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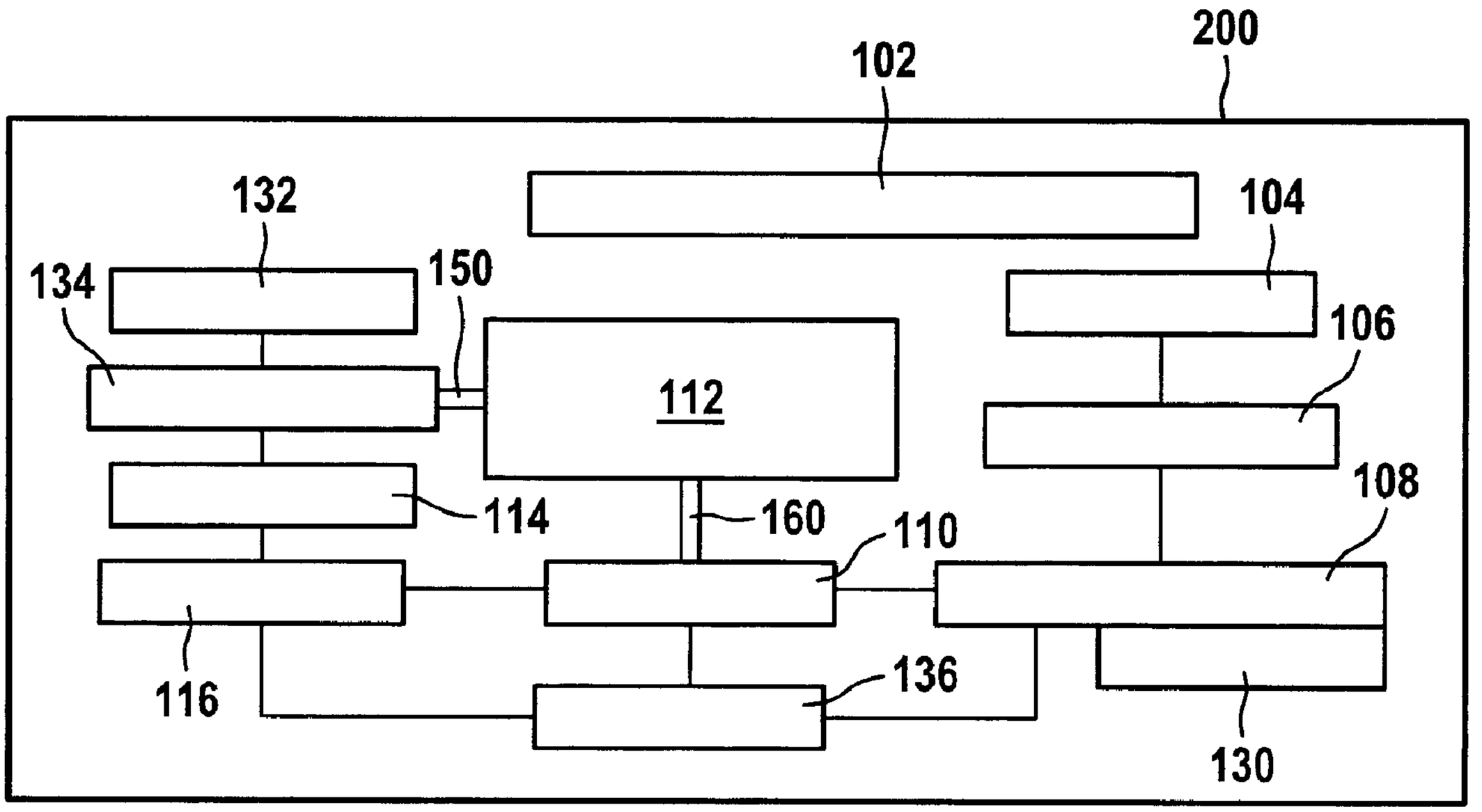
(54) Title: MEASUREMENT SYSTEM WITH DISTRIBUTED FUNCTIONS



(57) Abrégé/Abstract:
Analysis system (300), comprising an analysis appliance and a test strip magazine (134), for determining an analyte in a body fluid, characterized in that the analysis system contains a group (120) of reusable components and a further group (140) of components of a disposable article from which components (132, 134) without any electronics can be disconnected at a disconnection point (302). Critical interfaces (150, 160) are assembled and tested during production of the appliance.

Abstract

Analysis system (300), comprising an analysis appliance and a test strip magazine (134), for determining an analyte in a body fluid, characterized in that the analysis system contains a group (120) of reusable components and a further group (140) of components of a disposable article from which components (132, 134) without any electronics can be disconnected at a disconnection point (302). Critical interfaces (150, 160) are assembled and tested during production of the appliance.

Measurement system with distributed functions

Prior art

Integrated systems for blood glucose measurement have been available commercially for some time. These integrated systems comprise a measurement appliance, a battery which can be inserted in it, and a test strip magazine. The test strip magazine may be in the form of a disc (Bayer Dex) or may be configured in the form of a drum (AccuChek Compact). The test strip magazines generally contain coding means, for example in the form of a barcode for transferring batch-specific information to the measurement appliance on which the test strip magazine is used. For cost reasons, the information content contained in the coding is limited. Electronic coding means, such as ROM keys, which contain a large amount of information and in consequence are intrinsically correspondingly more flexible are not used.

Coding means such as these which have a high information content are intended to be used in more recent developments. This therefore results in the problem on the one hand of reducing the costs and on the other hand of solving the problem of the remaining electronics scrap in conjunction with the domestic refuse problem.

Reliable coupling of the coding means to the appliance represent one critical interface. Electrical contacts for an ROM key or a smart card require compliance with tight mechanical tolerances and the use of contacts which can be reused many times. Although RFID chips can be read without contact, they lead, in the final analysis, to higher costs however and to considerably greater energy consumption.

WO 2005/006985 A2 relates to an analysis appliance and an analysis method for body fluids. The analysis appliance has a housing, which is provided with a holder for a body part to engage in, as well as an opposing bearing, which can be moved between a release point and an effective position with respect to the holder, for the body part. The analysis appliance also has a piercing member which can be inserted with a linear piercing movement into the body part resting on the opposing bearing, as well as a test ribbon for application of body fluid emerging from the body part. The test ribbon is held in a test ribbon unit. Furthermore, the analysis appliance has a detection unit for examination of the body fluid applied to a section of the test ribbon.

WO 2004/047642 A1 relates to an analysis appliance for body fluids in which a test strip ribbon is provided which absorbs the body fluid. An unused supply of the test strip ribbon in held in a supply area. The part of the test strip ribbon which has been contaminated with body fluid is stored in a storage area. An area of the test strip ribbon is exposed in an exposure area between the supply area and the storage area, in order to absorb the body fluid, with the exposure area having a point on which the test medium for the body fluid is provided.

WO 2004/056269 A1 likewise relates to an analysis appliance for body fluids. The analysis appliance has a test strip ribbon to which the body fluid is applied. The test strip ribbon has a ribbon and sections which are provided with a test medium, with a section without any test medium extending between successive test media sections. The analysis appliance also has a supply area, having a housing which contains an uncontaminated test strip supply in the form of a ribbon, with the housing having an opening. The supply area furthermore has sealing devices for sealing the opening from the environment. When the opening is sealed, a section of the test strip ribbon without any test medium is located between the sealing element and a surface which is typically a wall of the housing.

In the case of the analysis appliances known from the prior art, in particular according to WO 2005/006985, the analysis appliance is very largely based on integration of the magazine holding the test strips. There is also a piercing aid in the analysis appliance, and this likewise has a disadvantageous influence on the physical size of the analysis appliance.

The development trends for analysis appliances which can be handled by the user are heading towards future containers for test elements being in the form of ribbon cassettes. The test media are held in the cassettes as a ribbon which, for example, is provided in places with a single-layer or multiple-layer coating for glucose determination. Furthermore, these cassettes contain mechanical elements for transport of the test strips, which are in ribbon form, as well as keys, in particular for the outlet opening of the unused ribbon material from a supply chamber within the magazine. In the case of the solution known from WO 2005/006985 A2, the magazine must be inserted into the analysis appliance thus leading, not least, to the analysis appliance according to WO 2005/006985 A2 being physically relatively large.

WO 2006/002432 A1 relates to an appliance for dispensing test strips. There is at least one opening on the housing of the instrument. A stack of test strips is pressed against the housing in a first direction by a feed mechanism, with one of the test strips, which are held in the form of a stack in the housing, being positioned such that it can be moved out of the housing. A number of movable seals are designed such that, when in a closed position, the seals seal the at least one opening and represent a package which is essentially moisture-tight and essentially air-tight. One of the movable seals is designed such that one of the multiplicity of test strips can be moved through in an open position.

In virtually all the appliances which are known from the prior art, the critical interface between the disposable (which should be understood as meaning test strips and the test strip magazine) and the measurement appliance is produced by the customer. The physical complexity and the costs for the interface are considerable without being able to ensure effective functional reliability in all cases.

Description of the invention

The invention is based on the object of simplifying the coupling between an analysis appliance and a test element magazine, designing it to be more reliable, avoiding electronics scrap, and saving costs by reuse.

The invention proposes that a measurement unit for evaluation of the test elements which have been wetted with a human body fluid be integrated in a magazine in which the test strip material is stored in the form of a ribbon. The measurement unit comprises optics associated with electronics with LEDs, photodiodes and at least one ASIC. The at least one ASIC preferably contains a serial interface which, for example, can be fitted to a rear face of the housing of the magazine, so that the analysis appliance can simply be plugged onto the serial interface in order to emit preprocessed data which is present at the serial interface, for example relating to a glucose measurement. The magazine proposed according to the invention and which has a greater level of integration, for holding the test strip material, which is in the form of a ribbon, allows the magazine to be mechanically coupled to the analysis appliance more easily. Signals are transmitted robustly via the serial interface, which may be provided either on the rear face of the housing of the magazine or one of its side surfaces, by means of a serial protocol between the magazine, which has a higher level of integration, and the analysis appliance which can easily be connected thereto.

This creates the basis for smaller physical forms both for the analysis appliance and for the magazine, which is in form of a cassette. Because of the fact that the more highly integrated magazine proposed according to the invention need no longer be inserted or pushed into the analysis appliance, but can simply be plugged onto it, this results in greater design freedom for the physical size.

The solution proposed according to the invention means that the moisture within the chamber of the magazine, in which the unused test strip supply is stored on a wound coil, can also be measured by means of moisture sensors, as a result of the electronics being integrated in the cassette. Moisture ingress adversely affects the long-term use of the test strip material. The solution proposed according to the invention allows the moisture, which is either contained in this test strip material as a result of the production process or has entered it via an opening during use or while the test material is being fed out of the supply chamber, to be determined, thus allowing prediction of the remaining useful life of the test strip material stored in the supply chamber. The more highly integrated magazine proposed according to the invention is therefore able to provide the user with information about the quality and about the useful life which may remain for the unused test material supply.

The magazine which holds the test material which is in the form of a ribbon as proposed according to the invention also a board which can be detachable connected to the magazine holding the test strip material, on which board at least one energy store is also accommodated. When the board is fitted to the housing of the magazine, for example by means of guide rails, or a bayonet fitting, for example by pushing it on, an electrical connection is made between the energy store arranged on the board and the electronics, for example, the ASIC, within the housing of the more highly integrated magazine. An ROM key for coding is also arranged on the board. On the basis of the proposed solution, the board together with ROM key and energy store can be disconnected from the cassette, which holds the test strip material that is in the form of a ribbon, before disposal. While the contaminated test strip material can be disposed of in the domestic refuse, the board can either be disposed of during the course of electronics component disposal; a preferable option is for the user to collect each of the boards and to recycle them. The test strip material which can no longer be reused is disconnected, and the components which can be recycled, for example the board, can be fed back into the material cycle, and can be reused.

Drawing

The invention will be described in more detail in the following text with reference to the drawing, in which:

Figure 1 shows a configuration of an appliance known from the prior art (AccuChek Compact) in which the elements of the appliance are combined in one group, and the elements of a disposable article are combined in another group,

Figure 2 shows an analysis appliance which is entirely in the form of a disposable system, and

Figure 3 shows a schematic illustration of the measurement system proposed according to the invention, with distributed functions, with the components of the analysis appliance being combined in one group and the components of an extended disposable article being combined in another, separate group, with the disposable group being formed from two parts which can be disconnected from one another.

Exemplary embodiments

In the following text, the expressive magazine means a holding element in which a number of test elements are held. The magazine may be in the form of a cassette, in which case the supply of test elements can be presented, for example in form of wound coils with one coil for unused test elements and one coil for used test elements. The magazine may also be in the form of a stack, in which case individual test elements can, for example, be held in strip form arranged vertically, horizontally or at an angle to one another. The magazine may also be in the form of a disc-type body on whose circumference individual test elements are held in slots, with a drive moving the magazine configured in the form of a disc on from one test element to another.

The present invention will be described in the following text with reference to an appliance having a test element supply in the form of ribbon strips, and with an optical evaluation capability, although the invention is not intended to be restricted to an embodiment such as this. The invention can be implemented just as well for a test

element which can be evaluated electrochemically and is in the form of a strip, and which is held in a stack magazine or some other embodiment.

In the following text, test elements should be understood as meaning a medical consumable material which, for example, is stored in strip form in the magazine and is used to determine an analyte in a human body fluid, for example blood glucose, lactate or cholesterol and the like. The expression opening in the following text should be understood as meaning an outlet opening for the medical consumable material which, for example, is in the form of test strips, from the magazine, and which for example may be in the form of a seal fitted to the housing of the magazine or a longitudinal slot with sealing lips in order to prevent undesirable ingress of moisture in the interior of the magazine holding the test elements.

The illustration in Figure 1 shows an analysis appliance known from the prior art. By way of example, this analysis appliance is the AccuChek Compact system produced by the applicant. The appliance 100, whose major components are illustrated schematically in Figure 1, has an appliance housing 102 which is generally in the form of a plastic injection-moulded part. There is a display 104 in the appliance housing 102, on which the user can read the results obtained, for example the blood glucose content, cholesterol content and much more. The display 104 is integrated in the appliance housing 102 and is controlled via a display controller 106. The display controller 106 is itself connected to calculation electronics, which are annotated with the reference symbol 108 and in which the data displayed on the display 104 is calculated. The calculation electronics 108 in the appliance housing 102 are themselves in turn connected to measurement electronics 110, which are likewise accommodated in the appliance housing 102. A first critical interface 150 connects the disposable (that is to say the disposable part) and the measurement appliance to one another. The first critical interface must be reproduced by the customer whenever each unused disposable is newly inserted, thus requiring correspondingly tight tolerances and therefore increased production costs.

The measurement electronics 110 are connected to a measurement peripheral 112 via a second critical interface 160. By way of example, the measurement peripheral of the appliance housing 102 of the appliance 100 as illustrated in Figure 1 contains an optical evaluation system as well as other electronic components, for example a potentiometer and an ammeter for determining the current level. The electrical components which are integrated within the measurement peripheral 112 in the

appliance housing 102, (the above list does not include all of these components) are used to evaluate a test strip which has been stored in a test strip magazine 134 and has been wetted with a body fluid such as blood, for example, by means of an opening which has previously been produced in the human skin, which body fluid is then examined for at least one analyte, using a chemical or optical process.

Furthermore, the appliance housing 102 contains a drive 114 which is used, for example, to feed test strips from the test strip magazine 134. The drive 114, which is generally an electrical drive has an associated drive controller 116.

As can be seen from the illustration in Figure 1, the components mentioned above, that is to say the appliance housing 102, the display 104, its display controller 106, the calculation electronics 108, the measurement electronics 110, the measurement peripheral 112 together with its components including optics, ammeter, potentiometer etc. as well as the drive 114 and as well as the drive controller 116 all form elements of the appliance 100, and are combined in a group 120 in the illustration shown in Figure 1.

The illustration in Figure 1 also shows that a coding means 130 and a waste container 132 which is used to hold used test strips from the test strip magazine 134 represent components of a disposable article, which is annotated with the reference symbol 140 in the illustration in Figure 1. The energy store 136 represents a further and separate energy store. In this case, as in the case of many other appliances in daily use, the battery contacts which make contact with the energy stores, preferably in the form of batteries, represent a source of frequent malfunctions.

In the solution illustrated in Figure 1, the first interface 150 is located between the group 140 of components of the disposable article and the measurement peripheral 112 of the group 120 of components of the appliance, while the second critical interface 160 is located with the group 120, that is to say the components of the appliance. The coding means 130, which is a component of the group 140, that is to say a component of the disposable article, must be very simple in this solution and in consequence has only a restricted information content. This is because the coding means 130 represents an element of the group 140 which characterizes the disposable article. Furthermore, the energy store 136, which is generally a battery represents a further disposable article, which represents a separate consumable item and is not customer-friendly. The solution based on the appliance 100 and sketched in Figure 1

admittedly offers the advantage that the generally expensive and therefore high-value, components are reused, this advantage does not, however, make up for the disadvantages that have been matched.

The illustration in Figure 2 shows a further embodiment variant of an analysis system which is configured in its entirety as a disposable system.

As can be seen from the illustration in Figure 2, the appliance housing 102, the display 104 integrated in it, the display controller 106, the calculation electronics 108 and the coding means 130 which interacts with these electronics, the measurement electronics 110, the measurement peripheral 112 are connected to one another by means of the second critical interface 160, and the drive 114, the drive controller 116, the energy store 136 as well as the test strip magazine 134, which is connected to the measurement peripheral 112 via the first critical interface, together with the waste container 132 represent a disposable system 200. This disposable system 200 illustrated schematically in Figure 2 has the disadvantage that expensive components, such as the electronics and the display as well as the appliance housing, are also disposed of after a number of measurements, although it offers the advantage that it allows greater integration of the electronic components.

Figure 3 illustrates the analysis system proposed according to the invention with the functions arranged in a redistributed form, and this will be compared in the following text with the known embodiments shown in Figures 1 and 2.

As can be seen from Figure 3, the group 120 which comprises the elements of the analysis appliance comprises the appliance housing 102, the display 104, its display controller 106, the calculation electronics 108, as well as the drive 114 and its controller 116. This means that expensive appliance components, such as the drive 114, its controller and the display together with its controller 106 and the calculation electronics 108 are reused when the analysis system as illustrated in the Figure 3 and with distributed functions 300 is fitted with a new test strip magazine 134.

As can also be seen from the illustration in Figure 3, the group 140 which contains the elements of the disposable article comprises the waste container 132, the already mentioned test strip magazine 134 and, in this case, the measurement peripheral 112 and the measurement electronics 110, which are associated with a coding means 130, as well as an energy store 136. These components represent the elements of the group

140, which can be disposed of separately after use. The group which is annotated with the reference symbol 140 in Figure 3 and comprises the elements of the disposable article includes the first critical interface 150 and the second critical interface 160. In the analysis system proposed according to the invention, the first critical interface 150 coincides with a disconnection point 302, at which the user connects the test strip magazine 134 together with the waste container 132 associated with it to the measurement peripheral 112. The disconnection point 302, which coincides with the first critical interface 150, advantageously allows the group 140 which represents the disposable article of the analysis system proposed according to the invention to be disconnected. The consumable materials without any electronics, for example the waste container 132 and the test magazine 134 can be disposed of in the domestic refuse while, a disconnection of the group 140 at the disconnection point 302, the electronic components, that is to say the measurement peripheral 112, the measurement electronics 110 connected to it via the second critical interface 130, together with coding means 130 associated with these electronics, in particular such as the battery storage device 136, to be recycled or at least to be supplied to an electronic strap disposal system, which was not possible in the case of the appliance 100 illustrated in Figures 1 and 2, or the disposable system 200 illustrated in Figure 2.

As can also be seen from the solution proposed according to the invention that is illustrated schematically in Figure 3, the first and the second critical interface 150, 160 are located in a component which is connected during production, that is to say the group 140. All the critical interfaces are joined and checked by the manufacturer. The functional reliability is improved, with less stringent requirements of mechanical tolerances, therefore reducing the production costs.

The configuration of the group 140, which comprises the elements of the disposable article, with the disconnection point 302 makes it possible for the user of the analysis system as illustrated in Figure 3 to separately dispose of the electronic components 112, 110, 136 in the group 140 of the disposable article, or send them for recycling, without any problems. The separation between the waste container 132, which can be disposed of in the domestic reference, and the test strip magazine 134 without any test strips in it from the electronic components 110, 112, 130, 136 takes place at the interface 132, and this is extremely simple and convenient for the user.

As can also be seen from the schematic illustration in Figure 3, the coding means 130 is directly associated with the measurement electronics 110. The direct association of

the coding means 130 with the measurement electronics 110 has the advantage, to quote just one example, that this allows a higher level of integration, that is to say a smaller physical size of the appliance with an increase in the functionalities and a reduction in the costs, because of the lack of plug connections, which are susceptible to defects. Furthermore, it is possible to match the measurement electronics and measurement apparatus with a new disposable to the latest state of development, and to update the measurement electronics and measurement apparatus by means of a new disposable, so that the appliance 100 that is in use can be reused by the user. In this case, the disposable then represents the medium via which new information is passed to the appliance 100.

As can be seen from the illustration in Figure 3, the group 140 of components of the disposable article includes the coding means 130. In comparison to the solutions according to the prior art, in which the coding means 130 contained only a limited amount of information, the coding means 130 which, according to the invention, is integrated in the group 140 of the disposable article, may be in the form of an ROM key or the like, for example, thus providing flexibility with regard to the information content. In the case of electronic storage media, the costs are generally split in a ratio of 1/3 for the storage chip, 1/3 for the housing and 1/3 for electrical contacts. The solution proposed according to the invention makes it possible to save 2/3 of these costs.

In a modification of the group 140 illustrated in Figure 3, which shows the components of the disposable article of the analysis system proposed according to the invention with functions arranged in a distributed manner, it would also be feasible to disconnect the components comprising the waste container 132 as well as the empty and therefore used test strip magazine 134 from the electronic components 112, 110 and 136 along the disconnection point 302, and to fit a new test strip magazine 134, fitted with a fresh unconsumed supply, together with a waste container 132 to the electronic components 112, 110, 136 which may still be intact, and once again use a reusable group 140 such as this within the system 300 with functions arranged in a distributed manner.

The system 300 illustrated in Figure 3 with functions arranged in a distributed manner allows reuse of expensive components such as the drive 114, the motor controller 116 associated with it, the display 104, the display controller 106, the calculation electronics 108 and the appliance housing 102.

List of reference symbols

100 Appliance
102 Appliance housing
104 Display
106 Display controller
108 Calculation electronics
110 Measurement electronics
112 Measurement peripheral
114 Drive (electric motor)
116 Drive controller
120 Components of the analysis appliance

130 Coding means
132 Waste container
134 Test strip magazine
136 Energy store (disposable 2)

140 Components of a disposable article (disposable 1)

150 First critical interface
160 Second critical interface

200 Disposable system

300 Analysis system with functions arranged in a distributed manner
302 Disconnection point (= first critical interface)

Patent Claims

1. Analysis system (300), comprising an analysis appliance and a test strip magazine (134), for determining an analyte in a body fluid, characterized in that the analysis system contains a group (120) of reusable components and a further group (140) of components of a disposable article which, in addition to components (132, 134) without any electronics, has electronic components (110, 112, 136), and from which the components (132, 134) without any electronics can be disconnected at a disconnection point (302).

2. Analysis system (300) according to Claim 1, characterized in that the further group (140) of components of a disposable article has measurement electronics (110) in which a coding means (130) is integrated.

3. Analysis system (300) according to Claim 2, characterized in that the coding means (130) is in the form of an electronic memory chip.

4. Analysis system (300) according to Claim 1, characterized in that a first critical interface (150) between a measurement peripheral (112) and a test strip magazine (134) is located within the further group (140) of components of a disposable article.

5. Analysis system (300) according to one or more of preceding claims, characterized in that a second critical interface (160) between the measurement electronics (110) and the components of the measurement peripheral (112) is located within the further group (140) of components of a disposable article.

6. Analysis system (300) according to one of the preceding claims, characterized in that at least one critical interface (150, 160) between

- the test strip magazine (134) and the measurement peripheral (112),
- the measurement peripheral (112) and the measurement electronics (110) as well as between the measurement electronics (110) and at least one energy store

is produced and tested during production of the analysis system (300).

7. Analysis system (300) according to Claim 1, characterized in that measurement electronics (110) and a measurement peripheral (112) can be updated with a new, unused, further group (140) of components of a disposable article while being fitted.

8. Analysis system (300) according to Claim 1, characterized in that the group (120) of reuseable components of the analysis appliance has an appliance housing (102) together with a display (104), a display controller (106) and calculation electronics (108), which are reusable.

9. Analysis system (300) according to one or more of the preceding claims, characterized in that the measurement peripheral (112) contains an optical evaluation system for optical evaluation of the test strips which are stored in the test strip supply (134) and can be wetted with a human body fluid.

10. Analysis system (300) according to one or more of the preceding claims, characterized in that the measurement peripheral (112) contains an electrochemical evaluation system, in particular an ammeter or a potentiometer for electrochemical evaluation of the test strips which are stored in the test strip supply (134) and can be wetted with a human body fluid.

11. Analysis system (300) according to Claims 4 or 5, characterized in that the first critical interface (150) between the test strip magazine (134) and the measurement peripheral (112) and the second critical interface (160) between the measurement peripheral (112) and the measurement electronics (110) are located on a component which is connected during production.

12. Analysis system (300) according to one or more of the preceding claims, characterized in that this analysis system (300) has at least one energy store (136) which is part of the further group (140) of components of a disposable article.

13. Analysis system (300) according to Claim 12, characterized in that the at least one energy store (136) represents a separate disposable article outside the further group (140) of components of a disposable article.

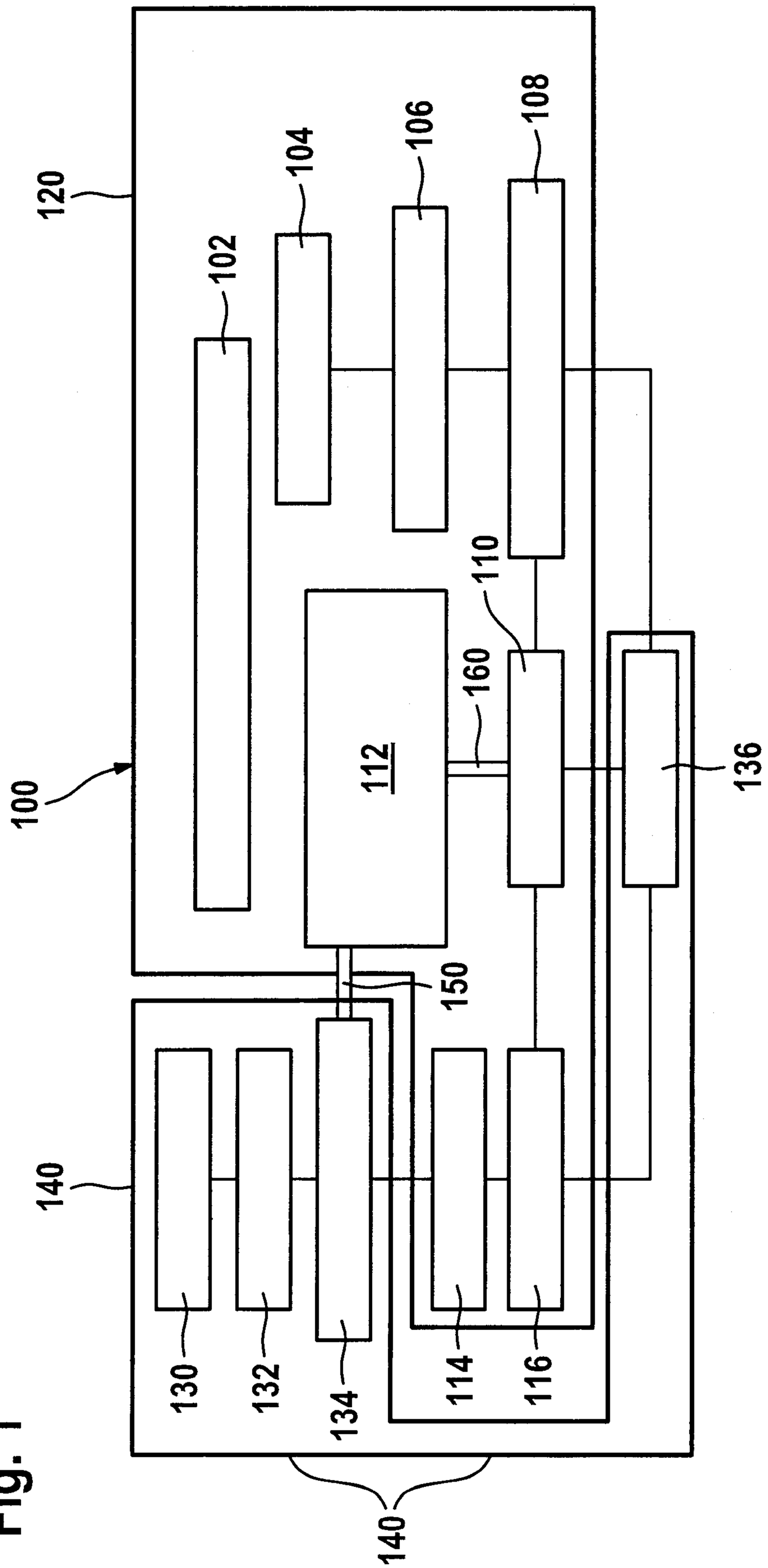

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Fig. 1

Fig. 2

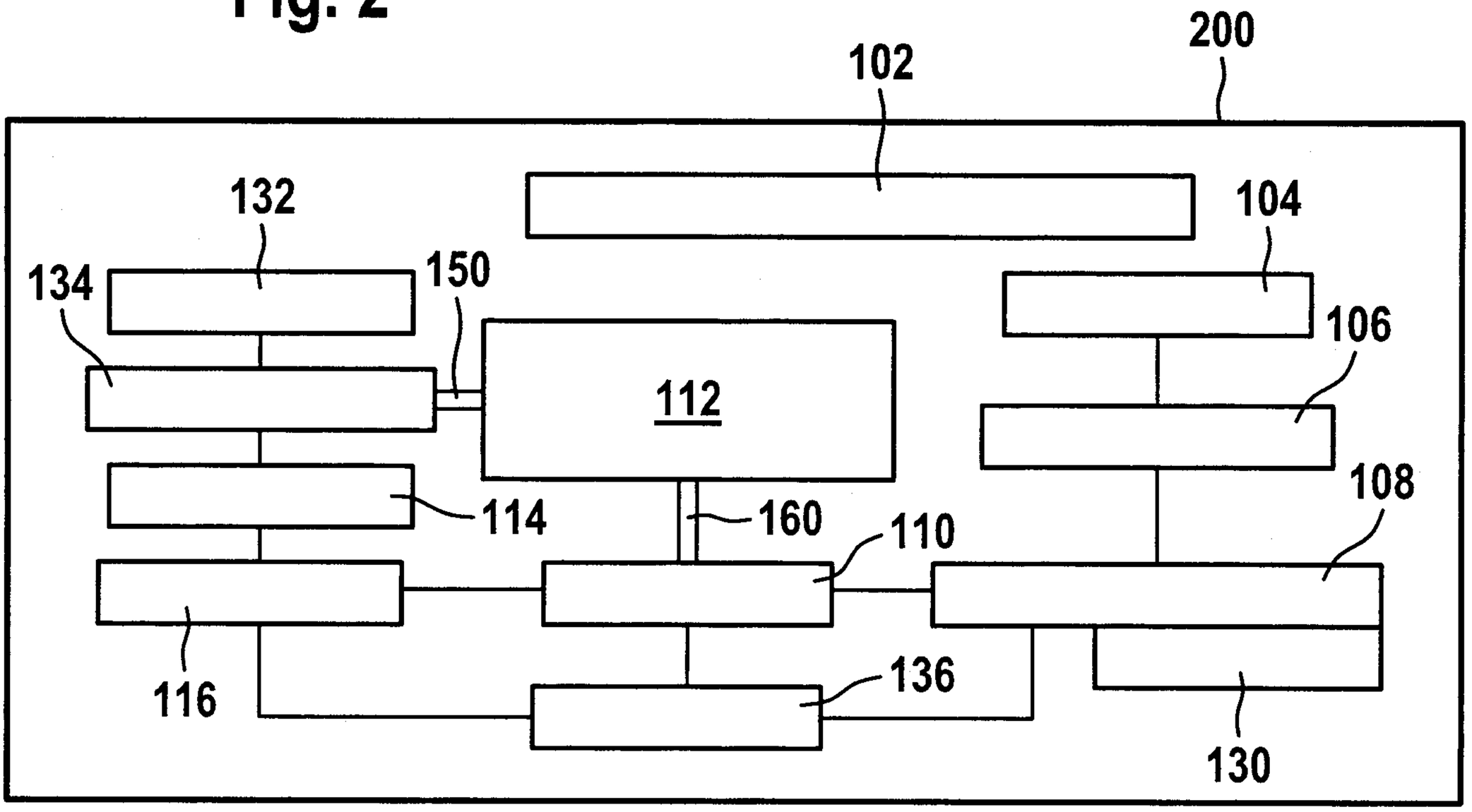
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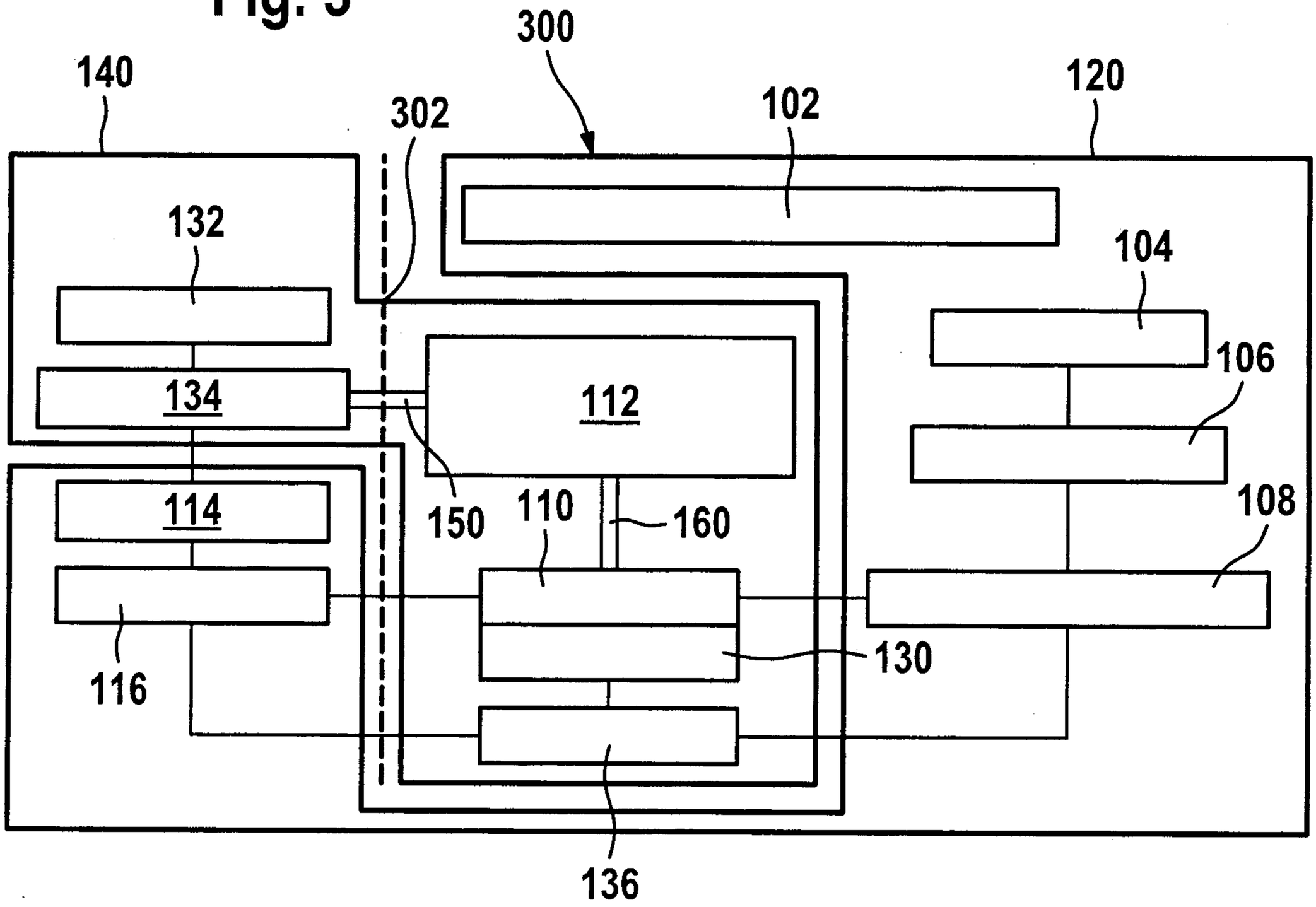
Fig. 3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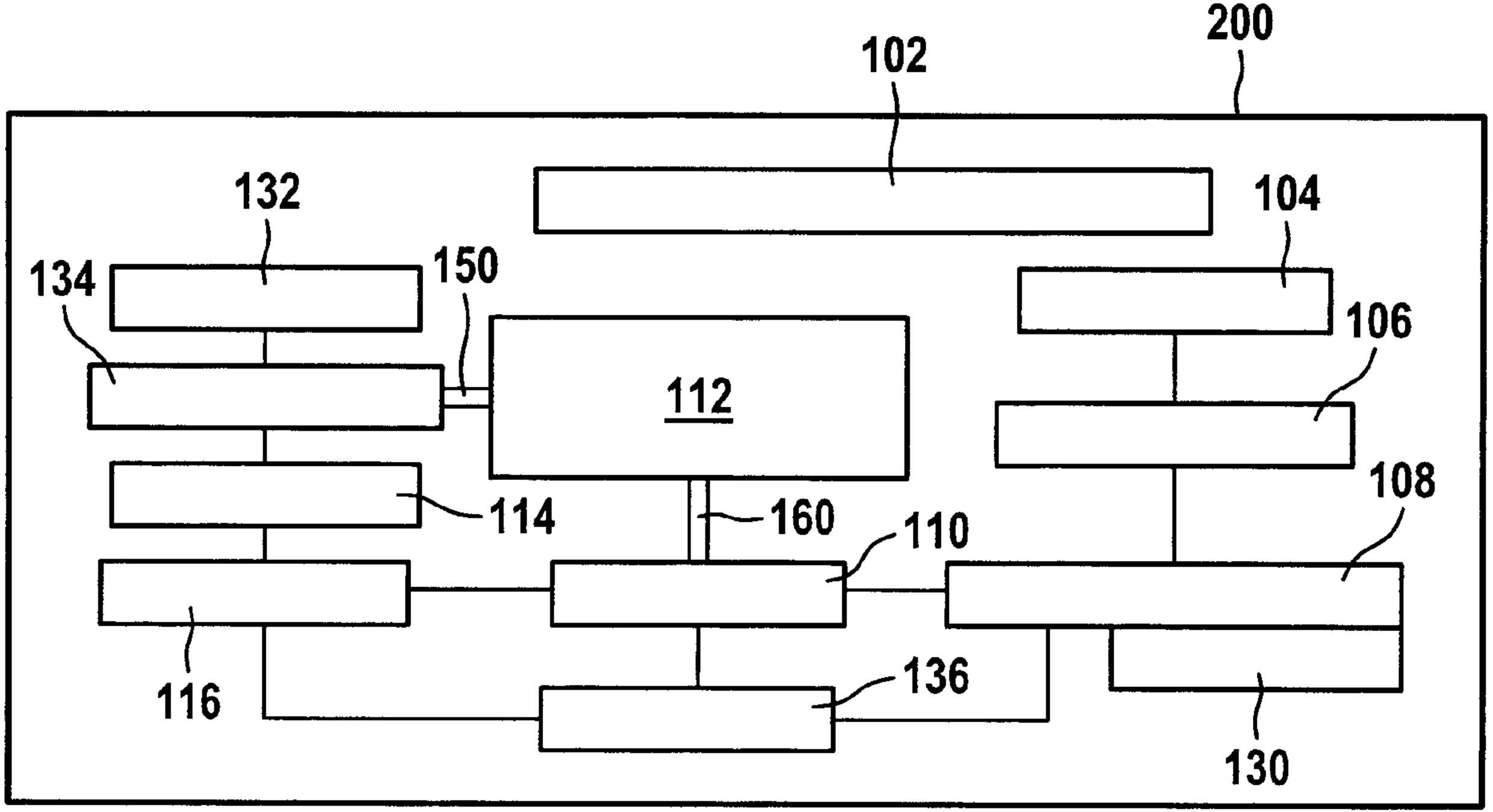
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