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5 The present invention relates to the medical field
and particularly medical equipment and, more especially,
relates to an air-conditioned container for the
conservation and transporting of live organs for
transplant.

10 As is known, in the medical field, a technique
currently used at present consists in carrying out
complete organ grafts when all other treatments have
proved ineffective for treating pathological anomalies
or failures of function.

15 This technique uses a donor from whom an organ or
set of organs is or are taken and a recipient into whom
the organ or set of organs taken is transplanted to
replace the defective organ which has previously been
removed.

20 This type of intervention is now conventional for
heart, liver, kidney and even heart/lung transplants.

25 The medical teams charged with removing the organs
and those charged with transplanting them use
procedures, of which there are in general numerous
schools with some variations. Obviously, the procedures
for removing and transplanting the organs must be
correlated and compatible with one another.

30 It is not very common for the donor and recipient
to be close together in time and space. This is why it
is necessary to conserve and, in most cases, transport
the organ between its removal and its reimplantation.

35 After removal the actual condition of the organ has
to be checked and also steps must be taken to ensure
that the organ is preserved under good conditions before
reimplantation, and it is also necessary to ensure,
before this reimplantation, that the state of
histological and functional conservation is correct to
give a reasonable probability of the transplant taking
with the maximum chance of success.

The techniques for preserving an organ during the transporting phase are many and also depend on the procedures for organ removal and reimplantation. Thus, in heart transplantation, it has been proposed first to
5 stop the heart before its removal by injecting a cold cardioplegia solution at about 4°C and then to preserve the organ under cold conditions by immersing it in a Collins solution and/or by carrying out continuous
10 hypothermic intracoronary perfusion of a Fluosol solution, whilst ensuring that the conservation temperature does not approach 0°C, so as to avoid the harmful effect to the myocardium resulting from cryolesions.

The state which the organ is in at the time of
15 reimplantation must also be checked. It will be appreciated that this state depends not only on the original state when the organ is removed but is also dependant on the conditions of conservation and transporting. It is therefore imperative that the
20 medical team in charge of the graft can have the maximum information concerning the organ, its actual removal as well as the conditions under which it has been transported. This information, in addition to that
25 obtained directly by examination and analysis of the organ just before its reimplantation, make it possible to determine whether the state in which the organ is received justifies the recipient being "prepared" to receive the transplanted organ. Such information might be, for example, that which is obtained from
30 histological studies and measurements by birefringence on myocardia biopsies and measurements of the intramyocardiac pH using a probe.

The transporting conditions are many and varied. Depending on the place, the ambient outer temperatures
35 may range between -20°C and +50°C, in broad terms. The transporting means may involve boats, lorries, ambulances, cars, motor cycles, aircraft and

helicopters, which have their own systems of shocks and vibrations with specific amplitudes and frequencies.

5 The complexity and variety of these techniques for removal, transportation and implantation, as well as the success of the transplants thus carried out, are largely subordinated to the suitability of the technique for conserving and transporting the organ.

10 Thus, the importance and value of having a container which makes it possible to conserve and transport a donated organ, whilst being able to adapt readily, at will, to the actual procedures chosen by the medical teams, and which will also allow these teams to have the maximum information relating to the conditions of conservation and transporting of the organ between
15 its removal and its implantation, will therefore be appreciated.

A container for transporting kidneys is described in US patent 4 745 759. This document discloses a specialised container for conserving kidneys which,
20 although it is relatively satisfactory for these organs, is suitable only for this type of organ and cannot by any means be adapted to the particular choice of operating and preserving procedures, nor does it give any information as to the conditions in which the organ
25 has been preserved and transported. This container has no pretensions to universal use.

The aim of the invention is to overcome the majority of the disadvantages of the prior art and to allow the conservation and transporting of live organs
30 for transplant under conditions chosen at will in accordance with the decisions of the medical teams, the progress of which is known precisely at all times so as to facilitate diagnosis of the state of the organ received just before it is due to be implanted.

35 The invention relates to an air-conditioned container for the conservation and transporting of live organs for transplant, consisting, *inter alia*, of a box

having a hinged lid defining an insulated inner enclosure and outer compartments, a refrigerating unit which is housed partly in one of these compartments and partly in this enclosure and which is adapted to
5 maintain a predetermined selected temperature in this enclosure, a pumping unit which is housed partly in another of these compartments and partly in this enclosure and which is adapted to supply at least one
10 organ placed in this enclosure with a liquid for physiological use at a predetermined selected pressure and flow rate, a control unit which is connected to the refrigerating unit and pumping unit and which is adapted to make them operate and to monitor the functions assigned to them, as well as a source of electrical
15 energy which is connected to the refrigerating unit and pumping unit and to the control unit and which is intended to provide them with a supply. This container is remarkable in particular because it comprises a disposable aseptic removable transporting assembly
20 provided, *inter alia*, with a reservoir pouch adapted to contain the liquid for supplying the organ, a collecting sachet adapted to collect the liquid which has supplied the organ, a transporting vessel for accommodating the organ and adapted to be fitted with a suspension device
25 for holding the organ in place and a distributor element for supplying the organ with the liquid and also a tube connecting this pouch and the distributor element, passing through the pumping unit and connecting the vessel and the sachet.

30 Further features of the invention will become apparent from reading the description and claims which follow as well as from studying the accompanying drawings, given solely by way of example, wherein:

35 Figure 1 is a diagrammatic general perspective view of a container according to the invention;

Figure 2 is a perspective view of the removable transporting assembly and part of the box;

Figure 3 shows part of the transporting vessel and an embodiment of the suspension device in exploded view; and

5 Figure 4 is a plan showing the functional connections between various components of the container according to the invention.

10 The containers for the conservation and/or transporting of live organs or tissue are well known in the art and consequently the following is a description solely of that which is directly or indirectly concerned with the invention. As for the rest, any one skilled in the art in question will be able to call on the conventional solutions at his disposal to deal with the particular problems with which he is confronted.

15 A single reference numeral will be used hereinafter to identify similar elements in the various embodiments.

For the sake of convenience, each of the components of an air-conditioned container for the conservation and transporting of live organs for transplant according to the invention will be described in succession.

20 As can be seen from a study of the drawings, this embodiment of a container according to the invention comprises a box 10, a refrigerating unit 20, a pumping unit 30, a control unit 40, an electrical energy source 50 and a removable transporting assembly 60.

25 The box 10 essentially comprises a resistant shell, for example of metal or synthetic resins, with thermal insulation, eg. consisting of glass wool or expanded polystyrene which ensures good insulation, and to which is fixed a hinged lid 11. This box has cells 110 in which are accommodated clasps 111 and transporting handles 112, only one of which is shown, of any conventional kind. Staggered portions 113 and a joint 114 provide a seal between the box and the lid when the latter is in the closed position, locked by the clasps 111. A chain or strap or tie shown but not given a reference numeral restricts the range of opening of the

lid.

As can be seen, the box 10 defines on the outside service compartments 12, for example two compartments arranged laterally opposite one another, which will be
5 discussed hereinafter, as well as an inner, insulated enclosure 100 adapted to receive, *inter alia* an organ Q which is to be transplanted.

The refrigerating unit 20 comprises a cryogenic generator 21, preferably by absorption by the Peltier
10 effect, and an exchanger 22. This unit comprises a bellows 23, for example turbine-operated, for circulating the atmosphere of the enclosure 100 over the exchanger 22 in order to fix and maintain the internal temperature required. This unit comprises a regulator
15 24, for example an electronic regulator, which enables the temperature inside the enclosure to be compared with a reference value and to control the cryogenic generator 21 and the blower 23 in order to maintain the temperature in the insulated enclosure 100 at the
20 desired reference level, within certain tolerance limits. For reasons explained hereinafter, this pumping unit is connected to the control unit 40 and to the electrical energy source 50.

This refrigerating unit 20 is partly housed in one
25 of the compartments 12. The remainder of the unit, particularly the exchanger 22, the blower 23 and the regulating probe 24 are placed in the enclosure 100.

The pumping unit 30 comprises a pump 31, preferably a peristaltic pump, with a motor 310 and a pump head 311
30 fitted with a guide 312 and a rotor, for example with three bearings 313, preferably ball bearings, as shown. This pumping unit also comprises a guide cell 32, a bubble detector 33 and safety means 34, which will be described more fully hereinafter. This motor is
35 preferably a stepping motor, each step of which is divided into 16 microsteps.

This pumping unit 30 is partly housed in the other

compartment 12. The remainder of this unit, particularly the pump head 311 and the probes of these guide cell 32, bubble detector 33 and safety means 34 are positioned in the enclosure 100. This pumping unit
5 makes it possible to achieve continuously regulatable flow rates of between about 1 ml/h and 300 ml/min at pressures of the order of 10 to 100 mm/hg, namely 1.33 to 13.3 kPa approximately, for example.

This pumping unit is connected to the control unit
10 40 and to the electrical energy source 50 for the reasons explained hereinafter.

The control unit 40 essentially comprises an alfa-numerical and functional keyboard 41, a display screen 42, an electronic circuit 43, activator/sensors 44 and
15 connections 45. The electronic circuit 43 essentially comprises memories, logic circuits, comparators and instruction files. The activator/sensors 44 are intended, in particular, for guiding the refrigerating unit 20 and the pumping unit 30, particularly by means
20 of their probes, as will become apparent from reading the text which follows. This control unit 40 is at least partly accommodated in at least one of the compartments 12. The activator/sensors 44, in particular, are placed in the enclosure 100. It is
25 clear that this control unit 40 may also be accommodated in a double-base or in a double-wall, for example at the front and/or back, provided with a removable panel to give access thereto from the inside and/or outside.

The electronic circuit 43 constitutes a logic
30 control centre and a management and material control centre.

The structure of this electronic circuit is such that the logic control centre is implanted in a personal microcomputer of the portable kind which is constructed
35 so as to pick up and memorise, ie. input, all the parameters necessary for operating the container and monitoring it throughout the transporting process. This

logic control centre has the functions of, for example:
recording general data (place of removal, date,
time, identities of surgeons...);

5 recording the temperatures θ , flow rates q ,
pressures P , pH, ... prevailing;
recording the reference values of the temperatures,
flow rates, pressures, pH, ...;

10 introducing special instructions (different
perfusion cycles, changes of operation of the container
depending on certain findings for specific
parameters...);

continuously tracing the development of the
parameters on the screen, preferably by means of a
coloured graph;

15 displaying and printing the record of the
transportation process.

This management and material control centre
comprises:

20 - a "micro computer" card 431 which is the keystone
of the assembly;

- a specific "memory" card 432 to act as a "black
box";

25 - a "bubble detector, safety means" card 433 for
monitoring the conditions of flow of the physiological
liquid through the tubing and the presence of the tube
thereof in the pump head, this card being controlled by
the "micro computer" card;

30 - a "pump" card 434 which is also controlled by the
"micro computer" card to regulate the intensity of the
current in the drive motor 310 of the pump head 311 in
order to fix the drive couple thereof and if necessary
to enslave it in a speed couple to obtain a known
pressure at about $\pm 20\%$;

35 - a "cold" card 435 which is also controlled by the
"micro computer" card to regulate the operation of the
refrigerating unit;

- a "supply" card 436 for delivering all the

voltages and currents necessary for the operation of the container and to carry out automatic switching during connection to external energy sources.

5 For this, a micro computer PC of the Motarola 68000 kind may be used, for example, with two 430 connections of the standardise type RS 232 for communication between the computer and the electronic server associated with the activator/sensors 44.

10 Moreover, a suitable socket 401 placed in a convenient location will permit any connection which may be required to an external computer for authorising an exchange and processing of information.

15 It goes without saying that visual, acoustical or other alarms can be used to signal any particularly serious anomaly or deviation from a reference value, in real time or at a later time.

20 The electrical energy source 50 is intended to supply the refrigerating unit 20 of the pumping unit 30 and of the control unit 40. This electrical energy source consists, for example, of an internal battery such as a Pb or Ni-Cd accumulator, which ensures autonomy of operation of the container according to the invention in the absence of any connection to external energy sources. It also includes connecting plugs 51,52
25 and electric convertors both of frequency and voltage, which make it possible to use external direct current energy sources at various voltages and alternating current sources with various voltages and various frequencies. These external sources can be used to
30 replace or relay the internal energy source. This is conventional and will not be discussed in more detail as numerous solutions are possible. It is sufficient to point out that the container according to the invention is capable of operating when connected to external dc
35 energy sources of voltages ranging from 5 to 24 V, approximately, and AC external energy sources of voltages preferably ranging from 90 to 270 V

approximately and at frequencies of between 50 and 400 Hz, approximately.

The removable transporting assembly 60 consists, *inter alia*, of a support basket 600. Placed in this
5 basket are a pouch 61 which is a reservoir for physiological liquid L provided with a connector 610, a collecting sachet 62 also provided with a connector 620, an organ transporting vessel 63 with a suspension device 64 and a distributor element 65. A tube 66 connects the
10 connector 610 of the reservoir pouch 61 to the distributor element 65 and the transporting vessel 63 to the connector 620 of the collecting sachet 62. The part of the tube 66 which acts as a duct 661 for connecting the connector 610 of the reservoir pouch 61 to the
15 distributor element 65 comprises a section which forms a tube 6610 adapted to be associated with the pump head 311, between the guide 312 and the rotor 313 and adapted to be deformed periodically by the rollers 313, as is conventional for a peristaltic pump. As can be seen,
20 the guide 312 of circular configuration envelopes part of the outer circular trajectory of the rollers of the rotor of the pump head. The free space between the guide and rollers is adapted to receive the tube. This tube is preferably silicone-based. All this is clearly
25 shown in the drawings.

The bubble detector 33 is meant to monitor the quality of flow of the physiological liquid. The aim of the safety means 34 is to ensure that the pumping unit can only operate if the tube has been engaged in the
30 pump head and correctly inserted therein. An appropriate device ensures that the tube thus positioned is held in place.

The transporting vessel 63 essentially comprises a body 630 with a connector 631 adapted to be connected to
35 that part of the tube 66 which acts as a duct 662 for connecting the connector 631 of the vessel 63 to the connector 620 of the collecting sachet 62. The body 630

is adapted to receive a lid 632, optionally held in place by a fixing of any suitable type, for example a screw fixing, flexible fixing, "frog", etc. As can be seen from the drawing, this lid 632 has various openings. Among these various openings is a peripheral notch 634, which is approximately semicircular, adapted for the passage of the duct 661 going to the distributor element 65. These openings also include an approximately rectangular slot 635 which opens out on the periphery of the lid and is adapted to receive the suspension device 64, preferably in a sliding engagement. Apart from this notch and this slot, these openings also include perforations 636 arranged in a circle close to the edge of the lid, which will be described hereinafter. All this is clearly shown in the drawings.

In the embodiment shown, the suspension device 64 is of the clamp variety, for example. This clamp has two branches 640 joined by an articulation spindle 641 in the manner of scissors. A spring 642 tends to hold the clamp shut. The branches 640 terminate at one end in gripping lugs 643 intended to control the manual opening thereof, and at the other end in clamping jaws 644 adapted to engage with part of the organ which is to be transported. As will be seen, each of these branches is provided with a groove 645 situated close to the spindle and the side which is close to the gripping lugs. These grooves 645 are intended to engage in the slot 635. As can be seen, when the clamp is thus mounted on the lid it is locked and fixed in the closed position. When the lid is thus fixed to the body of the vessel, the clamp is further immobilised in position.

According to an alternative embodiment (not shown) the suspension device 64 consists, for example, of a net optionally coated with a foam or the like for holding the organ which is to be transplanted, which may or may not be suspended from the clamp discussed above. This

net is then attached to the lid by means of the perforations 636 in any appropriate manner.

As shown in the drawings, the vessel 63 is held in the basket 600 by means of a bracket 601 or the like.

5 The pouch 61 is suspended, for example, or otherwise fixed to the basket by means of brackets, as shown, whereas the sachet 62 rests or is otherwise held on the bottom of the basket, which is not shown so as not to complicate the drawing.

10 The distributor element 65 may be, for example, a catheter or the like intended to be implanted in the organ for transplantation, eg. approximately either horizontally or vertically. This catheter, which may be of any known type, should be of a "non-traumatising" and
15 "non-removable" type so that once the duct 661 is connected to the organ the latter cannot bruise and/or separate therefrom during transportation as a result of any vibration or shocks.

Preferably, the reservoir pouch 61, the collecting
20 sachet 62, the transporting vessel 63, the suspension device 64, the distributor element 65 and the tube 66 and possibly the support basket 600 are of the disposable, single-use type. As a result, conditions of asepsis can be strictly observed, because these
25 disposable components are used only once and therefore do not have to be cleaned and sterilised for re-use. They are manufactured using materials which are commonly in medical use and appropriate to each application.

It is clear that, if the transportation period is
30 expected to be considerable, and greater than the inherent capacities of the pouch 61 and sachet 62, either these are changed or the pouch is refilled and/or the sachet is emptied, whilst maintaining and preserving strict conditions of asepsis.

35 Among the sensors 44 are probes for measuring the temperature θ at one or more points of the enclosure and of the organ, such as the ventricles, and the septum of

the organ which is to be transplanted as well as the temperature of the liquid for physiological use, probes for measuring the flow rate Q and the pressure P thereof as well as the pH values and other parameters required by the medical teams and needed for their information, such as the partial pressures of gases such as CO_2 and O_2 .

The container according to the invention is capable of operating in ambient temperatures ranging from about $-10^\circ C$ to $+38^\circ C$, for example, whilst maintaining a temperature inside the insulated enclosure of between $4^\circ C$ and $12^\circ C$ approximately, plus or minus $1.5^\circ C$.

The electrical energy source gives total and absolute autonomy for 2 hours with an internal 12 V battery, for example.

The control unit can be used to monitor and record apart from the time, the deliberate or accidental opening and closing of the container, the external temperature, the temperature in the insulated enclosure, the temperature of the organ to be transplanted and of the physiological liquid, the flow rate and pressure of the physiological liquid, parameters such as the pH, the content of carbon dioxide, oxygen, etc., of the physiological liquid and the electrical supply. It goes without saying that this list is not exhaustive.

The control unit can be used to monitor and record all these data for a period of 72 hours, for example. This information can be read and/or released at any time and kept, if necessary, for one year, for example, by means of the "black box".

The reference values may be pre-recorded or recorded on request depending on the requirements of the medical teams.

The useful volume of the insulated enclosure is of the order of about 40 litres. The reservoir pouch has a capacity of between about 5 and 10 litres, for example, and the collecting sachet has a capacity of the order of

6 to 12 litres, for example, whereas the capacity of the transporting vessel is between about 2 and 4 litres.

5 The value of the container according to the invention will be realised, as it makes it possible to improve the quality and duration of conservation, whilst being reliable, easy to use and safe and universally suitable.



CLAIMS

1. Air-conditioned container for the conservation and transporting of live organs for transplant, consisting,
5 *inter alia*, of a box (10) having a hinged lid (11) defining an insulated inner enclosure (100) and outer compartments (12); a refrigerating unit (20) which is housed partly in one of these compartments (12) and partly in this enclosure (100) and which is adapted to
10 maintain a predetermined selected temperature in this enclosure (100), a pumping unit (30) which is housed partly in another of these compartments (12) and partly in this enclosure (100) and which is adapted to supply at least one organ (O) placed in this enclosure (100)
15 with a liquid (L) for physiological use at a predetermined selected pressure and flow rate, a control unit (40) which is connected to the refrigerating unit (20) and pumping unit (30) and which is adapted to make them operate and to monitor the functions assigned to
20 them, a source of electrical energy (50) which is connected to the refrigerating unit (20) and pumping unit (30) and to the control unit (40) and which is intended to provide them with a supply, the container being characterised in that it comprises a disposable
25 aseptic removable transporting assembly (60) provided, *inter alia*, with a reservoir pouch (61) adapted to contain the liquid (L) for supplying the organ (O), a collecting sachet (62) adapted to collect the liquid (L) which has supplied the organ (O), a transporting vessel
30 (63) for accommodating the organ (O) and adapted to be fitted with a suspension device (64) for holding the organ (O) in place and a distributor element (65) for supplying the organ (O) with the liquid (L), a tube (66) connecting this pouch (61) and the distributor element
35 (65), passing through the pumping unit (30) and connecting the vessel (63) and the sachet (62).



2. Container according to claim 1, characterised in that the transporting vessel (63) comprises a body (630) having a connector (631) for receiving the tube (66), and a lid (632) with openings (634, 635, 636) for the suspension device (64) to pass through and for the tube (66) leading to the distributor element (65) to pass through.
3. Container according to claim 1 or 2, characterised in that the suspension device (64) comprises a clamp.
4. Container according to claims 2 and 3, characterised in that the openings comprise a substantially rectangular slot (635) which opens out at the periphery of the lid (632) and which is adapted to receive the clamp in sliding manner by means of complementary grooves provided therein.
5. Container according to claim 2, characterised in that the openings comprise a substantially semi-circular peripheral channel (634) adapted to receive the tube (66) leading to the distributor element (65).
6. Container according to claim 1 or 2, characterised in that the suspension device (64) comprises a net and the openings comprise perforations (636) distributed in a circle close to the periphery of the lid (632) in order to receive this net.
7. Container according to any one of claims 1 to 6, characterised in that this pumping unit (30) comprises a peristaltic pump head (311) with a rotor having three rollers (313) and with a circular guide (312) enveloping part of the circular outer trajectory of these rollers and in that the tube (66) connecting the pouch (61) and the distributor element (65) comprises a duct (661) with a flexible fine tube (6610) adapted to be inserted



against this guide (312) in order to be pressed therein by the rollers (313).

8. Container according to any one of claims 1 to 7, characterised in that the distributor element (65) is a non-traumatising "non-removable" catheter.

9. Container according to any one of claims 1 to 8, characterised in that the control unit (40) comprises a keyboard (41), a display screen (42), electronic data processing circuits (43) with memories, logic functions and comparison functions, activator-sensors (44) for sending information to these circuits and receiving information from them, as well as electrical connections (45) connecting them to one another and to the refrigerating unit (20) and pumping unit (30) and electrical energy source (50).

10. Container according to claim 9, characterised in that the control unit (40) comprises a connecting socket (401) for an external computer.

11. Container according to any one of claims 1 to 10, characterised in that the electrical energy source (50) comprises an autonomous internal accumulator, connecting sockets (51, 52) for external generators and voltage-frequency converters for supplying, from external generators, energy comparable to that of the internal autonomous accumulator.

12. Disposable aseptic removable transporting assembly (60) for live organs (O) for transplant, which is adapted to be placed in a container and is characterised in that it is provided, *inter alia*, with a reservoir pouch (61) adapted to contain a liquid (L) for physiological use for supplying the organ (O), a collecting sachet (62) adapted to collect the liquid (L)



which has supplied the organ (O), a transporting vessel (63) for accommodating the organ (O) and adapted to be fitted with a suspension device (64) for holding the organ (O) in place and a distributor element (65) for
5 supplying the organ (O) with this liquid (L), a tube (66) connecting the pouch (61) and the distributor element (65) and connecting the vessel (63) and the sachet (62).

10 13. Transporting assembly according to claim 12, characterised in that the transporting vessel (63) comprises a body (630) with a connector (631) for receiving the tube (66), and a lid (632) with openings (634, 635, 636) for the suspension device (64) to pass
15 through and for the tube (66) leading to the distributor element (65) to pass through.

14. Transporting assembly according to claim 12 or 13, characterised in that the suspension device (64)
20 comprises a clamp.

15. Transporting assembly according to claims 13 and 14, characterised in that these openings comprise a substantially rectangular slot (635) which opens out at
25 the periphery of the lid (632) and which is adapted to receive the clamp, in sliding manner, by means of complementary grooves (645) provided therein.

16. Transporting assembly according to claim 13,
30 characterised in that the openings comprise a substantially semi-circular peripheral channel (634) adapted to receive the tube (66) leading to the distributor element (65).

35 17. Transporting assembly according to claim 12 or 13, characterised in that the suspension device (64) comprises a net and the openings comprise perforations



(636) distributed in a circle close to the periphery of the lid (632) to receive the net.

- 5 18. Transporting assembly according to any one of claims 12 to 17, characterised in that the tube (66) connecting the pouch (61) and the distributor element (65) comprises a duct (661) with a flexible fine tube (6610) adapted to cooperate with a pumping unit.
- 10 19. Container according to any one of claims 12 to 18, characterised in that the distributor element (65) is a non-traumatising "non-removable" catheter.