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(54) Medical devices identification method, particularly for safe supplying devices and improved medical devices according to said method

(57) The invention relates to a method of identifying medical devices, specifically safety-type dispensing devices, and to an improved medical device implementing the method. The method consists of:

- providing the device (2) with an electronic memory unit (10);
- storing identification data of the medical device (2) into the memory unit (10); and
- reading the contents of the memory unit (10) and storing fresh data about a maintenance and service operation through a supply interface (15) of the memory unit (10) arranged to act on the memory unit strictly for the time required to complete said data reading and storing steps.

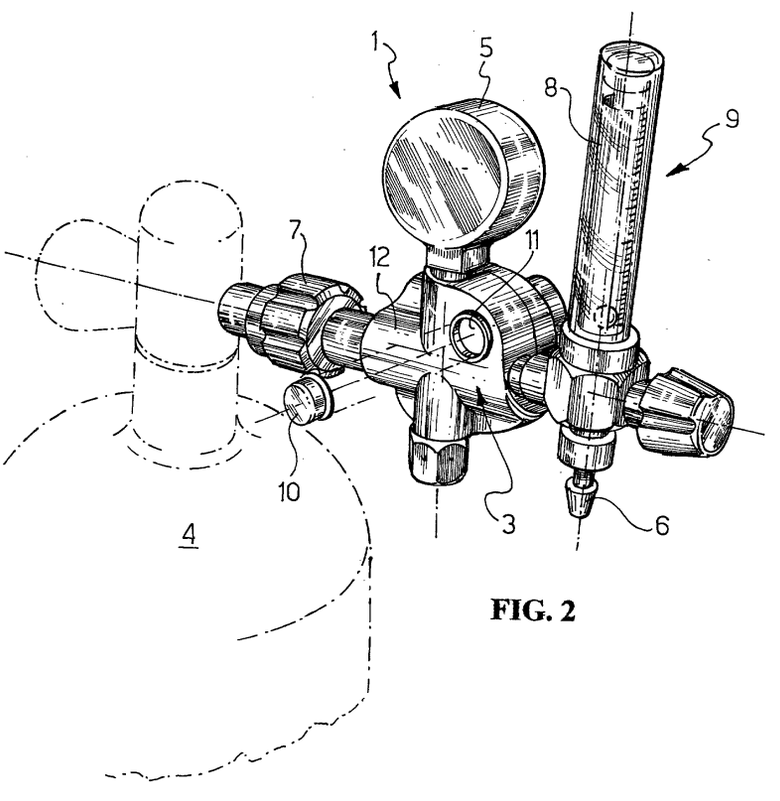


FIG. 2

EP 1 260 756 A1

Description

Field of Application

[0001] The present invention relates to a method of identifying medical devices, specifically safety-type dispensing devices.

[0002] The invention further relates to a medical device of improved design for implementing this method.

Background Art

[0003] As it is well known in this technical field, a great many medical devices are operated by means of fluids, which constitute a potential hazard either on account of their nature, perhaps inherently toxic and/or inflammable, or of their conditions of use, e.g. under a high pressure.

[0004] For example, this is the case with pressure reducing assemblies of cylinders storing gas, as for example cylinders storing oxygen gas for use as an inhalant or in therapy, which assemblies include flowmeters for outflow rate adjustment and must be operated in a condition of maximum safety to the operator and/or the patient.

[0005] Throughout its working life, a pressure reducing assembly is subjected to substantial mechanical stress due to a high operating pressure, which is apt to deteriorate the device components in the long run. Also, pressure-reducing assemblies are likely to receive harsh treatment, mainly because the cylinders are transferred and handled with their dispensing units installed.

[0006] In addition, certain vital components of the pressure reducing assemblies, such as the pressure gauge and the flowmeter, are expected to retain an extreme measure accuracy with time, which is also imposed by the referring standards. Lasting accuracy is necessary to ensure that the apparatus will remain functional and safe as originally intended.

[0007] For the purpose, regular maintenance and service routines by skilled personnel are arranged. In the event of this periodic checking by skilled technicians being omitted, or in consequence of the checking having been carried out by unauthorized personnel, such risks may be incurred as the burning of the apparatus internal parts or even the device burst. In this respect, accidents due to negligence tor unskilled servicing during the maintenance operations are amply documented in the pertinent literature.

[0008] A second aspect worth to be mentioned in order to better illustrate the invention, is that of certain types of dispensers for compressed or vacuumized medicinal gases, which are guaranteed by the manufacturer for a given life span, to be reckoned in months or years of operation, or for a given number of cycles, before they must be replaced or require a maintenance technical service.

[0009] This is the case of wall-mounted, system outlets for dispensing medicinal gases. These units, which also are to be regarded as "medical devices", are generally installed in hospitals and have a wall-mounted working end that can be accessed by an operator for quick connection to any apparatus or gas administering appliances to be replenished.

[0010] To ensure proper operation of such outlets according to the type of gas that they are to dispense, periodic inspection by skilled personnel is needed in order to have all the fittings checked for gas-tightness and the connections to the outlet points checked for safe performance.

[0011] In this respect, a European directive on medical devices, No. 93/42/CE, specifies *inter alia* which is the information the supplier is to pass to the user for long-term conservation of his products on the market, as well as for procuring all the materials, so that after-sale support can be ensured.

[0012] In order to overcome the above problems of periodic maintenance, the users of medical devices usually enter agreements with technical service contracts, whereby the latter are obliged to perform a series of periodic checks of the operative conditions of the medical devices. The device status check may take place on the spot or at outside premises, and must be carried out by skilled personnel purposely trained by the manufacturer.

[0013] A serious problem encountered during the managing of these maintenance contracts is that the effectiveness and punctuality of the maintenance operations totally depend on the expertness, skill and willingness of the maintenance personnel.

[0014] Thus a supervision of this kind is somewhat aleatory, whereas it should be stringent, timely and effective.

[0015] Most times, to a scarcely professional maintenance service corresponds further expenses for the medical devices manufacturer, who has to face possible objections for the damages suffered by the user in case of accident.

[0016] At the moment, no prior proposals are known that show ways to improve the maintenance managing system so that more effective and satisfactory checks for both the manufacturer and the user of medical devices are obtained.

[0017] The underlying technical problem of this invention is to provide a method of positively identifying various types of medical devices, which method would have features such to guarantee periodic checking of a high standard totally unconstrained by the skill of service personnel.

[0018] Another aspect of the technical problem is to provide an improved medical device adapted to be checked for identification by the inventive method.

Summary of the Invention

[0019] The principle on which this invention stands is

to have each medical device equipped with an electronic non-volatile memory unit having an unmodifiable portion in which data and parameters of initial device identification are stored, and having a portion into which data and information about maintenance operations can be written in an unmodifiable fashion.

[0020] Thus, the device and its original state can be readily identified in a reliable manner and its service and maintenance history be logged through its life cycle.

[0021] Based on this principle, the technical problem is solved by a method as previously indicated and as defined in the characterizing part of Claim 1.

[0022] The technical problem is further solved by a medical device, specifically a medicinal gas-dispensing device, as defined in Claims 8 foll..

[0023] The features and advantages of the method and the device of this invention will be apparent from the following description of embodiments thereof, given by way of non-limitative examples with reference to the accompanying drawings.

Brief Description of the Drawings

[0024]

- Figure 1 shows a perspective view of a medical device for dispensing medicinal gases.
- Figure 2 shows a perspective view, from behind, of the medical dispenser device shown in Figure 1 highlighting the improved portion thereof according to this invention.
- Figure 3 shows a schematic sectional view of a detail of the medical device shown in Figure 2.
- Figure 4 shows a perspective view of another type of an improved medical device according to the invention.
- Figure 5 shows a schematic sectional view of a detail of the medical dispenser device shown in Figure 4.

[0025] Figure 6 schematically shows an example of an electronic apparatus implementing the method of this invention.

[0026] Figure 7 shows schematically a screen display of a PC in one mode of the inventive method.

Detailed Description

[0027] With reference to the drawing views, a safety medical device that incorporates improvements according to this invention is generally and schematically shown at 1, the improvements allowing it to be identified, traced back to, and run, and allowing a log of its service history to be recorded.

[0028] In the embodiment shown here by way of example and not of limitation, the medical device 1 comprises a pressure reducing assembly 3 associated with a cylinder 4 of a pressurized gas, e.g. oxygen.

[0029] The medical device 1 allows the gas to be dispensed in a safe condition and its flow rate adjusted. The device 1 is mounted on the cylinder 4 by means of a gas-tight fitting 7 provided at the location of the pressure reducing assembly 3.

[0030] It should be noted, for the sake of thoroughness, that the medical device 1 further comprises a pressure gauge 5, an outlet fitting 6, and a flowmeter cap 9 marked with graduations 8 for reading the gas flow rate.

[0031] Advantageously in this invention, the medical device 1 is equipped with a non-volatile memory unit 10 received in a recessed housing seat 11 purposely provided in the middle body 12 of the medical device.

[0032] The memory unit 10 is a button-type read-only non-volatile memory, e.g. of the model referenced in the market with DS909P, available from the company Dallas Semiconductor.

[0033] The memory unit 10 is in the form of a flat disc, being a bare 6mm thick and having a diameter of about 15 mm.

[0034] As shown in Figure 3, the seat 11 is a circular socket of predetermined depth and diameter into which the memory 10 is pressure force fitted such that it cannot be removed without tampering with the medical device. In other words, any attempts at intruding or removing the memory unit 10 would leave clear and evident signs of the medical device 1 having been tampered with at the seat 11.

[0035] The seat 11 is formed in a backside portion of the medical device. Alternatively, it could be provided in some other portion of the medical device, depending on the shape of the latter.

[0036] Reference is made in this respect to the embodiment of Figure 4, where a system terminal unit 2 is shown, comprising a quick-connect fitting 20 for delivering compressed or vacuumized medicinal gases, which is flush-mounted in a masonry wall to form a terminal outlet of a medicinal gas supply system. The system terminal outlet is also to be regarded as belonging to the broader category of medical devices.

[0037] An operator would usually access this kind of fittings to quickly connect either some medical devices or delivery hoses of the patient assisting apparatus.

[0038] The quick-connect fitting 20 is housed in a plastics box or case 19, in its turn mounted in a respective recessed housing in the wall. The fitting 20 juts out of the box 19 through a cover 21 on which an indication of the type of gas can be accessed.

[0039] In this particular instance, the memory unit 10 is housed in a corresponding seat 22 formed on the bottom of the box 19 close to the fitting 20.

[0040] What does matter in this invention is that the memory unit 10 is fastened with the medical device 1 also in this kind of dispensing devices.

[0041] Advantageously, the memory unit 10 is adapted to store identification data of the medical device 2, and especially of medical device 1, in an unerasable manner. Of special significance among such data is an identification of the manufacturer of the device.

[0042] In a preferred embodiment, the memory unit 10 is a read/write non-volatile memory, such as an EPROM, EEPROM, or flash EEPROM, that allows the reading of its informational contents and storage of fresh data about the maintenance phases applied to the device 1 carried out with preset periodicity.

[0043] It is important to observe that the memory unit 10 is externally supplied induced power, and requires no electric power supply. The read/write electric pulses to the memory 10 are delivered to the latter through a supply interface 15 arranged to interact with the memory 10 for the time strictly required for such read and write operations to be completed.

[0044] The interface 15 may be a palm top computer, i.e. a small electronic card controlled by a microprocessor and mounted in a plastics container that also houses a keypad 16 and a display 17.

[0045] More particularly, the palm top computer 15 is supplied a DC voltage from rechargeable batteries, and includes a connector for connection to an external power supply in order to renew the battery charge, a connector for a contact probe 14 provided to contact said memory unit 10, and a connector for a serial interface of the RS232 type.

[0046] The palm top computer 15 comprises an internal working memory, bidirectionally communicating to the microprocessor, and a number of interfaces for the keypad 16, the display 17, the probe 14, and said serial interface.

[0047] The palm top computer 15 is used in implementing the method of this invention, and in particular, for recording the service inspections that have been carried out at the user's of the medical devices 1. It would be possible, of course, to provide for conditional access using a password or a non-volatile memory (EPROM), so that the computer 15 can be operated by authorized personnel only.

[0048] An operator is simply to make contact with the free end 13 of a probe 14 to directly read the contents of the memory unit 10 installed in the medical device 1.

[0049] Stored information is read from the memory 10 in this way. For example, the information can be: a product serial number, a product code, a primary product batch, a secondary product batch, the date of manufacture, the name of the person who tested the product originally before releasing it to the market, the name of the manufacturer, and some remarks. Obviously, the information may be suitably encoded to reduce the memory space required in the unit 10 and within the palm top computer 15.

[0050] After the serviceman has read the set of data stored in the memory unit 10 using the palm top computer 15, the data may be dumped into a PC, e.g. a portable PC, for more convenient handling of the same, as shown in the example of Figure 2.

[0051] This operation would be performed only by service personnel authorized by the manufacturer to operate the medical devices, and is made feasible thanks to the serial interfaces that are incorporated to the palm top computer 15.

[0052] By having the data read from the memory 10 dumped into a personal computer, information about the maintenance operations to be performed can be received, such as the manufacturer's code, production batch, serial number, user's code, etc.. Also, by working directly at the PC, the serviceman is able to handle the service information through a very simple graphic interface and a specially friendly program language. For example, the serviceman can command an overall view of all the information extracted from the memory 10, as shown in Figure 5. Using simple program instructions, the serviceman can enter new identification data and technical data, transfer the data to the palm top computer 15, receive identification and technical data from the palm top computer 15, and can have the data displayed in any desired order, have the data printed out, and profit from help-on-line functions.

[0053] A suitable program language, e.g. Visual Basic, will allow every detail of the graphic interface, as well as the controls available for recording the kind of service operation performed, to be defined for the operator.

[0054] Once the serviceman has entered in the palm top computer 15 the information about the maintenance operation performed, the memory unit 10 is again contacted through the free end 13 of the probe 14 to directly store the information into the unit 10.

[0055] Thus, the method of this invention allows a log of the service inspections performed through the life of the medical device 2 to be recorded.

[0056] Also, the inventive method also allows to record a log of the authorized technical and maintenance operations performed during the life cycle of the medical device 1.

[0057] The method and medical device according to this invention are uniquely simple and effective, and do solve the technical problem of having potentially hazardous medical devices properly maintained and serviced.

[0058] The added cost brought about by the improved medical devices of this invention is trivial, represents but a trifling proportion of the overall cost for the service operations currently performed, and is fully paid back by the promptness and safety of the operations.

Claims

1. A method of identifying generic medical devices (1,2), specifically safety-type dispensing devices and general medical devices, **characterized in**

that it comprises the following steps:

- providing the device (1,2) with an electronic non-volatile memory unit (10);
- storing identification data of the medical device (1,2) into said memory unit (10);
- reading the contents of the memory unit (10); and

performing a maintenance and service operation and storing fresh data about said maintenance and service operation into said unit (10) through a supply interface (15) of the memory unit (10), said interface acting on said memory unit strictly for the time required to complete said data reading and storing steps.

2. A method according to Claim 1, **characterized in that** said memory unit (10) is a read-only memory.

3. A method according to Claim 1, **characterized in that** said memory unit (10) is a read/write memory.

4. A method according to Claim 1, **characterized in that** said memory unit (10) power supply is induced externally.

5. A method according to Claim 1, **characterized in that** said supply interface (15) is a palm top computer having a contact probe (14) for reading and transferring data from/into said memory unit (10).

6. A method according to Claim 1, **characterized in that** said reading step is carried out before the data storing step.

7. A method according to Claim 1, **characterized in that** said fresh data is stored additionally to the existing data in the memory (10).

8. A medical device (1,2), comprising a safety-type of fluid dispensing device, **characterized in that** it further comprises an electronic non-volatile memory unit (10) for storing identification data of the medical device (1).

9. A device according to Claim 8, **characterized in that** said memory unit is a read-only memory.

10. A device according to Claim 8, **characterized in that** said memory unit (10) is a read/write memory.

11. A device according to Claim 8, **characterized in that** said memory unit (10) power supply is induced externally.

12. A device according to Claim 8, **characterized in that** a supply interface (15), having a contact probe (14) for reading and writing data into/from said memory unit (10).

13. A device according to Claim 8, **characterized in that** said electronic memory unit (10) is a button-type EPROM or EEPROM.

14. A device according to Claim 13, **characterized in that** said button-type electronic memory unit (10) is force fitted into a recessed seat (11) formed in the medical device (1).

15. A device according to Claim 13, **characterized in that** said button-type electronic memory unit (10) is associated with the medical device (2) inside a wall-mounted box (19) accommodating the medical device (2)

16. A device according to Claim 12, **characterized in that** said supply interface (15) is a palm top computer.

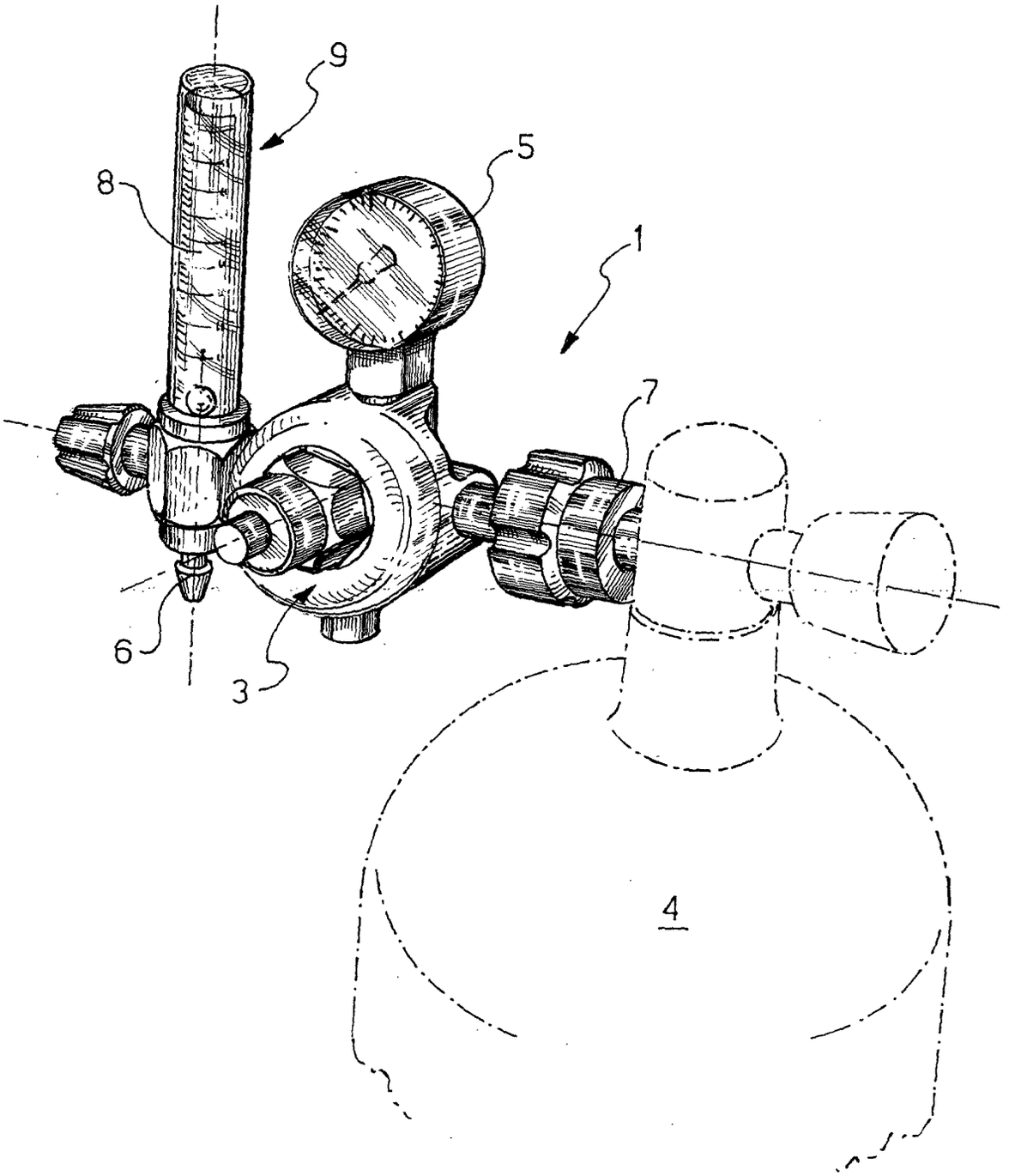


FIG. 1

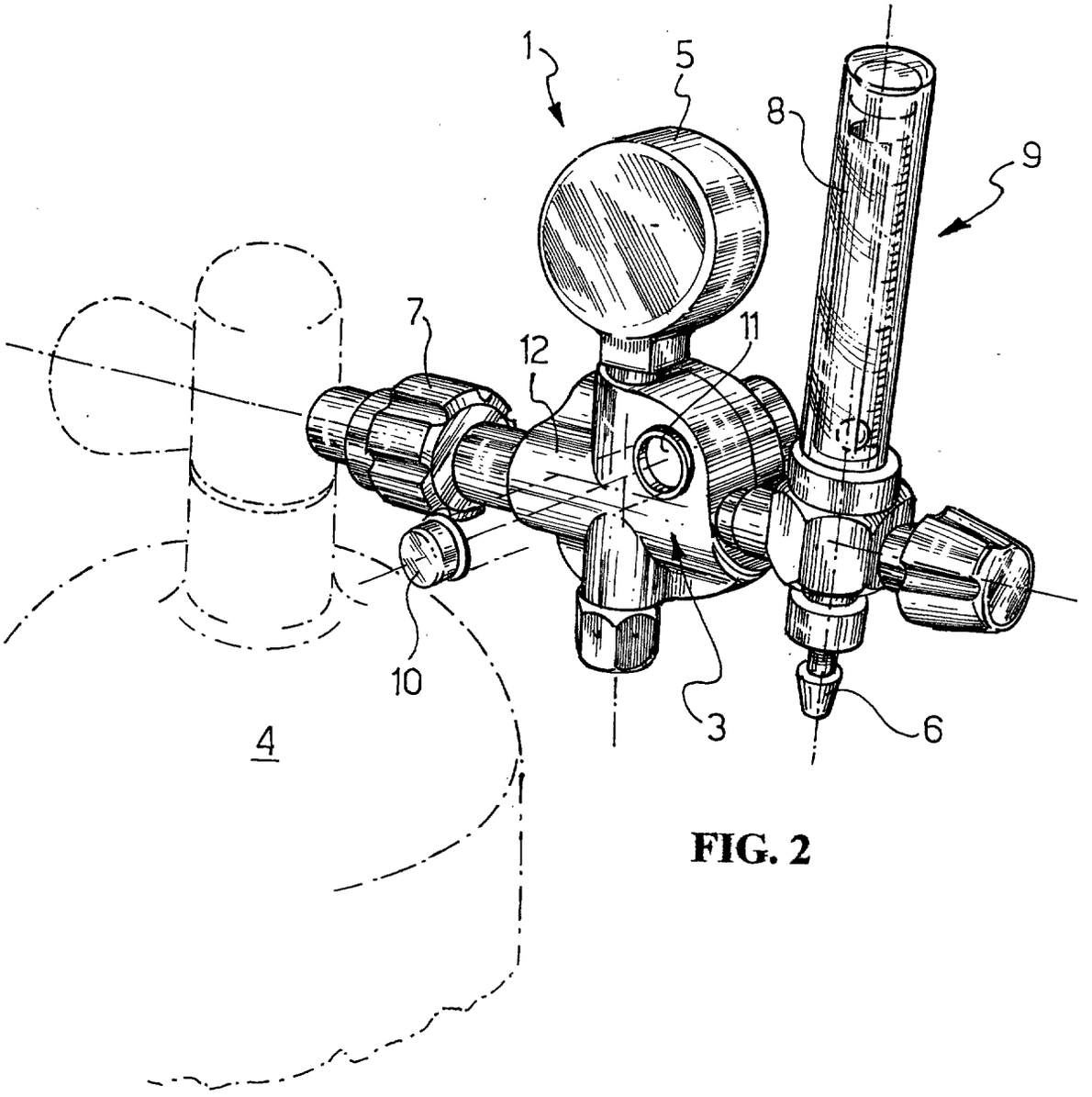


FIG. 2

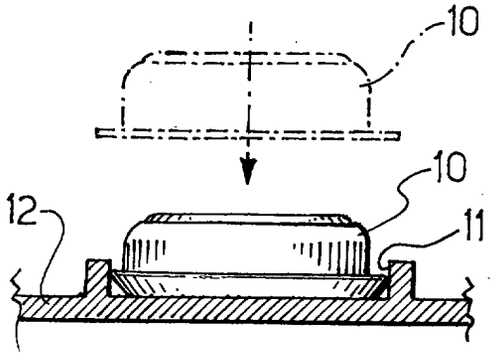


FIG. 3

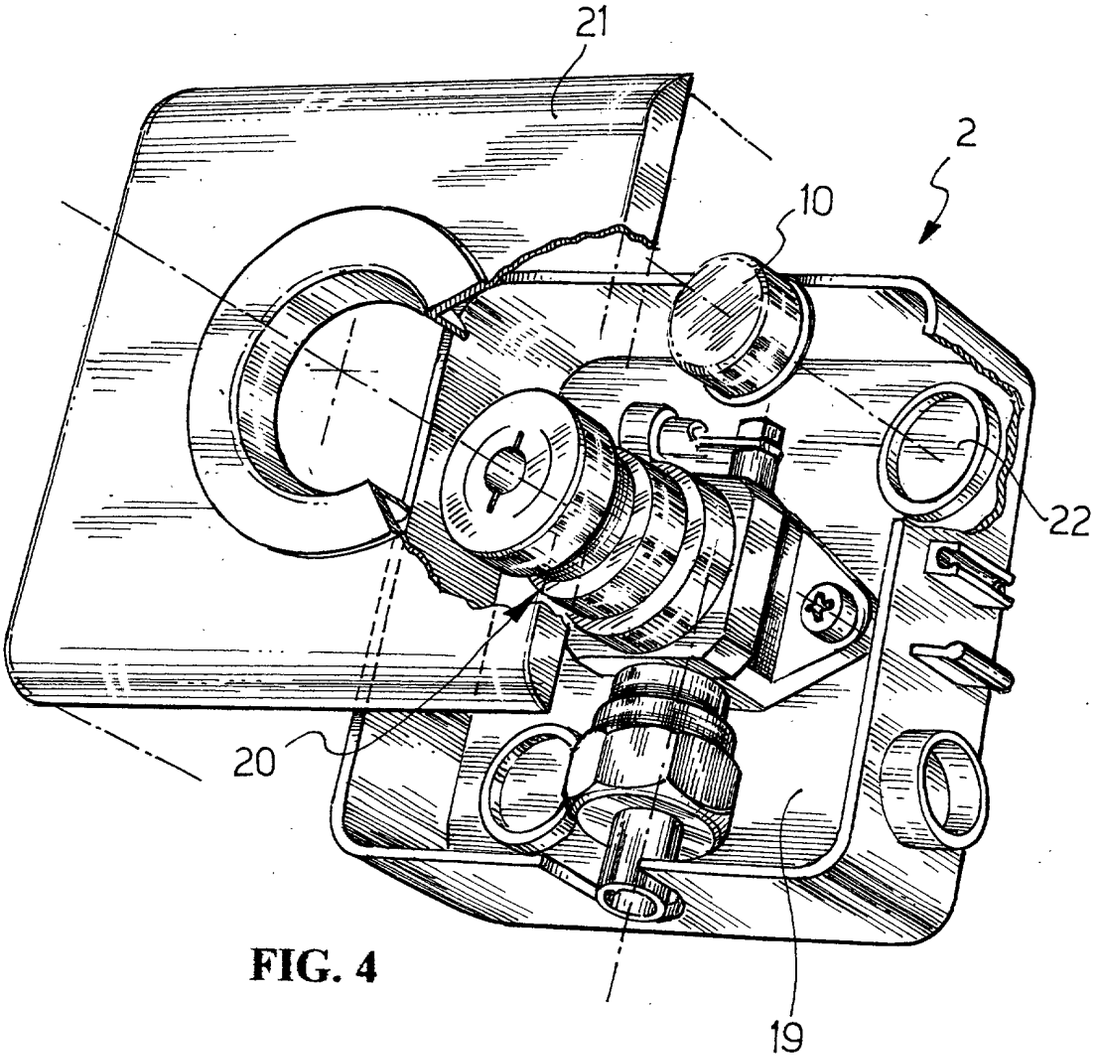


FIG. 4

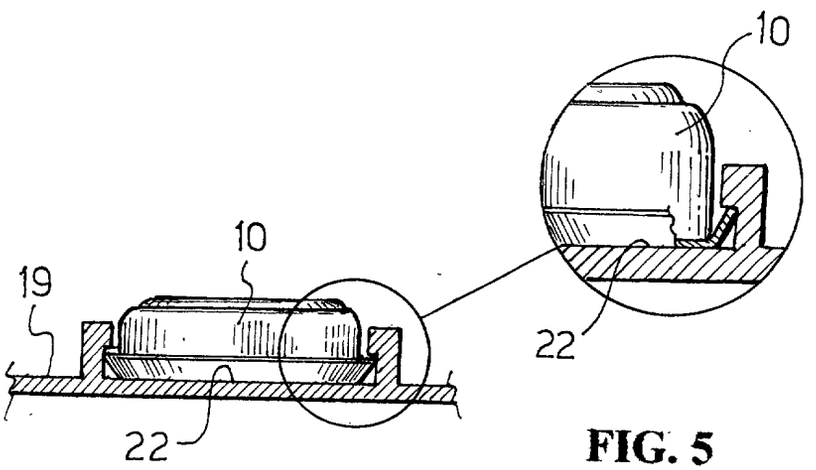


FIG. 5

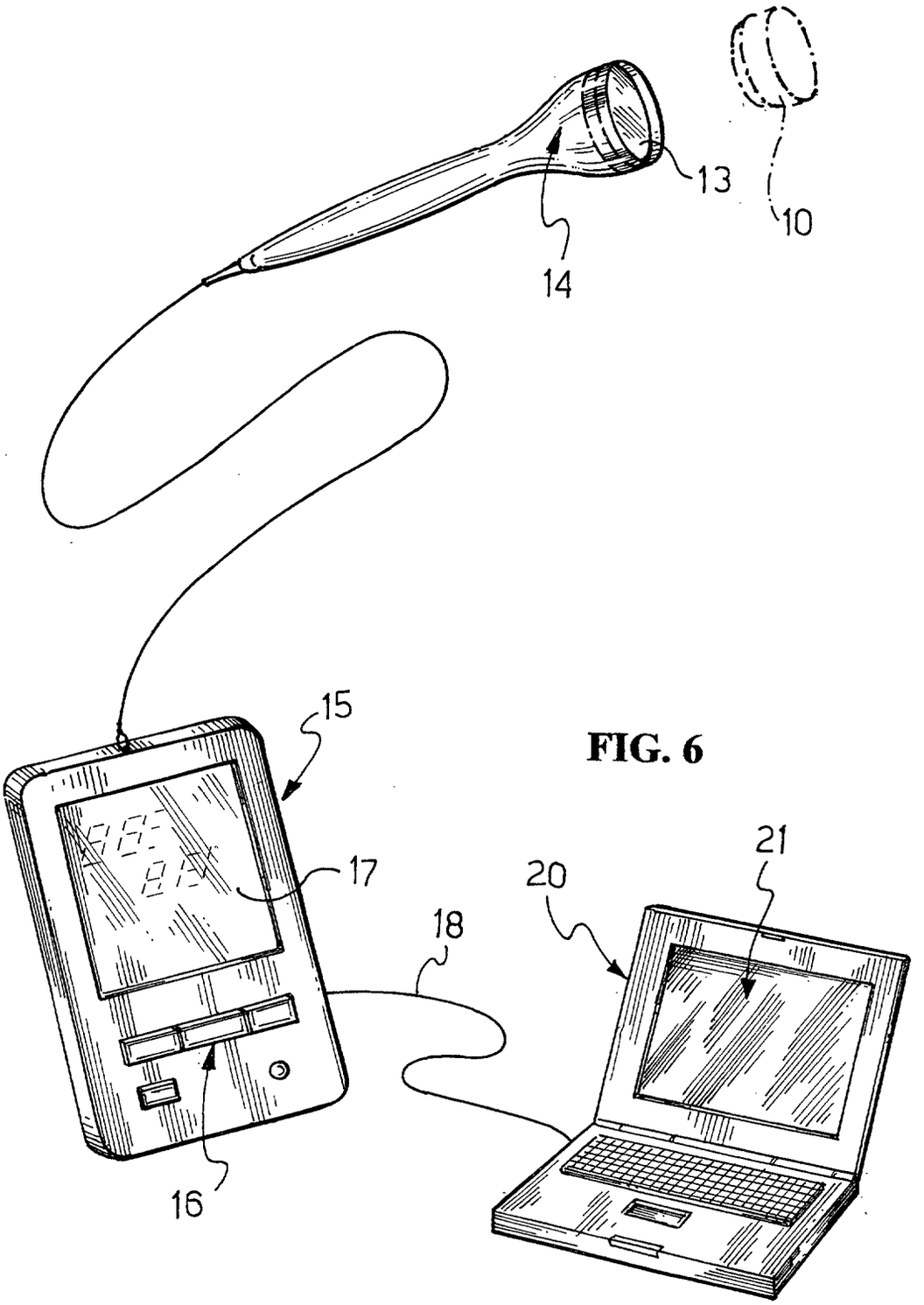
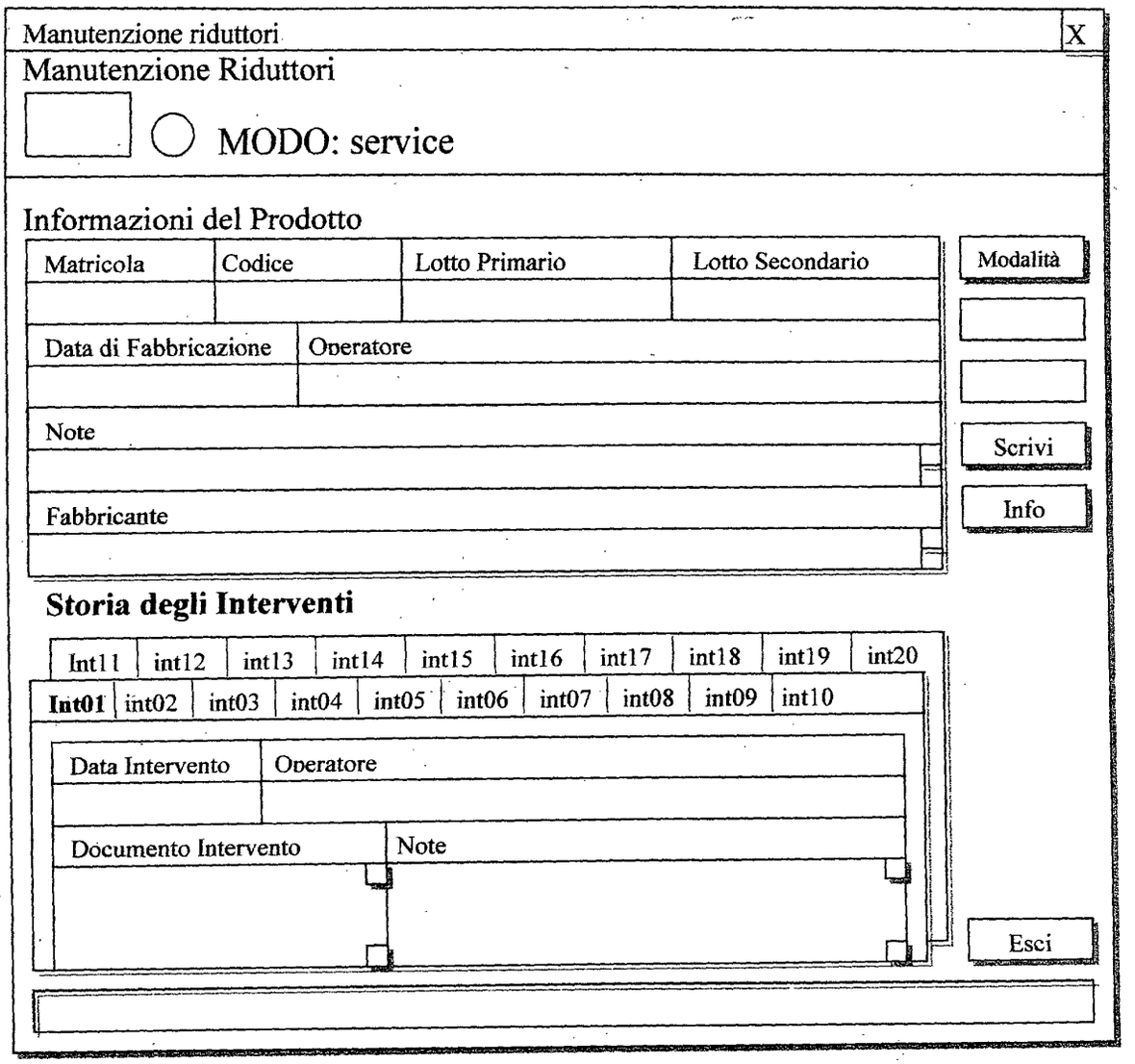


FIG. 6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MODO: service
Informazioni del Prodotto
Matricola
Codice
Lotto Primario
Lotto Secondario
Modalità
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Operatore
Note
Scrivi
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Data Intervento
Operatore
Documento Intervento
Note
Esci

FIG. 7

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EUROPEAN SEARCH REPORT

Application Number
EP 01 83 0341

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The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	22 October 2001	Bertin-van Bommel, S

CATEGORY OF CITED DOCUMENTS

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