

User Manual



VisioClick®



CE

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1. Introduction

1.1. List of Equipment Supplied

Unpacking the box, you will find the following equipment:

- VisioClick® device
- 1 USB cable (cable length 1 m)
- 1 audio headphones (3.5mm jack connector, cable length 1.2 m)
- 1 metallic headphones stand
- CD containing the VisioClick® User Manual and VISIOLITE® software
- Information sheet
- Transport cover

Note: The VisioClick® must be returned to the After-Sales Service in its original packaging. For repairs under warranty, the device will not be covered if it is not in its original packaging.

1.2. Presentation

We recommend reading this User Manual before using the equipment.

This User Manual is intended for users of the Visiolite® vision device with the VisioClick® automatic solution. The VisioClick® automatic solution is compatible with Visiolite® V4 computerized vision devices (from 2012) and the v5 version of the Visiolite® software.

The VisioClick® is a device for automating the VISIOLITE® vision device. The principle of operation of this device is to give voice instructions to the patient via audio headphones, to take into account his answers via a push button, and to relay the communication between the PC and the FIM MEDICAL screening device.

The VisioClick® is composed of a response unit (shell) and audio headphones. The device is connected to a computer via a first USB connection, and to the Visiolite® vision device via a second USB connection. The operator controls the device via the Visiolite® software.

The VISIOCLICK® is a new device intended to alleviate the work of health professionals by rendering a patient autonomous during a test. The professional will be able to focus on other tasks during one or more simultaneous patient examinations. Also, VisioClick® allows for sounds generation in the patient's own language. However, the presence of a professional in the vicinity is mandatory throughout the duration of the test.

1.3. Technical Features

VisioClick® Features	
Storage Temperature	-10 - 60°C
Operational Temperature	15 - 35°C
Humidity	75% maximum
Operational Altitude	< 2000 metres
Voltage	5VDC (via USB port)
Power Consumption	2.5W maximum
Output Impedance	16 Ω - 32 Ω
Audio Connector	3.5 mm
Reference Standards	IEC 60601-1, IEC 60601-1-2
Medical Class	I (rule 12)
Firmware Safety Class	A
Electrical class	Class I
Applied Part	BF Type
GMDN Code	
Dimensions	250x140x50 mm (without headphones stand)
Device Weight	476 g (unit only) 706 g (with cable + stand + headphones)

Year of first CE Marking affixing: 2019

Features of Supplied Headphones (Ref. SS1104)	
Cable length	1.2 m
Shell diameter	70 mm
Impedance	32 Ω
Frequency Range	20 Hz - 20 KHz
Connector	3.5 mm stereo 3-pole audio jack (TRS)

1.4.Symbols

Labels bear the following markings:



CE Marking Directive 93/42/EEC



Type BF applied part



Not to be disposed of with normal household waste. To dispose of this product at the end of its life, please contact the manufacturer.



Consult accompanying documents

SN

Serial number



Manufacturer Identification



Do not reuse. Single-use only

2. Safety

2.1.General

Warning:

- Use only the cables supplied by FIM MEDICAL
- Do not dismantle or work on the unit. Only the FIM MEDICAL After-Sales Service and authorized distributors are qualified to work on the equipment
- Do not connect or use the VisioClick® in an explosive environment or in the presence of anaesthetic gases
- Do not pull on the cables
- Do not use the device with damaged cables
- No modification of the equipment is authorized
- In the event of accidental damage (falling or impact), return the device to FIM MEDICAL After-Sales Service or to your distributor if he has been authorized by FIM MEDICAL for maintenance
- Do not wet the device, protect it from any splashing liquid. Never clean the VisioClick® under running water or spray the device directly with a liquid
- The device must be placed on a flat and stable surface
- In the event of visible damage to the device or its accessories, contact FIM MEDICAL After-Sales Service or your distributor
- VisioClick® is intended for use with the Visiolite® vision device or any other authorized FIM MEDICAL device. Any other connection to third party devices is not permitted
- A visual check and proper functioning of the equipment before any use and after each test with a patient is required
- The headphones stand must not be removed during a test. Please do not allow young children to play with the device
- To avoid electromagnetic or other interference problems with other devices, do not use VisioClick® in a turbulent environment or too close to other devices
- For safety reasons, access to the USB cable connection on the computer or device must be left accessible
- Avoid using the VisioClick® in a noisy environment that impedes correct understanding of the oral instructions given by the headphones
- Although the VisioClick® device gives the patient some autonomy, a healthcare professional must always be present in the vicinity to monitor correct running of tests
- VisioClick® is a Medical Device according to the terms of the regulations applicable to it. Its connection to a computer can only be made if it complies with the IEC60950 standard for the safety of information technology equipment

Warning: to meet the biocompatibility constraints of ISO 10993 materials, it is mandatory to use the FIM MEDICAL brand single-use hygienic earpad covers with the headphones.

2.2.Users

VisioClick® is reserved exclusively for healthcare professionals (nurse, doctor, ophthalmologist, optician...) who use the Visiolite® vision device and its software.

Given the level of education of health professionals, the device does not present any difficulty in its use.

The operator must be sufficiently trained in the use of computers and the associated operating system.

The operator must be made aware of the rules of hygiene and bacterial contamination.

If in doubt, the healthcare professional should refer to the User Manual and/or contact the FIM MEDICAL company or its distributor.

2.3.Medical Contraindications

Since VisioClick® works with the VISIOLITE® vision device, medical contraindications are those that apply to the VISIOLITE® vision device. Refer to §2.3 of the VISIOLITE® User Manual.

The VisioClick® is an auditive device with audio headphones for voice-activated commands. Ensure that the patient is able to understand the instructions in the chosen language and is able to wear the headphones.

Wearing a hearing aid is not permitted during the test.

2.4.Precautions Before Tests

Before using the VisioClick® device, the operator must inform and explain to the patient how the automated system works (listening to instructions, answers, etc.). Refer to the VISIOLITE® User Manual.

3. Installation

3.1. Equipment Installation Procedure

3.1.1. Unpacking

Remove the bag containing the VisioClick® elements from its cardboard box.

We strongly recommend keeping the original VisioClick® packaging in its entirety for future maintenance.



Figure 1 Opening the original VisioClick® packaging

3.1.2. Nomenclature



Figure 2 VisioClick® and accessories

1 Unit

The VisioClick® unit is composed of a base on which the headphones stand is placed, a functional part for the response button and a connector part.

2 Headphones Stand

The headphones stand can be used to hold the headphones when not in use.

3 Headphones

The headphones are connected to the VisioClick® base to receive instructions during tests.

4 USB Cable

The USB cable connects to another device or computer. This is the power supply for the VisioClick®.

3.1.3. Operating Mode

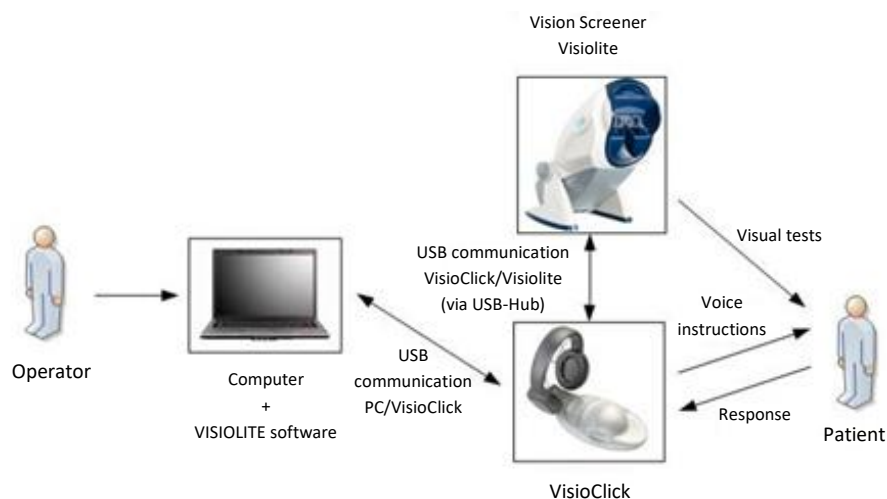


Figure 3 Diagram of VisioClick® operating mode

3.1.4. Assembly and Connection



Figure 4 Installation of headphones stand

- Insert the arms of the headphones stand into the 2 holes of the base provided for this purpose. The ring or buckle must be facing the user. Check that the arms are fully inserted and that the stand is securely held in place.



Figure 5 Rear side - Connector support

1 Audio headphones cable

2 USB cable to FIM device

3 USB cable to computer

- Connect the headphones cable to the jack plug (1) of the VisioClick® base. Then place the headphones onto the stand.



Figure 6 VisioClick® with headphones placed correctly onto the stand

- Use the 1m USB cable provided with the VisioClick® to connect the Visiolite® to the VisioClick®. The flat section of the cable is connected to the VisioClick® (2) while the square section is connected to the Visiolite®.
Warning: the power cable of the Visiolite® must still be connected. See Visiolite® User Manual.
- Use the 3 m USB cable provided with the Visiolite® to connect the VisioClick® to the computer. The square section of the cable is connected to the VisioClick® (3) and the flat section is connected to the computer.

3.2. Compatible Operating Systems

VisioClick® works with the following operating systems: **Windows XP, Windows Vista, Windows 7, Windows 8, Windows 8, Windows 8.1 and Windows 10.**

3.3. Using the FIM Device Software

VisioClick® is designed to operate from the software developed for the FIM device to which it is connected. Refer to the User Manual of the latter to use the software interface.

In order to ensure correct operation of the VisioClick®, the software of the FIM device must be updated (refer to the User Manual of the connected device).

4. Available Accessories

4.1. Hygienic Single-use Earpad Covers (Ref. SS1105)

FIM MEDICAL has specifically developed single-use hygienic earpad covers for use with the headphones supplied with the VisioClick®.

Warning: These single-use hygienic earpad covers must be used for every test and changed between patients.

Warning: For hygiene and biocompatibility reasons, it is essential to use the FIM MEDICAL single-use hygienic earpad covers with the audio headphones.

These covers have been specifically developed to meet the biocompatibility requirements of ISO 10993 materials as well as the dimensions of the headphones supplied with the VisioClick®.

If you require FIM MEDICAL single-use hygienic earpad covers, contact FIM MEDICAL or your distributor. Different packaging types are available.

4.2. Audio Headphones (Ref. SS1104)

With the VisioClick®, FIM MEDICAL markets audio headphones, the features of which are specified in §1.2.

Other commercial headphones may be suitable by complying with the technical specifications specified in §1.2. (impedance range, connector format...) and provided that a shell diameter of 70mm is respected in order to use the single-use earpad covers specifically developed by FIM MEDICAL (Ref. SS1105).

Warning: For hygiene and biocompatibility reasons, it is essential to use the FIM MEDICAL single-use hygienic earpad covers with the audio headphones (Ref. SS1105).

These covers have been specifically developed to meet the biocompatibility requirements of ISO 10993 materials as well as the dimensions of the headphones supplied with the VisioClick®.

To obtain audio headphones, contact FIM MEDICAL or your distributor.

4.3. USB Cable (Ref. SS1103)

With the VisioClick®, FIM MEDICAL markets a USB cable from type A to type B, of 1-m length.

5. Use

5.1. Installation of Hygienic Single-use Earpad Covers



Figure 7 Positioning the hygienic earpad cover onto the earcups of the headphones

- ✓ Position a single-use earpad cover on each earcup of the audio headphones (loudspeaker side).
- ✓ Adjust the cover to avoid excess thickness from possible folds between the headphones and the patient.

Reminder: These single-use hygienic earpad covers must always be used for each test and replaced between each patient.

These earpad covers have been specifically developed to meet the biocompatibility requirements of ISO 10993 materials as well as the headphones size. As such, it is essential to use the FIM MEDICAL brand of covers with headphones.

5.2. Use With a Visiolite®

- ✓ Position the Visiolite® on the table, and connect its power supply unit to the 230V mains supply.
- ✓ Position the VisioClick® to the left or right of the Visiolite®.
- ✓ Connect the VisioClick® to a computer and to the Visiolite® as indicated in §**Erreur ! Source du renvoi introuvable.** of this Manual.
- ✓ Turn on the Visiolite® software on the computer. The VisioClick® and the Visiolite® should be detected and ready to use.

The VisioClick® device is designed to operate with the Visiolite® device and the associated software. It is necessary to read the relevant paragraph in the User Manual of the Visiolite® software on the setup and use of VisioClick® with a Visiolite®. The Visiolite® software User Manual is supplied with the CD included with the VisioClick®.

Reminder: the VisioClick® device is compatible with the Visiolite® v4 device from version v05.00.00.00 of the Visiolite® software.

6. Care - Maintenance

6.1. Cleaning the Unit

For hygiene reasons, it is essential to disinfect the surfaces of the VisioClick® in contact with the skin (unit) between each test. The unit can be cleaned with a cloth soaked in a bactericidal fungicidal product approved by FIM MEDICAL (see list in §6.3).

- **Warning:** Never sterilize the VisioClick® or its accessories
- **Warning:** Never clean the VisioClick® under running water or immerse it directly into any kind of liquid.
- If the unit becomes damaged, contact FIM MEDICAL or your distributor for a change of equipment.

6.2. Cleaning of Headphones

For hygiene reasons, it is important to disinfect the headphones surfaces (shells, headband) with a cloth soaked in a bactericidal fungicide product approved by FIM MEDICAL (see list in §6.3).

- **Warning:** The use of single-use earpad covers does not exempt the equipment from disinfection.
- **Warning:** Never sterilize the headphones
- **Warning:** Never clean the headphones under running water or immerse it directly into any kind of liquid.
- If the headphones are damaged, contact FIM MEDICAL or your distributor for a change of equipment.

6.3. List of Generic Bactericidal Fungicidal Products Validated by FIM MEDICAL

Due to a large number of brands and references of disinfectant wipes on the market, FIM MEDICAL has validated references for its products that do not alter the appearance or resistance of the plastic materials in the shells of its equipment.

For the disinfection of its products, FIM MEDICAL has validated the use of the following wipes or cloths:

- 70% isopropyl alcohol
- Bactynyl® disinfection wipes
- Clorox® Healthcare Bleach
- Sani-Cloth® Bleach
- Sani-Cloth® Plus
- Sani-Cloth® HB
- Super Sani-Cloth®
- Sanicloth® AF3
- Formula 409®
- Virex® Plus

6.4. Breakdowns

If a breakdown occurs, check the USB connections to the PC and FIM MEDICAL device. Check that the drivers are installed on the computer and that the device is recognized. If necessary, reinstall the supplied software and restart the computer.

The FAQ (Frequently Asked Questions) chapter gives some answers to other most commonly asked questions. If the unit still won't operate, disconnect it and, if possible, place in its original packaging with the cable and accessories. The FIM MEDICAL After-Sales Service or your distributor (if he has been authorized by FIM MEDICAL) are at your disposal for maintenance.

6.5. Warranty

The VisioClick® has a **2-year warranty**.

The headphones have a **1-year warranty**.

Under the contractual warranty, only repairs are covered. The warranty is only applicable if normal and customary conditions of use of the device have been respected.

6.6. Recycling – End of Life

The VisioClick® and its accessories must be returned to FIM MEDICAL upon termination of use. FIM MEDICAL will take care of recycling and destruction.

The device can also be handled by an electronic device recycling system that guarantees low environmental impact.

Hygienic earpad covers must be part of a selective collection for biologically contaminated waste.

7. FAQ

7.1. I do not hear any sound

- Check that the USB cable is connected between the PC and the connector (3) of the VisioClick®.
- Check that the headphones are correctly connected to the VisioClick® connector (1).
- Check that the headphones work with another source (on your computer for example), then reconnect them to the VisioClick®.
- Check the volume control settings on the Visiolite software. Refer to the Visiolite® User Manual.
- If the problem persists, contact the FIM MEDICAL After-Sales Service or your distributor (if he has been authorized by FIM MEDICAL to provide after-sales service).

7.2. Can I use other audio headphones than the one provided by FIM MEDICAL?

- Other commercial headphones may be suitable by complying with the technical specifications specified in §1.2. (Impedance range, connector format, etc.).
- The headphones must also have a shell diameter of 70mm in order to be able to use the single-use earpad covers specifically developed by FIM MEDICAL (Ref. SS1105).

7.3. Can I connect a device other than the Visiolite® to the USB port of the VisioClick®?

- The VisioClick® is only intended for use with the Visiolite® vision device or any other authorized FIM MEDICAL device.
- Any other connection to third party devices is not authorized.



Thank you for reading this User Manual.

*If you would like more information, please don't
hesitate to contact us.*



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