



(86) Date de dépôt PCT/PCT Filing Date: 2000/03/04

(87) Date publication PCT/PCT Publication Date: 2000/09/08

(85) Entrée phase nationale/National Entry: 2001/09/05

(86) N° demande PCT/PCT Application No.: US 2000/005566

(87) N° publication PCT/PCT Publication No.: 2000/051663

(30) Priorité/Priority: 1999/03/05 (09/263,656) US

(51) Cl.Int.⁷/Int.Cl.⁷ A61M 16/00, A61H 31/00

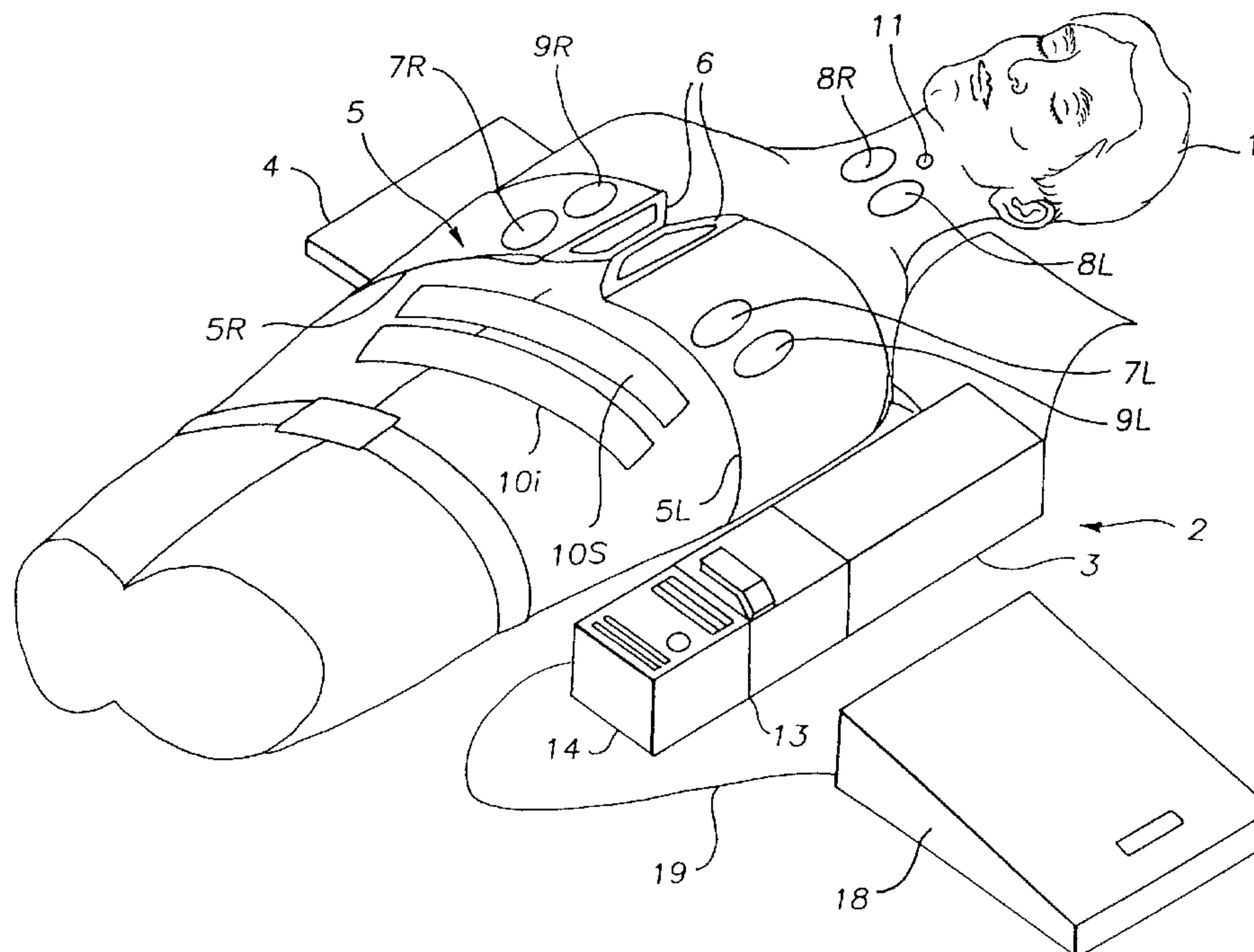
(71) Demandeur/Applicant:
EMERGENCY MEDICAL SYSTEMS, INC., US

(72) Inventeurs/Inventors:
SHERMAN, DARREN R., US;
BYSTROM, STEVEN R., US

(74) Agent: SMART & BIGGAR

(54) Titre : DISPOSITIF DE REANIMATION CARDIO-RESPIRATOIRE ET DEFIBRILLATEUR AUTOMATIQUE
D'URGENCE D'ACCES PUBLIC

(54) Title: PUBLIC ACCESS CPR AND AED DEVICE



(57) **Abrégé/Abstract:**

A system for resuscitation of a heart attack victim. The system includes CPR device which compresses the victim's chest, a defibrillator which may be used to defibrillate the patient, and an identification system for identifying the person operating the system. Depending on the identity of the operator, the system permits varying degrees of access to components and enablement of the functions of the various subsystems.

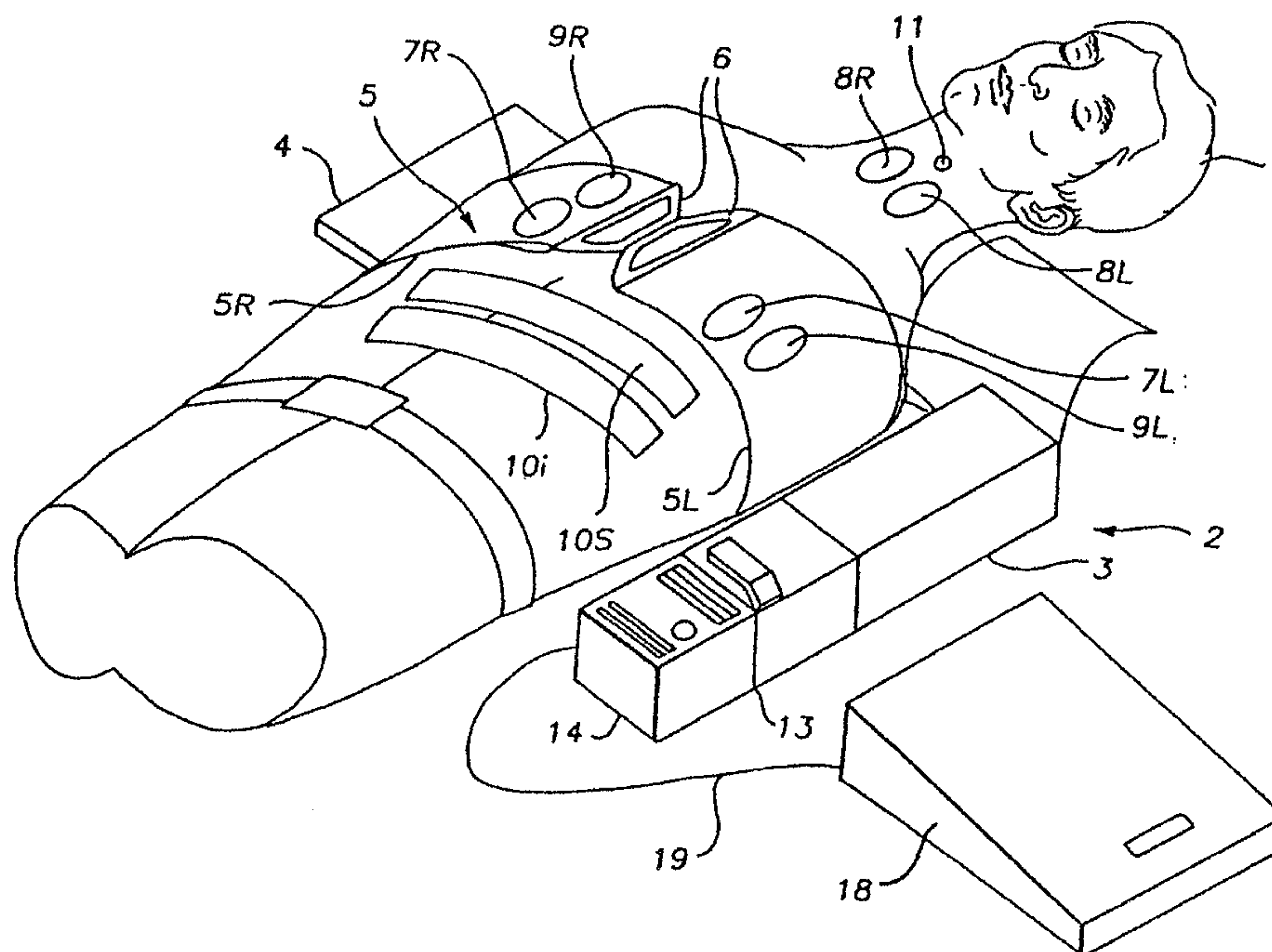


**PCT**WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ : A61M	A2	(11) International Publication Number: WO 00/51663 (43) International Publication Date: 8 September 2000 (08.09.00)
(21) International Application Number: PCT/US00/05566 (22) International Filing Date: 4 March 2000 (04.03.00) (30) Priority Data: 09/263,656 5 March 1999 (05.03.99) US (71) Applicant: EMERGENCY MEDICAL SYSTEMS, INC. [US/US]; 775 Palomar Avenue, Sunnyvale, CA 94086 (US). (72) Inventors: BYSTROM, Steven, R.; 775 Palomar Avenue, Sunnyvale, CA 94086 (US). SHERMAN, Darren, R.; 775 Palomar Avenue, Sunnyvale, CA 94086 (US). (74) Agent: CROCKETT, K., David; Crockett & Crockett, Suite 400, 24012 Calle de la Plata, Laguna Hills, CA 92653 (US).		(81) Designated States: AU, BR, CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>Without international search report and to be republished upon receipt of that report.</i>

(54) Title: PUBLIC ACCESS CPR AND AED DEVICE



(57) Abstract

A system for resuscitation of a heart attack victim. The system includes CPR device which compresses the victim's chest, a defibrillator which may be used to defibrillate the patient, and an identification system for identifying the person operating the system. Depending on the identity of the operator, the system permits varying degrees of access to components and enablement of the functions of the various subsystems.

Public Access CPR and AED DeviceField of the Invention

This invention relates to the resuscitation of cardiac arrest victims.

5

Background of the Invention

Cardiopulmonary resuscitation (CPR) is a well known and valuable method of first aid. CPR is used to resuscitate people who have suffered from cardiac arrest after heart attack, electric shock, chest injury and many other causes. During cardiac arrest, the heart stops pumping blood, and a person suffering cardiac arrest will soon suffer brain damage from lack of blood supply to the brain. Thus, CPR requires repetitive chest compression to squeeze the heart and the thoracic cavity to pump blood through the body. Very often, the victim is not breathing, and mouth to mouth artificial respiration or a bag valve mask is used to supply air to the lungs while the chest compression pumps blood through the body. The methods of providing oxygenated airflow to the lungs are referred to as ventilation.

20

It has been widely noted that CPR and chest compression can save cardiac arrest victims, especially when applied immediately after cardiac arrest. Chest compression requires that the person providing chest compression repetitively push down on the sternum of the victim at 80-100 compressions per minute. CPR and closed chest compression can be used

25

WO 00/51663

PCT/US00/05566

anywhere, wherever the cardiac arrest victim is stricken. In the field, away from the hospital, CPR may be accomplished by ill-trained by-standers or highly trained paramedics and ambulance personnel.

5 When a first aid provider performs chest compression well, blood flow in the body is typically about 25-30% of normal blood flow. This is enough blood flow to prevent brain damage. However, when chest compression is required for long periods of time, it is difficult if not impossible to maintain
10 adequate compression of the heart and rib cage. Even experienced paramedics cannot maintain adequate chest compression for more than a few minutes. Hightower, et al., Decay In Quality Of Chest Compressions Over Time, 26 Ann. Emerg. Med. 300 (Sep. 1995). Thus, long periods of CPR, when
15 required, are not often successful at sustaining or reviving the victim. At the same time, it appears that, if chest compression could be adequately maintained, cardiac arrest victims could be sustained for extended periods of time. Occasional reports of extended CPR efforts (45-90 minutes)
20 have been reported, with the victims eventually being saved by coronary bypass surgery. See Tovar, et al., Successful Myocardial Revascularization and Neurologic Recovery, 22 Texas Heart J. 271 (1995).

 In efforts to provide better blood flow and increase the
25 effectiveness of bystander resuscitation efforts, chest compression devices capable of performing the tasks of the basic CPR procedure have been proposed and used. Our own modular CPR device, described in our co-pending U.S. patent

WO 00/51663

PCT/US00/05566

applications 08/922,723 and 09/087,299 provide for
circumferential chest compression performed by a battery
operated motor and clutch assembly. The chest compressions
are accomplished automatically after installation and
5 initialization of the system. The devices are designed for
use by both untrained and trained operators, so that they may
be used on patients as quickly as possible. It is intended
that any bystander recognizing a fallen patient will be able
to gain access to a nearby device, install the device, and
10 initiate the operation of the device to commence chest
compression and patient monitoring.

Our CPR devices described in our co-pending applications
08/922,723 and 09/087,299 also incorporate an automatic
emergency defibrillator. Defibrillation is a well known
15 technique for restoring normal heart rhythm to a patient who
is in cardiac arrest due to ventricular fibrillation or
ventricular tachycardia. It involves attaching electrodes to
the patient and applying a large electrical shock to the
patient. Defibrillation can resuscitate a large class of
20 cardiac arrest patients, and its success is enhanced by
application of the shock early in the resuscitation effort. A
minute or so of chest compression also enhances the
effectiveness of defibrillation shocks in reviving the
patient.

25 Recently, automatic emergency defibrillators (AED) have
been installed in controlled areas such as airplanes, where
the presence of trained operators and secure access to the AED
can be maintained. The practice of installing AED's in

WO 00/51663

PCT/US00/05566

controlled areas is sometimes referred to as Public Access
Defibrillation. However, laws in most jurisdictions forbid
installation of the devices without maintenance of a number of
trained operators in the controlled area and oversight of the
5 program maintenance by a doctor.

Our co-pending application 09/100,840 provides a control
system for operating an automatic defibrillator and an
automatic chest compression device in coordination with each
other to enhance the effectiveness of the resuscitation. The
10 device also provides electro-stimulation for
electroventilation, electro-counterpulsion, abdominal binding
and glottic closure, all coordinated with the chest
compression device to effect electro-stimulation at various
points in the compression cycle.

15

Summary

The public access CPR and AED device described below is
intended to be installed in public areas where access is
readily available to bystanders, first responders, EMT's and
doctors. However, it is not necessary, nor desirable, to
20 permit full access of the device to the entire range of people
who might desire or require access since some users will not
be properly trained to supervise the device's operation. To
control and thus permit the optimal degree of access to the
system, a tiered access system is used to control physical
25 access and functional enablement of the system. Physical
access means access to the device itself, and/or access to
certain accessories used for patient treatment in conjunction

WO 00/51663

PCT/US00/05566

with the device that may be stored in the device or with the device (ET tubes, venous access kits, laryngoscopes, drugs, etc.). Functional enablement refers to the system allowing operation of certain functions, such as chest compression, alteration of setpoints, application of defibrillating shock, etc. Thus, the system must be told (or determine for itself) that it is permitted to initiate a therapeutic mode before it does so. One mechanism for differentiating the type of user accessing the device is through the identification subsystem sensors, since, for example, only trained personnel are "key holders" (as described in further detail below in reference to Figure 2.)

The intended models of use for these systems include installation in hospitals and ambulances, and widespread installation in public areas such as workplaces, shopping centers, athletic facilities and stadiums, and even in homes of patients with an identified high risk of cardiac arrest. The devices may be installed in hospitals and ambulances without concern about the level of training for the expected user, because the expected user will be a highly trained operator such as a physician, nurse or emergency medical technician. These trained users can be expected or required to have the expertise necessary to supervise and administer all phases of the resuscitation protocol. However, because installation and activation within minutes of the onset of cardiac arrest is critical to saving a patient's life, it is desirable to allow the device to be deployed by untrained bystanders or minimally trained first responders, and permit

WO 00/51663

PCT/US00/05566

trained first responders and untrained bystanders to operate the device in safe modes. The system reserves physical access to advanced equipment and/or functional enablement of advanced modes which may present some danger to the patient for trained first responders. The system may have additional treatment modules, such as drug delivery equipment, that should only be used by expert operators, and the system prohibits access to these modules to all but identified expert operators. Trained first responders and expert operators may identify themselves to the system through the use of access cards, identification numbers or access codes, while the system may assume lack of identification indicates use by an untrained bystander. In all instances of use, the system initiates communications with a remote medical center, where operator identity may be confirmed and the level of access and enablement of the system may be adjusted remotely.

Brief Description of The Drawings

Figure 1 is diagram of a chest compression, ventilation and defibrillation device controlled by the tiered access system.

Figure 2 is a block diagram of the system for controlling access to a resuscitation device.

Figures 3A and 3B show the system flow chart for system of Figure 2, with details of the tiered access system.

Figure 4 shows the device of Figure 1 installed in a locked mounting device.

Detailed Description of the Inventions

Figure 1 shows the Public Access CPR and AED Device mounted on a patient **1** and ready for use. The chest compression subsystem **2** comprises the motor box **3**, the belt cartridge **4**, and the compression belt **5** with left and right portions **5L** and **5R**. The belt is fastened around the patient with fasteners **6** (which may be buckles, Velcro™ hook and loop fasteners or other fasteners with sensors to sense when the belt is fastened). Ventilation electrodes **7L** and **7R** are mounted on the belts in the area of the lower chest and placed bilaterally over the diaphragm. Bipolar electrodes **8L** and **8R** (or electrode pairs) may also be placed on the neck, bilaterally, to stimulate the phrenic nerve which courses downwardly through the neck. Defibrillation electrodes **9R** and **9L** are placed on the right and left sides of the chest and they may also be located below the patient, on the spine between the shoulder blades, and on the center of the chest, respectively. These electrodes are used for establishing the electrical contact needed for EKG sensing, and also for defibrillating the patient. Counterpulsion electrodes **10i** and **10s** are placed on the skin over the abdominal or rectus muscles, with a line of positive electrodes placed in the superior position and a line of ground electrodes placed in the inferior position. Glottic control electrodes are disposed on an electrode patch **11** placed on the neck along the tracheo-esophageal groove.

The control box **12** houses a computer system that controls the various functions of the device. The computer system

WO 00/51663

PCT/US00/05566

controls operation of the chest compression device,
acquisition of signals from various feedback mechanisms such
as the EKG electrodes, and application of stimulating or
defibrillation pulses to the electrodes. (Commercially
5 available sensors, electrodes and EKG analysis systems such as
the ForeRunner™ AED sold by HP Heartstream can be used as the
basis for the cardioverting subsystem). The computer system
may also control operation of additional therapeutic modules,
such as drug injection modules. The computer system also
10 controls the communications subsystem **13** used to initiate and
maintain communication with a remote medical facility. The
communications subsystem may include a telephone handset,
keypad and display.

An identification subsystem **14** is operably connected to
15 the control box **12** and/or communication subsystem, **13** and may
include a key card reader **15** for reading an encoded card, a
keyboard or touchpad **16** for entry of an access code or
personal identification number, and a biometric sensor **17** for
reading a biometric parameter of the user such as a
20 fingerprint. A secure device enclosure **18** is connected to the
control box through electronic cable **19**, and is locked or
unlocked as controlled by the computer system. The secure
device enclosure may house ventilation equipment such as bag
valve masks or ventilation tubes, medication used in the ACLS
25 protocol, invasive devices such as intravenous needles (and,
if desired, defibrillation electrodes). The system also
includes diagnostic devices for sensing EKG, pulse,
respiration and temperature. Thus, the system includes

WO 00/51663

PCT/US00/05566

several means for resuscitation of the patient and several
means for sensing biological parameters of the patient to
diagnose the patient. Any number of medical devices, including
resuscitation devices and diagnostic devices, may be employed
5 in the system.

The Public Access CPR and AED Device illustrated in
Figure 1 compresses the chest to force blood circulation;
stimulates the patient's nerves to cause an inhaling
contraction of the diaphragm, the intercostal muscles, and the
10 abdominal muscles; stimulates the patient's abdominal muscles
to cause binding or counterpulsile contraction of the abdomen;
and delivers defibrillating electrical shock to the patient.
The computer system controls all of these therapeutic modes,
subject to initialization and enablement of these actions by
15 the operator or remote medical center.

The device is intended to be installed in public areas
where access is readily available to bystanders, first
responders, EMT's and doctors. The device should be quickly
installed on a heart attack victim, prior to the arrival of
20 specially trained users. However, it is not necessary, nor
desirable, to permit full access of the device to the entire
range of people who might desire or require access since some
users will not be properly trained to supervise the device's
operation. To control and thus permit the optimal degree of
25 access to the system, a tiered access system is used to
control physical access and functional enablement of the
system. Physical access means access to the device itself,
and/or access to certain accessories used for patient

WO 00/51663

PCT/US00/05566

treatment in conjunction with the device that may be stored in
the device or with the device (ET tubes, venous access kits,
laryngoscopes, drugs, etc.). Functional enablement refers to
the system allowing operation of certain functions, such as
5 chest compression, alteration of setpoints, application of
defibrillating shock, etc. The system must be told (or
determine for itself) that it is permitted to initiate a
therapeutic mode before it does so. One mechanism for
differentiating the type of user accessing the device is
10 through the identification subsystem sensors, since, for
example, only trained personnel are "key holders" (as
described in further detail below in reference to Figure 3.)

The system utilizes a remote medical facility (not
shown). The medical facility may maintain a database that
15 stores user identification information, an indication of the
user's permitted level of access, and the user's
authentication information.

Figure 2 illustrates the overall system functions. The
initialization module **20** waits for user input that indicates
20 the system is in use and must begin operation. Once the device
is accessed, the initialization module operates to start
several modules. The system establishes communications with a
remote medical facility through the communications module **21**.
During use, the system will accept user identification
25 information, as indicated by the user identification input
module **22**. The system analyzes the user's identification,
input from a remote medical facility if available, in the
identification processing module **23**. The system utilizes the

WO 00/51663

PCT/US00/05566

user's identity to determine whether or not a user will be
allowed physical access to the device, as indicated by the
physical access module **24**. The system also uses the user's
identity to determine which of the various capabilities of the
5 system will be enabled, as indicated by the functional
enablement module **25**. The remote input module **26** receives
input from a remote medical facility, and this input can be
used to control the resuscitation devices.

Figures 3A and 3B show the system flow chart for system
10 of Figure 2, with details of the tiered access system. The
initialization module 20 achieves the system's ready state.
The device is intended to be stored for extended periods of
time before it is used, thus making it impractical to keep the
computerized components fully operational at all times and the
15 system in constant communication with a remote medical
facility. Thus, whenever the system is used, it must be
started up so that the various subsystems can achieve a ready
state. The system can be designed to start up as any
computerized system, either from a completely un-powered
20 condition or from a sleep mode, in which the computer control
module is always energized to the extent necessary to sense an
input (comparable to a lap-top computer in sleep mode).

The initialization module monitors the system housing to
sense a unit access attempt. This is also known as an
25 initiating event, such as the removal of the device from a
storage location, disconnection from a charging battery
holder, insertion of a key card into the card reader, or
operation of any startup sequence initiated by the operator

WO 00/51663

PCT/US00/05566

(pushing a button, entering an access code, etc). Figures 3A and 3B illustrates an embodiment of the system which uses insertion of a key card (for trained users) as one initiating event, and a push button or telephone pick up (for bystanders) as an alternate initiating event.

Upon recognition of the initiating event, in addition to the steps taken in the CPR protocol as illustrated in our prior patents, the initialization module establishes a communication link with a remote medical facility. Via this link, the initialization module communicates the activation attempt to the medical facility, and differentiates to the medical facility the type of initiating event (physical removal of the device versus insertion of a key card). In this way, the medical facility is made aware of the device activation as well as the type of user activating the device.

The initialization module also communicates an encrypted device ID to the remote medical facility such that the remote medical facility will know where to send trained EMTs. The initialization module also optionally activates an associated video camera system.

The user identification module 22 seeks input from the identification subsystem 14. The identification subsystem may include a key card reader 15, an access code system (touchpad) 16, or mechanical key system (not shown). In this manner, operators of different training levels may be issued a key card, security code, or actual key, so that these trained operators can identify themselves to the system as "key

WO 00/51663

PCT/US00/05566

holders". Several levels of access may be provided by use of several "keys," each issued to different levels of trained users and each accepted by the system as identification of a different level of trained user. This provides for the
5 "tiered" access system.

The identification subsystem 14 may also include an optional biometric sensor 17 for use in coordination with a key card reader, using both the biometric information on the key card and the sensed biometric information to ensure the
10 user's identity, and using the training information on the key card to determine the appropriate access to the device.

The identification subsystem 14 is mounted on the resuscitation device, and while the resuscitation device is mounted in the wall mount, it is also detachably wired to the
15 wall mount (through releasable communications cables and connectors) so that it can communicate with any electronic or communications equipment housed within the wall mount. The identification subsystem is thereby carried with the resuscitation device after the system has permitted the device
20 to be detached from the wall mount.

The user identification module monitors the system waiting to sense an input from the identification subsystem 14. If the user identification module senses a key card, access code, or mechanical key, the module reads, for example,
25 the key card identification and communicates to the remote medical facility this information for the next step of determining the physical access level attainable.

WO 00/51663

PCT/US00/05566

If the user identification module does not sense a key card, access code, mechanical key, or if for some reason the local identification fails, redundancy and backup of the identification system is provided such that the user is
5 interrogated by the remote medical facility to ensure that the device is intended to be used for a cardiac arrest victim. This may be necessary when a trained first responder or expert user is available to supervise and operate the device, but cannot be identified by the device due to loss of an access
10 card or failure of the identification devices. If local identification fails, the communications subsystem 13 (not shown) may be used to communicate the identification information or backup identification information to the remote medical facility, and access can be granted by remote input
15 into the identification module. The backup information may be personal identifying numbers of the operator, such as a unique access code or a social security number. Thus the user identification module, upon failure of identification, will respond to an access control signal from the remote medical
20 facility. If the interrogation fails to confirm proper use, the device remains locked so that it remains available for an actual emergency. The system is reset and self check performed in anticipation of an actual emergency.

A concern with such a device is that it might be used by
25 unauthorized users wrongfully in possession of a key. To avoid this possibility, the system can require redundant identification information, which can be provided through biometric sensors. Trained users are issued a magnetic strip

WO 00/51663

PCT/US00/05566

card which stores the users training level and access level, along with additional authenticating information. At the very least, the authenticating information may be a personal identification number or PIN, which a user may enter through the keyboard after inserting the access card into the card reader. However, since some trained users may not use the system often enough to ensure that they will remember a PIN, a biometric sensor such as a fingerprint reader may be used. Trained users are issued a key comprising an access card capable of storing biometric information such as the user's fingerprint (retinal scan information, voice print, or other biometric data can be used). The purpose of the biometric data is to provide authentication with information that is guaranteed to be readily available to the user, and cannot be forgotten or lost. The access card may be a credit card sized card with a magnetic strip which contains the users identification, an indication of the users training level, and a representation of the users fingerprint, or unique fingerprint information. These access cards are then used in conjunction with an identification module which includes a card reader and determines the card users training level and recorded fingerprint information, and also includes a fingerprint reader which reads the users fingerprint and compares it with the recorded fingerprint information to ensure that the user is actually the trained user previously identified by a system oversight facility. The system oversight facility can issue the access cards after training the users, thereby maintaining control of the training and the access card. Using this system, there is no need for

WO 00/51663

PCT/US00/05566

communication with the system oversight facility, and no need to refer to an extensive database of user identification information or biometric information, so that the material requirements for the identification module are eased.

- 5 Biometric sensors which read and verify card-stored fingerprints are commercially available.

As illustrated in Figure 3A, the user identification module 22 refers to the physical access module 24 after the identification process has been completed. If the user is identified as a Level 1 bystander or Level 2 first responder, the physical access module 24 permits access to the device such that it allows the device to be removed from the wall mount (through operation of relay operated locks or other electro-mechanical locking devices). The device may then be installed on the patient by the bystander. If the user is identified as a level 3 expert operator or EMT, the physical access module may permit access to additional components, such as ACLS supplies (needles/IV/ET tubes) stored within the device or in the wall mount system (again, through operation of electro-mechanical locks such as electrically operated latches). If the user is identified as a level 4 paramedic or doctor, the physical access module may permit access to drugs. If the user is identified as a level 0 maintenance technician, the system may permit access to the internal workings of the device, such as mechanical components and computer systems to permit service access.

In a large portion of the expected uses, the resuscitation system will be removed from the wall mount by a

WO 00/51663

PCT/US00/05566

first operator, typically a bystander. Shortly thereafter, EMT's should arrive on scene. While it is advantageous to the patient to be fitted with the resuscitation device and sensing devices immediately, with the assistance of any available person, it is not necessarily advantageous to permit the system to operate treatment devices which apply power to the body until more experienced operators such as EMT's arrive on scene. Thus, the user identification module is designed so that operators arriving on scene after deployment of the system can enter their identification information, and the system will functionally enable power emitting medical devices and permit physical access to advanced equipment. When EMT's do arrive, communications with a remote medical facility should already be established by the system through the initialization module. The EMT can enter his identification information, which can be processed by the onboard operating system or by the remote medical facility, and either the onboard operating system or the remote medical facility can functionally enable power applying devices. The system may be redundant in its enablement capabilities, allowing enablement by either the remote medical facility or by the local operator (of appropriate level), so that enablement in proper situations is ensured by one or the other (i.e., in case of a communications failure with the remote medical facility).

The physical access module also provides for redundancy and backup where, after the EMT, paramedic, or doctor have arrived on the scene after an initial bystander access, the module monitors the device to sense a key card reader

WO 00/51663

PCT/US00/05566

insertion or other access such that the next level of care may be achieved. Essentially, the physical access module is in constant contact with the user identification module to perform this system update.

5 After the physical access module completes its task (or in parallel to the operation of the physical access module), the system refers to the functional enablement module 25 illustrated in Figure 3B. This module enables different parts of the control system depending on the access level indicated
10 by the identification module. We have illustrated in the flow chart an initial assignment of functional access which may change according to experience, medical indications and legal requirements at the time the device is used.

Where the user is identified as a level 1 bystander,
15 indicating an untrained user, the system will permit deployment of the device and use of the communications and sensing modules. For example, the system will allow the entire device to be removed from a storage base into which it is normally locked when not in use so that it may be
20 transported to a patient. The system will not allow compression, defibrillation, electro-stimulation, access to stored medication, etc. when the user is identified as a level 1 bystander. This is represented by Level 1 in Figure 3B.

Where the user is identified as a level 2 trained first
25 responder, the system will permit use of the communications modules, sensing modules, compression modules and electro-stimulation modules. The system permits all the actions of

WO 00/51663

PCT/US00/05566

the level 1 (bystander level), and additionally enables
compression. This is identified as Level 2 in Figure 3B.

Compression may be enabled in an automatic mode, meaning that
it commences as soon as proper installation of the compression
5 belt is verified by the system, or it may be enabled such that
compression commences when the user directs the system to
commence compression with user input from the keypad.

Where the user is identifies as a level 3 expert operator
or EMT, all the previous modules will be enabled and other
10 more sensitive modules such as the defibrillation module may
be enabled, and sensitive adjuncts such as the drug injection
devices and invasive sensing devices may be unlocked or
enabled. The precise allocation of therapeutic modules to
different access levels may vary as experience with the device
15 indicates that therapeutic modules require more or less
stringent controls. This is labeled as Level 3 in Figure 3B.

Finally, where the user is identified as a doctor, the
system enables all therapeutic modes (such as ACLS drug
delivery, pacing, etc.), and allows the doctor to adjust
20 system thresholds and parameters (such as maximum chest
compression, compression rate, defibrillation power, etc.)
This is labeled as Level 4 in the flow chart.

All levels provide for a dispatch of appropriate
emergency personnel. All levels provide a communication,
25 instruct and monitor deployment function. All levels provide
for monitoring and transmitting of physiological parameters
(heartbeat, EKG, blood pressure, etc) to the remote medical

WO 00/51663

PCT/US00/05566

facility. Finally, all levels provide communication modules_ so that the system may transmit the physiological data to the remote medical facility. It should be appreciated that the assignment of physical access and functional enablement levels to the different classes of users may vary considerably, and that therapeutic devices may be added to the system in addition to the devices used to illustrate the invention. For example, we expect that operation of the chest compression device will prove to have little adverse effect if applied to a patient who is not suffering from cardiac arrest, so that application of chest compression may be permitted when the device is used by a level 1 bystander.

The remote input module allows the remote medical facility to remain in the loop and control the operation in the field. The remote medical facility receives data via the functional access module. The remote facility may then analyze the data and send remote control communication to the field. For example, the remote medical facility may transmit signals via the feedback module to the device to enable chest compression or other features, as medically indicated by the sensed biological parameters provided by the functional access module.

Figure 4 shows the resuscitation device configured in a wall mount. The resuscitation device is mounted and locked into a base **27** which is installed in an accessible place where it is likely to be needed, such as in a shopping mall, workplace, theater or stadium. The wall mounted base preferably has a charger for continuously charging the

WO 00/51663

PCT/US00/05566

batteries required by the resuscitation system and telephone connections if the system is to be implemented through cordless telephone communication between the device and the remote medical facility (with the cordless telephone base incorporated into the base). The motor box 3, communications module 13, identification module 14 rest in the base, and are locked in the base when the system is not in use. The card reader 15 and telephone handset remain accessible to any potential user, so that the system can be initiated whenever desired. The chest compression subsystem and secure device box remain closed and locked with electro-mechanical locks. Thus, the device is secured in the base until needed. When needed, the device can be removed from the base in the several ways described above. A trained first responder with an access card may insert the card into the card reader, and this will unlock the entire device from the base so that it can be carried to a heart attack victim. An untrained bystander can initiate communications with the remote medical facility with the telephone handset, and upon interrogation and confirmation of the bystanders need for the device, the device may be unlocked through the transmission of an appropriate signal from the remote medical facility.

While the preferred embodiments of the devices and methods have been described in reference to the environment in which they were developed, they are merely illustrative of the principles of the inventions. Other embodiments and configurations may be devised without departing from the spirit of the inventions and the scope of the appended claims.

WO 00/51663

PCT/US00/05566

We claim:

1. A medical system for use on a patient, wherein said medical system requires an operator for use upon the patient, said medical system comprising;

5 a plurality of resuscitating means for resuscitating the patient;

an identification means for identifying an operator of the system, said identification means comprising an identification card and a card reader, wherein said
10 identification card stores identification information pertaining to the operator's predetermined permitted level of access;

controlling means for controlling the plurality of resuscitation means in response to the indication of
15 the operators permitted level of access as read from the identification card.

2. A medical system for use on a patient, wherein said medical system requires an operator for use upon the patient, said medical system comprising;

20 a plurality of resuscitating means for resuscitating the patient;

an identification means for identifying an operator of the system, said identification means comprising an identification card and a card reader, wherein said
25 identification card stores identification information

WO 00/51663

PCT/US00/05566

pertaining to the operator, an indication of the
operators permitted level of access, and authentication
information for the operator and;

means for entering authentication information into the

5 identification means for comparison with the
authentication information stored on the identification
card;

controlling means for controlling the plurality of

10 resuscitation means in response to the indication of
the operators permitted level of access as read from
the identification card.

3. A resuscitation system for use on a patient, wherein said
resuscitation system requires an operator for deployment on
the patient, said resuscitation system comprising;

15 a plurality of resuscitation means for resuscitating the
patient;

an identification means for identifying an operator of
the system, said identification means comprising an
identification card and a card reader, wherein said
20 identification card stores identification information
pertaining to the operator, and an indication of the
operators permitted level of access; and

means for entering authentication information into the

25 identification means for comparison with the
authentication information stored on the identification
card;

WO 00/51663

PCT/US00/05566

controlling means for controlling the plurality of
resuscitation means in response to the indication of
the operators permitted level of access as read from
the identification card.

- 5 4. A resuscitation system for use on a patient, wherein said
resuscitation system requires an operator for deployment on
the patient, said resuscitation system comprising;

sensing means for sensing biological parameter of the
patient;

- 10 a plurality of resuscitation means for resuscitating the
patient;

- an identification means for identifying an operator of
the system, said identification means comprising an
identification card and a card reader, wherein said
15 identification card stores identification information
pertaining to the operator, an indication of the
operators permitted level of access, and authentication
information for the operator; and

- means for entering authentication information into the
20 identification means for comparison with the
authentication information stored on the identification
card;

- controlling means for controlling the plurality of
resuscitation means in response to the indication of
25 the operators permitted level of access as read from
the identification card.

WO 00/51663

PCT/US00/05566

5. The resuscitation system of claim 4, further comprising:

a remote system oversight facility comprising a database storing identification information, the indication of the operators permitted level of access, and the authentication information pertaining to a plurality of known operators to whom cards have been issued;

communication means coupling the identification means and the remote system oversight facility, said communication means being capable of transmitting identification and authentication information from the operator to the remote system oversight facility;

said remote system oversight facility being capable of comparing the identification and authentication information from the operator with the stored identification information, access indication and authentication information, and communicating with the system to indicate to the system the operators permitted level of access as determined from the stored information.

6. A medical treatment system for treatment of a patient which is intended to be used in an environment wherein the device may be removed from a secure storage device and deployed upon the patient by a first operator pending arrival of a second operator, said medical treatment system comprising;

a plurality of medical devices;

WO 00/51663

PCT/US00/05566

means for controlling physical access to the plurality of
medical devices;

means for controlling functional enablement of a medical
device included within the plurality of medical
5 devices;

means for identifying the first operator and permitting
physical access to a medical device by the first
operator;

means for identifying the second operator and permitting
10 functional enablement of a medical treatment device
included within the plurality of medical devices upon
identification of the second operator;

wherein the means for controlling physical access is
operable to permit physical access to a medical
15 treatment device included within the plurality of
medical devices depending upon the identity of the
first operator; and

the means for controlling function enablement is operable
to permit functional enablement of a medical device
20 included within the plurality of medical devices
depending upon the identity of the second operator.

7. The system of claim 6, wherein the means for controlling
physical access to a medical treatment comprises a computer
programmed to operate electro-mechanical locks securing the
25 medical devices to hold or release the medical devices in

WO 00/51663

PCT/US00/05566

response to identification information inputted by the first_ or second operator.

8. The system of claim 6, wherein the means for controlling functional enablement to a medical device comprises a computer
5 programmed to permit operation of the medical devices in response to identification information inputted by the first or second operator.

10. The device of claim 6 wherein the means for identifying the first operator comprises a communication system in
10 communication with a remote medical facility, and means for receiving a signal from the remote medical facility which causes the means for controlling physical access hold or release the medical devices in response the signal from the remote medical facility.

15 11. The device of claim 6 wherein the means for identifying the second operator comprises an access card provided to the second operator, identification information stored on the access card, and a card reader coupled to the device which is capable of reading the access card and transmitting
20 identification information to the means for controlling functional enablement.

12. A medical treatment system for treatment of a patient which is intended to be used in an environment wherein the device may be removed from a secure storage device and
25 deployed upon the patient by any one of a number of potential operators, said medical treatment system comprising;

WO 00/51663

PCT/US00/05566

a plurality of medical devices;

means for controlling physical access to the plurality of
medical devices;

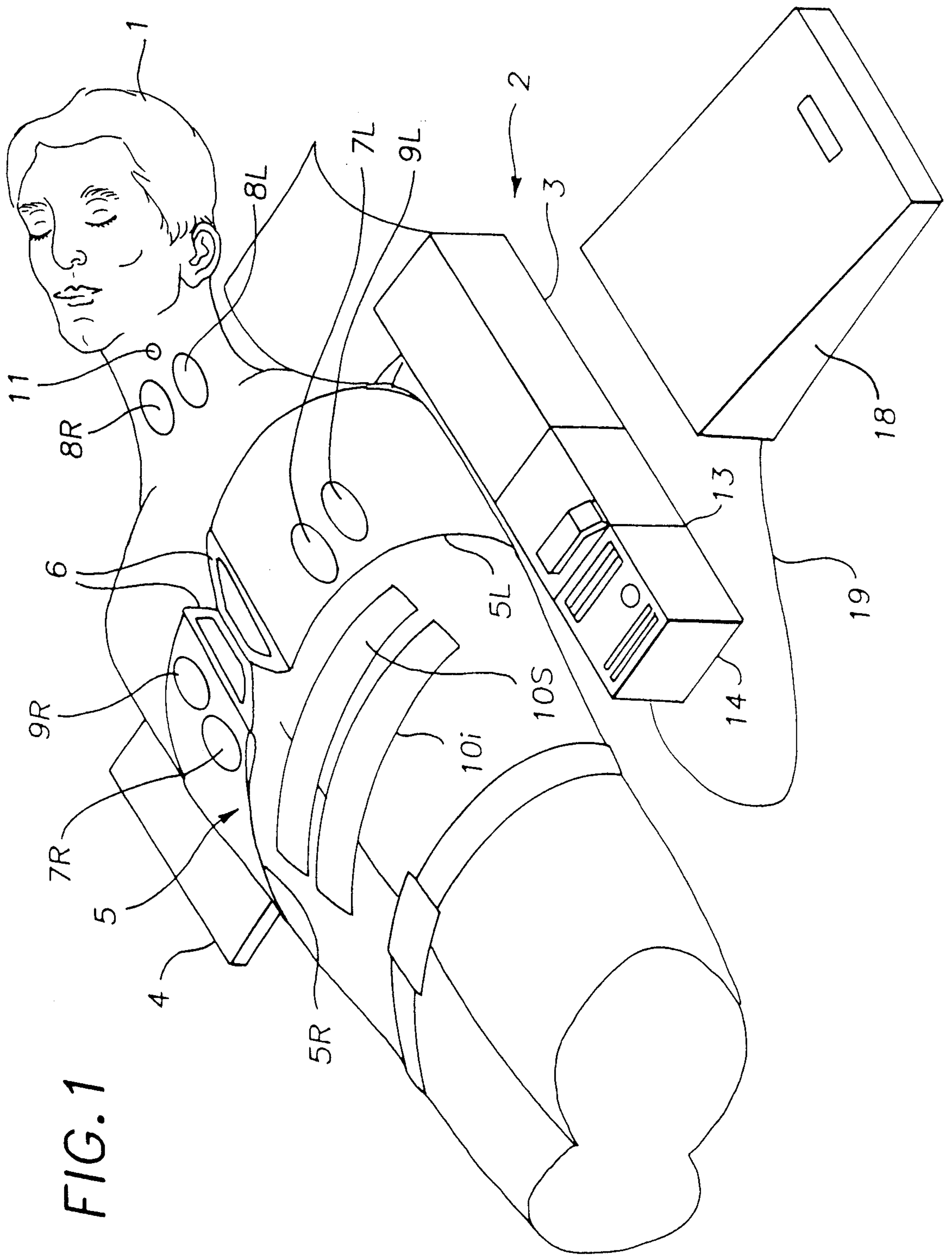
means for controlling functional enablement of a medical
5 device included within the plurality of medical
devices;

means for identifying a particular operator attempting to
use the medical treatment system and permitting
physical access to a medical device by the operator;

10 means for identifying a particular operator attempting to
use the medical treatment system and permitting
functional enablement of a medical treatment device
included within the plurality of medical devices upon
identification of the second operator;

15 wherein the means for controlling physical access is
operable to permit physical access to a medical
treatment device included within the plurality of
medical devices depending upon the identity of the
operator; and

20 the means for controlling function enablement is operable
to permit functional enablement of a medical device
included within the plurality of medical devices
depending upon the identity of the operator.



2/8

FIG. 2

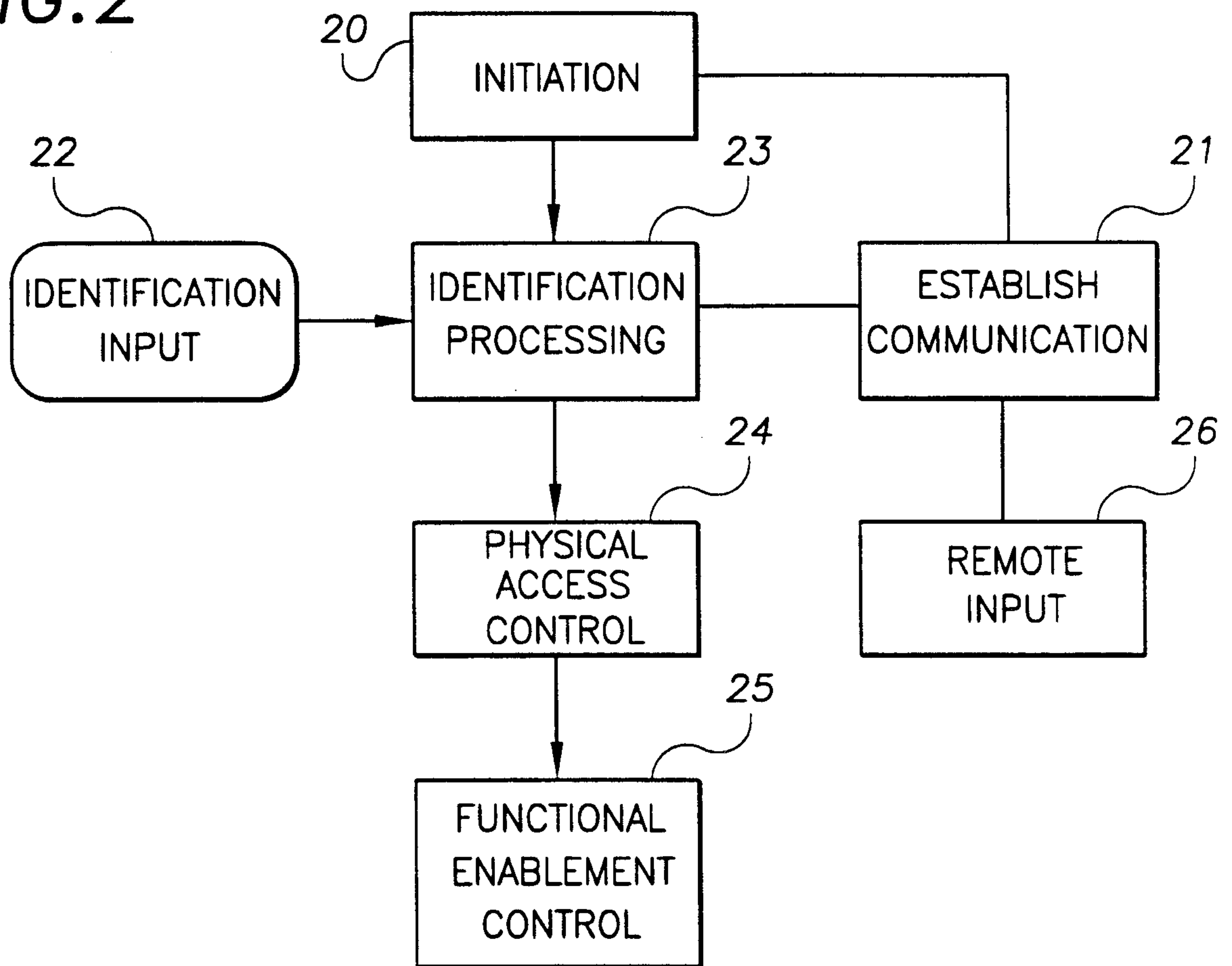


FIG. 4

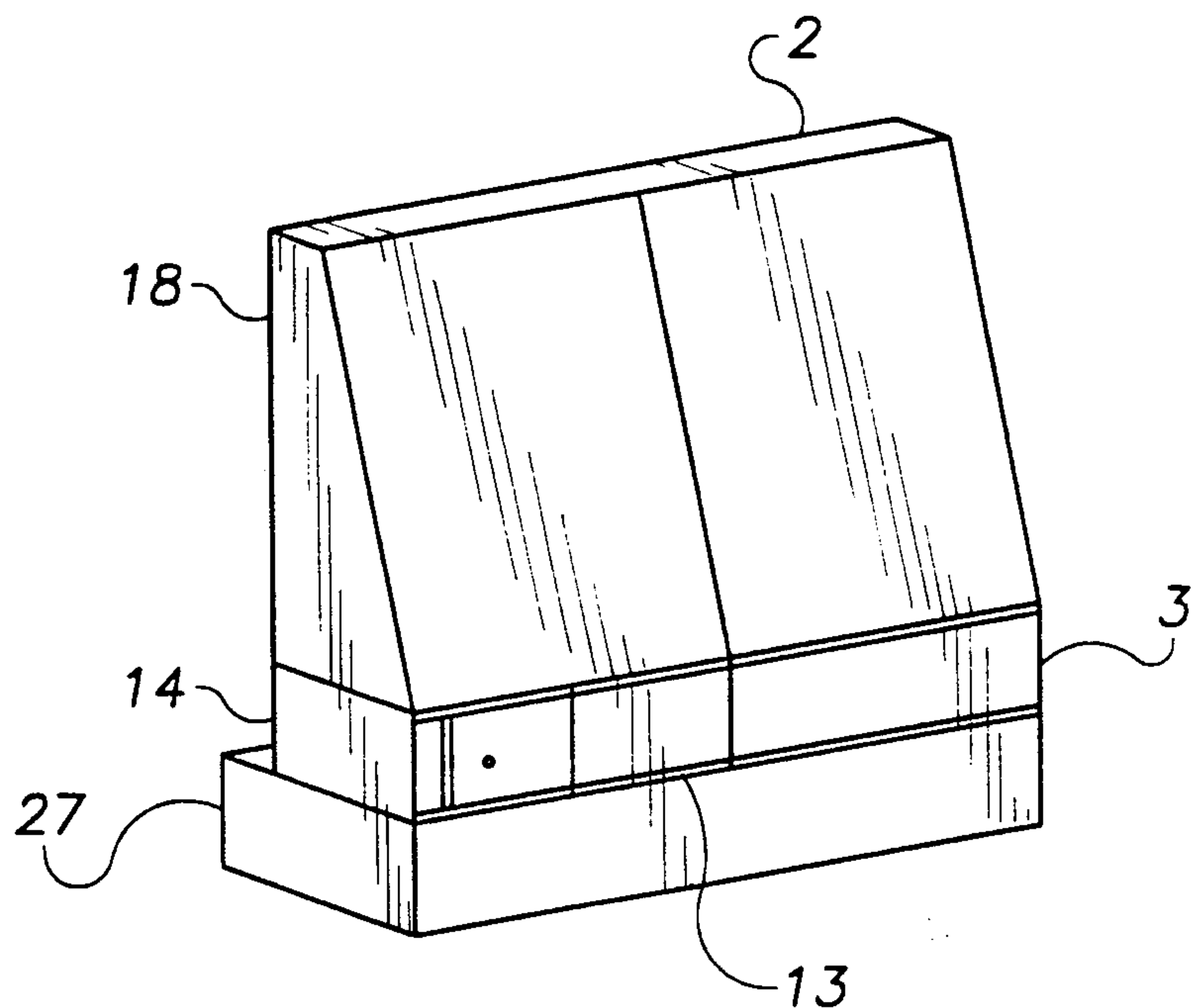
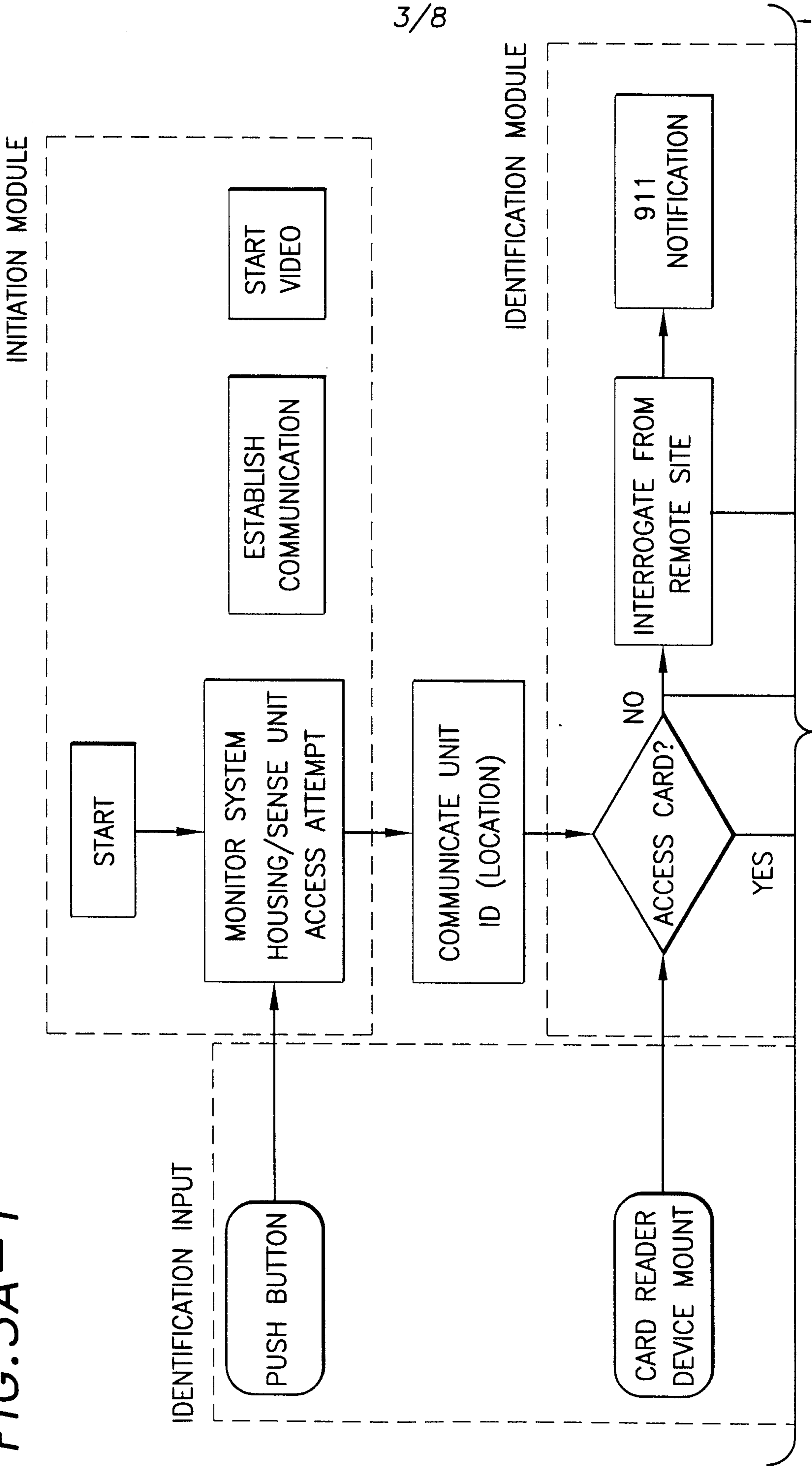


FIG. 3A-1



TO FIG. 3A-2

FROM FIG.3A-1

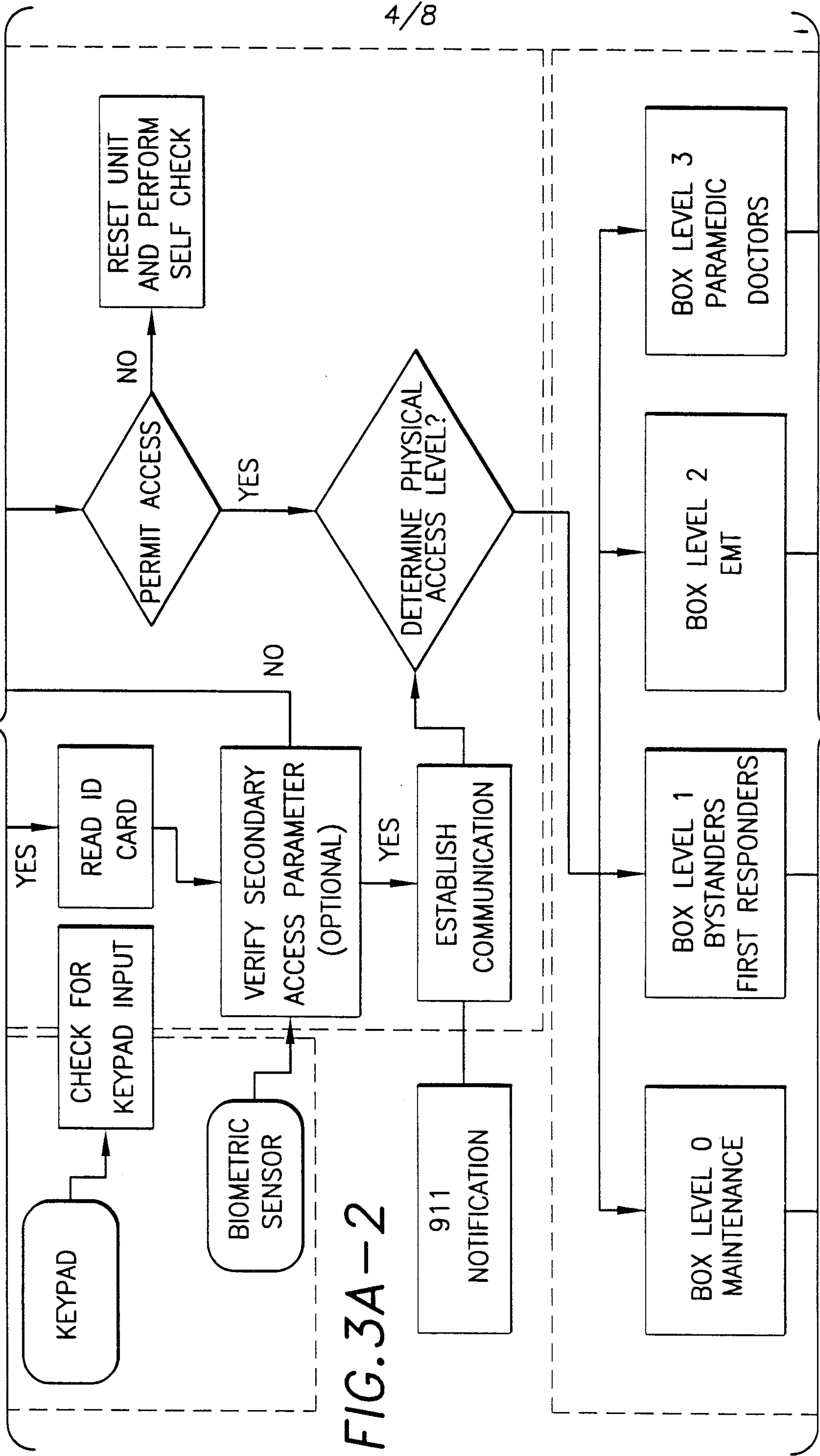
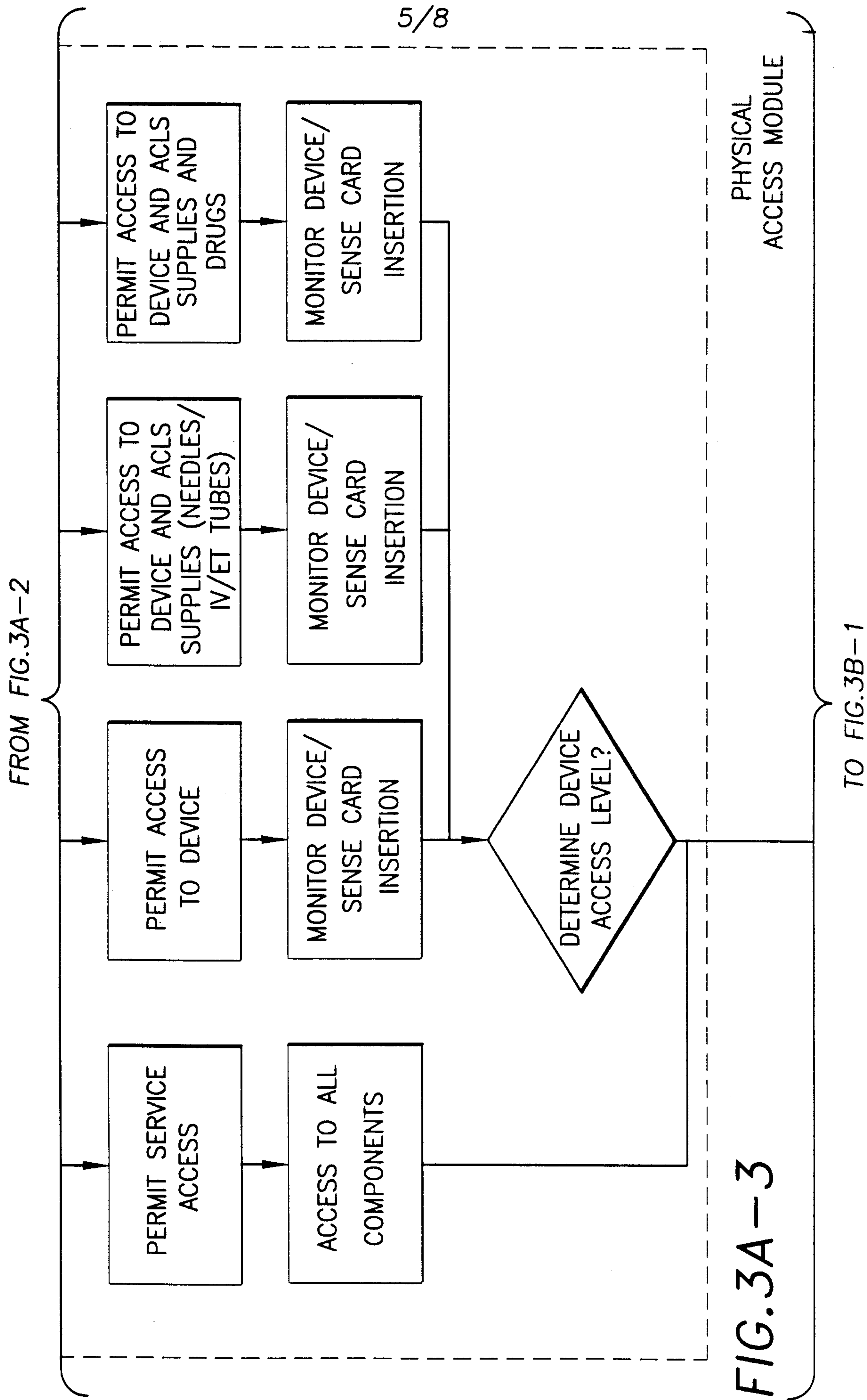


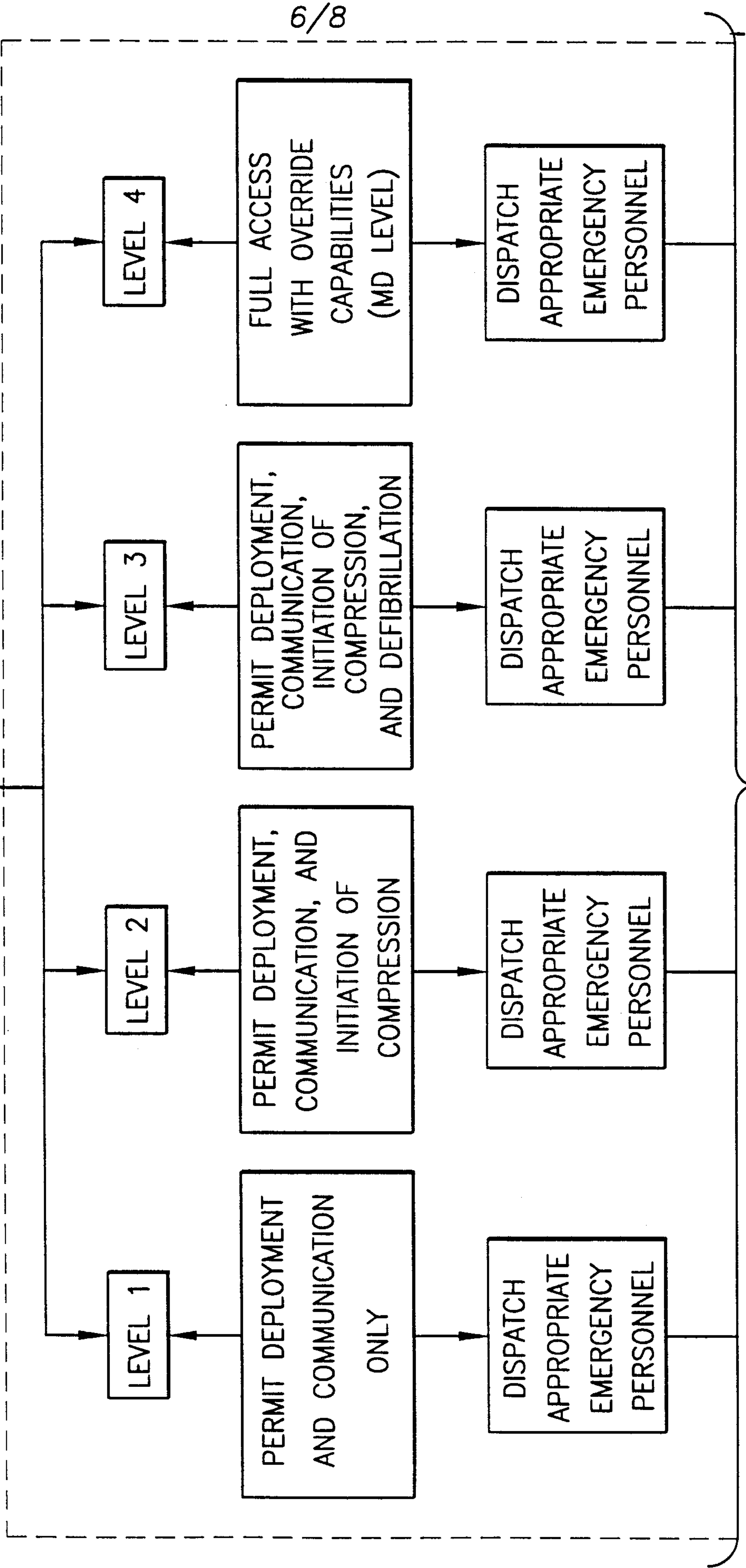
FIG.3A-2

TO FIG.3A-3

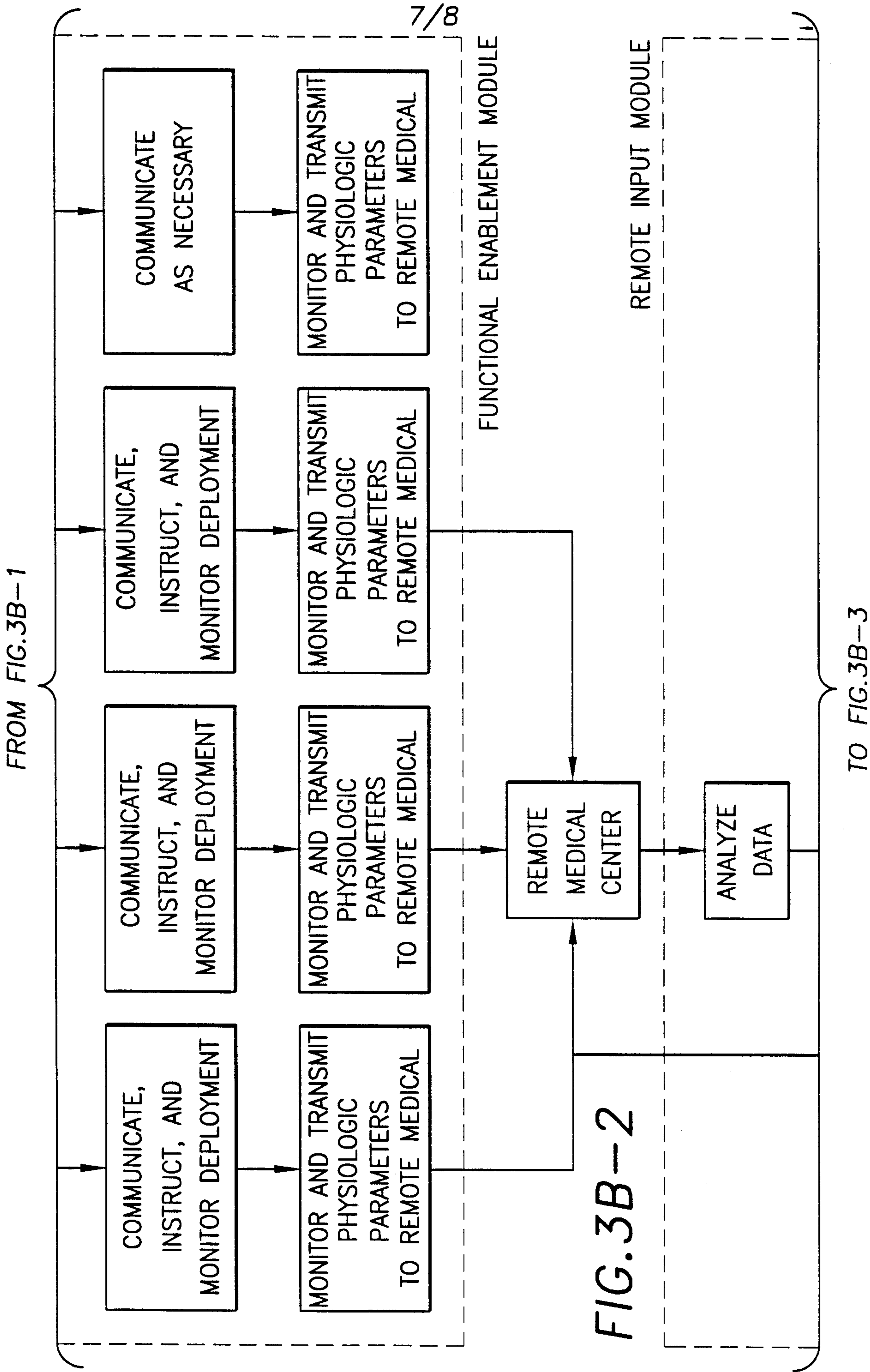


FROM FIG.3A-3

FIG.3B-1



TO FIG.3B-2



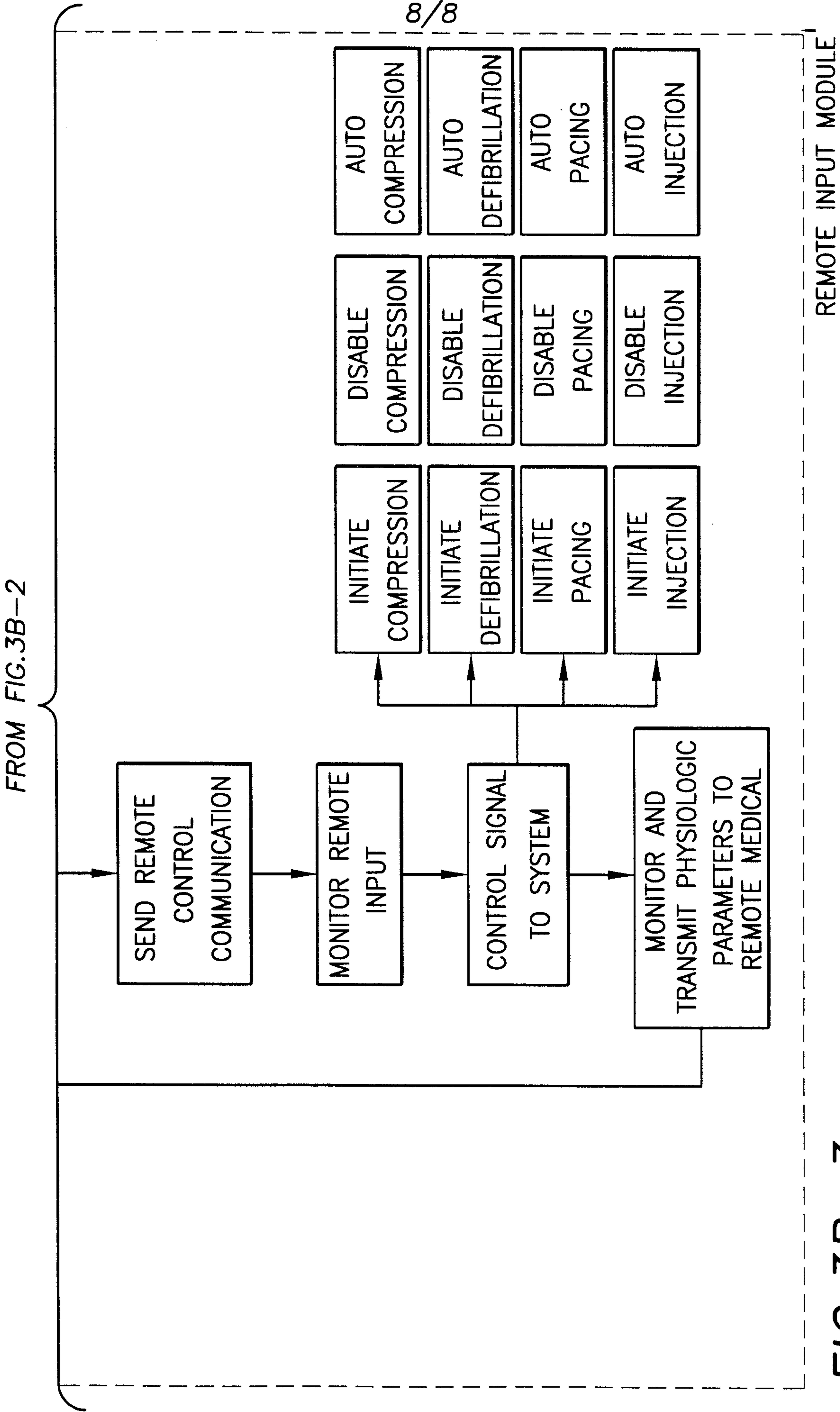


FIG.3B-3

