A device for simulating pathological states, in particular cardiovascular, comprising: a manikin with an external shell reproducing the skin of a patient, a plurality of actuators (1) associated with different parts of the shell and arranged to move said parts, means (2) for feeding a reference signal for each of said pathological states, and means (3) for individually activating the actuators by providing the actuators with an activation signal correlated with the fed reference signal so as to cause the respective parts of the shell to move in a predetermined manner. The device also comprises a control unit connected to selection means (5, 6, 7) enabling the user to set, for each of said actuators, a variation in at least one of the characteristic quantities of the fed reference signal, and means (8) for generating, for each actuator, a feed signal for said activation means (3), said feed signal being dependent on a check, effected for each actuator by comparator means (9), on the value assumed by said characteristic quantity of the reference signal and the value of said characteristic quantity set by the user by said selection means.
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DEVICE FOR SIMULATING PATHOLOGICAL STATES, IN PARTICULAR CARDIOVASCULAR, COMPRISING MEANS FOR MODIFYING THE SIMULATION, AND THE OPERATING AND CONTROL METHOD FOR THE DEVICE

This invention relates to a device for simulating pathological states, in particular cardiovascular, in accordance with the precharacterising part of the main claim, and the operating and control method for the device.

Devices of the aforesaid type have been known for some time (see for example the patents US 3,880,020, US 3,947,974, US 4,601,665 and EP 0,561,658). For each of the actuators which move the various parts of the manikin, these devices generally comprise means for feeding the actuator with a specific signal for each of the pathological states to be simulated, so that the actuators can simulate the movements typical of the pathology selected. US patent 4,601,665 describes for example a manikin comprising: a memory device containing a predetermined digital movement program for the actuators, a processor programmed by the memory device and presenting a plurality of analog electrical output signals in response to the program, and means for individually powering the actuators in relation to the analog output signals to move the various parts of the manikin in a predetermined programmed manner.

In all known manikins the actuators are each fed with a previously memorized signal relative to the pathology to be simulated, this being obtained by means of a memorized program which cannot be modified by the device user, but only by the device manufacturer. The user of the manikin is hence unable in any way to modify the feed signals to one or more actuators of the manikin, except by
selecting a different set of signals or programs relative to a
different pathology. In other words, after the manikin user has
commenced simulation of a determined previously memorized
pathology, he has no facility for varying the rhythm or pulsation
of one or more of those parts of the manikin in movement, nor is
he able to "delay", i.e. desynchronize, the movement of one of said
parts relative to the others. Consequently the user of known
manikins has to be content with "standardized" simulations of
determined pathologies, and cannot "correct" the memorized
standard simulations.

Hence with known manikins, the user is unable to simulate a non-
standard case which has been actually observed, or a theoretical
case which it is wished to study.

An object of the present invention is to provide a device for
simulating pathological states, in which the user is able at his
own will to modify at least one of the characteristic quantities
relative to the movement of one or more of the actuators provided
in the various moving parts of the manikin, and is able to
introduce delays in the movements of one of said parts relative to
the other.

A further object is to provide a device of which the modifications
to the characteristic quantities and the delays set by the device
user can be memorized, so that the user can reuse the simulation
of personalized non-standard pathological states.

A further object is to provide a low-cost device of easy use and
simple operation.

A further object of the present invention is to provide a method
for operating and controlling a device for simulating pathological
states, in which having once commenced simulation, the user is
able to modify the previously memorized operation of one or more
actuators provided in the manikin to simulate movement of part of
the manikin, and if required can cause the modifications made to
said operation to be memorized.

These and further objects which will be apparent to an expert of the art are attained by a device and method in accordance with the accompanying claims.

The invention will be more apparent from the accompanying drawings, which are provided by way of non-limiting example and in which:

Figure 1 is a circuit diagram of the main components of the device;
Figure 2 is a possible embodiment of the means for varying one of the characteristic quantities and for setting a "delay" in the movements indicated in the manikin by the various actuators;
Figures 3A to 3E show possible actuator feed signals;
Figure 4 is a possible flow diagram of a program for a device according to the invention.

With reference to Figure 1, the device according to the invention comprises a usual manikin (not shown) comprising a conventional outer shell reproducing the skin of the patient, a plurality of actuators 1 acting conventionally on different parts of the shell, usual means 2 for feeding a reference signal characteristic of a pathological physical state, and usual individual activation means 3 for the actuators, arranged to provide these latter with an activation signal based on the reference signal, such as to cause the respective parts of the shell to move in a predetermined manner. The device also comprises a control unit 4 connected to selection means 5, 6, 7, to set for each actuator 1 a variation in amplitude (5) and/or frequency (6) or a delay (7) in the reference signal fed by the means 2, means 8 generating for each of the actuators a feed signal for each of said activation means 3. This signal is based on a check conducted for each actuator by comparator means 9 on the reference signal and on any frequency variations, amplitude variations or delays set by the user for each actuator by said selection means 5, 6, 7.
The reference signal feed means 2 comprise usual memorizing means for said signal and usual reading means for the memorizing means, arranged to provide the reference signal at the input of the comparator means 9. Said means are advantageously of the type usually provided in a conventional electronic processor, such as a personal computer. The reference signal can for example be that relative to the heartbeat of a patient suffering from a particular cardiac pathology. The reference signal, preferably memorized in digital form, is a periodic signal of determined frequency and amplitude. Advantageously the reference signal coincides with the audio signal which the device can emit via conventional transmission means (for example of the type comprising an infrared transmitter and a receiver connected to a headset or earpieces worn by the device user during the palpitation of the manikin).

Advantageously a plurality of reference signals are memorized each relative to a particular pathological state to be simulated by the device. In this case the reference signal feed means also comprise usual selection means for the desired reference signal, said selection means being for example, as is conventional for the expert of the art, the interfaces of the personal computer and a usual memory handling program, and of the monitor of the processor. This latter could for example be of the window type and comprise a window 17 for selecting the pathological case to be simulated.

The selection means 5, 6, 7 by which for each actuator 1 the user sets a desired frequency, and/or an amplitude different from those of the reference signal, and/or a delay in the feed of said signal to the actuator, comprise a personal computer monitor interface.

By means of a program of conventional type to the expert of the art, there appears on the personal computer monitor a configuration 10 comprising (see Figure 2) a first window 11 relative to one or more actuators which simulate the movement of a first part of the manikin, for example the diaphragm, and a window 12 relative to the actuators of another part or other parts of the
manikin, for example the manikin's "pulses". The window 11 comprises three boxes 5A, 6A, 7A for modifying, for example decreasing, a standard frequency, amplitude and a delay for the diaphragm actuator.

Each box 5A, 6A, 7A comprises three sub-boxes A, B, C, the central sub-box B carrying the automatically preset standard frequency, amplitude and delay, which in the illustrated example are 25 and 0 respectively, the lateral sub-boxes A and C being for modifying the preset values. In this respect, it is sufficient, using the computer keyboard or mouse, to merely position onto one of the boxes A or C and press the enter key to automatically change the value by one unit.

The windows 12 relative to the manikin's pulses comprise three boxes 5A, 6A, 7A identical to those already described for the window 11, and a series of eight further boxes 13A-E, one for each actuator, for simulating the movements of the "pulses", i.e. of the actuators of the right and left carotid artery (13A, B), of the right and left groin (13C, D), of the right and left wrist (13E, F) and of the right and left elbow (13G, E). To vary the amplitude, frequency or delay of an actuator, the user must first position onto the desired actuator and proceed in the manner already described for the window 11. It should be noted that again in this case, if the user does not modify the amplitude, frequency or delay, the central sub-box B of the boxes 5A, 6A, 7A always presents a preset standard value common to all the "pulse" actuators, this value being in the illustrated example 65 for amplitude and frequency and 0 for the delay. The program for handling the monitor and the described selection means is of immediate implementation to the expert of the art, and is therefore not described in detail hereinafter.

The selection means 5, 6, 7 could also be of a different type from those described heretofore and comprise for example a usual microprocessor device of a more simple type than a personal computer, comprising a keyboard and a display for the data set for
each actuator.

The values selected by the means 5, 6, 7 are automatically saved in a temporary memory 13 (Figure 1) for the entire duration of the simulation. These values can however also be saved in another memory (Figure 1), for example on the hard disk of a personal computer or on a floppy disc, so as to be able to be recalled for subsequent simulations. For this purpose, on the configuration 10 appearing on the computer monitor there are provided two further windows 15 and 16, the use of which is described hereinafter.

The comparator means 9 are arranged to check for each actuator whether the amplitude and frequency set by the user or preset automatically are the same as or different from those of the reference signal memorized by the means 2 and selected by the user. If the values are different, the difference between the amplitude and frequency is calculated and the result fed to the signal generator means 8.

For each actuator, the comparator means also check whether the delay set by the user is different from zero, in which case they feed this value different from zero to the generator means 8.

Said comparator means can be implemented by a computer program of conventional type to the expert of the art and is therefore not described in detail hereinafter, the program comparing the data present in the memories 13 and 2 and computing the difference. Said comparator means could however be implemented by a conventional combination of usual electronic comparator devices.

The signal generator means 8 are arranged to generate a suitable signal for each actuator on the basis of the results of the comparisons effected by the means 9. In the most simple case in which neither frequency nor amplitude variations have been set for any of the actuators and in which the preset standard values automatically coincide with those of the reference signal, a signal identical to the reference signal is fed to all actuators.
In the case in which, as generally happens in pathological states, either the user has set, or the program has automatically preset, variations in frequency, amplitude or delay, the generator means create a suitable signal for each actuator.

By way of example, Figures 3A-E show respectively a reference signal relative to a particular pathological state (Figure 3A), the same signal but with double the frequency (Figure 3B), the same signal but with double the amplitude variation (Figure 3C), the same signal but with a half period delay (Figure 3D), and the same signal but with double the frequency and amplitude variation and with a half period delay (Figure 3E).

The signal generator means 8 for the actuators can for example comprise a usual personal computer and a suitable program for generating the desired signals. By way of example a possible program of this type is reproduced hereinafter arranged to generate output signals with a determined delay (time-delay) relative to a reference signal of determined frequency (time-pulse) and with a determined actuator activation time (time-solenoid) relative to the periodic cycle time of the actuator.

```c
#include <stdio.h>
#include <io.h>
#include <dos.h>

int data,i;

main()
{
    int i;
    long int j;
    long int time_pulse, time_solenoid, time_delay;
    unsigned char out;

    init_vs8100;
textbackground(LIGHTBLUE);
```
textcolor(LIGHTGRAY);
cirscrO;
time_pulse=25;
time_solenoid=1000;
time_delay=1000;

out=0xF;
outportb(address;PORT_B,out);
do{
    .for (j=0;j<time_delay;j++)
        outportb(address;PORT_B, 0x00);
    .for (j=0;j<time_delay;j++)
        outportb(address;PORT_B, 0x0F);
    .for (j=0;j<time_delay;j++)
        outportb(address;PORT_B, 0xFF);
    .for (j=0;j<time_delay;j++)
        outportb(address;PORT_B, 0x0F);
}
    while(1);
}

The program for generating signals of different frequency and/or amplitude than the reference signal is not described as it is of immediate implementation for the expert of the art.

The signal generation means 8 can also be implemented not only by using a usual personal computer and a relative program, but also by combining conventional electronic devices of microprocessor type which are simpler than a processor for performing like functions, these devices not being described hereinafter in detail as they are of usual type for the expert of the art.

The digital output signals from the generator means 8 are each fed to one of the actuator activation means 3. The activation means 3 are electronic devices conventional to the expert of the art and can be of different types according to the type of actuator with which they are associated. These devices transform the digital
output signal from the generator means 8 into a suitable
electrical activation and feed signal for the actuator to which
they are connected.

The actuators 1 can be of usual type, for example of the solenoid
type described in US 4,601,665, or of the loudspeaker type
described in DE 2,012,035. It should be noted that in actuators
of the first type only the frequency of movement of the movable
part can be varied but not also the amplitude of its movement,
whereas in actuators of the second type the amplitude of the
movement of the movable part can also be varied, but to a very
limited extent.

Actuators of a different type, satisfactorily adjustable not only
in frequency but also in amplitude could also be used, for example
electric motors, on the shaft of which there is keyed a cam acting
on a flat surface in contact with the shell of the manikin. The
oscillatory movement of the manikin part is obtained by rotating
the motor reciprocatingly through a predetermined angle of less
than 360°, firstly in one direction and then in the other. In
this case amplitude variations can easily be achieved by varying
the predetermined angle of rotation of the motor shaft. The
actuators used could also be usual electromagnetic devices of the
moving coil and fixed core type, for example linear motors, in
which the amplitude and frequency of movement of the moving part
of the actuator are easily varied by varying the feed to the
moving coil.

The manikin (not shown) and the outer shell are of conventional
type and could be of the type described in the aforesaid patents
(see for example US 4,601,665), they therefore not being described
in detail hereinafter.

To activate the device of the invention, the user firstly selects
via the box 17A one of the memorized pathological cases to be
simulated, then by acting on the box 17B he activates the manikin,
the movable parts of which are moved by the actuators to simulate
the selected pathology.

In this first mode of operation the signals for the actuators are generated by the means on the basis of the selected reference signal and on the basis of the preset fixed values, relative to amplitude and frequency variations and/or to a delay, of the actuator activation signals relative to the reference signal.

Said preset values are also memorized in the memory 2 and are automatically displayed in the boxes 5A, 6A, 7A of the windows 11 and 12 and made available to the means 8.

When he wishes to modify the movement of one or more parts of the manikin, the user, by positioning onto one of the windows 11, 12 which appear on the personal computer monitor, can achieve this by modifying the activation signal of one or more actuators, as heretofore described.

Before the end of a simulation in which the user has varied the values of the activation signals of one or more actuators, he can cause these values to be memorized by positioning onto the window 15, writing a suitable name in the box 15A and pressing the enter key. A suitable conventional program is used to hence save said values in the memory 14. The user is able to use the modified values by positioning onto the window 16 and acting in the manner already described for selecting a pathological case.

Figure 4 shows by way of example a possible flow diagram of a control program for the device.

Finally, it should be noted that the embodiment heretofore described is provided by way of example only, and that numerous modifications are possible, all falling within the same inventive concept.
Claims:

1. A device for simulating pathological states, in particular cardiovascular, comprising: a manikin with an external shell reproducing the skin of a patient, a plurality of actuators (1) associated with different parts of the shell and arranged to move said parts, means (2) for feeding at least one reference signal for each of said pathological states, and means (3) for individually activating the actuators by providing the actuators with an activation signal correlated with the fed reference signal so as to cause the respective parts of the shell to move in a predetermined manner, characterised by comprising: a control unit connected to selection means (5, 6, 7) enabling the user to set, for each of said actuators, a variation in at least one of the characteristic quantities of the fed reference signal, means (8) for generating, for each actuator, a feed signal for said activation means (3), said feed signal being dependent on a check, effected for each actuator by comparator means (9), on the value assumed by said characteristic quantity of the reference signal and the value of said characteristic quantity set by the user by said selection means.

2. A device as claimed in claim 1, characterised in that the characteristic quantities which can be set by the user are the amplitude of, the frequency of, and a delay in, the fed reference signal.

3. A device as claimed in claim 1, characterised in that the selection means (5, 6, 7) comprise at least one electronic processor interface.

4. A device as claimed in claim 1, characterised in that the selection means (5, 6, 7) comprise a display device and a display control program of "window" type.

5. A device as claimed in claim 1, characterised in that the control unit is of microprocessor type.
6. A device as claimed in claim 1, characterised by comprising means (14, 15) for memorizing the amplitude, frequency and delay values selected by the user for the actuators.

7. A device as claimed in claim 1, characterised by comprising means (16) for feeding amplitude, frequency and delay values previously memorized by the user.

8. A device as claimed in claim 1, characterised in that said feed means (2), selection means (5, 6, 7), generator means (8) and comparator means (9) are included in an electronic processor.

9. A device as claimed in claim 1, characterised in that the feed signal generated by the generator means (8) is the reference signal with at least one of its characteristic quantities varied in accordance with values set by the user using the selection means (5, 6, 7).

10. A method for operating and controlling a device for simulating pathological states, in particular cardiovascular, comprising a first stage in which one of the memorized pathological cases is selected for simulation, and a second phase in which the selected case is activated or "entered", so as to actuate in a predetermined manner actuators (1) provided in different parts of a manikin, and arranged to move said parts to simulate the selected pathology, characterised by comprising a third stage preceding or following said second stage, in which the user modifies the movement of at least one of the manikin parts.

11. A method as claimed in claim 10, characterised by comprising a fourth stage, following the third, in which the device user causes the modification set in said third stage to be memorized.

12. A method as claimed in claim 11, characterised by comprising a fifth stage in which one of the modifications memorized by the user in the fourth stage is selected.
13. A method as claimed in claim 10, characterised by comprising an automatic check on whether the device user, during the simulation of a pathological state, has set a modification to the movement of at least one of the manikin parts.

14. A method as claimed in claim 13, characterised by automatically generating, for the actuators (1) of those manikin parts for which the user wishes to vary the movement, an activation signal modified in accordance with information set by the user.

15. A method for controlling a device claimed in claim 1, characterised in that the feed signal generated by the generator means (8) is the reference signal with at least one of its characteristic quantities varied in accordance with values set by the user using the selection means (5, 6, 7).
SWITCH ON

LOAD REF. SIGNAL FOR A CASE
SELECTED BY USER.

CHECK WHETHER USER
WISHES TO SET NEW AMP.
OR FREQ. VALUES OR
A DELAY

YES

MEMORIZE VALUES
SET BY USER

NO

LOAD FIXED
PRESET VALUES

LOAD VALUES
SELECTED BY USER

CHECK WHETHER USER WISHES TO LOAD
THE VALUES PREVIOUSLY
MEMORIZED BY HIM

YES

FOR EACH ACTUATOR

CHECK WHETHER A AND F
VALUES OF REF. SIGNAL ARE
EQUAL TO THOSE SET OR MEMORIZED
FOR THAT ACTUATOR AND
WHETHER THE DELAY IS 0

NO

FEED REF. SIGNAL
TO ACTUATOR

YES

FROM THE REF. SIGNAL
GENERATE A NEW SIGNAL
OF MODIFIED A AND/OR F
AND/OR D

CHECK WHETHER DURING
SIMULATION THE USER WISHES
TO MODIFY A, F, D VALUES
FOR ANY ACTUATOR

YES

AWAIT POSSIBLE SWITCH-OFF AND POSSIBLE MEMORIZATION
OF VALUES SET BY USER.

NO

Fig. 4
**INTERNATIONAL SEARCH REPORT**

**International Application No**
PCT/EP 96/03133

### A. CLASSIFICATION OF SUBJECT MATTER

**IPC 6** G09B23/28

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)

**IPC 6** G09B

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 practical, search terms used)

### C. DOCUMENTS CONSIDERED TO BE RELEVANT

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<td>A</td>
<td>WO,A,94 18657 (ROFEH SIMULATIONS LTD) 18 August 1994 see page 9, line 22 - page 60, line 11; claims 1-3,5-12,28,29,54,55</td>
<td>1,5,10</td>
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<tr>
<td>A</td>
<td>US,A,4 828 501 (INGENITO MICHAEL ET AL) 9 May 1989 see the whole document</td>
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<tr>
<td>A</td>
<td>US,A,5 385 474 (BRINDLE CHARLES) 31 January 1995 see column 3, line 10 - column 12, line 31</td>
<td>1,3-5,8, 10</td>
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<td>A</td>
<td>DE,A,36 38 192 (ASMUND S LAERDAL A S) 19 May 1988 see the whole document</td>
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Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

- **X** Special categories of cited documents:
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Name and mailing address of the ISA
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx 31 651 epo nl, Fax (+31-70) 340-3016

Authorized officer
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<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
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<td>US,A,5 391 081 (LAMPOTANG SAMSUN ET AL) 21 February 1995 see the whole document</td>
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