

Description

Sensor Instrument

The invention relates to a sensor instrument comprising the features of the preamble of claim 1 for examining the mucous membrane of the esophagus, stomach and duodenum of a patient to see whether it is infected with bacteria.

Such a sensor instrument is described in the laid-open document DE 10 2010 006 969 A1, which can be traced back to the applicant.

A possible reason for discomfort of a patient in the region of the upper gastrointestinal tract is an infection with *Helicobacter pylori* bacteria.

DE 10 2010 006 969 A1 has disclosed a test method, with the aid of which a patient can be examined for such an infection. To this end, use is made of a gastroscope with an insertion tube, at the distal end of which a sensor, which reacts sensitively to ammonia, is arranged. Here, use is made of the fact that *Helicobacter pylori* bacteria split urea into carbon dioxide and ammonia by means of the urease enzyme and that ammonia is typically only detectable in relevant amounts in the stomach of a patient in the case of an infection with *Helicobacter pylori* bacteria. Therefore, the presence of an increased amount of ammonia and, as a consequence, also an infection with *Helicobacter pylori* bacteria can be deduced in the case of a corresponding reaction of the sensor, which is positioned in the stomach of a patient.

The basic functional principle of the sensor was presented, inter alia, within the scope of the presentation "Immediate detection of *Helicobacter* infection with a novel electrochemical system" (Gastroenterology, volume 138, issue 5,

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supplement 1, pages S-114, May 2010) by Helmut Neumann, Stefan
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during the "DIGESTIVE DISEASE WEEK 2010". According thereto, a change in an electric variable is registered metrologically when an electrode pair comes into contact with ammonia, wherein one electrode of the electrode pair reacts chemically with the ammonia.

A gastroscope is a special endoscope for examining the mucous membrane of the esophagus, stomach and duodenum and it is therefore a relatively complex medical instrument, which is produced with a relatively high technical and financial outlay. Particularly as a result of continuously increasing costs in the health sector as well, it is advantageous to configure sensor instruments for the medical field in such a way that the production thereof can be carried out as easily and cost-effectively as possible.

Proceeding from this, the invention is based on the object of specifying a simple sensor instrument.

According to the invention, this object is achieved by a sensor instrument comprising the features of claim 1. The dependent claims contain partly advantageous and partly independently inventive developments of this invention.

The sensor instrument serves for examining the mucous membrane of the esophagus, stomach and duodenum of a human or else animal patient to see whether it is infected with bacteria which, due to a corresponding metabolic reaction, emit ammonia to the surroundings thereof, i.e., also, bacteria of the genus *Helicobacter*, such as e.g. *Helicobacter pylori*, *Helicobacter heilmannii* or "*Candidatus Helicobacter suis*", wherein said sensor instrument is constructed as an assembly of an evaluation unit and a catheter probe comprising an ammonia-sensitive sensor and comprising a catheter.

Here, an assembly is understood to mean that the individual

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components form a functional unit, i.e. they are matched to one another technically and only designed for

the interaction with the other components. The sensor instrument therefore has a very simple design and it is accordingly producible without major technical or financial outlay. This applies, in particular, to the evaluation unit, which preferably only interacts with the sensor and, furthermore, preferably has no freely allocatable connectors. Here, the evaluation unit preferably consists of a simple circuit for evaluating the signals formed by the sensor element and an indication element for displaying the evaluation result, and possibly also includes a memory.

Preferably, the sensor instrument comprises no further functional units in addition to the evaluation unit, sensor and catheter functional units. Overall, the structure follows that of e.g. a simple commercial digital clinical thermometer.

In accordance with an advantageous embodiment, the catheter probe of the sensor instrument is embodied for use in an endoscopic work channel such that the sensor instrument can be used within the scope of gastroscopy, wherein the sensor instrument is then inserted into the work channel of the gastroscope catheter already inserted into the esophagus of a patient. Thus, in this case, the sensor instrument serves as an optionally usable probe which, just like further instruments, e.g. an instrument for biopsy, is used where necessary during gastroscopy and, to this end, is inserted into the work channel of the in-use gastroscope. Here, in particular, the sensor instrument has such a configuration that it is suitable for, and compatible with, as many differently configured gastroscopes, i.e. different models from different producers, as possible.

Furthermore, the catheter probe is preferably detachably connected to the evaluation unit. In this case, the handling of the sensor instrument is simplified by virtue of, in particular, the catheter probe initially being inserted into

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e.g. the work channel of a gastroscope and the evaluation

unit, which e.g. is housed in a convenient housing, only subsequently being connected to the catheter probe and, in particular, being plugged onto the catheter probe with the aid of a simple plug-in connection.

Advantageously, the catheter probe is moreover embodied as a disposable (or single-use) article which, in particular, can be disposed of by way of clinical refuse. This disposable article is preferably enclosed in sterile packaging within the scope of production and, furthermore preferably, it is not used only a few times but rather, within the meaning of the term single-use article, in fact only used a single time. In particular, disposable articles offer the advantage that these need not be cleaned and disinfected after use, said work steps generally being accompanied by relatively high work and time outlay.

In a preferred development, the sensor instrument is embodied as a complete, intrinsically sealed and therefore non-dismountable (without destruction) assembly, and preferably in addition as a disposable article. The evaluation unit is therefore an integral, non-detachable component and preferably likewise embodied as a disposable article. This article is then removed from sterile packaging when necessary, used and subsequently disposed of.

In accordance with a further embodiment variant, the sensor instrument additionally includes preferably simple endoscopic optics, wherein the sensor instrument in this case is not embodied in the style of a micromechanical tool for use in an endoscopic work channel of a gastroscope, but rather it is used itself as a type of simple disposable gastroscope. In addition to conventional gastroscopes with high quality optics and a work channel for micromechanical instruments, medical endoscopes with a very simple design are currently also being developed and used; the latter are provided as disposable articles and disposed of after a single use. By contrast, in

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the case of conventional gastroscopes, it is necessary

to clean and disinfect these after use, wherein cleaning of the work channel in particular is connected with relatively high outlay. In order to avoid this outlay, simplified instruments are being developed for specific application scenarios, in which e.g. a work channel is dispensed with and the number of Bowden cables for the movement control is reduced. In particular, by reducing the functions of these instruments, the production outlay is also markedly reduced - both from a technical and a financial point of view - such that these too can be considered disposable articles.

Furthermore, the evaluation unit is preferably only configured for evaluating the signals from the sensor and, in particular, housed in a disinfectable plastic housing. In the case of a necessary power supply for the evaluation electronics, provision is preferably made for a battery. In the case of a disposable article, provision is preferably made for an alternative energy supply that is uncritical in terms of disposal. Here, the evaluation unit is kept as simple as possible, as is also the case in e.g. a commercial digital clinical thermometer. By way of example, an embodiment is provided which is substantially constituted by a circuit made of an operational amplifier, an analog/digital transducer and a processor for balancing a characteristic, for value discrimination and for controlling an indicator.

Depending on the application scenario, the evaluation unit is moreover configured to output an examination report, wherein, in this case, provision is preferably made for a wireless transmission of the examination report to a terminal. Therefore, the evaluation unit comprises a data interface, e.g. a wireless module, as a further functional unit. The evaluation unit on the one hand and the terminal on the other hand are configured for wireless transmission and for receiving information. A corresponding examination report then contains e.g. information such as the result of the

examination, an instrument number identifying the respective instrument, a measurement number identifying the examination, date and time of the examination, etc. Here, transmission protocols based on Bluetooth, WLAN or Wireless USB are preferably used for the wireless transmission of information between the sensor instrument and the terminal. The examination reports received by the terminal are then further preferably directly entered into the clinical software, i.e., for example, saved in a stored patient file.

If such data interchange is provided between sensor instruments and a terminal, it is furthermore advantageous if the terminal confirms the reception of an examination report and if, as a result of a corresponding confirmation communication by the terminal, the corresponding sensor instrument, from which the examination report was sent, is put into a standby mode as a result of the confirmation message. As a result, the sensor instrument is only activated during the actual use, which, in the case of battery operation, lengthens the battery replacement cycle.

Moreover, the evaluation unit and therefore the sensor instrument preferably includes an indicator with two optical signals, wherein one signal shows the presence of e.g. *Helicobacter pylori* bacteria and one signal shows the non-presence of said bacteria. Thus, for example, a light-emitting diode is attached at the evaluation unit, which light-emitting diode lights up red if an infection with *Helicobacter pylori* bacteria is to be deduced and which light-emitting diode lights up green if the findings are negative.

In an alternative or complementary manner thereto, the evaluation unit includes an acoustic signal output with two output values, wherein one output value symbolizes the presence of corresponding bacteria and one output value symbolizes the non-presence thereof. The corresponding output values

can, for example, be realized by pulse sequences with different frequencies.

Moreover, provision is made for signaling an active measurement to a user, either by a further output value of the acoustic signal output and/or by a further optical signal of the indicator.

Exemplary embodiments of the invention will be explained in more detail below on the basis of a schematic drawing. In detail:

figure 1 shows a side view of a sensor instrument comprising one sensor,

figure 2 shows a magnified illustration of the sensor and

figure 3 shows a view of the sensor instrument without a lining.

Parts corresponding to one another have respectively been provided with the same reference signs in all figures.

The sensor element 2 described below in an exemplary manner serves for examining the mucous membrane of the esophagus, stomach and duodenum of a patient and is used within the scope of gastroscopy.

Within the scope of such a gastroscopy, a flexible endoscope or video endoscope is used for subjecting the gastrointestinal tract of the patient to a visual examination. In the case of an examination of the upper gastrointestinal tract, a tube or catheter with optical components is, to this end, introduced into the mouth of the patient and subsequently gradually advanced until the desired position for the examination is reached. Within this catheter, there typically is at least one

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work channel for inserting micromechanical instruments, such as
small forceps, such

that e.g. a biopsy can be undertaken in addition to the visual examination.

If there now is a suspected infection with *Helicobacter pylori* bacteria, testing whether an infection with these bacteria is present should be carried out in the simplest possible way within the scope of the gastroscopy. The sensor element 2, which is inserted into the work channel of the endoscope, serves this purpose.

The sensor instrument 2 schematically depicted in figure 1 has a two-part design, wherein the two parts - an evaluation unit 4 and a catheter probe 6 comprising an ammonia-sensitive sensor 8 - are connected to one another by way of a simple plug-in connection.

The catheter probe 6 is flexible and configured as a disposable article, wherein, prior to use, the disposable article is removed from sterile packaging and disposed of via clinical refuse after a single use. When necessary, the catheter probe 6 is inserted into the work channel of the endoscope and advanced until the end opposite to the evaluation unit 4, at which and the sensor 8 is positioned, is in contact with the mucous membrane to be examined or with the stomach contents of the patient.

In an alternative embodiment variant not depicted here in any more detail, endoscopic optics are integrated into the catheter probe such that the sensor instrument 2, embodied as a disposable article, has a dual function and the path of the catheter probe 6 can be followed optically. The optical signals are transmitted to a display unit. The actuation of the integrated optical elements and the evaluation of the optical signals are preferably carried out in the evaluation unit 4.

At the end side, the sensor 8 - depicted in a magnified manner

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in figure 2 - includes two electrodes 12 embedded in a plastic casing 10, the ends of which electrodes protrude out of the plastic casing 10

and are therefore exposed. The two electrodes 12 are stainless steel wires 14, the ends of which have been provided with a different coating 16. One of the two electrodes 12 serves as a reference electrode and is coated with gold or platinum. The other electrode 12 serves as an ammonia-sensitive electrode 12 and is coated with a silver chloride layer and, lying therebelow, a silver layer.

If the two electrodes 12 now lie in an electrolyte, such as the stomach contents, the two electrodes 12, together with the electrolyte, form a type of galvanic cell which, due to the silver chloride coating on one of the two electrodes 12, is initially inactive. The silver chloride layer is insoluble in water and stomach acid and prevents an ion flow such that no potential difference can be established between the two electrodes 12.

However, in the case of an infection with *Helicobacter pylori* bacteria, there is an increased concentration of ammonia in the stomach contents, said ammonia chemically reacting with the silver chloride. This produces a water-soluble complex such that the silver chloride layer is removed. As soon as the silver layer lying therebelow is exposed, the galvanic cell is activated and a potential difference that can be registered metrologically is established between the electrodes 12. The metrological registration is brought about with the aid of the evaluation unit 4, which is plugged onto the catheter probe 6 for this purpose.

A particularly simple configuration of the sensor instrument 2 is depicted in a schematic-like manner in figure 3 without lining, i.e. without the plastic casing 10 and without the housing for the evaluation unit 4. Here, the stainless steel wires 14 are depicted with the coating 16 at one end, once with gold and once with silver chloride and, lying therebelow, silver, which wires are connected in an electrically conducting

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manner to a circuit by means of simple plug-in contacts 18. The circuit substantially

comprises an amplifier 20 and a voltage measuring device 22 comprising an indicator.

For particularly simple handling, provision is alternatively made for equipping the evaluation unit - as depicted in figure 1 - with an optical indicator made of two light-emitting diodes 24, wherein, in the case of a positive examination result, one of the light-emitting diodes lights up red and wherein, in the case of a negative examination result, i.e. if there clearly is no infection with *Helicobacter pylori* bacteria, the other light-emitting diode lights up green.

The invention is not restricted to the exemplary embodiment described above. Rather, a person skilled in the art can also derive other variants of the invention therefrom, without departing from the subject matter of the invention. Furthermore, in particular, all individual features described in conjunction with the exemplary embodiment are also combinable with one another in a different manner, without departing from the subject matter of the invention.

Patent claims

1. A sensor instrument (2) for examining the mucous membrane of the esophagus, stomach and duodenum of a patient to see whether it is infected with bacteria, characterized in that it is constructed as an assembly consisting of an evaluation unit (4) and a catheter probe (6) comprising an ammonia-sensitive sensor (8) and comprising a catheter.
2. The sensor instrument (2) as claimed in claim 1, wherein the catheter probe (6) is embodied for use in an endoscopic work channel.
3. The sensor instrument (2) as claimed in claim 1 or 2, wherein the catheter probe (6) is detachably connected to the evaluation unit (4).
4. The sensor instrument (2) as claimed in claim 3, wherein the catheter probe (6) is embodied as a disposable article.
5. The sensor instrument (2) as claimed in claim 1 or 2, wherein it is embodied as a complete, intrinsically sealed and non-dismountable assembly.
6. The sensor instrument (2) as claimed in claim 5, wherein it is embodied as a disposable article.
7. The sensor instrument (2) as claimed in claim 6, wherein it additionally includes endoscopic optics.
8. The sensor instrument (2) as claimed in one of claims 1 to 7, wherein the evaluation unit (4) is only configured for evaluating the signals from the sensor (8).

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9. The sensor instrument (2) as claimed in one of claims 1 to
8,

wherein the evaluation unit (4) is configured to output an examination report.

10. The sensor instrument (2) as claimed in claim 9, wherein the evaluation unit (4) is configured for wireless transmission of the examination report to a terminal.

11. The sensor instrument (2) as claimed in claim 10, wherein the evaluation unit (4) includes a wireless receiver and it is configured in such a way that, after receiving a reception confirmation from the terminal confirming the reception of the examination report at the terminal, it switches to a standby mode.

12. The sensor instrument (2) as claimed in one of claims 1 to 11, wherein the evaluation unit (4) includes an indicator (24) with two indicator values, wherein one indicator value indicates the presence of *Helicobacter pylori* bacteria and one indicator value indicates the non-presence of *Helicobacter pylori* bacteria.

13. The sensor instrument (2) as claimed in one of claims 1 to 12, wherein the evaluation unit (4) is configured for an acoustic signal output with two output values, wherein one output value symbolizes the presence of *Helicobacter pylori* bacteria and one output value symbolizes the non-presence of *Helicobacter pylori* bacteria.

14. The sensor instrument (2) as claimed in one of claims 1 to 13, wherein the evaluation unit (4) is configured for a signal output of a signal, wherein the signal signals an active measurement.