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(54) Title: PROCESS FOR SUPERVISING AND CONTROLLING THE OPERATION OF INFANT INCUBATORS

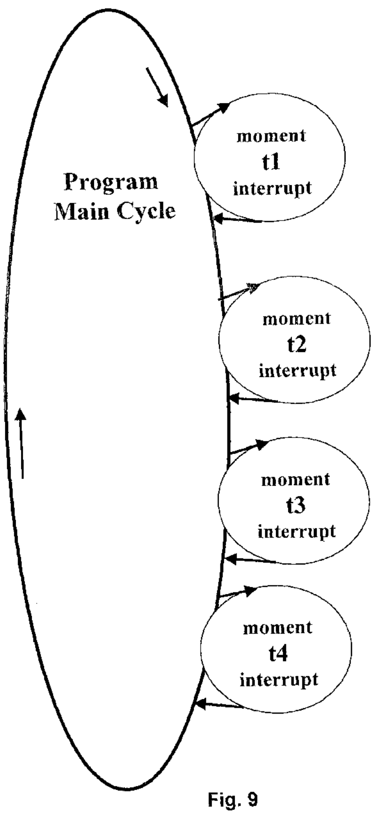

Fig. 9

(57) Abstract: Process for supervising and controlling the operation of infant incubators, which is primarily usable for the supervision and control of the operation of infant incubators that have been developed as the improvement with new electronic hardware and software technology of the infant incubator type BLF-2001 of the mark name BABYLIFE. During the process according to the invention the temperature and humidity parameters of the incubator space is measured with the help of sensors, and the values are converted to electrical data, and based on these data, the operation of the incubator is supervised and controlled. It is characterized by that, during the process a main control cycle is applied, which constantly runs in a main loop during the process, during which main control cycle the adjustments of the incubator (20) constantly occur, including the handling of peripherals, handling of inputs and outputs, checking of fault condition, as well as the measures taken in response to these actions, and in relation to the main control cycle the interruption is used at least at one moment (t_1), during which the measuring, checking cycle, belonging to the given moment (t_1) is proceeded.

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Process for supervising and controlling the operation of infant incubators

Process for supervising and controlling the operation of infant incubators, which is primarily usable for the supervision and control of the operation of infant incubators that have been developed as the improvement with new electronic hardware and software technology of the infant incubator type BLF-2001 of the mark name BABYLIFE.

During the operation of the incubators, one of the most important task is to ensure appropriate temperature and humidity content within the incubator. It is also important that the commissioning and testing of the incubator is simple and reliable. Furthermore, it is desirable to comply with constructional requirements, which can ensure the suitable supervision and care of prematurely born infants.

It is also important to allow access to the infant, to provide infusion, oxygen, weighing, X-raying with minimum disturbance to the infant, and that the temperature and humidity conditions are not disturbed significantly. That is why there are a number of openings for pipes, a door with iris type closing for the hand, external X-ray tray, installable scale, installable O2 automatic control.

It is extremely important, that the internal temperature and humidity content inside the incubator are set according to the required conditions for the infants, and to control these parameters continuously during the working of the incubator with high reliability. There is a related important aspect, namely that the parameters of the inside space of the incubator should be restored to the set operating values as quickly as possible in case of malfunction or failure of voltage, thus saving the health of the prematurely born infant and preventing eventual damage. It is also important to maintain the temperature features of the internal space of the incubator within certain range, and that the criteria of the safe operation could be checked during commissioning and testing in this respect.

A number of various solutions are available according to the state of art for the control and appropriate regulation of the parameters of the incubator operation.

The Hungarian patent description HU 192 716 makes known, which describes an equipment for humidifying the internal hood space of the incubator. The equipment consists of an incubator hood space containing the cradle, and air ducts that are connected through intake and outlet openings, in which heating unit and fan is installed, and it is provided with an incubator water tank. The essential feature of the solution is that the water tank is installed in a part of the space which is separated from the air duct with wall, a pump is connected to the water tank through the intake pipe, the delivery pipe of which is terminated in the air duct above the blades of the fan, the heating unit is installed between the fan and the air intake opening, where a humidity detector is also installed, the outlet of which is connected to the control circuit of the pump.

The US 2002 188 168 patent publication makes known a process and system is provided for regulating the air temperature in an incubator, which accommodates a patient, especially a premature or newborn infant, and which is part of a so-called hybrid device. When the function of the hybrid device is changed over between the two device types of "closed incubator" and "open care unit," the problem arises that the air temperature set point cannot be maintained and the patient cools down as a consequence. The process uses a heat radiation source, which is located outside the incubator, which can be closed with a hood that is transparent to the radiated heat. The corresponding value measured by an air temperature sensor, which is used as an actual air temperature value, is evaluated by an evaluating and control unit along with a value measured by a body temperature sensor. When the actual values that continue to be measured by the air temperature sensor exceed a preset set point, the radiation dose of the heat radiation source is reduced, and increased in the contrary case, until the preset set point and the actual value of the air temperature sensor agree.

The US 2003 197 003 patent publication makes known a system for controlling the heating and temperature monitoring of infant incubators and infant warmers is provided with an incubator or infant warmer space, a heater for heating the space as well as a first temperature sensor and a second temperature sensor. An input device for input of one or more control setting works in conjunction with a control device connected to the heater and to the first temperature sensor and the second temperature sensor. The control device forms a control temperature from an input first skin temperature target control setting for a first patient and an input of a second skin temperature target control setting for a second patient and further patients if present and controls the heater based on a difference between the control temperature and an actual temperature value based on a first actual temperature sensed by the first temperature sensor and a second actual temperature sensed by the second temperature sensor.

The EP 0933075 patent publication makes known an infant incubator having a heating system that provides a flow of heated air into the infant compartment and which exhausts air from the infant compartment. A temperature sensor is located in the air inlet of the warm air into the infant compartment and another temperature sensor is located in the air outlet of the air from the infant compartment. The system thus monitors the temperature of the air to the infant compartment and the air from the infant compartment. By analyzing the temperatures from the inlet and the outlet the overall incubator heating system can be controlled and yet a further advantage is provided by using the temperature information to recognize a fault or deficiency in the incubator system.

The GB 2045 978 patent description makes known a temperature monitoring and control system, for an infant incubator, comprises a pair of temperature sensitive skin probes adapted to be attached to the skin of the patient, each probe having associated comparative circuit adapted to sense a high or low skin temperature and to activate corresponding indicators or alarms, and an associated comparative circuit adapted to monitor probe integrity and to activate a corresponding indicator or alarm whenever a probe failure condition is sensed. The two probes are coupled to comparative circuitry designed to check the performances of the probes one against the other and to activate a corresponding indicator or alarm should the probe outputs differ by an unacceptable degree. A heater element is powered in dependence upon the output of one of the probes. A power monitoring circuit monitors the current through the heater element and is arranged to trip an alarm should the power to the heater exceed a predetermined level for longer than a predetermined time period.

The GB 2346560 patent description makes known an apparatus for controlling the temperature of an infant incubator comprising a heater for heating air within the incubator, a fan for circulating the heated air, and a sensing means. The sensing means is responsive to at least one of an access door, the temperature inside the incubator, and the temperature of the skin of the infant, and a controlling means is responsive to said sensing means for controlling the speed of the fan and the heat generated by the heater. In a preferred embodiment, the sensing means responsive to the movement of the access door is a magnetic sensing means.

Deficiencies, critics of the state of art:
In the earlier solutions, the control of temperature was done generally with hardware, which did not allow the supervision and control of the internal hood space of the incubator for ensuring the desirable accurate temperature, and it was not possible to have fully implemented safety functions. The hardware solutions provided inadequately flexible embodiment. It was not possible to have a continuous recording and monitoring of the system operation. As a result, the debugging was also much more difficult.

In the later solutions working with electronic control, the regulation and the system supervision were not safe enough, which could lead to overheating or underheating of the incubator hood space, which might have caused even damage to the health of the infant.

The supervision done by purely hardware or by purely by software itself does not allow the possibility of maximum safety. In earlier solutions it was not possible to carry out testing in the entire operating range and at the extreme limits during commissioning or during test operation. In this respect, with traditional electronic measuring instruments and software tools it was not possible to carry out the full test.

The objective of establishing the solution according to the invention was to developed an incubator that has the major features as follows:
- Application of exchangeable sensory and control modules
- Simple cabling
- A software that can be further developed in a flexible manner
- Application of graphic LCD display instead of alphanumeric LCD display (in order to obtain additional information, storing of trends, curves, retrieving of operating modes)
- Establishing the possibility of new language versions (the operation is more reliable if the operator uses his/her mother tongue)
- Using common electronic and software basis for the BLF (closed incubator) and the BLR (open incubator)

Further aim was to establish a basic construction of components (control, power supply, cable, display pushbuttons), which can be produced in large series, and which would be finalized according to the actual use. For developing the incubator hardware, it was necessary to maintain the operating model of the incubator, the major requirements of which are as follows:

- The infant should be accessible from any direction.
- Means shall be provided to allow introduction of external devices, e.g. infusion pump, guard monitoring, oxygen head hood, blue coloured lamp, possibility of taking X-ray images, scale, installed equipment for measuring the body weight.

The aim of developing the incubator software was to ensure the display, control and limit values of temperature, in a broader sense, the harmonisation of the entire operation, ensuring the joint operation of partial functions; complying with the standard provisions relevant for medical devices, particularly for the infant incubators.

A further aim was to develop a control and regulating software containing multiple control and safety levels, which can ensure the internal temperature and humidity conditions of the incubator space, and that the incubator can resume the operation with the adjusted parameters within the shortest period of time in case of malfunction.

A further aim was to use a linking protocol that can ensure the connection of the incubator to the older as well as to the latest computer systems for the purpose of testing and for continuous supervision of the operation.

When we created the solution according to the invention, we realized, if we use a number of sensors for measuring the temperature of the incubator space, which are installed in a regulating circuit, which ensure embedded protection and regulating system, than the set aim can be achieved.

This regulating system is established in a manner, that the hardware and software means work together, and the hardware means are selected and placed, so that they mutually supervise each one another continuously. As a result, a fault of a component is recognised by another one which works properly, and it corrects the fault and/or sends an error message to the user.

We recognized that the accurate and safe operation is facilitated by the simultaneous and suitable use of these features. The system and process thus established is capable of continuing the operation in case of power failure or other malfunction with the values of incubator temperature and other operating parameters that were present when the malfunction or fault occurred. This reduces the danger of serious damage to the health of the infant in the incubator significantly, when an eventual malfunction occurs or the operation fails for a couple of minutes, and allows that the incubator keeps operating in the adjusted parameter range.

The invention is a process for supervising and controlling the operation of infant incubators, during which process the temperature and humidity parameters of the incubator space is measured with the help of sensors, and the values are converted to electrical data, and based on these data, the operation of the incubator is supervised and controlled. It is characterised by that, during the process a main control cycle is applied, which constantly runs in a main loop during the process, during which main control cycle the adjustments of the incubator constantly occur, including the handling of peripherals, handling of inputs and outputs, checking of fault condition, as well as the measures taken in response to these actions, and in relation to the main control cycle the interruption is used at least at one moment (t_1), during which the measuring, checking cycle, belonging to the given moment (t_1) is proceeded.

In one preferable application of the process according to the invention two interruptions are applied at two different moments (t_1, t_2) in the main control cycle running in the main loop, during which the measuring, checking cycles, belonging to the given moments (t_1, t_2) are proceeded.

In another preferable application of the process according to the invention three interruptions are applied at three different moments (t_1, t_2, t_3) in the main control cycle running in the main loop, during which the measuring, checking cycles, belonging to the given moments (t_1, t_2, t_3) are proceeded.

In a further preferable application of the process according to the invention four interruptions are applied at four different moments (t_1, t_2, t_3, t_4) in the main control cycle running in the main loop, during which the measuring, checking cycles, belonging to the given moments (t_1, t_2, t_3, t_4) are proceeded.

In a further preferable application of the process according to the invention the value of T_1 temperature of display sensor is transferred to the main program in the measuring, checking cycle taking place during the interruption which is started at t_1 moment, then the return to the main program occurs.

In a further preferable application of the process according to the invention the value of T_2 temperature of regulating sensor is transferred to the main program in the measuring, checking cycle taking place during the interruption started at t_2 moment, then the return to the main program occurs.

In a further preferable application of the process according to the invention the value of T_3 temperature of sensor ensuring the protection No. II is transferred to the main program in the measuring, checking cycle taking place during the interruption which is started at t_3 moment, then the return to the main program occurs.

In a further preferable application of the process according to the invention the value of T_4 temperature of measured by the thermistor is transferred to the main program in the measuring, checking cycle taking place during the interruption which is started at t_4 moment, then the return to the main program occurs.

In a further preferable application of the process according to the invention the control cycle running constantly in the main loop keeps on repeating itself, it runs in circle, and this is temporarily interrupted at programmed moments with the sub-loops, and then these sub-loops return the values to the main loops, the main loops is interrupted and subsequently started again, the main loop runs continuously, and these sub-loops run in timed manner starting at moments t_1, t_2, t_3, t_4.

In a further preferable application of the process according to the invention data are continuously collected during the running of main loop, and the main loop continuously runs onto the supervisory program module, which evaluates the temperature data received as mentioned above, and during this evaluation it performs the tasks of displaying and executing the regulating cycle, checking the protection limit values, intervening in case of fault, and shutting down the heating as an ultimate measure.

In a further preferable application of the process according to the invention the following steps occur during the checking of fault conditions,
- in the first step the value of the display sensor and the values of the regulating sensor are compared, and if the difference between them exceeds a given value, or they deviate significantly, then a so called "joint running error" signal is generated,
- in the second step it is checked whether the T_2 value of t_2 regulating sensor is within the target temperature range of +/- d2, if not, then the "time out" error signal is generated.

In a further preferable application of the process according to the invention a "Low limit" error signal is generated if the temperature proves to be too low during the checking of fault condition, and a "High limit" error signal is generated if the temperature proves to be too high during the checking of fault condition.

In a further preferable application of the process according to the invention the following protecting levels are included in the system:
- protecting level I ensures that a "High limit" error signal is generated, if the T_1 display temperature exceeds the first level, i.e. 38.5 °C,
- protecting level II ensures that also a "High limit" error signal is generated, if the T_3 temperature (heat sensor II) exceeds 39.5 °C,
- protecting level III ensures that a "technical error" signal is generated, if the T_4 (thermistor) temperature reaches 40.5 °C, and at the same time the hardware is turned off automatically,
- protecting level IV provides a general protection by comparing all the four sensors with the T_{lower} and T_{upper} temperature limits, and a "outside the limit" signal is generated, if these values are outside the limits.

In a further preferable application of the process according to the invention a hardware-based protection is also used against overheating, meaning that the heater wire is dimensioned in a way, that the temperature cannot increase above 45.5 °C even if the heating system is not turned off.

In a further preferable application of the process according to the invention the sensor providing protection level II contains the thermometer as well as the humidity meter, and it has a serial connection, the A/D converter is included in the temperature and humidity sensors, these are protected from noise, the thermistor and the external sensors emit analogue signals, the noise of the signal of these components is filtered by passing the current of a current generator through them, this way the voltage $U = I \times R(T)$ is measured, which is the function of the temperature.

In a further preferable application of the process according to the invention there is an additional external connector, which allows the measurement of the temperature and humidity of the incubator space, as well as that the incubator calibrates itself with the help of a test software, determining a series of temperatures during this test, and the frequency of this measuring cycle could be 3 days.

In a further preferable application of the process according to the invention regulating electronic unit of the incubators keeps contact with the outside world by means of an Excel program running on a PC via an RS 232 port, the data are placed by the program into an Excel table, and it is possible to handle the change of data in graphical manner, which happens during calibration, but it can be applied also during operation, the RS 232 allows the connection to certain hospital systems, while UTP ports is used for connecting to other LAN systems.

In a further preferable application of the process according to the invention an opto coupler is used for isolating the incubator from connected external device for the purpose of protection against electrical chock, the supply voltage for this purpose is obtained from the external device, 1 cm leakage current distance is use on the printed circuit board of the control card, which allows the insulation of 600 V.

In a further preferable application of the process according to the invention the software resumes the operation of the incubator with the values that were present when the malfunction occurred, for this purpose the values are stored in a non-volatile memory (FRAM) when the controller is set up, and these “set” values are taken as initial values when the software starts, and this “Trend” storage is made in the FRAM in 3 hour, 24 hour and 170 hour intervals.

In a further preferable application of the process according to the invention a further safety function is applied during the process, and this function is accomplished by placing the sensors so that they are protected from mechanical damage during cleaning and use, and a sensor mounted on a cable hanging in the incubator space provides actual information about the temperature prevailing in the incubator space, while the rest of the checking, regulating and display modules are installed in protected housing, therefore, it always shows a value corrected with an offset corresponding to its location, as the values are to be corrected with so called offsets because they are not actually placated in the incubator space, and they interact to a certain extent, because the heat generated by the respective units influences the sensors located there, in this way the additional sensor mounted on the hanging cable provides the possibility of correcting the signals of the other sensors with an offset value.

The solution according to the invention is furthermore set forth by the enclosed figures:
Fig. 1 is the front view of the incubator working with the process according to the invention, shown partly from the side.
Fig. 2 is the rear view of the incubator working with the process according to the invention, shown partly from the side.
Fig. 3 shows the block diagram of the electronic hardware of the incubator working with the process according to the invention.
Fig. 4 shows the constant control cycle (main loop) that runs during the process.
Fig. 5, 6, 7, 8 show the details of the measuring interruptions occurring during the main cycle.
Fig. 9 shows the constant control cycle (main loop) that runs during the process, including the measuring interruptions.
Fig. 10 and 11 show the process of fault-condition checking that runs during the process.

Fig. 1 is the front view of the incubator 20 working on the basis of the process according to the invention, shown partially from the side. Fig. 1 shows the hood 1, lateral handling window 2, front handling window 3, door 4, cradle with pillow 5, display-handling foil 6. Further components that can be seen in the figure include the middle part 7 of the incubator 20, the leg structure 8, storage shelf 9, and the wheel 10. The Fig. 1 shows furthermore the front panel 45 of the incubator 20, with the LCD display 46 mounted on it, 9-LED panel 47 and pushbuttons 48.

Fig. 2 is the rear view of the incubator 20 working on the basis of the process according to the invention, shown partially from the side. The infusion stand 11 above the incubator 20 can be seen in Fig. 2. The humidifier pump 12 is located at the rear part of the incubator 20, together with the connecting terminal 13, air filter 14, mains connector part 15, distilled water tank 16 and the residual water tank 17. Furthermore, a connecting terminal 13 used for connecting to the electronic hardware 18 are mounted on the rear of the incubator 20, which are electrically connected to the control card 19 installed within the incubator 20.

Fig. 3 shows the block diagram of the electronic hardware of the incubator 20 working on the basis of the process according to the invention. The components that can be seen in Fig 3 include the control card 19 which constitute the electronic hardware part 18 of the incubator 20, in which the microprocessor card 21 is installed with the internal connectors 22. The internal memory of the microprocessor card 21 includes the operating program too. The control card 19 contains the thermistor block 23, which ensures the level III protection, together with the test block 24, watch-dog block 25, warning block 26, power failure block 27, RS232 opto block 28 and ISP programming block 29, as well as the analogue amplifier block 31, motor driver block 32 and the heating switching block 33. On the side of control card 19 there are installed the connectors 30, which control the heating 34 working with a ~230 V voltage from the outside, as well as the power supply unit 35, which is connected to the external mains 36 having a voltage of ~230 V.

An external PC 37 is connected to the control card 19 from the outside through the RS232 opto block 28, or through the ISP programming block 29. The external sensors 38 (skin, rect, Ox1, Ox2), as well as the internal sensors 39 (regulating temperature sensor, display temperature sensor, humidity sensor, thermistor, opto-sensor that regulates the speed of fan) are connected through connectors 30. Also, through the connectors 30 are connected the scale 40, motors 41 (cradle motor A, cradle motor B, foot lifting motor), pump 42, fan 43, oxygen servo and warmer 44, together with LCD display 46 located on the front panel 45, 9-LED display panel 47 and the pushbuttons 48.

Fig. 4 shows the constant control cycle (main loop) that runs during the process. In the main control cycle the events that occur continuously include the adjustments of incubator, handling of peripherals, handling of inputs and outputs, checking of fault conditions, indications of faults, and the interventions made in response to the faults. The process of checking the fault condition is described with reference to Fig 9 and 10. The various interruptions occur at the moments t_1, t_2, t_3, t_4 in the main control cycle, in which the measuring cycles, belonging to the given moments, are completed.

Fig. 5, 6, 7, 8 show the details of measuring interruptions that occur during the main control cycle.
The measuring cycle executed at the moment t_1 is shown in Fig. 5. This is the time when the T_1 temperature value of the indicating sensor is transmitted to the main program, and then the return to the main program occurs.

Fig. 6 shows the measuring cycle that occurs during the interruption occurring at the moment t_2. This is the time when the T_2 temperature value of the control sensor is transmitted to the main program, and then the return to the main program occurs.

Fig. 7 shows the measuring cycle that occurs during the interruption executed at the moment t_3. This is the time when the T_3 temperature value of the sensor providing protection No. II is transmitted to the main program, and then the return to the main program occurs.

Fig. 8 shows the measuring cycle that occurs during the interruption executed at the moment t_4. This is the time when the T_4 temperature value measured by the thermistor is transmitted to the main program, and then the return to the main program occurs.

Fig. 9 shows the constant control cycle (main loop) running during the process with the measuring interruptions. In the main loop this constantly running control cycle keeps on repeating itself, runs in circle, and it is temporarily interrupted at the programmed moments:
at moment t_1 – the T_1 temperature is measured (display temperature),
at moment t_2 – the T_2 temperature is measured (temperature of regulating sensor),
at moment t_3 - the T_3 temperature is measured for protection II (for internal use),
at moment t_4 – the T_4 temperature is measured – measuring the temperature of thermistor T (protection III).

These sub-loops return the values to the main loop. The main loop is interrupted, and then its operation is resumed. The main loop runs continuously, and these values arrive at t moment in an almost unobservable manner in timed mode (t_1, t_2, t_3, t_4).

Data are continuously collected during the running of the main loop, the main loop continuously runs onto the checking program module, which evaluates the temperature data received in a manner described above. It performs the following functions during this process:
- displays and
- controls the control cycles,
- checks the protecting limit values,
- intervenes in case of fault,
- shuts off the heating as a final measure.

Figs. 10-11 show the process of checking the fault conditions during the process. The following steps occur during the checking of fault condition.

Step 1: The values of the display and the control sensor are compared, and if the difference of values exceeds a given value (deviates extensively), then a so called "joint running error" signal is generated.

Step 2: After a certain time (after the adjusting time) it is checked whether the value T_2 of the control sensor t2 arrives at the target temperature range, i.e. at the range +/- d2. If not, then the "time out" error signal is generated.

Also, if the temperature is too low, then the "Lower limit" error signal is generated.
If the temperature is too high, then the "Upper limit" error signal is generated.

The following protecting levels are available in the system:
Protecting level I
If the T_1 Display temperature exceeds Level I, i.e. 38.5 °C, then the "Upper limit" error signal is generated.

Protecting level II
If the T_3 temperature (heat sensor II) exceeds 39.5 °C, then the "Upper limit" error signal is generated.

Protecting level III
If the T_4 (thermistor) temperature reaches 40.5 °C, then the "Technical error" signal is generated, and at the same time the hardware is shut off automatically.

General protection:
- All the four sensors are compared to the T_{lower} and T_{upper} temperature limits, and an "outside the limit" signal is generated if the values are outside the limits.

Hardware protection is also used for preventing overheating:
The heating wire is dimensioned in a way, that the temperature in the hood space cannot exceed 45.5 °C even if the heating system does not turn off.

The possible preferred actual applications and embodiments of the solution according to the invention are described below:

Major features of the hardware and the software are as follows:
- The essential concept for the hardware is that all units should be located on the motherboard (card).
- The power supply part and the control electronic part should be separated effectively.
- The construction should make sure that the electronic part receives voltage only after the power supply unit has been checked next to it.
- The motherboard can be separated physically also at the connection of the supply voltage, therefore, the two parts can be located separately also if required, and then the two parts can be connected with cable.
- The customer hospital may order various optional functions to be implemented in the incubator.
- The software is optimized fully to the hardware, it can be coupled to the hardware.
- The software is unified, it can handle all options that can be installed subsequently (sensing, operating), but the settings at the series of DIP (Dual Inline Package) switches located on the motherboard determine what functions are handled actually.
- The input and output are separated on the motherboard.
- The connectors at the rear panel provide the input.
- The connectors towards the inside of the machine provide the output.

The major characteristics of the sensors and the signal processing are as follows:
- Serial communication is used in the electronic circuits because of the large number of peripherals, sensors, controls and output indications.
- There are seven I^2C bus peripherals, which may be output or input – e.g. reading DIP switches or operation of motors, or keyboard and LED indicating module.
- The Sensors: work on 1-wire basis (Dallas) (supply, ground, 1 sensing signal)
- A number of independent heat sensors are used:
    - 1. Sensor of display – 1-wire
    - 2. Sensor of regulating loop - 1-wire
    - 3. Sensor of the so called „Protection II" (serial)

The sensors receive the same values, and they check one another.
These ensure the three levels of safety, which are handled by the system with the help of a software.
- There is a forth level of safety too, - which is based on intervention by the hardware, i.e. a thermistor turns off the heating, if the temperature reaches a given value (>40.5 °C).

The equipment includes two optional features for handling two external sensors,
- skin sensor
- rectal temperature sensor
The length of the lead for these sensors can be up to 2 m.

The thermistor, as well as the two external sensors (skin, rectal) are NTC type components (with negative thermal coefficient). These components efficiently filter the noise in a digital manner with current generator drive.

The thermometer and the humidity meter are jointly installed in the sensor that provides Protection II, and the sensor also has a serial connection. The A/D converter is included in the temperature and humidity sensor, this has to be read only, these are protected from noise. The thermistor and the external sensors emit analogue signals, which should be provided with noise filtering, should be made protected from noise. The protection against noise is accomplished by passing the current of a current generator through them, and then the U = I x R(T) is measured, which is the function of the temperature.

There is yet another extra possibility for external connection, which could be used for supplementary checking the temperature and humidity content in the incubator. This is suitable for the incubator to carry out a self calibration. With the help of the software the incubator performs a self calibration, during which a serious of temperatures are measured with a frequency of 3 days for example.

External connection:
The electronic control unit of the incubator keeps contact with the external world with an Excel program running on a PC through an RS 232 port. The program places the data into an Excel table, and can handles the changes in the data in a graphical manner. This happens during calibration, but is can be used also during operation.
Through this RS232 port it is possible to communicate with the PC back and forth, the PC can send measuring data and can receive commands. This feature allows the connection to certain hospital systems, e.g. Philips devices. There is a LAN port for connecting to other systems (UTP). The older hospital devices are not suitable for UTP connection, that is why the RS232 is used, as the system has to be compatible from above.

Other operating features:
It is important to ensure the protection from electrical shock, including the galvanic isolation of connected external devices. A suitable device for this purpose is the opto coupler, which is capable of ensuring galvanic isolation. For this purpose the supply voltage is obtained from external sources (diode + filtering capacitor), and 1 cm leakage current distance is used on the printed circuit board, which allows the insulation of 600 V.

In a preferred embodiment a commercially available assembled card, control card can be used with the belonging microcontroller, which has a software that can be modified (ICP In Circuit Programming) during operation.

One of the tasks was to find a solution, so that the software could resume the operation of the incubator where the malfunction occurred. This solution includes the storing of the operating settings in a non-volatile memory (FRAM), and the values set here are regarded as initial values when the software is induced. This "trend" storage during the operation takes place in FRAM in intervals of 3 hours, 24 hours and 170 hours. In this way, it is possible to retrieve the history of events from the device.

Further options:
Further two oxygen sensors can be used for the operation of the incubator, one for indication and one for regulating. The display and the regulations must be independent here too. The output of the sensors is voltage, which is measured with the A/D converter. The oxygen is passed through lukewarm water for preliminary warming before introducing it into the hood space.

Major characteristics of the software development:
- One of the objectives of the development of the software was to establish display and regulation of the temperature, and to ensue that it is kept within the specified limits.

Safety, protection levels:
Multiple levels of safety and protection are available:
First level: Constantly running software-based control (regulating sensor)
Second level: Indication of temperature (display sensor)
Further level: Protection level sensing.
Further level: Reading the hardware-based protection level.

Four independent programs run simultaneously to compare and harmonize these protection levels, including lower/upper limit value checking by each one of them, as well as the continuous comparison of four different temperature values.

Supervisory functions:
In addition to these, there are further supervisory functions, that can be accomplished with further checking channels and functions. These include the skin sensor and the rectal sensor, as well as an external thermometer, which measures the internal temperature of the incubator independently. This is good for increasing the basic safety technology of the device during the calibration, because this is the heat sensor which provides the real temperature of the incubator space independently during the calibration test process.

This includes a further safety function, because the heat sensors are installed at different locations, so that they would be protected against mechanical damages during cleaning and use. The sensor mounted on the additional cable, introduced into the hood space, provides actual information about the temperature prevailing in the hood space. The rest of the sensory, regulating and display module is placed in a protecting housing, and it always shows a value corrected with an offset value as a result of its physical location. The sensors are not located in the incubator space, therefore, the values are corrected with so called offsets, which interacts with one another in certain sense, because the heat generated by the respective units influence the data of the nearby sensors. The additional sensor mounted on the hanging cable allows the correction of the signals of the other sensors with the appropriate offset during calibration.

In the present case the structure of the incubators means a direct constraint regarding the location of the sensors, because they cannot be placed just anywhere, and at the same time proper conditions shall be ensured to allow calibration and the possible most reliable operation.

The main regulating functions of the control software of the incubator.
The incubator must meet the following major requirements:
- appropriate temperature
- appropriate humidity content
- measuring the mass
- introducing external probes and measuring instruments (oxygen, EKG, infusion supply, etc.),

while maintaining the basis function of the incubators.
The operating program must harmonize, provide and correct these basic functions.

In association with the provision of the operating functions, it is an important aspect, that it should be possible to distinguish a random malfunction or shut off/restarting from the normal shut off. Depending on that, the software should start with the factory default values after a certain time. If shutdown occurred because of malfunction, then the software should resume the control of the operation on the basis of the values saved most recently. This malfunction restoring time can be adjusted in the range of 10-20 sec, while the full shut off is a longer interval. This can be an optional preferred application.

New features in the operation and control of the incubator:
With regard to the operation and control of the incubator, the checking of temperature, and the multiple software-based checking of incubator operation can be regarded as a novelty.

The multiple checking with software takes place as follows:
1. Basic function: Serial reading of displaying sensor (This is the 1-WIRE sensor).
The value of this sensor is displayed at the LCD display. The sensor 2 (1-WIRE) is included in the circuit of the regulating cycle, the value of sensor 3 is compared with regard to the lower and upper limits of the protection, the sensor 4 (thermistor) is compared through an AD converter with the uppermost limit of 40 degrees. This process takes place in 1 second long cycles.
2. The numerical value of each sensor is compared to all other values (to make sure that they are equal), and that they are within (or outside) the given range.
3. Expectation also exists regarding the timing, which means that the desired temperature values reach the target range in due time.
4. A check is made to reveal any alarm condition that occurred during this time.

The hardware elements of the used sensor system:
1. Display sensor (1-wire)
2. Sensor of regulating circle (1-wire)
3. Sensor of protection II (higher than 39.5 °C) and serial reading
4. Hardware intervention with thermistor (to make sure that the temperature does not exceed 40.5 °C)

Multiple occurrence of these faults can happen, therefore, the software is designed to store these faults in the memory. For deleting the error messages, each error has to be acknowledged separately by the user, and each and every error has to be reset. All occurred faults are to be recorded. The faults are stored in the sequence of their occurrence (LIFO – Last In First Out), that is why they can be deleted only one by one.

Advantages:
The advantage of the solution according to the invention is that it supervises and checks the temperature of the incubator inner space in a highly reliable manner, and it regulates the temperature with the required extent to the desired value or range. By integrating a complex hardware, that can be handled by means of software too, it was possible to expedite the process of calibration significantly, and that the system could be tested also at the extreme value ranges. It also allows the installation of interchangeable components, that have been calibrated already in the factory.

The advantage of the solution is that the construction allows a more accurate adjustment of the operation with hardware-based as well as by software-based means, and at the same time it is possible to achieve measuring values from which further useful information and conclusion can be extracted for further improve the quality and safety of the system. The combination of the formerly used purely hardware-based solution and the later software-based solution allows to ensure maximum safety during the operation based on the fact, that the two systems mutually supervise each other.

The computer protocol associated with the controller regulating system allows the connection to the external complex hospital systems or to other computerised systems through the older RS232 lines, as well as through the newer Ethernet type lines. This features extends the field of application within the various modern health care institutes, as well as the capability of cooperation with other devices, and the remote supervision in hospitals, as a result, ensuring safety at a higher level.

List of references

1 - hood
2 - lateral handling window
3 - front handling window
4 – door
5 - cradle (with pillow)
6 - indicating-handling foil
7 - middle part
8 - leg structure
9 - storage shelf
10 - wheel
11 - infusion stand
12 - humidifier pump
13 - connecting terminal
14 - air filter
15 - mains connector part
16 - distilled water tank
17 - residual water tank
18 - electronic hardware
19 - control card
20 - incubator

21 - microprocessor card program
22 - internal connectros
23 - (Protection III) thermistor block
24 - test block
25 - watch-dog block
26 - alarms block
27 - power failure block
28 - RS232 opto block
29 - ISP programming block
30 - connectors
31 - analogue amplifier block
32 - motor 3 driver block
33 - heating switching block
34 - heating (~230 V)
35 - power supply unit
36 - external network (~230 V)
37 - PC
38 - external sensors (skin, rect, ox1, ox2)
39 - internal sensor module
40 - scale
41 - motors (cradle motor A, cradle motor A, foot lifting motor)
42 - pump
43 - fan
44 - oxygen servo and warmer
45 - front panel
46 - LCD display
47 - 9-LED panel
48 - pushbuttons

CLAIMS:

1. Process for supervising and controlling the operation of infant incubators, during which process the temperature and humidity parameters of the incubator space is measured with the help of sensors, and the values are converted to electrical data, and based on these data, the operation of the incubator is supervised and controlled,

characterized by that,

during the process a main control cycle is applied, which constantly runs in a main loop during the process, during which main control cycle the adjustments of the incubator (20) constantly occur, including the handling of peripherals, handling of inputs and outputs, checking of fault condition, as well as the measures taken in response to these actions, and in relation to the main control cycle the interruption is used at least at one moment (t_1), during which the measuring, checking cycle, belonging to the given moment (t_1) is proceeded.

2. Process according to claim 1, characterized by that, two interruptions are applied at two different moments (t_1, t_2) in the main control cycle running in the main loop, during which the measuring, checking cycles, belonging to the given moments (t_1, t_2) are proceeded.

3. Process according to claim 1 or 2, characterised by that, three interruptions are applied at three different moments (t_1, t_2, t_3) in the main control cycle running in the main loop, during which the measuring, checking cycles, belonging to the given moments (t_1, t_2, t_3) are proceeded.

4. Process according to any of the claims 1 - 3, characterized by that, four interruptions are applied at four different moments (t_1, t_2, t_3, t_4) in the main control cycle running in the main loop, during which the measuring, checking cycles, belonging to the given moments (t_1, t_2, t_3, t_4) are proceeded.

5. Process according to any of the claims 1 - 4, characterized by that, the value of T_1 temperature of display sensor is transferred to the main program in the measuring, checking cycle taking place during the interruption which is started at t_1 moment, then the return to the main program occurs.

6. Process according to any of the claims 1 - 5, characterized by that, the value of T_2 temperature of regulating sensor is transferred to the main program in the measuring, checking cycle taking place during the interruption started at t_2 moment, then the return to the main program occurs.

7. Process according to any of the claims 1 - 6, characterized by that, the value of T_3 temperature of sensor ensuring the protection No. II is transferred to the main program in the measuring, checking cycle taking place during the interruption which is started at t_3 moment, then the return to the main program occurs.

8. Process according to any of the claims 1 - 7, characterized by that, the value of T_4 temperature of measured by the thermistor is transferred to the main program in the measuring, checking cycle taking place during the interruption which is started at t_4 moment, then the return to the main program occurs.

9. Process according to any of the claims 1 - 8, characterized by that, the control cycle running constantly in the main loop keeps on repeating itself, it runs in circle, and this is temporarily interrupted at programmed moments with the sub-loops, and then these sub-loops return the values to the main loops, the main loops is interrupted and subsequently started again, the main loop runs continuously, and these sub-loops run in timed manner starting at moments t_1, t_2, t_3, t_4.

10. Process according to any of the claims 1 - 9, characterized by that, data are continuously collected during the running of main loop, and the main loop continuously runs onto the supervisory program module, which evaluates the temperature data received as mentioned above, and during this evaluation it performs the tasks of displaying and executing the regulating cycle, checking the protection limit values, intervening in case of fault, and shutting down the heating as an ultimate measure.

11. Process according to any of the claims 1 - 10, characterized by that, the following steps occur during the checking of fault conditions,
- in the first step the value of the display sensor and the values of the regulating sensor are compared, and if the difference between them exceeds a given value, or they deviate significantly, then a so called "joint running error" signal is generated,
- in the second step it is checked whether the T_2 value of t_2 regulating sensor is within the target temperature range of +/- d2, if not, then the "time out" error signal is generated.

12. Process according to any of the claims 1 - 11, characterized by that, a "Low limit" error signal is generated if the temperature proves to be too low during the checking of fault condition, and a "High limit" error signal is generated if the temperature proves to be too high during the checking of fault condition.

13. Process according to any of the claims 1 - 12, characterized by that, the following protecting levels are included in the system:
- protecting level I ensures that a "High limit" error signal is generated, if the T_1 display temperature exceeds the first level, i.e. 38.5 °C,
- protecting level II ensures that also a "High limit" error signal is generated, if the T_3 temperature (heat sensor II) exceeds 39.5 °C,
- protecting level III ensures that a "technical error" signal is generated, if the T_4 (thermistor) temperature reaches 40.5 °C, and at the same time the hardware is turned off automatically,
- protecting level IV provides a general protection by comparing all the four sensors with the T_{lower} and T_{upper} temperature limits, and a "outside the limit" signal is generated, if these values are outside the limits.

14. Process according to any of the claims 1 - 13, characterized by that, a hardware-based protection is also used against overheating, meaning that the heater wire is dimensioned in a way, that the temperature cannot increase above 45.5 °C even if the heating system is not turned off.

15. Process according to any of the claims 1 - 14, characterized by that, the sensor providing protection level II contains the thermometer as well as the humidity meter, and it has a serial connection, the A/D converter is included in the temperature and humidity sensors, these are protected from noise, the thermistor and the external sensors emit analogue signals, the noise of the signal of these components is filtered by passing the current of a current generator through them, this way the voltage $U = I \times R(T)$ is measured, which is the function of the temperature.

16. Process according to any of the claims 1 - 15, characterized by that, there is an additional external connector, which allows the measurement of the temperature and humidity of the incubator space, as well as that the incubator calibrates itself with the help of a test software, determining a series of temperatures during this test, and the frequency of this measuring cycle could be 3 days.

17. Process according to any of the claims 1 - 16, characterized by that, regulating electronic unit of the incubators keeps contact with the outside world by means of an Excel program running on a PC via an RS 232 port, the data are placed by the program into an Excel table, and it is possible to handle the change of data in graphical manner, which happens during calibration, but it can be applied also during operation, the RS 232 allows the connection to certain hospital systems, while UTP ports is used for connecting to other LAN systems.

18. Process according to any of the claims 1 - 17, characterized by that, an opto coupler is used for isolating the incubator from connected external device for the purpose of protection against electrical chock, the supply voltage for this purpose is obtained from the external device, 1 cm leakage current distance is use on the printed circuit board of the control card, which allows the insulation of 600 V.

19. Process according to any of the claims 1 - 18, characterized by that, the software resumes the operation of the incubator with the values that were present when the malfunction occurred, for this purpose the values are stored in a non-volatile memory (FRAM) when the controller is set up, and these set values are taken as initial values when the software starts, and this "Trend" storage is made in the FRAM in 3 hour, 24 hour and 170 hour intervals.

20. Process according to any of the claims 1 - 18, characterized by that, a further safety function is applied during the process, and this function is accomplished by placing the sensors so that they are protected from mechanical damage during cleaning and use, and a sensor mounted on a cable hanging in the incubator space provides actual information about the temperature prevailing in the incubator space, while the rest of the checking, regulating and display modules are installed in protected housing, therefore, it always shows a value corrected with an offset corresponding to its location, as the values are to

be corrected with so called offsets because they are not actually placated in the incubator space, and they interact to a certain extent, because the heat generated by the respective units influences the sensors located there, in this way the additional sensor mounted on the hanging cable provides the possibility of correcting the signals of the other sensors with an offset value.

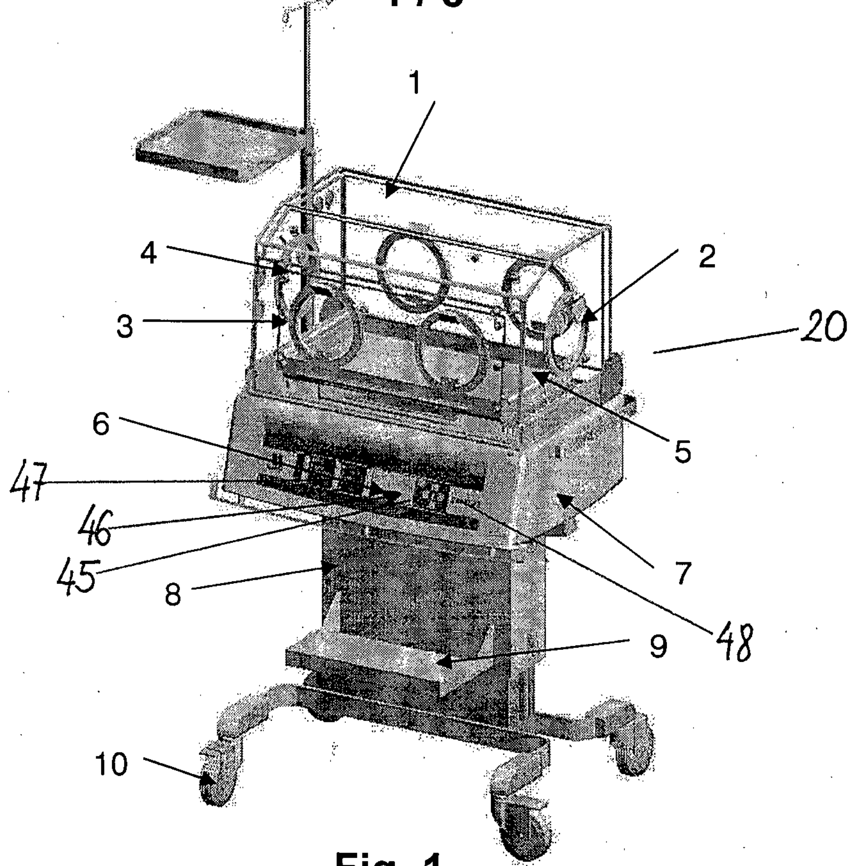

Fig. 1

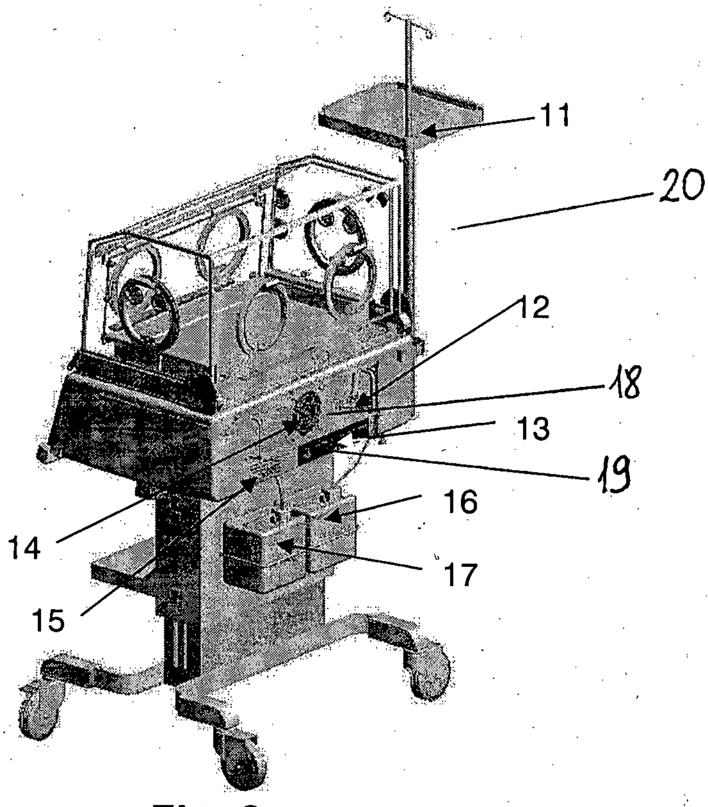

Fig. 2

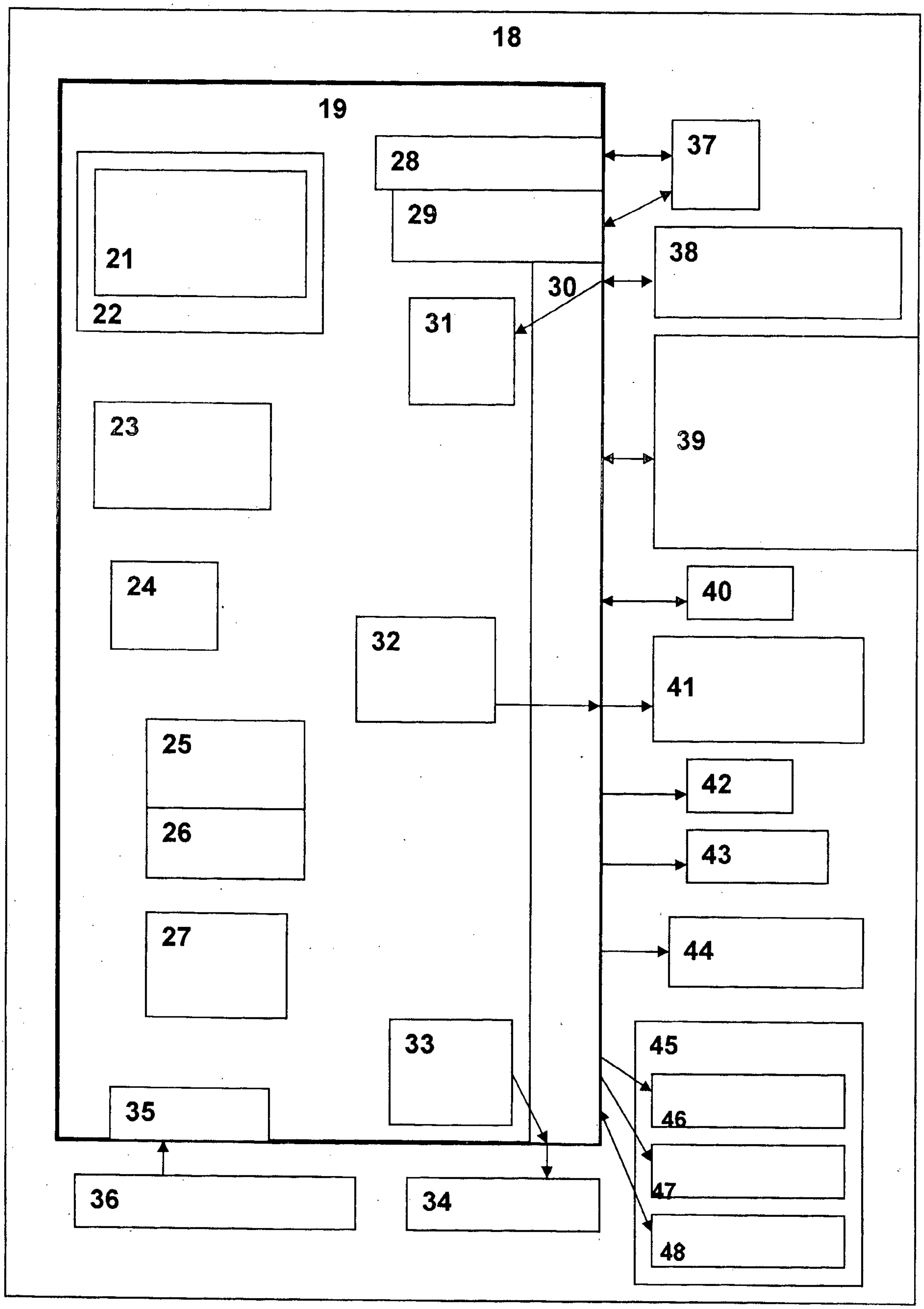
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Fig. 3

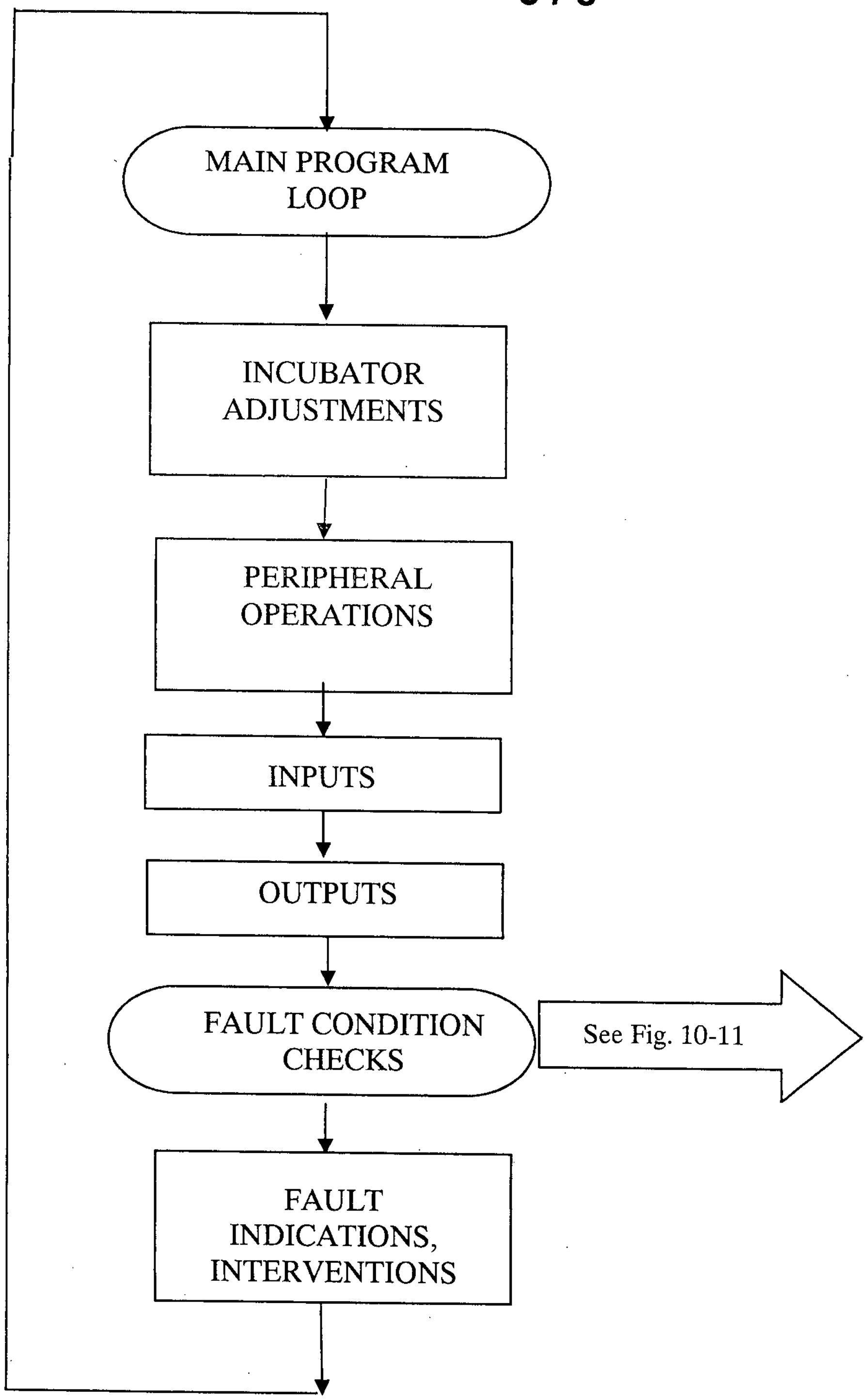
MAIN PROGRAM LOOP
INCUBATOR ADJUSTMENTS
PERIPHERAL OPERATIONS
INPUTS
OUTPUTS
FAULT CONDITION CHECKS
See Fig. 10-11
FAULT INDICATIONS, INTERVENTIONS

Fig. 4

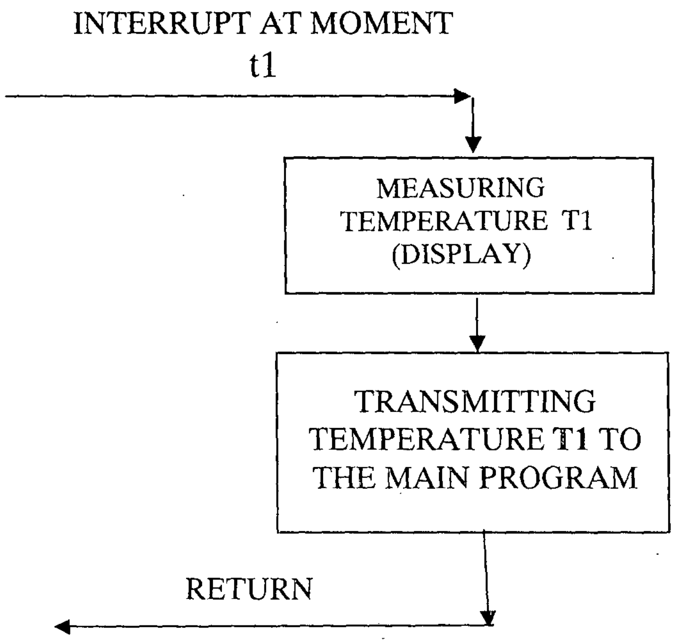
INTERRUPT AT MOMENT t1
MEASURING TEMPERATURE T1 (DISPLAY)
TRANSMITTING TEMPERATURE T1 TO THE MAIN PROGRAM
RETURN

Fig. 5

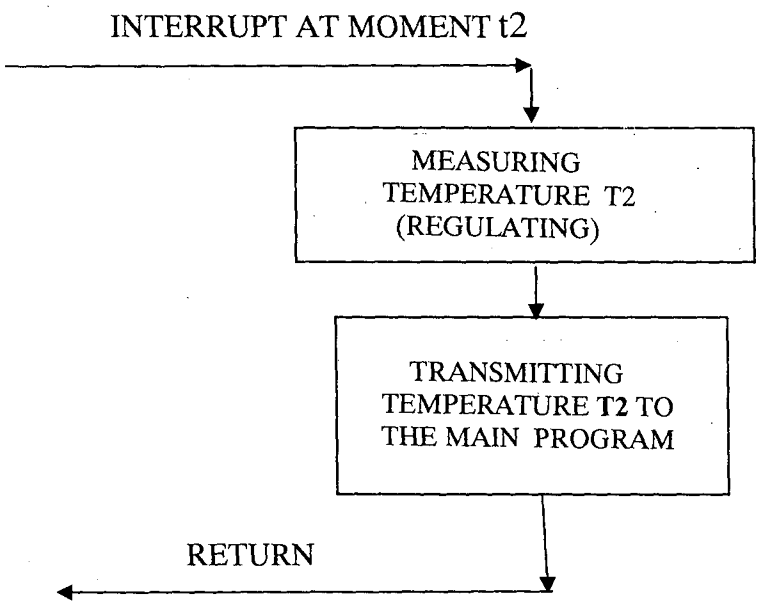
INTERRUPT AT MOMENT t2
MEASURING TEMPERATURE T2 (REGULATING)
TRANSMITTING TEMPERATURE T2 TO THE MAIN PROGRAM
RETURN

Fig. 6

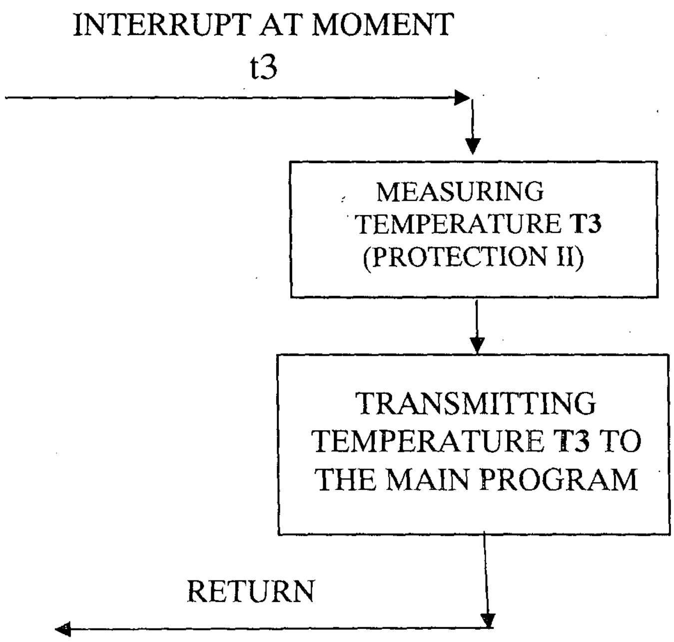
INTERRUPT AT MOMENT t3
MEASURING TEMPERATURE T3 (PROTECTION II)
TRANSMITTING TEMPERATURE T3 TO THE MAIN PROGRAM
RETURN

Fig. 7

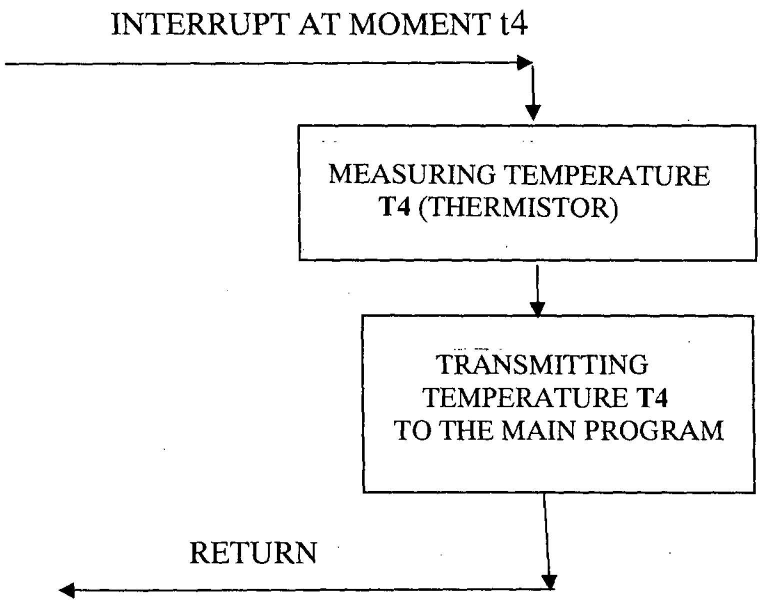
INTERRUPT AT MOMENT t4
MEASURING TEMPERATURE T4 (THERMISTOR)
TRANSMITTING TEMPERATURE T4 TO THE MAIN PROGRAM
RETURN

Fig. 8

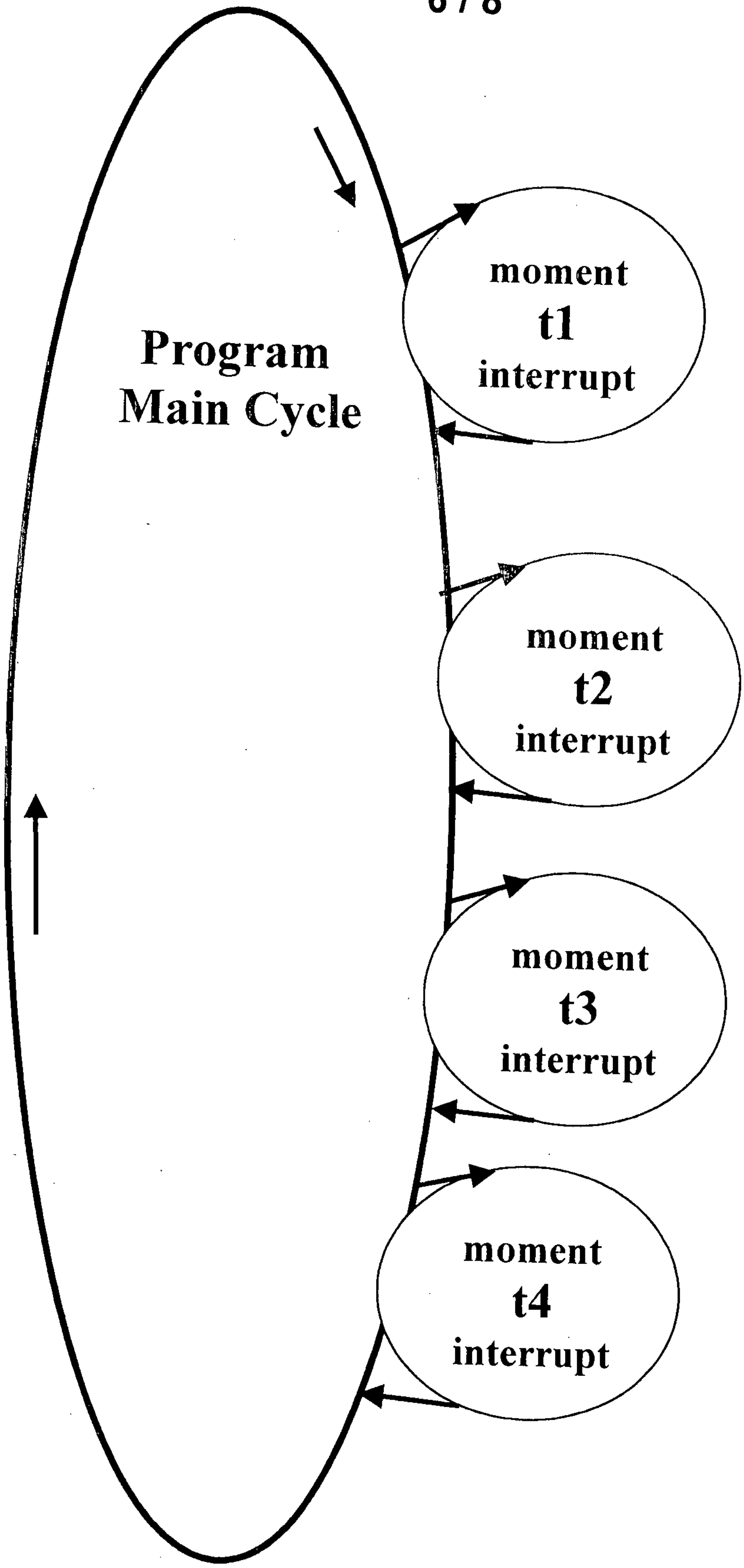
Program
Main Cycle
moment
t1
interrupt
moment
t2
interrupt
moment
t3
interrupt
moment
t4
interrupt

Fig. 9

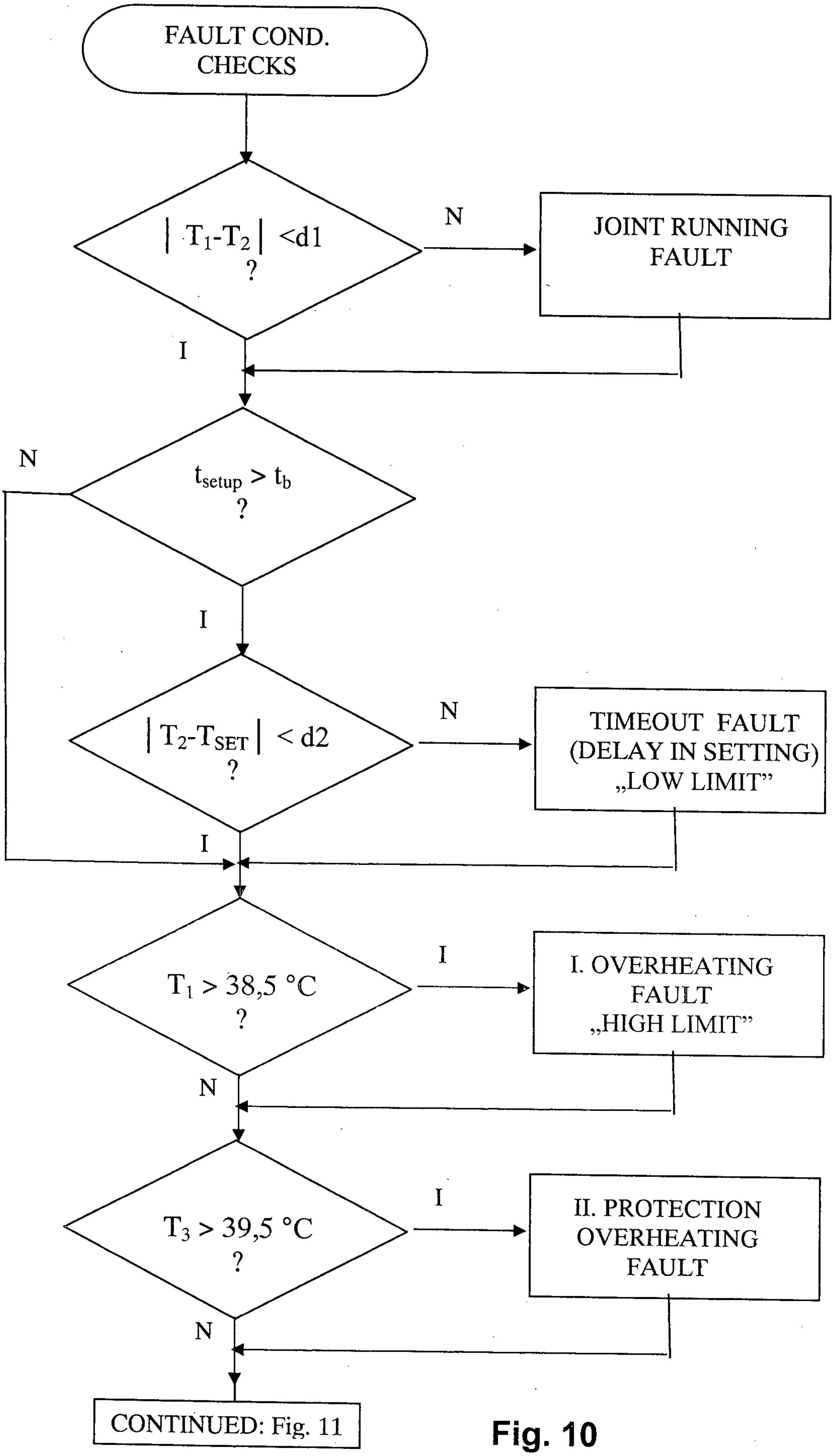
FAULT COND. CHECKS
| T1-T2 | <d1 ?
N
JOINT RUNNING FAULT
I
tsetup > tb ?
N
I
| T2-TSET | < d2 ?
N
TIMEOUT FAULT (DELAY IN SETTING) „LOW LIMIT”
I
T1 > 38,5 °C ?
I
I. OVERHEATING FAULT „HIGH LIMIT”
N
T3 > 39,5 °C ?
I
II. PROTECTION OVERHEATING FAULT
N
CONTINUED: Fig. 11

Fig. 10

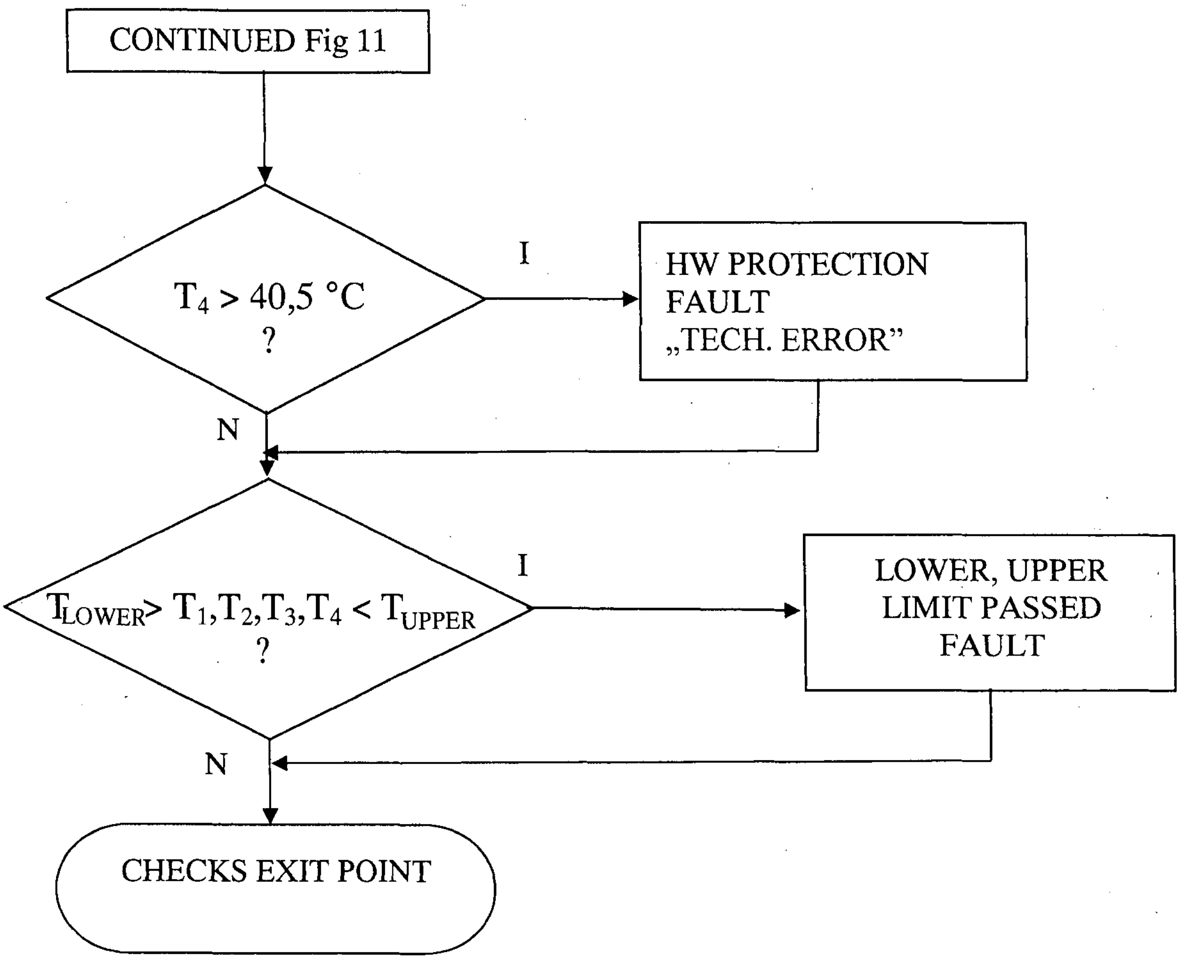
CONTINUED Fig 11
T4 > 40,5 °C
?
I
HW PROTECTION
FAULT
„TECH. ERROR"
N
TLOWER> T1,T2,T3,T4 < TUPPER
?
I
LOWER, UPPER
LIMIT PASSED
FAULT
N
CHECKS EXIT POINT

Fig. 11

INTERNATIONAL SEARCH REPORT

International application No.

PCT/HU 2012/000030

A. CLASSIFICATION OF SUBJECT MATTER ***A61G 11/00*** *(2006.01)*
H05B 1/02 *(2006.01)*
G05B 9/03 *(2006.01)*
G05D 23/24 *(2006.01)*

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61G 11/00, H05B 1/00-1/02, G05B 9/00-9/03, G05D 23/00-23/24

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PatSearch (RUPTO internal), Esp@cenet, PAJ, USPTO

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/0197003 A1 (HERALD ALEXANDR KNEUER) 23.10.2003, [0058], [0060], [0009]-[0011], [0036]-[0037], fig. 2, 4b, [0039], [0042], [0015]-[0016]	1
Y		10-11
Y	RU 2365362 C1 (FEDERALNOE GOSUDARSTVENNOE UNITARNOE PREDPRIYATIE "NAUCHNO-PROIZVODSTVENNY TSENTR AVTOMATIKI I PRIBOROSTROENIA IMENI AKADEMIKA N. A. PILYUGINA" (FGUP "NPTS AP")) 27.08.2009, p. 5, line 48-p. 6, line 22, p. 7, lines 12-53	10-11
A	RU 90325 U1 (FEDERALNOE GOSUDARSTVENNOE UNITARNOE PREDPRIYATIE "PROIZVODSTVENNOE OBIEDINENIE "URALSKY OPTIKO-MEKHANICHESKY ZAVOD" IMENI E. S. YALAMOVA" (FGUP "PO "UOMZ")) 10.01.2010, abstract	1-20
A	US 2002/0173696 A1 (RONALD S. KOLAROVIC et al.) 21.11.2002, fig. 4	1-20

☐ Further documents are listed in the continuation of Box C.   ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 November 2012 (12.11.2012)	22 November 2012 (22.11.2012)

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