

Recommendation

ITU-T F.780.1 (V3) (04/2023)

SERIES F: Non-telephone telecommunication services

Multimedia services

Framework for telemedicine systems using ultra-high definition imaging



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Recommendation ITU-T F.780.1

Framework for telemedicine systems using ultra-high definition imaging

Summary

Recommendation ITU-T F.780.1 describes requirements for using ultra-high definition (UHD) imaging, such as 4K and 8K video, for telemedicine. The purpose of these requirements is to use UHD systems for medical practices that use endoscopes and/or microscopes. This Recommendation also describes a list of requirements for using a UHD-based "endoscopic video camera" as a medical device.

In addition, Annex A describes the requirements for the use of this technology as a medical device.

This revision adds the clause for profiles of UHD imaging for medical services, as well as new definitions and abbreviations.

History

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Recommendation ITU-T F.780.1

Framework for telemedicine systems using ultra-high definition imaging

1 Scope

This Recommendation describes use cases and requirements for using ultra-high definition (UHD) imaging for telemedicine. The purpose of these requirements is to use UHD systems as part of an endoscope and/or microscope for medical practices. This Recommendation also describes a list of requirements for using a UHD-based "endoscopic video camera" as a medical device.

2 References

The following ITU-T Recommendations and other references contain provisions which, through reference in this text, constitute provisions of this Recommendation. At the time of publication, the editions indicated were valid. All Recommendations and other references are subject to revision; users of this Recommendation are therefore encouraged to investigate the possibility of applying the most recent edition of the Recommendations and other references listed below. A list of the currently valid ITU-T Recommendations is regularly published. The reference to a document within this Recommendation does not give it, as a stand-alone document, the status of a Recommendation.

- [ITU-T H.265] Recommendation ITU-T H.265 (2021), *High efficiency video coding*.
- [ITU-R BT.709-6] Recommendation ITU-R BT.709-6 (2015), Parameter values for the HDTV standards for production and international programme exchange.
- [ITU-R BT.1120-9] Recommendation ITU-R BT.1120-9 (2017), Digital interfaces for studio signals with $1\,920\times1\,080$ image formats.
- [ITU-R BT.2020-2] Recommendation ITU-R BT.2020-2 (2015), Parameter values for ultra-high definition television systems for production and international programme exchange.
- [ITU-R BT.2100-2] Recommendation ITU-R BT.2100-2 (2018), *Image parameter values for high dynamic range television for use in production and international programme exchange*.
- [ARIB STD-B58] ARIB STD-B58 (2014), Interface for UHDTV Production Systems.
- [CISPR 11] CISPR 11:2015+AMD1:2016+AMD2:2019 CSV Consolidated version,

 Industrial, scientific and medical equipment Radio-frequency disturbance characteristics Limits and methods of measurement.
- [IEC 60601-1] IEC 60601-1:2005+AMD1:2012, CSV Consolidated version, Medical electrical equipment Part 1: General requirements for basic safety and essential performance.
- [IEC 60601-1-2] IEC 60601-1-2:2014+AMD1:2020 CSV Consolidated version, *Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance Collateral Standard: Electromagnetic disturbances Requirements and tests.*
- [IEC 61000-3-2] IEC 61000-3-2:2014, Electromagnetic compatibility (EMC) − Part 3-2: Limits − Limits for harmonic current emissions (equipment input current ≤ 16 Aper phase.

- [IEC 61000-3-3] IEC 61000-3-3:2013+AMD1:2017+AMD2:2021 CSV Consolidated version, Electromagnetic compatibility (EMC) Part 3-3: Limits Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current \leq 16 A per phase and not subject to conditional connection.
- [IEC 61000-4-2] IEC 61000-4-2:2008, Electromagnetic compatibility (EMC) Part 4-2: Testing and measurement techniques Electrostatic discharge immunity test.
- [IEC 61000-4-3] IEC 61000-4-3:2006, Electromagnetic compatibility (EMC) Part 4-3: Testing and measurement techniques Radiated, radio-frequency, electromagnetic field immunity test.
- [IEC 61000-4-4] IEC 61000-4-4:2012, Electromagnetic compatibility (EMC) Part 4-4: Testing and measurement techniques Electrical fast transient/burst immunity test.
- [IEC 61000-4-5] IEC 61000-4-5:2014+AMD1:2017 CSV Consolidated version, Electromagnetic compatibility (EMC) – Part 4-5: Testing and measurement techniques – Surge immunity test.
- [IEC 61000-4-6] IEC 61000-4-6:2003/AMD2:2006, Amendment 2 Electromagnetic compatibility (EMC) Part 4-6: Testing and measurement techniques Immunity to conducted disturbances, induced by radio-frequency fields.
- [IEC 61000-4-8] IEC 61000-4-8:2009, Electromagnetic compatibility (EMC) Part 4-8: Testing and measurement techniques Power frequency magnetic field immunity test.
- [IEC 61000-4-11] IEC 61000-4-11:2004/AMD1:2017, Amendment 1 Electromagnetic compatibility (EMC) Part 4-11: Testing and measurement techniques Voltage dips, short interruptions and voltage variations immunity tests.
- [IETF RFC 3550] IETF RFC 3550 (2003), RTP: A Transport Protocol for Real-Time Applications.
- [IETF RFC 4175] IETF RFC 4175 (2005), RTP Payload Format for Uncompressed Video.
- [SMPTE 424M] SMPTE ST 424:2012 SMPTE Standard 3 Gb/s Signal/Data Serial Interface.
- [SMPTE 425-1] SMPTE ST 425-1:2017 SMPTE Standard Source Image Format and Ancillary Data Mapping for the 3 Gb/s Serial Interface.
- [SMPTE 2022-6] SMPTE ST 2022-6:2012 SMPTE Standard *Transport of High Bit Rate Media Signals over IP Networks (HBRMT)*.
- [SMPTE 2082-10] SMPTE ST 2082-10:2018 SMPTE Standard 2160-line and 1080-line Source Image and Ancillary Data Mapping for 12G-SDI.
- [SMPTE 2110-20] SMPTE ST 2110-20:2017 SMPTE Standard *Professional Media Over Managed IP Networks: Uncompressed Active Video*.

3 Definitions

3.1 Terms defined elsewhere

None.

3.2 Terms defined in this Recommendation

This Recommendation defines the following terms:

- **3.2.1 4K UHD**: A video format in which the horizontal screen resolution is 3 840 and the vertical screen resolution is 2 160 pixels (2160p).
- **3.2.2 8K UHD**: A video format in which the horizontal screen resolution is 7 680 and the vertical screen resolution is 4 320 pixels (4320p).
- **3.2.3 dual green Bayer**: A colour filter array for arranging RGB colour filters on a square grid of image sensors. Its particular arrangement of colour filters is found in most single-chip digital image sensors used in digital cameras to create a colour image. The filter pattern is 50% green, 25% red (R) and 25% blue (B), hence it is also called RGBG, GRGB, RGGB.
- **3.2.4 microsurgery**: Surgery requiring an operating microscope.
- **3.2.5 ultra-high definition**: A video format of digital display and camera in which the horizontal screen resolution is on the order of over 4 000 pixels.
- **3.2.6 ultra-high definition imaging**: Video imaging using system parameters of an ultra-high definition television (UHDTV) as defined by [ITU-R BT.2020-2].

4 Abbreviations and acronyms

This Recommendation uses the following abbreviations and acronyms:

B Blue colour

CCU Camera Control Unit

CMOS Complementary Metal Oxide Semiconductor

DG Dual Green

Fps Frames per second

G Green colour

GI Graded-Index multimode

HD High-Definition

HDMI High-Definition Multimedia Interface

IP Internet ProtocolIPS In-Plane Switching

IR Infra-Red

LCD Liquid Crystal Display
LED Light Emission Display

OLED Organic LED

POF Plastic Optical Fibres

R Red colour

SDI Serial Digital Interface

TN Twisted Nematic

UHD Ultra-High Definition

UHDTV Ultra-high definition television

VA Vertical Alignment

5 Conventions

The following conventions are used in this Recommendation:

- The keywords "is required to" indicate a requirement which must be strictly followed and from which no deviation is permitted, if conformance to this Recommendation is to be claimed.
- The keywords "is recommended" indicate a requirement which is recommended but which
 is not absolutely required. Thus, this requirement need not be present to claim conformance.
- The keywords "can optionally" indicate an optional requirement which is permissible, without implying any sense of being recommended. This term is not intended to imply that the vendor's implementation must provide the option and the feature can be optionally enabled by the network operator/service provider. Rather, it means the vendor may optionally provide the feature and still claim conformance with this Recommendation.

Requirements are identified using the following conventions:

- Requirement number xx in clause n.m is of the form R-xx;
- Recommended requirement number yy in clause n.m is of the form RR-yy;
- Optional requirement number zz in clause n.m is of the form OR-zz.

6 Background

Ultra-high definition (UHD) video technologies, including 8K technology, are advancing rapidly. The present burgeoning of 8K UHD imaging technology is ushering in an era of video with a 16-fold higher resolution (7.680×4.320 pixels, about 33 million pixels) than the current high-definition (HD) (1.920×1.080 pixels, about 2 million pixels) technology and enabling the development of the next-generation 8K broadcasting system.

In this context, there are growing expectations for many important contributions of 8K UHD technology to innovative medical imaging in advanced image-guided diagnosis and treatment. Midway between HD and 8K UHD, 4K UHD imaging technology (3 $840 \times 2 160$ pixels, about 8 million pixels) is also gradually progressing for medical use.

Endoscopic surgery, where surgeons operate by watching a lesion on a video screen with a camera in the body, cannot be performed without utilizing video imaging technology. However, the use of low-resolution images creates issues such as poor depth perception and lack of detail when zoomed in. These problems can be solved by implementing UHD imaging technology such as 8K technology. Experimental and clinical studies have revealed the mechanical and technical feasibility of the 8K UHD endoscope, providing a positive outlook on its prospective use in clinical practice. Appendix II gives a summary of the outcome of a feasibility study on the current 8K UHD endoscopy.

The operating microscope, like the endoscope, is indispensable in today's medical care. Microsurgery is an accurate operation performed by watching an enlarged view of a small lesion using a binocular microscope. The operating microscope differs from the endoscope in the following ways:

- No video monitor is used in the operation, and the view of the operating field is shared only by the surgeon and an assistant surgeon. (Although operating microscopes generally have a built-in video camera function, it is not suitable for operations because the quality of the image drops significantly compared to that of the microscope due to poor resolution).
- It is optically advantageous because the microscope has fewer restrictions on the lens sizes than the endoscope.

Essentially, the only drawback of the operating microscope is that the real-time HD video image of the operating field cannot be shared with other members of the operation staff besides the two surgeons. This problem, however, can be solved by displaying the operating field on an 8K monitor through an 8K camera connected to the operating microscope.

Furthermore, an even wider variety of applications, such as teleconferencing and UHD medical imaging may be expected if the above system is utilized in remote environments. Appendix I

describes some of these applications of UHD for telemedicine. As indicated above, UHD imaging technology has much to offer telemedicine.

7 Requirements for UHD endoscopic system

This clause describes the requirements for the framework of a telemedicine system using UHD imaging for the applications described in the previous clause. In particular, it describes the requirements of a UHD endoscopic system, especially requirements for a UHD rigid endoscopic system, an example of which is given in Appendix II. For actual medical uses, such a system is required to be approved as a medical device by a national regulatory authority, as described in Annex A.

7.1 System requirements on systems in local usage

This clause describes requirements for a UHD endoscopic system employed in a closed local use, such as in an operating room. It is assumed that there is no external network connected to the system. Figure 1 shows the general architecture of the system in this setting.

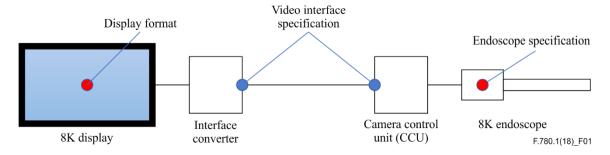


Figure 1 – Typical configuration of a UHD endoscope system in a closed local setting

A UHD endoscope system in this setting consists of the following components:

- UHD endoscope lens;
- UHD endoscope camera head including a UHD image sensor;
- Camera control unit (CCU);
- Video signal converter;
- UHD display.

7.1.1 Physical requirements

7.1.1.1 Camera size

Generally, a rigid endoscope for surgery is assumed to be held by the surgeon in one or both hands while adjusting its position and direction to optimize the endoscopic view of the surgical field during surgery. An endoscopic camera body is recommended to be small to avoid interference with a patient's body and other surgical instruments. In addition, the weight of the camera body is recommended to be light because surgeons must generally hold it for longer than a few hours.

RR-01: A UHD endoscope system is recommended to have a camera head with the following characteristics:

- A diameter less than 120 mm:
- A weight less than 500 g.

NOTE – These characteristics are for hand-held operations.

7.1.1.2 Image sensor size

A general surgical endoscopic camera is connected to a rigid endoscope including some combination of optical rod lenses. The F number of this optical system is roughly over 10, so in order to realize a proper image of 8K UHD resolution, the size of an 8K UHD image sensor is recommended to be as large as possible.

On the other hand, because the size and weight of an endoscopic camera body are limited for surgical use, a proper sized image sensor should be selected.

RR-02: A UHD endoscope system is recommended to support a complementary metal oxide semiconductor (CMOS) sensor with the following characteristics:

- A size less than or equal to 'super-35 mm' (e.g., 24.6×13.9 mm, about 1.7 inches);
- A pixel pitch less than 3.2 μm.

7.1.1.3 Video interfaces

7.1.1.3.1 Output from camera

A medical endoscopic camera is generally used in combination with a CCU, which outputs image signals to an endoscopic display. During surgery, a blackout of the display due to video cables being pulled out from devices in this system must be avoided, so serial digital interface (SDI) cables with strong connections to devices are generally used in operating rooms. Transformation of the 8K UHD image requires synchronized multi-SDI cables, of which the shape and length are the same.

In Appendix II, the 8K UHD endoscopic camera has a dual-green image sensor with a Bayer pattern colour filter array and requires a total of 24 Gbit/s of transmission from the camera to the CCU. For the transmission of the 8K UHD video signal, HD-SDI (1.5 Gbps \times 16 ch), 3G-SDI (3 Gbps \times 8 ch), 12G-SDI (12 Gbps \times 2ch) or U-SDI (optical, 24 Gbps \times 1 ch) are generally selected. In operating rooms, a smaller number of cables is desirable, but fewer cables require high-quality SDI cables. When using a U-SDI optical cable, it is easy to connect but the transmission may not be steady if the cable is bent, subjected to other external forces, or gathers dust.

RR-03: A UHD endoscope system is recommended to support at least one of the following video interfaces for the source signal from the camera unit:

For full 8K signals:

- High-definition multimedia interface (HDMI) 2.1×1 ch;
- 3G-SDI (as defined in [SMPTE 424M] and [SMPTE 425-1]) \times 16 ch;
- 12G-SDI (as defined in [SMPTE 2082-10]) \times 4 ch;
- U-SDI [ARIB STD-B58] \times 1 ch.

For 8K dual green (DG):

- 3G-SDI (as defined in [SMPTE 424M] and [SMPTE 425-1]) \times 8 ch;
- HD-SDI \times 16 ch;

7.1.1.3.2 Input to display

The input interface for the 8K UHD display should be matched to the output interface of the 8K UHD camera (CCU). In the operating room, endoscopic displays are mounted on, e.g., carts, stands or arms suspended from the ceiling, and their height, position and direction should be adjustable during surgery. Therefore, SDI interfaces are desirable.

The high-definition multimedia interface (HDMI), which is mainly for consumer use must be locked while in use in the operating room so that it is not accidentally pulled out from the endoscopic display.

RR-04: A UHD endoscope system is recommended to support at least one of the following video interfaces for the input signal to the video display:

For a full 8K signal

- 3G-SDI (as defined in [SMPTE 424M] and [SMPTE 425-1]) \times 16 ch
- 12G-SDI (as defined in [SMPTE 2082-10]) \times 4 ch
- U-SDI [ARIB STD-B58] \times 1 ch
- HDMI 2.0×4 ch
- HDMI 2.1×1 ch.

For 8K dual green:

- HD-SDI (i.e., 1.5G-SDI as defined in [ITU-R BT.1120-9], [b-SMPTE 292M]) × 16 ch
- 3G-SDI (as defined in [SMPTE 424M] and [SMPTE 425-1]) \times 8 ch

7.1.1.4 Video display panel type

Displays in the operating room are observed from various directions by medical staff, so in-plane switching (IPS) displays are often introduced with a wide viewing angle and less colour-shift.

However, for the 8K UHD display, vertical alignment (VA) displays are also used to obtain high contrast from the front side, high presence and real 8K UHD resolution with a large panel size.

RR-05: A UHD endoscope system is recommended to support at least one of the following display panel types:

For LC: IPS, twisted nematic (TN), VA.

NOTE – Other display formats, such as the UHD projector and UHD-organic light emission display (OLED), are for future study.

7.1.2 Signal requirements

7.1.2.1 Resolution of capture format

For advanced endoscopic observation with high resolution and a wide viewing angle, 8K UHD resolution (7 $680 \times 4~320$ pixels) is recommended. During endoscopic surgery, surgeons can control the digital zooming of an 8K UHD image up to 4 times to observe the surgical field in detail by not closing the tip of the rigid endoscope to the surgical field.

RR-06: A UHD endoscope system is recommended to support the following resolution:

- 7.680×4.320 pixels

NOTE – Other resolutions, such as square resolutions are for future study.

7.1.2.2 Colour filter

To minimise endoscopic camera size so that it can be held in one hand for a long period of time during surgery, a single plate type colour image sensor is recommended. Here, both the image sensor unit and the circuit boards for signal processing and signal conversion should be small with as much power saving as possible.

Human eyes are especially sensitive to the colour green, so the Bayer pattern colour filter array with two green, one red (R) and one blue (B) is recommended.

RR-07: A UHD endoscope system is recommended to support:

Bayer pattern colour filter array (i.e., green1, green2, red, blue).

7.1.2.3 Frame frequency and scan mode

7.1.2.3.1 Frame frequency

Endoscopic surgery requires close observation of the endoscopic display so that the surgeon can control the endoscope itself and the various surgical instruments. Therefore, a frame frequency of less than 30 frames per second (fps) is not recommended, whereas more than 50 fps is recommended to support safer surgical procedures.

RR-08: A UHD endoscope system is recommended to support at least one of the following frame frequencies (Hz):

- 120, 120/1.001, 100, 60, 60/1.001, and 50.

NOTE – The frame frequencies 30, 30/1.001, 25, 24, and 24/1.001 as defined in [ITU-R BT.2020-2] are not suitable for medical purposes.

7.1.2.3.2 Scan mode

RR-09: A UHD endoscope system is recommended to support progressive scan mode, as defined in [ITU-R BT.2020-2].

7.1.2.4 Display format

7.1.2.4.1 Resolution

In operating rooms, HD medical displays are conventionally used. For example, to record endoscopic images for the entire length of a surgery, it is common to use down-conversion from 8K UHD to 4K UHD/HD resolution for downsizing video data. Therefore, both 8K UHD and also 4K UHD/HD resolutions are recommended.

RR-10: A UHD endoscope system is recommended to support the following resolutions:

- 7 680 × 4 320 pixels;
- 3840×2180 pixels;
- 1920×1080 pixels.

7.1.2.4.2 Colour signal

In endoscopic surgery, it is important to be able to recognize subtle colour differences across tissues and organs on the display with high-bit gradation. It is also useful to compress the colour data of the UHD video data without being noticeable to surgeons.

RR-11: A UHD endoscope system is recommended to support both the following:

- RGB (4:4:4);
- YCbCr (4:2:2).

7.1.2.4.3 Colour space

In endoscopic surgery, it is important to recognize subtle colour differences across tissues and organs on a display with wide colour space.

RR-12: A UHD endoscope system is recommended to support one of the following:

- [ITU-R BT.2020-2];
- [ITU-R BT.2100-2].

NOTE 1 – For some legacy systems, [ITU-R BT.709-6] is a valid option.

NOTE 2 – It is preferable for the display used for real-time image displays of medical procedures to have a low delay so as to have as little effect as possible on the transmission delay, while maintaining high-contrast resolution and performing quality image calibration.

7.2 Wide-area network usage

Advanced endoscopic images are not for surgeons in operating rooms but for medical staff outside the operating room (including outside the hospital) to share for conferences, education, telemedicine, and so on.

This clause describes the requirements for a UHD endoscopic system employed with an external Internet protocol (IP) network (remotely) connected to the system.

Figure 2 shows the general architecture of the system in this setting.

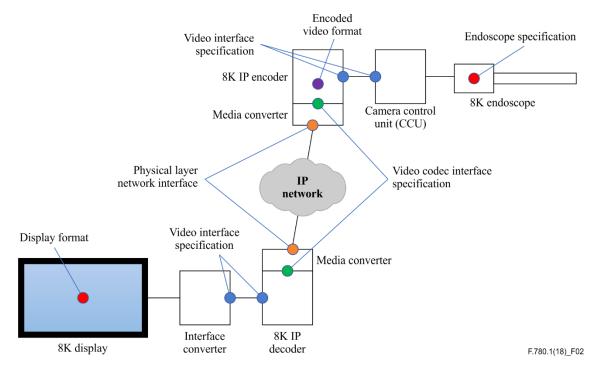


Figure 2 – Typical remote UHD endoscope system using an IP network

A UHD endoscopic system in this setting consists of the following ten components:

- 1) UHD endoscope lens;
- 2) UHD endoscope camera head including UHD image sensor;
- 3) Camera control unit;
- 4) Video encoder;
- 5) Media converter (encoder);
- 6) IP network;
- 7) Media converter (decoder);
- 8) Video decoder;
- 9) Video signal converter;
- 10) UHD display.

7.2.1 Video codec

Endoscopic surgery requires real-time and low-delay transmission times of endoscopic images into the display. Therefore, it is recommended to introduce uncompressed transmission at least in the operating room. If real-time transmission is not necessary, for example, while recording video images that are only for monitoring outside the operating room, compressed video transmission is also useful.

RR-13: A UHD endoscope system with an IP connection is recommended to support either "uncompressed" or "compressed" video formats.

For compressed video, it is recommended that at least one of the following coding formats is used:

- [ITU-T H.265];
- SMPTE RDD 35 (TICO);
- SMPTE RDD 34 (LLVC).

7.2.2 Video over IP interface

To transmit HD endoscopic video outside the operating room, it is recommended to use the established IP networking infrastructure using an IP encoder / decoder in the hospital or outside the hospital.

RR-14: A UHD endoscope system is recommended to support the transport of SDI signals over IP, according to either of the following:

- [SMPTE 2022-6] or [SMPTE 2110-20] for uncompressed video;
- [IETF RFC 3550] for compressed video.

7.2.3 Physical layer network interface

RR-15: A UHD endoscope system should specify the network interface of the physical layer such that the system can be physically connected to a network.

7.2.4 End-to-end latency

In endoscopic surgery, the delay time between the camera and the display should be as short as possible for safe and comfortable surgical procedures. Realistically, there must be some type of signal conversion between the camera and the display and a certain delay time for some frames. Therefore, it is recommended that the total delay time is kept within the allowance range of the endoscopic surgical procedures.

RR-16: A UHD endoscope system is recommended to keep the total delay of video transmission for real-time medical procedures, such as operations, at no more than 85 ms, or no more than 5.1 frames with 60/1.001 or 10.2 frames with 120/1.001.

NOTE – For remote interactive service, it is preferable for a UHD endoscope system to be able to keep the total delay of video transmission for real-time medical procedures, such as operations, at no more than 150 ms between the camera input and display output [b-Bate].

7.2.5 Encapsulation

RR-17: A UHD endoscope system is recommended to support the encapsulation of its signal data according to at least [IETF RFC 3550] or [IETF RFC 4175] for uncompressed data.

7.2.6 Forward error correction

RR-18: A UHD endoscope system is recommended to support forward error correction (FEC), e.g., according to the following:

[SMPTE ST 2022-5].

8 Environmental conditions

This clause describes the requirements on the environment surrounding a UHD endoscopic system.

8.1 Operating room

An endoscope is a surgical device used in an operating room and must be sterilized for use on patients. As shown in Appendix II, an example of an 8K UHD endoscopic camera is covered by a transparent

sterile drape. An endoscope for surgery is often not fixed in the surgical field and is instead held in a surgeon's hand (and rarely mounted on an arm holder). Therefore, the cable between the endoscopic camera and the CCU should be flexible and durable for easy handling. For transmission from the camera to the CCU, optical fibre cables should be used. These cables must be examined regularly for failures from bending, outer forces, etc., because the fibres are usually glass and therefore fragile. Failures can cause blackouts of the endoscopic image on the display. For example, it is recommended to adopt durable protective tubing or plastic optical fibre (POF) cable [b-Koike].

8.2 Safety considerations

An example of a test standard for "endoscopic video camera" medical devices in Japan is shown in Annex A. The abovementioned requirements include a variety of conditions in the 8K UHD endoscopic system (as shown in Appendix II) approved for class 1 medical devices in Japan.

For example, the temperature of the camera body surface should be no more than 41 degrees celsius if it is to be held in a surgeon's hand for an extended period of time during surgery (regulated by [b-JIS T 0601-1]).

In addition, the leakage of current flow to a patient from the endoscopic camera must be no more than $10~\mu A$ for a Type cardiac floating (CF) device used in heart surgery (regulated by [b-JIS T 0601-1]). Regarding leakage current from CCU to earth, it must be no more than $10~\mu A$ for Type body (B) devices that are not used in heart surgery (also regulated by [b-JIS T 0601-1]).

9 Profiles

In this clause, different profiles of UHD medical devices are described. These are not exhaustive, and there may be more profiles as the use cases of UHD medical devices develop. Such additions are for future study.

9.1 Endoscopy

Endoscopes are divided into three broad categories, depending on their shape:

- 1) rigid endoscopes,
- 2) flexible endoscopes, and
- 3) capsule endoscopes.

9.1.1 Types of endoscopes

9.1.1.1 Rigid endoscopes

Rigid endoscopes capture images with a base camera that uses a relay lens system, with little restriction on the size of the camera, so the applicability of UHD resolution is very high.

9.1.1.2 Flexible endoscopes

Flexible endoscopes capture images with a camera mounted on the distal end or a camera guided by an optical fibre to be inserted into the body.

9.1.1.3 Capsule endoscopes

9.1.2 Application areas of endoscopy

Endoscopy is used for the following application areas:

- transnasal endoscopy,
- laryngeal endoscopy,
- bronchoscopy,
- upper gastrointestinal endoscopy,

- duodenal endoscopy,
- enteroscopy, colonoscopy,
- thoracoscopic laparoscopy,
- fetoscopy, cystoscopy,
- cholangioscopy,
- arthroscopy,
- spinal (neuro) endoscopy,
- vascular endoscopy,
- epidural endoscopy,
- capsule endoscopy.

The list is not exhaustive.

9.2 **Microscopy**

Microsurgery, surgery requiring an operating microscope, is an accurate operation performed by watching an enlarged view of a small lesion using a binocular microscope. The operating microscope is indispensable in today's medical care as is the endoscope. The current widely used components of a surgical microscope are an illumination device, an objective lens, a zoom lens, a focus lens, and an eyepiece (for surgeon and the assistant), which is connected to a camera using one assistant port. The image from the camera is displayed on the display/monitor.

9.2.1 Application areas of UHD microscopy

UHD microscopy is used in the following areas:

- surgical microscopes,
- pathological microscopes,
- biological microscopes.

The list is not exhaustive.

9.2.2 **UHD** microsurgery

Using UHD resolution makes it possible to capture surgical field images at a higher resolution compared to images obtained by looking through the eyepiece with the naked eye. This type of surgery, performed while watching the display/monitor, is called "heads-up surgery", and it is likely that there will be a shift to this style of microscopic surgery.

9.2.2.1 Use of 3D

As microscopic surgery is performed while obtaining precise depth information of the surgical field using stereoscopic vision with images obtained by both eyes, it is best to use a 3D display/monitor system in a heads-up surgery. Current surgical microscopes are equipped with two ports for assistants, so it is possible to connect two UHD cameras. UHD resolution and 3D heads-up surgery can be achieved by acquiring the image for the right eye and the image for the left eye and outputting them to a 3D display/monitor with UHD resolution.

9.3 **UHD** medical imaging

UHD medical imaging refers to real-time or recorded images of a medical procedure using a UHD resolution camera. Each field of examination and treatment has its own specific name, and the main types are:

endoscopic imaging,

- microscopic imaging,
- surgical procedure imaging (e.g., recordings of a laparotomy or thoracotomy or the like taken from above, usually near a shadow-less light).

9.4 Teleconferencing

UHD teleconferencing is a practice of sharing medical images, such as those related to medical examinations, tests, diagnoses, treatment, or rehabilitation, taken with a UHD resolution camera with other locations within a premise (e.g., within the same hospital, clinic, university, research institution) or remote locations (i.e., locations not within the same building or place), see Figure I.3, and used for presentations, training, lectures, and tests in real time.

9.4.1 In-premise teleconferencing

Teleconferencing images are shared within a premise.

9.4.2 Distance teleconferencing

Teleconferencing images are shared with a location distantly situated.

Annex A

Test standard of medical device "endoscopic video camera" in Japan

(This annex forms an integral part of this Recommendation.)

Table A.1 – Test standard of [IEC 60601-1-2], EMI: [CISPR 11] Group 1 Class B $(230~\mathrm{V}\,/\,50~\mathrm{Hz})$

No.	Standard	Test item	Test port	Content	Note	Test voltage	Time [H]
1	[CISPR 11] Gr1-Class B	Radiation EMI (10 m)	Body	30-230 MHz; 30 dB 230-1000 MHz; 37 dB		AC 230V/ 50 Hz	1
2	[CISPR 11] Gr1-Class B	Conduction EMI including click	AC	0.15-0.5 MHz; QP66-56 dB/AV56-46 dB		AC 230V/ 50 Hz	0.5
				0.5-5 MHz; QP56 dB/AV46 dB 5-30 MHz; QP60 dB/AV50 Db AC 230 V/50 Hz			
3	[IEC 61000-4-2]	Electrostatic radiation	Body	Contact: ±(2,4,6) kV, Air: ±(2,4,8) kV (Horizontal / Vertical)		AC 230V/ 50 Hz	3
4	[IEC 61000-4-3]	Radiation immunity	Body	80 MHz-2.5 GHz, 3 V/m, 4 phase (Horizontal / Vertical) not for a life support system	80% AM 1 kHz	AC 230V/ 50 Hz	4
5	[IEC 61000-4-4]	Fast transient/ burst	AC	±2.0 kV (L,N,PE,L+N+PE)		AC 240V/ 50 Hz AC 100V/ 50 Hz	1
			Camera cable (camera side)	±1.0 kV		AC 230V/ 50 Hz	0.25
			Camera cable (CCU side)	±1.0 kV		AC 230V/ 50 Hz	0.25
6	[IEC 61000-4-5]	Lightning surge	AC	Common ± (0.5, 1, 2) kV/ normal ± (0.5, 1) kV per 5 times	0°, 90°, 270°	AC 240V/ 50 Hz AC 100V/ 50 Hz	6
7	[IEC 61000-4-6]	Conduction EMI	AC	0.15-80 MHz, 3 Vrms	80% AM 1 kHz	AC 230V/ 50 Hz	0.75
		immunity	Camera cable (camera side)	0.15-80 MHz, 3 Vrms		AC 230V/ 50 Hz	0.5
			Camera cable (CCU side)	0.15-80 MHz, 3 Vrms		AC 230V/ 50 Hz	0.5
8	[IEC 61000-4-8]	Magnetic field	Body	50/60 Hz, 3 A/m	X/Y/Z	AC 230V/ 50 Hz, 60 Hz	1
9	[IEC 61000-4-11]	Dip	AC	More than 95% drop, 10 ms (0°, 180°) 60% drop, 100 ms 30% drop, 500 ms		AC 240V/ 50 Hz AC 100V/ 50 Hz	2

Table A.1 – Test standard of [IEC 60601-1-2], EMI: [CISPR 11] Group 1 Class B $(230~\mathrm{V}\,/\,50~\mathrm{Hz})$

No.	Standard	Test item	Test port	Content	Note	Test voltage	Time [H]
		Instantaneous power failure	AC	More than 95% drop, 5000 ms			
10	[IEC 61000-3-2]	Power harmonics	AC	For devices driven by more than 220 V	only Class B	AC 230V/ 50 Hz	0.5
11	[IEC 61000-3-3]	Flicker	AC	For devices driven by more than 220 V	only Class B	AC 230V/ 50 Hz	1

Table A.2 – Test standard of [IEC 60601-1-2], EMI: [CISPR 11] Group 1 Class B $\,$ (120 V / 60 Hz)

No.	Standard	Test item	Test port	Content	Note	Test voltage	Time [H]
1	[CISPR 11] Gr1-Class B	Radiation EMI (10 m)	Body	30-230 MHz; 30 dB		AC 120V/ 60 Hz	1
	GIT-Class B	Livii (10 iii)		230-1000 MHz; 37 dB		00112	
2	[CISPR 11] Gr1-Class B	Conduction EMI including	AC	0.15-0.5 MHz; QP66-56 dB/AV56-46 dB		AC 120V/ 60 Hz	0.5
		click		0.5-5 MHz; QP56 dB/AV46 dB			
				5-30 MHz; QP60 dB/AV50 dB			
3	[IEC 61000-4-2]	Electrostatic radiation	Body	Contact: ±(2, 4, 6) kV, Air: ±(2, 4, 8) kV (Horizontal / Vertical)		AC 120V/ 60 Hz	3
4	[IEC 61000-4-3]	Radiation immunity	Body	80 MHz-2.5 GHz, 3 V/m, 4 phase (Horizontal / Vertical) not for a life support system	80% AM 1 kHz *1	AC 120V/ 60 Hz	4
5	[IEC 61000-4-4]	Fast transient/ burst	AC	±2.0 kV (L,N,PE,L+N+PE)		AC 120V/ 60 Hz	0.5
			Camera cable (camera side)	±1.0 kV	*3	AC 120V/ 60 Hz	0.25
			Camera cable (CCU side)	±1.0 kV	*3	AC 120V/ 60 Hz	0.25
6	[IEC 61000-4-5]	Lightning surge	AC	Common ± (0.5, 1, 2) kV/ normal ±(0.5, 1) kV per 5 times	0°, 90°, 270°	AC 120V/ 60 Hz	3
7	[IEC 61000-4-6]	Conduction EMI	AC	0.15-80 MHz, 3 Vrms	80% AM 1 kHz *1	AC 120V/ 60 Hz	0.75
		Immunity	Camera cable (camera side)	0.15-80 MHz, 3 Vrms	*1*2	AC 120V/60 Hz	0.5
			Camera cable (CCU side)	0.15-80 MHz, 3 Vrms	*1*2	AC 120V/ 60 Hz	0.5
8	[IEC 61000-4-8]	Magnetic field	Body	60 Hz, 3 A/m	X/Y/Z	AC 120V/ 60 Hz	1

Table A.2 – Test standard of [IEC 60601-1-2], EMI: [CISPR 11] Group 1 Class B $\,$ (120 V / 60 Hz)

No.	Standard	Test item	Test port	Content	Note	Test voltage	Time [H]
9	[IEC 61000-4-11]	Dip	AC	More than 95% drop, 10 ms (0°, 180°) 60% drop, 100 ms 30% drop, 500 ms		AC 120V/ 60 Hz	1
		Instantaneous power failure	AC	More than 95% drop, 5 000 ms			

Table A.3 – Test standard of [IEC 60601-1-2], EMI: [CISPR 11] Group 1 Class B $(100~V\,/\,50~Hz)$

No.	Standard	Test item	Test port	Content	Note	Test voltage	Time [H]
1	[CISPR 11]	Radiation	Body	30-230 MHz; 30 dB		AC 100V/	1
	Gr1-Class B	EMI (10 m)	230-1000 MHz; 37 dB		50 Hz		
2	[CISPR 11] Gr1-Class B	Conduction AC EMI		0.15-0.5 MHz; QP66-56 dB/AV56-46 dB		AC 100V/ 50 Hz	0.5
		including click		0.5-5 MHz; QP56 dB/AV46 dB			
			5-30 MHz; QP60 dB/AV50 dB				
7	[IEC 61000-4-6]	Conduction EMI Immunity	AC	0.15-80 MHz, 3 Vrms	80% AM 1 kHz *1	AC 100V/ 50 Hz	0.75

Table A.4 – Test standard of [IEC 60601-1-2], EMI: [CISPR 11] Group 1 Class B (DC)

No.	Standard	Test item	Test port	Content	Note	Time [H]
1	[CISPR 11]	Radiation EMI	Body	30-230 MHz; 30 dB		1
	Gr1-Class B	(10 m)		230-1000 MHz; 37 dB		
3	[IEC 61000-4-2]	Electrostatic radiation	Body	Contact: ±(2,4,6) kV, Air: ±(2,4,8) kV (Horizontal / Vertical)		3
4	[IEC 61000-4-3]	Radiation immunity	Body	80 MHz-2.5 GHz, 3 V/m, 4 phase (Horizontal / Vertical) not for a life support system	80% AM 1 kHz	4
5	[IEC 61000-4-4]	Fast transient / burst	Camera cable (camera side)	±1.0 kV		1
7	[IEC 61000-4-6]	Conduction EMI immunity	Camera cable (camera side)	0.15-80 MHz, 3 Vrms		0.75
8	[IEC 61000-4-8]	Magnetic field	Body	50/60 Hz, 3 A/m	X/Y/Z	1

Table A.5 – Product security test standard of [IEC 60601-1] $(AC\ 100\text{-}240\ V, 50/60\ Hz)$

No.	Test item
1	Electricity test
2	Structural measurement
3	Ball pressure test
4	Modelling stress test
5	Noise measurement
6	Document check
7	Risk management confirmation
8	Usability check

Appendix I

Applications of UHD for telemedicine

(This appendix does not form an integral part of this Recommendation.)

Real-time or recorded images taken with a UHD resolution camera are sent to, or shared with, other locations within a premise (e.g., within the same hospital, clinic, university, or research institution) or remote locations (i.e., locations not within the same building or place) and used for medical procedures such as medical examinations, tests, diagnoses, treatment, and rehabilitation. The images do not necessarily have to be real-time images. Figure I.1 shows an 8K endoscope with a real-time recorder.

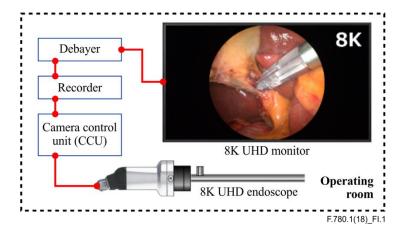


Figure I.1 – 8K endoscope system with real-time recorder

I.1 Teleconference

Medical images, such as those related to medical examinations, tests, diagnoses, treatment, or rehabilitation, taken with a UHD resolution camera are sent to, or shared with, other locations within a premise (e.g., within the same hospital, clinic, university, research institution), see Figure I.2 or remote locations (i.e., locations not within the same building or place), see Figure I.3 and used for presentations, training, lectures, and tests in real time.

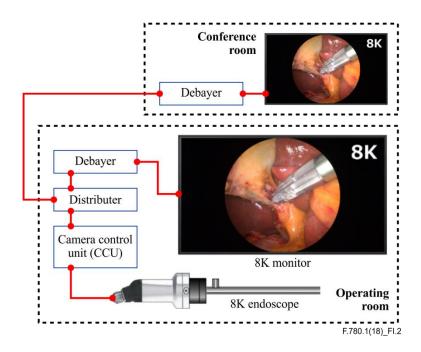


Figure I.2 – 8K endoscope system with teleconference (in-house)

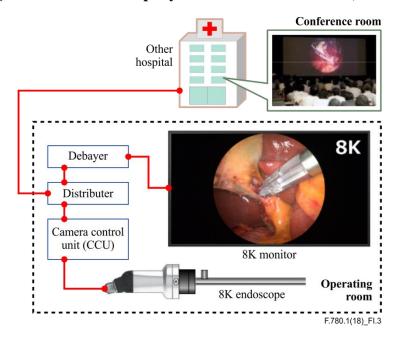


Figure I.3 – 8K endoscope system with teleconference (remote site)

I.2 UHD medical imaging

UHD medical imaging refers to real-time or recorded images of a medical procedure using a UHD resolution camera.

Each field of examination and treatment has its own specific name, and the main types are endoscopic imaging (e.g., transnasal endoscopy, laryngeal endoscopy, bronchoscopy, upper gastrointestinal endoscopy, duodenal endoscopy, enteroscopy, colonoscopy, thoracoscopic laparoscopy, fetoscopy, cystoscopy, cholangioscopy, arthroscopy, spinal (neuro) endoscopy, vascular endoscopy, epidural endoscopy, and capsule endoscopy), microscopic imaging (e.g., surgical microscopes, pathological microscopes, and biological microscopes), and surgical procedure imaging (recordings of a laparotomy or thoracotomy or the like taken from above, usually near a shadow-less light).

I.3 Endoscope with UHD resolution

Endoscopes are divided into three broad categories, depending on their shape:

- 1) rigid endoscopes,
- 2) flexible endoscopes, and
- 3) capsule endoscopes.

Rigid endoscopes capture images with a base camera that uses a relay lens system, with little restriction on the size of the camera, so the applicability of the UHD resolution is very high.

Flexible endoscopes capture images with a camera mounted on the distal end or a camera guided by an optical fibre to be inserted into the body.

With the former, UHD conversion is difficult due to limitations to the size of the image sensor. With the latter, it is difficult to incorporate the number of optical fibres needed for UHD resolution while maintaining flexibility.

As with flexible endoscopes, UHD conversion is difficult due to limitations in the size of the image sensor that can be mounted on capsule endoscopes.

I.4 Microscope with UHD resolution

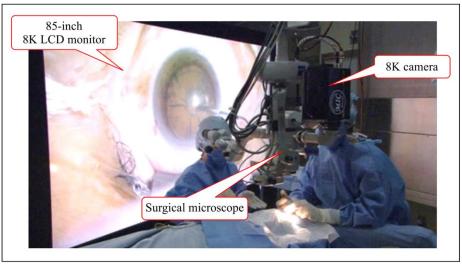
The standard components of a surgical microscope is an illumination device, an objective lens, a zoom lens, a focus lens, and an eyepiece (for surgeon and assistant), which is connected to a camera using one assistant port. The image from the camera is displayed on the display/monitor, but currently, surgeons mostly perform surgery while looking through the eyepiece and not while watching the display/monitor.

Setting the camera and the display/monitor to UHD resolution makes it possible to capture surgical field images at a higher resolution compared to the images obtained by looking through the eyepiece with the naked eye. This type of surgery, performed while watching the display/monitor, is called "heads-up surgery", and it is likely that there will be a shift to this style of microscopic surgery.

As microscopic surgery is performed while obtaining precise depth information of the surgical field using stereoscopic vision with images obtained by both eyes, it is best to use a 3D display/monitor system in a heads-up surgery. Current surgical microscopes are equipped with two ports for assistants, so it is possible to connect two UHD cameras. UHD resolution and 3D heads-up surgery can be achieved by acquiring the image for the right eye and the image for the left eye and outputting them to a 3D display/monitor with UHD resolution.

The operating microscope is indispensable in today's medical care as is the endoscope. Microsurgery is an accurate operation performed by watching an enlarged view of a small lesion using a binocular microscope. Figure I.4 shows an example microscopic eye surgery set-up. The operating microscope is different from the endoscope in the following ways:

- No video monitor is used in the operation, and the view of the operating field is shared only by the surgeon and an assistant surgeon. (Although operating microscopes, in general, have a built-in video camera function, it is not suitable for operation because the quality of the image largely drops as compared to that of the microscope due to its poor resolution.); and
- Optically advantageous because the microscope has less restriction on lens sizes than the endoscope.



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Figure I.4 – Set-up for 8K microscopic eye surgery

A potential drawback of the operating microscope is the inability to share the real-time HD video image of the operating field with other members of the operation staff except for the two operating surgeons. Connecting the 8K camera to an operating microscope and displaying the view of the operating field on an 8K monitor can solve this problem.

In an ophthalmic surgery using an 8K endoscope performed at Miyake eye hospital in Tokyo, Japan on 5 December 2014, an operating microscope (which was suspended from the ceiling) was used and was connected to an 8K camera via a lens adaptor. An 85-inch 8K monitor was located near the surgeon and patient so that all the surgeons, assistants, and operation staff present could closely watch the UHD images at the same time.

A total of eleven cases of cataract, glaucoma, corpus vitreum and retina surgeries were performed, and each surgery was done within the planned timeline. Since removal of the cortex lentis and the insertion of an intraocular lens in cataract surgery, fibre pillar zone incision in goniotomy, express surgery, and trabeculotomy (operation that cuts open and removes part of the column zone with an electrosurgical knife) were all surgeries on the surface side of the eye (anterior ocular segment), the quality of view obtained and shared was equally bright and had UHD, as that which was viewed by the surgeon through the operating microscope. See Figure I.5 for example eye surgeries using an 8k microscope.

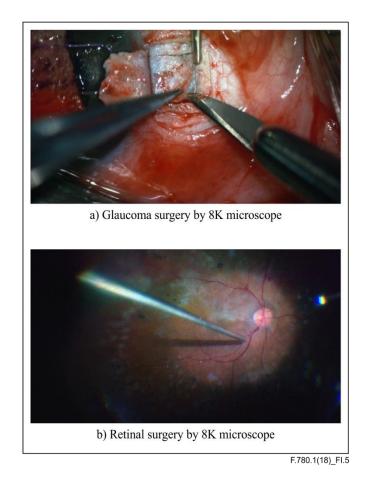


Figure I.5 – Example of eye surgery using an 8K microscope

Appendix II

Example of endoscopic surgery using UHD

(This appendix does not form an integral part of this Recommendation.)

II.1 8K UHD endoscopic system configuration

An 8K UHD endoscopic system comprises an 8K UHD endoscope, a light source with a 300 W xenon lamp, CCU, 8K UHD recorder, an interface converter, and an 8K UHD liquid crystal display (LCD) as shown in Figure II.1. The 8K UHD endoscope consists of an 8K UHD camera head, lens adapter, and rigid endoscope. The CCU has a signal processing board with various functions, such as calibration of the colour balance and gain in real-time, digital zooming ($\times 1.0 \sim \times 4.0$), gamma curve compensation, and resolution enhancement of the 8K UHD endoscopic images.

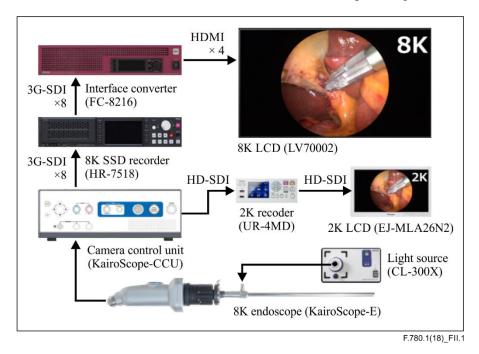


Figure II.1 – System configuration example of an 8K UHD endoscope

The 8K UHD recorder is used to keep and reproduce 8K UHD endoscopic images of a clinical laparoscopic cholecystectomy. Therefore, the 8K UHD recorder should have a long recording time and very high-speed access. An 8TB storage capacity solid state drive (SSD) installed in the 8K recorder makes it possible to store the 8K images for as long as 160 minutes by using signal compression technologies.

The 8K UHD LCD can clearly present 8K UHD endoscopic images of a clinical laparoscopic cholecystectomy with a resolution of $7\,680\times4\,320$ pixels and colour depth of 10 bits. This large display is preferable to surgeons and operating-room staff because the most favourable viewing distance from the 8K UHD display has been estimated to be around 0.75 times the display/screen height in the operation room. A 2K recorder and 2K LCD are used in a standard and usual surgical setting. The total delay time of the 8K UHD endoscopic system is about 75 ms – sufficiently shorter than the human response time of 150 ms.

Figure II.2 shows a typical 8K UHD endoscopic system. All signal processing equipment is installed in one pack, and the total size of the 8K UHD endoscopic system is the same as that of a conventional 2K endoscopic system. A surgeon can operate the 8K UHD endoscope freely with a single hand while simultaneously viewing the 8K UHD display image.



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Figure II.2 – A typical 8K UHD endoscopic system

II.2 Mass production model of the 8K UHD endoscope

The first prototype model, P1-model, of an 8K UHD camera head was developed in 2014 based on a broadcasting camera [b-Yamashita]. The 8K UHD camera head had a single-chip 2.5-inch CMOS image sensor with an 8K UHD resolution and dual-green colour (G) filters (red \times 1, green \times 2, blue \times 1). The dimensions of the 8K UHD camera head were 125 mm (W) \times 125 mm (H) \times 185 mm (L), and its weight was 2.2 kg. A handle was attached to the outer case of the camera head to be easily held with a single hand. A standard type of a 300-W xenon lamp for conventional endoscopes was used as the light source. A lens adapter was mounted between the rigid endoscope and the 8K camera head to enlarge the endoscopic field of view and adjust the focus point of the endoscopic image.

The second prototype model, the P2-model, of an 8K UHD camera head was made in 2016, and its dimensions were 80 mm (W) \times 80 mm (H) \times 215 mm (L), and its weight was 450 g. The mass production model of an 8K UHD camera head had succeeded in getting more compact in size with the dimensions of 75 mm (W) \times 75 mm (H) \times 170 mm (L) and a reduced weight of 370 g in 2017 (Figure II.3).

The production model of the 8K UHD camera head has a super-35-mm CMOS imaging sensor that is smaller than the 2.5-inch CMOS image sensor and offers up to 120 frames per second (fps) at 8K UHD resolution of 7 680 × 4 320 pixels with a wide dynamic range (> 68 dB), very high sensitivity (> 1.6 V/lux-s), and low power consumption (< 3 W). A rigid endoscope is employed for medical applications using an 8K UHD camera head, because the rigid endoscope can be 8K friendly as it has a series of built-in relay lenses of high quality and a specific camera that can be mounted on the eyepiece. A new lens adapter has been uniquely developed as both ranges of the view of the 8K UHD camera and endoscope are adjusted absolutely when they are connected and operated with a single and manual focus. The outer diameter of the rigid endoscope is 10 mm, and inner relay lenses of 6 mm are incorporated in the endoscope. These relay lenses are specially selected for 8K UHD

imaging, and the total f-number of the rigid endoscope is over 16. A fogless lens is installed on the tip of the 8K UHD rigid endoscope to defog an objective lens when inserted into an abdominal cavity. The fogless lens functions at all times due to the heat generated from a part of the xenon light. Using the control buttons on the 8K UHD camera head, a surgeon can operate the digital zooming ($\times 1.0 \sim \times 4.0$) to change the endoscopic image from a normal image to a magnified image.

In Japan, this production model of the 8K UHD endoscope was approved as a new medical device by the pharmaceuticals and medical devices agency (PMDA) on 15 September 2017.

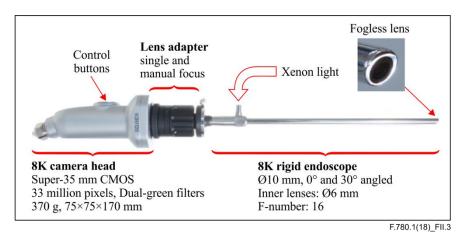


Figure II.3 – An example of a mass production model of the 8K UHD endoscope

To downsize and minimize the weight of the 8K UHD camera head, a specially developed air cooling system was installed in the camera head. The camera case temperature was kept at less than 41°C within the safety standard temperature by the air cooling system. Therefore, the 8K camera could be designed to be a compact-size figure without a handle to be held in the surgeon's hand.

II.3 8K UHD endoscopic image performance

This clause compares the performance between an 8K UHD endoscopic system and a conventional 2K endoscopic system. It presents the evaluation results of an 8K UHD endoscopic system regarding the resolution, zooming, and sensitivity.

II.3.1 8K UHD endoscopic image resolution

Figure II.4 shows examples of a surgical thread in the abdominal cavity of a pig for comparison between an 8K UHD endoscope and a conventional 2K endoscope. The images of a surgical 3-0 thread ($200 \sim 249 \,\mu\text{m}$) used in a standard laparoscopic surgery are shown in Figure II.4, of which the left-hand side is a 2K image, and the right-hand side is an 8K UHD image. In the 2K image, the outline and texture of the thread look ambiguous and jaggy. On the contrary, in the 8K UHD image, the outline and texture of the thread look clear and smooth. Furthermore, the capillaries on the small intestine can be observed in the 8K UHD image. In addition, a surgical 12-0 thread ($1 \sim 9 \,\mu\text{m}$), the thinnest thread used in microscopic surgery, was observed, and the thread was clear in the 8K UHD endoscopic image (Figure II.5).

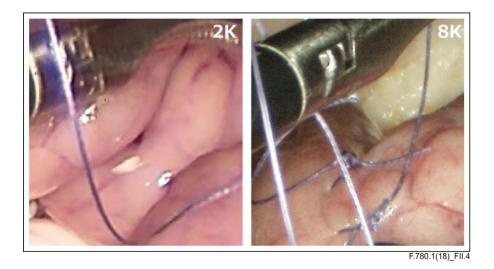


Figure II.4 – Surgical 3-0 thread images of the 2K endoscope (left) and 8K UHD endoscope (right)

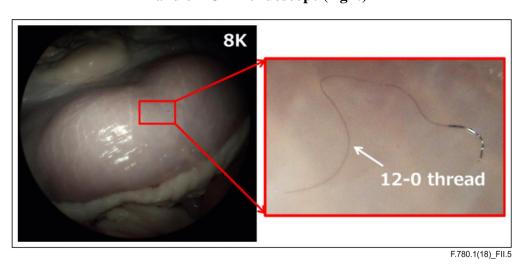
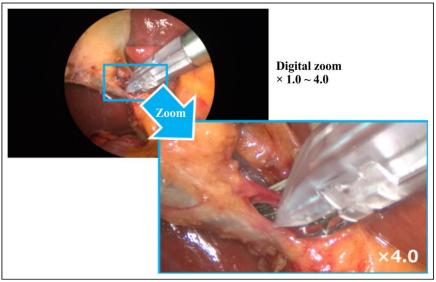


Figure II.5 – Surgical 12-0 thread is also observed with an 8K UHD endoscope

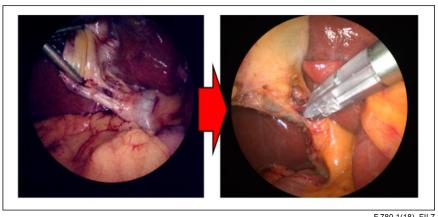
II.3.2 Zooming and sensitivity

Figure II.6 shows an example of a digital image zooming into the surgical field of an abdominal cavity. The 4-times magnified image of the surgical field is still clear in detail, and the resolution is good enough for the surgery. Figure II.7 also shows the improvement of image sensitivity in the surgical field compared between (a) the P1-model of the 8K endoscope with "double" xenon light sources and (b) the P2-model of the 8K UHD endoscope with a "single" xenon light source. The image brightness of the new 8K UHD endoscope is superior to that of the P1-model of the 8K endoscope despite the illumination being halved. This improvement is due to the 4-times sensitivity, gamma curve optimization, and noise reduction of the image sensor of the P2-model of the 8K UHD camera.



F.780.1(18)_FII.6

Figure II.6 – Digital image zooming into the surgical field of an abdominal cavity



F.780.1(18)_FII.7

Figure II.7 – Comparison of surgical field images obtained by (a) the first model 8K UHD endoscope and (b) the second model 8K endoscope

II.4 Clinical case study

II.4.1 Four cases of cholecystectomy using the P2-model of 8K UHD endoscopic system

A study was conducted where the P2-model of the 8K UHD endoscopic system was evaluated during four cases of cholecystectomy performed in Kyorin university hospital (Tokyo, Japan) as described in the following:

- The first patient was a female in her sixties with right-sided hypochondriac pain;
- The second patient was a female in her seventies with epigastric pain;
- The third patient was a female in her seventies with right-sided stomach pain;
- The fourth patient was a male in his fifties with epigastric and back pain and was diagnosed with choledocholithiasis.

The four cases of cholecystectomy, similar to the two cases of cholecystectomy in 2014 [b-Yamashita], were performed by the same surgeons and in the same operating room at Kyorin University Hospital. An 8K LCD was placed adjacent to the operating table so that the surgeon could stand near, and in front of, the 8K LCD as much as possible because the 8K image is viewed with the best quality when it is in front from a distance of 0.75 times the height of the display as shown in Figure II.8.



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Figure II.8 – Surgeon's view of 8K UHD LCD in the operation room

Figure II.9 shows the P2-model of the 8K UHD endoscope used during a cholecystectomy. One laparoscopist held the 8K UHD endoscope covered with a sterilized drape and monitored the surgical field in the patient's abdominal cavity.



Figure II.9 – 8K UHD endoscope in a cholecystectomy

II.4.2 Clinical evaluation of a cholecystectomy

In the cholecystectomy of the two patients operated on with the P1-model of the 8K UHD endoscope, the surgeons and other surgical staff reported the following positive evaluations of the 8K UHD endoscope:

- With sufficient illumination, laparoscopic images with quite high resolution were viewed;
- 8K laparoscopic images were excellent in reproducing the appearances of solidity and reality;
- Vessels on the multilayer membrane around the bile duct and the gallbladder were clearly recognized;
- Viewing of 8K laparoscopic images caused less eye strain.

However, the following limitations were also reported:

- The heavy weight of the 8K camera head made it difficult to hold it in position even by two laparoscopists;
- The large size of the 8K camera head interfered with the surgical field;

 Without sufficient illumination, darkness and low quality of colour reproduction of the images made laparoscopic surgery impossible.

The P2-model of the 8K UHD endoscope was successfully used to complete the four cases of cholecystectomy.

The P2-model of the 8K endoscope was able to solve the issues raised above. The P2-model of the 8K UHD endoscope is light enough for one laparoscopist to hold it in position, and the compact 8K camera head did not interfere with the surgical field. Furthermore, the laparoscopic view was sufficiently bright with a single 300-W xenon light source.

The operating surgeons and other members of the surgical staff reported new evaluations of the 8K UHD endoscope and provided the following advice:

- The fogless lens was a very useful system because the conventional endoscope was taken out
 of the abdominal cavity many times and the operation was stopped when the tip of the
 endoscope became cloudy;
- The 8K laparoscopic images had a more natural 3D effect than that of the 3D endoscope with 2K resolution;
- The wide colour gamut of the 8K images covered an infrared area and made it possible to recognize the different colours of the texture in detail;
- The 8K endoscopic system is applicable to surgical fields involving fine sutures in addition to laparoscopic surgery;
- The microscopic images of lymph vessels and membrane structure were clearly visible. New knowledge of anatomy could be obtained;
- In mediastinoscopic surgery, the degree of freedom for forceps increased by moving the field of view backward, so there was the benefit of reducing one forceps;
- The 8K endoscopic system led to a reduction in the time required for taking instruments in and out since the switching of the wide image to a magnified image was done freely;
- The blurring of the HD image was eliminated in combination with the robot arm.

II.4.3 Improvement of 8K UHD camera cable using durable and noiseless plastic optical fibre

The above-mentioned cable between the 8K UHD camera head and the camera control unit (CCU) includes glass optical fibres for transmitting the 8K UHD video signal. It is reasonable and useful to use glass optical fibres for transmitting a large amount of data over a long distance. On the other hand, they perform poorly with respect to bending motion and eternal force, such as when they are trampled or run over by a surgical table or surgical instrument cart in the operating room. When part of the glass fibre is broken, it becomes impossible to transmit the video signal.

By replacing glass fibres with POF ([b-Koike]), the 8K UHD camera was resilient against external force. Graded-index multimode (GI) plastic optical fibres (POF) possesses the material characteristics of being highly flexible, difficult to break, easy to handle due to its large diameter, and not requiring high-precision alignment. GI POF achieves high-speed transmission (40 Gbit/s@1.55 μ m) exceeding silica-based multimode fibre (Figure II.10).

In addition, a special connector with 12 GI-POF cables with a ball lens on each cable end was developed (Figure II.11). As each GI-POF cable transmits up to 10 Gbps, the total transmission speed increases to 120 Gbps maximum. The unique point of the connector is the method of attaching a ball lens on each fibre end. Technologies that were used to produce ballpoint pens were applied and the connector was made at a low cost with precise alignment of the ball and the fibre.

A prototype was developed where GI-POF for the 8K UHD camera cable is connected to the CCU and a ballpoint-pen interconnection, and to output an 8K UHD real-time image on the 8K UHD LCD (Figure II.12).

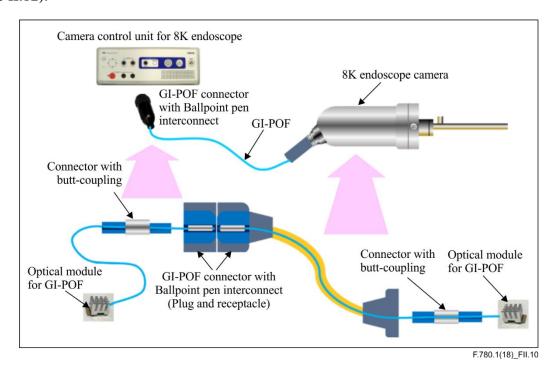


Figure II.10 – Graded index-plastic optical fibre (GI-POF) interface for 8K UHD video transmission

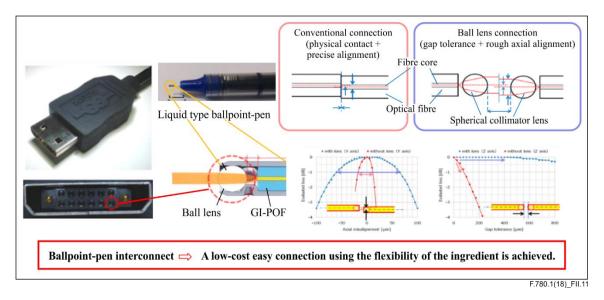


Figure II.11 – Ballpoint-pen interconnection



F.780.1(18)_FII.12

Figure II.12 – Prototype of the 8K UHD endoscope cable including a GI-POF cable, which connects the 8K UHD camera head and the CCU with a ballpoint-pen interconnection

Appendix III

Real-time transmission of uncompressed UHD images

(This appendix does not form an integral part of this Recommendation.)

III.1 Method of measuring the time delay of transmission of uncompressed UHD images

- 1) A tester for measuring time delay is connected via HDMI to the LCD. The LCD is then measured through the interpretation of the test pattern shown in an image captured by the installed image sensor.
- 2) The image is taken with an 8K endoscope camera.
- 3) The test pattern of the lag tester is shown on an 8K display after the transmission by a real-time video transmission system.
- 4) The amount of delay of the overall system is measured by reading the test pattern with the image sensor of the lag tester.
- 5) The time delay of the real-time image transmission system is calculated by subtracting the delay of the LCD for measurement (point 1 listed above) from the overall delay.

III.2 Time delay in local connection between the 8K UHD camera and the 8K UHD LCD

The delay time of the liquid crystal display (LCD) is calculated by subtracting the time delay of the system from the overall delay. The top and bottom of the display patterns are, respectively, the fastest and slowest parts shown. The results for the measurements at the top, middle and bottom were: 0.6 ms, 8.5 ms, and 15.4 ms, respectively.

III.3 Time delay in local connection between the 8K UHD camera and the 8K UHD LCD

When the delay was measured in a situation similar to that of an operating room environment, where an 8K endoscope camera was directly connected to an 8K display, the delay was 82.1 ms at the top of the display, 82.4 ms at the middle and 84.4 ms at the bottom, for an average of 82.3 ms. With an 8K display alone, the delay was 30.8 ms at the top of the display, 34.2 at the middle and 38.2 ms at the bottom, a delay of roughly two frames. See Figure III.1.



Figure III.1 – Local connection between 8K UHD camera and 8K UHD LCD

III.4 Time delay in QG encoding / decoding transmission

Next, delay time was measured in a case where an 8K endoscope camera image was displayed on an 8K display after being encoded for IP transmission from a 3G-SDIx8ch dual (dual green) signal, transmitted through four optical fibres in a local environment, and then decoded into a 3G-SDI×8ch (dual green) signal. In the encoding / decoding process, four 8K/4K/HD uncompressed transmission

devices were used synchronously with an RS-232 connection. The time needed for encoding / decoding with one device alone was about 19 ms.

The delay time of the system was 101 ms at the top of the display, 101.6 ms at the middle and 101.4 ms at the bottom, for an average of 101.3 ms. See Figure III.2.

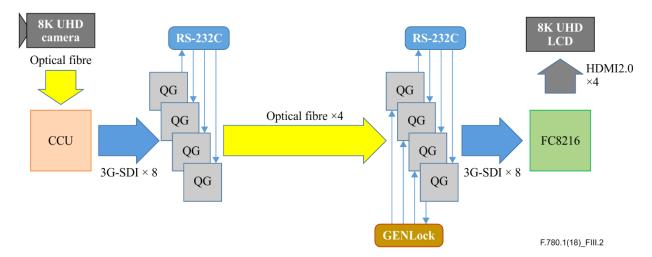


Figure III.2 – Connection between 8K UHD camera and 8K UHD LCD through the encoding / decoding transmission

III.5 Time delay in IP network between Japan and Singapore

Finally, delay was measured where an 8K endoscope camera image was converted to IP using a QG70 displayed on an 8K image after being sent from Japan to Singapore, and then sent back to Japan.

The delay time of the system was 176.5 ms at the top of the display, 176.9 ms at the middle and 177.8 ms at the bottom, for an average of 177.1 ms.

In addition, the round-trip transmission time between Japan and Singapore alone was 75.8 ms; when this delay was added to the delay time for QG encoding / decoding transmission calculated in the preceding paragraph (average of 101.3 ms), the overall delay time roughly matched the result calculated here. See Figure III.3 and Figure III.4.

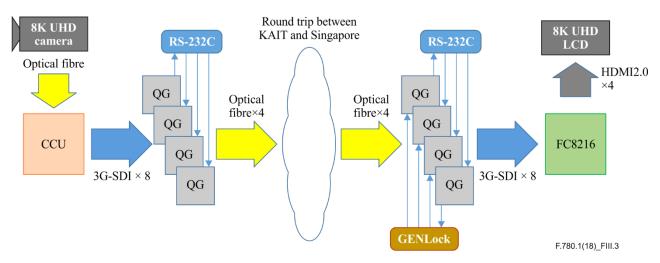


Figure III.3 – Connection between 8K UHD camera and 8K UHD LCD by way of a round trip between Japan (KAIT) and Singapore

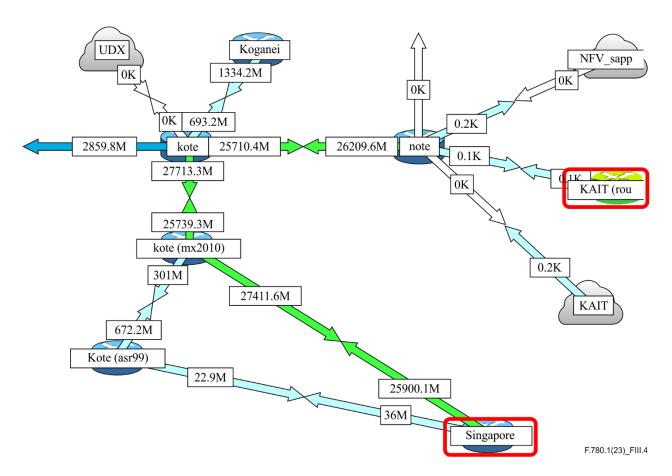


Figure III.4 – IP network between Japan (marked as KAIT) and Singapore

III.6 Discussion and conclusion

In recent measurements, it was found that the delay is large even with a direct connection between an 8K endoscope camera and an 8K display because an 8K image by itself is particularly large. Because the existing systems are square-division systems that connect four 4K-resolution screens, it appears that much time is spent in buffering the data. It may be possible to reduce the delay time by using a two-sample interleave (2SI) system. In addition, the 19 ms of overhead for the QG70 used to convert to/from the IP transmitted signal is extremely small; this can be considered a strong point of the uncompressed transmission.

Lastly, it is important to note that further efficiency in the low-latency exchange of uncompressed UHD images over a wide-area network can be achieved by all-optical, end-to-end path transmission through all the IP networking equipment in the network. In fact, uncompressed 8K UHD video generated at a rate of 72 Gbit/s has been successfully exchanged between Tokyo and Ibaraki, in Japan, over 173-km fibre distance via optically switched "dynamic optical path network" to transmit a remote interactive musical session, where the round-trip time of the uncompressed 60-fps full 8K image exchange was less than approximately 30 ms, including the processing time from camera capture, transmission, video display. Details are reported in [b-Kurosu].

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