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(72) Inventors; and

(71) Applicants: **MACCARIELLO, Elizabeth Regina** [BR/BR]; Rua Engenheiro Cortes Sigaud, 100/102, Leblon, Rio de Janeiro, RJ, Cep: 22.450-150 (BR). **ROCHA, Eduardo** [BR/BR]; Rua Prudente de Moraes 768, Casa 5, Ipanema, Rio de Janeiro, RJ, CEp: 22.420-040 (BR). **DE SÁ TEIXEIRA, Alessandra Cananéa** [BR/BR]; Estrada dos Três Rios, nº1721, Bloco 1, Apto 108, Freguesia, Jacarepaguá, Rio de Janeiro, RJ, Cep: 22.745-004 (BR). **DO**

AMARAL SILVA, Guilherme Henrique [BR/BR]; Rua Ipatinga 375, Bosque dos Eucaliptos, São José dos Campos, São Paulo, SP, Cep: 12.233-370 (BR). **VILLAR JUNIOR, Indalecio** [BR/BR]; Rua Professor Roberval Froes 390, APT 64B, Jardim Esplanada, São José dos Campos, São Paulo, SP, Cep: 12.242-460 (BR). **SIQUEIRA ARMANI, Leandro** [BR/BR]; Avenida Engenheiro David Monteiro Lino, nº3781, Casa A17, Jardim Marcondes, Jacaré, São Paulo, SP, Cep: 12.305-021 (BR).

(74) Agent: **DO NASCIMENTOS SOUZA ADVOGADOS**; Rua Sete de Setembro, nº112, 6º andar - Centro, Rio de Janeiro, RJ, Cep: 20.050-002 (BR).

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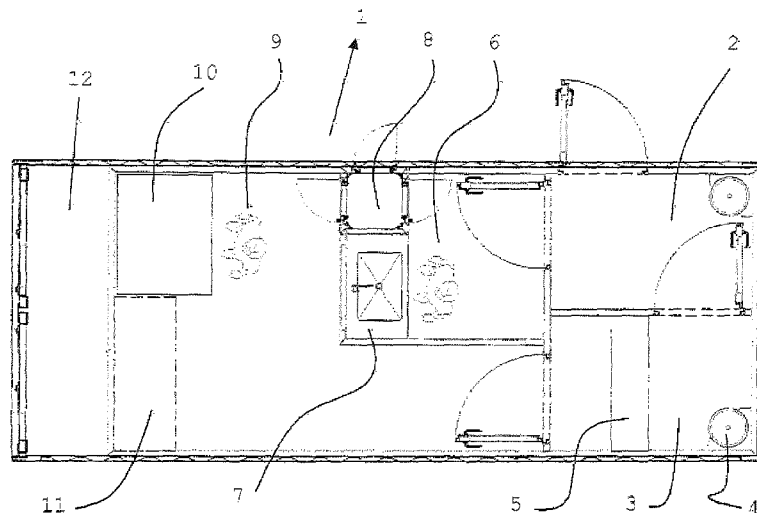


FIGURE 1.1

(57) Abstract: Constructive layout in container (1), to provide clean areas for medical and hospital care, such as fractionation of solid and liquid oral drugs (ISO8) and handling of sterile drugs (ISO7), as well as the configuration of the containers for the infusion, diagnosis, surgery, ICU and hemodialysis areas.



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“CONSTRUCTIVE LAYOUT IN CONTAINER”

FIELD OF APPLICATION

[001] The present utility model refers to the field of medical-hospital treatment and biosafety units, specifically to a mobile, modular clean room, more specifically, to a container equipped with a complete autonomous clean room structure for drug handling and medical treatment.

PRIOR ART AND EXISTING PROBLEMS

[002] The American patent US5656491 granted for Cassani et al. teaches, briefly, the installation of mobile modules for the preparation of biotechnological products on a pilot scale, comprising equipment for the production, separation, purification and finishing of the products. The installation consists of at least two mobile modules suitable for being connected together and integrated one with the other.

[003] The American patent US2012007429 granted for Wernimont et al. refers, briefly, to a clean room made up of pre-assembled modules. The first pre-assembled module includes an air filtration system with a ceiling chamber to provide clean air to the interior of the module. The system is transported and delivered in its pre-assembled form.

[004] Patent PI0709832-4 granted for Vladimir Grcevic, reveals, briefly, a laboratory consisting of antechambers for the analysis of consistent pathogenic agents in a transportable mobile container containing a base chamber isolated from the outside by a watertight box inserted in said chamber. The box equipped with a pressure device to allow maintenance of the negative pressure relative to the external environment. Said watertight box comprising a first antechamber of

the protection equipment, a second antechamber communicating with the pathogenic agents' analysis zone and a third antechamber communicating with the analysis zone and the first antechamber.

[005] Several mobile clean rooms are known. However, mobile clean rooms specifically designed for hospital application are not found among the available solutions.

[006] As is well known to those skilled in the art, hospitals use clean rooms for the handling of all injectable, such as individualized solutions for intravenous infusion (IV), fractionation of intravenous antibiotics, fractionation of chemotherapy doses and biopharmaceuticals, production of individualized dialysis solutions and parenteral or enteral nutrition.

[007] A remaining problem refers to the fact that the lack of clean area for handling drugs often prevents the treatment of a more complex patient in hospital units or advanced health clinics; in the case of relying on bedside manipulation, there is an added risk of contamination and error of dose fractionation and it may also expose the handler to the risk of toxic substances; if the hospital unit chooses to outsource manipulation, the high cost, displacement and proximity of urban centers are issues to be considered.

[008] All clean-area pharmacies are built according to the client's physical space and planned demand. Its construction is time-consuming (space analysis, adaptation or new construction), fixed, with high construction and maintenance costs, and is not standardized or reproducible (for being created according to the characteristics of the space and conditions of the pharmaceutical industry or hospital unit).

[0009] Therefore, it would be highly desirable and advantageous to obtain a mobile hospital clean room, intended for diagnosis, implementation of therapy, specially the handling and dispensing of injectables.

[0010] Although some prior art documents report mobile clean rooms, functional parameters achieved by the present model are not found therein.

MODEL SOLUTION

[0011] The present model aims to provide a mobile unit for the provision of a complete and ready for use scalable clean room, with pressure, temperature, humidity and air HVAC control for medical treatment and drug handling, the unit being delivered as equipment, with the whole system installed.

[0012] Thus, the unit may be integrated into the existing hospital units as well as be displaced for complex care in poor areas affected by wars, conflicts or disasters.

[0013] These and other purposes are achieved by means of a constructive layout applied in a container consisting in the installation of all the equipment suitable for the structuring of the clean area and medical-hospital care.

NOVELTY AND INVENTIVE STEP

[0014] The layout revealed herein and further detailed, which consists of the application on containers of clean areas for medical-hospital care, such as fractionation of solid and liquid oral drugs (ISO8) and handling of sterile drugs (ISO7), as well as the configuration of the containers for the infusion, diagnosis, surgery, ICU and hemodialysis areas, are not taught by the representative documents of the state of the art relating to the field of application of this model,

being uncommon and unusual choices in relation to the normal activity of the technical area. According to the available teachings, technicians are led to erect clean rooms incorporated into the construction and design of hospitals.

FUNCTIONAL IMPROVEMENT

[0015] Applying the form and layout taught herein, the present model provides containers structurally configured as clean rooms of hospitals and therapeutic hospital centers.

[0016] Among the advantages of the model are: reduction of the cost and time of manufacture of clean areas; agility in the implantation in existing hospitals and for the care in deprived, conflict or disaster areas; possibility of enlarging or resizing the area of interest by coupling a new container; better use of the patient care intra-hospital area, while the stocking and preparation of the drug can be performed in modules outside the main building.

[0017] Another advantage is to provide greater safety for the patient with adequate preparation of the drug doses: reduction of the microbiological contamination risk; lower risk of dose errors; safety for the handler due to the lower risk of contamination with toxic material.

[0018] As the unit includes GMP controlled areas and equipment compatible with FDA, ANVISA or equivalent foreign regulatory agencies, another benefit of the model is to meet the hospitals aiming for international quality and safety certification, as they need to implant a unit dose system.

[0019] It is also possible to point out as advantage of the model its reproducibility given the standardization of the clean area modules, drug inventory, ICU, surgical center, infusion center, dialysis center.

DESCRIPTION OF THE DRAWINGS

[0020] The model is clarified below by its representation in the drawings that show:

[0021] Figure 1.1 – top view of the clean handling and washing room (ISO7);

[0022] Figure 1.2 – cross-sectional side view of the clean handling (ISO7) and washing (ISO8) room;

[0023] Figure 2.1 – top view of the clean fractionation room (ISO8);

[0024] Figure 2.2 – cross-sectional side view of the clean fractionation room (ISO8);

[0025] Figure 3.1 – top view of a constructive variant of the model for the support/ labeling/ storage area.

DESCRIPTION OF THE MODEL

[0026] Figures 1.1 and 1.2 show the constructive embodiment of the layout according to the model applied in container (1) in the constructive form of clean handling and washing room ISO7, intended for handling of injectables, which includes a modular installation of isopanel-coated container or flat partition in sheet steel with thermal and acoustic insulating substrate of polystyrene (EPS) or polyurethane (PUR) or polyisocyanurate (PIR) or rock wool (LDR) or in aluminum wire mesh, the entire interior finished with sanitary rounded profiles (aluminum / PVC / stainless steel or similar) to facilitate cleaning and prevent dirt buildup, vinyl-coated floor with high traffic resistance and resistance against fungi and bacteria, lighting of the rooms will be made through built-in or overlapping luminaires with

sealing to the maintenance area, LED lamps, sink drainage system in PVC pipe or similar, sink feeding system in PVC pipe or similar, all doors, displays and accessories in GMP standard, equipped with HVAC system, pressure monitoring, the said modular installation being composed of: primary antechamber (2) (1.63m²) for people entrance, said primary antechamber containing alcohol gel dispenser, electromagnetic door interlock system by CLP control and cabinet for supplies; gowning antechamber (3) (1.95m²) for people containing: sink (4) for sanitizing in AISI 304 stainless steel and (sensor driving) high spout faucet, fed by water purified by reverse osmosis system or similar, electromagnetic door interlock system by CLP control, bench (5) with AISI 304 stainless steel coating with storage compartment for gowning, cabinet for storage of supplies and waste for disposal; washing/ sterilization room (6) (2.15m²) containing: washing countertop (7) in AISI 304 stainless steel with lower shelves for storage, fed by water purified by reverse osmosis system or similar, cabinet for storage of supplies and waste for disposal; double pass-through (8) 550x550x1100mm for material input and output with electromagnetic door interlock system by CLP control; handling area (9) (5.5m²) containing: II B2 biosecurity cabin (10), workbench (11) with AISI 304 stainless steel on 2 levels; engine room (12) comprising: fan coil (13) with coarse, fine and absolute filtration for air cooling and cleaning, power and control board for electrical supply of the container, automation board of the air conditioning system, interlocking board for doors and pass-throughs, reverse osmosis system.

[0027] Figures 2.1 and 2.2 show the constructive embodiment of the layout according to the model applied in container (1) in the constructive form of clean room for fractionation area ISO8, which includes a modular installation of isopanel-

coated container or flat partition in sheet steel with thermal and acoustic insulating substrate of polystyrene (EPS) or polyurethane (PUR) or polyisocyanurate (PIR) or rock wool (LDR) or in aluminum wire mesh, the entire interior finished with sanitary rounded profiles (aluminum / PVC / stainless steel or similar) to facilitate cleaning and prevent dirt buildup, vinyl-coated floor with high traffic resistance and resistance against fungi and bacteria, lighting of the rooms will be made through built-in or overlapping luminaires with sealing to the maintenance area, LED lamps, sink drainage system in PVC pipe or similar, sink feeding system in PVC pipe or similar, all doors, displays and accessories in GMP standard, equipped with HVAC system, pressure monitoring, the said modular installation being composed of: antechamber (14) (1.71m²) for people entrance containing: washbasin (15) for sanitizing in AISI 304 stainless steel and high spout faucet, electromagnetic door interlock system by CLP control; liquid fractionation area (16) (4.7m²) containing: benches (17) with AISI 304 stainless steel coating on 2 levels for material handling and storage; solid fractionation area (18) (4.7m²) containing: benches (19) with AISI 304 stainless steel coating on 2 levels for material handling and storage, double pass-through 550x550x1100mm for material input and output with electromagnetic door interlock system by CLP control; engine room (19) containing: fan coil with coarse and fine filtration for air cooling and cleaning, power and control board for electrical supply of the container, automation board of the air conditioning system, interlocking board for doors and pass-throughs.

[0028] Figure 3.1 shows the constructive embodiment of the layout according to the model applied in container (1) in the constructive form of support/ labeling/ storage area which includes a modular installation of isopanel-coated

container or flat partition in sheet steel with thermal and acoustic insulating substrate of polystyrene (EPS) or polyurethane (PUR) or polyisocyanurate (PIR) or rock wool (LDR) or in aluminum wire mesh, the entire interior finished with sanitary rounded profiles (aluminum / PVC / stainless steel or similar) to facilitate cleaning and prevent dirt buildup, vinyl-coated floor with high traffic resistance and resistance against fungi and bacteria, lighting of the rooms will be made through built-in or overlapping luminaires with sealing to the maintenance area, LED lamps, sink drainage system in PVC pipe or similar, sink feeding system in PVC pipe or similar, all doors, displays and accessories in GMP standard, equipped with HVAC system, pressure monitoring, being composed of support area (7.2m² or 11.6m²), said modular installation containing: benches (21) coated with AISI 304 stainless steel (as modulation), the area can be redivided to accommodate the desired modulation, split cooling system for comfort; engine room (22) containing: condenser, power and control board for electrical supply of the container.

[0029] Other variants of the modular container units refer to the infusion, diagnosis, surgery, hemodialysis and ICU centers.

[0030] All variants being equipped, where appropriate, with a monitoring system connected to information interfaces in connection with external networks to send data and alarms by internet protocol (IP) for remote management purposes. This monitoring may refer to air pressure, humidity, safety, chemical or biological contamination. The units are validatable or validated through an applicable regulatory agency, with modulations to meet the required environments for ISO8, ISO7, ISO 6, ISO5.

[0031] The modules are equipped with a waste control and treatment center according to national or international normative requirements, can be self-sufficient in energy (solar, wind, generator), and have a water collection and treatment center coupled.

[0032] The dimensions of the container and its components may also vary according to the application and use, being manufactured in various measures.

[0033] Variants of the model presented do not exclude the inclusion of other distinct or additional elements, constructive or configurative variants that contemplate modular units of containers prepared for medical-hospital use, variations that may be applied by those skilled in the art without prejudice to the scope of the invention covered by the following claims.

CLAIMS

1. Constructive layout in container (1) **characterized by** a clean handling and washing room ISO7 equipped with HVAC system, pressure monitoring, the said modular installation being composed of: primary antechamber (2) (1.63m²) for people entrance, said primary antechamber containing alcohol gel dispenser, electromagnetic door interlock system by CLP control and cabinet for supplies; gowning antechamber (3) (1.95m²) for people containing: sink (4) for sanitizing in AISI 304 stainless steel and (sensor driving) high spout faucet, electromagnetic door interlock system by CLP control, bench (5) with AISI 304 stainless steel coating with storage compartment for gowning, cabinet for storage of supplies and waste for disposal; washing/ sterilization room (6) (2.15m²) containing: washing countertop (7) with AISI 304 stainless steel with lower shelves for storage, fed by water purified by reverse osmosis system or similar, cabinet for storage of supplies and waste for disposal; double pass-through (8) 550x550x1100mm for material input and output with electromagnetic door interlock system by CLP control; handling area (9) (5.5m²) containing: II B2 biosecurity cabin (10), workbench (11) with AISI 304 stainless steel on 2 levels; engine room (12) comprising: fan coil (13) with coarse, fine and absolute filtration for air cooling and cleaning, power and control board for electrical supply of the container, automation board of the air conditioning system, interlocking board for doors and pass-throughs, reverse osmosis system.

2. Constructive layout in container (1) according to Claim 1 **characterized by** finishing with rounded sanitary profiles (aluminum / PVC / stainless steel or similar), floor coated in high resistance vinyl blanket, lighting

sealed to the maintenance area, LED lamps, drainage/ feeding system for sinks in PVC pipe, doors, displays and accessories in GMP standard, equipped with HVAC system, e de pressure monitoring.

3. Constructive layout in container (1) according to Claim 1 **characterized by** isopanel coating.

4. Constructive layout in container (1) according to Claim 1 **characterized by** coating on flat partition in steel sheet with thermal and acoustic insulating substrate of polystyrene (EPS).

5. Constructive layout in container (1) according to Claim 1 **characterized by** polyurethane (PUR) coating.

6. Constructive layout in container (1) according to Claim 1 **characterized by** polyisocyanurate (PIR) coating.

7. Constructive layout in container (1) according to Claim 1 **characterized by** rock wool (LDR) coating.

8. Constructive layout in container (1) according to Claim 1 **characterized by** aluminum wire mesh coating.

9. Constructive layout in container (1) according to Claim 1 **characterized by** monitoring system connected to information interfaces in connection with external networks to send data and alarms by internet protocol (IP) for remote management purposes, this monitoring may refer to air pressure, humidity, safety, chemical or biological contamination.

10. Constructive layout in container (1) according to Claim 1 **characterized by** a waste control and treatment center, equipped with self-sufficient energy system and water collection and treatment center.

11. Constructive layout in container (1) according to Claim 1 **characterized by** a constructive variant of a clean room for fractionation area equipped with antechamber (14) (1.71m²) for people entrance containing: washbasin (15) for sanitizing in AISI 304 stainless steel and high spout faucet, electromagnetic door interlock system by CLP control; liquid fractionation area (16) (4.7m²) containing: benches (17) with AISI 304 stainless steel coating on 2 levels for material handling and storage; solid fractionation area (18) (4.7m²) containing: benches (19) with AISI 304 stainless steel coating on 2 levels for material handling and storage, double pass-through 550x550x1100mm for material input and output with electromagnetic door interlock system by CLP control; engine room (19) containing: fan coil with coarse and fine filtration for air cooling and cleaning, power and control board for electrical supply of the container, automation board of the air conditioning system, interlocking board for doors and pass-throughs.

12. Constructive layout in container (1) according to Claim 1 **characterized by** a constructive variant of a support/ labeling/ storage area equipped with benches (21) coated with AISI 304 stainless steel (as modulation), the area can be redivided to accommodate the desired modulation, split cooling system for comfort; engine room (22) containing: condenser, power and control board for electrical supply of the container.

13. Constructive layout in container (1) according to Claim 1 **characterized by** a constructive variant of infusion center.

14. Constructive layout in container (1) according to Claim 1 **characterized by** a constructive variant of diagnostic center.

15. Constructive layout in container (1) according to Claim 1 **characterized by** a constructive variant of surgery center.

16. Constructive layout in container (1) according to Claim 1 **characterized by** a constructive variant of hemodialysis center.

17. Constructive layout in container (1) according to Claim 1 **characterized by** a constructive variant of ICU.

1/3

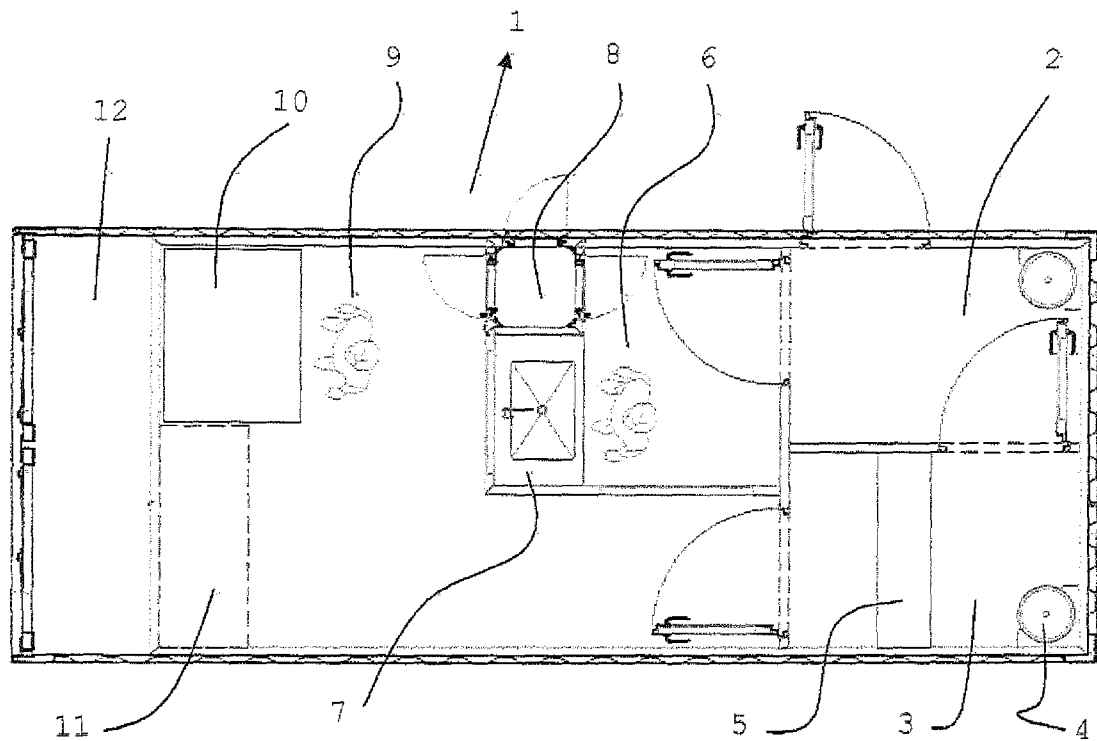


FIGURE 1.1

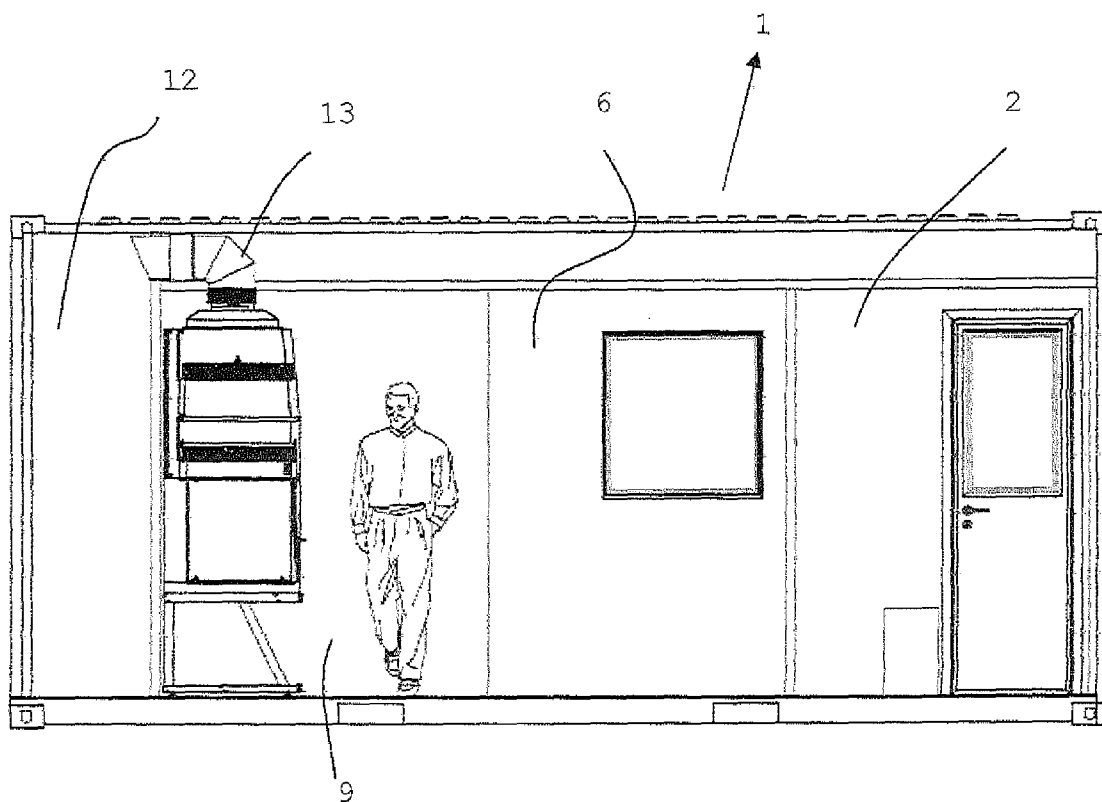


FIGURE 1.2

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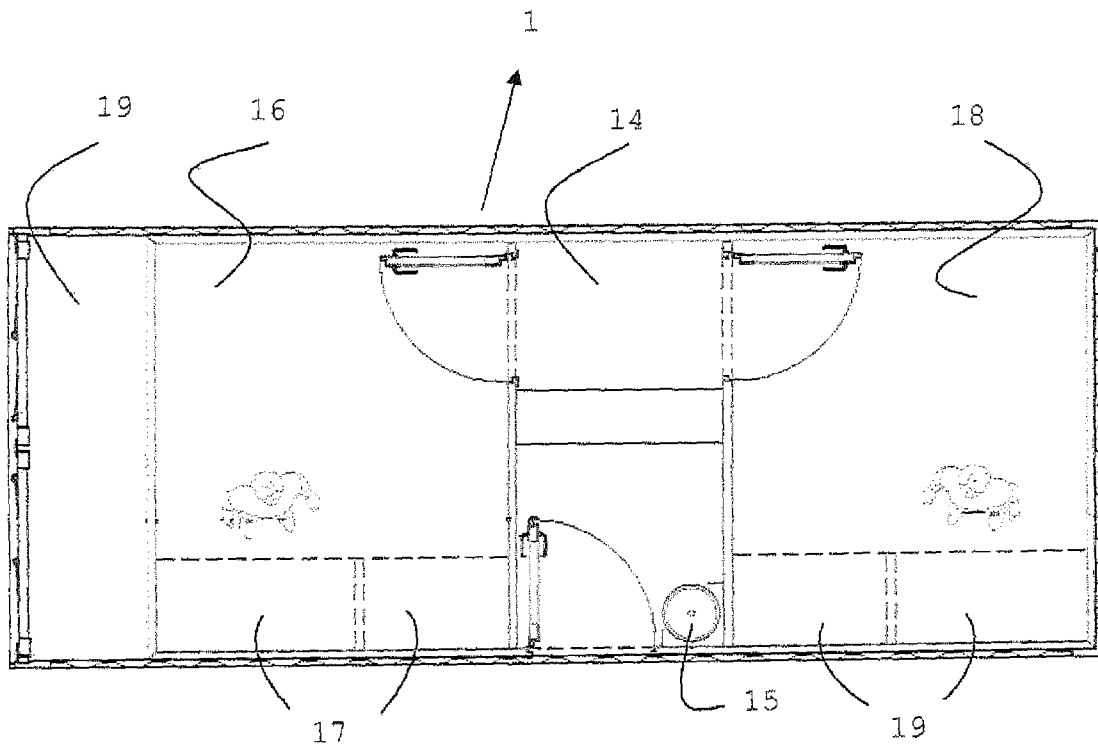


FIGURE 2.1

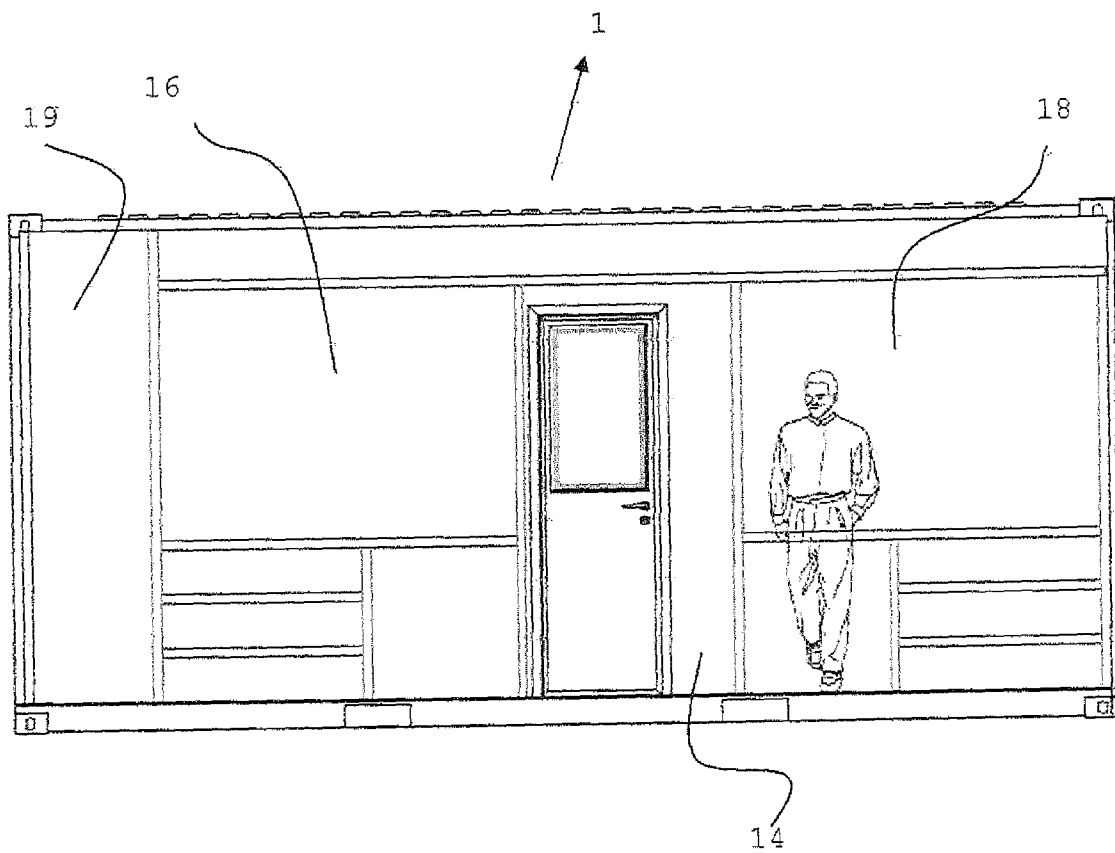


FIGURE 2.2

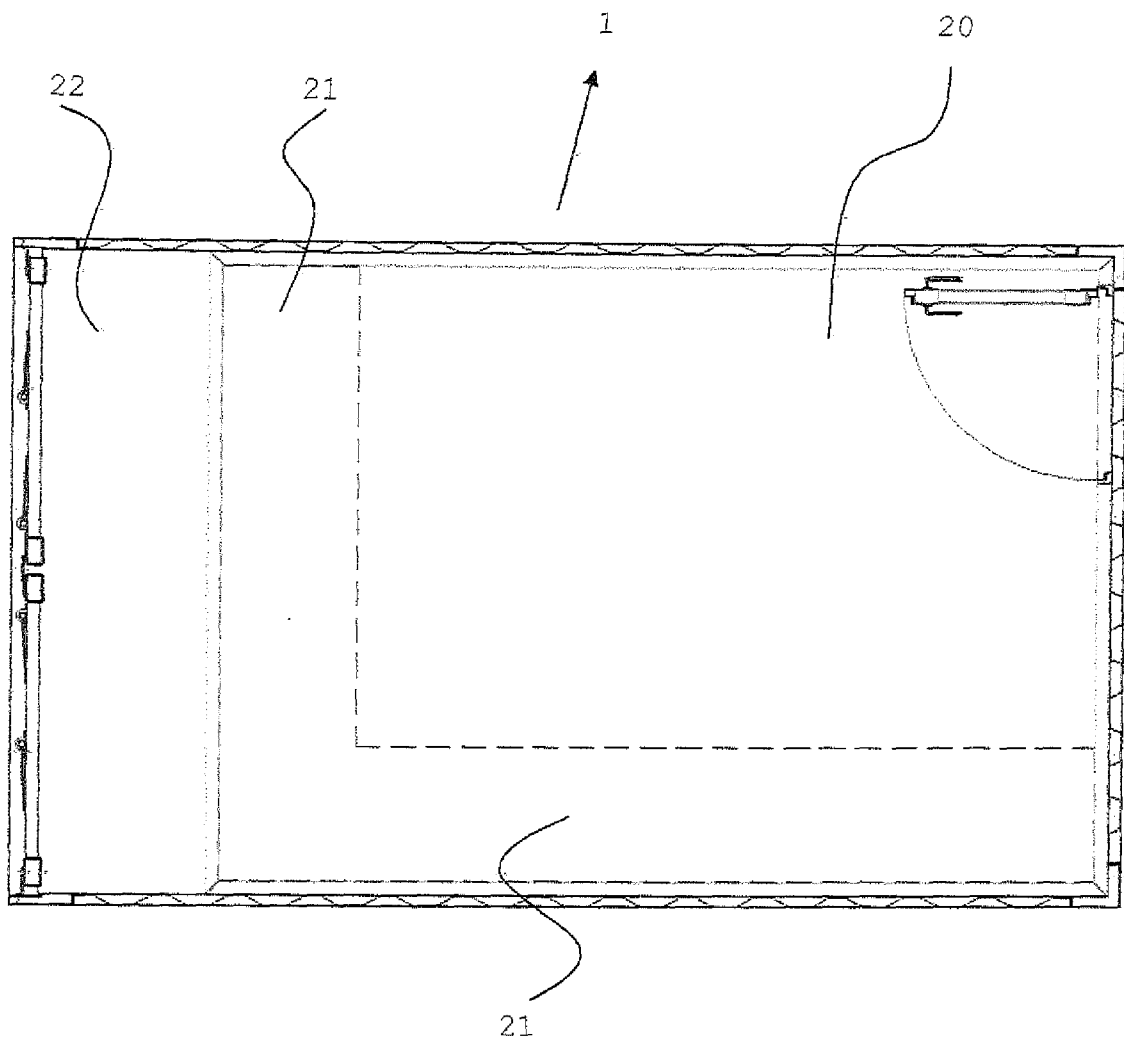


FIGURE 3.1

A. CLASSIFICAÇÃO DO OBJETO

E04H3/00 (2006.01), E04H3/08 (2006.01), E04H3/28 (2006.01), E04H1/00 (2006.01), E04H1/02 (2006.01)

De acordo com a Classificação Internacional de Patentes (IPC) ou conforme a classificação nacional e IPC

B. DOMÍNIOS ABRANGIDOS PELA PESQUISA

Documentação mínima pesquisada (sistema de classificação seguido pelo símbolo da classificação)

IPC E04H

Documentação adicional pesquisada, além da mínima, na medida em que tais documentos estão incluídos nos domínios pesquisados

Base de dados eletrônica consultada durante a pesquisa internacional (nome da base de dados e, se necessário, termos usados na pesquisa)

EPODOC; ESPACENET

C. DOCUMENTOS CONSIDERADOS RELEVANTES

Categoria*	Documentos citados, com indicação de partes relevantes, se apropriado	Relevante para as reivindicações N°
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☐ Documentos adicionais estão listados na continuação do Quadro C☒ Ver o anexo de família da patentes

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Data da conclusão da pesquisa internacional

04 de junho de 2018

Data do envio do relatório de pesquisa internacional:

13/07/2018

Nome e endereço da ISA/



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Categoria*	Citação do documento com indicação de partes relevantes, quando apropriado	Relevante para as reivindicações Nº
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RELATÓRIO DE PESQUISA INTERNACIONAL
 Informação relativa a membros da família da patentes

Depósito internacional Nº

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CN 202913719 U	2013-05-01	NENHUMA	
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INTERNATIONAL SEARCH REPORT

International application N°

PCT/BR2018/000002

A. CLASSIFICATION OF SUBJECT MATTER

E04H3/00 (2006.01), E04H3/08 (2006.01), E04H3/28 (2006.01), E04H1/00 (2006.01), E04H1/02 (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)

IPC E04H

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)

EPODOC; ESPACENET

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claims N°
A	EP 2007953 A1 (GRCEVIC VLADIMIR [FR]) 31 December 2008 (2008-12-31) All document	
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☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

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Date of the actual completion of the international search

June. 4 th. 2018

Date of mailing of the international search report

13/07/2018

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INSTITUTO NACIONAL DA
PROPRIEDADE INDUSTRIAL
Rua Sao Bento n° 1, 17° andar
cep: 20090-010, Centro - Rio de Janeiro/RJ
+55 21 3037-3663

Authorized officer

Aline Amaral de Sousa

Telephone N°:

+55 21 3037-3493/3742

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