Appeal decision

Appeal No. 2017-9266

Switzerland
Appellant ZECHA AG

Tokyo, Japan
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The case of appeal against the examiner's decision of refusal of Japanese Patent Application No. 2013-512755, entitled "DEVICE FOR MODULAR ANALYSIS" (International Publication No. WO2011/150916 published on December 8, 2011, National Publication of the International Patent Application No. 2013-534837 published on September 9, 2013) has resulted in the following appeal decision.

Conclusion

The appeal of the case was groundless.

Reason

No. 1 History of the procedures

The application was filed on May 30, 2011 (priority claim under the Paris Convention received by a foreign patent office on May 31, 2010, Germany) as an international filing date. A notice of reasons for refusal was issued on January 8, 2015, and in response a written opinion and a written amendment were submitted on June 29, 2015. A notice of reasons for refusal (final) was issued on November 12, 2015. A written opinion and a written correction of mistranslation were submitted on May 16, 2016. A notice of reasons for refusal (final) was issued on September 12, 2016. A written opinion was submitted on February 13, 2017. The examiner's decision of refusal was issued on February 23, 2017. In response to this, an appeal against the examiner's decision of refusal was made on June 26, 2017, and an amendment was made at the same time. A written statement was submitted on November 29, 2017.

No. 2 Decision to dismiss the amendment made on June 26, 2017

[Conclusion of decision to dismiss the amendment]

The amendment (hereinafter referred to as "the Amendment") dated June 26, 2017 shall be dismissed.

[Reason]

1 Regarding the Amendment

The Amendment includes correcting the description in Claim 1 of the scope of claims of the written amendment submitted on June 29, 2015 regarding the invention according to Claim 1 of the scope of claims,

"[Claim 1]

A device comprising at least one analysis mechanism for analyzing at least one biological parameter of a living organism, the mechanism including at least one data input for detecting measurement data from at least one sensor, which measures at least one biological parameter of the living organism, and at least one output mechanism for outputting an analysis result,

wherein the analysis mechanism includes a control unit and a program memory, the program memory containing a plurality of program modules that can be activated selectively or in partial or complete combination as a function of an externally specifiable control instruction so that the activated program modules provide data for the selected analysis result,

wherein the sensor and the analysis mechanism are connected to each other by a data section,

wherein a display mechanism is provided, the display mechanism and the analysis mechanism being connected to each other by a data section,

wherein the analysis mechanism comprises an interface for an input of data not metrologically acquired,

and wherein automatic configuration of the device can be implemented as a suggestion to an operator"

to the following description (underlines indicate the amended parts), aiming at the matters stipulated in Article 17-2(5)(ii) of the Patent Act (the restriction of the scope of claims),

"[Claim 1]

A device comprising at least one analysis mechanism for analyzing at least one biological parameter of a living organism, the mechanism including at least one data input for detecting measurement data from at least one sensor, which measures at least one biological parameter of the living organism, and at least one output mechanism for outputting an analysis result,

wherein the analysis mechanism includes a control unit and a program memory, the program memory containing a plurality of program modules that can be activated selectively or in partial or complete combination as a function of an externally specifiable control instruction so that the activated program modules provide data for the selected analysis result,

wherein the sensor and the analysis mechanism are connected to each other by a data section,

wherein a display mechanism is provided, the display mechanism and the analysis mechanism being connected to each other by a data section,

wherein the analysis mechanism comprises an interface for an input of data not metrologically acquired,

wherein <u>an analysis module is provided for combining analysis parameters based on a measurement parameter and/or an input parameter</u>,

and wherein automatic configuration of the device can be implemented as a suggestion to an operator."

2 Examination on the independent requirements for patentability

(1) We will examine whether the invention (hereinafter referred to as "the Amended Invention") according to Claims 1 of the scope of claims after the Amendment falls under the provisions of Article 126(7) of the Patent Act which is applied mutatis mutandis pursuant to the provisions of Article 17-2(6) of the Patent Act (whether or not the invention is independently patentable at the time of filing of the patent application).

(2) Regarding the requirement stipulated in Article 36(4)(i) (enablement requirement)

A The Amendment adds to Claim 1 the matters specifying the invention (herein after referred to as "the Matters specifying the invention 1"), "an analysis module is provided for combining analysis parameters based on a measurement parameter and/or an input parameter."

We will examine below whether the "analysis module for combining analysis parameters based on a measurement parameter and/or an input parameter" is described in the detailed description of the invention clearly and sufficiently for a person with usual knowledge in the technical field to the extent to which the present invention belongs (hereinafter referred to as "the person skilled in the art") to carry out the invention.

(A) Matters described in the detailed description of the invention

In the detailed description, only the following description is considered to be related to the Matters specifying the invention 1, except for [0004] which is the same description as Claim 1.

"[0010]

For comprehensive configurability, the at least one sensor selects at least one measurement parameter from the group: body weight, impedance, height, blood pressure, EKG, heart rate, blood values, pulse oximetry, temperature, respiratory parameters, auscultatory parameters, and/or energy consumption, to metrologically detect the measurement parameter.

...

[Brief description of drawings]

[0012]

Exemplary embodiments of the invention are illustrated schematically in the drawings.

FIG. 1 shows a block diagram illustrating the basic design of the device of the invention.

FIG. 2 shows an example of how the analysis results are displayed.

FIG. 3 shows an example of how detailed analysis results are displayed on a first level of detail.

FIG. 4 shows an example of how detailed analysis results are displayed on a second level of detail.

FIG. 5 shows an example of how the raw data of the analysis are displayed.

FIG. 6 shows a detailed diagram of the raw data of the analysis.

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[Description of Embodiments]

[0013]

The inventive device has at least one measuring instrument or at least one sensor, for measuring or detecting at least one of the following parameters of a patient: weight, impedance, height, blood pressure, EKG (electrocardiogram), heart rate, blood values, pulse oximetry, temperature, respiratory parameters, auscultatory parameters, and/or energy consumption. In general, the measurement parameters can pertain to any desired physical variables of the patient collected within the scope of a medical examination. The measurement parameters can be supplied directly to the analysis mechanism or supplied by way of external data sources such as a laboratory information system.

[0014]

In addition to the measurement parameters, input parameters can also be used, which are determined on the basis of patient identification or by the answers to questions asked before the examination. These can be questions about, for example, the sex and/or the age and/or the ethnicity of the patient.

[0015]

Analysis parameters are determined on the basis of the measurement parameters and/or the input parameters. This can be done, for example, by the use of mathematical formulas implemented in an analysis mechanism, which determine the associated values for the analysis parameters. The formulas can be taken from the published prior art, for example, or they can be determined on the basis of clinical trials. The analysis parameters are interpreted by the use of references. These references are normal ranges, which are published in scientific articles or determined by series of measurements. An example of a graphic representation of this type relating to a reference value is the phase angle.

[0016]

By the use of analysis modules, it is possible to combine different analysis parameters with each other. The analysis modules serve to provide the values for actually existing questions. One such question can pertain to the energy status of a patient.

[0017]

As a function of the selection made by the operator of the device, the analysis modules relevant to the examination situation in the actual case at hand are combined with each other.

[0018]

FIG. 1 illustrates the appropriate linking of the input parameters with the measurement parameters via the calculation of the analysis parameters and the corresponding provision of the analysis modules for deriving the result.

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[0020]

FIG. 2 shows a display screen of the device for one patient as an example. With respect to the analysis, an overall view of the selected module is illustrated.

[0021]

FIG. 3 shows the display screen of a first level of detail of an analysis situation serving as an example. Being able to visualize the results makes it easier to see whether or not selected parameters are within a tolerance range.

[0022]

FIG. 4 shows a second level of detail for the analysis with a magnified visualized graphic analysis.

[0023]

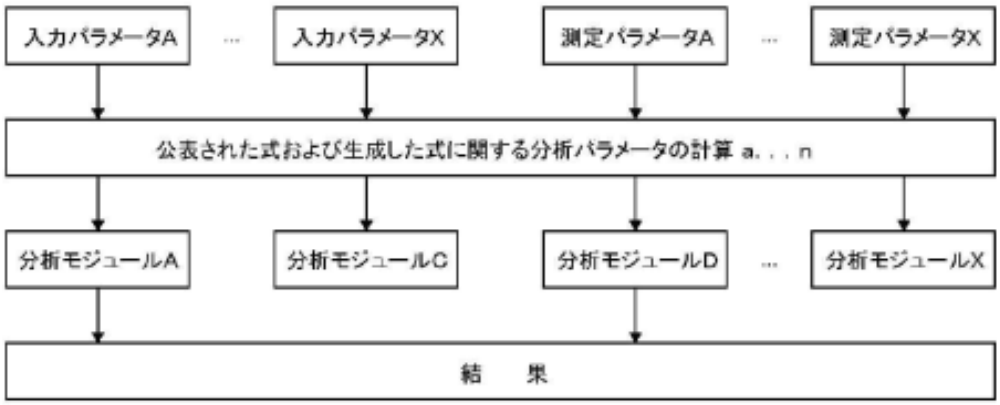
FIG. 5 shows an overall view of the raw data module of the analysis.

[0024]

FIG. 6 shows, for further illustration, detail level 1 of the raw data analysis module.

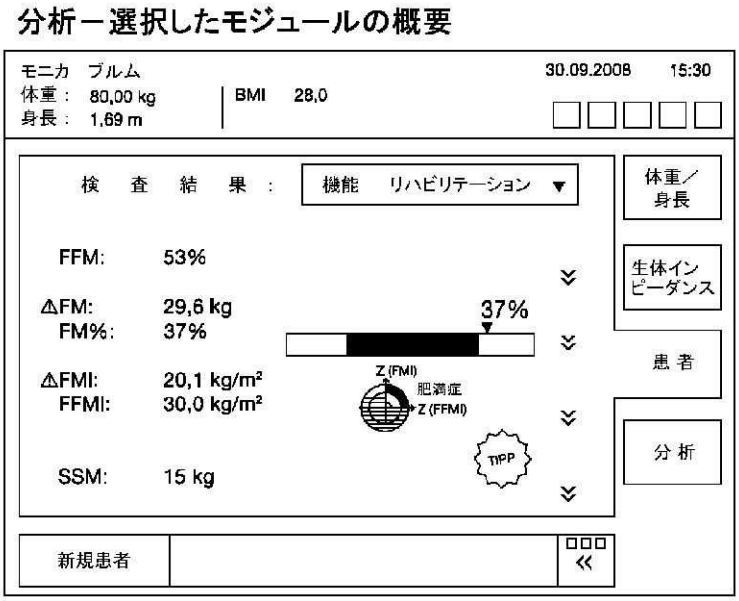
The FIGS. 1 to 6 are as follows.

[FIG. 1]



入力パラメータ　Input Parameter
測定パラメータ　Measurement Parameter
公表された式および生成した式に関する分析パラメータの計算
Calculation of analysis parameter a…n by the use of published and generated formulas
分析モジュール　Analysis module
結果　Result

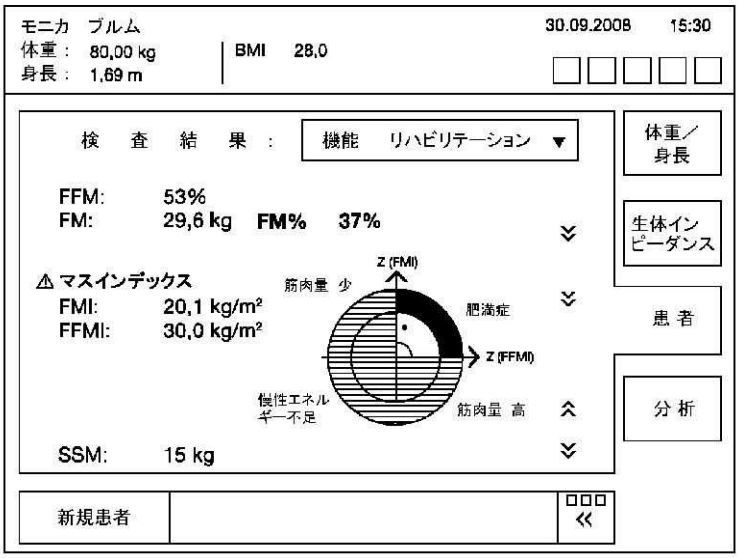
[FIG. 2]



分析－選択したモジュールの概要　Analysis - overview of the selected module
モニカ　ブルム　Monika Blum
体重　Weight
身長　Height
検査結果　Examination results
機能　Function
リハビリテーション　Rehabilitation
肥満症　obesity
生体インピーダンス　bioelectrical impedance
患者　patient
分析　analysis
新規患者　new patient

[FIG. 3]

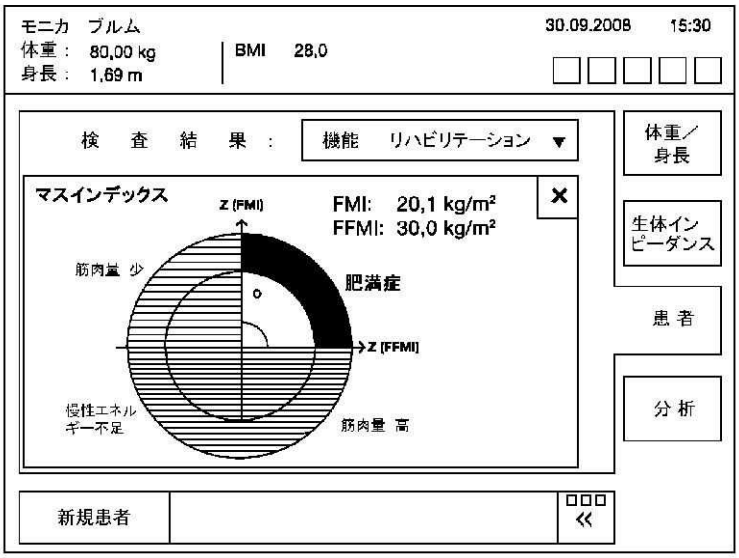
分析－精査段階1



分析－精査段階 1　Analysis - Detail level 1
モニカ　ブルム　Monika Blum
体重　Weight
身長　Height
検査結果　Examination results
機能　Function
リハビリテーション　Rehabilitation
生体インピーダンス　bioelectrical impedance
患者　patient
分析　analysis
新規患者　new patient
筋肉量　少　low muscle mass
肥満症　obesity
慢性エネルギー不足　chronic lack of energy
筋肉量　高　high muscle mass

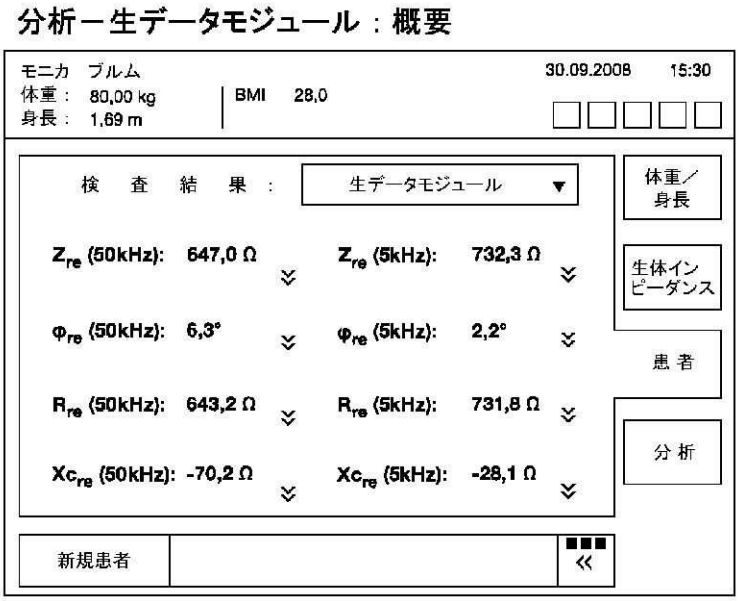
[FIG. 4]

分析－精査段階2



分析－精査段階２　Analysis - Detail Level 2
モニカ　ブルム　Monika Blum
体重　Weight
身長　Height
検査結果　Examination results
機能　Function
リハビリテーション　Rehabilitation
生体インピーダンス　bioelectrical impedance
患者　patient
分析　analysis
新規患者　new patient
マスインデックス　Mass indices
筋肉量　少　low muscle mass
肥満症　obesity
慢性エネルギー不足　chronic lack of energy
筋肉量　高　high muscle mass

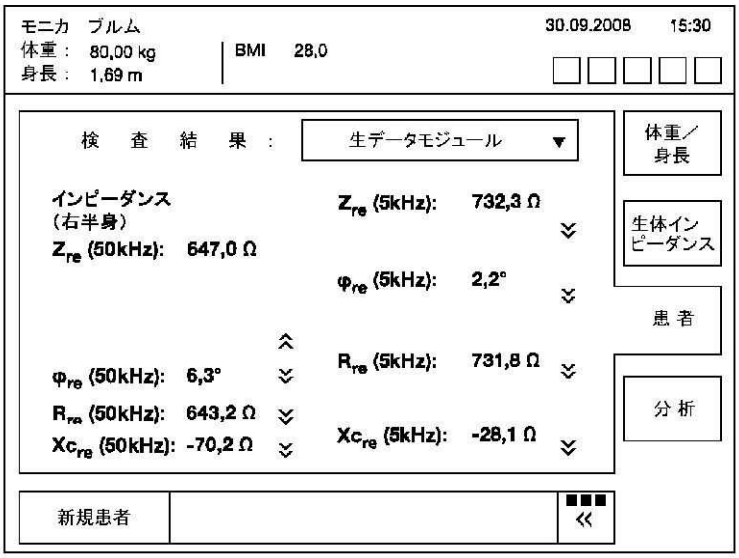
[FIG. 5]



分析－生データモジュール：概要　Analysis - Raw Data Module: Overview
モニカ　ブルム　Monika Blum
体重　Weight
身長　Height
検査結果　Examination results
生データモジュール　Raw data module
生体インピーダンス　bioelectrical impedance
患者　patient
分析　analysis
新規患者　new patient

[FIG. 6]

分析－生データモジュール：精査段階1



分析－生データモジュール：精査段階 1　Analysis - Raw Data Module: Detail Level 1
モニカ　ブルム　Monika Blum
体重　Weight
身長　Height
検査結果　Examination results
生データモジュール　Raw data module
生体インピーダンス　bioelectrical impedance
患者　patient
分析　analysis
新規患者　new patient

(B) Judgment

According to the descriptions in the detailed description of the invention, "For comprehensive configurability, the at least one sensor selects at least one measurement parameter from the group: body weight, impedance, height, blood pressure, EKG, heart rate, blood values, pulse oximetry, temperature, respiratory parameters, auscultatory parameters, and/or energy consumption, to metrologically detect the measurement parameter" ([0010] The underlines were added by the body; the same applies hereinafter in the descriptions citing the detailed description of the invention), and "The inventive device has at least one measuring instrument or at least one sensor, for measuring or detecting at least one of the following parameters of a patient: weight, impedance, height, blood pressure, EKG (electrocardiogram), heart rate, blood values, pulse oximetry, temperature, respiratory parameters, auscultatory parameters, and/or energy consumption. In general, the measurement parameters can pertain to any desired physical variables of the patient determined within the scope of a medical examination" ([0013]), it can be understood that the "measurement parameter" indicates "physical variables of the patient, such as weight or impedance, metrologically detected by a

measuring instrument or a sensor."

According to the description in the detailed description of the present invention "In addition to the measurement parameters, input parameters can also be used, which are determined on the basis of patient identification or by the answers to questions asked before the examination. These can be questions about, for example, the sex and/or the age and/or the ethnicity of the patient" ([0014]), it can be understood that the "input parameter" indicates "information on the sex and/or the age and/or the ethnicity of the patient."

The detailed description of the present invention includes the description "Analysis parameters are determined on the basis of the measurement parameters and/or the input parameters. This can be done, for example, by the use of mathematical formulas implemented in an analysis mechanism, which determine the associated values for the analysis parameters. The formulas can be taken from the published prior art, for example, or they can be determined on the basis of clinical trials" ([0015]).

FIGS. 2 and 3 illustrate items, such as "BMI" and "FM%," and values corresponding thereto.

Considering that calculating percent body fat by use of mathematical formulas from data of weight, impedance, height, sex, or the like, or calculating BMI by use of mathematical formulas from data of weight, height, or the like, was a matter of general technical knowledge at the time of the priority date for the invention, it can be understood that the "analysis parameter" to be "determined" "on the basis of the measurement parameter and/or the input parameters" is "a value calculated by use of mathematical formulas from the measurement parameter and/or the input parameter."

We will examine the analysis module below.

According to the description in the detailed description of the invention, "By the use of analysis modules, it is possible to combine different analysis parameters with each other. The analysis modules serve to provide the values for actually existing questions" ([0016]), the "analysis module" is considered to "provide the values for actually existing questions" by "combining different analysis parameters with each other." However, there is no description about what kinds of analysis parameters are combined or how they are combined for proving the values for actually existing questions. Regarding the item "the energy status of a patient" ([0016]) as an example of the "actually existing questions," we cannot conceive of what kinds of analysis parameters are combined and how they are combined in order to obtain the values for "the energy status of a patient."

The description in [0017], "As a function of the selection made by the operator of the device, the analysis modules relevant to the examination situation in the actual case at hand are combined with each other," the description in [0018], "FIG. 1 illustrates the appropriate linking of the input parameters with the measurement parameters via the calculation of the analysis parameters and the corresponding provision of the analysis modules for deriving the result," and FIG. 1 also do not describe what kinds of analysis parameters are combined and how they are combined in order to provide the values for

actually existing questions.

According to [Brief description of drawings], FIGS. 2 to 4 illustrate examples of how the analysis results are displayed. The detailed description of the invention includes only the descriptions about FIGS. 2-4, "FIG. 2 shows a display screen of the device for one patient as an example. With respect to the analysis, an overall view of the selected module is illustrated" [0020]), "FIG. 3 shows the display screen of a first level of detail of an analysis situation serving as an example. Being able to visualize the results makes it easier to see whether selected parameters are within a tolerance range or not" ([0021]), and "FIG. 4 shows a second level of detail for the analysis with a magnified visualized graphic analysis" ([0022]).

FIGS. 2 to 4 illustrate graphs, or the like, showing the title "Examination results: Function Rehabilitation," the values of "FMI" and "FFMI" considered to correspond to analysis parameters, and four items "obesity," "high muscle mass," "chronic lack of energy," and "low muscle mass" allocated to four quadrants.

According to the description in [0016], "The analysis modules serve to provide the values for actually existing questions. One such question can pertain to the energy status of a patient," the "chronic lack of energy" in [0020] to [0022] and the graphs in FIGS. 2 to 4 is considered to indicate a value provided by an analysis module. However, from FIGS. 2 to 4, we cannot conceive of what kinds of analysis parameters are combined and how they are combined in order to obtain the values for the "chronic lack of energy."

According to [Brief description of drawings], FIGS. 5 and 6 show an example of how the raw data of the analysis are displayed. The detailed description of the invention includes only the descriptions about FIGS. 5 and 6, "FIG. 5 shows an overall view of the raw data module of the analysis" ([0023]), and "FIG. 6 shows, for further illustration, detail level 1 of the raw data analysis module" ([0024]).

FIGS. 5 and 6 show the title "Examination results: Raw data module," and values of "Zre" considered to correspond to a measurement parameter.

These descriptions about FIGS. 5 and 6 relate to raw data, and do not describe an analysis module.

Consequently, even a person skilled in the art cannot grasp what kinds of analytical parameters are combined and how they are combined by the "analysis module" in the Amended Invention, from the descriptions in the detailed description of the invention.

Therefore, regarding the Matters specifying the invention 1 of the Amended Invention, it cannot be recognized that the detailed description of the invention is clear and sufficient for a person skilled in the art to carry out the invention.

(C) Appellant's allegation

The appellant makes the following allegation in the written statement submitted on November 29, 2017, "There is a description about the 'analysis module' in [0016], "By the use of analysis modules, it is possible to combine different analysis parameters with each other. The analysis modules serve to provide the values for actually existing questions. One such question can pertain to the energy status of a patient." There is a

description about the "analysis parameters" to be combined with each other by the "analysis module" in [0015], "Analysis parameters are determined on the basis of the measurement parameters and/or the input parameters. This can be done, for example, by the use of mathematical formulas implemented in an analysis mechanism, which determine the associated values for the analysis parameters. The formulas can be taken from the published prior art, for example, or they can be determined on the basis of clinical trials." FIG. 1 shoes a relationship between the "analysis module" and the "measurement parameters and/or the input parameters." FIGS. 2 to 6 show the overview of the "analysis module" and examples. In light of the above descriptions, a person skilled in the art can carry out the "analysis module" in the invention. Matters included in the "analysis module" described in Claim 1 are also clear from the above descriptions."

However, as indicated in (B), we cannot grasp what kinds of analysis parameters are combined and how they are combined, from the descriptions in [0015] and [0016] of the detailed description of the invention and FIG. 1.

Regarding the statement, "FIGS. 2 to 6 show the overview of the "analysis module" and examples. In light of the above descriptions, a person skilled in the art can carry out the "analysis module" in the invention, " the allegation does not describe details of the "analysis module," and we cannot grasp what kinds of analysis parameters are combined and how they are combined, from the descriptions in FIGS. 2 to 6, as indicated in (B).

Therefore, even in consideration of the appellant's allegation, we cannot grasp what kinds of analytical parameters are combined and how they are combined by the "analysis module" of the Amended Invention.

B Claim 1 includes the matters specifying the invention (hereinafter referred to as "Matters specifying the invention 2"), "automatic configuration of the device can be implemented as a suggestion to an operator," which are the grounds for the reason for refusal of violation (enable requirement) in the examiner's decision in 2 of No. 3 described below.

We will examine below whether the description, "automatic configuration of the device can be implemented as a suggestion to an operator," is described in the detailed description of the invention clearly and sufficiently for a person skilled in the art to carry out the invention.

(A) Matters described in the detailed description of the invention

In the detailed description of the invention, there is only the following description which is considered to be related to the Matters specifying the invention 2, except for [0004] which is the same description as Claim 1.

" [0003]

The goal of the present invention is to design a device of the type described above in such a way that analysis results which pertain to specifiable questions can be provided.

...

[0005]

The inventive device thus comprises a modular structure, such that the hardware or software modules required in a particular case can be activated and linked together. The device can, for example, have the basic structure of an apparatus for analyzing body composition ('Body Composition Analyzer'). Other possible applications include, for example, scales and height-measuring devices.

...

[0017]

As a function of the selection made by the operator of the device, the analysis modules relevant to the examination situation in the actual case at hand are combined with each other.

...

[0019]

The hardware components being used can be connected by, for example, a wireless network, especially with the use of USB wireless adapters. Switching between different wireless networks is possible. It is also possible to connect several workplaces together, preferably by an ethernet network.

...

[0025]

In the inventive device, the selected sensor or the measuring instrument being used is connected to the assigned analysis unit by a data section. The data section can be realized in wireless or wired fashion. Both the analysis unit and the display unit have a functionally modular design, so that whatever functionality is needed can be easily configured.

...

[0033]

According to one embodiment of the analysis mechanism, it is provided that the unit configures itself as a function of the acquired metrological parameters. This self-configuration can be completely automatic, or the configuration can be suggested to the operator. During a preliminary examination of the measurement values, it is determined which modules are suitable for the concrete case at hand as a function of the metrologically detected situation.

[0034]

According to another variant, it is provided that, to minimize the required analysis time as a function of the modules selected during the configuration step, only the measurement values required for the modules which have in fact been activated are determined and selected.

[0035]

According to an exemplary embodiment, the use of the adapter (2) makes it possible for the printer (1) to calculate automatically the parameters of one program module for which the required input values and measurement values are available. It is also possible to use the adapter (2) to define which modules are to appear on the printout of the printer (1) by means of a module selection previously configured in the machine.

[0036]

A program module is typically defined by a predetermined number of parameters.

A parameter is in this case a measurement value or a calculated value, which yields information on the health status of a patient. Different parameters can be assembled freely into a user-specific module by using selection.

(B) Judgment

In the detailed description of the invention, the description which directly relates to the Matters specifying the invention 2 is only the following description in [0033], "According to another embodiment of the analysis mechanism, it is provided that the unit configures itself as a function of the acquired metrological parameters. This self-configuration can be completely automatic, or the configuration can be suggested to the operator. During a preliminary examination of the measurement values, it is determined which modules are suitable for the concrete case at hand as a function of the metrologically detected situation."

In [0033], the description, "During a preliminary examination of the measurement values, it is determined which modules are suitable for the concrete case at hand as a function of the metrologically detected situation," can be recognized to describe the content of "as a function of the acquired metrological parameters" in "it is provided that the unit configures itself as a function of the acquired metrological parameters." Therefore, the "automatic configuration of the device" can be done by "determining which modules are suitable for the concrete case at hand as a function of the metrologically detected situation." In light of the above, it can be recognized that the "automatic configuration of the device" can be done through selecting a "device" to be used by "determining which 'devices' are suitable for the concrete case at hand" "during a preliminary examination of the measurement values, as a function of the acquired metrological parameters."

However, the "preliminary examination of the measurement values" is done before measurement by use of a result obtained from past measurement, while the "metrologically detected situation" is recognized to be related to a measurement value of an actual measurement in process. Thus, the contents of the description, "during a preliminary examination of the measurement values, as a function of the acquired metrological parameters," is not clear.

According to other descriptions in the detailed description of the invention, the description in [0003], "in such a way that analysis results which pertain to specifiable questions can be provided," cannot be recognized to relate to "preliminary examination of the measurement values" or "metrologically detected situation."

Paragraphs [0005], [0019], and [0025] including the description on connection of a device, do not indicate how the device is selected.

The description in [0017], "As a function of the selection made by the operator of the device, the analysis modules relevant to the examination situation in the actual case at hand are combined with each other," is not recognized to relate to automatic selection of the device.

The description in [0034], "According to another variant, it is provided that, to minimize the required analysis time as a function of the modules selected during the configuration step, only the measurement values required for the modules which have in fact been activated are determined and selected," which describes about post-

configuration, does not describe how the device is configured.

The description in [0035], "It is also possible to use the adapter (2) to define which modules are to appear on the printout of the printer (1) by means of a module selection previously configured in the machine," does not describe how the device is configured.

The description in [0036], "Different parameters can be assembled freely into a user-specific module by using selection," also does not describe how the device is configured.

Consequently, even a person skilled in the art cannot grasp how the "automatic configuration of the device" in the Amended Invention is executed, from the detailed description of the invention.

Therefore, regarding the Matters specifying invention 2 of the Amended Invention, it cannot be recognized that the detailed description of the invention is clear and sufficient for a person skilled in the art to carry out the invention.

(C) Appellant's allegation

The appellant makes the following allegation in the written request for appeal, "The 'configuration of the device' is to select and start a required function module, in accordance with an actual case at hand. The 'automatic configuration of the device' is that a control unit automatically selects and starts a required function module in accordance with an actual problem in hand. When an operator or a user receives a function module automatically configured by the control unit, the configured function module is started, while the user can reject the suggestion. In this case, the user can correct it. Therefore, the function module is automatically configured and corrected manually. The control unit automatically configures the function module, as a 'program module,' by statistically considering which is suitable for obtaining health status or nutritional status of an operator, on the basis of the 'data not metrologically acquired' (Claim 1) or the 'input parameters obtained by the answers to questions asked before the examination' (for example, the sex, age, and the ethnicity of the patient; See [0014]), and automatically configures a device required for executing 'program module,' to be suggested to the operator. When the operator wants to correct the 'program module,' or to include other measurement parameters other than the suggested program module including the measurement parameters such as blood pressure, temperature or heart rate, the operator can manually include the parameters to configure a new program module."

However, the patent description or drawings of the application does not clearly indicate the above appellant's allegation, "The control unit automatically configures the function module, as a 'program module,' by statistically considering which is suitable for obtaining health status or nutritional status of an operator, on the basis of the 'data not metrologically acquired' (Claim 1) or the 'input parameters obtained by the answers to questions asked before the examination' (for example, the sex, age, and the ethnicity of the patient; See [0014]), and automatically configures a device required for the 'program module,' to be suggested to the operator."

The description in [0033] about the "automatic configuration of the device," "During a preliminary examination of the measurement values, it is determined which

modules are suitable for the concrete case at hand as a function of the metrologically detected situation," is not recognized to mean the appellant's allegation, "statistically considering which is suitable for obtaining health status or nutritional status of an operator, on the basis of the 'data not metrologically acquired' (Claim 1) or the 'input parameters obtained by the answers to questions asked before the examination' (for example, the sex, age, and the ethnicity of the patient; See [0014])."

From the description in [0003], "in such a way that analysis results which pertain to specifiable questions can be provided," we cannot immediately recognize that the "automatic configuration of the device" corresponds to the appellant's allegation, "The control unit automatically configures the function module, as a 'program module,' by statistically considering which is suitable for obtaining health status or nutritional status of an operator, on the basis of the 'data not metrologically acquired' (Claim 1) or the 'input parameters obtained by the answers to questions asked before the examination' (for example, the sex, age, and the ethnicity of the patient; See [0014])."

Thus, the above appellant's allegation cannot be accepted.

C In light of the above, regarding the Matters specifying the invention 1 and the Matters specifying the invention 2, it cannot be recognized that the detailed description of the invention is clear and sufficient for a person skilled in the art to carry out the invention. Therefore, the detailed description of the invention is not clear or sufficient for a person skilled in the art to carry out the Amended Invention.

Thus, the detailed description of the invention does not fall under the provisions of Article 36(4)(i). The appellant should not be granted a patent for the Amended Invention independently at the time of patent application.

(2) Regarding the provisions of Article 29(2) of the Patent Act (Inventive step)
A Described matters in the Cited documents
(A) Japanese Unexamined Patent Application Publication No. 2003-168178 (hereinafter referred to as "Cited Document 1"), which is a publication distributed before the priority date of the application and cited in reasons for refusal of the examiner's decision, includes the following matters (underlines were added by the body).

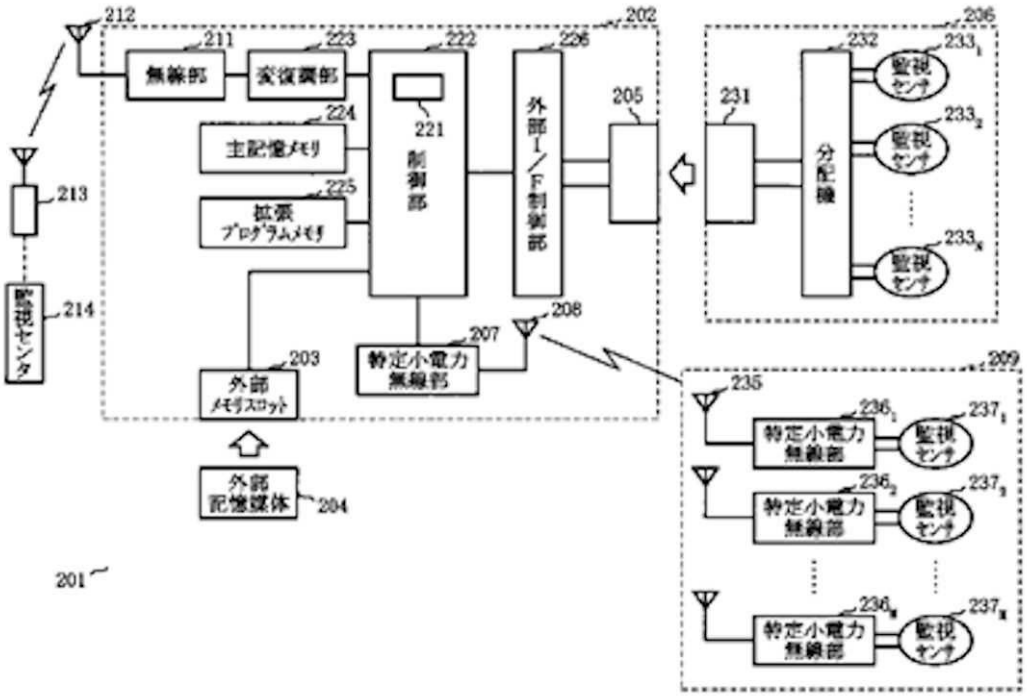
(Citation 1-A) "[0026]
[Examples] This invention is described in detail below about the following examples.
[0027] FIG. 1 illustrates a structure of a monitoring control system in one example of the invention. The monitoring control system 201 includes: a mobile phone body 202; an external storage medium 204 detachably mounted on an external memory slot 203; a wired monitoring unit 206 detachably mounted on an external slot 205 of the mobile phone body 202; a wireless monitoring unit 209 which communicates with an antenna 208 connected to a specified low power radio section 207 in the mobile phone body 202; and a monitoring center 214 which communicates with an antenna 212 connected to a wireless section 211 in the mobile phone body 202, via a base station 213.
[0028] The mobile phone body 202 includes a control section 222 with a CPU (central processing unit) 211. The control section 222 is connected to a wireless section that generates line frequency corresponding to a mobile-phone network, for example,

connected to a modulation-demodulation section 223 which modulates a signal for mobile-phone network or demodulates it, a main storage memory 224 storing a control program or data for implementing control of the control section 222, an extended program (application program) memory 225 storing an extended program for implementing a function other than mobile-phone function, the specified low power radio section 207, and an external interface (I/F) control section 226. The wired monitoring unit 206 includes: an insertion card part 231, a distributor 232 connected thereto, and the first to N-th monitoring sensors 2331-233N (N is an integer equal to or larger than 2) connected to the distributor 232. When only one of the monitoring sensors 233 is connected to the mobile phone body 202, no distributor 203 is required. In this case, it is only required to directly connect a cable (not shown) on an output side of the monitoring sensor 233 to the insertion card part 231. Depending on the type of the monitoring sensors 223, some can be included in the insertion card part 231.

[0029] The extended program memory 225 is a memory in a device where a program stored in the external storage medium 204 mounted on the external memory slot 203 is installed. Some devices may cause the external storage medium 204 to serve as the extended program memory 225. In this case, it is necessary to mount the external storage medium 204 on the mobile phone body 202 which is to serve as a part of a specific monitoring control system. The mobile phone body 202 in this example can modify or add the contents of an extended program by the external storage medium 204. In response to that, by changing as necessary the number of the value N of the first to N monitoring sensors 2331-233N or the type of the first to N-th monitoring sensors 2331-233N, a monitoring control system with different contents using one mobile phone body 202 can be implemented."

(Citation 1-B) [FIG. 1]

"



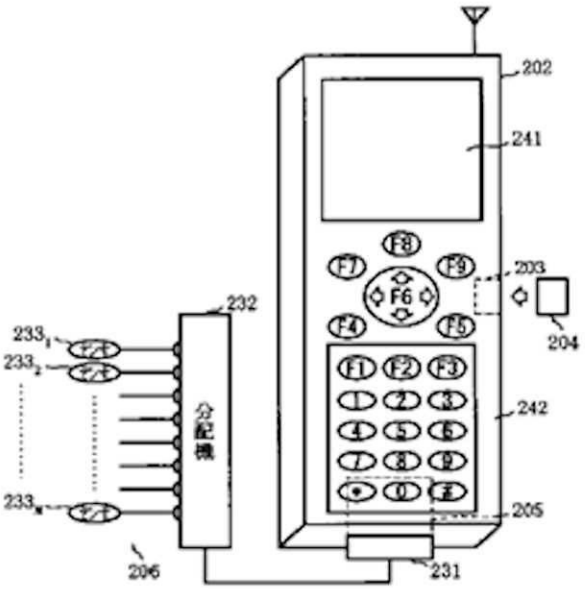
監視センタ　monitoring center
無線部　wireless section
変復調部　modulation/demodulation section
主記憶メモリ　main storage memory
拡張プログラムメモリ　extended program memory
外部メモリスロット　external memory slot
外部記憶媒体　external storage medium
制御部　control section
特定小電力無線部　specified low power radio section
外部Ｉ／Ｆ制御部　external I/F control section
分配器　distributor
監視センサ　monitoring sensor

"

(Citation 1-C) "[0032] FIG. 2 illustrates how necessary devices are connected to the mobile phone in this example. The mobile phone body 202 includes a display 241 for displaying various kinds of information arranged in an upper part of a top surface thereof, and an operation section 242 arranged below including operation keys and function keys. In the figure, the external memory slot 203 is arranged in a right-hand part, and the external slot 205 is arranged in a lower end part.
[0033] In the external memory slot 203 of the mobile phone body, an external storage medium 204 adapted to a monitoring control system to be implemented is to be mounted when the system is installed. In this example, a monitoring control system for monitoring each of sections of a human body (hereinafter referred to as Medical monitoring control system) is implemented. A control program as an extended program required for medical monitoring control is stored in the external storage medium 204 to be used. The CPU 221 (FIG. 1) in the mobile phone body 202 is configured to implement the Medical monitoring control system in accordance with the extended program stored in the external storage medium 204.
[0034] In this example, which implements the Medical monitoring control system, no wireless monitoring unit 209 is used. The wireless monitoring unit 209 is used, for example, in a monitoring control system for observing a water level in each of measurement points in a dam or a river.
[0035] The insertion card part 231 of the wired monitoring unit 206 is connected to the external slot 205 of the mobile phone body 202. In this example, which implements the Medical monitoring control system, the first to N-th monitoring sensors 2331-233N are formed of, for example, thermometer, pulsometer, blood pressure manometer, electrodes for forming electrocardiogram, or the like. The outputs detected by the first to N-th monitoring sensors 2331-233N are directly received by the mobile phone body 202 from the insertion card part 231, to be processed by the CPU 221 after being stored in the main storage memory 224 or a work memory area (not shown) in the control section 222."

(Citation 1-D) [FIG. 2]

"



分配機　distributor
センサ　sensor

"

(Citation 1-E) "[0036] FIG. 3 illustrates a flow of installing an extended program for implementing the Medical monitoring control system of the example. An administrator of the Medical monitoring control system operates the operation section 242 to set the mobile phone body 202 to extended-program installation mode (Step S301: Y). Otherwise (N), other modes are executed as a normal mobile phone. Details thereof are omitted.
[0037] In the extended-program installation mode, the CPU 221 (FIG. 1) searches for an extended program to be installed (Step S302). When the extended programs exist (Step S303: Y), all of them are displayed on the display 241 shown in FIG. 2 (Step S304). The system stands by for the administrator to select an extended program (Step S305).
[0038] FIG. 4 illustrates what is displayed on the display of the mobile phone body in selecting an extended program. The display 241 displays all programs stored in the external storage medium (FIG. 2). In this example, 5 monitoring programs are displayed. Only one program may be displayed in other cases. The administrator operates 'F6' key (four-direction key) of the operation section 242 shown in FIG. 2, for example, for moving up/down a cursor 251, to specify a desired extended program, and can execute installation of the extended program by pressing a predetermined key.
...
[0040] When the administrator selects a program to be installed from among the extended programs by the above operation (Step S305: Y), processing to install the corresponding extended program stored in the external storage medium 204 on the mobile phone body 202 is executed (Step S307)."

(Citation 1-F) "[0052] Operation of the Medical monitoring control system of the example is described in detail below. In this example, the system is operated in such a manner that the first to N-th monitoring sensors 2331-233N shown in FIG. 8 are set to patients, respectively. The first to N-th monitoring sensors 2331-233N are formed of, for example, thermometer, pulsometer, blood pressure manometer, electrodes for forming electrocardiogram, or the like. The patients can manage by themselves the contents monitored to some degree, and a notification is sent to a department in charge in the hospital when an abnormal result is obtained.

[0053] FIG. 11 illustrates a schematic flow of the control of the Medical monitoring control system. In the Medical monitoring control system, when the mobile phone body 202 shown in FIG. 1 is turned on, the CPU 221 displays a screen, as an initial screen, for confirming necessity of monitoring control settings on the display 241 (Step S331). The monitoring control settings indicate, in this example, that a patient or an administrator of the system performs necessary settings or modification (hereinafter referred to as 'settings' unless specified) for operating the system.

[0054] FIG. 12 illustrates an example of a screen displayed for confirming necessity of the monitoring control settings. In the display 241 shown in FIG. 2, a window 351 is displayed for confirming whether to execute the settings. Options 'YES' and 'NO' are displayed for confirming the necessity of the settings.

[0055] When the screen for confirming the necessity of the monitoring control setting is displayed on the display 241, a patient or an administrator of the system (hereinafter referred to as 'operator'), for configuring the settings, performs an operation input indicating affirmative 'YES' through the operation section 242 (FIG. 2) (Step S332: Y). In this case, the following sensor parameter setting mode is executed (Step S333). After completing the settings of parameters, state monitoring mode is executed (Step S334).

[0056] When the settings for the monitoring control are not configured, an operation input indicating negative 'NO' is performed through the operation section 242 (Step S332: N, Step S335: Y). In this case, reception standby mode is executed (Step S336). The reception standby mode indicates processing to stand by for reception as a function of a general mobile phone.

[0057] FIG. 13 illustrates specific contents of the sensor parameter setting mode described in Step S333. In the sensor parameter setting mode, a parameter n for processing is initially set to '1' (Step S361). An n-th parameter setting screen is displayed on the display 241. In this case, the parameter n is '1,' and the first parameter setting screen is displayed.

[0058] FIG. 14 illustrates how the first parameter setting screen is displayed. In the first parameter setting screen displayed on the display 241, information specifying the monitoring sensor 233, such as 'the first sensor,' is displayed above, to indicate the monitoring sensor on which the parameters are to be set, among the monitoring sensors 2331-233N. Items for setting start and end time of the monitoring, interval of the monitoring, a prescribed value, and whether parameter settings have been completed or not, are displayed below. The 'prescribed value' is a boundary value for generating an alarm. When exceeding the boundary value or falling below the boundary value, an alarm is generated. The item 'Setting completed?' is to be used for inputting whether all parameters have been set completely. The operator selectively inputs 'affirmative

(Y)' or 'negative (N).'
[0059] The operator presses a portion selecting a direction in 'F6' as a function key of the operation section 242, to move up/down a cursor (not shown) along the items. When a desired setting item is selected (color is reversed, for example), a corresponding value is input through a key of a numeric keypad, or the like.
[0060] When all parameters displayed on the display 241 are set for the first parameter, the operator selects one of the two items in the 'parameter settings completed.' When the 'affirmative (Y)' is selected, the current parameter settings are considered to be completed (Step S363: Y), the contents of the first parameter are registered in a predetermined area of a random access memory (not shown) in the control section 222 (Step S364). The process proceeds to the next step S365."

(Citation 1-G) "[0066] FIG. 17 illustrates a schematic flow of the state monitoring mode in the example. This corresponds to the step S334 in FIG. 11. In this mode, the parameter n for processing is initially set to '1' (Step S391). Whether or not the current time, for the first monitoring sensor 2331 is within a detection time zone is checked (Step S392). For example, during sleeping time, the first monitoring sensor 2331 is removed from a patient. The sleeping time is not in a detection time zone (N), and monitoring is not performed using the sensor. In this case, the process immediately proceeds to the step S393 and '1' is added to the parameter n. A determination is made as to whether or not the value exceeds 'Nt,' which is the total number of monitoring sensors 2331-233N (Step S394).
[0067] When "Nt" is two or more, other monitoring sensors 2332-233N remain left. In this case (N), the process returns to the step S392, and detection time zone is checked for the second monitoring sensor 2332.
[0068] When the current time for the second monitoring sensor 2332 is within the detection time zone (Step S392: Y), the CPU 221 checks whether the time has reached a preset interval measurement time (Step S395). When the measurement time has not been reached (N), the process proceeds to step S393 in the same way as above, and processing for the third monitoring sensor 2333 is to be started.
[0069] When the measurement time for the second monitoring sensor 2332 has been reached (Step S395: Y), a measurement value is acquired using the sensor (Step S396). Whether the acquired value has exceeded the prescribed value in an abnormal direction is checked (Step S397). When the value has exceeded (Y), an alarm is issued to an alarm destination described in FIG. 15, and data thereof are transmitted to an e-mail address of a data destination (Step S398). The alarm destination may be a mobile phone of a patient, or a place (monitoring center 214) which can cope with an emergency, such as a telephone number of a nurse. Multiple alarm destinations may be set. The data destination may be a place that manages data in the hospital, or an e-mail address corresponding to a personal computer (not shown) of the patient. Multiple data destinations may be set as well.
[0070] When the measurement value does not indicate an abnormal condition in step S397 (N), data thereof are transmitted to the e-mail address of the data destination and no alarm is issued (Step S399). After steps S398 and S399, the process proceeds to the step S393, and processing for the next monitoring sensor 233 is executed.
[0071] When a sequence of processing for the first to N-th monitoring sensors 2331-233N is completed (Step S394: y), process returns to the step S391 (return).

Processing for the first to N-th monitoring sensors 2331-233N is repeated in a time-division manner.
[0072] When the condition of the patient suddenly changes, some of the first to N-th monitoring sensors 2331-233N generate alarms in substantially the same time zone, in some cases. In such a case, the types of abnormal conditions for one patient can be identified from different types of alarms. The e-mail messages transmitted can be analyzed. In a monitoring department (monitoring center 214), such as a nurse's station, in the hospital, alarms of different patients are congested temporally, in some cases. In such a case, a telephone set outputting an alarm can be identified by caller number display of the caller mobile phone.
[0073] In the above example, the Medical monitoring control system as a monitoring control system in a hospital is described, and the invention can be applied to various kinds of monitoring control systems, of course. For example, this invention can be applied to a system which treats a home-care patient in the same medical field."

(Citation 1-H) "[0077]
[Advantage of the invention] As described above, according to the invention described in Claims 1 to 7, various kinds of monitoring can be implemented by use of mobile communication terminals which are likely to be relatively mass produced, thereby reducing monitoring cost and also enabling simple transportation for portability and setup in multiple locations. The mobile communication terminal having a communication function has the advantage of being able to simply transmit monitor data or processing results when an abnormal condition occurs. As the mobile communication apparatus with an extended program installed thereon executes desired monitoring control, the one hardware mobile communication terminal is used, and monitoring control can be implemented only by creating a control program even for special monitoring control. Existing monitoring control can be also simply modified, as well.

(B) Recognition of the invention described in Cited Document 1
a In (Citation 1-E), there is a description that the Medical monitoring control system of the example, in the extended program installation mode, installs a selected extended program. According to the description in (Citation 1-A) [0029], "The extended program memory 225 is a memory in a device where a program stored in the external storage medium 204 mounted on the external memory slot 203 is installed. Some devices may cause the external storage medium 204 to serve as the extended program memory 225. In this case, it is necessary to mount the external storage medium 204 on the mobile phone body 202 which is to serve as a part of a specific monitoring control system," it can be recognized that a mode is described where the "external storage medium 204" mounted on the external memory slot 203 is used as the "extended program memory 225" and the selected "extended program" is executed without installation.

b Therefore, according to the (Citation 1-A) to (Citation 1-H), Cited Document 1 describes the following invention (hereinafter referred to as "Cited Invention 1"):

"A medical monitoring control system 201 for monitoring each of sections of a human

body including: a mobile phone body 202; an external storage medium 204 detachably mounted on an external memory slot 203; a wired monitoring unit 206 detachably mounted on an external slot 205 of the mobile phone body 202; and a monitoring center 214 which communicates with an antenna 212 connected to a wireless section 211 in the mobile phone body 202, via a base station 213, wherein

the mobile phone body 202 includes a display 241 for displaying various kinds of information arranged in an upper part of a top surface thereof, and an operation section 242 arranged below including operation keys and function keys, the external memory slot 203 arranged in a right-hand part, and the external slot 205 arranged in a lower end part,

the external storage medium 204 stores a control program as an extended program required for medical monitoring control,

the wired monitoring unit 206 includes an insertion card part 231, a distributor 232 connected thereto, and the first to N-th monitoring sensors 2331-233N (N is an integer equal to or larger than 2) connected to the distributor 232, the first to N-th monitoring sensors 2331-233N being formed of, for example, thermometer, pulsometer, blood pressure manometer, electrodes for forming electrocardiogram, or the like,

the external storage medium 204 is mounted on the external memory slot 203 when the mobile phone body 202 is used as a part of the Medical monitoring control system 201,

the insertion card part 231 of the wired monitoring unit 206 is connected to the external slot 205,

the mobile phone body 202 includes a control section 222 with a CPU (Central Processing Unit) 221, the CPU 221 being configured to implement the Medical monitoring control system in accordance with the extended program stored in the external storage medium 204,

the display 241 displays all programs stored in the external storage medium 204 for selecting an extended program, and 'F6' key (four-direction key) of the operation section 242 is operated for moving up/down a cursor 251, to specify a desired extended program,

in sensor parameter setting mode, an n-th parameter setting screen is displayed on the display 241, in the first parameter setting screen, information specifying the monitoring sensor 233 is displayed above, items for setting start and end time of the monitoring, interval of the monitoring, a prescribed value, and whether or not parameter settings have been completed, are displayed below, a portion selecting a direction in 'F6' as a function key of the operation section 242 is pressed to move up/down a cursor along the items, and when a desired setting item is selected, a corresponding value is input through a key of a numeric keypad, or the like, the 'prescribed value' is a boundary value for generating an alarm,

in state monitoring mode, a measurement value is acquired, whether the acquired value has exceeded the prescribed value in an abnormal direction is checked, when the value has exceeded, an alarm is issued to an alarm destination, and data thereof are transmitted to an e-mail address of a data destination, when the measurement value does not indicate an abnormal condition, data thereof is transmitted to the e-mail address of the data destination and no alarm is issued, when some of the first to N-th monitoring sensors 2331-233N generate alarms in substantially the same time zone, the types of abnormal conditions for one patient can be identified from different types of alarms."

(C) Japanese Unexamined Patent Application Publication No. H10-334161 (hereinafter referred to as "Cited Document 3"), which is a publication distributed before the priority date of the application and cited in reasons for refusal of the examiner's decision, includes the following matters (underlines were added by the body).

(Citation 3-A) [0013]
[Embodiments of the invention] FIG. 1 illustrates an embodiment of a home-care medical system according to the invention. Reference numeral 1 indicates a medical terminal which measures blood pressure, heart rate, and electrocardiogram of a user, inputs a temperature or weight of the user, and inputs answers to questions from a medical institution. Reference numeral 2 indicates user communication means. The medical terminal 1 and the user communication means 2 constitute a medical device 8, which is installed in a house of each user. Reference numeral 3 indicates medical institution communication means. The communication means 2 and 3 are connected by a communication line 4 of CATV, or the like. The communication means 2 and 3 may be configured to communicate with each other by a telephone line or wireless communication, of course (not shown). Reference numeral 5 indicates a medical-institution host computer with display device, which includes accessory devices, such as a printer device 6 and an external storage device 7.
[0014] FIG. 2 illustrates a perspective view of the medical device 8. According to the drawings, an arm band 10 for blood-pressure check is set in a storage section 11, on the top side of the medical terminal 1 set on the top of the user communication means 2. Reference numeral 12 indicates a cover for covering the top, with one side hinged to one side of the medical terminal 1. Reference numeral 13 indicates a speaker, 14 display means including a liquid crystal display, for example, 15 a button for (YES), 16 a button for (NO), and 17 a (Selection) operation button. At the front side, measurement electrodes 18, 18 for measuring electrocardiogram are detachably connected via a conductor 19."

(Citation 3-B) "[0019] A start menu for operation is different depending on whether or not the medical terminal 1 has been removed from the user communication means 2 (S1). When a power switch (not shown) is turned on while the terminal is off the device (S1), or when the medical terminal 1 is removed after the power switch is turned on, the liquid crystal display is turned on to display 'Press any button.' When one of the operation buttons 15, 16, 17 is pressed (S2), a start menu 1 (see FIG. 6) is displayed (S3). In accordance with the display, measurement or input of various biometric information (blood pressure heart rate, electrocardiogram, medical interview, temperature, weight, and urinalysis result) is performed. The start menu 1 includes date, time, registration number, name, or the like."

(Citation 3-C) "[0024] (Medical interview) A case of medical interview using the system according to the embodiment is described below.
[0025] Each of the host computer 5 and the medical terminal 1 includes minimal medical interview questions numbered serially. In the medical institution, when a doctor inputs the numbers of the questions to be asked to a user on the host computer 5, the numbers are stored in the host computer. When the input is completed, the

numbers of the questions are transmitted to the medical device 8 of the user via the medical institution communication means 3. The medical device 8 performs medical interview based on the received question numbers to the user, and transmits a result to the host computer 5 via the user communication means 2. The host computer 5 needs to transmit the question numbers only once, since the question numbers received by the medical device 8 are stored in storage means 33 of the medical device 8. The interview questions to the user can be changed merely by changing the question numbers stored in the host computer. The host computer 5 transmits the new question numbers to the medical device 8 of the user via the medical institution communication means 3. The interview questions can be specified for each user, thereby enabling effective medical interview for each disease and symptom of users. This operation is performed as follows.
(1) When No. 1 of the start menu 1 is selected, the medical terminal 1 asks a user, 'Start medical interview?' by voice and screen display by use of the display means 14 and the speaker 13 of description means 31.
(2) A user answers with one of the operation buttons 15, 16 for YES or NO of the input means 27. When the answer is NO, medical interview is not started. When the answer is YES, the medical interview is started.
(3) The medical interview proceeds as a user operates the operation buttons 15, 16, 17 for YES, NO, and Selection of the input means 27 for the questions displayed on a screen of the display means 14. (Example) 'Do you have pain in your chest?' (YES) (NO) (Sometimes), 'Do you feel listless?' (YES) (NO) (Sometimes), or the like.
(4) When all questions are answered, the medical terminal 1 asks, 'OK?' by voice and screen display. When the operation button 16 for NO is pressed, the terminals asks, 'Do over?' by voice and screen display. When the operation button 15 for YES is pressed, medical interview biometric information is not stored and the process returns to (1). When the operation button 15 for YES is pressed, the medical interview biometric information is stored in the storage means 33 and the process ends."

(Citation 3-D) "[0026] (Measurement of blood pressure/heart rate (See FIG. 7))
(1) When No. 2 of the start menu 1 is selected, the medical terminal 1 asks a user, 'Measure blood pressure/heart rate?' by voice and screen display by use of the display means 14 and the speaker 13 of the description means 13. The user answers with one of the operation buttons 15, 16 for YES or NO of the input means 27. When the answer is NO, measurement is not started and the process proceeds to the next electrocardiogram measurement item. When the answer is YES, the process proceeds to the next step.
(2) The medical terminal 1 asks, 'Ready?' by voice and screen display, as described above.
(3) Then, the medical terminal 1 instructs the user, 'Put the arm band on' by voice and screen display.
(4) The user opens the cover 12, and puts the arm band 10 of the measurement means 35 equipped in the medical terminal 1 on his or her arm.
(5) When the user is ready for measurement, the user presses the operation button 15 for YES.
(6) Air is automatically supplied by pump 32 to the arm band 10, and discharged therefrom, to start measuring blood pressure and heart rate by, for example, an

oscillometric method. When any of the operation buttons 15 (YES), 16 (NO), 17 (Selection) of the input means 27 is pressed, the measurement is immediately stopped, as necessary, and the process returns to (1).
(7) Measurement results are displayed on the screen of the display means 14, as follows.
Measurement results
Maximal blood pressure=123 mmHg
Minimal blood pressure =89 mmHg
Heart rate= 60/min
(8) The measurement of blood pressure and heart rate ends in this manner.
(9) Then, the medical terminal 1 asks, 'OK?' by voice and screen display. When the user presses the operation button 16 for NO, the terminal asks, 'Do over?' by voice and screen display. When the user presses the operation button 15 for YES, the biometric information is not stored and the process returns to (1). When the user presses the operation button 15 for YES of the input means 27, the measured biometric information is stored in the storage means 33 and the operation ends.
[0027] The blood check starts with the maximal pressure of 160 mmHG. When a blood-pressure value exceeding the range is detected, the information is given by voice and the measurement starts with the maximal pressure of 240 mmHG. In case that a pressure beyond necessity is applied with the arm band 10 for measuring blood pressure/heart rate due to a failure of the pump 32, the medical device includes a software safety circuit as well as a hardware safety circuit (not shown).
[0028] (Measurement of electrocardiogram (See FIG. 8))
(1) When No. 3 of the start menu 1 is selected, the medical terminal 1 asks a user, 'Start measurement of electrocardiogram?' by voice and screen display by use of the display means 14 and the speaker 13 of the description means 31. Voice announcement is repeated at intervals of 5 seconds until the user answers with the operation button 15 for YES of the input means 27. The user answers by pressing one of the operation button 15 for YES and the operation button 16 for NO of the input means 27. When the answer is NO, measurement is not started and the process proceeds to the next temperature measurement value input item. When the answer is YES, the process proceeds as follows.
(2) The medical terminal 1 asks, 'Ready?' by voice and screen display.
(3) The medical terminal 1 gives guidance, 'Put the electrodes on your body,' to the user by voice and screen display.
(4) The user puts the measurement electrodes 18, 18 of the measurement means 35 of the medical terminal 1, on his or her both arms.
(5) When the user is ready, the user presses the operation button 15 for YES of the input means 27.
(6) Measurement of electrocardiogram is started. When any of the operation buttons 15 (YES), 16 (NO), 17 (Selection) of the input means 27 is pressed, the measurement is immediately stopped, as necessary, and the process returns to (1).
(7) Electrocardiographic waveform of the user is displayed on the screen of the display means 14 in real time.
(8) The medical terminal 1 starts measurement, and terminates the measurement automatically when one minute passes after automatic gain adjustment ends.
(9) The medical terminal 1 asks, 'OK?' by voice and screen display. When the user presses the operation button 16 for NO of the input means 27, the terminal asks, 'Do

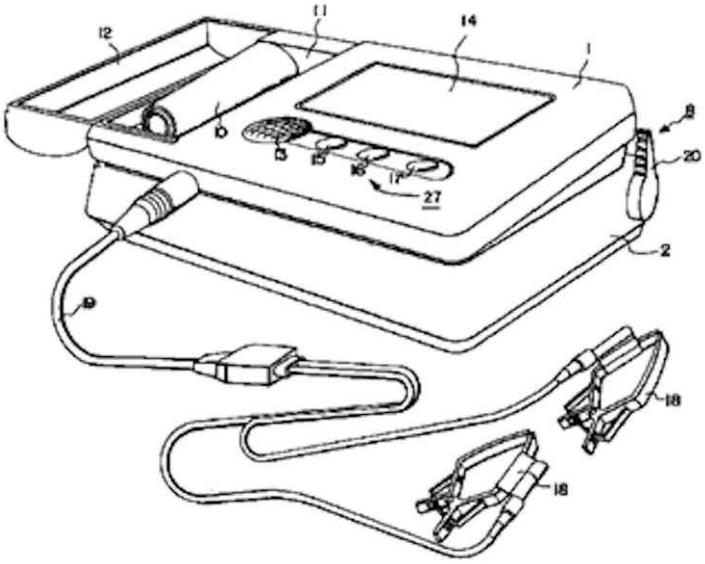
over?' by voice and screen display. When the user presses the operation button 15 for YES, the measured biometric information is not stored in the storage means 33, and the process returns to (1). When the user presses the operation button 15 for YES of the input means 27, the measurement biometric information is stored in the memory 33 and the process ends."

(Citation 3-E) "[0031] (Input of urinalysis result (See FIGS. 9 to 15)) The kidney generates urine by impurities in the body flowing from all of the tissues of the body transported by blood, and excess water. The urine generated by the kidney enters the bladder, and is discharged to the outside of the body through the urethra when reaching a predetermined quantity. However, when the bladder or other sections of the body has an abnormality, the impurities cannot be discharged, or something not to be discharged is mixed into the urine. The urinalysis to check the components or properties of the urine for finding an abnormality of the body is very important examination.
[0032] A patient immerses a urinalysis test slip in the urine (FIG. 10), to allow the test slip to change color, or allow the test slip to produce a color, and compares the color with a color check chart (FIG. 11), to measure protein and sugar contained in the urine, in advance.
[0033] [Measurement principle of urinalysis test slip] Protein check is based on the principle that pH indicator (Tetra Bromo Phenol Blue (TBPB)) that changes color by forming a composite with the protein. Color check is conducted in accordance with FIG. 12.
[0034] Sugar check is based on the principle that glucose is oxidized by glucose oxidase to generate hydrogen peroxide, the hydrogen peroxide oxidizes orthotolidine with peroxidase to produce red color. The color degree of the red color is proportional to urine glucose concentration. Different colors may be produced depending on chromogen (orthotolidine, or the like). Color check is conducted in accordance with FIG. 13.
[0035] The color check uses a commercially available color check chart (FIG. 11). The degree of the color presented in the urinalysis test slip is visually checked on the basis of the color check chart, to select color ranks in 6 levels (ABCDEF for protein, GHIJKL for sugar).
[0036] When the measurement ends and urinalysis results are obtained, the medical terminal 1 is operated (FIG. 9).
(1) When No. 6 of the start menu 1 is selected, the medical terminal 1 asks a user, 'Input urinalysis results?' by voice and screen display.
(2) The user presses one of the operation buttons 15, 16, 17 for YES, NO, Selection. When the user presses the operation button 15 for YES, urinalysis data recording is started. When the user presses the operation button 16 for NO, a last screen is displayed without recording the urinalysis data. When the user presses the operation button 17 for Selection, previous input data are recorded and stored.
(3) When the user presses the operation button 15 for YES, cautions for urine check are displayed on the liquid crystal display (FIG. 14).
(4) ABCDE levels for urine protein rank and GHIJKL levels for urine sugar rank are displayed on the liquid crystal display (FIG. 15). The user operates the operation buttons 15, 16 to input data of the urinalysis results.

[0037] In inputting urine protein result data, the user presses the operation button 15 for YES first. The color band (reversed part) is moved sequentially from rank A in the urine protein field by pressing the button. When reaching F, the color band starts from A. The user stops the color band at an appropriate rank position for the color corresponding to the urine protein check result data.
[0038] In inputting urine sugar result data, the user presses the operation button 16 for NO. The color band is moved sequentially from rank G in the urine sugar field by pressing the button. When reaching L, the color band starts from G. The user stops the color band at an appropriate rank position for the color corresponding to the urine sugar check result data.
(5) After input, the user presses the operation button 17 for Selection, to complete the input.
(6) The medical terminal 1 asks, 'OK?' by voice and screen display. When the user presses the operation button 15 for YES, the urinalysis result data are stored.
(7) An end screen is displayed. When the user presses the operation button 16 for NO in (6), the process returns to (1) without recording the urinalysis result data."

(Citation 3-F) [FIG. 2]

"



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(D) Japanese Unexamined Patent Application Publication No. 2002-56099 (hereinafter referred to as "Cited Document 4"), which is a publication distributed before the priority date of the application and cited in reasons for refusal of the examiner's decision, includes the following matters (underlines were added by the body).

(Citation 4-A) "[0101] Operation examples of one embodiment is described below in reference to FIG. 1, FIG. 2, and FIGS. 14 to 16. FIGS. 14 to 16 are flowcharts showing operation examples of a health management system according to one embodiment. For example, a user with hypertension to use the health management

system starts operating an Internet terminal 11 (Step S1). The users input a URL of a server 22 of a health management center B, to connect a line between the Internet terminal 11 and the server 22 (Step S2, Step S3).

[0102] The server 22 extracts a selection screen of the health management system, as a screen of an initial web page for providing services in the health management system, from an internal storage unit, to be transmitted to the Internet terminal 11 (Step S4, Step S5). The Internet terminal 11 displays the selection screen transmitted from the server 22 as shown in FIG. 16 (note by the body: "FIG. 16" is admitted as an error of "FIG. 17" from the descriptions in the drawings; the same applies hereinafter), on a display screen.

[0103] The selection screen includes: a care-service button 31 which is clicked to select a care service for starting a program for health management; a lifestyle-related disease button 32 which starts a program for searching a health information DB 25 for information on the cause or treatment of lifestyle-related diseases; a life information button 33 which starts a program showing a lifestyle such as diet or sleeping time; a health food information button 34 which starts a program for searching for foods suitable for each of diseases; a chat button 35 which starts a program for users having the same disease to exchange treatment information with each other; and an expert information button 36 which starts a program for searching the health information DB 25 for expert information on the lifestyle-related diseases to be transmitted to the Internet terminal 11.

[0104] The user moves a cursor K to the care-service button 31 indicating care service in the display screen, to click the care-service button 31 with a mouse for selection (Step S7). The selection information is transmitted to the server 22. The server 22 starts a program for health management with the selection information, and extracts a selection screen for selecting a disease to be managed from the internal storage unit, to be transmitted to the Internet terminal 11.

[0105] The Internet terminal 11 displays the selection screen shown in FIG. 18 in the display screen. An initial selection screen shown in FIG. 16 is displayed in an area A of the display screen, and buttons for selecting the type of disease to be subjected to care-service are displayed in an area B of the display screen. The selection screen in the area B includes a hypertension button 41 which starts a program for health management of hypertension, a hyperlipidemia button 42 which starts a program for health management of hyperlipidemia, a diabetes button 43 which starts a program for health management of diabetes, and an asthma button 44 which starts a program for health management of asthma/COPD.

[0106] When a top button 40 indicating Top is clicked, the initial selection screen shown in FIG. 16 is displayed. The user moves the cursor K to the hypertension button 41 indicating Hypertension in the display screen, and clicks the hypertension button 41 with the mouse for selection (Step S8).

[0107] The selection information is transmitted to the server 22. The server 22 starts the program for heath management of hypertension with the selection information, and extracts from the internal storage unit an authentication screen for user authentication to authenticate a user who receives hypertension health management service, to be transmitted to the Internet terminal 11.

...

[0114] The Internet terminal 11 displays a care-service selection screen shown in FIG.

20 in the display screen (Step S15). The care-service selection screen is configured as shown in FIG. 20, and includes an area A displaying an initial selection screen shown in FIG. 16 and an area D displaying a management journal for selecting a management service of a user.

[0115] The selection screen in the area D includes: a health check button 61 which is clicked to start a program for health check of a user; a personal chart button 62 which starts a program for browsing the contents recorded in data A, data B, and data C of the user; a counseling button 63 which starts a program for the user to take advice from a doctor in a medical institution H about a condition of the disease; and a management target button 64 which starts a program for confirming current management target of management items in inspection items in the data B and data C of the user.

[0116] The user moves the cursor K to the health check button 61 indicating Health check in the display screen shown in FIG. 20, and clicks the health check button 61 with the mouse, to select a service for health check (Step S16). When the user clicks the health check button 61, the Internet terminal 11 transmits to the server 22 a control signal to start health check. The server 22 starts processing of the program for health check of the user, or such as health level analysis shown in FIG. 12 and continuous determination of calculation/displaying a health management target shown in FIG. 13.

[0117] The server 22 starts processing of the program for health check of the user, such as health level analysis shown in FIG. 12, and continuous determination of calculation/displaying a health management target shown in FIG. 13. The server 22 extracts a vital value input screen shown in FIG. 21 from the internal storage unit, to be transmitted to the Internet terminal 11.

[0118] In the Internet terminal 11, the vital value input screen is configured as shown in FIG. 21, and includes an area A displaying an initial selection screen shown in FIG. 16, and an area E displaying an input section for inputting measurement values of the data B of the user (Step S17). In the user system shown in FIG. 2, the Internet terminal 11 may be configured to acquire data of a vital sensor connected to a vital sensor control section 1, from the vital sensor control section 1, and to input measurement data to the input section.

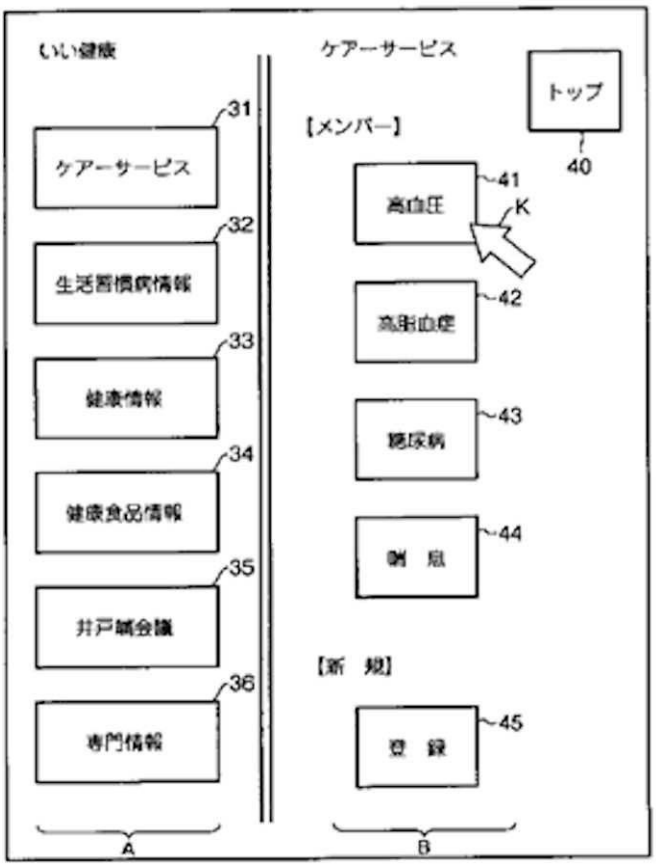
[0119] The input section in the area E includes: a display area for displaying a blood-pressure value, which is a management target of a user who desires health management of hypertension; a date input section 72 for inputting a date when the user inputs vital values of the data B; a selection button 73 for selecting morning, noon, night, or before sleep for an input time; a time input section 74 for inputting the time when the vital values are input; an attack input confirmation button 75 for selecting whether an attack has occurred or not and a level of the attack; a blood-pressure data input section 76 for inputting measurement data of blood pressure of the user; a medication confirmation button 77 for selecting whether the user is on medication or not; a temperature input section 78 for inputting measurement data of temperature of the user; and a comment input section 79 for inputting symptoms of the health condition.

[0120] When the data of measurement results of the vital sensors connected to the vital sensor control section 1 are incorrect, the user clicks a cancel button 54, to delete the input data of measurement results, and inputs data again. The user inputs necessary data, in the area E, the display area 71, the date input section 72, the selection button 73, the time input section 74, the attack input confirmation button 75, the blood-pressure data input section 76, the medication confirmation button 77, the temperature input

section 78, and the comment input section 79.
[0121] When the input data require no correction, the user moves the cursor K to the OK button 80, clicks the OK button 80, and terminates inputting measurement data of required management items (Step S18). The vital sensor control section 1 transmits to the Internet terminal 11 the measurement data of the required management items from the vital sensors connected thereto. The Internet terminal 11 displays the measurement data on the display screen. The user prints out the measurement data of the vital sensors by a printer, or the like, and inputs the measurement data of the required management items on the basis of the printed data.
[0122] In this example, as required management items of daily management data in hypertension, for example, blood pressure and temperature data are measured, and the blood pressure is set as a management target(Percent body fat, weight, and amount of exercise may also be used.). As required management items of daily management data in hyperlipidemia, for example, percent body fat, weight, and amount of exercise are used. As required management items of daily management data in diabetes, for example, blood pressure, percent body fat, weight, and amount of exercise are used. As required management items of daily management data in asthma/COPD, for example, peak flow value, asthma/COPD journal, oxygen saturation, and weight are used. Vital sensors required for measuring the above inspection items are connected to the vital sensor control section connected to the Internet terminal 11 of the user."

(Citation 4-B) [FIG. 18]

"

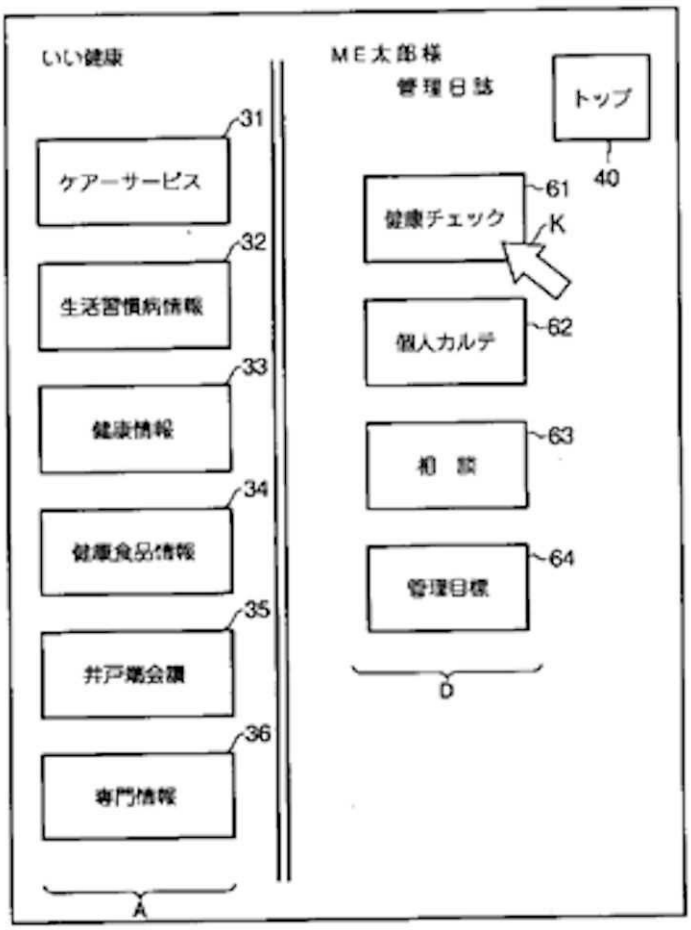


いい健康　Good health
ケアーサービス　Care service
トップ　Top
生活習慣病情報　Lifestyle-related diseases
健康情報　Health information
健康食品情報　Health food information
井戸端会議　Chat
専門情報　Expert information
メンバー　Member
高血圧　Hypertension
高脂血症　hyperlipidemia
糖尿病　Diabetes
喘息　Asthma
新規　New
登録　Registration

"

(Citation 4-C) [FIG. 20]

"



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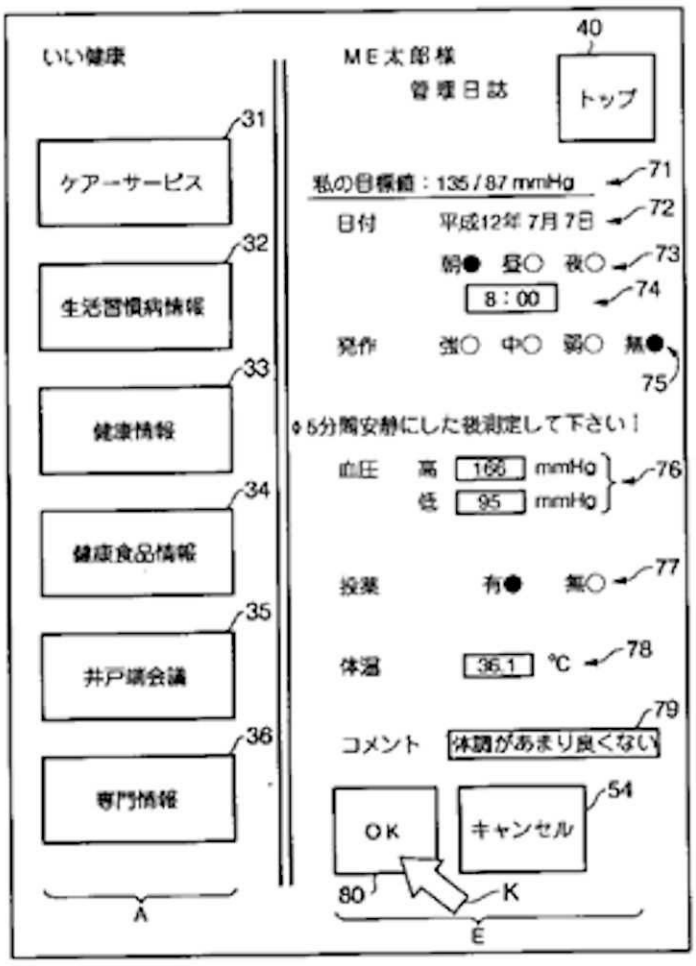
井戸端会議　Chat
専門情報　Expert information
ＭＥ太郎様　管理日誌　Mr. TARO ME Management journal
健康チェック　Health check
個人カルテ　Personal chart
相談　Counseling
管理目標　Management target

"

(Citation 4-D) [FIG. 21]

"



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健康情報　Health information
健康食品情報　Health food information
井戸端会議　Chat
専門情報　Expert information
ＭＥ太郎様　管理日誌　Mr. TARO ME Management journal
私の目標値　My target
日付　平成１２年７月７日　Date　July 7, 2000
朝　Morning
昼　Noon
夜　Night
発作　Attack
強　Strong
中　Middle
弱　Weak

無　None
５分間安静にした後測定して下さい　Start measurement after resting for 5 minutes.
血圧　Blood pressure
高　High
低　Low
投薬　Medication
有　Yes
体温　Temperature
コメント　Comments
体調があまり良くない　Not in good health
キャンセル　Cancel

"

B　Comparison between the Amended Invention and Cited Invention 1
(A) In Cited Invention 1, the "temperature," "heart rate," and "blood pressure" measured by "the first to N-th monitoring sensors 2331-233N" "formed of the thermometer, pulsometer, blood pressure manometer, electrodes for forming an electrocardiogram, or the like" correspond to the "at least one biological parameter of a living organism" in the Amended Invention.

(B) It is obvious that the "acquired value" in "acquiring a measurement value and checking whether the acquired value has exceeded a prescribed value in an abnormal direction or not" in Cited Invention 1 means "temperature," "heart rate," and "blood pressure." The description in Cited Invention 1, "Whether the acquired value has exceeded the prescribed value in an abnormal direction is checked" corresponds to the description in the Amended Invention, "analyzing at least one biological parameter."

(C) In Cited Invention 1, the "CPU 221" "implements a medical monitoring control system in accordance with an extended program," and "in the state monitoring mode, a measurement value is acquired and whether the acquired value has exceeded a prescribed value in an abnormal direction is checked." Therefore, the "control section 222" with the "CPU 221" in Cited Invention 1 has a function of "analyzing at least one biological parameter of a living organism" in "at least one analysis mechanism" in the Amended Invention.

(D) "The first to N-th monitoring sensors 2331-233N" "formed of a thermometer, pulsometer, blood pressure manometer, electrodes for forming electrocardiogram, or the like" in Cited Invention 1 corresponds to "at least one sensor which measures at least one biological parameter of a living organism" in the Amended Invention.

(E) The "external slot 205" in Cited Invention 1 is configured so that "the insertion card part 231 of the wired monitoring unit 206" is connected thereto, the wired monitoring unit 206 "including the insertion card part 231, a distributor 232 connected thereto, and the first to N-th monitoring sensors 2331-233N (N is an integer equal to or larger than

2) connected to the distributor 232. Therefore, the "external slot 205" corresponds to "at least one data input" "for detecting measurement data" in the Amended Invention.

(F) In Cited Invention 1, "in the state monitoring mode, a measurement value is acquired, whether the acquired value has exceeded the prescribed value in an abnormal direction is checked, and when the value has exceeded, an alarm is issued to an alarm destination." It is obvious that the "control section 222" in Cited Invention 1 includes a mechanism for outputting a result of "checking whether or not the acquired value has exceeded the prescribed value in an abnormal direction or not."

Therefore, it can be said that the "control section 222" in Cited Invention 1 is configured to "include at least one output mechanism for outputting an analysis result..." in the "analysis mechanism" in the Amended Invention.

(G) The "medical monitoring control system 201" in Cited Invention 1 corresponds to the "device" in the Amended Invention.

(H) The "CPU 221" in Cited Invention 1 corresponds to the "control unit" in the Amended Invention.

(I) The "external storage medium 204" in Cited Invention 1 corresponds to the "program memory" in the Amended Invention.

(J) The "extended program" in Cited Invention 1 corresponds to the "program module" in the Amended Invention.

(K) Cited Invention 1 is configured so that "in selecting an extended program, the display 241 displays all programs stored in the external storage medium, and an "F6" key (four-direction key) of the operation section 242 is operated for moving up/down a cursor 251, to specify a desired extended program." It is obvious that the "external storage medium 204" in Cited Invention 1 "stores" "a plurality of" "extended programs."

Therefore, the "external storage medium 204" in the Cited Invention is configured so that "the program memory stores a plurality of programs."

(L) Cited Invention 1 is configured so that "in selecting an extended program, the display 241 displays all programs stored in the external storage medium 204, and an "F6" key (four-direction key) of the operation section 242 is operated for moving up/down a cursor 251, to specify a desired extended program." The multiple extended programs are specified by operating the "F6" key (four-direction key) of the operation section 242 and selectively actuated.

It is obvious that, in the state monitoring mode of Cited Invention 1, the CPU 221 arranged in the control section 222 acquires a measurement value of a monitoring sensor to be used by the extended program for monitoring, in accordance with the specified extended program, and checks whether the acquired value has exceeded a prescribed value in an abnormal direction.

Therefore, Cited Invention 1 includes a configuration of the Amended Invention, "a plurality of program modules that can be activated selectively or in partial or

complete combination as a function of an externally specifiable control instruction so that the activated program modules provide data for the selected analysis result."

(M) The "operation section 242 including operation keys and function keys" in Cited Invention 1 corresponds to the "interface" in the Amended Invention.

(N) In Cited Invention 1, the "control section 222," "external slot 205," and "operation section 242 including operation keys and function keys" constitute a part of the "mobile phone body 202." The "external storage medium 204" "is mounted on the external memory slot 203" of the "mobile phone body 202" "when the mobile phone body 202 is used as a part of the Medical monitoring control system 201." Thus, the "control section 222 with a CPU 221," "external slot 205," "external storage medium 204," and "operation section 242 including operation keys and function keys" can be considered as one mechanism collectively.

The analysis mechanism for analyzing at least one biological parameter of living organism in the Amended Invention includes a data input, an output mechanism, a control unit, a program memory, and an interface.

As indicated in (C) and (F), the "control section 22" in the Cited Invention includes a function of "analyzing at least one biological parameter of a living organism" in the "analysis mechanism" in the Amended Invention, and a configuration, "including at least one output mechanism for outputting an analysis result..." As indicated in (E), (H), (I), and (M), the "external slot 205," "CPU 221," "external storage medium 204," and "operation section 242 including operation keys and function keys" in Cited Invention 1 correspond to the "data input," "control unit," "program memory," and "interface," respectively in the Amended Invention.

In light of the above, an integrated section formed of the "control section 222 with a CPU 221," "external slot 205," "external storage medium 204," and "operation section 242 including operation keys and function keys" in the Cited Invention; in other words, a section obtained by excluding the display 241 from the mobile phone body 202 with the external storage medium 204 connected to the external memory slot 203, includes the function and configuration of the "analysis mechanism" in the Amended Invention.

Therefore, it can be said that in Cited Invention 1, the section obtained by excluding the display 241 from the mobile phone body 202 with the external storage medium 204 connected to the external memory slot 203 corresponds to "at least one analysis mechanism for analyzing at least one biological parameter of at least one living organism" in the Amended Invention.

(O) The meaning of the "data section" in the Amended Invention is not clear. In light of the description in the detailed description of the invention, according to the description in [0025], "In the inventive device, the selected sensor or the measuring instrument being used is connected to the assigned analysis unit by a data section. The data section can be realized in wireless or wired fashion," the "data section" can be recognized as a "data transmission medium."

Thus, the configuration in Cited Invention 1, "The insertion card part 231 of the wired monitoring unit 206 is connected" "to the external slot 205 of the mobile phone body 202," and "The first to N-th monitoring sensors 2331-233N" are "connected" to

the "distributor 232 connected to" "the insertion card part 231," corresponds to the configuration of the Amended Invention, "the sensor and the analysis mechanism are connected to each other by a data section."

(P) The "display 241" in Cited Invention 1 corresponds to the "display mechanism" in the Amended Invention.

It is obvious, in Cited Invention 1, that the "display 241" is connected to the "control section 222" by wiring, or the like, (corresponding to the "data section" in the Amended Invention). Therefore, Cited Invention 1 has a configuration of the Amended Invention, "the display mechanism and the analysis mechanism are connected to each other by a data section."

(Q) According to the above (A) to (P), the Amended Invention and Cited Invention 1 correspond to each other in the following points:

"A device comprising at least one analysis mechanism for analyzing at least one biological parameter of a living organism, the mechanism including at least one data input for detecting measurement data from at least one sensor, which measures at least one biological parameter of the living organism, and at least one output mechanism for outputting an analysis result,

wherein the analysis mechanism includes a control unit and a program memory, the program memory containing a plurality of program modules that can be activated selectively or in partial or complete combination as a function of an externally specifiable control instruction so that the activated program modules provide data for the selected analysis result,

wherein the sensor and the analysis mechanism are connected to each other by a data section,

wherein a display mechanism is provided, the display mechanism and the analysis mechanism being connected to each other by a data section, and

wherein the analysis mechanism comprises an interface,"

and they are different in the following points.

(Different Feature 1)

In the Amended Invention, the interface is "for an input of data not metrologically acquired," while Cited Invention 1 does not include such specification.

(Different Feature 2)

In the Amended Invention, "an analysis module is provided for combining analysis parameters based on a measurement parameter and/or an input parameter," while Cited Invention 1 does not include such specification.

(Different Feature 3)

In the Amended Invention, "automatic configuration of the device can be implemented as a suggestion to an operator," while Cited Invention 1 does not include such specification.

D Judgment

We will examine the above different features below.

(A) Regarding Different Feature 1

According to (Citation 3-A), (Citation 3-D), and (Citation 3-F), Cited Document 3 describes "a home-care medical system including a medical device 8 to be installed in a house of each user and comprising a medical terminal 1 which measures blood pressure, heart rate, and electrocardiogram of a user, and inputs answers to questions from a medical institution, and communication means 2."

(Citation 3-C) describes that a user uses the input means of the medical terminal to input answers to the questions, "Do you have pain in your chest?," "Do you feel listless?," or the like. The answers to the questions are based on senses of a user and can be considered as data not metrologically acquired.

(Citation 3-E) describes that a user uses the input means of the medical terminal to input data on urinalysis results determined by the user visually on the basis of the color check chart. The urinalysis result data is determined visually by the user and can be considered as data not metrologically acquired.

Therefore, it can be recognized that Cited Document 3 describes "inputting data not metrologically acquired to a medical terminal 1 of a medical device 8 installed in a house of each user, in a home-care medical system including the medical device 8 to be installed in a house of each user and comprising the medical terminal 1 which measures blood pressure, heart rate, and electrocardiogram of a user, and inputs answers to questions from a medical institution, and communication means 2" (hereinafter referred to as "Technical matters described in Cited Document 3").

Cited Invention 1 and the Technical matters described in Cited Document 3 relate to a common technical field as a medical monitoring control system which can monitor health status of a user, such as a patient, located at home or far from a medical institution. It is obvious that "inputting data not metrologically acquired" in the Technical matters described in Cited Document 3 is significant also in Cited Invention 1. Therefore, there is a sufficient motivation in Cited Invention 1 for employing the Technical matters described in Cited Document 3.

Thus, in Cited Invention 1 a person skilled in the art can easily obtain the configuration of the Amended Invention according to Different feature 1 by inputting data not metrologically acquired through the operation section 242, on the basis of the Technical matters described in Cited Document 3.

(B) Regarding Different Feature 2

It is well known at the time of the priority date of the application, without specifying documents, that evaluation values (corresponding to the "analysis parameters based on a measurement parameter and/or an input parameter" in the Amended Invention) obtained from measurement data or the like, in medical/health management, are presented, by calculating evaluation values (corresponding to the "analysis parameters" in the Amended Invention), such as body composition or body-mass, from measurement data (corresponding to the "measurement parameter" in the Amended Invention), such as weight, height, and impedance, and age/sex data (corresponding to the "input parameter" in the Amended Invention), or by performing comprehensive

evaluation on blood (corresponding to the "analysis parameter" in the Amended Invention) from multiple pieces of measurement data (corresponding to the "measurement parameter" in the Amended Invention) relating to the blood.

In health checkup for various kinds of inspections, a comprehensive evaluation value indicating a comprehensive health status is determined from various kinds of evaluation values for presentation, generally.

In Cited Invention 1, which is a medical monitoring control system having a plurality of monitoring sensors, it is obviously significant to present a health status of a user to be grasped from measurement values of the monitoring sensors to the user.

Consequently, a person skilled in the art can easily conceive of adding a function, in Cited Invention 1, on the basis of the above well-known matters, of determining multiple kinds of evaluation values in accordance with measurement items from measurement values of monitoring sensors, and determining a comprehensive evaluation value indicating a comprehensive health status from the above value, to be presented to the user.

It can be said that the configuration of determining multiple kinds of evaluation values in accordance with measurement items from measurement values of monitoring sensors, and determining a comprehensive evaluation value indicating a comprehensive health status from the above value, to be presented to the user, corresponds to combining analysis parameters based on a measurement parameter and/or an input parameter in the Amended Invention according to Different Feature 2.

Therefore, a person skilled in the art can easily obtain the configuration of the Amended Invention according to Different Feature 2 as a result by adding a function of determining multiple kinds of evaluation values in accordance with measurement items from measurement values of monitoring sensors, and determining a comprehensive evaluation value indicating a comprehensive health status from the above value, to be presented to the user, in Cited Invention 1, on the basis of the above well-known matters, or a function of "providing the values for actually existing questions" described in the detailed description of the invention.

(C) Regarding the Different Feature 3

According to (Citation 4-A) and (Citation 4-D), Cited Document 4 describes "a health management system in which buttons for selecting the type of disease to be subjected to care-service are displayed on a display screen, a server starts a program for health check corresponding to a disease selected by clicking a button indicating the disease with a mouse, and displays a care-service selection screen on the display screen, and the server starts a program for health check of a user when a service for health check is selected by clicking a health-check button with the mouse, displays a vital value input screen, and displays an input section used by the user for inputting measurement values of user data, wherein items for the measurement values displayed on the input section are required management items of daily management data corresponding to the selected disease."

In other words, Cited Document 4 describes "a health management system that provides multiple health check programs corresponding to multiple diseases, in which a server starts a health check program corresponding to a disease selected, displays measurement items corresponding to the disease, and prompts a user to measure the measurement items and input data of measurement values" (hereinafter referred to as

"Technical matters described in Cited Document 4").

Cited Invention 1 and the Technical matters described in Cited Document 4 relate to a common technical field as a medical monitoring control system which can monitoring health statues of a user, such as a patient, located at home or far from a medical institution. In the Cited Invention 1, it can be assumed that the user, such as a patient, using the system at home is highly likely to be bothered in daily life when wearing many monitoring sensors. Therefore, there is a sufficient motivation in Cited Invention 1 for displaying measurement items corresponding to the extended program to be executed by the CPU 221 and prompting a user at home to measure the measurement items and input measurement values of data, as described in the Technical matters described in Cited Document 4.

Thus, a person skilled in the art can easily conceive of displaying measurement items corresponding to the extended program to be executed by the CPU 22 and prompting a user at home to measure the measurement items and input measurement values of data, on the basis of the Technical matters described in Cited Document 4, in Cited invention 1.

In the Technical matters described in Cited Document 4, the description, "a server starts a health check program corresponding to a disease selected, displays measurement items corresponding to the disease, and prompts a user to measure the measurement items and input data," is nothing less than the fact that the server automatically selects measurement items required for executing the health check program and prompts a user for measurement using a measuring instrument required for measuring the measurement items and data input of measurement values. It can be said that the description means that "the server automatically selects a measuring instrument required for executing a health check program and suggests starting it to a user," accordingly.

It can be said that the description, "the server automatically selects a measuring instrument required for executing a health check program" means "executing automatic configuration of the measuring instrument," and that the description, "suggests starting" the automatically selected measuring instrument "to a user," means "executing automatic configuration of a measuring instrument as a suggestion to a user."

In light of the above, it can be said that the technical matters described in Cited Document 4 have a configuration of the Amended Invention according to Different Feature 3.

Thus, a person skilled in the art can easily obtain the configuration of the Amended Invention according to Different Feature 3 as a result by displaying measurement items corresponding to the extended program to be executed by the CPU 221 and prompting a user at home to measure the measurement items and input measurement values of data, on the basis of the technical matters described in Cited Document 4, in Cited Invention 1.

(D) Working effect exerted by the Amended Invention

The effect exerted by the Amended Invention is within the scope that can be

expected by a person skilled in the art from the matters described in Cited Documents 1, 3, and 4 and the well-known matters at the time of the priority date of the application.

(E) Summary

As described above, the Amended Invention can be easily invented by a person skilled in the art on the basis of Cited Invention 1, technical matters described in Cited Document 3 and Cited Document 4, and the well-known matters at the time of the priority date of the application.

Therefore, the appellant should not be granted a patent for the Amended Invention independently at the time of patent application under the provisions of Article 29(2) of the Patent Act.

3 Closing on the decision to dismiss amendment

As described above, it cannot be said that the appellant can be granted a patent for the Amended Invention independently at the time of patent application. Therefore, the Amendment violates the provisions of Article 126(7) of the Patent Act as applied mutatis mutandis pursuant to the provisions of Article 17-2(6) of the Patent Act, and, therefore, it should be dismissed under the provisions of Article 53(1) of the Patent Act as applied mutatis mutandis pursuant to the provisions of Article 159(1) of the Patent Act.

No. 3 Regarding the Invention

1 The Invention

As the amendment dated on June 26, 2017 was dismissed as above, the invention (hereinafter referred to as "the Invention") according to Claim 1 of the present application is as specified by the matters described in Claim 1 of the scope of claims in the written amendment submitted on June 29, 2015 (see the descriptions in No. 2 [Reason] 1).

2 Reasons for refusal stated in the examiner's decision

The outline of the reasons for refusal stated in the examiner's decision is as follows.

(Reason 1) (Omitted)

(Reason 2) (Enablement requirement) This application does not meet the requirements stipulated in Article 36(4)(i) of the Patent Act in the description of the detailed description of the invention, in the following points.

(Reason 3) (Inventive step) The invention according to Claims 1 to 3 of the application could be easily made on the basis of the invention described in the following Cited Document 1 and the matters described in Cited Document 3 and Cited Document 4 distributed or available to public over an electric communication network before the priority date of the application, and the invention according to Claims 4 to 7 could be easily made on the basis of the invention described in following Cited Document 1 and

the matters described in Cited Document 2 to Cited Document 4 distributed or available to public over an electric communication network before the priority date of the application, by a person with usual knowledge in the technical field to which the present invention belongs before filing date. Therefore, the appellant should not be granted a patent for it under the provisions of Article 29(2) of the Patent Act.

Cited Document 1: Japanese Unexamined Patent Application Publication No. 2003-168178
Cited Document 2: Japanese Unexamined Patent Application Publication No. H05-007560
Cited Document 3: Japanese Unexamined Patent Application Publication No. H10-334161
Cited Document 4: Japanese Unexamined Patent Application Publication No. 2002-056099

3 Regarding (Reason 2) the requirements stipulated in Article 36(4)(i) of the Patent Act (Enablement requirement)

The Invention includes, as matters specifying the invention, the description, "automatic configuration of the device can be implemented as a suggestion to an operator," corresponding to the Matters specifying invention 2 of the Amended Invention examined in No. 2 [Reason] 2.

Therefore, since the Amended Invention includes the Matters specifying invention 2, the description in the detailed description of the invention is not described clearly and sufficiently for a person skilled in the art to carry out the Amended Invention, as described in No. 2 [Reason] 2 (2). The description in the detailed description of the invention is not described clearly and sufficiently for a person skilled in the art to carry out the Invention, accordingly.

4 Regarding (Reason 3) the provisions in Article 29(2) of the Patent Act (Inventive step)

(1) Cited Documents

The matters described in Cited Documents 1, 3, and 4 cited in reasons for refusal of the examiner's decision are as described in No. 2 [Reason] 2 (3) B.

(2) Comparison/Judgment

The Invention is formed by deleting the matters specifying the invention, "an analysis module is provided for combining analysis parameters based on a measurement parameter and/or an input parameter," from the Amended Invention examined in No. 2 [Reason] 2.

The Amended Invention corresponding to an invention including all matters specifying the invention of the Invention and other matters additionally could be easily invented by a person skilled in the art on the basis of Cited Invention 1, the technical matters described in Cited Document 3 and Cited Document 4, and the well-known matters at the time of the priority date of the application, as described in No. 2 [Reason] 2 (3). Therefore, the Invention (note by the body: having no Different Feature 2 with Cited Invention 1) can be also easily invented by a person skilled in the art on the basis of Cited Invention 1 and the technical matters described in Cited Document 3 and Cited

Document 4.

5 Regarding the appellant's allegation in the written statement

The appellant alleges in the written statement submitted on November 29, 2017 that the reasons for refusal can be resolved by amending the description in Claim 1 of the scope of claims to the following description (hereinafter referred to as "Amendment draft"),

"[Claim 1]

A device comprising at least one analysis mechanism for analyzing at least one biological parameter of a living organism, the mechanism including at least one data input for detecting measurement data from at least one sensor, which measures at least one biological parameter of the living organism, and at least one output mechanism for outputting an analysis result,

wherein the analysis mechanism includes a control unit and a program memory, the program memory containing a plurality of program modules that can be activated selectively or in partial or complete combination as a function of an externally specifiable control instruction so that the activated program modules provide data for the selected analysis result,

wherein the sensor and the analysis mechanism are connected to each other by a data section,

wherein a display mechanism is provided, the display mechanism and the analysis mechanism being connected to each other by a data section,

wherein the analysis mechanism comprises an interface for an input of data not metrologically acquired,

wherein an analysis module is provided for determining and analyzing only the measurement values required for the program modules which have in fact been selected, as a function of the program modules selected during the configuration step, and combining various measurement parameters and/or input parameters at that time."

However, the description in the underlined part of the Amendment draft, "an analysis module for combining various measurement parameters and/or input parameters" is not described in the detailed description of the invention. As described in [0016] of the detailed description of the invention (see No. 2 [Reason] 2 (2) A (A)), the analysis module does not combine the measurement parameters and/or input parameters but the analysis parameters.

It can be recognized that the description underlined in the Amendment draft specifies that the analysis module only determines and analyzes only the measurement values required for the program modules which have in fact been selected as a function of the program modules selected during the configuration step. In connection with that, paragraph [0034] of the detailed description of the invention describes "According to another variant, it is provided that, to minimize the required analysis time as a function of the modules selected during the configuration step, only the measurement values required for the modules which have in fact been activated are determined and selected." However, there is no description that the analysis module "determines and selects only the measurement values required."

Thus, it cannot be recognized that the Amendment draft is based on the description of the detailed description of the invention, and the Amendment draft falls

under addition of new matter or violation of requirements for support. The appellant should not be granted a patent for it, accordingly.

The "configuration" in the Amendment draft does not clearly indicate the object of the configuration. Even if it indicates "automatic configuration of the device," the Amendment draft does not meet the enablement requirement, as indicated in No. 2 [Reason] 2 (2) B. Therefore, the Amendment draft does not clarify requirement or enablement requirement. Thus, the appellant should not be granted a patent for it, accordingly.

Therefore, the Amendment draft of the appellant cannot be accepted.

No. 4 Closing

As described above, the description in the detailed description of the invention of the present application fails to comply with the provisions of Article 36(4)(i), and the appellant should not be granted a patent for the Invention under the provisions of Article 29(2) of the Patent Act.

The present application should be rejected without mentioning the invention according to other claims.

Therefore, the appeal decision shall be made as described in the conclusion.

July 2, 2018

Chief administrative judge: MISAKI, Hitoshi
Administrative judge: WATADO, Masayoshi
Administrative judge: TOMATSU, Shutaro