Title: DEVICE FOR TRANSPORT OF BIOLOGICAL SAMPLES AND MONITORING METHOD THEREOF

Abstract: The present invention concerns the field of transport and storage of biological fluids, materials, tissues in general. The present invention discloses an innovative transport device provided with means that make easier its transport also by dragging by a single operator, said device being furthermore provided with regulation, control and monitoring systems of the inner temperature of the container in which the biological samples are stored.
Declarations under Rule 4.17:
— of inventorship (Rule 4.17(iv))
Published:
— with international search report (Art. 21(3))
The present invention relates to the field of transport and preservation of fluids, materials and biological tissue. As it is known, both preservation and transport of biological material mostly concerning health field or the like, comprises a series of complicated procedures to comply with and it is strictly controlled by legal and health regulations. That appears obviously logical and strictly recommended because it deals in general with transport of blood or hemo components or biological material and/or biological sample and/or organs. In particular, what is interesting for the present invention, is that said material transport from one facility to another, in particular from the taking spots such as hospitals, clinics, laboratories and others similar locations (for instance biochemical analysis laboratories, laboratories for transfusion operations, ambulances and medical cars).

Nowadays it is known to the operators that the transport of said materials done by an operator, although it is an operation subject to many rules, as hereinbefore said, is carried out through simple thermal or cooled sealed containers or provided with ice bars or conventional small commercial refrigerators, but not specific ones. It appears immediately obvious that for both cases extraordinary problems occur; for sealed containers it is difficult to set a desired temperature, both hot and cold, and above all to keep it constant, for small commercial refrigerators instead the transport is easier and more reliable, and temperature should be regulated. But it is known that commercial refrigerators are characterized by a very approximate temperature regulation, and they usually do not give information when the temperature is affected by a variation respect to the one set, unless important thermal shocks. Anyhow information concerning the temperature inside the refrigerator are not given, there is not any monitoring of its openings that could cause the contained biological material or organ to be affected by thermal shocks.

Furthermore said devices are very heavy, often they require to be non-stop powered (even if there are models provided with batteries that are less reliable and heavier). In more advanced commercial refrigerators the temperature is recorded
usually by devices for saving data, which adversely record only the refrigerator
temperature and not other data such that inserting or removing materials, device
position, etc.

It appears obvious that transport of perishable biological materials, transport
of samples or infectious substance or potentially infectious, are justified grounds of
problems for all stakeholders, for instance researchers, laboratory personnel,
transport service personnel, biological material receiving personnel, users, nurses,
surgeons, etc.

It is obvious that specifications, rules, strict standards and further procedures
are adopted for said material and substance transport, suitable for guaranteeing
safety of personnel involved in transport and shipment operations, supervising the
device for preventing dispersion of infectious agents or potentially infectious for
environment and persons, ensuring material reaches its destination in time and in
excellent conditions in order to be analyzed, or used or sorted, in conditions of
maximum security, better ensuring the shipment/transport/delivery and use chain,
anyway to not deteriorate materials which are very important for man's health.

It was seldom noticed cases of infectious diseases spread by transport,
however very often transported materials result to be deteriorated by their transport.
The WHO is one of the institutes that established very strict rules and specifications
to be followed, which involve the use of exact protocols, and accurate preservation
and monitoring conditions. Furthermore there are several procedures about
transport labelling, packaging, monitoring, documentation arranging, all stages that
shall give suitable warranties. For instance there are packaging procedures
comprising use of a primary container, a secondary container, and an outer
container to guarantee the material sterility and the right temperature preservation
(for instance transport of hemo material, medicines, samples to be analyzed,
organs).

However it appears surprising that such lack of technologically transport
equipment, causes many of these protocols strictly controlled by regulations to
provide for cases wherein is involved the transport with ice, the total lack of
monitoring of the actual transport time, outer temperature during transport, other
environmental variables, etc.

As hereinbefore said, prior art discloses technical solutions which however
do not provide for the innovative features of the present invention.

Document WO 02/26034 A2 actually discloses a complex apparatus for maintaining organ vitality during their transport. Such apparatus, besides being hardly transportable, cannot be easily dragged, unless crawling it on the ground, furthermore it is not provided with inner temperature sensors measuring air inside the container, in which the transported organs and/or biological materials are arranged; indeed the sensor 2115 measures the liquid solution temperature wherein the organ to be transported is immersed.

Document US 6354104 B1 discloses a container which is provided with neither any sensors measuring air temperature inside the transport device, nor even any device to facilitate its dragging.

Document WO 2015/042841 B1 discloses a container which is provided neither with any inner temperature sensors measuring air inside the transport device, nor even any device to facilitate its dragging. It has to be pointed out that the sensor 26 measures the control device surface temperature and not the environmental air, as clearly specified at paragraph 37 of the description.

Document EP 2668847 A1 discloses an attache case which is provided neither with any inner temperature sensors measuring air inside the transport device, nor even any device to facilitate its dragging.

Document US 2013/0106607 A1 discloses a container which is provided neither with any inner thermic machine configured for cooling and/or heating the container inner housing, nor even any device to facilitate its dragging.

Finally also document US 8539790 B1 discloses a container which is provided neither with any inner thermic machine configured for cooling and/or heating the container inner housing, nor even any device to facilitate its dragging.

Therefore an object of the present invention is to disclose a device for transport biological materials or the like, which is provided with an inner accurate monitoring of the temperature in real time.

A further object of the present invention is to provide for a transport device which is versatile, reliable, and efficient for maintaining material cooling and heating temperatures.

A further object of the present invention is to describe a device suitable for regulating the temperature adjustment according to the device outer temperature as
well.

It is a purpose of the present invention to provide for a device allowing the real time monitoring of the device position, and the device tracking.

A further object of the present invention is to provide for a device also allowing to control and regulate the device openings, duration of such openings and any material removal and insertion.

Another object of the present invention is to disclose a device which is secure in particular from an anti-tampering point of view.

Finally another object of the present invention is to disclose a smart device, which is able to interact in real time with the surrounding environment and can be controlled in real time.

A further object of the present invention is to disclose a device, which is simple, compact and easy to be transported and dragged, even by a single operator and versatile to organize its inner room, to insert any samples of biological material, and at the same time easy to be cleaned and maintained, and meets any WHO, national, regional and similar regulations.

These and other purposes will be achieved by the transport device according to the present invention, said device comprising a handle and a couple of wheels, a refrigerating and/or heating body provided with real time temperature monitoring and regulation, radiofrequency reading sensors for material insertion and removal, monitoring for a continuous control of transported materials, a device lid opening controlled so as to be locked at a predetermined time, and/or opened only by authorized personnel, provided for instance with a special code or key or card or any other opening device control suitable for this purpose, the whole being enclosed in a compact body, characterized by its dimensions, volume and weight consistent with a single operator handling, made easier by an telescopic handle like a trolley case and by at least a couple of wheels for its movement.

Moreover said transport device comprises battery charge detectors and temperature control detectors, preferably at least two, for being always able to adjust the temperature according to the environment conditions.

Said device furthermore is provided with GPS control and monitoring sensors allowing a real time device tracking.

The device further comprises a monitoring system to allow real time
displaying temperature data, temperature variation data, opening alarm, position, etc, besides additional signals which can be configured according to user requirements and customized through device implementation with a control method with changeable variables.

Said device shall be monitored and controlled, in a particular advantageous way, by a method suitable designed for monitoring innovative parameters implemented in said device, since never before such a transport and temperature control device was achieved suitable for biological materials, samples, fluids, provided with safety systems for transport, transporter, said device complying with safety and health regulations, to guarantee the best possible management and control of transported materials and accurate step by step monitoring of important biological and similar substances.

Let us think for instance to an unforeseen circumstance during the transport which causes its protraction, with consequent possible deteriorations in turn caused by unexpected temperature variations, or accidental or voluntary tampering as well, or accidents, or necessity of temperature dynamic adjustment according to a contents better management.

These and other objects attained by the innovative and versatile device for transport of biological samples will be analysed in great detail hereinafter, by the description of some preferred embodiments of the device according to the present invention and of a following method for monitoring and controlling said device, and illustrated in the accompanying drawings, in which:

fig. 1 is a front view of a preferred embodiment of the transport device for biological samples according to the present invention;

fig. 2 is a lateral/rear view of the preferred embodiment shown in fig. 1 of the transport device for biological samples according to the present invention and

fig. 3 is an exploded view of said embodiment according to the present invention, showing a possible alternative variation.

In particular with reference to figure 1, a device for biological sample transport by an operator is shown in an embodiment according to the present invention. In particular said device 1 is an integrated system, which allows to add many other functions to add to a particularly reliable transport, for instance in the embodiment shown in figure 1 an insulated container 2 for containing biological materials
provided with comfortable lateral handles 3, for allowing the device lifting for its transport, rotating elements 4, for instance one or more wheels arranged on the device base and a handle 5 for instance a telescopic handle, suitable for a convenient and easy transport of a heavy device as well, and again a lid 6 for said device, which is characterized by a controlled opening and it is also insulated, in another advantageous embodiment of the present invention (provided with a comfortable handle 7). In addition in a particular advantageous way said device comprises a rear container structure 8 wherein the handle 5 for instance a telescopic handle is inserted, which comprises electric and electronic components of the device (which will be described hereinafter). On said rear container structure 8 control detectors and any data transmission of said innovative device 1 are arranged, such as at least an indicator of charge of the battery power supply 9, an interface 10 for instance an inner temperature control display of said insulated container 2, which will be connected to one or more temperature monitoring sensors of the system with 0.1 °C variation detected control step, a radiofrequency reader 11 for real time monitoring of inserting materials and for monitoring lid opening and closing (operation which is done according to the dedicated method hereinafter described). In the present embodiment connections 12 for charge supplying/power operation of the device, arranged on the rear container structure 8, are illustrated.

Figure 2 is a rear view of the same embodiment of the device illustrated in fig. 1, according to the present invention, showing further technical details, in particular with reference to the container 8 for the electric and electronic part comprising also said connections 12 for charging the device battery and/or elements for connecting directly the device to the power grid as necessary, said electronic part including therefore also a battery for journeys without power supply connection.

Furthermore, in case of unexpected events (no possibility to charge the battery and no power supply connection), it is possible to connect to said device as well an auxiliary battery, not illustrated in the figures, but available on request by the user. Said device 1 may comprise, arranged anyhow, for instance said control sensors of the inner container temperature being positioned in the storage cell of the insulated container 2, with a role of cooling and heating adjustment, malfunction alarm sensors, temperature alarm sensors, closed lid sensors and lock opening sensors, lid closing system electrically controlled or differently controlled, a reading
system for enabling opening of the container lid (for instance a R-feed reader
suitable for being activated by a card, a tag, or by any other element suitable for that
purpose with a dedicated controlled code). Said device 1 may further comprise
buttons or transport certified delivery detectors, (for instance through r-feed or tag
recognition), alarm control lighting and/or acoustic indicators, an interface 10 for
setting temperature, with possible remote setting, and with an integrated GPS
system.

It has to be noted that laterally the insulated container 2 may be provided with
a dispersion hot/cold grid 13 for heating/cooling bodies respectively.

In figure 3 an exploded view of an example of a storage cell 20 comprised in
the insulated container 2 is shown. In particular said storage cell 20 may be split, as
here described, into one or more containers 21, usually top opened, said containers
21 being insulated with a insulation layer suitable for this purpose, and furthermore
containers 21 are closed by an upper lid 6, in turn insulated, being provided with a
interposed seal between the lid and the upper edge of the lid 21. Said lids 21, for
instance, may be sterilisable through known and certified methods, and may be
cooled by a thermic machine 23, 24 configured for increasing and/or reducing the
inner temperature of storage cell 20 and of containers 21, said thermic machine 23,
24 may consist of a single cooling and heating machine and furthermore may consist
of a cooling unit 23 controlling a gas refrigeration cycle, through a compressor, or a
cooling electric fan radiator, or one or more gas evaporators arranged in contact
with inner parts of the storage cell 20, said thermic machine 23, 24 in addition to a
heating unit 24. As above mentioned said containers 21 and storage cell 20 may be
heated by a heating unit 24 e.g. comprising one or more electric resistors, e.g. on/off
controlled by the thermal sensors probes and a dedicated control system.

Inside said storage cell 20 feelers or sensors 25, 26 are arranged for
controlling temperature with for example heating and cooling control functions; in
particular in a further embodiment (as here described) sensors 25 are arranged
each on one container 21, said sensors 25 for example may transmit temperature
data to a control external unit through wi-fi or gps transmissions, or a radio
transmission methods suitable for this purpose, while one or more sensors 26 are
arranged inside the storage cell 20 for its inner temperature control, for example for
implementing a double temperature control of the thermic machine 23, 24, or of
heating unit 24 and/or cooling unit 23, in order to substantially control every zone of
the container, for maintaining temperature inside the container as much constant as
possible.

In the exploded view of figure 3 it may be seen also for example a battery 27
for power supply of the device 1, which, as said hereinbefore, can be rechargeable,
replaceable, additionable with another support battery etc.

Again in the here described embodiment the container 8 for electric and
electronic parts comprises said interface 10 for displaying and setting the desired
temperature parameters, said device further comprising in an advantageous way a
lock 28, for example an electric lock, for controlling the opening/closure of the
insulated container 2 of the device 1. Said lock 28, may be programmed in order to
be opened only through dedicated magnetic cards or similar, or through any device
which allows to set openings of the lid 6 of the device 1, and allows openings by
only authorized personnel and/or in predetermined scheduled times or moments or
positions authorized in the same way. Said device 1 comprises also a door opening
sensor 29 which gives door opening/closure signal, acting either in cooperation with
the lock 28 or in autonomous way, in order to counting opening time and non
authorized openings.

The device 1 may further comprise, substantially, a plurality of control and
monitoring sensors suitable for the object of the present invention, thanks to the
innovative characteristics here described, in cooperation with the transport
monitoring method for said device, said device 1 being an innovative and performing
product for monitoring biological material transport, which will allow to be
customized according to final user requirements and the requested transport mode.

For instance an implemented version of the method according to the present
invention may comprise the following steps:

• The temperature control of the container (2) of the cooling/heating part,
the control of one or more sensors (25,26) and their monitoring and regulation also
in remote control;

• The control of the transport journey - length and time - outside
temperature - real-time position monitoring (justified and unjustified stops, etc.);

• Monitoring of voltage and charge of the battery power supply;

• The control of the opening / closing operation of the lid (6);
• The setting of the opening/closing permission by a coded card (electronic, magnetic coded, numeric keypads etc.);
• Inhibition of permission and timing for opening the device (1);
• Alarm for tampering attempts - general management of the control system and signalizing anomalies in real time;
• Supervision of the integrated control system alarms and customizable management;
  • Alarms via SMS, sound alarm, to the social structures, via phone or e-mail etc.
• Remote alarm of charge/discharge of the battery in advance of a preset time;
  • Monitoring of extracted or inserted material by tags or the like;
  • Other settings and sending of monitoring statistics and remote control via GPS system or suitable system;
• Data storage for further checks.

Said method for controlling the device 1 for transport of biological samples by an operator, may be carried out through any remote control device suitable for this purpose.

It is clearly apparent that these and further advantages described and obtained through the here disclosed innovative control and regulation device for biological materials transport and its monitoring method are to be considered subject to different embodiments according to user’s requirements, and further arrangements, which may comprise possible different rotating elements (balls, wheels or equivalent elements) arranged on the device base, the interface may be constituted by a display possibly a touch screen, transport container of different shape, larger or smaller, modified inner room organization, different integrated monitoring sensors, alarms, and concerning features of the control and monitoring method, may be changed and implemented falling anyway within the scope of the invention. It is to be understood that the here disclosed embodiments and the relevant method are mere examples and any more or less integrated variations will fall anyway within the scope of the invention as defined in the appended claims.
CLAIMS

1. A device (1) for the manual transport of biological samples by an operator, comprising at least one insulated container (2) equipped with at least one handle (3, 5) for the handling and transport of the device (1), a lid (6) for said container (2) and characterized in that it further comprises at least one battery (27) for the autonomous transport, temperature sensors (25,26) arranged inside a storage cell (20) for measuring inner temperature and configured for the regulation of at least one thermic machine (23, 24) configured for cooling and/or heating the inner temperature of the storage cell (20), and for monitoring the inner temperature with function of control of the heating and/or cooling in at least one or more areas of the storage cell (20) of said insulated container (2), further comprising rotating elements (4) arranged on the device base for easy transport and drag of the device (1).

2. The device (1) according to claim 1, wherein said at least one handle (5) is a telescopic handle and said rotating elements (4) are one or more wheels (4).

3. The device (1) according to claim 1, wherein said device (1) comprises at least one sensor for the monitoring and GPS or wi fi control for the traceability and changing of settings of the device (1) in real time.

4. The device (1) according to preceding claim, wherein said storage cell (20) comprises one or more containers (21) for containing the biological samples to be transported.

5. The device (1) according to claim 4, wherein each of said containers (21) comprises a sensor (25) for controlling and regulating the internal temperature of said containers (21).

6. The device (1) according to the preceding claims, wherein said thermic machine (23, 24) comprises at least one sensor (26) for monitoring and regulating the temperature, said sensor (26) being arranged inside the storage cell (20).

7. The device (1) according to the preceding claims, comprising at least an interface on said device (1) for the external display of the monitored data and for the adjustment of said data.

8. The device (1) according to the preceding claims, wherein said lid (6) of said insulated container (2) comprises a lock (28) for controlling the closing and opening of the insulated container (2) of the device (1), said lock (28) being
programmable for the opening at certain authorized times or moments or positions.

9. The device (1) according to the preceding claims, wherein said device (1) comprises a radio frequency reader (11) for the monitoring in real time of the introduction of materials in said device (1) and monitoring the opening and closing operations of the lid (6).

10. The device (1) according to the preceding claims, wherein said device (1) comprises a temperature sensor external the device (1) configured for allowing the adjustment of inner temperature of the device (1) according to the temperature external the device (1) as well.

11. The device (1) according to the preceding claims, wherein said thermic machine (23, 24) consists in a cooling unit (23) and/or a heating unit (24).

12. A method for the control of the device (1) according to claims 1 to 11, which comprises one or more and preferably all of the following steps:
   • The temperature control of the container (2) of the cooling/heating part, the control of one or more sensors (25,26) and their monitoring and regulation also in remote control;
   • The control of the transport journey - length and time - outside temperature - real-time position monitoring (justified and unjustified stops, etc.);
   • Monitoring of voltage and charge of the battery power supply;
   • The control of the opening / closing operation of the lid (6);
   • The setting of the opening/closing permission by a coded card (electronic, magnetic coded, numeric keypads etc.);
   • Inhibition of permission and timing for opening the device (1);
   • Alarm for tampering attempts - general management of the control system and signalizing anomalies in real time;
   • Supervision of the integrated control system alarms and customizable management;
   • Alarms via SMS, sound alarm, to the social structures, via phone or e-mail etc.
   • Remote alarm of charge/discharge of the battery in advance of a preset time;
   • Monitoring of extracted or inserted material by tags or the like;
   • Other settings and sending of monitoring statistics and remote control
via GPS system or suitable system;
  
  - Data storage for further checks.

13. The method for the control of the device (1) according to claim 12, which can be implemented by any remote control device suitable for the purpose.
Fig. 3
A. CLASSIFICATION OF SUBJECT MATTER

INV. A01N 1/02

ADD.

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)

A01N

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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<th>Relevant to claim No.</th>
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<td>Y</td>
<td>page 18, line 3 - page 24, line 27; figures 19-23</td>
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Date of the actual completion of the international search: 16 November 2016

Date of mailing of the international search report: 12/12/2016
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### INTERNATIONAL SEARCH REPORT

**Information on patent family members**

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