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## Patent Public Search | Text View

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United States Patent Application Publication	20250255461
Kind Code	A1
Publication Date	August 14, 2025
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### MEDICAL SUPPORT DEVICE, ENDOSCOPE SYSTEM, MEDICAL SUPPORT METHOD, AND PROGRAM

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#### Abstract

A medical support device includes a processor. The processor acquires a difficulty level of intubation into a duodenal papilla, the difficulty level being determined based on the duodenal papilla and/or a peripheral region of the duodenal papilla, which is shown in an intestinal wall image obtained by imaging an intestinal wall of a duodenum via an endoscope. The processor outputs support information for supporting the intubation in a case in which the difficulty level is equal to or higher than a reference difficulty level.

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<b>Appl. No.:</b>	<b>18/977935</b>
<b>Filed:</b>	<b>December 12, 2024</b>

#### Foreign Application Priority Data

JP	2024-018839	Feb. 09, 2024
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#### Publication Classification

**Int. Cl.:** A61B1/00 (20060101); A61B1/273 (20060101)

**U.S. Cl.:**

**CPC** A61B1/00045 (20130101); A61B1/000094 (20220201); A61B1/000096 (20220201); A61B1/273 (20130101);

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## Background/Summary

CROSS-REFERENCE TO RELATED APPLICATIONS [0001] This application claims priority under 35 USC 119 from Japanese Patent Application No. 2024-018839, filed on Feb. 9, 2024, the disclosure of which is incorporated by reference herein.

### BACKGROUND

#### 1. Technical Field

[0002] The present disclosure relates to a medical support device, an endoscope system, a medical support method, and a program.

#### 2. Related Art

[0003] JP2022-105685A discloses a technology of displaying an image from a camera on a flexible elongated member (see FIGS. 6A and 6B and FIGS. 6D and 6E) and executing detection and identification of a papilla for a medical worker. In addition, a controller described in JP2022-105685A determines a target trajectory based on an image of the papilla and provides a visual intubation path for the medical worker by superimposing the target trajectory on the image.

### SUMMARY

[0004] One embodiment according to the present disclosure provides a medical support device, an endoscope system, a medical support method, and a program that can support intubation into a duodenal papilla in a case in which a difficulty level of the intubation into the duodenal papilla is equal to or higher than a reference difficulty level.

[0005] A first aspect according to the present disclosure relates to a medical support device comprising: a processor, in which the processor acquires a difficulty level of intubation into a duodenal papilla, the difficulty level being determined based on the duodenal papilla and/or a peripheral region of the duodenal papilla, which is shown in an intestinal wall image obtained by imaging an intestinal wall of a duodenum via an endoscope, and outputs support information for supporting the intubation in a case in which the difficulty level is equal to or higher than a reference difficulty level.

[0006] A second aspect according to the present disclosure relates to the medical support device according to the first aspect, in which, in a case in which the difficulty level is determined based on the duodenal papilla, the difficulty level is determined based on an aspect of the duodenal papilla.

[0007] A third aspect according to the present disclosure relates to the medical support device according to the second aspect, in which the aspect of the duodenal papilla includes a shape of the duodenal papilla.

[0008] A fourth aspect according to the present disclosure relates to the medical support device according to the second or third aspect, in which the aspect of the duodenal papilla includes a size of the duodenal papilla.

[0009] A fifth aspect according to the present disclosure relates to the medical support device according to any one of the second to fourth aspects, in which the aspect of the duodenal papilla includes a type of an opening part of the duodenal papilla.

[0010] A sixth aspect according to the present disclosure relates to the medical support device according to any one of the second to fifth aspects, in which the aspect of the duodenal papilla includes a confluence form of a bile duct and a pancreatic duct in the duodenal papilla.

[0011] A seventh aspect according to the present disclosure relates to the medical support device according to any one of the second to sixth aspects, in which the aspect of the duodenal papilla includes a length of an oral side elevation.

[0012] An eighth aspect according to the present disclosure relates to the medical support device according to any one of the first to seventh aspects, in which, in a case in which the difficulty level is determined based on the peripheral region, the difficulty level is determined based on an aspect

of the peripheral region.

[0013] A ninth aspect according to the present disclosure relates to the medical support device according to the eighth aspect, in which the aspect of the peripheral region includes presence or absence of a diverticulum.

[0014] A tenth aspect according to the present disclosure relates to the medical support device according to the eighth or ninth aspect, in which the aspect of the peripheral region includes deformation of the duodenum.

[0015] An eleventh aspect according to the present disclosure relates to the medical support device according to any one of the first to tenth aspects, in which the support information includes information indicating that the difficulty level is equal to or higher than the reference difficulty level.

[0016] A twelfth aspect according to the present disclosure relates to the medical support device according to any one of the first to eleventh aspects, in which the support information includes incision region specification information for specifying an incision region for incising the duodenal papilla.

[0017] A thirteenth aspect according to the present disclosure relates to the medical support device according to the twelfth aspect, in which the incision region is included in a region avoiding a blood vessel that is included in the duodenal papilla and that has an attention level equal to or higher than a certain attention level.

[0018] A fourteenth aspect according to the present disclosure relates to the medical support device according to the twelfth or thirteenth aspect, in which the incision region is predicted by executing image processing on the intestinal wall image, and the incision region specification information is a prediction result of the incision region obtained by the image processing.

[0019] A fifteenth aspect according to the present disclosure relates to the medical support device according to the fourteenth aspect, in which the image processing is processing of causing a first trained model to generate the prediction result by inputting the intestinal wall image to the first trained model.

[0020] A sixteenth aspect according to the present disclosure relates to the medical support device according to the fourteenth or fifteenth aspect, in which the intestinal wall image includes a first intestinal wall image in which a blood vessel that is included in the duodenal papilla and that has an attention level equal to or higher than a certain attention level is shown in a state of being specifiable, and the incision region is predicted to be within a region avoiding the blood vessel by executing the image processing on the first intestinal wall image.

[0021] A seventeenth aspect according to the present disclosure relates to the medical support device according to any one of the first to sixteenth aspects, in which the support information includes operation assistance information for assisting an operation of the endoscope.

[0022] An eighteenth aspect according to the present disclosure relates to the medical support device according to any one of the first to seventeenth aspects, in which the difficulty level is determined based on the duodenal papilla and/or the peripheral region recognized by executing recognition processing on the intestinal wall image.

[0023] A nineteenth aspect according to the present disclosure relates to the medical support device according to the eighteenth aspect, in which the recognition processing is processing of causing a second trained model to recognize the duodenal papilla and/or the peripheral region shown in the intestinal wall image by inputting the intestinal wall image to the second trained model.

[0024] A twentieth aspect according to the present disclosure relates to an endoscope system comprising: the medical support device according to any one of the first to nineteenth aspects; and the endoscope.

[0025] A twenty-first aspect according to the present disclosure relates to a medical support method comprising: acquiring a difficulty level of intubation into a duodenal papilla, the difficulty level being determined based on the duodenal papilla and/or a peripheral region of the duodenal papilla,

which is shown in an intestinal wall image obtained by imaging an intestinal wall of a duodenum via an endoscope; and outputting support information for supporting the intubation in a case in which the difficulty level is equal to or higher than a reference difficulty level.

[0026] A twenty-second aspect according to the present disclosure relates to a program causing a computer to execute a medical support process comprising: acquiring a difficulty level of intubation into a duodenal papilla, the difficulty level being determined based on the duodenal papilla and/or a peripheral region of the duodenal papilla, which is shown in an intestinal wall image obtained by imaging an intestinal wall of a duodenum via an endoscope; and outputting support information for supporting the intubation in a case in which the difficulty level is equal to or higher than a reference difficulty level.

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## Description

### BRIEF DESCRIPTION OF THE DRAWINGS

[0027] Exemplary embodiments of the technology of the disclosure will be described in detail based on the following figures, wherein:

[0028] FIG. 1 is a conceptual diagram showing an example of an aspect in which a duodenoscope system is used;

[0029] FIG. 2 is a conceptual diagram showing an example of an overall configuration of the duodenoscope system;

[0030] FIG. 3 is a block diagram showing an example of a hardware configuration of an electric system of the duodenoscope system;

[0031] FIG. 4 is a conceptual diagram showing an example of aspects of a duodenum, a bile duct, and a pancreatic duct;

[0032] FIG. 5 is a block diagram showing an example of main functions of a processor included in a medical support device and an example of information stored in a storage;

[0033] FIG. 6 is a conceptual diagram showing examples of recognition processing using a papilla recognition model executed by a recognition unit and display processing of an intestinal wall image executed by a controller;

[0034] FIG. 7 is a conceptual diagram showing an example of recognition processing using a difficulty level recognition model executed by the recognition unit;

[0035] FIG. 8 is a conceptual diagram showing an example of prediction processing using an insertion direction prediction model executed by the recognition unit;

[0036] FIG. 9 is a conceptual diagram showing an example of processing of acquiring support information from a support information table via the controller and processing of generating high difficulty level notification information via the controller;

[0037] FIG. 10 is a conceptual diagram showing an example of display processing using insertion direction information, support information, and the high difficulty level notification information executed by the controller;

[0038] FIG. 11A is a flowchart showing an example of a flow of a medical support process;

[0039] FIG. 11B is a continuation of the flowchart shown in FIG. 11A;

[0040] FIG. 12 is a conceptual diagram showing a modification example of the recognition processing using the difficulty level recognition model executed by the recognition unit;

[0041] FIG. 13 is a conceptual diagram showing an example of an aspect in which the high difficulty level notification information is generated based on a plurality of difficulty levels obtained by the recognition processing using the difficulty level recognition model shown in FIG. 12 and is displayed on a screen;

[0042] FIG. 14 is a conceptual diagram showing an example of processing contents of the controller in a case in which a difficulty level of intubation into a duodenal papilla is determined

based on a confluence form and deformation of the duodenum;

[0043] FIG. 15 is a conceptual diagram showing an example of image processing using an incision region prediction model executed by the recognition unit;

[0044] FIG. 16 is a conceptual diagram showing an example of an aspect in which visible information (that is, an incision planned region mark) based on incision region specification information obtained by the image processing using the incision region prediction model executed by the recognition unit is displayed in a superimposed manner on the intestinal wall image displayed on the screen; and

[0045] FIG. 17 is a conceptual diagram showing an example of a series of pieces of processing in which a processor included in a computer issues a processing execution request to an external device via a network, the external device executes processing in accordance with the processing execution request, and the processor included in the computer receives a processing result from the external device.

#### DETAILED DESCRIPTION

[0046] Hereinafter, examples of embodiments of a medical support device, an endoscope system, a medical support method, and a program according to the present disclosure will be described with reference to the accompanying drawings.

[0047] First, the terms used in the following description will be described.

[0048] CPU is an abbreviation for “central processing unit”. GPU is an abbreviation for “graphics processing unit”. GPGPU is an abbreviation for “general-purpose computing on graphics processing units”. APU is an abbreviation for “accelerated processing unit”. TPU is an abbreviation for “tensor processing unit”. RAM is an abbreviation for “random-access memory”. NVM is an abbreviation for “non-volatile memory”. EEPROM is an abbreviation for “electrically erasable programmable read-only memory”. ASIC is an abbreviation for “application-specific integrated circuit”. PLD is an abbreviation for “programmable logic device”. FPGA is an abbreviation for “field-programmable gate array”. SoC is an abbreviation for “system-on-a-chip”. SSD is an abbreviation for “solid-state drive”. USB is an abbreviation for “Universal Serial Bus”. HDD is an abbreviation for “hard disk drive”. EL is an abbreviation for “electro-luminescence”. CMOS is an abbreviation for “complementary metal-oxide-semiconductor”. CCD is an abbreviation for “charge-coupled device”. AI is an abbreviation for “artificial intelligence”. BLI is an abbreviation for “blue light imaging”. LCI is an abbreviation for “linked color imaging”. I/F is an abbreviation for “interface”. LAN is an abbreviation for “local area network”. WAN is an abbreviation for “wide area network”. 5G is an abbreviation for “5th generation mobile communication system”. IC is an abbreviation for “integrated circuit”.

[0049] In the following description, a processor with a reference numeral (hereinafter, simply referred to as “processor”) may be one physical or virtual operation device or a combination of a plurality of physical or virtual operation devices. Further, the processor may be one type of operation device or a combination of a plurality of types of operation devices. Examples of the operation device include a CPU, a GPU, a GPGPU, an APU, and a TPU.

[0050] In the following description, a memory with a reference numeral is a memory such as a RAM that temporarily stores information, and is used as a work memory by the processor.

[0051] In the following description, a storage with a reference numeral is one or a plurality of non-volatile storage devices storing various programs and various parameters or the like. Examples of the non-volatile storage device include a flash memory, a magnetic disk, or a magnetic tape. Other examples of the storage include a cloud storage.

[0052] In the following embodiment, an external I/F with a reference numeral controls the transmission and the reception of various types of information among a plurality of devices connected to each other. Examples of the external I/F include a USB interface. A communication I/F including a communication processor, an antenna, and the like may be applied to the external I/F. The communication I/F controls communication among a plurality of computers. Examples of

a communication standard applied to the communication I/F include a wireless communication standard including 5G, Wi-Fi (registered trademark), or Bluetooth (registered trademark).

[0053] In the following embodiment, “A and/or B” is synonymous with “at least one of A or B”. That is, “A and/or B” may mean only A, only B, or a combination of A and B. In the present specification, the same concept as “A and/or B” also applies to a case in which three or more matters are expressed by association with “and/or”.

[0054] For example, as shown in FIG. 1, a duodenoscope system **10** comprises a duodenoscope **12** and a display device **13**. The duodenoscope **12** is used by a doctor **14** in endoscopy. In the present embodiment, the duodenoscope system **10** is an example of an “endoscope system” according to the present disclosure, and the duodenoscope **12** is an example of an “endoscope” according to the present disclosure.

[0055] The duodenoscope system **10** is connected communicably to a communication device (not shown), and information obtained by the duodenoscope system **10** is transmitted to the communication device. The communication device receives the information transmitted from the duodenoscope system **10** and executes processing using the received information (for example, processing of recording the information in an electronic medical record).

[0056] The duodenoscope **12** is inserted into an upper gastrointestinal tract of a subject **20** (for example, a patient). The duodenoscope **12** is an endoscope having an optical imaging function of irradiating the inside of the upper gastrointestinal tract of the subject **20** with light and imaging reflected light obtained by being reflected by an intestinal wall **30** which is a part of the upper gastrointestinal tract of the subject **20**. The duodenoscope **12** images the intestinal wall **30** to acquire an image showing an aspect of the intestinal wall **30**, and outputs the image to the display device **13**. The intestinal wall **30** imaged by the duodenoscope **12** is observed by the doctor **14** through the display device **13**.

[0057] The duodenoscope **12** comprises a light source device **22**, a control device **24**, and a medical support device **25**. The light source device **22**, the control device **24**, and the medical support device **25** are installed in a wagon **34**. The wagon **34** is provided with a plurality of stages along an up-down direction, and the medical support device **25**, the light source device **22**, and the control device **24** are installed from a lower stage to an upper stage. The display device **13** is installed on the uppermost stage in the wagon **34**.

[0058] The control device **24** controls the entire duodenoscope **12**. The medical support device **25** executes various types of image processing on the image obtained by imaging the intestinal wall **30** via the duodenoscope **12** under the control of the control device **24**.

[0059] The display device **13** displays various types of information including the image. Examples of the display device **13** include a liquid-crystal display and an EL display. In addition, a tablet terminal with a display may be used instead of or together with the display device **13**.

[0060] The display device **13** displays plurality of screens side by side. In the example shown in FIG. 1, screens **36A** and **36B** are shown as examples of the plurality of screens. On the screen **36A**, an intestinal wall image **40** obtained by imaging the intestinal wall **30** via the duodenoscope **12** is displayed. The intestinal wall image **40** shows the intestinal wall **30**. Further, in the example shown in FIG. 1, the intestinal wall **30** includes a duodenal papilla **30A** and a peripheral region **30B** of the duodenal papilla **30A**.

[0061] In the present embodiment, the intestinal wall image **40** is an example of an “intestinal wall image” according to the present disclosure. Further, in the present embodiment, the duodenal papilla **30A** is an example of a “duodenal papilla” according to the present disclosure. Further, in the present embodiment, the peripheral region **30B** is an example of a “peripheral region of the duodenal papilla” according to the present disclosure.

[0062] The intestinal wall image **40** is a moving image and is composed of a plurality of frames **41** in time series. The plurality of frames **41** in time series are displayed on the screen **36A** at a predetermined frame rate (for example, several tens of frames/second).

[0063] The screen **36A** is a main screen, whereas the screen **36B** is a sub-screen. Various types of information for supporting a procedure using the duodenoscope **12** performed by the doctor **14** are displayed on the screen **36B**. A size of the screen **36A** and a size of the screen **36B** may be fixed, or may be changed in response to an instruction issued from the doctor **14** to the duodenoscope system **10** or in accordance with various conditions.

[0064] As shown in FIG. **2** as an example, the duodenoscope **12** comprises an operating part **42** and an insertion part **44**. The insertion part **44** is partially bent by operating the operating part **42**. The insertion part **44** is inserted while being bent in accordance with a shape of the upper gastrointestinal tract (for example, a shape of a duodenum) in accordance with an operation of the operating part **42** performed by the doctor **14**.

[0065] A camera **48**, an illumination device **50**, a treatment opening **51**, and an elevating mechanism **52** are provided at a distal end part **46** of the insertion part **44**. The camera **48** and the illumination device **50** are provided on a side surface of the distal end part **46**. That is, the duodenoscope **12** is configured as a side-view endoscope, and an interior wall of the duodenum, that is, the intestinal wall **30**, is easily observed.

[0066] The camera **48** is a device that generates the intestinal wall image **40** as a medical image by imaging an inside of a body of the subject **20**, that is, the inside of the upper gastrointestinal tract. Examples of the camera **48** include a CMOS camera. However, this is merely an example, and another type of camera such as a CCD camera may be used.

[0067] The illumination device **50** includes an illumination window **50A**. The illumination device **50** emits light through the illumination window **50A**. Examples of the type of the light emitted from the illumination device **50** include visible light (for example, white light) and invisible light (for example, near-infrared light). In addition, the illumination device **50** emits special light through the illumination window **50A**. Examples of the special light include light for BLI and/or light for LCI. The camera **48** images the inside of the subject **20** by using an optical method in a state in which the inside of the subject **20** is irradiated with the light by the illumination device **50**.

[0068] The treatment opening **51** is used as a treatment tool protruding port through which a treatment tool **54** protrudes from the distal end part **46**, a suction port for suctioning blood, internal waste, and the like, and a delivery port for delivering a fluid.

[0069] The treatment tool **54** protrudes from the treatment opening **51** in accordance with the operation of the doctor **14**. The treatment tool **54** is inserted into the insertion part **44** from a treatment tool insertion port **58**. The treatment tool **54** passes through the inside of the insertion part **44** through the treatment tool insertion port **58** and protrudes from the treatment opening **51** into the body of the subject **20**. In the example shown in FIG. **2**, a cannula **54A** protrudes from the treatment opening **51** as the treatment tool **54**. The cannula **54A** is merely an example of the treatment tool **54**, and other examples of the treatment tool **54** include a catheter, a guide wire, a papillotomy knife, and a snare.

[0070] The elevating mechanism **52** changes a protrusion direction of the treatment tool **54** protruding from the treatment opening **51**. The elevating mechanism **52** comprises a guide **52A**, and the guide **52A** rises with respect to the protrusion direction of the treatment tool **54**, so that the protrusion direction of the treatment tool **54** is changed along the guide **52A**. Therefore, it is easy to cause the treatment tool **54** to protrude toward the intestinal wall **30**. In the example shown in FIG. **2**, the protrusion direction of the treatment tool **54** is changed to a direction orthogonal to a traveling direction of the distal end part **46** by the elevating mechanism **52**. The elevating mechanism **52** is operated by the doctor **14** using the operating part **42**. As a result, a degree of change in the protrusion direction of the treatment tool **54** is adjusted.

[0071] The duodenoscope **12** is connected to the light source device **22** and the control device **24** via a universal cord **60**. A reception device **62** is connected to the control device **24**. In addition, the medical support device **25** is connected to the control device **24**. Further, the display device **13** is connected to the medical support device **25**. That is, the control device **24** is connected to the

display device **13** via the medical support device **25**.

[0072] It should be noted that, here, since the medical support device **25** is described as an external device for expanding the functions executed by the control device **24**, the form example is described in which the control device **24** and the display device **13** are indirectly connected to each other via the medical support device **25**, but this is merely an example. For example, the display device **13** may be directly connected to the control device **24**. In this case, for example, the functions of the medical support device **25** need only be provided in the control device **24**, or a function of executing, via a server (not shown), the same process as a process (for example, a medical support process described below) executed by the medical support device **25** and receiving and using a processing result from the server need only be provided in the control device **24**.

[0073] The reception device **62** receives an instruction from a user (for example, the doctor **14**) and outputs the received instruction to the control device **24** as an electric signal. Examples of the reception device **62** include a keyboard, a mouse, a touch panel, a foot switch, and a microphone.

[0074] The control device **24** controls the light source device **22**, controls the transmission and the reception of various signals with the camera **48**, and controls the transmission and the reception of various signals with the medical support device **25**.

[0075] The light source device **22** emits light under the control of the control device **24** to supply the light to the illumination device **50**. The illumination device **50** is provided with a built-in light guide, and the light supplied from the light source device **22** is emitted from the illumination window **50A** via the light guide. The control device **24** causes the camera **48** to execute the imaging, acquires the intestinal wall image **40** (see FIG. **1**) from the camera **48**, and outputs the intestinal wall image **40** to a predetermined output destination (for example, the medical support device **25**).

[0076] The medical support device **25** executes various types of image processing on the intestinal wall image **40** input from the control device **24**. The medical support device **25** outputs the intestinal wall image **40** on which various types of image processing are executed, to a predetermined output destination (for example, the display device **13**).

[0077] It should be noted that, here, the form example is described in which the intestinal wall image **40** output from the control device **24** is output to the display device **13** via the medical support device **25**, but this is merely an example. The control device **24** and the display device **13** may be connected to each other, and the intestinal wall image **40** on which the image processing has been performed by the medical support device **25** may be displayed on the display device **13** via the control device **24**.

[0078] As shown in FIG. **3** as an example, the control device **24** comprises a computer **64**, a bus **66**, and an external I/F **68**. The computer **64** comprises a processor **70**, a memory **72**, and a storage **74**. The processor **70**, the memory **72**, the storage **74**, and the external I/F **68** are connected to a bus **66**.

[0079] The external I/F **68** controls the transmission and the reception of various types of information between one or more devices (hereinafter also referred to as “first external devices”) present outside the control device **24** and the processor **70**.

[0080] The camera **48** is connected to the external I/F **68** as one of the first external devices, and the external I/F **68** controls the transmission and the reception of various types of information between the camera **48** and the processor **70**. The processor **70** controls the camera **48** via the external I/F **68**. In addition, the processor **70** acquires, via the external I/F **68**, the intestinal wall image **40** (see FIG. **1**) obtained by imaging the inside of the body of the subject **20** via the camera **48**.

[0081] The light source device **22** is connected to the external I/F **68** as one of the first external devices, and the external I/F **68** controls the transmission and the reception of various types of information between the light source device **22** and the processor **70**. The light source device **22** supplies the light to the illumination device **50** under the control of the processor **70**. The illumination device **50** emits the light supplied from the light source device **22**.



[0082] The reception device **62** is connected to the external I/F **68** as one of the first external devices, and the processor **70** acquires the instruction received by the reception device **62** via the external I/F **68** and executes processing in response to the acquired instruction.

[0083] The medical support device **25** comprises a computer **76** and an external I/F **78**. The computer **76** comprises a processor **80**, a memory **82**, and a storage **84**. The processor **80**, the memory **82**, the storage **84**, and the external I/F **78** are connected to a bus **86**. In the present embodiment, the medical support device **25** is an example of a “medical support device” according to the present disclosure, the computer **76** is an example of a “computer” according to the present disclosure, and the processor **80** is an example of a “processor” according to the present disclosure.

[0084] The external I/F **78** controls the transmission and the reception of various types of information between one or more devices (hereinafter also referred to as “second external devices”) present outside the medical support device **25** and the processor **80**.

[0085] The control device **24** is connected to the external I/F **78** as one of the second external devices. In the example shown in FIG. 3, the external I/F **68** of the control device **24** is connected to the external I/F **78**. The external I/F **78** controls the transmission and the reception of various types of information between the processor **80** of the medical support device **25** and the processor **70** of the control device **24**. For example, the processor **80** acquires the intestinal wall image **40** (see FIG. 1) from the processor **70** of the control device **24** via the external I/Fs **68** and **78**, and executes various types of image processing on the acquired intestinal wall image **40**.

[0086] The display device **13** is connected to the external I/F **78** as one of the second external devices. The processor **80** controls the display device **13** via the external I/F **78** to display various types of information (for example, the intestinal wall image **40** on which various types of image processing have been executed) on the display device **13**.

[0087] As one of medical treatments for the duodenum using the duodenoscope **12**, a treatment called endoscopic retrograde cholangiopancreatography (ERCP) examination is known. As shown in FIG. 4 as an example, in the ERCP examination, for example, first, the duodenoscope **12** is inserted into a duodenum **88** through an esophagus and a stomach. In this case, an insertion state of the duodenoscope **12** may be checked by using an X-ray image obtained by X-ray imaging. Then, the distal end part **46** of the duodenoscope **12** reaches the vicinity of the duodenal papilla **30A** present in the intestinal wall **30**.

[0088] In the ERCP examination, for example, the cannula **54A** is inserted from a lumen side of the duodenum **88** into the duodenal papilla **30A**. Here, the duodenal papilla **30A** is a part that is elevated from the intestinal wall **30**. In a papillary elevation **90A**, which is a distal end part of the duodenal papilla **30A**, an opening part **90A1** is present, which leads to an end part of one or more tubes **92** leading to an internal organ (for example, a gallbladder and a pancreas), that is, which leads to the tube **92**. In other words, the tube **92** communicates with the opening part **90A1** present in the papillary elevation **90A**.

[0089] Examples of one or more tubes **92** include a bile duct **92A** and a pancreatic duct **92B**. The opening part **90A1** may be individually present with respect to each of the bile duct **92A** and the pancreatic duct **92B**, or may be present in common to the bile duct **92A** and the pancreatic duct **92B**.

[0090] In the ERCP examination, the X-ray imaging is executed in a state in which a contrast agent is injected into the tube **92** through the opening part **90A1**. Here, in a case in which the doctor **14** inserts the cannula **54A** into the tube **92**, it is necessary to accurately understand a running direction **94** of the tube **92**. In particular, since the running direction **94** in the vicinity of the opening part **90A1** substantially matches an insertion direction of the cannula **54A** with respect to the opening part **90A1**, it is very important for the doctor **14** to visually understand the running direction **94** in the vicinity of the opening part **90A1**.

[0091] Examples of the running direction **94** of the tube **92** include a running direction **94A** of the bile duct **92A** and a running direction **94B** of the pancreatic duct **92B**. It is effective for the doctor

**14** to visually understand the running direction **94A** in a case in which the cannula **54A** is inserted into the bile duct **92A**, and it is effective for the doctor **14** to visually understand the running direction **94B** in a case in which the cannula **54A** is inserted into the pancreatic duct **92B**.

[0092] A difficulty level of the insertion of the cannula **54A** into the tube **92**, that is, a difficulty level of intubation into the duodenal papilla **30A**, varies greatly depending on the conditions. For example, depending on a combination of a confluence form of the bile duct **92A** and the pancreatic duct **92B** (hereinafter, simply referred to as a “confluence form”) in the duodenal papilla **30A** and a type of the opening part **90A1**, the intubation into the duodenal papilla **30A** is more difficult. In addition, the intubation into the duodenal papilla **30A** is made more difficult due to a shape of the duodenal papilla **30A**, a size of the duodenal papilla **30A**, a length of an oral side elevation of the duodenal papilla **30A**, an aspect of the peripheral region **30B** (for example, whether or not there is a diverticulum), and/or deformation of the duodenum.

[0093] Therefore, in a case in which the difficulty level of the intubation into the duodenal papilla **30A** is equal to or higher than a certain difficulty level (for example, a difficulty level in which a doctor with an average ability to perform the intubation into the duodenal papilla wants information that is useful for supporting the intubation into the duodenal papilla), it is preferable that support information, which is the information that is useful for supporting the intubation into the duodenal papilla **30A**, is displayed on the screen **36A** and/or **36B**.

[0094] However, the doctor **14** during the procedure does not have time to determine by himself/herself whether or not the difficulty level of the intubation into the duodenal papilla **30A** is equal to or higher than a certain difficulty level and to execute an operation for displaying the necessary support information on the screen **36A** and/or **36B**.

[0095] Therefore, in view of such circumstances, in the present embodiment, as shown in FIG. 5 as an example, the medical support process is executed by the processor **80** of the medical support device **25**. A medical support program **96** is stored in the storage **84**. In the present embodiment, the medical support program **96** is an example of a “program” according to the present disclosure. The processor **80** reads out the medical support program **96** from the storage **84** and executes the readout medical support program **96** on the memory **82** to execute the medical support process. The medical support process is implemented by the processor **80** operating as a recognition unit **80A** and a controller **80B** in accordance with the medical support program **96** executed on the memory **82**.

[0096] The storage **84** stores a papilla recognition model **98**, a difficulty level recognition model **100**, an insertion direction prediction model **102**, and a support information table **104**. As will be described below, the difficulty level recognition model **100** and the insertion direction prediction model **102** are used by the recognition unit **80A**, and the support information table **104** is used by the controller **80B**.

[0097] As shown in FIG. 6 as an example, the recognition unit **80A** and the controller **80B** acquire the intestinal wall image **40**. For example, the recognition unit **80A** and the controller **80B** acquire the intestinal wall image **40** generated by being captured by the camera **48** in accordance with an imaging frame rate (for example, several tens of frames/second) from the camera **48** in units of one frame. The controller **80B** displays, on the screen **36A**, the intestinal wall image **40** acquired from the camera **48**.

[0098] Meanwhile, the recognition unit **80A** recognizes the duodenal papilla **30A** and the peripheral region **30B** shown in the frame **41** based on each of the plurality of frames **41** included in the intestinal wall image **40** acquired from the camera **48**. In the present embodiment, in order to implement this, the recognition unit **80A** recognizes the duodenal papilla **30A** and the peripheral region **30B** by using an AI method. Here, the recognition processing using the papilla recognition model **98** is executed. In the present embodiment, the papilla recognition model **98** is an example of a “second trained model” according to the present disclosure.

[0099] The papilla recognition model **98** is a trained model for object recognition using a

segmentation method via AI, and is obtained by executing machine learning for the frame **41**. The papilla recognition model **98** has been optimized by training a neural network through machine learning using first training data that is a data set including a plurality of data (that is, data for a plurality of frames) in which first example data and first correct answer data are associated with each other. That is, the papilla recognition model **98** is a trained model that has been optimized to receive input of first example data to generate first correct answer data.

[0100] The first example data is an image that corresponds to the frame **41** (in other words, a sample image assuming the frame **41**). A first example of the image that corresponds to the frame **41** is an optical image actually obtained by a duodenoscope having the same configuration as the duodenoscope **12**. A second example of the image that corresponds to the frame **41** is a virtually generated image (for example, an image generated by generative AI).

[0101] The first correct answer data refers to correct answer data (that is, an annotation) for the first example data. That is, the first correct answer data is information for specifying the duodenal papilla and the peripheral region of the duodenal papilla, which are shown in the image used as the first example data, in a distinguishable manner. Here, as an example of the first correct answer data, annotations are used for specifying geometrical characteristics (for example, the position, the size, and the shape) of the duodenal papilla shown in the image used as the first example data, anatomical features (for example, the type of the opening part and the length of the oral side elevation) of the duodenal papilla, geometrical characteristics (for example, the position, the size, and the shape) of the peripheral region of the duodenal papilla, and anatomical features (for example, the presence or absence of the diverticulum) of the peripheral region of the duodenal papilla.

[0102] The recognition unit **80A** inputs the frame **41** to the papilla recognition model **98** at a frame rate at which the frame **41** is displayed on the screen **36A**. The papilla recognition model **98** recognizes the duodenal papilla **30A** and the peripheral region **30B** shown in the input frame **41** each time the frame **41** is input, generates a papilla recognition result **106**, which is a recognition result, and outputs the generated papilla recognition result **106** to the controller **80B**. The papilla recognition result **106** includes information indicating each of the geometrical characteristics of the duodenal papilla **30A**, the anatomical features (for example, the type of the opening part **90A1** and the length of the oral side elevation) of the duodenal papilla **30A**, the geometrical characteristics of the peripheral region **30B**, and the anatomical features (for example, the presence or absence of the diverticulum) of the peripheral region **30B**.

[0103] As shown in FIG. **7** as an example, the recognition unit **80A** determines whether or not the duodenal papilla **30A** and the peripheral region **30B** are shown in the frame **41** input to the papilla recognition model **98** to obtain the papilla recognition result **106**, based on the papilla recognition result **106**. Here, in a case in which the duodenal papilla **30A** and the peripheral region **30B** are shown in the frame **41** input to the papilla recognition model **98** to obtain the papilla recognition result **106**, the recognition unit **80A** inputs the frame **41** input to the papilla recognition model **98** to obtain the papilla recognition result **106**, to the difficulty level recognition model **100**.

[0104] The difficulty level recognition model **100** is a trained model for image processing via AI, and is obtained by executing the machine learning for the frame **41**. The difficulty level recognition model **100** has been optimized by training a neural network through machine learning using second training data that is a data set including a plurality of data (that is, data for a plurality of frames) in which second example data and second correct answer data are associated with each other. That is, the difficulty level recognition model **100** is a trained model that has been optimized to receive input of second example data to generate second correct answer data.

[0105] In the example shown in FIG. **7**, training data **108** is shown as the second training data. The training data **108** includes a sample image **110** as an example of the second example data and difficulty level data **112** as an example of the second correct answer data, and the sample image **110** and the difficulty level data **112** are associated with each other.

[0106] The sample image **110** is the same image as the image used in the above-described first example data. An intestinal wall **111** of the duodenum, a duodenal papilla **111A**, and a peripheral region **111B** of the duodenal papilla **111A** are shown in the sample image **110**.

[0107] The difficulty level data **112** is data indicating the difficulty level of the intubation into the duodenal papilla **111A**. The difficulty level of the intubation into the duodenal papilla **111A** is determined based on the duodenal papilla **111A** and the peripheral region **111B**. In the example shown in FIG. 7, a difficulty level X is shown as the difficulty level of the intubation into the duodenal papilla **111A**. The difficulty level data **112** is data indicating the difficulty level X.

[0108] In the example shown in FIG. 7, the difficulty level X is determined based on a papilla aspect **114** and a peripheral region aspect **116**. The papilla aspect **114** is an aspect of the duodenal papilla **111A**. The papilla aspect **114** includes a shape **114A** of the duodenal papilla **111A**, a size **114B** of the duodenal papilla **111A**, an opening part type **114C** (that is, a type of an opening part of the duodenal papilla **111A**), and an oral side elevation length **114D** (that is, a length of an oral side elevation of the duodenal papilla **111A**).

[0109] Meanwhile, the peripheral region aspect **116** is an aspect of the peripheral region **111B**. The peripheral region aspect **116** includes diverticulum presence/absence **116A** (that is, the presence or absence of the diverticulum).

[0110] A difficulty level x1 is given to a shape **114A**. A difficulty level x2 is given to a size **114B**. A difficulty level x3 is given to an opening part type **114C**. A difficulty level x4 is given to an oral side elevation length **114D**. A difficulty level x5 is given to diverticulum presence/absence **116A**.

[0111] The difficulty level x1 means a difficulty level of the intubation into the duodenal papilla **111A** in a case of the shape **114A**. The difficulty level x2 means a difficulty level of the intubation into the duodenal papilla **111A** in a case of the size **114B**. The difficulty level x3 means a difficulty level of the intubation into the duodenal papilla **111A** in a case of the opening part type **114C**. The difficulty level x4 means a difficulty level of the intubation into the duodenal papilla **111A** in a case of the oral side elevation length **114D**. The difficulty level x5 means a difficulty level of the intubation into the duodenal papilla **111A** in a case of the diverticulum presence/absence **116A**.

[0112] For example, the difficulty level X is a difficulty level that is comprehensively determined from the difficulty levels x1 to x5 by an annotator (that is, a creator of the difficulty level data **112**). An example of the difficulty level that is comprehensively determined from the difficulty levels x1 to x5 is an average difficulty level of the difficulty levels x1 to x5.

[0113] The difficulty level recognition model **100** is a trained model in which a model **107** (for example, a neural network) has been optimized by executing machine learning using the training data **108** on the model **107**.

[0114] The recognition unit **80A** inputs the frame **41** to the difficulty level recognition model **100** at the frame rate at which the frame **41** is displayed on the screen **36A**. The difficulty level recognition model **100** recognizes the difficulty level of the intubation into the duodenal papilla **30A** shown in the input frame **41** each time the frame **41** is input, and generates a difficulty level recognition result **118** which is the recognition result. The difficulty level recognition result **118** is output to the controller **80B**.

[0115] The difficulty level recognition result **118** includes a difficulty level Y. The difficulty level Y means a difficulty level of the intubation into the duodenal papilla **30A** shown in the frame **41** input to the difficulty level recognition model **100**.

[0116] The difficulty level recognition model **100** is a trained model obtained through the machine learning using the training data **108** including the difficulty level data **112** determined based on the duodenal papilla **111A** and the peripheral region **111B**. Therefore, the difficulty level Y included in the difficulty level recognition result **118** generated by the difficulty level recognition model **100** can be said to be a difficulty level determined based on the duodenal papilla **30A** and the peripheral region **30B**.

[0117] In addition, the difficulty level recognition model **100** is a trained model obtained through

the machine learning using the training data **108** including the difficulty level data **112** determined based on the papilla aspect **114** and the peripheral region aspect **116**. Therefore, the difficulty level Y included in the difficulty level recognition result **118** generated by the difficulty level recognition model **100** can be said to be a difficulty level determined based on the aspect of the duodenal papilla **30A** and the aspect of the peripheral region **30B**.

[0118] In addition, the difficulty level recognition model **100** is a trained model obtained through the machine learning using the training data **108** including the difficulty level data **112** determined based on the shape **114A**, the size **114B**, the opening part type **114C**, the oral side elevation length **114D**, and the diverticulum presence/absence **116A**. Therefore, the difficulty level Y included in the difficulty level recognition result **118** generated by the difficulty level recognition model **100** can be said to be a difficulty level determined based on the shape of the duodenal papilla **30A**, the size of the duodenal papilla **30A**, the type of the opening part **90A1** of the duodenal papilla **30A**, the length of the oral side elevation of the duodenal papilla **30A**, and the presence or absence of the diverticulum in the peripheral region **30B**.

[0119] As shown in FIG. **8** as an example, the recognition unit **80A** determines whether or not a specific opening part is shown in the frame **41** input to the papilla recognition model **98** to obtain the papilla recognition result **106**, based on the papilla recognition result **106**. Here, the specific opening part means the opening part **90A1** (for example, the opening part **90A1** of a nodular type or a villous type) for which it is generally recognized that it is difficult to perform the intubation into the duodenal papilla **30A**. In addition, the recognition unit **80A** determines whether or not the difficulty level Y included in the difficulty level recognition result **118** is equal to or higher than a reference difficulty level.

[0120] Here, a first example of the reference difficulty level is a difficulty level in which a time required for a doctor, who has an ability lower than the average ability to perform the intubation into the duodenal papilla, from the start of the intubation to the end of the intubation is expected to be equal to or longer than a certain time (for example, 10 minutes). A second example of the reference difficulty level is a difficulty level in which a time required for a doctor, who has the average ability to perform the intubation into the duodenal papilla, from the start of the intubation to the end of the intubation is expected to be equal to or longer than a certain time (for example, 5 minutes). In addition, a third example of the reference difficulty level is a difficulty level in which a time required for a doctor, who has an ability higher than the average ability to perform the intubation into the duodenal papilla, from the start of the intubation to the end of the intubation is expected to be equal to or longer than a certain time (for example, 2 minutes). It should be noted that the reference difficulty level is statistically derived in advance based on a plurality of cases in which the intubation into the duodenal papilla is actually executed by each of a plurality of doctors.

[0121] In a case in which the specific opening part is shown in the frame **41** input to the papilla recognition model **98** to obtain the papilla recognition result **106** and the difficulty level Y included in the difficulty level recognition result **118** is equal to or higher than the reference difficulty level, the recognition unit **80A** predicts a direction in which the cannula **54A** is inserted into the duodenal papilla **30A** (hereinafter, simply referred to as an “insertion direction”), based on the insertion direction prediction model **102**. The insertion direction includes a direction in which the cannula **54A** is inserted into the bile duct **92A** and a direction in which the cannula **54A** is inserted into the pancreatic duct **92B**.

[0122] The insertion direction prediction model **102** is a trained model for prediction via AI, and is obtained by executing the machine learning for the frame **41**. The insertion direction prediction model **102** has been optimized by training a neural network through machine learning using third training data that is a data set including a plurality of data (that is, data for a plurality of frames) in which third example data and third correct answer data are associated with each other. That is, the insertion direction prediction model **102** is a trained model that has been optimized to receive input of third example data to generate third correct answer data.

[0123] The third example data includes the image used in the above-described first example data and the confluence form. The third correct answer data refers to correct answer data (that is, an annotation) for the third example data. That is, the third correct answer data is information for specifying the insertion direction (for example, the insertion direction applied to the bile duct **92A** and the insertion direction applied to the pancreatic duct **92B**) suitable for the duodenal papilla shown in the image used as the third example data.

[0124] The recognition unit **80A** inputs the same frame **41** as the frame **41** input to the papilla recognition model **98** to obtain the papilla recognition result **106** at the frame rate at which the frame **41** is displayed on the screen **36A**, and confluence form information **120** to the insertion direction prediction model **102**. Here, the confluence form information **120** is received by the reception device **62**. The confluence form information **120** is, for example, information indicating the confluence form that is specified in advance from an examination result obtained by performing a CT examination, an MRI examination, or the like on the subject **20**.

[0125] In a case in which the frame **41** and the confluence form information **120** are input to the insertion direction prediction model **102**, the insertion direction prediction model **102** generates insertion direction information **122** that is information for specifying the insertion direction, and outputs the generated insertion direction information **122**. In the present embodiment, the insertion direction information **122** is an example of “support information” according to the present disclosure.

[0126] As shown in FIG. **9** as an example, the support information table **104** includes support information **124**. The support information **124** includes a plurality of pieces of opening part specification information **124A**, a plurality of pieces of confluence form specification information **124B**, and a plurality of pieces of operation assistance information **124C**. The opening part specification information **124A** is information for specifying the opening part **90A1**. The confluence form specification information **124B** is information for specifying the confluence form. The operation assistance information **124C** is information for assisting the operation of the duodenoscope **12**. In the present embodiment, the operation assistance information **124C** is an example of “operation assistance information” according to the present disclosure.

[0127] The support information table **104** is provided with the opening part specification information **124A** for each type of the opening part **90A1**. The opening part specification information **124A** is information in which an opening part schema **124A1**, which is a schema for specifying the type of the opening part **90A1**, and opening part text **124A2**, which is text for specifying the type of the opening part **90A1**, are associated with each other.

[0128] The support information table **104** is provided with the confluence form specification information **124B** for each confluence form. In addition, the confluence form specification information **124B** is associated with the opening part specification information **124A** for each type of the opening part **90A1**. The confluence form specification information **124B** is information in which a confluence form schema **124B1**, which is a schema for specifying the confluence form, and confluence form text **124B2**, which is text for specifying the confluence form, are associated with each other.

[0129] The operation assistance information **124C** is associated with the opening part specification information **124A** for each type of the opening part **90A1**. In addition, the operation assistance information **124C** is associated with the confluence form specification information **124B** for each confluence form. The operation assistance information **124C** is information in which scope position information **124C1** and approach method information **124C2** are associated with each other. The scope position information **124C1** is information (here, as an example, text) for specifying a position (for example, a position at which an objective lens of the camera **48** faces the opening part **90A1** in front view) recommended as a position of the duodenoscope **12**. The approach method information **124C2** is information (here, as an example, text) for specifying a method of approach to the opening part **90A1** (for example, a proximity method, a look-up method, and the like).

[0130] In a case in which the difficulty level Y included in the difficulty level recognition result **118** acquired from the recognition unit **80A** is equal to or higher than the reference difficulty level, the controller **80B** generates high difficulty level notification information **126**. The high difficulty level notification information **126** is information for giving notification that the difficulty level Y is equal to or higher than the reference difficulty level. An example of the high difficulty level notification information **126** includes text indicating that the difficulty level Y is equal to or higher than the reference difficulty level. In the present embodiment, the high difficulty level notification information **126** is an example of “information indicating that the difficulty level is equal to or higher than the reference difficulty level” according to the present disclosure. In addition, in the present embodiment, the high difficulty level notification information **126** is an example of “support information” according to the present disclosure.

[0131] In a case in which the difficulty level Y included in the difficulty level recognition result **118** acquired from the recognition unit **80A** is equal to or higher than the reference difficulty level, the specific opening part is included in the frame **41** input to the papilla recognition model **98** to obtain the papilla recognition result **106**, and the confluence form specified by the confluence form information **120** received by the reception device **62** is a specific confluence form (for example, a partition wall type or a common tube type), the controller **80B** acquires the support information **124** that meets the conditions from the support information table **104**. Here, the support information **124** that meets the condition means, for example, the opening part specification information **124A** corresponding to the specific opening part, the confluence form specification information **124B** corresponding to the specific confluence form, and the operation assistance information **124C** corresponding to the opening part specification information **124A** and the confluence form specification information **124B**.

[0132] As shown in FIG. **10** as an example, the controller **80B** outputs the insertion direction information **122** obtained from the insertion direction prediction model **102**, the support information **124** acquired from the support information table **104**, and the high difficulty level notification information **126** to the display device **13**.

[0133] That is, in a case in which the difficulty level Y included in the difficulty level recognition result **118** is equal to or higher than the reference difficulty level and the specific opening part is included in the frame **41** input to the papilla recognition model **98**, the insertion direction information **122** is output to the display device **13**. In addition, in a case in which the difficulty level Y included in the difficulty level recognition result **118** is equal to or higher than the reference difficulty level, the specific opening part is included in the frame **41** input to the papilla recognition model **98**, and the confluence form specified from the confluence form information **120** received by the reception device **62** is the specific confluence form, the support information **124** is output to the display device **13**. Further, in a case in which the difficulty level Y included in the difficulty level recognition result **118** is equal to or higher than the reference difficulty level, the high difficulty level notification information **126** is output to the display device **13**.

[0134] As described above, the insertion direction information **122**, the support information **124**, and the high difficulty level notification information **126** are output to the display device **13**, and thus visible information is displayed on the screens **36A** and **36B** of the display device **13**. For example, the controller **80B** converts the insertion direction information **122** into an image, and displays the converted image on the screen **36A**. In the example shown in FIG. **10**, arrow marks **122A** and **122B**, which are obtained by converting the insertion direction information **122** into an image, are displayed in a superimposed manner on the frame **41** displayed on the screen **36A**. A direction indicated by the arrow mark **122A** is the direction in which the cannula **54A** is inserted into the bile duct **92A**, and a direction indicated by the arrow mark **122B** is the direction in which the cannula **54A** is inserted into the pancreatic duct **92B**. Further, the controller **80B** displays the support information **124** on the screen **36B**. Further, the controller **80B** displays the high difficulty level notification information **126** on the screen **36B** as text TX1.

[0135] Next, an operation of a portion of the duodenoscope system **10** according to the present disclosure will be described with reference to FIGS. **11A** and **11B**.

[0136] FIGS. **11A** and **11B** show an example of a flow of the medical support process executed by the processor **80**. The flow of the medical support process shown in FIGS. **11A** and **11B** is an example of a “medical support method” according to the present disclosure.

[0137] In the medical support process shown in FIG. **11A**, first, in step **ST10**, the controller **80B** determines whether or not the camera **48** images the intestinal wall **30** for one frame. In step **ST10**, in a case in which the camera **48** does not image the intestinal wall **30** for one frame, a negative determination is made, and the medical support process proceeds to step **ST42** shown in FIG. **11B**. In step **ST10**, in a case in which the camera **48** images the intestinal wall **30** for one frame, an affirmative determination is made, and the medical support process proceeds to step **ST12**.

[0138] In step **ST12**, the recognition unit **80A** and the controller **80B** acquire the intestinal wall image **40** from the camera **48**. The controller **80B** displays the intestinal wall image **40** on the screen **36A**. After the processing in step **ST12** is executed, the medical support process proceeds to step **ST14**.

[0139] In step **ST14**, the recognition unit **80A** inputs the frame **41** included in the intestinal wall image **40** acquired in step **ST12** to the papilla recognition model **98**. As a result, the papilla recognition model **98** generates the papilla recognition result **106**. After the processing in step **ST14** is executed, the medical support process proceeds to step **ST16**.

[0140] In step **ST16**, the recognition unit **80A** acquires the papilla recognition result **106** generated by the papilla recognition model **98**. After the processing in step **ST16** is executed, the medical support process proceeds to step **ST18**.

[0141] In step **ST18**, the recognition unit **80A** determines whether or not the duodenal papilla **30A** is shown in the frame **41** input to the papilla recognition model **98** in step **ST14**, based on the papilla recognition result **106** acquired in step **ST16**. In step **ST18**, in a case in which the duodenal papilla **30A** is not shown in the frame **41** input to the papilla recognition model **98**, a negative determination is made, and the medical support process proceeds to step **ST42** shown in FIG. **11B**. In step **ST18**, in a case in which the duodenal papilla **30A** is shown in the frame **41** input to the papilla recognition model **98**, an affirmative determination is made, and the medical support process proceeds to step **ST20**.

[0142] In step **ST20**, the recognition unit **80A** inputs the frame **41** input to the papilla recognition model **98** in step **ST14** to acquire the papilla recognition result **106** in step **ST16**, to the difficulty level recognition model **100**. As a result, the difficulty level recognition model **100** generates the difficulty level recognition result **118**. After the processing in step **ST20** is executed, the medical support process proceeds to step **ST22**.

[0143] In step **ST22**, the recognition unit **80A** acquires the difficulty level recognition result **118** generated by the difficulty level recognition model **100**. After the processing in step **ST22** is executed, the medical support process proceeds to step **ST24**.

[0144] In step **ST24**, the controller **80B** determines whether or not the difficulty level **Y** included in the difficulty level recognition result **118** acquired in step **ST22** is equal to or higher than the reference difficulty level. In step **ST24**, in a case in which the difficulty level **Y** included in the difficulty level recognition result **118** acquired in step **ST22** is lower than the reference difficulty level, a negative determination is made, and the medical support process proceeds to step **ST42** shown in FIG. **11B**. In step **ST24**, in a case in which the difficulty level **Y** included in the difficulty level recognition result **118** acquired in step **ST22** is equal to or higher than the reference difficulty level, an affirmative determination is made, and the medical support process proceeds to step **ST26**.

[0145] In step **ST26**, the controller **80B** generates the high difficulty level notification information **126**. The controller **80B** displays the high difficulty level notification information **126** on the screen **36B** as the text **TX1**. After the processing in step **ST26** is executed, the medical support process proceeds to step **ST28**.



[0146] In step ST28, the recognition unit **80A** determines whether or not the specific opening part is shown in the frame **41** input to the papilla recognition model **98** in step ST14 to acquire the papilla recognition result **106** in step ST16, based on the papilla recognition result **106** acquired in step ST16. In step ST28, in a case in which the specific opening part is not shown in the frame **41** input to the papilla recognition model **98** in step ST14 to acquire the papilla recognition result **106** in step ST16, a negative determination is made, and the medical support process proceeds to step ST42 shown in FIG. 11B. In step ST28, in a case in which the specific opening part is shown in the frame **41** input to the papilla recognition model **98** in step ST14 to acquire the papilla recognition result **106** in step ST16, an affirmative determination is made, and the medical support process proceeds to step ST30.

[0147] In step ST30, the recognition unit **80A** acquires the confluence form information **120** received by the reception device **62**. After the processing in step ST30 is executed, the medical support process proceeds to step ST32.

[0148] In step ST32, the recognition unit **80A** inputs the frame **41** input to the papilla recognition model **98** in step ST14 to acquire the papilla recognition result **106** in step ST16, along with the confluence form information **120** acquired in step ST30, to the insertion direction prediction model **102**. As a result, the insertion direction prediction model **102** generates the insertion direction information **122**. After the processing in step ST32 is executed, the medical support process proceeds to step ST34.

[0149] In step ST34, the controller **80B** acquires the insertion direction information **122** generated by the insertion direction prediction model **102** to which the frame **41** and the confluence form information **120** are input in step ST32. Then, the controller **80B** displays, as the arrow marks **122A** and **122B**, the insertion direction information **122** in a superimposed manner on the frame **41** displayed on the screen **36A**. After the processing in step ST34 is executed, the medical support process proceeds to step ST36 shown in FIG. 11B.

[0150] In step ST36, the controller **80B** determines whether or not all of a first condition, a second condition, and a third condition are satisfied. The first condition refers to a condition in which the difficulty level **Y** included in the difficulty level recognition result **118** acquired in step ST22 is equal to or higher than the reference difficulty level. The second condition refers to a condition in which the specific opening part is shown in the frame **41** input to the papilla recognition model **98** in step ST14 to acquire the papilla recognition result **106** in step ST16. The third condition refers to a condition in which the confluence form specified from the confluence form information **120** acquired in step ST30 is the specific confluence form. In step ST36, in a case in which all of the first condition, the second condition, and the third condition are not satisfied, a negative determination is made, and the medical support process proceeds to step ST42. In step ST36, in a case in which all of the first condition, the second condition, and the third condition are satisfied, an affirmative determination is made, and the medical support process proceeds to step ST38.

[0151] In step ST38, the controller **80B** acquires the support information **124** that meets the condition from the support information table **104**. After the processing in step ST38 is executed, the medical support process proceeds to step ST40.

[0152] In step ST40, the controller **80B** displays the support information **124** acquired in step ST38 on the screen **36B**. After the processing in step ST40 is executed, the medical support process proceeds to step ST42.

[0153] In step ST42, the controller **80B** determines whether or not a medical support process end condition is satisfied. An example of the medical support process end condition is a condition in which an instruction to end the medical support process is issued to the duodenoscope system **10** (for example, a condition in which the instruction to end the medical support process is received by the reception device **62**).

[0154] In step ST42, in a case in which the medical support process end condition is not satisfied, a negative determination is made, and the medical support process proceeds to step ST10 shown in

**FIG. 11A.** In a case in which the medical support process end condition is satisfied in step **ST42**, an affirmative determination is made, and the medical support process ends.

[0155] As described above, in the present embodiment, in a case in which the difficulty level **Y** determined based on the duodenal papilla **30A** and the peripheral region **30B** shown in the intestinal wall image **40** obtained by imaging the intestinal wall **30** via the duodenoscope **12** is equal to or higher than the reference difficulty level, the support information **124** is displayed on the screen **36B**. Therefore, in a case in which the difficulty level **Y** of the intubation into the duodenal papilla **30A** is equal to or higher than the reference difficulty level, the intubation into the duodenal papilla **30A** can be supported. That is, since the support information **124** is displayed on the screen **36B** in a case in which the difficulty level **Y** is equal to or higher than the reference difficulty level, the doctor **14** during the procedure can perform the intubation into the duodenal papilla **30A** with high accuracy in a short time without determining whether or not the difficulty level **Y** of the intubation into the duodenal papilla **30A** is equal to or higher than the reference difficulty level **Y** by himself/herself or performing an operation for displaying the support information **124** on the screen **36A** and/or **36B**.

[0156] In the present embodiment, the operation assistance information **124C** is included in the support information **124** displayed on the screen **36B**. Therefore, it is possible to make it easier for the doctor **14** during the procedure to perform an operation required for the intubation into the duodenal papilla **30A** as the operation of the duodenoscope **12**, as compared to a case in which the operation assistance information **124C** is not displayed.

[0157] In addition, in the present embodiment, the difficulty level **Y** is determined based on the duodenal papilla **30A** and the peripheral region **30B** recognized by executing the recognition processing via AI (that is, the recognition processing using the papilla recognition model **98**) on the intestinal wall image **40**. Therefore, the difficulty level **Y** of the intubation into the duodenal papilla **30A** can be determined with high accuracy as compared to a case in which the doctor **14** during the procedure visually specifies the duodenal papilla **30A** and the peripheral region **30B** to determine the difficulty level of the intubation into the duodenal papilla **30A**.

[0158] In addition, in the present embodiment, in a case in which the difficulty level **Y** determined based on the duodenal papilla **30A** and the peripheral region **30B** shown in the intestinal wall image **40** obtained by imaging the intestinal wall **30** via the duodenoscope **12** is equal to or higher than the reference difficulty level, the insertion direction information **122** is displayed on the intestinal wall image **40** in a superimposed manner as the arrow marks **122A** and **122B**. Therefore, it is possible for the doctor **14** to accurately insert the cannula **54A** into the bile duct **92A** and the pancreatic duct **92B** in a short time.

[0159] In addition, in the present embodiment, in a case in which the difficulty level **Y** determined based on the duodenal papilla **30A** and the peripheral region **30B** shown in the intestinal wall image **40** obtained by imaging the intestinal wall **30** via the duodenoscope **12** is equal to or higher than the reference difficulty level, the high difficulty level notification information **126** is displayed on the screen **36B**. As a result, the doctor **14** during the procedure can visually recognize that the difficulty level **Y** of the intubation into the duodenal papilla **30A** is equal to or higher than the reference difficulty level.

[0160] In addition, in the present embodiment, the difficulty level **Y** is determined based on the aspect of the duodenal papilla **30A**. Therefore, the difficulty level of the intubation into the duodenal papilla **30A** can be determined with high accuracy as compared to a case in which the difficulty level of the intubation into the duodenal papilla **30A** is determined without considering the aspect of the duodenal papilla **30A**.

[0161] In addition, in the present embodiment, the difficulty level **Y** is determined based on the shape of the duodenal papilla **30A**. Therefore, the difficulty level of the intubation into the duodenal papilla **30A** can be determined with high accuracy as compared to a case in which the difficulty level of the intubation into the duodenal papilla **30A** is determined without considering

the shape of the duodenal papilla **30A**.

[0162] In addition, in the present embodiment, the difficulty level Y is determined based on the size of the duodenal papilla **30A**. Therefore, the difficulty level of the intubation into the duodenal papilla **30A** can be determined with high accuracy as compared to a case in which the difficulty level of the intubation into the duodenal papilla **30A** is determined without considering the size of the duodenal papilla **30A**.

[0163] In addition, in the present embodiment, the difficulty level Y is determined based on the type of the opening part **90A1** of the duodenal papilla **30A**. Therefore, the difficulty level of the intubation into the duodenal papilla **30A** can be determined with high accuracy as compared to a case in which the difficulty level of the intubation into the duodenal papilla **30A** is determined without considering the type of the opening part **90A1** of the duodenal papilla **30A**.

[0164] In addition, in the present embodiment, the difficulty level Y is determined based on the length of the oral side elevation of the duodenal papilla **30A**. Therefore, the difficulty level of the intubation into the duodenal papilla **30A** can be determined with high accuracy as compared to a case in which the difficulty level of the intubation into the duodenal papilla **30A** is determined without considering the length of the oral side elevation of the duodenal papilla **30A**.

[0165] In addition, in the present embodiment, the difficulty level Y is determined based on the aspect of the peripheral region **30B**. Therefore, the difficulty level of the intubation into the duodenal papilla **30A** can be determined with high accuracy as compared to a case in which the difficulty level of the intubation into the duodenal papilla **30A** is determined without considering the aspect of the peripheral region **30B**.

[0166] In addition, in the present embodiment, the difficulty level Y is determined based on the presence or absence of the diverticulum in the peripheral region **30B**. Therefore, the difficulty level of the intubation into the duodenal papilla **30A** can be determined with high accuracy as compared to a case in which the difficulty level of the intubation into the duodenal papilla **30A** is determined without considering the presence or absence of the diverticulum in the peripheral region **30B**.

[0167] In the above-described embodiment, the data indicating the difficulty level X is described as an example of the difficulty level data **112** included in the training data **108** used in the machine learning for creating the difficulty level recognition model **100**, but this is merely an example. For example, as shown in FIG. **12**, the difficulty level data **112** may include the data indicating the difficulty level x1, the data indicating the difficulty level x2, the data indicating the difficulty level x3, the data indicating the difficulty level x4, and the data indicating the difficulty level x5, in addition to the data indicating the difficulty level X. In a case in which the difficulty level recognition model **100** is generated by executing the machine learning on the model **107** using the training data **108** including the difficulty level data **112** composed as described above, the difficulty level recognition model **100** generates a difficulty level recognition result **128**, and outputs the generated difficulty level recognition result **128**.

[0168] As shown in FIG. **13** as an example, the difficulty level recognition result **128** includes a difficulty level y1, a difficulty level y2, a difficulty level y3, a difficulty level y4, and a difficulty level y5, in addition to the difficulty level Y. The difficulty level Y included in the difficulty level recognition result **128** is a difficulty level comprehensively evaluated from the difficulty level y1, the difficulty level y2, the difficulty level y3, the difficulty level y4, and the difficulty level y5, as the difficulty level of the intubation into the duodenal papilla **30A**. An example of the difficulty level comprehensively evaluated from the difficulty level y1, the difficulty level y2, the difficulty level y3, the difficulty level y4, and the difficulty level y5 is an average difficulty level of the difficulty level y1, the difficulty level y2, the difficulty level y3, the difficulty level y4, and the difficulty level y5.

[0169] The difficulty level y1 is a difficulty level corresponding to a shape **128A** of the duodenal papilla **30A**. That is, the difficulty level y1 means a difficulty level of the intubation into the duodenal papilla **30A** in a case of the shape **128A**. The difficulty level y2 is a difficulty level

corresponding to a size **128B** of the duodenal papilla **30A**. That is, the difficulty level **y2** means a difficulty level of the intubation into the duodenal papilla **30A** in a case of the size **128B**. The difficulty level **y3** is a difficulty level corresponding to an opening part type **128C** (that is, the type of the opening part **90A1** of the duodenal papilla **30A**). That is, the difficulty level **y3** means a difficulty level of the intubation into the duodenal papilla **30A** in a case of the opening part type **128C**. The difficulty level **y4** is a difficulty level corresponding to an oral side elevation length **128D** (that is, the length of the oral side elevation of the duodenal papilla **30A**). That is, the difficulty level **y4** means a difficulty level of the intubation into the duodenal papilla **30A** in a case of the oral side elevation length **128D**. The difficulty level **y5** is a difficulty level corresponding to a diverticulum presence/absence **128E** (that is, the presence or absence of the diverticulum). That is, the difficulty level **y5** means a difficulty level of the intubation into the duodenal papilla **30A** in a case of the diverticulum presence/absence **128E**.

[0170] The controller **80B** generates high difficulty level notification information **129** based on the difficulty level recognition result **128**. The high difficulty level notification information **129** includes the high difficulty level notification information **126** according to the above-described embodiment and includes element specification information. The element specification information refers to information for specifying an element that increases the difficulty level of the intubation into the duodenal papilla **30A** among a plurality of elements (here, as an example, the shape **128A**, the size **128B**, the opening part type **128C**, the oral side elevation length **128D**, and the diverticulum presence/absence **128E**). Among the plurality of elements, an element that increases the difficulty level of the intubation into the duodenal papilla **30A** is an element having a difficulty level equal to or higher than the reference difficulty level. The controller **80B** specifies the element having the difficulty level equal to or higher than the reference difficulty level based on the difficulty level recognition result **128**, generates the element specification information based on the specification result, and generates high difficulty level notification information **129** including the element specification information. The controller **80B** displays the high difficulty level notification information **129** on the screen **36B** in a text format. Accordingly, the text **TX1** is displayed on the screen **36B** and text **TX2** is displayed on the screen **36B**, as in the above-described embodiment. The text **TX2** is text for specifying the element that increases the difficulty level of the intubation into the duodenal papilla **30A** among the plurality of elements (here, as an example, the shape **128A**, the size **128B**, the opening part type **128C**, the oral side elevation length **128D**, and the diverticulum presence/absence **128E**). Here, the text **TX1** and the text **TX2** are described as examples, but this is merely an example, and the visible display may be performed by using an image (for example, a mark) or the like instead of the text.

[0171] In the example shown in FIG. **13**, the difficulty level **Y** is determined based on the shape **128A**, the size **128B**, the opening part type **128C**, the oral side elevation length **128D**, and the diverticulum presence/absence **128E**, but this is merely an example. For example, the difficulty level **Y** may be determined based on the confluence form, which is one of the aspects of the duodenal papilla **30A**, and on the deformation of the duodenum, which is one of the aspects of the peripheral region **30B**. The deformation of the duodenum is caused by the medical treatment on the upper gastrointestinal tract (for example, resection of at least a part of the stomach).

[0172] Examples of the determination of the difficulty level **Y** based on the confluence form and the deformation of the duodenum, as shown in FIG. **14**, include an example in which the controller **80B** adjusts the difficulty level recognition result **128** based on confluence form information **120** and duodenum deformation information **130**. In the example shown in FIG. **14**, the confluence form information **120** and the duodenum deformation information **130** are received by the reception device **62**. The duodenum deformation information **130** includes information related to the duodenum deformation, such as information indicating that the duodenum is deformed, information indicating a degree of the deformation of the duodenum, and information for specifying a portion in which the deformation of the duodenum is equal to or more than a certain

level.

[0173] The controller **80B** adjusts the difficulty level y1, the difficulty level y2, the difficulty level y3, the difficulty level y4, and the difficulty level y5 in accordance with the confluence form information **120** and the duodenum deformation information **130**. For example, the controller **80B** adjusts the difficulty level y1, the difficulty level y2, the difficulty level y3, the difficulty level y4, and the difficulty level y5 by multiplying coefficients determined in accordance with the confluence form information **120** and the duodenum deformation information **130** by the difficulty level y1, the difficulty level y2, the difficulty level y3, the difficulty level y4, and the difficulty level y5. For example, the coefficients multiplied by the difficulty level y1, the difficulty level y2, the difficulty level y3, the difficulty level y4, and the difficulty level y5 need only be calculated from an arithmetic expression in which the confluence form information **120** and the duodenum deformation information **130** are independent variables and the coefficients are dependent variables. Here, although the form example is described in which both the confluence form information **120** and the duodenum deformation information **130** are used, this is merely an example, and one of the confluence form information **120** or the duodenum deformation information **130** may be used.

[0174] As described above, in the example shown in FIG. **14**, since the difficulty level recognition result **128** is adjusted based on the confluence form, which is one of the aspects of the duodenal papilla **30A**, the difficulty level Y of the intubation into the duodenal papilla **30A** can be determined with high accuracy as compared to a case in which the difficulty level of the intubation into the duodenal papilla **30A** is determined without considering the confluence form. In addition, in the example shown in FIG. **14**, since the difficulty level recognition result **128** is adjusted based on the deformation of the duodenum, which is one of the aspects of the peripheral region **30B**, the difficulty level Y of the intubation into the duodenal papilla **30A** can be determined with high accuracy as compared to a case in which the difficulty level of the intubation into the duodenal papilla **30A** is determined without considering the deformation of the duodenum.

[0175] In the example shown in FIG. **14**, the form example is described in which the duodenum deformation information **130** received by the reception device **62** is acquired by the controller **80B**, but this is merely an example. For example, in a process from the insertion of the duodenoscope **12** into the upper gastrointestinal tract to the duodenum, recognition processing using an AI method on the part of the upper gastrointestinal tract may be executed, and the duodenum deformation information **130** may be generated based on the recognition result of the part of the upper gastrointestinal tract (for example, non-recognition of the part, a certainty level lower than a threshold value, recognition of a deformed stomach, and/or recognition of a deformed duodenum).

[0176] In a case in which it is difficult to perform the intubation from the duodenal papilla **30A**, the doctor **14** may incise the duodenal papilla **30A** and expose the tube **92** from the duodenal papilla **30A**. In this case, in order to implement high-accuracy incision of the duodenal papilla **30A**, for example, information (for example, visible information such as a line) for specifying an incision region (that is, a region planned to be incised) for incising the duodenal papilla **30A** may be displayed in a superimposed manner on the intestinal wall image **40** displayed on the screen **36A**. In order to implement such superimposed display, it is important to predict the incision region for incising the duodenal papilla **30A** first.

[0177] Therefore, in order to implement the prediction of the incision region, as an example, as shown in FIG. **15**, in a case in which the duodenal papilla **30A** and the peripheral region **30B** are shown in the frame **41** input to the papilla recognition model **98** to obtain the papilla recognition result **106**, the recognition unit **80A** executes prediction processing using the AI method. The prediction processing using the AI method is implemented by image processing using an incision region prediction model **132**. That is, the recognition unit **80A** inputs the frame **41** input to the papilla recognition model **98** to obtain the papilla recognition result **106** to the incision region prediction model **132**, to cause the incision region prediction model **132** to execute image

processing. In the present embodiment, the incision region prediction model **132** is an example of a “first trained model” according to the present disclosure. In the present embodiment, the image processing using the incision region prediction model **132** is an example of “image processing” according to the present disclosure.

[0178] The incision region prediction model **132** is a trained model for prediction via AI, and is obtained by executing the machine learning for the frame **41**. The incision region prediction model **132** has been optimized by training a neural network through machine learning using fourth training data that is a data set including a plurality of data (that is, data for a plurality of frames) in which fourth example data and fourth correct answer data are associated with each other. That is, the insertion direction prediction model **102** is a trained model that has been optimized to receive input of fourth example data to generate fourth correct answer data.

[0179] In the example shown in FIG. **15**, training data **133** is shown as the fourth training data. The training data **133** includes a sample image **135** as an example of the fourth example data, and incision region data **137** as an example of fourth correct answer data, and the sample image **135** and the incision region data **137** are associated with each other.

[0180] The sample image **135** is the same image as the image used in the above-described first example data. An intestinal wall **134** of the duodenum, a duodenal papilla **134A**, and a peripheral region **134B** of the duodenal papilla **134A** are shown in the sample image **135**.

[0181] The incision region data **137** is data for specifying an incision region **136** for incising the duodenal papilla **134A**. The data for specifying the incision region **136** is data (for example, coordinates) for specifying the geometrical characteristics (for example, the position, the size, and the shape) of the incision region **136** in the sample image **135**.

[0182] The incision region **136** is included in a region avoiding a plurality of blood vessels **134C** in the duodenal papilla **134A**. The plurality of blood vessels **134C** are blood vessels that are included in the duodenal papilla **134A** and that have an attention level equal to or higher than a certain attention level. A certain attention level means an attention level to a thinnest blood vessel in which the tube (for example, the bile duct and/or the pancreatic duct) is expected to be invisible due to bleeding associated with damage to the blood vessel. In a case in which the sample image **135** is an image obtained by imaging the reflected light obtained by irradiating the intestinal wall **134** with the special light, a presence position of the blood vessel that is included in the duodenal papilla **134A** and that has the attention level equal to or higher than a certain attention level is visually specified by the annotator.

[0183] The incision region prediction model **132** has been optimized by executing the machine learning using the training data **133** on a model **139** (for example, a neural network).

[0184] The recognition unit **80A** inputs the frame **41** to the incision region prediction model **132** at the frame rate at which the frame **41** is displayed on the screen **36A**. Examples of the frame **41** input to the incision region prediction model **132** include an image obtained by imaging the reflected light obtained by irradiating the intestinal wall **30** with the special light. The image obtained by imaging the reflected light obtained by irradiating the intestinal wall **30** with the special light is an image in which the blood vessel that is included in the duodenal papilla **30A** and that has the attention level equal to or higher than a certain attention level is shown in a state of being specifiable. In the example shown in FIG. **15**, the frame **41** input to the incision region prediction model **132** is an example of a “first intestinal wall image” according to the present disclosure.

[0185] The incision region prediction model **132** predicts the incision region (that is, the region planned to be incised) for incising the duodenal papilla **30A** shown in the input frame **41** each time the frame **41** is input. The incision region for incising the duodenal papilla **30A** is expected to be within the region avoiding the blood vessel that is included in the duodenal papilla **30A** and that has the attention level equal to or higher than a certain attention level by executing the image processing using the incision region prediction model **132** on the frame **41**. The incision region

prediction model **132** generates incision region specification information **138** as a prediction result. The incision region specification information **138** refers to information for specifying the incision region for incising the duodenal papilla **30A**. In the present embodiment, the incision region specification information **138** is an example of “incision region specification information” and “support information” according to the present disclosure.

[0186] As shown in FIG. **16** as an example, the controller **80B** acquires the incision region specification information **138** from the recognition unit **80A**. The controller **80B** displays the incision region specification information **138** in a superimposed manner on the frame **41** displayed on the screen **36A** in a display aspect that is distinguishable from other image regions as an incision planned region mark **142**, which is a mark for specifying the incision region. In the example shown in FIG. **16**, the incision planned region mark **142** is a linear mark. The incision region specified by the incision planned region mark **142** is included in a region avoiding a plurality of blood vessels **140** included in the duodenal papilla **30A**. The plurality of blood vessels **140** are blood vessels that are included in the duodenal papilla **30A** and that have the attention level equal to or higher than a certain attention level. In the present embodiment, the plurality of blood vessels **140** are an example of a “blood vessel that is included in the duodenal papilla and that has an attention level equal to or higher than a certain attention level” according to the present disclosure.

[0187] As described above, in the examples shown in FIGS. **15** and **16**, the incision region specification information **138** is displayed in a superimposed manner on the frame **41** displayed on the screen **36A** in a display aspect that is distinguishable from other image regions as the incision planned region mark **142**, and thus the doctor **14** can incise the duodenal papilla **30A** with high accuracy as compared to a case in which the incision region specification information **138** is not displayed.

[0188] In addition, in the example shown in FIG. **15**, the incision region is predicted by the incision region prediction model **132** in a region avoiding the plurality of blood vessels **140** that are included in the duodenal papilla **30A** and that have the attention level equal to or higher than a certain attention level. Therefore, the doctor **14** can incise the duodenal papilla **30A** without damaging the blood vessel **140**.

[0189] In addition, in the example shown in FIG. **15**, the incision region is predicted by executing the image processing using the incision region prediction model **132** on the frame **21**, and the incision region specification information **138** is obtained as the prediction result obtained by the image processing. Therefore, the doctor **14** can specify the incision region with high accuracy as compared to a case in which the doctor **14** specifies the incision region only through visual observation.

[0190] In addition, in the example shown in FIG. **15**, an image in which the blood vessel that is included in the duodenal papilla **30A** and that has the attention level equal to or higher than a certain attention level is shown in a state of being specifiable is used as the frame **21** input to the incision region prediction model **132**. Therefore, the doctor **14** can specify the incision region avoiding the blood vessel that is included in the duodenal papilla **30A** and that has the attention level equal to or higher than a certain attention level, with high accuracy as compared to a case in which the doctor **14** specifies the incision region only through visual observation.

[0191] In the above-described embodiment, the form example is described in which the difficulty level data **112** is determined based on the papilla aspect **114** and the peripheral region aspect **116**, but this is merely an example, and the difficulty level data **112** may be determined based on one of the papilla aspect **114** or the peripheral region aspect **116**.

[0192] In the above-described embodiment, the form example is described in which the shape **114A**, the size **114B**, the opening part type **114C**, and the oral side elevation length **114D** are included in the papilla aspect **114**, but this is merely an example, and the papilla aspect **114** need only include at least one of the shape **114A**, the size **114B**, the opening part type **114C**, or the oral side elevation length **114D**.

[0193] In the above-described embodiment, the description is made on the premise that the doctor **14** completes the intubation into the duodenal papilla **30A**, but in a case in which it is recognized by the AI method recognition processing that the intubation into the duodenal papilla **30A** is not completed even after a certain time (for example, 10 minutes) or more has elapsed, the processor **80** may display information prompting a change of an operator and/or information prompting a change of a surgical method on the screen **36A** and/or **36B**. Further, the information for prompting the change of the operator and/or the information for prompting the change of the surgical method may be output by voice.

[0194] In the above-described embodiment, the form example is described in which the insertion direction information **122**, the support information **124**, and the high difficulty level notification information **126** are displayed as the visible information, but this is merely an example, and at least a part of the insertion direction information **122** and the support information **124** and/or the high difficulty level notification information **126** may be output by voice.

[0195] In the above-described embodiment, the trained model for object recognition using the segmentation method via the AI is described as the papilla recognition model **98**, but the present disclosure is established even in a case in which a trained model for object recognition using a bounding box method via AI is used.

[0196] In the above-described embodiment, the form example is described in which the insertion direction information **122** is displayed in a superimposed manner on the frame **21** as the visible information, but the present disclosure is not limited to this. For example, the position of the opening part **90A1** may be specified by the image processing using the papilla recognition model **98**, and an image (for example, a mark) for specifying the position of the opening part **90A1** may be displayed in a superimposed manner on the frame **21**.

[0197] In the above-described embodiment, as an example of the confluence form information **120**, the information indicating the confluence form that is specified in advance from the examination result is described, but the present disclosure is not limited to this. For example, the confluence form may be specified by the doctor **14** through visual observation from the image obtained by the X-ray imaging during the ERCP examination, or the confluence form may be specified by executing image analysis processing via the computer **76** or the like on the image obtained by the X-ray imaging during the ERCP examination, to generate the confluence form information **120** based on the specification result.

[0198] In the above-described embodiment, the form example is described in which the medical support process is executed by the computer **76**, but the present disclosure is not limited thereto, and at least a part of the processing included in the medical support process may be executed by a device provided outside the computer **76**. Hereinafter, an example of such a case will be described with reference to FIG. **17**.

[0199] FIG. **17** is a conceptual diagram showing an example of a configuration of a duodenoscope system **144**. The duodenoscope system **144** is an example of an “endoscope system” according to the present disclosure. The duodenoscope system **144** differs from the duodenoscope system **10** according to the above-described embodiment in that an external device **146** is provided.

[0200] The external device **146** is connected communicably to the computer **76** via a network **148** (for example, a WAN and/or a LAN).

[0201] Examples of the external device **146** include at least one server that directly or indirectly transmits and receives data to and from the computer **76** via the network **148**. The external device **146** receives a processing execution instruction issued from the processor **80** of the computer **76** via the network **148**. The external device **146** executes processing corresponding to the received processing execution instruction and transmits a processing result to the computer **76** via the network **148**. In the computer **76**, the processor **80** receives the processing result transmitted from the external device **146** via the network **148**, and executes processing using the received processing result.



[0202] Examples of the processing execution instruction include an instruction to cause the external device **146** to execute at least a part of the medical support process. A first example of at least a part of the medical support process (that is, the processing executed by the external device **146**) is AI processing using the papilla recognition model **98**, the difficulty level recognition model **100**, the insertion direction prediction model **102**, and/or the incision region prediction model **132**. In this case, the external device **146** executes the AI processing in response to the processing execution instruction given from the processor **80** via the network **148**, and transmits the AI processing result to the computer **76** via the network **148**. In the computer **76**, the processor **80** receives the AI processing result and executes the same processing as in the above-described embodiment by using the received AI processing result.

[0203] A second example of at least a part of the medical support process (that is, the processing executed by the external device **146**) is partial processing executed by the controller **80B**. Examples thereof include processing of acquiring the support information **124** from the support information table **104**, processing of executing various determinations, and/or processing of generating information. In this case, the external device **146** executes the processing of acquiring the support information **124** from the support information table **104**, the processing of executing various determinations, and/or the processing of generating information in response to the processing execution instruction given from the processor **80** via the network **148**, and transmits the processing result to the computer **76** via the network **148**. In the computer **76**, the processor **80** receives the processing result to execute the same processing as in the above-described embodiment by using the received processing result.

[0204] For example, the external device **146** is implemented by cloud computing. It should be noted that the cloud computing is merely an example, and the external device **146** may be implemented by network computing such as fog computing, edge computing, or grid computing. Instead of the server, at least one personal computer or the like may be used as the external device **146**. In addition, an operation device having a communication function equipped with a plurality of types of AI functions may be used.

[0205] In the above-described embodiment, the form example is described in which the medical support program **96** is stored in the storage **84**, but the present disclosure is not limited thereto. For example, the medical support program **96** may be stored in a portable computer-readable non-transitory storage medium such as an SSD or a USB memory. The medical support program **96** stored in the non-transitory storage medium is installed in the computer **76** of the duodenoscope system **10**. The processor **80** executes the medical support process in accordance with the medical support program **96**.

[0206] In addition, the medical support program **96** may be stored in a storage device of another computer or server connected to the duodenoscope system **10** via a network, and the medical support program **96** may be downloaded in response to a request from the duodenoscope system **10** and installed in the computer **76**.

[0207] It should be noted that it is not necessary to store the entire medical support program **96** in a storage device of another computer or server connected to the duodenoscope system **10** or to store the entire medical support program **96** in the storage **84**, and a part of the medical support program **96** may be stored.

[0208] Various processors described below can be used as a hardware resource for executing the medical support process. Examples of the processor include a CPU which is a general-purpose processor that functions as the hardware resource executing the medical support process by executing software, that is, a program. In addition, examples of the processor include a dedicated electric circuit which is a processor of which a circuit configuration is specially designed for executing specific processing, such as an FPGA, a PLD, or an ASIC. Any processor has a memory built in or connected to it, and any processor executes the medical support process by using the memory.

[0209] The hardware resource for executing the medical support process may be configured by one of the various processors or by combining two or more processors of the same type or different types (for example, by combining a plurality of FPGAs or by combining a CPU and an FPGA). The hardware resource for executing the medical support process may also be one processor.

[0210] As an example of the configuration using one processor, first, there is a form in which one processor is configured by combining one or more CPUs and software, and the processor functions as the hardware resource for executing the medical support process. As a second example, as typified by an SoC or the like, there is a form in which a processor that implements all functions of a system including a plurality of hardware resources executing the medical support process with one IC chip is used. As described above, the medical support process is implemented by using one or more of the various processors as the hardware resource.

[0211] As a hardware structure of these various processors, more specifically, an electric circuit in which circuit elements, such as semiconductor elements, are combined can be used. Further, the medical support process is merely an example. Therefore, it goes without saying that unnecessary steps may be deleted, new steps may be added, or the processing order may be changed within a range that does not deviate from the gist.

[0212] The above-described contents and the above-shown contents are the detailed description of the parts according to the present disclosure, and are merely examples of the present disclosure. For example, the description of the configuration, the function, the operation, and the effect is the description of examples of the configuration, the function, the operation, and the effect of the parts according to the present disclosure. Accordingly, it goes without saying that unnecessary parts may be deleted, new elements may be added, or replacements may be made with respect to the above-described contents and the above-shown contents within a range that does not deviate from the gist of the present disclosure. In addition, in order to avoid complications and facilitate understanding of the parts according to the present disclosure, the description of common technical knowledge or the like, which does not particularly require the description for enabling the implementation of the present disclosure, is omitted in the above-described contents and the above-shown contents.

[0213] All of the documents, the patent applications, and the technical standards described in the present specification are incorporated into the present specification by reference to the same extent as in a case in which the individual documents, patent applications, and technical standards are specifically and individually stated to be described by reference.

## Claims

1. A medical support device comprising: a processor, wherein the processor is configured to: acquire a difficulty level of intubation into a duodenal papilla, the difficulty level being determined based on the duodenal papilla and/or a peripheral region of the duodenal papilla, which is shown in an intestinal wall image obtained by imaging an intestinal wall of a duodenum via an endoscope, and output support information for supporting the intubation in a case in which the difficulty level is equal to or higher than a reference difficulty level.
2. The medical support device according to claim 1, wherein, in a case in which the difficulty level is determined based on the duodenal papilla, the difficulty level is determined based on an aspect of the duodenal papilla.
3. The medical support device according to claim 2, wherein the aspect of the duodenal papilla includes a shape of the duodenal papilla.
4. The medical support device according to claim 2, wherein the aspect of the duodenal papilla includes a size of the duodenal papilla.
5. The medical support device according to claim 2, wherein the aspect of the duodenal papilla includes a type of an opening part of the duodenal papilla.
6. The medical support device according to claim 2, wherein the aspect of the duodenal papilla

includes a confluence form of a bile duct and a pancreatic duct in the duodenal papilla.

**7.** The medical support device according to claim 2, wherein the aspect of the duodenal papilla includes a length of an oral side elevation.

**8.** The medical support device according to claim 1, wherein, in a case in which the difficulty level is determined based on the peripheral region, the difficulty level is determined based on an aspect of the peripheral region.

**9.** The medical support device according to claim 8, wherein the aspect of the peripheral region includes presence or absence of a diverticulum.

**10.** The medical support device according to claim 8, wherein the aspect of the peripheral region includes deformation of the duodenum.

**11.** The medical support device according to claim 1, wherein the support information includes information indicating that the difficulty level is equal to or higher than the reference difficulty level.

**12.** The medical support device according to claim 1, wherein the support information includes incision region specification information for specifying an incision region for incising the duodenal papilla.

**13.** The medical support device according to claim 12, wherein the incision region is included in a region avoiding a blood vessel that is included in the duodenal papilla and that has an attention level equal to or higher than a certain attention level.

**14.** The medical support device according to claim 12, wherein the incision region is predicted by executing image processing on the intestinal wall image, and the incision region specification information is a prediction result of the incision region obtained by the image processing.

**15.** The medical support device according to claim 14, wherein the image processing is processing of causing a first trained model to generate the prediction result by inputting the intestinal wall image to the first trained model.

**16.** The medical support device according to claim 14, wherein the intestinal wall image includes a first intestinal wall image in which a blood vessel that is included in the duodenal papilla and that has an attention level equal to or higher than a certain attention level is shown in a state of being specifiable, and the incision region is predicted to be within a region avoiding the blood vessel by executing the image processing on the first intestinal wall image.

**17.** The medical support device according to claim 1, wherein the support information includes operation assistance information for assisting an operation of the endoscope.

**18.** The medical support device according to claim 1, wherein the difficulty level is determined based on the duodenal papilla and/or the peripheral region recognized by executing recognition processing on the intestinal wall image.

**19.** The medical support device according to claim 18, wherein the recognition processing is processing of causing a second trained model to recognize the duodenal papilla and/or the peripheral region shown in the intestinal wall image by inputting the intestinal wall image to the second trained model.

**20.** An endoscope system comprising: the medical support device according to claim 1; and the endoscope.

**21.** A medical support method comprising: acquiring a difficulty level of intubation into a duodenal papilla, the difficulty level being determined based on the duodenal papilla and/or a peripheral region of the duodenal papilla, which is shown in an intestinal wall image obtained by imaging an intestinal wall of a duodenum via an endoscope; and outputting support information for supporting the intubation in a case in which the difficulty level is equal to or higher than a reference difficulty level.

**22.** A non-transitory computer-readable storage medium storing a program executable by a computer to execute a medical support process comprising: acquiring a difficulty level of intubation into a duodenal papilla, the difficulty level being determined based on the duodenal

papilla and/or a peripheral region of the duodenal papilla, which is shown in an intestinal wall image obtained by imaging an intestinal wall of a duodenum via an endoscope; and outputting support information for supporting the intubation in a case in which the difficulty level is equal to or higher than a reference difficulty level.

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