

MiniLiVE: miniaturized light- and video-unit for a wireless and networkable medical video endoscope

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Abstract: Recently, video endoscopes have become the standard technology and already convey high-quality images on monitors in the operation room. Nevertheless, the large-sized and relatively heavy-weighted hand piece and electric cables existing between the control unit and the endoscope disturb the physician’s freedom of movement. To overcome these drawbacks and bring an innovation to the endoscope, miniLiVE research team conducted research on the miniaturized light- and video unit for a wireless video transmission. During a two-year research project, miniLiVE research team developed an executable prototype for the examination of the upper trachea, esophagus, and nasal cavity.

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Keywords: wireless video transmission, miniaturization of endoscope, digitalization of endoscope, network capability, electronics, usability

1. INTRODUCTION

In the last few years, video endoscopes have become the standard technology, and it allows physicians to observe ever-changing surgical situations on multiple monitors in the operating room by delivering high-quality images to multiple monitors. For this purpose, a relatively heavy camera is placed on the hand piece, or a small-sized integrated camera sensor is located on the distal tip of the endoscope, a so-called chip-in-tip-endoscope (CIT). Furthermore, electric cables existing between the control unit and the endoscope are one of the essential components for data transfer from the endoscope and supplying power to the endoscope. In addition to electric cables, the control unit contains a light source, which generates light and delivers it to the endoscope over fiber optic cables. In this way, it can prevent patients and physicians from being damaged, due to incidental heats. Despite these advantages of video endoscopes, the large-sized and relatively heavy-weighted hand piece of endoscopes and electrical cables connected to the endoscope for power supply and conveyance of data restrict the freedom of physicians’ movement. This is where miniLiVE research project comes to overcome these drawbacks and bring an innovation to the endoscope. (Chatzipapas et al., 2020) placed a consumer action camera and a portable LED light source on a regular rigid laparoscope, mirroring the image to a tablet computer using either Wi-Fi or Bluetooth and the camera’s app on the tablet. It is reported that wireless laparoscopic surgery could have been performed successfully despite a short observed latency between the operation and the projection to the tablet. Moreover, this setup has low costs compared to a full endoscopic system and allows simple mobility. (Lim et al., 2020) developed prototypes for nasopharynx endoscopy using a 3.5 mm miniaturized system. It consists of an LED, an image sensor, a battery and a 2.5 GHz wireless transmission system. No further specification of the

components is given, nor details about the system’s latency, but a low image quality has been reported.

Our approach aims to incorporate all components into one hardware device, yielding for maximal miniaturization while profiting from the wireless format. In this context, miniLiVE stands for the miniaturized light- and video- unit for a wireless and networkable medical video endoscope, and CoHMed (Connected Health in Medical Mountain) supports the research project “miniLiVE” (CoHMed, 2022, Bae H. R. and Fornefett M., 2022)

1.1 miniLiVE research team and plan

Our research team is composed of Furtwangen University (HFU), Kiehn Engineering Services GmbH (K.E.S), and EMOS Technology GmbH, and the research team aims to realize all aspects of endoscope wirelessly, addressing the following topics: wireless, miniaturization of the endoscope, and network capability. To produce a wireless video endoscope, a cordless endoscope will replace electric cables and these systems encompass a LED light source, a battery system with charging coils, and associated electronics for data transmission.

MiniLiVE: Challenges

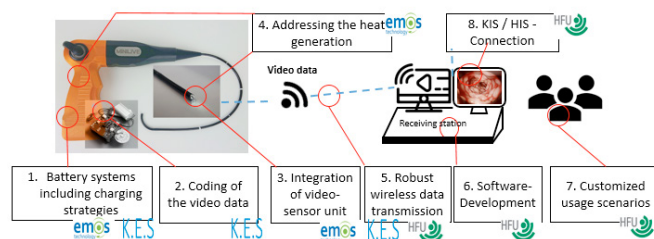


Figure 1: Challenges in miniLiVE research project. It demonstrates existing eight challenges, and they can be divided into three sections: device (EMOS), hardware (K.E.S), and software (HFU)

Subsequently, a camera sensor will be integrated into the distal tip of the endoscope, and incoming video data from the camera sensor is transferred via channels to the associated electronics located in the hand piece. In the development process, our research team have encountered eight challenges and addressed them during our two-year CoHMed project (Figure 1).

1.2 Challenges in the miniLiVE research project

Battery systems including charging strategies: While using the endoscopes, problems pertaining to the weight and size arise. Therefore, designing the hand piece of the endoscope ergonomically and fulfilling user requirements are of importance. In an attempt to handle these issues, the miniLiVE research will insert the cordless endoscope system into the hand piece in confined spaces.

Integration of video sensor unit: In terms of video sensor integration, the diameter of the endoscope top is insufficient so that the miniLiVE research team should miniaturize some relevant 1mm²-sized sensors as a video sensor unit and mount it to the endoscope tip.

Addressing heat generation: In the course of sensor integration at the endoscope tip, constructing the small-sized electronic modules is essential, and it results in some issues related to the heat generation. While using the endoscope, the temperature of the endoscope tip should not exceed maximum 40 °C and the hand piece should not remain heated in the long term. Therefore, it is crucial to develop suitable LED light and explore a proper method for heat dissipation to avoid heat-related risks in the operating system.

Coding of the video data and robust wireless data transmission: In the operation room, physicians should reliably observe surgical procedures to make decisions for further steps and respond to unexpected situations. In addition, the miniaturized video sensor unit requires more energy density compared to its original dimension to complete its tasks. Hence, low-latency and energy-efficient coding of video data, as well as robust data transmission, plays a significant role in consistent presentation of the live view on the monitor.

Software development: In the development of the wireless video endoscope, a series of technologies are required to implement some specialized requirements. The necessitated software technologies are accordingly to be researched while developing a software architecture for client software that serves as a receiving station. This receiving station will enable physicians to retrieve video data from the endoscope and display a live view on multiple monitors.

Customized usage scenarios: The integration of wireless to video endoscopes is not a notable concept. Therefore, the miniLiVE research team should analyze usage contexts in relation to endoscopes and develop usage scenarios. Subsequently, developed usage scenarios should be customized to the wireless video endoscope, and they should be validated by potential users.

HIS/KIS Connection: Video endoscopes or other conventional endoscopes are not so distributed that developing software should be connected to the hospital information system (HIS) for data exchange.

2. METHOD

The eight challenges in figure 1 can be largely categorized into three sections with respective project partner: Device (EMOS Technology GmbH), Electronics (K.E.S), and software (Furtwangen University)

2.1 Device: Construction of the prototype

In incorporating the wireless endoscope systems into the hand piece, the eyepiece was removed from the original hand piece of the Naso-pharyngo-laryngoscope manufactured by EMOS Technology GmbH and a CMOS camera sensor is integrated into the distal tip of the endoscope. An additional housing was added under the hand piece, which encompasses LED light source, batteries, and electronics as shown in Figure 2. The LED light source at the top is connected to the light guide. Beneath the LED light source, two batteries power the electronics and light source. At the bottom, the electronics with charging coils are located, and they allow the batteries in the hand piece to be charged with a charging tray.

Device: Construction of the Prototype

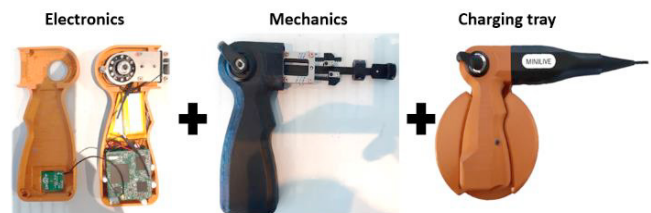


Figure 2: Construction of the prototype. Under the hand piece, additional housing is constructed where the electronics with charging coils are placed. Thereby, the batteries can be charged with a charging tray

2.2 Device: Addressing heat generation

The LED light source has some beneficial properties: generating less heat than halogen and small construction size. Therefore, the LED light source is utilized in the hand piece as shown in Figure 2. Despite the benefits of LED light source, it is required to figure out how to diffuse heat so that the temperature of the hand piece should be kept 40 °C or less over the long term. To cope with these heat generation issues, EMOS Technology has conducted some experiments to select a suitable material for cooling variants and determine a proper place to put the material in the hand piece. These experiments were only preliminary and could not be completed during our research project. A simulation study has not been performed.

2.3 Device: endoscope tip and deflection

In terms of the endoscope tip, the mechanics enable the endoscope tip to be bendable. Nevertheless, it is apparently challenging to fit 1mm²-sized sensors to the endoscope tip. Using light guides, EMOS Technology integrates sensors on the endoscope tip and these light guides would surround the

sensors. Thereby, the integrated sensors are encased firmly and tightly (Figure 3).

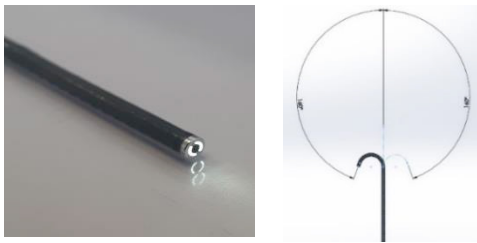


Figure 3: Endoscope tip. Endoscope tip is deflectable up to 180° degrees.

2.4 Electronics: Battery systems

The video unit consisting of an FPGA and a microcontroller realizes the integration of sensors at the tip of the endoscope, and two lithium-ion batteries power all electronics for approximately 2.5 hours of operation (Figure 4). The FPGA plays a decisive role in the video unit in that it is effective in converting analog signal from the sensor into digital signal, compressing images, and sending processed data through a Wi-Fi module in terms of energy consumption and performance.

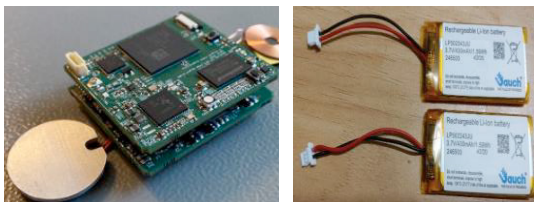


Figure 4: FPGA and microcontroller with lithium-ion batteries. Lithium-ion batteries power all electronics, and the FPGA handles A/D conversion, image compression, and data transfer.

The FPGA monitors a battery status and illuminates a corresponding RGB-status-LED (Table 1).

LED	Battery status
Red	≤ 25%
Blue	Accumulator is charging
Green	> 25%

Table 1: RGB-LED, according to the battery status

2.5 Electronics: Coding of video data and data transmission

Once image data from the camera sensor on the distal endoscope is forwarded to the electronics via channels, the data processing procedures programmed with FPGA take place. For example, the analog image data with 400 × 400 resolution is encoded in JPEG format. Following this, encoded image data is transmitted to the receiving station via WebSocket, using the access point generated by the microcontroller.

2.6 Software: Customize usage scenarios

To implement client software, while fulfilling the user’s perspectives, understanding the usage context of the endoscope is crucial. A usage context includes four elements, such as users, tasks, resources (hardware, software, and

materials), and the environment. Among other methods to collect contextual usage information, the interview offers some advantages: the interviewer can conduct the interview specifically based on prepared guiding questions in contrast to the observation, opportunity to talk openly about user’s working environment and tasks utilizing the interactive system. Hence, contextual interviews with users were conducted to analyze the usage contexts.

Contextual Interviews: In the context of miniLiVE research project, the interactive system is the endoscope. Therefore, physicians, nurses, and technicians belong to users. Subsequently, the research team selected interviewees among physicians, nurses, and service technicians for 90–120 minutes contextual interviews. Each interview is based on a master-apprentice model.

Documentation of usage information: contextual scenario or as-is scenario describes how users perform their tasks with interactive systems. Every contextual scenario would be labeled, such as IAKS, IBIKS in the alphabetical sequence of the interview participants. For example, IA indicates the participant and KS refers to the contextual scenarios. In structuring the scenarios, the collected statements as well as answers of participants would be assigned to respective topics. These structured scenarios allowed the research team to identify what users need and derive user requirements, including system requirements. While system requirement specifies a requirement in terms of technical features of the system, user requirements correspond to the perspective of the users from a user group when utilizing the interactive system (Geis & Polkehn, 2018).

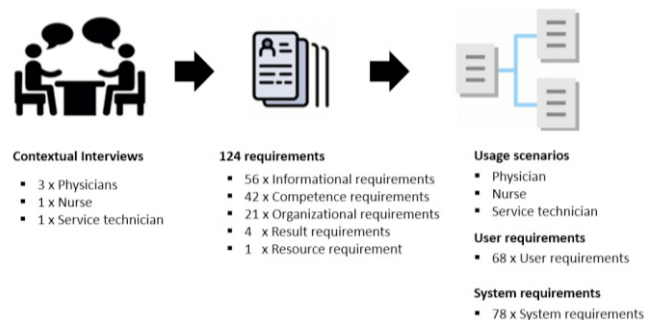


Figure 5: Overview of the usage scenarios and user requirements. It shows the process from the elicitation of user requirements to analyzing user requirements.

In the course of the usage context analysis, a total of five contextual interviews were conducted, and 124 requirements were derived from the contextual scenarios (Figure 5).

Development and customization of the usage scenarios for a wireless video endoscope: the usage scenario stands for a prospective usage situation that users can encounter while interacting with the system (Geis & Polkehn, 2018).

User	Main tasks
Physician	KAM1. Prepare for the minimally invasive procedure

	KAM2. Perform the minimally invasive procedure
	KAM3. Debrief after completing the minimally invasive procedure
Nurse	KAK1. Prepare for the minimally invasive procedure
	KAK2. Assist physician during the minimally invasive procedure
Service technician	KAS1. Do maintenance

Table 2: Respective main tasks for physicians, nurses, and service technicians

Tasks	KAM3. Conversation after completing the minimal invasive operation		
User group	Physician		
Pre condition	A performed minimally invasive procedure must be debriefed		
Post condition	A conducted minimally invasive procedure was debriefed		
Sub tasks	Action (of the user)	Reaction (on the user interface)	User requirement (NA) from the usage content
TAM3.1. Retrieve data of the treated patient.	The user chooses a patient who was treated by a performed surgical operation	The user interface shows the user data of the conducted surgical operation (indication, surgery plan, surgery team)	<p>NA40. The hospital administration must be able to recognize on the system (HIS) who performed the surgical operation, when it was conducted. (indication, surgery plan, by which team and how it was successfully conducted)</p> <p>NA49. The physicians must be able to overview the process of the operation on the system when debriefing the surgical operation</p>

Figure 6: Use scenario for the physician. It shows how the physician as a user handles the user interface to explain the conducted surgical operation.

After developing use scenarios for each user (physician, nurse, and service technician), the users who had participated in the contextual interviews validated the developed usage scenarios. Through the validation process, the usage scenarios could be tailored to the wireless endoscope system (Table 2, Figure 6).

2.7 Software: Software architecture for client software

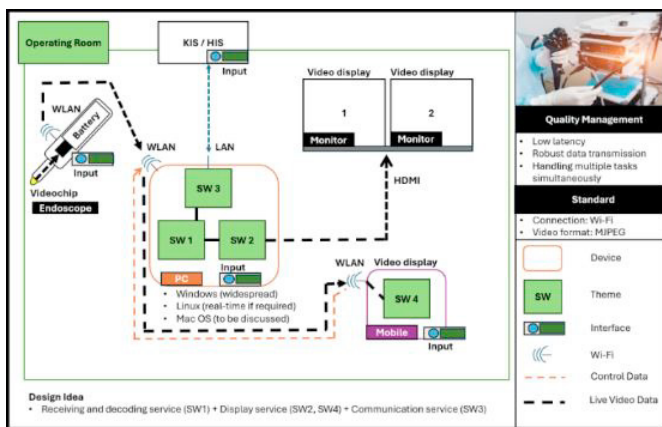


Figure 7: Sketch of the wireless endoscope system. It demonstrates how to exchange data between the endoscope and software and process data for displaying a live view in the operating room.

The software architecture is a document that structures the overall system into parts, according to responsibilities and interactions, such as external systems and events. This document describes how elements interact with each other, utilizing available resources (Geis & Polkeh, 2018, Zörner, 2015). In the context of MiniLiVE research project, the overall system is the wireless endoscope systems and stakeholders interact with the wireless systems. These stakeholders stand for any person with interests in the product or results of the product, and they would read associated documents, providing feedback on the product (Geis & Polkeh, 2018). In Table 4, they are analyzed in accord with importance, roles, and functions.

Role	Users
Preparation of the system	Nurse
Execution of the system	Physician, Nurse
Post process of the system	Nurse
Maintenance and service personnel	Service technician
Software development	Researcher, Engineer

Table 3: Users of the wireless endoscope system

In terms of documentation, developers must consider the regulatory requirements in designing the interactive system (Geis & Polkeh, 2018). However, these regulatory requirements were not fully considered in the research project.

Medical Regulation	Description
MDR	EU law for medical devices
ISO13485	Standard for quality management
ISO 14971	Standard for risk management
IEC 60601-1	Standard for electrical safety
IEC 60601-2-18	Special supplementary standard IEC 60601-1 for endoscopic devices

Table 4: Medical regulations (selection)

Sketch of the wireless endoscope system: the sketch of the wireless endoscope system was created with derived stakeholder requirements and the software architecture (Figure 7). In the operating room, the video stream will be forwarded to the video unit via channels located in the hand piece and processed for data transmission. Client software retrieves continuous MJPEG video stream from the wireless endoscope over Wi-Fi, and it consists of the following three pieces of software: receiving and decoding service (SW1), display service (SW2, SW4), and communication service for data exchange between client software and hospital information system (SW3). To realize this sketch, low latency in data transfer, and managing multiple tasks simultaneously and robust data transmission are required.

2.8 Software: Development of client software

According to the conducted contextual interviews, in general, there are several monitors in the operating rooms, during the surgical operation. It means that video data should be continuously displayed on the main monitor, and the operator

should be able to adjust endoscope settings on the second monitor in the non-sterile area of the operating room (Figure 8).

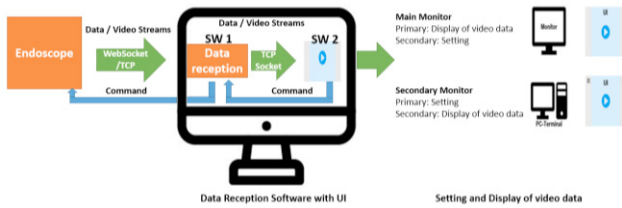


Figure 8: Development of a demonstrator-UI (SW2) with receiving software (SW1). The demonstrator-UI receives the video data over WebSocket from the endoscope, presenting it on the external monitor without additional information.

2.9 Software: Performance and functions

When using client software (receiving software), the users can establish a maximum 1,5m Wi-Fi connection between the endoscope and client software (Figure 9). Regarding the functionality of client software, the user can capture images, record a video and client software will convey notifications as well as error messages to users. In terms of latency, the research team initially aimed to reach less than 200ms latency. Nevertheless, it took steadily 200-250ms latency from data acquisition to presenting incoming video streaming with UI-SW. In conducting a unit-testing, it did not reveal data loss when using WebSocket. However, there could be data loss in case of the data transfer over RTSP/RTP protocol.

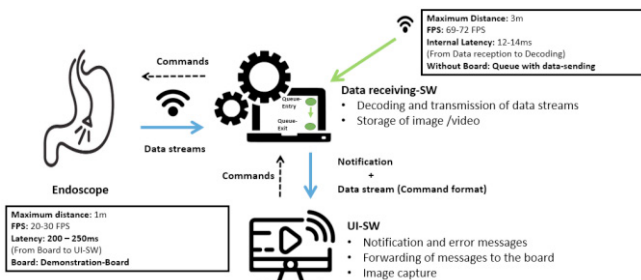


Figure 9: Performance and functions of receiving software. A maximum 1,5m Wi-Fi connection can be established, and the latency falls in the range of 200ms to 250ms.

By delivering the developed software to project partners, one could obtain feedback on the GUI application and functions of client software and enhance client software through implementing a new feature (Figure 10).

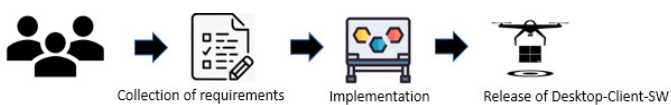


Figure 10: Process to obtain feedback on client software. After collecting feedback on delivered software from project partners, this feedback will be prioritized and implemented.

3. RESULTS

During the two-year research project, miniLiVE research team developed an executable prototype with integrated sensors,

miniaturized associated electronics, and client software for the examination of the upper trachea, esophagus, and nasal cavity (Figure 11, 12). In terms of the endoscope, the endoscope tip can be deflectable up to 160° and the users can utilize the developed prototype either as a flexible endoscope or as a rigid endoscope by mounting an additional attachment to the endoscope tip. The receiving station would retrieve incoming video data with 400 × 400 resolution from the sensor via video unit over Wi-Fi and display it with maximum 900 × 900 resolution on an external monitor within 200ms latency. In the end, usage scenarios were tailored to wireless endoscope systems and a formative user test was conducted on body models in collaboration with the University Hospital of Tübingen. At the stage of planning the formative user test, a risk analysis was not considered. Nevertheless, wireless technology in the 2.4 GHz waveband is used in OP scenarios, e.g., in wireless foot switches.

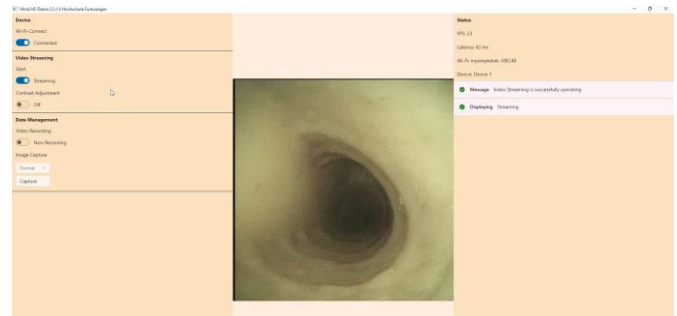


Figure 11: UI for user test (formative testing) in Tübingen. The user can control the Wi-Fi connection and observe the live view.



Figure 12: MiniLiVE endoscope in its latest development version. The current version of the hand piece.

4. DISCUSSIONS

4.1 Device: Addressing heat generation

While using the endoscope, the temperature of the endoscope tip and hand piece should remain below 40 °C in the long term. Otherwise, it can cause some damage to tissues or physicians during the surgical operation and affect miniaturized electronic modules. For instance, after using the prototype for 6 minutes, the entire built-in components were deactivated so that the prototype needs 15 minutes cooling time. Despite attempts to find an appropriate material for cooling variants and a proper location within the hand piece, these questions are not yet resolved.

4.2 Electronics: Coding of video data and data transmission

In realizing video streaming via Wi-Fi, the latency during data transfer should not be in the range of seconds but a few hundredths of a second. Accordingly, algorithms for data processing in FPGA were implemented, and they enabled low-

latency and energy-saving data transmission over Wi-Fi in 200ms. Currently, the data is transferred in the 2,4 GHz band that offers a limited data rate. Therefore, some further developments can be made by transferring data in the 5 GHz band or implementing automatic Wi-Fi channel switching during the data transmission. In addition, the data transfer could be enhanced over RTSP/RTP communication protocol with H.264 video compression. The endoscope tip's dimension allowed the 1mm²-sized sensors camera sensor. Depending on the use case, the image resolution could be sufficient, but new sensors with higher resolution have been made available shortly.

4.3 Electronics: Battery systems

Initially, the miniLiVE research team aimed to achieve 4 hours of operation time. However, it was believed that 2.5 hours operation time should be sufficient for most use cases. If potential users require a longer operating time, more accumulators should be supplemented, leading to problems in terms of weight and ergonomics of the endoscope hand piece due to the limited space.

4.4 Software: Wireless data transmission

To achieve license free software, open-source libraries, especially in data reception and data processing, have been employed. Hence, it can reduce some additional costs for the commercialization process. By modularizing classes in accordance with their objectives, developers can customize specific modules. For example, one could switch the GUI platform from WinUI3 to Qt, by replacing specific classes as newly implemented classes for Qt. Regarding HIS connection, one could connect client software to the HIS and exchange data over the HIS server.

4.5 Other Recommendations

The current prototype could provide another possibility of quality assurance for endoscopic images, using sensor data. This could be implemented by integrating, e.g., pressure- and motion- sensors at the tip of the endoscope, and it would serve as a mobile medical device, while guaranteeing the quality of endoscopic images with measurement data from these sensors.

5. CONCLUSIONS

Recently, video endoscopes have become the standard technology and already deliver high-quality images on monitors in the operating room. The miniLiVE research team aimed for innovation in the video endoscope techniques, through miniaturizing the light- and video unit, enabling wireless video transmission. During a two-year research project, the team successfully developed an executable prototype through the integration of sensors, miniaturized pertinent electronics, and client software for the examination. Finally, it was impossible to clarify whether a standard Wi-Fi connection is sufficient for a robust connection in a medical context, or whether proprietary technologies must be used for the wireless connection. In contrast to a laptop, for example, the medical device does not stand still on a table but is moved flexibly. In addition, a connection failure without a prompt reconnection would be an unacceptable risk for a visual

inspection of an operation. It has also not yet been possible to conclusively address the dissipation of the heat generated in the handle by the electronics and the LED. However, it should be possible to address this through heat channels. Further development of powerful video sensors and processors will also be able to provide a constantly improved image resolution, so that an automatic improvement can be expected here.

7. ACKNOWLEDGEMENTS

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