

CapiScope HVCS User Guide

Preface

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Introduction

This manual provides operating instructions and guidelines for the **CapiScope HVCS Handheld Video Capillary Microscope** .

A battery powered notebook computer is necessary to use The CapiScope HVCS.

Assumptions

The instructions in this manual assume that the user has been trained in the proper use of the **CapiScope HVCS** and that he or she has the required medical education and experience to operate this equipment safely and effectively.

Intended Use

The CapiScope HVCS is intended solely for the visualization and characterization of the microcirculation system of the surface of the skin and other sites such as mucosal tissue. No diagnostic or therapeutic claims are made for the device.

The CapiScope HVCS is intended for invasive and transient use (continuous use < 60 minutes). It is not intended for surgically invasive use.

System Requirements

The CapiScope HVCS requires a battery powered notebook computer running Windows XP, Windows 7,8, 32bit or 64bit, a USB 2.0 port and a viewing screen. A processor running at least 1.6 GHz and 1 Gbyte RAM is recommended. The computer must not have any electrical connections to other devices. If powered from a mains supply, the power supply must be IEC60601-1 compliant.

Warnings and Cautions

Read and practice the following general warnings and cautions when you use the **CapiScope HVCS**.

General Warnings and Cautions

Do not attempt to operate the **CapiScope HVCS** until you have read and thoroughly understood the directions and warnings in this user manual.

Warnings

A warning statement in this manual identifies a condition or practice, which if not discontinued or immediately, could lead to injury, illness, or death.

| | |
|---------|--|
| WARNING | To ensure safe operation of the CapiScope HVCS , you must place the CapiScope HVCS Probe Cover on the probe before applying the probe to tissue. To avoid exposure to biohazardous material, adhere to standard protection from blood-borne pathogen exposure procedures, including the following: <ul style="list-style-type: none"> – Wearing protective gloves, – Wearing protective goggles or using a biohazard shield, – Wearing a lab coat. |
| WARNING | Do not touch the HVCS and the patient simultaneously without the Probe Cover fitted. |
| WARNING | Risk of explosion. Do not use the CapiScope HVCS in the presence of flammable liquids or gases, including flammable anaesthetics. |
| WARNING | If you apply the probe to live tissue, do NOT exert excessive pressure. If you do, tissue damage may result. |
| WARNING | Medical professionals should never make a diagnosis based solely on the CapiScope HVCS images. |
| WARNING | High energy concentrated light. Do not look directly into the light source. |
| WARNING | This product has no user serviceable or replaceable parts except for the probe lens and probe cover. Repairs made by anyone other than KK Research Technology Limited certified individuals will void the product warranty. |
| WARNING | No modification of this equipment is allowed. |
| WARNING | The USB port output connector must ONLY be connected to a battery powered notebook computer with no other wired connections to any other device. The laptop computer must only be ever powered from a mains supply using a IEC 60601-1 certified power supply. |
| WARNING | This equipment is intended for use by healthcare professionals only. This equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the CapiScope HVCS or shielding the location. |

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Cautions

A caution statement in this manual identifies a condition or practice, which if not discontinued or immediately, could lead to equipment failure, equipment damage, or data loss.

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| CAUTION | In order to obtain optimum performance and to ensure patient safety, thoroughly read this document. |
| CAUTION | Never grab the probe by its objective (probe tip). |
| CAUTION | Never use if you notice any signs of damage to any components of the system. |
| CAUTION | Do not attempt to disinfect the CapiScope HVCS with glutaraldehyde products, ethylene oxide gas, steam, or any other liquid or gas disinfectant. |
| CAUTION | This product complies with current required standards for electromagnetic interference and should not present problems to other equipment or be affected by other devices. As a precaution, avoid using this device in close proximity to other devices. |

Probe Cover Warnings and Cautions



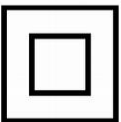

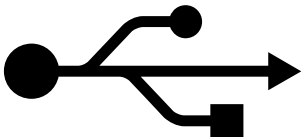

Warnings

| | |
|---------|--|
| WARNING | Do not reuse the Probe Cover. Reuse could result in patient infection. Dispose of used Probe Covers in biohazard containers. |
| WARNING | It is unsafe to operate the CapiScope HVCS without a Probe Cover. To ensure safe operation, you must check for the presence of the Probe Cover before you use the probe. |
| WARNING | Do not make contact with the patient whilst changing Probe Covers. |
| WARNING | If the Probe Cover package is open or damaged, do NOT use that Probe Cover. Dispose of it and obtain a replacement. |
| WARNING | Always inspect the Probe Cover before use. If the Probe Cover is disfigured or broken, if it has a sharp edge, or if it has any type of noticeable damage, do NOT use it. Dispose of it properly and install a new Probe Cover on the probe. |
| WARNING | Maximum duration of Probe Cover contact with patient is 60 minutes. |

Cautions

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| CAUTION | Install the Probe Cover securely to minimize the chances of accidental dislodging. |
|---------|--|

Symbols and Labels

| | |
|---|---|
|  | <p>Consult Operating instructions</p> |
|  | <p>TYPE B APPLIED PART</p> |
|  | <p>CLASS II EQUIPMENT</p> |
| <p>IPX0</p> | <p>NOT PROTECTED FROM THE INGRESS OF WATER</p> |
|  | <p>The CE mark on this product indicates that it has been tested to and conforms with the provisions noted within the 93/42/EEC Medical Devices Directive</p> |
|  | <p>USB</p> |
|  | <p>Recycle the product separate to other disposables. See Recycling.</p> |
| <p>TRIGGER</p> | <p>Capture image. Start/stop video recording.</p> |

Software Installation

Before plugging the **CapiScope HVCS** USB connector into the computer, install the Drivers and **CapiScope** analysis software.

CapiScope

Download and run

<http://kktechnology.com/support/hvcs/HVCS.exe>

Drivers

Download and run either:

a) for 32 bit Windows

http://kktechnology.com/support/hvcs/hvcs_driver32.exe

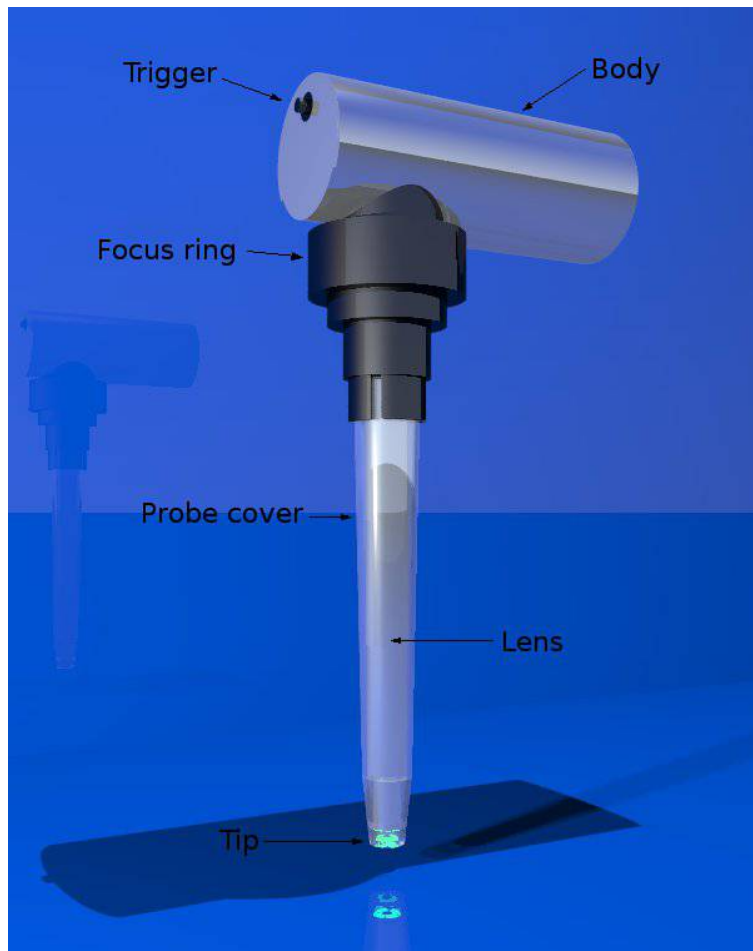
b) or for 64 bit windows

http://kktechnology.com/support/hvcs/hvcs_driver64.exe

Operation

Parts of the CapiScope HVCS

The **CapiScope HVCS** is a handheld device with a body, lens probe, focus ring and disposable Probe Cover.



Using the CapiScope HVCS

CapiScope Probe Cover

The Probe Cover is the APPLIED PART, a precision-manufactured disposable that fits over the probe. The closed end of this cover is a precision optical window. This provides protection for the probe objective and also electrical and biohazard protection for the patient. The Probe Cover is a single-use disposable accessory. Do not reuse it. Dispose of each used Probe Cover in biohazard containers.

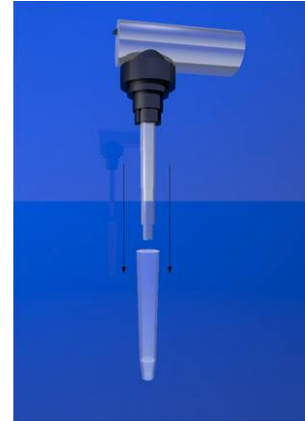
Do not use the **CapiScope HVCS** without a Probe Cover.

Do not touch the patient whilst changing a Probe Cover.

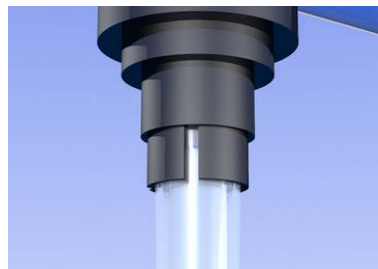
Replace the probe cover with a new one.

Remove the old probe by pulling straight down.

Push on the new probe cover.



Make sure the cover pushes fully into the clip. The top of the probe cover should reach the top of the slots in the clip.



When you've finished using the **CapiScope HVCS** always put a Probe Cover on to protect the lens.

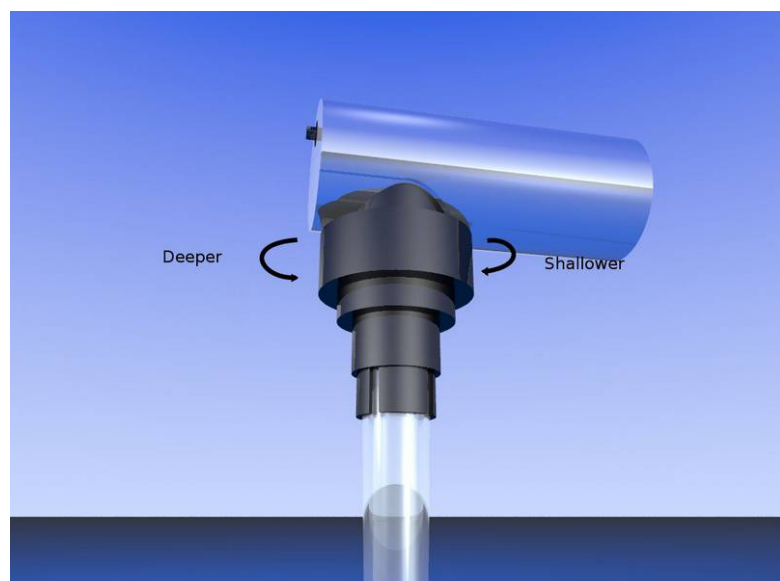
Using the Focus Ring

The **CapiScope HVCS** has a fixed focal plane a few millimeters beyond the probe tip.

Turning the focus ring moves the probe cover closer or further away.

Looking from the top, turn the focus ring clockwise to focus deeper into the tissue. Turn anticlockwise to focus closer to the surface.

When first using the **CapiScope HVCS**, turn the focus ring anticlockwise fully, then turn



clockwise about one turn until the tissue surface is in focus. Turn a little more to focus on the capillaries below the surface.

One turn = one millimeter.

Maintenance and Service

Cleaning Recommendation

Close the CapiScope Analysis program switch off and unplug the CapiScope HVCS.

Use only 70% isopropyl alcohol or SANI-CLOTH HB wipes to clean the external surfaces of the **CapiScope HVCS** between uses to avoid contamination and the transmission of disease.

CAUTION: Do NOT use excessive liquid which might ingress into the device.

CAUTION: Do NOT use acetone to clean any part of the **CapiScope HVCS**.

CAUTION: Do NOT attempt to sterilize the **CapiScope HVCS** using heat, steam, immersion, gas, or radiation.

Servicing

All repairs on products under warranty must be performed or approved by KK Technology. Unauthorized repairs will void the warranty. In addition, whether or not covered under warranty, any product repair shall exclusively be performed by KK Technology certified service personnel.

If the product fails to function properly, or if you need assistance, service, or spare parts, contact KK Technology.

Before contacting KK Technology, try to duplicate the problem, and check all accessories to ensure that they are not causing the problem. When calling, please be prepared to provide:

Product name and model number and complete description of the problem.

Serial number of your product (if applicable).

Complete name, address and phone number of your facility.

For out-of-warranty repairs or spare parts orders, a purchase order (or credit card) number.

For parts orders, the required spare or replacement part numbers.

If your product requires warranty, extended warranty, or non-warranty repair service, please call KK Technology. A representative will assist you troubleshooting the problem and will make every effort to solve it over the phone, avoiding potential unnecessary returns.

In case a return cannot be avoided, the representative will record all necessary information and will provide a Service Notification number, as well as the appropriate return address. The Service Notification number must be obtained prior to any return.

If you have to return goods for service, follow these recommended packing instructions: Remove all hoses, cables, sensors, power cords, and ancillary products (as appropriate) before packing, unless you suspect they are associated with the problem.

Wherever possible use the original shipping carton and packing materials.

Include a packing list and the KK Technology Service Notification number.

It is recommended that all returned goods be insured. Claims for loss or damage to the product must be initiated by the sender.

Accessories

| CODE | DESCRIPTION |
|--------|---|
| PC150 | Single use plastic Probe Covers. Non sterile. Box of 150. |
| LNFB | Non-contact nailfold capillaroscopy lens. High Power 6x3 |
| LNFL | Non-contact nailfold capillaroscopy lens. Low Power 3x |
| LNSH | Additional lens. High Power 6x3 |
| LNSL | Additional lens. Low Power 3x |
| WPXYZH | Workplatform stand for Nailfold HVCS including XYZ positioning. |

Recycling

Within the EU

Do not dispose of this product as unsorted municipal waste. Prepare it for reuse or separate collection as specified by Directive 2002/96/EC of the European Parliament and the Council of the European Union on Waste Electronic and Electrical Equipment (WEEE).

If this product is contaminated, this directive does not apply.

For more information see www.kktechnology.com/recycle.html

Outside the EU

When the product reach end of life, recycle it locally according to national, state, and local regulations, or return it to KK Technology.

Specifications

Imaging

| | HVCS | HVCS-HR |
|--------------------------|------------|-------------|
| Image size (pixels) | 752 x 480 | 1280 x 1024 |
| standard lens: | | |
| Magnification (µm/pixel) | 0.92 | 0.81 |
| field of view (µm) | 692 x 442 | 1037 x 829 |
| low power lens: | | |
| Magnification (µm/pixel) | 1.94 | 1.71 |
| field of view (µm) | 1459 x 931 | 2186 x 1749 |

Illumination: 4 x 525 nm light sources.
 Video output: USB uncompressed.

Dimensions

Body: 100 mm x 42 mm Diameter
 cap length: 129.5 mm
 cap diameter at tip: 10mm
 weight 270g

Operating Conditions

Temperature +10°C to +35°C
 Relative Humidity 30% to 75% noncondensing
 Altitude 700 to 1060 hPa

Shipping and Storage Conditions

Temperature -10°C to +45°C
 Relative Humidity 95% noncondensing maximum

Software

CapiScope software requires Windows XP, Vista, Windows7 or Windows8.

Standards

EN 60601-1:2006 Medical electrical equipment.
 CE Medical Devices Directive 93/42/EEC Annex VII. (class I device).

| Guidance and manufacturer's declaration – electromagnetic emissions | | |
|---|-------------------|--|
| The CapiScope HVCS is intended for use in the electromagnetic environment specified below. The customer or the user of the CapiScope HVCS should assure that it is used in such an environment. | | |
| Emissions test | Compliance | Electromagnetic environment – guidance |
| RF emissions CISPR 11 | Group 1 | The CapiScope HVCS 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. |
| RF emissions CISPR 11 | Class A | The CapiScope HVCS 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 emissions IEC 61000-3-2 | Not applicable | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Not applicable | |

| Guidance and manufacturer's declaration – electromagnetic immunity |
|---|
| The CapiScope HVCS was not tested for IMMUNITY to ELECTROMAGNETIC DISTURBANCES. |