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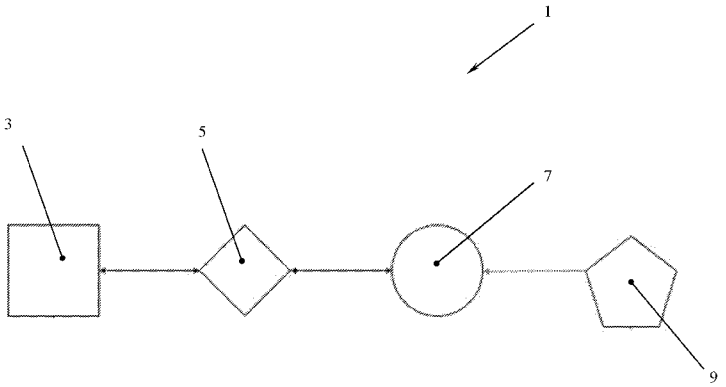

FIG. 1

(57) Abstract: A respiratory protection device (1) is described comprising: a structural protective element (3); a plurality, and preferably two filtering devices (5) operatively connected to the structural protection element (3), the filtering devices being composed of a plurality of TNT polymeric layers of filtering material; a management device (7) operationally connected to the structural protection element (3); a power supply device (9) operatively connected to the structural protection element (3), the power supply device (9) being designed to supply energy to the management device (7).

WO 2022/168128 A1

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RESPIRATORY PROTECTION DEVICE

The present invention refers to a respiratory protection device.

Respiratory protection devices (PPE), also defined Respiratory Protective Equipment (APVR), are devices designed to protect against hazardous substances in the gaseous state (particles, vapors, gases) by means of the filtration mechanism.

These devices, which partially or completely cover the face, are made of filter material or consist of a reusable structure equipped with replaceable filters; for the various classes of pollutants there are specific filters.

The protective masks differ in type, specifications and filtering capacity. In any case, they must comply with certain rules that define the technical and safety standards for the use for which they are intended.

Respiratory protection face masks are divided into two categories, depending on the characteristics and intended use:

• PPE (Personal Protective Equipment), designed to filter the air we breathe from the outside;

• DM (Medical Devices), designed to filter the exhaled air.

To these two categories must then be added the generic (or filtering) masks, which do not fall into the two previous categories. The specific characteristics of the PPE are reported in the harmonized technical standards.

Table 1 shows the reference standards for some APVRs.

UNI EN 136	Full masks (respiratory tract, eyes, face)
UNI EN 140	Half masks (respiratory tract, nose, mouth, chin)
UNI EN 141	Gas and combined filters (glutaraldehyde, formaldehyde, acids, bases, ammonia)
UNI EN 143	Dust filters (glass wool, demolition dust)
UNI EN 149	Dust filtering facepieces (biohazard, glass wool, demolition dust)
UNI EN 405	Anti-gas or anti-gas and anti-dust filter facepieces with valves (glutaraldehyde, formaldehyde)

Table 1

The filtering face-pieces are devices made mainly or entirely of filtering material, which cover the mouth, nose and chin that must be replaced entirely when they are no longer effective. The air can be eliminated through the

filter material itself or through a valve which, by reducing the resistance during exhalation, makes the device more comfortable.

Filtering face-pieces can be classified into:

- dustproof
- anti-gas
- combined

The anti-dust filtering face-pieces (UNI EN 149) based on their power to effectively filter increasing concentrations of polluting aerosols, are classified into: FFP1, FFP2, FFP3.

They are disposable and personal and must be kept away from pollutants until the moment of their use.

Furthermore, they must only be used for one work shift and must in any case be replaced immediately when they are damaged, or visibly contaminated, and if breathing becomes difficult due to saturation of the filter material.

Surgical face masks belong to the category of "Medical Device Masks (DM)".

These are made up of two or three layers of non-woven fabric (TNT), made up of polyester or polypropylene fibers.

The surgical masks are CE marked in accordance

with EU Reg. 2017/745 and the technical standard EN 14683: 2019 "Facial masks for medical use - Requirements and test methods" and EN ISO 10993-1: 2010.

The mask consists of a filter layer that is placed, glued or shaped between the layers of fabric. It limits the spread of potentially infecting particles into the environment, it has no filtering function in the inspiratory phase and therefore does not protect against inhalation of small areas.

They are intended to limit the transmission of infectious agents from staff to patients during surgical procedures and other medical activities with similar requirements. They can also be worn by patients and other people to reduce the risk of spreading infections, particularly in epidemic or pandemic situations, such as the present one.

Within the group of "Personal Protective Equipment Masks (PPE)" are included the masks that protect the person wearing them from external agents which, if inhaled, can cause serious health risks.

The respirators belonging to this category must comply with rigorous technical specifications

established in the UNI EN 149: 2009 standard.

Some models of masks belonging to this category include an exhalation valve to reduce humidity and heat inside. There are usually 3 FFP (Filtering Face Piece) classes, depending on the filtering efficiency of the mask.

The FFP1 mask filters 80% of environmental particles and is not recommended for protection from pathogens that are transmitted by air.

They ensure a first level of respiratory protection in dusty environments that contain suspended particles. These are therefore semi-face dust masks commonly used in various sectors (textile, food, mining, steel, building and construction industries).

The FFP2 mask filters 95% of environmental particles and is recommended for healthcare professionals caring for infected or potentially infected individuals.

The FFP3 mask filters 98-99% of environmental particles and is recommended for healthcare professionals assisting infected or potentially infected individuals, particularly during aerosol-producing maneuvers.

The "Half masks (UNI EN 140)" are reusable

devices, which cover only the mouth, nose and chin, equipped with an exhalation valve. One or more replaceable filters are inserted on the half mask, designed to retain the pollutants in the air.

The structure is made of elastic material in order to guarantee a good seal on the face.

The "Full masks (UNI EN 136)" are reusable devices consisting of a structure that covers the entire face with a visor made of transparent material, are equipped with an exhalation valve and guarantee a greater seal than the half masks.

Also on these devices are inserted replaceable filters designed to retain the pollutants present in the air.

Filters are devices that are inserted on masks and half masks and which are intended to retain pollutants, solids and/or gasses.

They are characterized by specific colors or colored bands for the different pollutants and white for dust.

Dust filters (UNI EN 143) for the filtration of solid particles. Based on their filtering efficiency they are classified into P1, P2, P3.

Gas filters (UNI EN 141), for the filtration of gas and/or vapors, are characterized by letters,

which indicate the pollutants retained. They are divided into three classes, with increasing capacity, marked by the numbers 1, 2, 3.

The filter can be identified by a characteristic color and by the association of letter and number, e.g. for ammonia K1, K2, K3 or for organic vapors and acid gases A1E1. For all three classes, whatever the concentration of the present aeriform, the ability to retain the pollutant is always the same, what varies is the time during which this characteristic is ensured.

Considering that, as the filter class increases, the respiratory resistance of the device to the passage of air also increases, in some cases it is preferable to adopt lower capacity filters that offer greater respiratory comfort while guaranteeing the same protection for a shorter time.

Combined filters (UNI EN 141), for the filtration of gases and/or vapors in the presence of dust. They are made by combining a dust filter and one or more antigas, and are identified by the combination of letters and numbers eg. A2B2E2K2P3.

The factors that determine the choice of filters are:

• for anti-dust the filtering efficacy;

• for those intended to retain gases and vapors, the exposure time as the filtration capacity is always the same for the entire duration (obviously besides the type of pollutant).

All filters must bear the CE marking and an expiry date beyond which they cannot be used, even if properly stored and never used.

The duration of the gas filter is subjectively determined by the user's ability to perceive the odor of the pollutant when it is no longer retained by the filtering material, the operator must promptly replace the filter when this condition occurs (this is why it is not possible to use filter respirators in the presence of odorless pollutants).

The types of masks and PPE listed above are often disposable devices, difficult to dispose of after use.

The design, wearability and comfort are often neglected in fact the various types of products on the market are uncomfortable to wear for long periods.

Finally, they offer passive protection against pathogens and pollutants.

In fact, they are limited to placing a layer of filtering fabric between the respiratory tract of the individual and the potentially polluted external environment that should ensure isolation from the pollutant in question.

Very often, however, due to problems of fit, adherence and useful life of the devices, these solutions are inadequate or at least not very effective.

Object of the present invention is solving the aforementioned prior art problems by providing a respiratory protection device which actively uses UV-C light in combination with photocatalytic nanomaterials to filter the air that is breathed, this system leads to an efficiency total filtration equal to 99.99%.

The respiratory protection device with UV filters and nanomaterials, unlike conventional N95 filters, does not just trap microorganisms but neutralizes them, breaking down the genetic material of viruses and bacteria in milliseconds.

Microorganisms smaller than 0.3 microns come in contact with a filter coated with photocatalytic nanomaterials that irradiated by UV-C rays destroys the microorganisms bringing the total filtration

efficiency to 99.99%.

Another object of the present invention is the innovative design that allows for a higher comfort of use than the masks currently on the market, ensuring greater adhesion of the device to the face and therefore greater insulation of the respiratory tract with respect to the external environment.

The aforementioned and other objects and advantages of the invention, as will emerge from the following description, are achieved with a protection device such as that described in claim 1. Preferred embodiments and non-trivial variants of the present invention form the subject of the dependent claims.

It is understood that all attached claims form an integral part of the present description.

It will be immediately obvious that innumerable variations and modifications (for example relating to shape, dimensions, arrangements and parts with equivalent functionality) can be made to what is described without departing from the scope of the invention as appears from the attached claims.

The present invention will be better described by some preferred embodiments, provided by way of

non-limiting example, with reference to the attached drawings, in which:

- FIG. 1 shows a block diagram of the macro components of the protection device according to the present invention;

- FIG. 2 shows a block diagram of an exploded view of the filtering system of the protection device according to the present invention;

- FIG. 3 shows a block diagram of the electronic component of the protection device according to the present invention; and

- FIG. 4 shows a block diagram of a configuration of the electronic diagram of the protection device according to the present invention.

The protective device 1 which is the subject of this application can be used both in the health sector (hospital/medical) and in the industrial and service sectors where respiratory protection is required.

Furthermore, the protection device 1 in question can be used as a mask for the protection of the respiratory tract.

The technological sector is that of nanotechnologies applied to biological systems and

in particular relating to the application of photocatalysis processes assisted by nanomaterials for the abatement of pathogens and pollutants on gas streams.

The protection device 1 is a latest generation device which, thanks to its design and the use of innovative technologies such as photocatalysis assisted by nanomaterials, improves the ability to protect individuals from pathogens (viruses and bacteria) and polluting chemicals.

Advantageously, the protection device 1 is a mask which exploits the photocatalysis process combined with nanomaterials to destroy viruses, bacteria and polluting chemicals.

The photocatalytic coating of the filters is activated by UV light and produces a reaction capable of degrading the genetic material of viruses and bacteria, this guarantees a complete regeneration of the filters for up to 80 hours.

In addition, the protective device (1) is equipped with a smartphone app that allows the management of the main functions of the mask as well as reporting any health risk situations.

Referring to the figures, it can be seen that the respiratory protection device 1 comprises:

- at least one structural protection element 3;

- a plurality, and preferably two, filtering devices 5 operatively connected to the structural protection element 3, the filtering devices 5 being composed of a plurality of TNT polymeric layers of filtering material;

- at least one management device 7 operationally connected to the structural protection element 3;

- at least one power supply device 9 operationally connected to the structural protection element 3, the power supply device 9 being designed to supply energy to said management device 7.

The protective device 1 is composed of a structural protective element 3 of transparent polymeric material that has an innovative anatomical shape that allows the device to cover the respiratory tract and to adapt to the conformation of the face by increasing adherence to the face.

In addition, to facilitate adhesion to the face, the protective structural element 3 is surrounded in its perimeter by a layer of variable

density polymeric material which, following the pressure on the face, takes its shape by modeling itself.

This highly elastic material resumes its normal condition in the absence of tension or stress due to the forces applied to it.

At the two ends of the structural protection element 3 the filtering devices 5 are placed.

The single filtering unit is composed of a containing element 19 in polymeric material which serves to contain the sandwich of filtering material composed of a coupled multilayer system of different filtering levels: the first layer 13 is composed of a series of layers of polymeric TNT; the second layer 15, on the other hand, is composed of a polymeric material functionalized with nanomaterials integrated into the fibers through various deposition processes.

Advantageously, in addition to the filtering device 5, inside the box there is at least one irradiation device 21 which, through the emission of UV-C radiation, illuminates the surface of the filtering device 5.

An electronic device 17 is placed outside the containment element 19 in special polymeric

housings.

The electronics inserted inside the electronic device 17 can be defined as shown in Figure 3:

- at least one feeding device 9;
- at least one management device 7;
- at least one monitoring device 23;
- at least one sterilization device 25.

In particular, the power supply device 9 comprises all components necessary to efficiently supply the power supply load to the electronic components.

The management device 7 is composed of a microcontroller which serves to manage the input signals (coming from the sensors) and the output signals (towards the actuators).

The monitoring device 23 is composed of the sensors 37, 45 (temperature, pressure, VO2Max, CO2) and the connection and geolocation systems 35, 39 (Bluetooth chip, accelerometer, gyroscope and GPS).

The sterilization device 25 is composed of the PCB and the configuration of the UV-C led 21 irradiation device which irradiates the filtering device 5.

Advantageously, the protective structural element 3 is composed of transparent polymeric

material molded by thermoforming with PetG sheets.

Alternatively, the protective structural element 3 can be made of different materials such as PMMA, polycarbonate sheets or other transparent or opaque polymeric resins.

In particular, the containing element 19 that encloses the filtering material is produced in SLA technology but can be made as before with different polymeric materials and through different production processes.

Depending on the material used, the component can be made with the following production processes:

FOR THERMOSET MATERIALS:

- Compression molding
- Piston transport molding with piston transport
- Injection molding

FOR THERMOPLASTIC MATERIALS:

- Injection molding
- Thermoforming
- Sintering molding

Advantageously, the filtering devices 5 are engaged in the structural protection element 3 through a pressure mechanism, but can also be

inserted through a through hole with a sealing block or through a bayonet coupling.

In addition, the structural protective element 3 is coated with a sealing system consisting of a gasket of polymeric material, typically hypoallergenic silicone but can be replaced with alveolar polymeric materials of different densities to improve adaptation to the face.

The support system (not shown) of the protection device 1 is currently composed of an elastic band (not shown) in silicone which crosses the user nape transversely (not shown) but the support modalities can also include elastic bands that wrap around the user ears at the base or bands in elastic fabric with adjustment systems.

The electronics now include 37, 45 temperature, CO2 sensors as well as 35 inertial navigation systems such as accelerometers and gyroscopes and 39 frequency transmission systems such as Bluetooth.

The electronics configuration can also include 37 sensors such as VO2 Max, sensors for air quality, sensors for measuring volatile organic substances, sensors for voice command and alarm system according to the directives of Legislative

Decree 81/08 and ISO 18001 also MEMS electronic components and interconnections can be made on silicon electronics or on flexible support.

Advantageously, the protection device 1 equipped with UV-C purification is an antiviral and anti-pollution face mask that filters dust, pathogens and allergens (such as pollen and leaf mulch) from the air you breathe.

The protective device 1, thanks to the active filtration technology with UV-C, is the only one to take advantage of the wearable assisted photocatalysis process.

Its design uses a combination of a filter functionalized with photoactive nanomaterials and two powerful UV-C LEDs to actively sterilize the air that normally passes through the filter material.

Advantageously, even during exhalation, the air is sterilized and filtered, effectively protecting people in both directions of air circulation.

In addition, the UV protection device 1 is equipped with an outer ring (not shown) in hypoallergenic polymeric material to create a convenient airtight seal, ensuring effective

protection from atmospheric pollutants.

In a preferred embodiment of the invention, the protection device 1 is composed of a structural protection element 3 on which the removable filter holder blocks are inserted which allow the filter to be accessed and replaced when it runs out, while the lighting device UV-C itself has a usage life of 10,000 hours, and the protective device 1 internal battery runs for 6 hours on a single full charge.

Figure 4 shows one of the potential configurations of the electronic diagram of the protection device 1 comprising:

- power input 27 (micro USB, USB-C, other state-of-the-art micro ports);
- fast charge regulator 29 (charge control system);
- charge accumulator 43 (lithium ions or subsequent state-of-the-art technologies);
- signal converter 41;
- temperature and pressure sensors 45;
- management device 7 for managing the electronic functions;
- UV LED driver 31;
- UV-C LED irradiation devices 21;
- inertial motion sensors 35 (accelerometer and

gyroscope)

- CO2 and VO2 Max sensors 37;
- radio frequency transmission modules 39 (Bluetooth).

CLAIMS

1. Respiratory protection device (1) characterized in that it comprises:

- at least one structural protection element (3);
- a plurality, preferably two, of filtering devices (5) operatively connected to said structural protection element (3), said filtering devices being composed of a plurality of TNT polymeric layers of filtering material;
- at least one management device (7) operatively connected to said structural protection element (3);
- at least one power supply device (9) operatively connected to said structural protection element (3), said power supply device (9) being designed to supply energy to said management device (7).

2. Protection device (1) according to claim 1, characterized in that said structural element (3) is composed of transparent polymeric material molded by thermoforming with PETG sheets or from PMMA or from polycarbonate sheets or in other transparent or opaque polymeric resins.

3. Protection device (1) according to claim 1, characterized in that said filtering devices (5) comprise at least one containing element (19), preferably made of polymeric material, designed to contain in said filtering devices (5):

- at least one UV-C radiation irradiation device (21);

- at least a first layer (13) composed of a plurality of layers of polymeric TNT;

- at least a second layer (15) composed of at least one polymeric material functionalized with nanomaterials integrated in the fibers.

4. Protection device (1) according to claim 1, characterized in that it comprises at least one electronic device (17) operatively connected to said structural protection element (3) comprising:

- at least one said power supply device (9) comprising a plurality of components designed to supply power to said electronic device (17);

- at least one said management device (7) comprising at least one microcontroller designed to manage the input signals coming from the sensors and the output signals towards the actuators;

- at least one monitoring device (23) comprising a plurality of sensors (37), (45) and a plurality of

connection and geolocation systems (35), (39);

- at least one sterilization device (25) composed of the PCB and the configuration of said irradiation device (21) UV-C LEDs designed to irradiate said filtering devices (5).

5. Protection device (1) according to any one of the preceding claims, characterized in that said sensors (37), (45) are temperature sensors and/or pressure sensors and/or VO2Max sensors and/or CO2 sensors.

6. Protection device (1) according to any one of the preceding claims, characterized in that said connection and geolocation systems (35), (39) are Bluetooth chips and/or accelerometer systems and/or gyroscope systems and/or GPS systems.

7. Protection device (1) according to any one of the preceding claims, characterized in that said containment element (19) is produced in SLA technology or in polymeric materials.

8. Protection device (1) according to any one of the preceding claims, characterized in that said filtering devices (5) are operatively connected to said structural element (3) through at least one pressure mechanism or through at least one through hole with locking seal or by at least one bayonet

coupling.

9. Protection device (1) according to any one of the preceding claims, characterized in that said structural element (3) is covered with a sealing system composed of at least one gasket of polymeric material, preferably hypoallergenic silicone, or with alveolar polymeric materials at different densities.

10. Protection device (1) according to any one of the preceding claims, characterized in that said protection device (1) comprises at least one support system comprising at least one elastic band, preferably made of silicone, designed to cross the nape of the neck transversely user or elastic bands that wrap the user ears or bands in elastic fabric with adjustment systems.

11. Protection device (1) according to any one of the preceding claims, characterized in that said protection device (1) is equipped with a smartphone app designed to manage the main functions of said protection device (1) and/or to report any health risk situations.

12. Protection device (1) according to any one of the preceding claims, characterized in that it is designed to be made by means of the following

production processes: for thermosetting materials, compression molding or molding with piston transport with piston transport or molding with injection; for thermoplastic materials, injection molding or thermoforming or sintering molding.

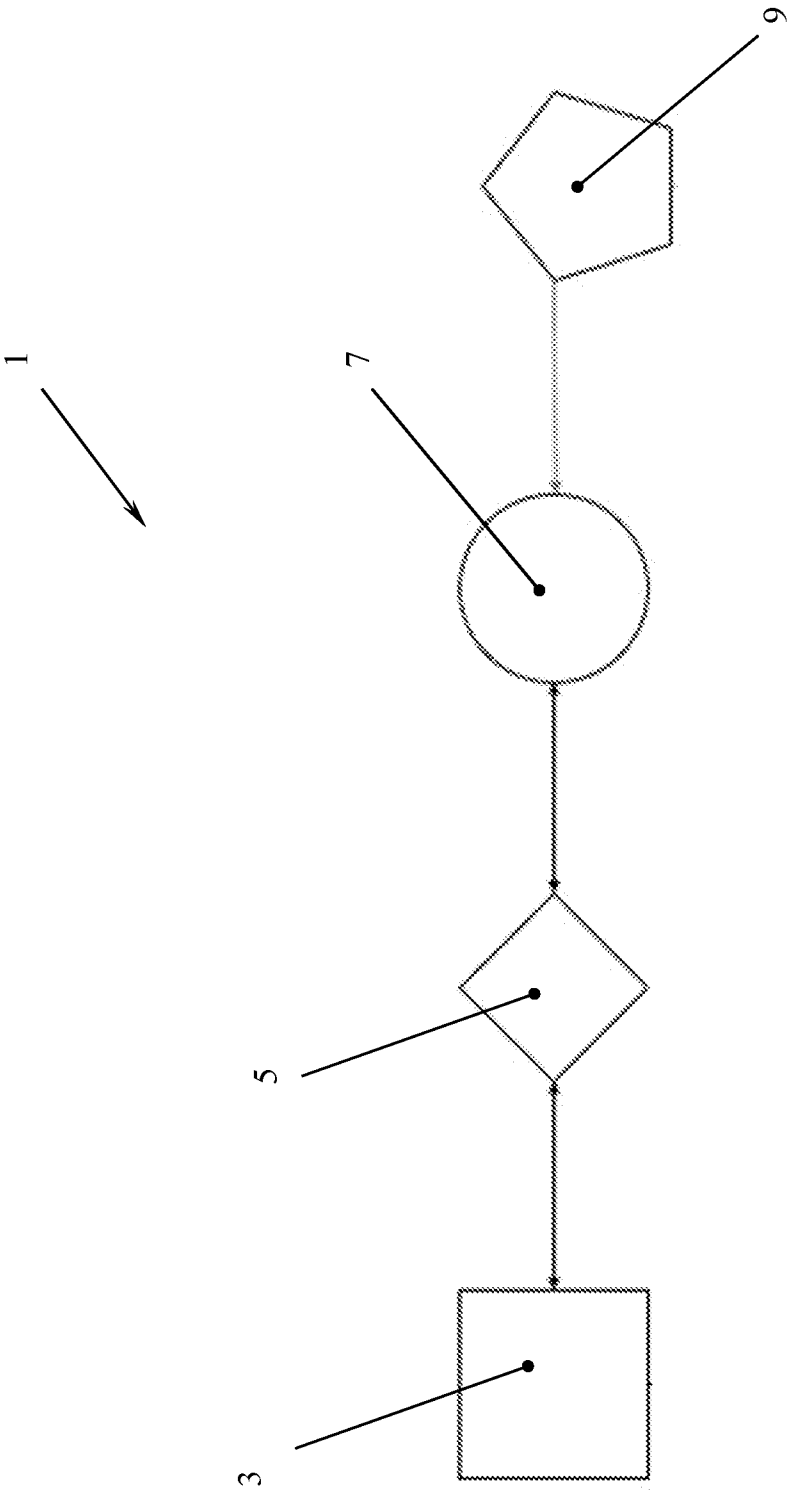

FIG. 1

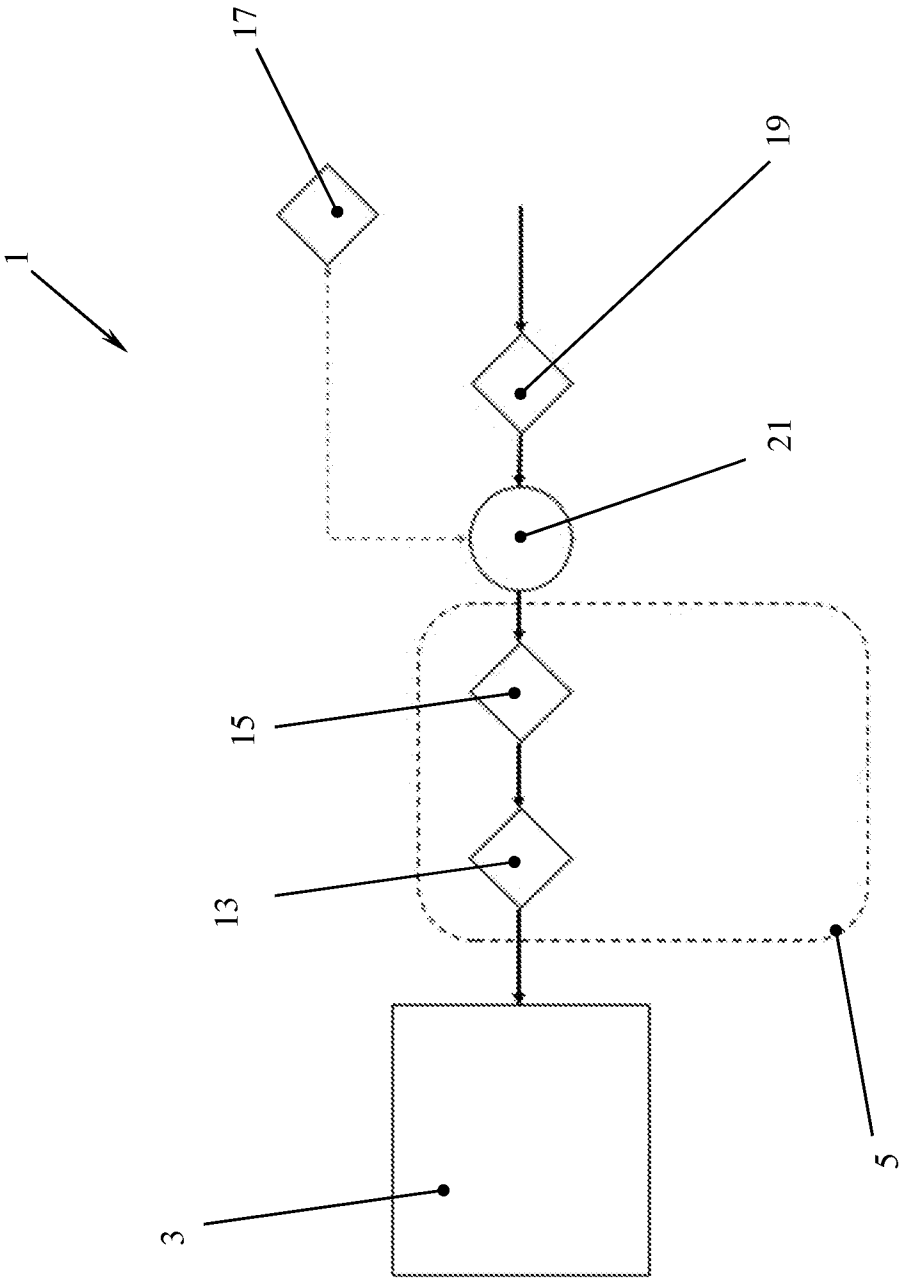

FIG. 2

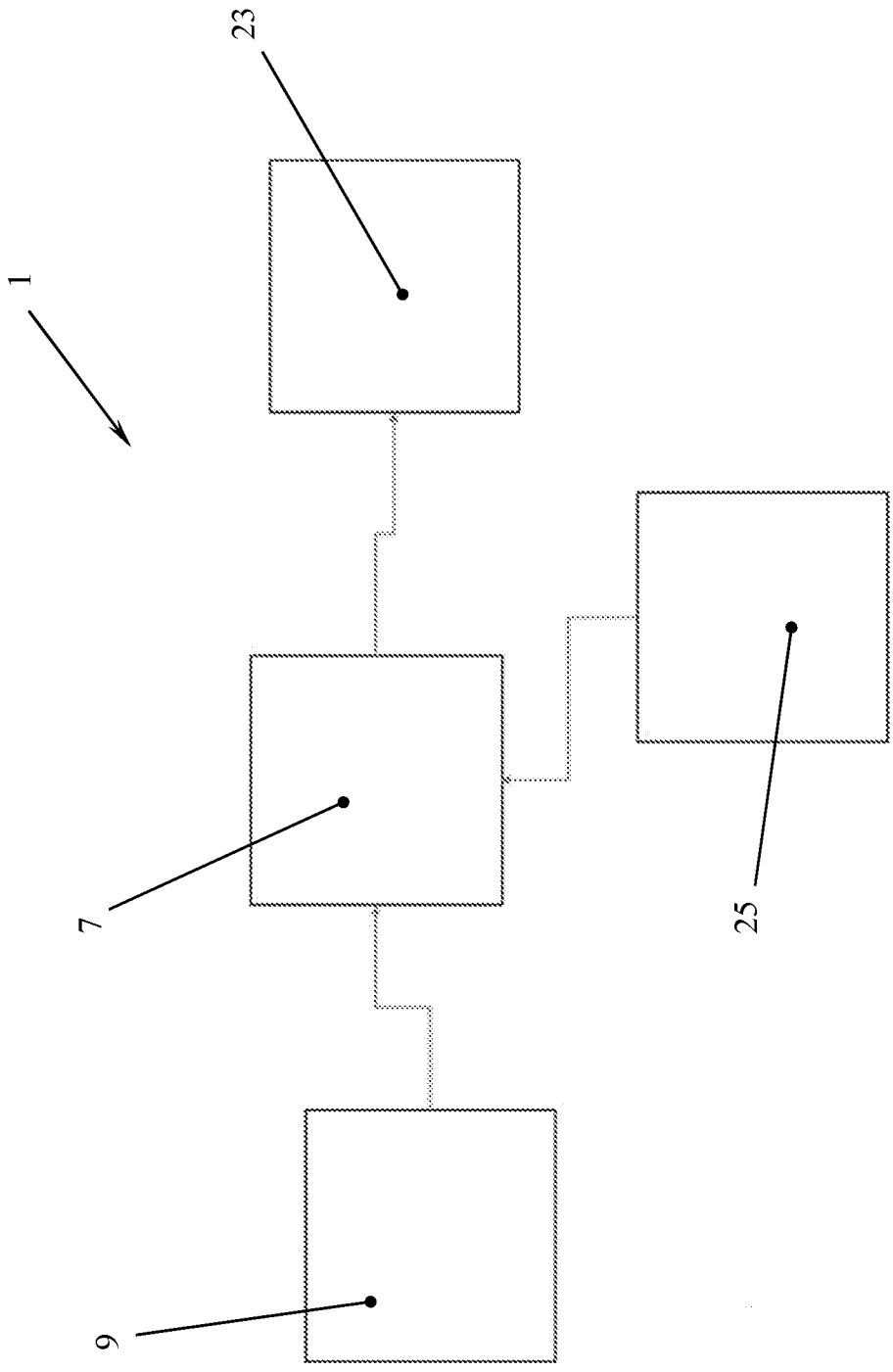

FIG. 3

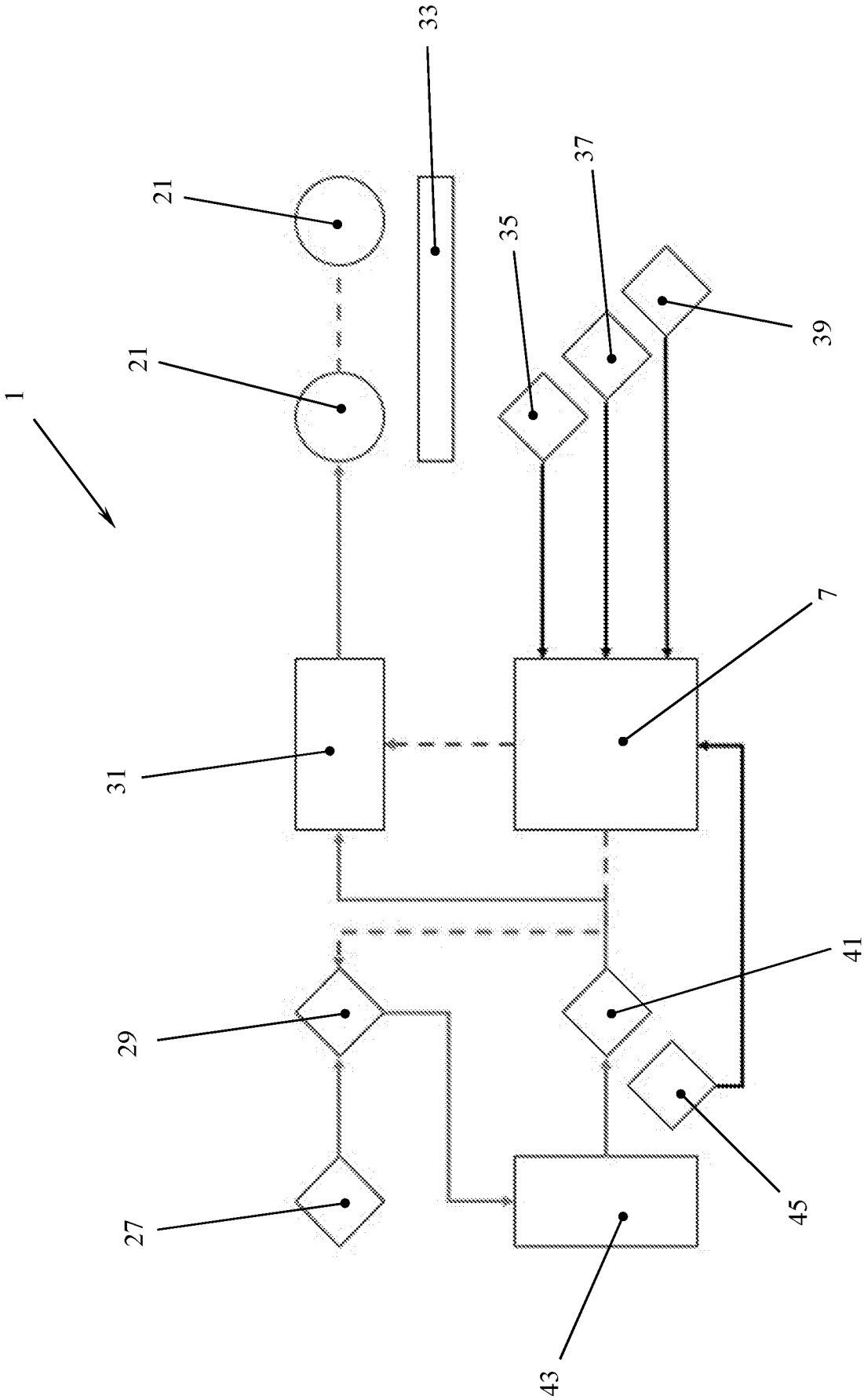

FIG. 4

INTERNATIONAL SEARCH REPORT

International application No
PCT/IT2021/050318

A. CLASSIFICATION OF SUBJECT MATTER
INV. A62B9/00 A62B18/02 A62B23/02
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)
A62B A41D

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)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	CN 111 194 955 A (SHENZHEN SITAN TECH CO LTD) 26 May 2020 (2020-05-26) figures 3-4 paragraph [0032] - paragraph [0056] -----	1-12
X	KR 102 139 446 B1 (YUNE SUNG HYUNE [KR]) 29 July 2020 (2020-07-29) figures 1-4 paragraph [0022] - paragraph [0030] -----	1-3,7-12

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

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Date of the actual completion of the international search	Date of mailing of the international search report
4 January 2022	12/01/2022

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Koszewski, Adam

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IT2021/050318

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
CN 111194955 A	26-05-2020	NONE	
KR 102139446 B1	29-07-2020	NONE	