Red (flashing)	Red (moving to the right)	N/A	Move back!
Too far beyond position	Red (flashing)	Red (moving to the right)	Yes	Move back!
Moving during test	Red	Red	Yes	Test aborted
Final result	Red or green	Red or green	Yes	Test completed

#### 2.5.3 Endoscope

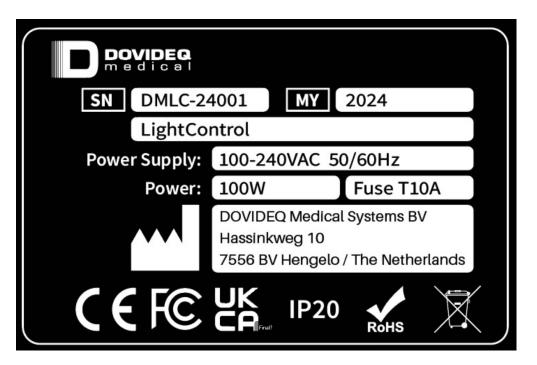
Below is an example of a straight, non-angled, rigid endoscope and the names of the parts that make it up.



Α	Eyepiece	Н	Light fibers
В	Light post	I	Objective assembly
С	Body	J	Field of view
D	Tubing	K	Angle of view
Е	Ocular	L	
F	Rod lens	М	
G	Spacer	N	

#### 2.6 Type Plate

The type plate is attached to the bottom of the LightContol.



Example of the type plate on the LightControl



#### 2.7 Endoscope Compatibility

To ensure optimal performance and safety, all endoscopes must meet the following specifications:

#### ▶ Type

Only rigid optics or rigid endoscopes are compatible.

#### ▶ Orientation

The endoscope must be straight. Angled, hooked, or curved endoscopes are incompatible as they do not provide the direct line of sight required by our system.

#### ► Camera/Eyepiece

Must be equipped with a camera or an eyepiece that conforms to DIN 58105 standards. This ensures the device can be attached appropriately and integrated with our imaging system.

#### ▶ Length

The endoscope must be within the 130 mm to 6700 mm range. This range ensures that the endoscope can navigate efficiently without being too short to reach the target area or too long to handle effectively.

#### ▶ Diameter (Thickness)

Endoscopes must have a minimum thickness of 1.7 mm and a maximum of 10 mm. This size range is critical for ensuring the endoscope fits through the sphere compartment.

# 3. Safety

# **A WARNING**

Read and understand this manual and its safety instructions before using this product. Failure to do so can result in serious injury, damage to the instrument, erroneous results, and data loss.

#### 3.1 Explanation of Graphical Symbols

Symbol	Meaning
<b>[</b> i	Read and understand the manual and its safety instructions before using this product.
(€	The CE marking on the product is the manufacturer's declaration that the product complies with the essential requirements of the relevant European health, safety, and environmental protection legislation.
	This marks that the equipment must be connected to an earthed mains socket outlet as required by some jurisdictions.  In jurisdictions such as Finland, Norway, and Sweden, class I pluggable electrical equipment type A intended for connection to other equipment or a network must, if safety relies on connection to protective earth or if surge suppressors are connected between the network terminals and accessible parts, have a marking stating the requirement.
	The symbol on the product, the accessories, or the packaging indicates that this device must not be treated as unsorted municipal waste but must be collected separately.

#### 3.2 Safety Information Related to the Intended Use

- ► The product shall only be used for applications as described by the manufacturer. The manufacturer cannot be liable for damage resulting from errors, unintended use, or unprofessional product use.
- ▶ Use the product, accessories, tools, software, etc., in accordance with these instructions, taking into account the working conditions and the work to be performed. Using the



- product for operations different from those intended could result in a hazardous situation.
- ▶ The manufacturer is not liable for cases of material damage or personal injury caused by incorrect handling or non-compliance with the user documentation. In such cases, the warranty will be voided.
- ▶ Do not operate electrical equipment in explosive atmospheric conditions, such as in the presence of flammable liquids, gasses, or dust. The equipment creates sparks which may ignite the dust or fumes.
- ▶ The device is intended for use indoors. Never use outdoors.
- ▶ Only persons able to receive training and who demonstrate the capability to use the product in a way which adheres to the instructions and requirements written in this manual should be allowed to use the device without direct supervision or instruction.'
- ► The product has been tested and complies with electromechanical device safety standards. The product is safe if handled properly and according to the instructions. Contact your physician if you have a pacemaker or other implanted device before use.
- ▶ Never leave children unattended with the packaging material. The packaging material represents a danger of suffocation. Children frequently underestimate the risks. Always keep children away from the packaging material.

#### 3.3 Safety Information Related to Transport and Storage

- ▶ Lift, handle, and transport the product carefully. Ensure the product cannot move or slide during transport.
- ▶ Make sure any endoscope is removed before transporting the product.
- ▶ Always be careful when handling, transporting, and storing the product. Always put the product in the original packaging during transport and storage. The product contains delicate and fragile parts. If the product is not used for an extended period, unplug, clean, and store it in a cool, dry place away from direct sunlight.
- ▶ Store the product out of the reach of unauthorized persons, and do not allow persons unfamiliar with the product or these instructions to use it. The product is dangerous when used by untrained users.
- ▶ Do not drop or hit the device.

#### 3.4 Installation Safety Information

- ► Check the product for damage before installation. If there is any visible damage, do not install the product and contact the manufacturer.
- ▶ Do not place or store the product where it can fall or be pulled into water or other liquids.

- ▶ Two people are always required for the installation process.
- ▶ Only use the product when correctly and completely installed. Be aware that the manufacturer cannot be held responsible for tool damage or personal injuries resulting from the incorrect installation of the product.
- ▶ Use only the original power plug supplied with the product. Other Power Plugs may damage the product. Do not use the supplied product power plug with other devices.
- ► Extension cables and multi-plug adapters are prohibited between the earthed AC wall socket and the appliance plug.
- ▶ Do not place the device on uneven or unstable surfaces.
- ▶ Do not expose the device to dirty or dusty environments.
- ▶ Do not install the device close to magnetic or electric fields/electrical devices.

#### 3.5 Safety Information Regarding the Use

- ▶ Always be vigilant and careful about your actions. Do not use the product if you are lacking in concentration or awareness or are under the influence of drugs, alcohol, or medication. Even a moment of inattentiveness can lead to severe accidents and injuries when using the product.
- ▶ The risk of injury can be reduced by placing the product at the correct working height and taking proper ergonomic measures into consideration.
- ▶ Risk of damage. The device is a highly sensitive measurement device. Handle with care to avoid damage to the device and endoscopes.
- ▶ Risk of damage. The device is a highly sensitive measurement device. Only use the device in a controlled electromagnetic environment.
- ► To avoid overheating, do not cover the device, do not use near heat sources or in direct sunlight, and only at ambient temperatures of between 15° and 35 °C (59° to 95 °F).
- ▶ Do not expose the device to direct sunlight; do not place it on heat-sensitive surfaces, near heaters, air conditioners, or flammable substances.

### 3.6 Maintenance Safety Information

- ▶ Only qualified, certified personnel may repair, disassemble, or discard the appliance.
- ▶ Alterations to the product and technical modifications are not permitted without written permission of the manufacturer.
- ▶ Disconnect the appliance from the power supply when you repair, disassemble, or discard the appliance.
- ▶ Maintenance and inspection should be done frequently. Non-frequent maintenance shortens the activity and life span of the machinery and voids the warranty.



- ▶ Use only original spare parts. Using other parts will void the warranty and the CE identification and could lead to injuries.
- ▶ All maintenance tasks shall only be performed by qualified and skilled personnel. Qualified personnel shall perform regular maintenance per the manufacturer's instructions to ensure the product's operational safety.
- ▶ Clean the appliance with a dry, lint-free cloth. Do not use detergents or other solvents to clean the appliance.
- ▶ Tasks on the appliance can result in injuries due to sharp edges and pointed objects.
- ▶ Disconnect the power supply before cleaning the product. Do not use abrasive cleaning cloths or chemicals to clean the product since these may damage the surface.

#### 3.7 Service and Repair Safety Information

- ▶ Only qualified, certified personnel may repair, disassemble, or discard the appliance.
- ▶ Do not try to repair the product yourself. Call the manufacturer (+31 (0)570 760 800) if the product is not functioning properly.
- ▶ Disconnect the plug from the power source before installation, maintenance, repair tasks, making any adjustments, or changing accessories. Such preventive safety measures reduce the risk of starting the product accidentally.

# 4. Preparation

#### 4.1 Installing the LightControl

# **A** WARNING

Lifting tasks shall always be conducted by at least two authorized persons. Lifting or moving the System without proper training and assistance can cause personal injury or damage to the instrument.

# NOTICE

- ▶ Keep the work area clean and well-lit. Cluttered or dark areas invite accidents.
- ▶ Do not expose the device to direct sunlight; do not place it on heat-sensitive surfaces near heaters, air conditioners, or flammable substances.
- ▶ Install the device on a stable, level, and vibration-free surface that can easily support the weight of the device.
- ▶ The device does not have adjustable feet, so do not try to loosen or tighten its feet.

#### 4.1.1 Unpacking the LightControl

#### To unpack the LightControl:

- 1. Remove the transport and packaging restraints.
- 2. Unpack the product.
- 3. Check if the packaging contains the following:
  - ▶ RJ-45 Ethernet cable
  - ▶ C13 Power cable
  - ▶ DoviScan
  - ▶ Installation and User Manual
  - ▶ Quick Start Guide
- 4. Remove the cardboard protection from the box.
- 5. Remove the LightControl from the box and place it on a clean, flat surface.
- 6. Inspect the product to make sure it is not damaged.



#### 4.1.2 Unpacking the DoviScan

#### To unpack the DoviScan:

- 1. Open the packaging.
- 2. Check if the packaging contains the following:
  - ▶ DoviScan
  - ▶ USB cable (2.0)
- 3. Remove the DoviScan from the box and place it on a clean, flat surface.
- 4. Inspect the product and the USB cable to ensure they are not damaged.

#### 4.1.3 Installing the LightControl

# **A** DANGER

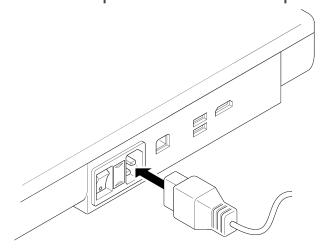
- ▶ Do not plug the power plug into an outlet with a voltage other than the one specified on the device
- ► Check the product for damage before installation. If there is any visible damage, do not install the product and contact the manufacturer.
- ► Tripping hazard! Place the product's power cable in such a way that people, including children, cannot trip over it.

#### To install the LightControl:

1. Make sure the **power switch** is in the O position, and the **power cable** is not plugged into the wall socket.

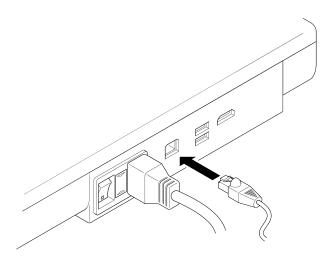
▲ NOTICE! Connecting the power cable plugged into the outlet while the power switch is in the I position could damage the device.

2. Connect the **power cable** to the **mains power inlet**.

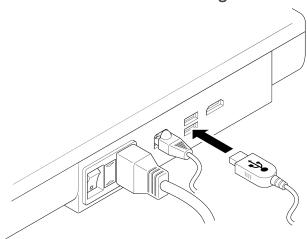


3. Connect the Ethernet cable to the **Ethernet socket**.

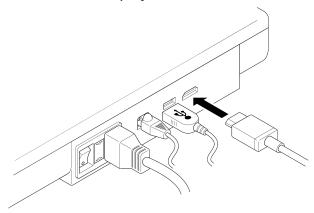
A NOTICE! Make sure the Ethernet cable is connected to your local network and has an active Internet connection. See 4.3.1 *IT Network Preparation*.



4. Connect the **DoviScan** to the **LightControl** using the provided USB cable.



5. OPTIONAL: Connect an external display monitor using an HDMI cable (not provided). The external display shows instructions and test results at the end of the test.





#### 4.2 Switching the LightControl ON and OFF

#### To switch the product ON:

1. Put the **power switch** in the ON position.

The Dove Circle lights up while the product boots up.

The LED bar lights up.

When the product is booted up, the DoviCircle pulses with blue light.

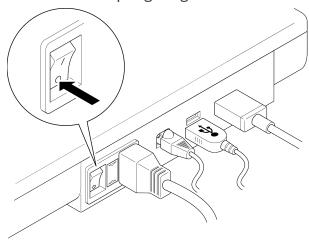
A NOTICE! If the DoviCircle lights continuously white, check that the product is connected to the Internet. For more information, see 7.3 *Troubleshooting*.

#### To switch the product OFF:

1. Put the **power switch** in the OFF position.

The DoviCircle stops lighting.

The LED bar stops lighting.



#### 4.3 Setting up EndoscopeManager

EndoscopeManager is a cloud-based inventory management system that stores your endoscopy equipment test data, tracks its performance, and ensures regulatory compliance.

#### 4.3.1 IT Network Preparation

### **NOTICE**

The LightControl uses an HTTPS connection to back up the database data and download new updates. For this purpose, an external connection must be made to the network to which LightControl is connected.

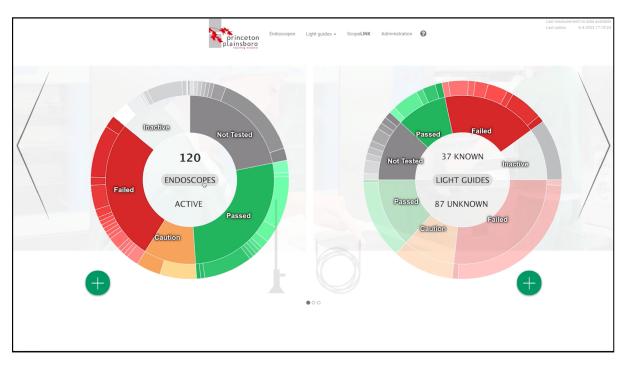
To prepare your IT network for connection to EndoscopeManager:

- 1. Ensure your IT department assigns a dedicated person to assist in preparing your IT network. Share this person's email address with service@dovideqmedical.com. Dovideq will contact this person directly. Under normal circumstances, the preparations should take at most one hour.
- 2. Provide your IT department contact person with the ethernet socket's address for LightControl.
- 3. Ensure your IT department contact person has filled out, checked, and sent the LightControl IT preparation checklist to Dovideq Support. The checklist can be found at http://prepare.endoscopemanager.com. You can add one Administrator and four regular users.

▲ NOTICE! All Dovided products (LightControl, GuideControl, LeakControl, etc.) communicate to data1p1.endoscopemanager.com (84.241.175.30) through HTTPS / port 443. Your systems' MAC addresses can be found in EndoscopeManager.

#### 4.3.2 Logging into EndoscopeManager

- ▶ To log in to EndoscopeManager, go to www.endoscopemanager.com and log in with your credentials. Contact our support team for assistance if you do not have an account.
- ▶ After logging in, you'll go to the main dashboard. The main dashboard gives a pie chart overview of your inventory and its status.



Example of the Main Dashboard on the EndoscopeManager



- ▶ From the main dashboard, you can:
  - add new endoscopes and light cables to your inventory,
  - see your test results,
  - see an overview of your labels,
  - generate customized reports,
  - set notifications, and
  - manage your account.
- ► For more information and a more detailed overview of all functions in your dashboard, go to: https://www.dovideqmedical.com/dovideq-academy-endoscopemanager.

#### 4.3.3 Adding an Endoscope to the Database

Before beginning the process, ensure you have the following:

- ► Access to your EndoscopeManager account.
- ► A DoviScan device.
- ▶ An endoscope equipped with a Unique Device Identification (UDI) code.

#### To add an endoscope to the database:

- 1. Navigate to www.EndoscopeManager.com and log in to your account. Contact our support team for assistance if you do not have an account.
- 2. Upon successful login, locate and click the plus (+) icon on the bottom left corner of the main dashboard, adjacent to the pie chart.
- 3. Click on the textbox labeled "Scan Data Matrix Code" and use DoviScan to scan the UDI code found on your endoscope. After scanning, click "Next".
- 4. Select the appropriate condition of your endoscope from the options: New, Used, or Refurbished. Then click 'Next' to proceed.
- 5. Enter your scope type. This is usually found on the endoscope. For example, for a Karl Storz 26046 AA, enter "26046 AA". The system may suggest a type as you type. *NOTICE:* If your endoscope type is not recognized, you can propose a new type for assessment by Dovideg. You will be contacted with further information.
- 6. Select the correct type if it appears, then click "Next".
- 7. Enter the serial number on your endoscope's shaft or housing. Click "Next" to continue. NOTICE: If the UDI was accurately scanned in Step 3, it should autofill. If not, rescan the UDI using DoviScan. If your endoscope lacks a serial number, assign a unique identifier to this device.
- 8. Review all entered details for accuracy. You can assign the endoscope to a specific department or add comments for clarification. Once verified, click "Next" to finalize the addition.

Your endoscope has been successfully added to the EndoscopeManager database. You are now ready to proceed with LightControl testing.

#### 4.3.4 Locating Test Results

EndoscopeManager stores test results under the corresponding endoscope serial number. To locate LightControl test results in EndoscopeManager:

- 1. Navigate to www.EndoscopeManager.com and log in to your account. Contact our support team for assistance if you do not have an account.
- 2. Click on the Endoscopes pie chart from the main dashboard or select "Endoscopes" in the top menu.
  - You will see an overview of all the endoscopes registered to your account. Every endoscope has a timeline. A green dot indicates a passed test, and a red dot indicates a failed test.
- 3. Your endoscopes are sorted by default by the most recent test. To find a specific endoscope, enter the serial number in the search box at the top right and hit enter.
- 4. Click on the endoscope on which you want to see the test results.

  You'll see a summary of the endoscope usage on the bottom and a timeline showing every parameter score it got within the set date range on the top.
- 5. Navigate to the bottom right section and click "Test Report". This section lists all tests conducted with the selected endoscope.
- 6. To generate a report, select the tests you wish to include and click "Create Report" on the right.
  - A test report will be automatically generated based on your selection.

A comprehensive test report has been generated, consolidating all the results to provide an overview of the endoscope's performance and condition.

#### 4.3.5 Adjusting Thresholds

Adjusting Thresholds is done in EndoscopeManager. The Threshold can be set for different parameters and is determined by the end-user based on their quality demands.

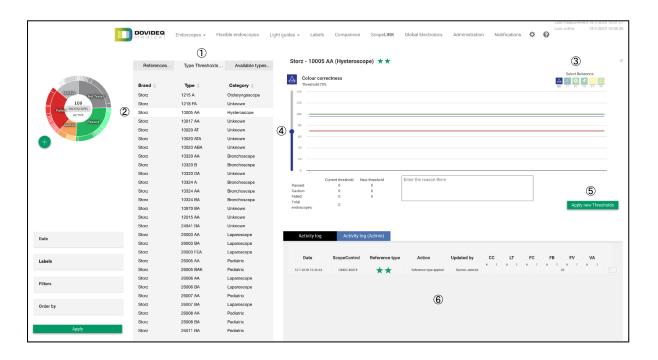
To adjust the threshold:

1. In EndoscopeManager, navigate to "Endoscopes" and select "Select Reference & Change Threshold".





- 2. Select the "Type Threshold" tab. ①
- 3. Select a type from the list you would like to adjust. ②
- 4. Select the parameter for which you wish to adjust the threshold value. ③
- 5. Adjust the threshold value with the slider. ④
  The value of the threshold changes.
- 6. Once you have made the necessary adjustments, save your settings by clicking the button on the right. ⑤
- 7. A log of your activity will be created once you successfully make the changes. ©



# 5. Operation



Always follow the intended use and operational guidelines. It ensures that the LightControl System operates effectively and provides accurate and reliable measurements.

#### 5.1 Setting Up the Testing Procedure

## **A** WARNING

- ▶ Read and understand the safety instructions in the chapter SAFETY.
- ▶ Risk of damage. The device is a highly sensitive measurement device. Only use the device in a controlled electromagnetic environment.

#### To set up the testing procedure:

1. Switch on the product.

The **DoviCircle** lights up while the product boots up.

The **LED bar** lights up.

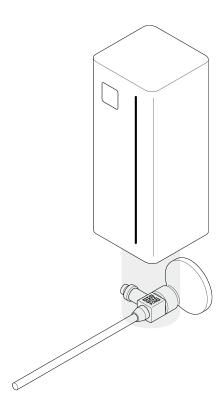
When the product is booted up, the **DoviCircle** has a breathing, blue-light effect.

A NOTICE! Make sure the DoviCircle pulses with blue light. This is an indication that the LightControl is connected with EndoscopeManager.



2. Use the **DoviScan** (or your preferred scanning method) to scan the endoscope's data matrix code (UDI).



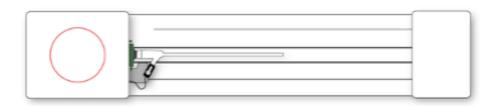


The **DoviCircle** lights up green when the LightControl recognizes the endoscope.

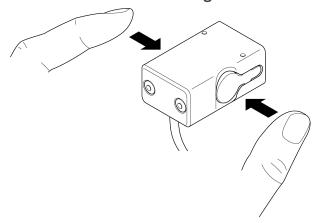


The **DoviCircle** lights up red when the LightControl does not recognize the endoscope.

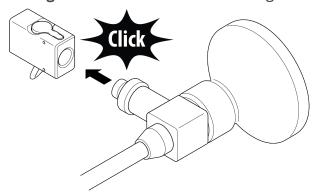
A NOTICE! Unknown endoscopes must be added to EndoscopeManager to be recognized by the LightControl. See 4.3.3 *Adding an Endoscope to the Database*.



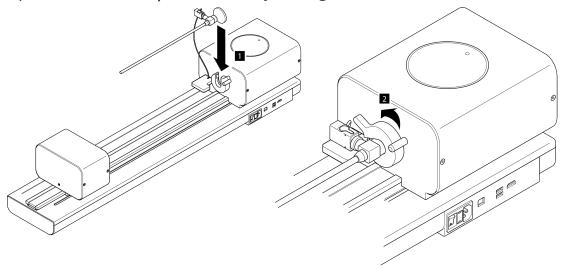
- 3. Connect the **light fiber sensor** to your endoscope. To do so:
  - a. Press both buttons on the **light fiber sensor**.



b. Slide the **light fiber sensor** onto the **light post** of your endoscope.
 The **light fiber sensor** makes a clicking sound when correctly positioned.



- c. Release the buttons on the **light fiber sensor**.
- 4. Put the endoscope with the attached light fiber sensor into the LightControl. To do so:
  - a. Open the **ocular clamp mechanism** by turning the handle clockwise.



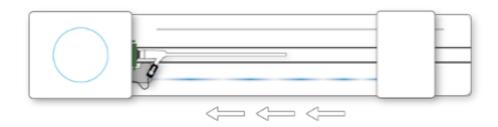
b. Place the **ocular assembly side** of the endoscope into the **ocular clamp mechanism**.



If the **light fiber sensor** rests on the fiber sensor support, it is properly positioned.

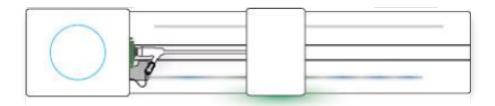
- c. Close the ocular clamp mechanism by turning the handle counterclockwise.
- 5. Manually slide the **sphere compartment** toward the tip of the endoscope.

The **LED bar** shows a moving blue light toward the endoscope.

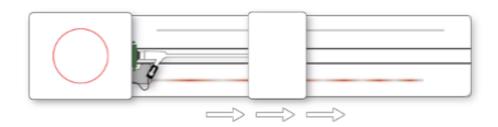


6. Slide the **sphere compartment** over the endoscope.

The tip detection mechanism is activated, and the **DoviCircle** lights up green when the correct position is reached.



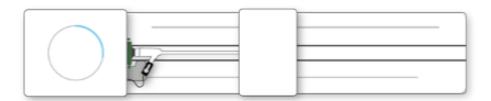
When the **sphere compartment** is pushed too far, the **LED bar** displays a moving <u>red light</u> in the opposite direction of the endoscope. A warning sound also goes off.



7. Push the **sphere compartment** back until it is in the correct position, and the **DoviCircle** lights up green.

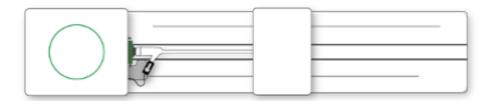
#### 5.2 Running the Testing Procedure

The endoscope's testing procedure starts automatically. During the testing procedure, the **DoviCircle** fills with blue light to indicate the procedure's progress. When the **DoviCircle** is completely filled, the procedure is complete.



The testing procedure takes +/- 2 minutes. The duration may vary depending on the quality of the endoscope.

If the endoscope passes the testing procedure, the **DoviCircle** lights up green, and an audible sequence of two long beeps sounds.



If the endoscope fails the testing procedure according to your set thresholds, the **DoviCircle** lights up red.





▲ NOTICE! The pass/fail indication is based on the user contract's parameters and the user's expressly set thresholds.

#### 5.3 Concluding the Testing Procedure

A NOTICE! If an external monitor display is connected to the LightControl, test results remain on screen until the sphere compartment is moved to its starting position.

To conclude the testing procedure:

- 1. Slide the **sphere compartment** back to the starting position.
- 2. Open the ocular clamp mechanism and remove the endoscope.
- 3. Remove the **light fiber sensor** from the endoscope.

Use the external monitor to view test results and images, or go to EndoscopeManager.com.

#### 5.4 Measurement Specifications

Depending on the end user's contract, LightControl performs tests based on the following measurement techniques.

- 1. Light Transmission (LT)
- 2. Fibers (FB)
- 3. Color Correctness (CC)
- 4. Focus (FC)
- 5. Lens Particle Detection (AI)
- 6. Lens Fracture Detection (AI)

▲ NOTICE! Lens Particle Detection and Lens Fracture Detection are shown in a single column.

#### **Explanation of the measurement techniques**

► Light Transmission (LT)

During the light transmission test, LightControl measures the light transmission through the endoscope's lenses. The output value is based on the measured value and the reference value of the measured endoscope type.

#### ► Fibers (FB)

The light fibers of the endoscope are measured in lux and based on light transmission between the fiber tester and sphere. The output value is based on the measured value and the reference value of the measured endoscope type.

#### ► Color Correctness (CC)

During the color correctness test, the output value is based on the measured value and the reference value of the measured endoscope type.

#### ► Focus (FC)

The focus of the endoscope is calculated using sphere shots, and the deviation of the endoscope is measured in relation to its reference value.

#### ► Lens Particle Detection (AI)

LightControl detects if particles are present on the endoscope's lenses. Images will be directly shown if a monitor is connected.

#### ► Lens Fracture Detection (AI)

LightControl detects if there is a lens fracture in one or more endoscope lenses. Images will be directly shown if a monitor is connected.



# 6. Maintenance and Cleaning

# **A** WARNING

- ▶ Read and understand the safety instructions in the chapter SAFETY.
- ▶ Unplug all connections before cleaning the product. Do not use wipes or chemicals, as these could damage the surface. Wipe the housing with a damp cloth. Electrical/electronic parts shall not be cleaned.
- ► Maintenance and cleaning should be done frequently. If there is any visible damage, a strong odor, or an excessive overheating of components, stop using the product.
- ▶ LightControl is assembled with great care. Periodic maintenance and proper device use will extend its accuracy and lifespan.
- ▶ Calibration and or repairs shall only be made by qualified personnel.
- ► The end user can do all maintenance and inspection work described in these user instructions unless clearly indicated otherwise.
- ▶ Use only original accessories and spare parts.

#### 6.1 Annual Checkup

LightControl must be serviced at least once a year by the manufacturer, distributor, or an authorized representative. For contact information, check *1.6 Service*.

An annual inspection consists of the following points of focus:

- ► Housing (damage and pollution)
- ► Power supply (damage)
- ▶ General electrical safety test

#### 6.2 Cleaning

### **A WARNING**

- ▶ Do not use any organic solvents, detergent agents, cleaning alcohol, or aerosols. These can damage the LightControl.
- ▶ Avoid the use of liquids. There is no moisture seal between the metal exterior and the electrical components of LightControl.

To clean the white and gray cover parts of the LightControl, use a clean, dry cloth to wipe the outer casing. Use disinfectant on a clean cloth when necessary.

The recommended frequency of cleaning the LightControl is once a month or when necessary.

# 7. Troubleshooting

#### 7.1 How to Identify and Solve Problems

# **A** WARNING

- ▶ Read and understand the safety instructions in the chapter Safety.
- ▶ Only qualified, certified personnel may repair, disassemble, or discard the appliance.
- ▶ Alterations to the product and technical modifications are not permitted without written permission of the manufacturer.
- ▶ Do not try to repair the product yourself. Contact the manufacturer if the product is not functioning correctly.

Issue	Cause	Solution
LightControl does not turn on.	No power.	Check if the power cord and a 115-240VDC power outlet are plugged into the machine.
		Check if the power switch is in the I position.
	Blown fuse.	Replace fuses.
The DoviCircle does not turn blue.	No internet connection.	Check if there is an RJ45 cable plugged into the ethernet port and is connected to your LAN. If the problem persists, contact your IT department or support team.
LightControl does not reset after a test cycle.		Turn LightControl off and on again by flipping the power switch to the O position, waiting a few seconds, then switching it back to the I position. If the problem persists, contact the manufacturer.
The fiber sensor gives "0".	The fiber sensor is not working.	Replace the Fiber Sensor.



Issue	Cause	Solution
LightControl flashes red on startup.	The Sphere compartment is not in the starting position.	Slide the sphere compartment to the end position.
DoviScan does not read the scope's UDI.		Let Dovideq check if the DoviScan is set to the correct language.

For more information and support, see https://expertise.dovideqmedical.com.

If none of the suggested solutions solve your issue, please email Dovideq Medical Systems at service@dovideqmedical.com.

# 8. Disposal

# **A** WARNING

- ▶ Read and understand the safety instructions in the chapter Safety.
- ▶ Disconnect the appliance from the power supply when you repair, disassemble, or discard the appliance.

#### 8.1 Disposal of Electronic Components



The symbol on the product, the accessories, or the packaging indicates that this device must not be treated as unsorted municipal waste but must be collected separately. Dispose of the device via a collection point for recycling electrical and electronic equipment waste if you live within the EU and in other European countries that operate separate collection systems for electrical and electronic waste. By properly disposing of the device, you help avoid possible environmental and public health hazards that could otherwise be caused by improper treatment of waste equipment. The recycling of materials contributes to the conservation of natural resources.

#### 8.2 Disposal of Packaging Waste

The packaging is made of environmentally friendly materials, which may be disposed of through your local recycling facilities. Disposing of the packaging and packaging waste properly helps avoid environmental and public health hazards. The symbol on the packaging indicates that the packaging is made of PAP.

#### 8.3 Disposal of Batteries

The product contains a battery. Batteries may not be disposed of with the usual domestic waste. They may contain toxic heavy metals and are subject to hazardous waste regulations. For this reason, dispose of used rechargeable batteries at a local collection point.



# 9. Spare Parts & Accessories

# NOTICE

- ▶ Use only original accessories and spare parts.
- ▶ Use the product, accessories, tools, software, etc., in accordance with these instructions, taking into account the working conditions and the work to be performed. Using the product for operations different from those intended could result in a hazardous situation.

Order spare parts by sending an email to service@dovideqmedical.com.

Part name	Part number
230VAC C13 Power cable	PROD0039 (EU) PROD0040 (UK) PROD0041 (USA/JPN)
UTP network cable	PROD0038
USB A-micro cable	PROD0028
DoviScan Datamatrix scanner	DMSP0001
Fiber sensor	DMSS0011

