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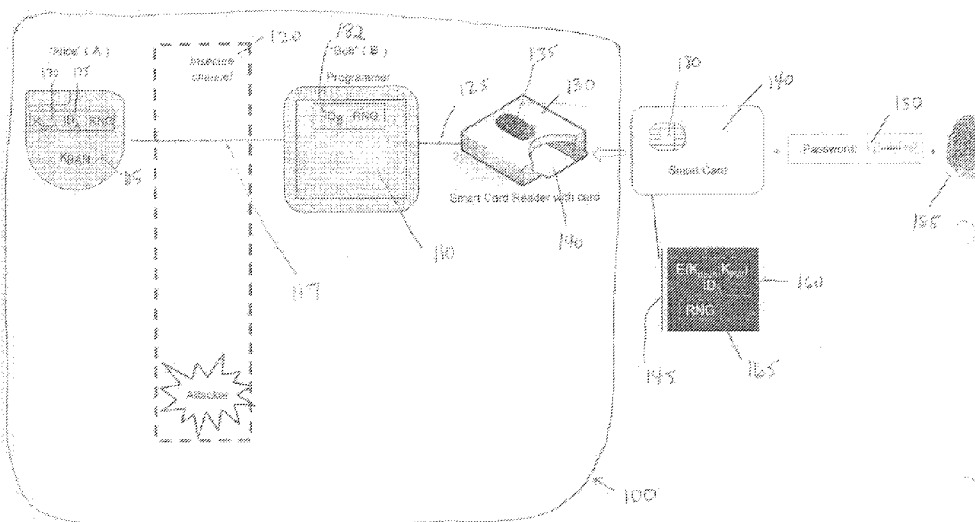
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(57) Abstract: A communications protocol is used to provide data privacy, message integrity, message freshness, and user authentication to telemetric traffic, especially to and from implantable medical devices in a body area network. Encryption, message integrity, and message freshness are provided through use of token-like nonces and ephemeral session-keys derived from device identification numbers and pseudorandom numbers.

SECURE TELEMETRIC LINK

FIELD

The present invention relates to providing secure communications in a data communications setting, particularly in providing security in telemetry between implantable medical devices and external device administration hardware, security in telemetry between implantable medical devices and other implantable medical devices, and security in telemetry between external medical devices and other external medical devices.

BACKGROUND

Improvements in technology relating to implantable medical devices (“IMDs”), especially in the areas of power storage, conservation, and miniaturization, have made it possible to equip modern implantable medical devices with wireless telecommunications functions. The benefits of such communication include the capability to make requests to the IMD to transmit information, for example, remaining battery life, number of therapeutic events that have occurred, or certain patient health data, as well as transmitting instructions to the device to change treatment modalities, frequency, or the like. All of these communications are motivated by the imperative on the part of all parties to maximize the patient’s health and treatment outcome, and as part of this criteria for success, are also driven by the desire to avoid a situation where the IMD must be removed from the patient or any invasive procedure relating to the patient becomes necessary. Attendant to the risk involved in any surgical or invasive procedure is the cost associated with such procedures when carried out according to the applicable standard of care.

In utilizing the benefits of communication with an IMD while leaving the IMD in the patient, wireless communications are ideally suited and to date are the only practical way to regularly exchange information with the IMD while it remains in its implanted state. Accordingly, the use of telecommunications for IMD administration may include communications to or from an IMD, or alternatively among *in vitro* (i.e., not implanted) IMD-administration devices (collectively referred to alternately herein as “telemetry,”

regardless of whether communications are being transmitted to or from the IMD or administration device, and further regardless of whether a measurement is being transmitted (as opposed to, for example, updated instructions to an IMD).

While telemetry, and particularly IMD telemetry, may make the treatment of disease states or other medical conditions more convenient and effective, it is important to ensure that the use of telemetry does not permit a third-party to interfere in the administration of such devices. For example, eavesdropping alone may compromise patient data that may be protected under certain data privacy regimes, e.g. the Health Insurance Privacy and Accountability Act ("HIPAA"). Even more critically, if a telemetry communication from an administration device to a medical device is interfered with, an important therapy that was intended may not be administered to a patient hosting the implanted device, presumably resulting in suboptimal treatment outcomes. If a malicious third party intercepted a communication and replaced it with a bogus instruction to a device, or even repeated a legitimate instruction to cause an implant to administer incorrect or excessive therapies, adverse effects on the implant's host may result.

To date, most common wireless communications protocols suitable to IMD telemetry applications are of a "broadcast," rather than of a directional nature. Accordingly, if an IMD is in range of a telemetry signal (or, when communications originate with the IMD, a receiving device is in range of the IMD), we may generally assume that any receiving device in range of the signal may access the signal, whether or not that access is intended by the caregiver and/or patient.

The low distance range of many telemetry transactions involving IMDs, has to a certain extent effected a kind of physical layer authentication. In other words, most unauthorized access to IMD-related communications is not feasible because an unauthorized party must be so close to the transmitting device that the physical presence of the eavesdropper (or their tools) would be apparent to the parties legitimately sending or receiving such information. However, the range of telemetry applications is constantly expanding, and at some point it may be contemplated, for example, to interrogate an IMD while a patient is seated in a physician waiting room, even though the intended receiving device is in another room altogether. As the distance necessary for communication between the IMD and external hardware becomes longer, so to does the opportunity for

interlopers or eavesdroppers to receive, interfere with, or even manipulate the communications signals.

It is also important that messages are “fresh,” i.e., that they have been transmitted recently, and only once. For example, duplicate communications of data from a diagnostic sensor that falsely indicate no change in a patient’s physiological condition in spite of therapy being applied may result in excess therapy or other unnecessary medical intervention with its attendant risks. In addition to message privacy (i.e., encryption), true data security requires both message integrity and message freshness. Without all three, gaps will exist that may be exploited by a malicious third party, or indeed may permit errors without malice. Of course, whether or not such exploitation is likely is not particularly relevant from a design standpoint—the security of the telemetry should be ensured to prevent any eavesdropping or interception regardless of the actual potential for problems arising from the interception scenario being considered.

Previous approaches to telemetry security involved, for example, server-based authentication and storage—in this way, no permanent key information would ever be stored on equipment. However, this approach requires a secure communications channel to a server that is available around the clock. It also requires clinicians to be authenticated to the server system prior to their administration of a body area network (BAN) device or node.

Alternatively, biometric tokens (such as key fobs), have been used to authenticate IMD support appliances to IMDs. However, this approach subjected the authentication keys (both the biometric key and the IMD key) to loss, and the token could also be forgotten by patients presenting for IMD administration, which would tend to inconveniently require that care be postponed. Tokens augmented by passwords similarly were subject to loss, noncompliance (failure to bring the token to an appointment, or forgetting the authentication information), and similarly were subject to compromise if lost or stolen.

SUMMARY

The present invention provides a secure system of telemetry communication, particularly well suited to IMD and other medical device administration. A system of

protecting the communications to and from IMDs, as well as to and from external devices, is provided. This system implements a system of encryption, in conjunction with an authentication method or methods, in order to ensure that communications to and from communication nodes, and particularly to and from an IMD, are legitimate. In certain embodiments, the legitimacy is ensured, for example, by a rigorous approach to data encryption and key management, and preferably, authentication is secured using at least one modality in addition to the holding of an authenticating card or token.

In certain embodiments, the invention provides for a proximity-dependant “backdoor” that may allow access to and administration of any IMD without the authentication information typically required to permit communications among the nodes or modules within a particular patient’s network of medical devices, to be called a “body-area network” or “BAN”. The present invention also provides for strong authentication in some embodiments, i.e., zero-knowledge proof of identity, in that authentication is effected without actually transmitting the authentication information (which may of course, subject the authentication information to being compromised).

An unauthorized third party with interests or motives contrary to the patient and authorized caregivers is termed generally herein as an “attacker,” regardless of an eavesdropper’s identity, location, or motivation. An attacker may wish to simply eavesdrop without actually disrupting communications, perhaps to obtain protected health information regarding the patient, or to learn aspects of the behavior of the BAN nodes proprietary to the BAN node manufacturer. For these purposes, embodiments of the instant invention provide for message privacy (i.e., encryption) through the use of a cipher.

It may also be contemplated that an attacker having sufficient telecommunications and computing power may be able to intercept and control all communications among nodes of a BAN, either eliminating, modifying, duplicating, or otherwise changing messages between nodes. Embodiments of the instant invention provide for message integrity (i.e., message authentication) through the use of message authentication protocols to ensure that instructions to an IMD, for example, and information provided to diagnostic nodes by an IMD are legitimate. Similarly, message freshness may be ensured through freshly-generated session keys and a token-based system, or in alternate embodiments of the instant invention, through the use of time-stamps. The instant invention, in certain

embodiments, provides that messages are kept secure from those who do not have the secret key, based on the subsidiary imperatives of message integrity (transmitted messages are received by their intended recipients in an unaltered state) and message freshness (messages are received in a timely fashion, and are not copies of previously transmitted messages, transmitted by an attacker).

Notwithstanding the protections afforded by embodiments of the present invention, the protection of communications is preferably motivated by, and where necessary is subsidiary to, the overall principle of optimal patient care. Accordingly, certain embodiments of the present invention may, in certain emergency or other compelling situations, permit communication with the device by means of a “backdoor” to the device circumventing certain security features of the implementation, in order to prevent adverse health effects, regardless of whether the emergency caregiver has the time or credentials to authenticate him or herself to the device.

Security mechanisms and protocols according to embodiments of the present invention, require that security services have been set up and enabled (rather than bypassed) with respect to at least one of the communicating devices, and may further require the use of an implementation of a block cipher. In other embodiments, all communicating devices of a BAN implementing the invention share an identical body-area network key, K_{BAN} , and cooperatively generate a new session key K_{ses} , at the start of each new telemetry session. Initially, such device identification exchanges take place via an unsecured exchange, required in order to open a communications session. Packet length for both incoming and outgoing packets are preferably fixed for the duration of a session, and packets not meeting the specified length are preferably rejected in the physical layer of the network.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 depicts the general network topography of a body area network according to embodiments of the present invention.

Figure 2 depicts protocols for the secure transmission of a network key between network nodes according to embodiments of the invention.

Figure 3 depicts an alternative embodiment of a network key transmission protocol.

Figure 4 depicts a topography of a body area network having two in-vitro devices according to an embodiment of the present invention.

Figure 5 depicts an alternate embodiment of network key propagation protocol according to the present invention.

Figures 6 through 9 depict data flow diagrams of pseudorandom number generator functions according to certain embodiments of the present invention.

Figure 10 is a data flow diagram of the generation of a session key according to embodiments of the present invention.

Figure 11 shows the data flow of the CTR-mode encryption and decryption of a message according to embodiments of the present invention.

Figure 12 shows the data structure of a nonce register according to embodiments of the present invention.

Figure 13 shows a data structure for a telemetry packet according to an embodiment of the present invention.

Figure 14 shows the data flow for encryption/decryption and authentication of messages according to an embodiment of the present invention.

Figure 15 depicts a schematic hardware architecture according to an embodiment of the present invention.

Figure 16 depicts a network topography for an emergency access protocol of an embodiment of the present invention.

Figure 17 depicts a pseudo-protocol and data flow for an emergency access protocol according to an embodiment of the present invention.

Figure 18 depicts a graphical representation of a secured wake-up packet.

Figure 19 is a block diagram depicting the generation of a MAC for a secured wake-up packet.

Figures 20 and 21 are flowcharts of a process to send and receive secured wake-up packets.

DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

Embodiments of a security implementation for wireless networks according to the present invention may implement a variety of tiers of security or degrees of multi-factor authentication. The tiers of security contemplated herein may be implemented, for example, by a smartcard i.e. a small plastic card or fob typically having an input/output facility (e.g. a port), one or more central processing units, (such as chips), and a number of memory locations. Smartcard technology may be used to implement security by acting as “something the user has” level of security, either by itself or as a component of multi-factor authentication, e.g., coupled with “something the user knows,” (i.e. a password) or “something the user is,” (i.e. biometric parameters associated with the user). The cards as implemented according to the present invention will preferably have memory, at least one processor, and data processing capabilities, of the type sometimes referred to as “processor cards” or “microprocessor multifunction cards.” The cards may preferably be of the type specified in the International Standards Organization standard ISO 7816 for Integrated Circuit Cards with Electrical Contact, and this assumption is made with respect to the representative embodiments herein. In certain embodiments, certain patient authentication is administered via a smartcard device, however, the IMD’s device key is preferably not stored on the smartcard in an unencrypted fashion.

Some embodiments of the present invention provide for the confirmation of what is known herein as the timeliness, or “freshness” of a telemetry communication. For example, a therapeutic modality that may be legitimately directed once, must not be repeatable by a malicious third-party—if a third party can eavesdrop on a communication, based on mere encryption alone, the third party may repeat the instructions repeatedly. Even though the malicious third party doesn’t know the content of the message to the IMD, they may reasonably expect the repetition of this message to not do any good for the patient. With enough trial and error, dangerous effects may be implemented by the malicious party even with complete ignorance of the message contents. Embodiments of the present invention therefore also effects a system of ensuring message freshness to prevent such attacks. It will be appreciated that herein, the terms “encrypted” and “secured” are not generally synonymous. *Encrypted messages* are messages for which only privacy (i.e., secrecy) is assured. *Secured messages* are messages for which privacy,

integrity, freshness, and identity are assured. This latter concept incorporates concepts of authentication, both user authentication (the message actually came from the person (or node) that apparently sent it), and message authentication (the message is in the form sent by the sender, and was sent solely at the time intended by the legitimate sender, and at no other times).

Herein, we may refer to the node (i.e., in a medical device context the implanted or external device, sensor, programmer, monitor, or other appliance within a BAN) transmitting or receiving a communication as “Alice,” or “Bob,” following the convention of cryptography literature. Alice or Bob will refer to devices or nodes, unless a device user or patient is explicitly mentioned, e.g., Alice’s patient or “host,” that is, the patient that has the Alice device implanted. Also, we use the term smartcard (including the smartcard when inserted into a smartcard reader/writer) in that in certain embodiments, a smartcard may carry out several functions typically associated with a trusted third-party certificate authority, and upon authentication by the card’s holder (e.g. by password and biometric authentication of the holder), the card is regarded as a trusted party within the system, and holds the IMD key corresponding to the IMD in the holder of the card. A third party not intended by the authorized administrators or users of a system to be able to send or receive a message (or a device under the control of such person) will generally be referred to as an “attacker.” Also consistent with cryptography literature, we use the symbol $\oplus$ or “XOR” for the bitwise-exclusive-or operation (i.e., bitwise modulo-2 addition), and the symbol $|$ or $||$ for concatenation. Frequently herein certain software processes or hardware components are described as “knowing,” “requesting,” “expecting,” or “sending” certain information, or carrying out certain functions or activities (e.g. “calculating”), in a manner that may appear to suggest that the software or hardware is a sentient agent. It will be appreciated by those skilled in the art that such anthropomorphic references are not intended to indicate or imply that the hardware or software in question has consciousness, motivation; or intelligence (artificial or otherwise), and these expressions generally are used to indicate the software or hardware’s automatic behavior as programmed or instructed, whether by humans or other hardware or software processes or components. For example, a software process that is said to “expect” a certain value

may refer to a software function having an argument specified to be a certain variable type or value, with non-conforming arguments processed by error-handling code.

Figure 1 depicts the topography of a body area network according to embodiments of the present invention. An exemplary body area network (BAN) 100 is shown, consisting of programmer “Bob” 110 and IMD “Alice” 115. These two nodes Alice and Bob have already established an insecure telemetry session 117 over insecure channel 120. Programmer 110 is connected for secure communications (e.g. via a wired connection 125) with authentication device 130, here, a smart card reader/writer having biometric input window 135. According to these embodiments, the following information may be used as authentication data, in increasing order of security, based in each case on a smartcard carried by the patient and used in IMD administration, as described more fully herein.

In a typical embodiment of the present invention, at a minimum, the patient (or other authorized administrator, as applicable) of a device will present a smartcard 140 (something the patient has), containing information annotated as K_{devA} (the key for device 115), ID_A (the identification number for device 115). Further security may be provided by using the patient smartcard 140, plus a password K_{PW} 150, also stored on smartcard element 145 (something the patient has, and something the patient knows), annotated herein as $E(K_{devA}; K_{PW})$, i.e., the device key K_{devA} encrypted by password K_{PW} (or “password key”), ID_A , where $E(x;y)$ denotes a function of encryption used to secure “x” using the key “y,” or stated otherwise, a certain ciphertext= $E(\text{plaintext}; \text{key})$. In certain embodiments, authentication of a user is effected by a patient smartcard 140, or non-electronic information card, plus a password K_{PW} 150, plus a biometric scan K_{bio} or “biometric key” 155 (something the patient has, knows and is), annotated herein as $E(E(K_{devA}; K_{PW}); K_{bio})$, ID_A .

As depicted in Figure 1, Alice’s patient (not depicted) has been provided with smartcard device 140, containing memory, firmware, local storage, and/or combination element 145. Alice’s patient has initialized smartcard 140 with a password 150 and the patient’s biometric feature, here, fingerprint 155.

In certain embodiments of the present invention, smartcards 140 or USB/Firewire® key fobs interfacing with an interface replacing smartcard reader 130 or

on-board programmer node 110, may be utilized to implement aspects of the security scheme herein. In certain embodiments, such smartcards or key fobs will have certain ciphers and message-authentication codes (MACs) already implemented and on board the smartcard 140 or key fobs, e.g. implemented in the chip hardware, or alternatively, stored in ROM or flash memory, indicated in the abstract as element 145 on the smartcard or key fob.

In setting up or initializing a BAN which includes an IMD and propagating the BAN key according to the protocols described above, initially the patient will provide their IMD's authentication material (e.g., a smartcard 140) to the bridge device 110. This smartcard 140, for example, may be issued together with the IMD 115 (and given to the patient after surgery), or the necessary information may be entered onto the patient's preexisting smartcard device 140. After inserting their smartcard 140 into the bridge device 110 (here via interface device 130), in certain embodiments, the patient will be prompted to enter their personal password K_{pw} 150 into the bridge device 110 (via a GUI residing on-board programmer 110 or via a suitable separate interface, ideally entered from the patient's own personal memory) and further present a biometric key K_{bio} , a value derived from the patient's unique biometric identifier, such as a fingerprint 155 or retinal scan. The bridge device 110 passes the personal password K_{pw} 150 and biometric key K_{bio} 155 onto the smartcard 140 via the smartcard reader 130, preferably without storing K_{pw} 150 and/or K_{bio} 155 in the interim. Using K_{pw} 150 and K_{bio} 155, the smartcard 140 is able to decrypt K_{devA} 170 (i.e., the smartcard may determine K_{devA} 170 using K_{pw} 150 and K_{bio} 155). In certain embodiments, the unencrypted K_{devA} 170 may reside initially in the smartcard's 140 RAM or other memory or storage element 145 until authentication is complete, whereupon preferably it is then deleted and replaced with an encrypted form of K_{devA} 170. Alternatively, non-electronic authentication material in the place of smartcard 140 could be provided to a bridge device 110 in the form of a non-electronic card with the IMD's K_{devA} printed in text or in barcode form, with the BAN propagated according to the protocol of Figure 3.

The key-delivery protocol of this embodiment of the instant invention provides secure wireless delivery of the current BAN key from IMDs to bridge devices and from bridge devices to IMDs, all within a patient's BAN. The protocol further effects

authentication and verification of the sender and receiver, as well as the BAN key itself. Moreover, the invention prevents an attacker from co-opting a device into the attacker's BAN, impersonating a device during delivery of the BAN key, eavesdropping on the delivery process itself, or staging a replay attack based on duplicating earlier communications, because of the requirement that smartcard 140 be available for the communications. Preferably, the K_{devA} key remains securely on the smartcard 140, not on the bridge device 110. Accordingly, even if the bridge device 110 were stolen by an attacker, the attacker would never learn the device key K_{devA} . Device keys, generally denoted as K_{devX} herein (such as K_{devA} 170) will preferably be factory programmed with respect to implant devices such as Alice 115, and may be factory-programmed with respect to bridge 110, smart-local, and dumb-local devices as well. These latter devices may also have an externally-labeled K_{dev} , or have a random-number K_{dev} that is generated and assigned as needed. Because of the limitations of dumb local devices (particularly in that they have no human interface), such devices will preferably have a factory assigned and externally labeled K_{devX} . Alternatively, any of the factory assigned or factory programmed implementations described herein may instead have a K_{devX} or similar information supplied attendant to an updating of flash memory via typical "firmware upgrade" procedures. Herein, the following abbreviations are used to designate different key values and other variables. K_{devX} is the secret device-key for the designated node named X. K_{BAN} is the current BAN session key. ID_X is a device ID, where X is the designated node name.

A suitable security scheme for implementing various privacy and message integrity functions in a representative embodiment of the present invention is the Advanced Encryption Standard ("AES"), similar to Rijndael, but having a fixed block and key size, and being a standard in common use by the U.S. federal government and communications industry. AES may be suitably used in the configuration CTR+CBC-MAC, as described further herein.

The BAN key will in certain key embodiments be communicated securely from in-vivo devices, particularly, implants such as IMD 115 to other in-vitro "bridge" devices 110 in a BAN 100. The BAN key should also be communicated securely from bridge devices 110 in a BAN 100 to implants 115. According to embodiments of the present

invention, there is an underlying communications session 120, which may be unsecured, providing communication between two in-vitro devices 110, or between in-vivo device 115 and in-vitro device 110. Secure communications, such security including encryption as well as integrity and freshness confirmation, is provided by means of authentication material held by the implanted device 115. Implant devices 115 deliver the BAN key to bridge devices 110 who possess the appropriate authentication material 160 and processes such as random number generating facility 165. Implanted devices 115 can also receive the BAN key from bridge devices 110 who possess the appropriate authentication material 160 and processes. According to embodiments of the present invention, the following protocols permit secure and wireless delivery of the BAN key to bridge devices capable of using the security protocol of the present invention.

Figure 2 depicts a protocols for the secure transmission of a network key between network nodes according to certain embodiments of the invention. As shown in Figure 2, implant Alice 115, receives a “deliver BAN-key” session request 210 from bridge device Bob 110, indicating to Alice 115 that Bob 110 wishes to establish or obtain a BAN key. Alice 115 and Bob 110 must initially initiate a telemetric communication session 215 where Alice 115 provides Bob 110 with a freshly-generated random number, Q_A . The human administrator of Alice 115 (e.g. the patient having the Alice device 115 implanted) must then present electronic authentication-material (EAM) to Bob 110, e.g. a smartcard 140 through a smartcard reader. This authentication material, typically taking the form of a smartcard 140 or USB/IEEE1394 (“Firewire®”) fob, is to contain Alice’s device key 170 in Figure 1, (optionally encrypted), K_{devA} 175, Alice’s ID number, ID_A , and an onboard microprocessor capable of implementing the block cipher in use (e.g., 128-bit AES). In the event that the copy of K_{devA} 170 residing on the EAM 140 is also encrypted, Alice’s human operator should also manually give Bob 110 the secret information needed to decrypt the device key 170, for example, via keypad input (not depicted) such as a PIN or password input, and optional biometric data 155. Once these steps have been completed, Bob 110 prepares and delivers a message 220 to the EAM 140 containing the following: Q_A , ID_A , ID_B , and (as necessary) the secret information 225 (PW 150 and biometric data 155) needed to decrypt the copy of K_{devA} 170 residing on the electronic authentication-material 140. Following the immediate transaction, Bob 110 preferably removes any local

record of PW 150 and any biometric information 155. Using its embedded microprocessor 180, the EAM 140 generates two 128-bit random numbers, Q_1 and Q_2 , as described in detail below. The EAM 140 then prepares a block-cipher secured message 230 to Alice 115, using K_{devA} 170 as the key input and Q_A as the nonce, the secured message 230 containing ID_A , ID_B , Q_1 , and Q_2 as the encrypted payload. The EAM 140 then passes this secured message 230 to Bob 110, along with “unsecured” (i.e., plaintext) copies of Q_1 and Q_2 . Acting as a courier from the EAM 140 to Alice 115, Bob 110 then transmits the EAM’s 140 secured message 230 on to Alice as message 235, and temporarily stores the unsecured copies of Q_1 and Q_2 . When Alice 115 receives the EAM’s message 230, by way of Bob’s telemetry transmission 235, she immediately decrypts the message 235, verifies the accuracy of her ID 175, and then verifies Bob’s ID (182 of Figure 1). If Alice’s received message 235 passes its integrity check, Alice 115 is assured that the message 235 is both genuine (from her patient’s EAM 140 via Bob 110) and fresh, on account of the fact that the message was secured using K_{devA} 170 and Q_A .

If Alice 115 is to deliver the BAN key to Bob 110, then Alice 115 may prepare and transmit an unsecured message 240 to Bob 110 consisting of Q_1 and $Q_2 \oplus K_{BAN}$, where K_{BAN} is the current BAN 100 key. On receiving Alice’s message 240, Bob 110 verifies that his local Q_1 matches Alice’s transmitted Q_1 (thereby assuring Bob 110 that Alice 115 is the “owner” of the EAM 140, i.e., that the EAM 140 corresponds to Alice’s secret device key K_{devA} 170), and XORs his local Q_2 with the received $Q_2 \oplus K_{BAN}$ resulting in K_{BAN} .

If, on the other hand, Alice 115 is to receive the BAN key from Bob 110, then Alice 115 may prepare and transmit an unsecured message 245 to Bob 110 consisting of Q_1 . On receiving Alice’s message 245, Bob 110 verifies that his local Q_1 matches Alice’s transmitted Q_1 (thereby assuring Bob 110 that Alice 115 is the “owner” of the EAM 140, i.e., that the EAM 140 corresponds to Alice’s secret device key K_{devA} 170). Bob 110 may then prepare and transmit an unsecured message 250 to Alice 115 containing $Q_2 \oplus K_{BAN}$. On receiving Bob’s message 250, Alice 115 XORs her local Q_2 with the received message 250 $Q_2 \oplus K_{BAN}$ resulting in K_{BAN} .

Figure 3 depicts an alternative embodiment of a body area network key transmission protocol, using authentication items other than the EAM 140 of Figures 1 and

2. According to this embodiment, a less secure protocol using less sophisticated non-electronic authentication materials may proceed as follows: According to this embodiment of the protocol 300, Bob 110 may initiate a “deliver BAN key” session request 210 as before. Alice, an implant 115, receives a “deliver BAN-key” session request 210 from a bridge device, Bob 110. Alice 115 and Bob 110 must initially initiate a telemetric communication session 215 where Alice 115 provides Bob 110 with a freshly generated random number, Q_A . The human administrator of Alice 115 (e.g. the patient having the Alice device implanted) may then present at 310 the non-electronic authentication-material, consisting of K_{devA} 170 and ID_A 175, to Bob 110. This authentication material may, for example, be printed on a identification card in alphanumeric characters or as a barcode, and be read with an optical scanner reader device that may, for example, be internal or integral to Bob, or may alternatively be a separate device in signal communication (e.g. networked) with Bob. Alternatively, the authentication material may be manually inputted by a human administrator directly into bridge device Bob 110 via a GUI or by typing it into a key pad. Using his block cipher (as described herein, or by other means) Bob 110 then generates two 128-bit random numbers, Q_1 and Q_2 , as described above. Bob 110 then prepares a block-cipher secured message 235 to Alice 115, using K_{devA} 170 as the key input and Q_A and the nonce, which contains ID_A 175, ID_B 182, Q_1 , and Q_2 . Bob 110 then transmits the secured message 235 on to Alice 115 and temporarily stores the unsecured copies of Q_1 and Q_2 . When Alice 115 receives Bob’s message 235, she immediately decrypts the message, verifies the accuracy of her ID 175, and then verifies Bob’s ID 182. If Alice’s received message 235 passes its integrity check, Alice 115 is assured that the message 235 is both genuine (i.e., is from Bob 110) and fresh on account of the fact that the message 235 was secured using K_{devA} 175 and Q_A . Other BAN key generation and transmission occurs as described above.

If Alice 115 is to deliver the BAN key to Bob 110, then Alice 115 may prepare and transmit an unsecured message 240 to Bob 110 consisting of Q_1 and $Q_2 \oplus K_{BAN}$, where K_{BAN} is the current BAN 100 key. On receiving Alice’s message 240, Bob 110 verifies that his local Q_1 matches Alice’s transmitted Q_1 (thereby assuring Bob 110 that Alice 115 is the “owner” of the EAM 140, i.e., that the EAM 140 corresponds to Alice’s secret device key K_{devA} 170), and XORs his local Q_2 with the received $Q_2 \oplus K_{BAN}$ resulting in

K_{BAN} . If, on the other hand, Alice 115 wishes to receive the BAN key from Bob 110, then Alice 115 may prepare and transmit an unsecured message to Bob 110 consisting of Q_1 . On receiving Alice's message, Bob verifies that his local Q_1 matches Alice's transmitted Q_1 (thereby assuring Bob 110 that Alice 115 is the "owner" of the EAM 140, i.e., that the EAM 140 corresponds to Alice's secret device key K_{devA} 170). Bob 110 then prepares and transmits an unsecured message to Alice containing $Q_2 \oplus K_{BAN}$. On receiving Bob's message, Alice XORs her local Q_2 with the received $Q_2 \oplus K_{BAN}$ resulting in K_{BAN} .

Embodiments of the present invention provide for a system by which the manufacturer may place a transceiver module in one of at least four permanent states, depending on the class of device to which the module belongs. These classes may be generally categorized as (1) implant devices (IMDs), (2) bridge devices, (3) smart-local devices, and (4) dumb-local devices. Smart-local devices are those with an extensive graphical user-interface (GUI), including facilities for user input (e.g. external drug pumps, external glucometer controllers, and implant controllers). Bridge devices have extensive GUIs and user inputs, and further are able to authenticate themselves to implant devices (e.g. physician programmers, and the more feature-rich and powerful implant controllers and home monitors). Dumb-local devices are those with no GUI or user input, although there may be some limited user display, and may include key fobs, external glucometers, comlinks, and certain limited capability patient controllers and home monitors.

Regardless of the type of device making up the various nodes of a BAN, in order for these devices to communicate securely with the minimum computing resources necessary, all devices will preferably share the BAN key, K_{BAN} . For example, according to the present invention, bridge and/or smart-local devices can deliver a legitimate BAN key to other bridge, smart-local device, dumb-local and implanted devices, on a per-session basis, and specifically the implant device securely delivers the current BAN key to authorized bridge devices of the BAN (e.g., a programmer appliance) or receives the current BAN key from authorized bridge devices (e.g., a programmer appliance). In certain embodiments of the invention, a key delivery protocol is used that prevents or hinders device impersonation during delivery of the BAN key, eavesdropping on BAN key delivery, and/or replay attacks (i.e. the mere repetition of a communication that was

eavesdropped upon, including with only a partial understanding or speculation, or even no understanding, of the substantive message contents). Because in-vitro (i.e., outside of body) BAN devices never receive an IMD's secret device key, a device in a patient's BAN, such as a programmer, never learns an IMD's unique device key, which remains secret at all times and is not communicated, the IMD is not compromised even if in vitro equipment used in that IMD's BAN is lost or stolen, as the existing session authentication information will become obsolete, and the IMD's secret key was never stored on the in vitro equipment. The BAN key is preferably securely communicated from in-vitro devices in a BAN (e.g. bridge and smart-local devices) to other in-vitro devices in a BAN (e.g. bridge, smart-local, and dumb-local devices). To effect this, in certain embodiments of the invention, an unsecured telemetry session is established according to the standard handshake, session request, or other pre-established protocol of the underlying wireless communications method. Where administered by a human, the device receiving the BAN key must be able to visually provide the human operating the device delivering the BAN key with the receiving device's device key K_{dev} , as well as the receiving device's ID number, in order to permit the human to verify the authentication of the BAN key recipient. The device key K_{dev} in particular will preferably be unique, at least with respect to other devices to be incorporated into a BAN, if not from all other devices the first device may encounter. Also in certain embodiments, smart-local devices and bridge devices will be used for securely delivering the BAN key they may have been provided to other eligible devices in the BAN (all dumb-local devices and/or other smart-local devices and/or other bridge devices). According to a representative embodiment of the present invention, the BAN key will be provided securely over the BAN's wireless connectivity functionality.

Figure 4 depicts a body area network 400 having two in-vitro devices according to an embodiment of the present invention. A BAN key delivery request may be initiated by the in-vitro device delivering the BAN key (Alice) 410, in this embodiment not an IMD as in previous examples but rather an in-vitro device such as a smart-local device 415 or a bridge device 420. As in earlier BAN key propagation examples, a telemetric communications session is established over an insecure channel 120 (e.g., by handshake or other pre-established compatible session protocol) with the device to receive the BAN key

(Bob) 110, and Bob 110 is required to transmit a freshly generated random number, Q_B (generated by RNG facility on-board Bob device 110 memory, storage, or other hardware or software element 435) to Alice 410 via message 425. Once Alice 410 and Bob 110 have otherwise established a telemetry session over insecure channel 120 according to the instant invention, Alice 410 (or the human administering the BAN key exchange session) may visually acquire (and input to Alice 410 via GUI or other input) Bob's device key, K_{devB} 430, which may, for example, be printed on a label affixed to Bob's exterior packaging, or displayed on Bob's electronic GUI and will also be stored in on-board memory or local storage element 435, shown as an abstraction in Figure 4. Alice and Bob will typically exchange IDs (ID_A and ID_B) at the outset of a telemetry session, providing their respective IDs to the other party via communications 445 and 450. In most instances, Alice 410 may also poll or interrogate Bob 110 to obtain Bob's identification number (ID_B) 440 via message 445.

Once Alice acquires ID_B 440 and K_{devB} 430, she may access ID_A (Alice's ID number) and the BAN key stored in on-board memory or secure storage 455, and prepare and transmit a message 460 to Bob containing ID_A , ID_B , and the current BAN key K_{BAN} , all secured using Bob's device key K_{devB} 430 as the key input to the block cipher (with Q_B as the nonce input to the block cipher, as detailed below). On receiving Alice's transmission 460, Bob 110 decrypts and verifies Alice's message 460 using K_{devB} 430 and logs the received ID_A , ID_B , and K_{BAN} . Bob then prepares and transmits a message 465 to Alice 410 containing ID_A , ID_B , all secured with K_{BAN} and Q_B+1 (i.e., an incrementation of Q_B). On receiving and decrypting/verifying Bob's message 465, Alice 410 verifies that the IDs she received match the IDs she transmitted.

For dumb-local devices 470, the device key K_{devX} may preferably be randomly or arbitrarily chosen "in the factory" and permanently programmed into the device 470 in firmware (or alternatively, flash memory) 435. Because dumb-local devices 470, as defined herein, don't generally have a significant GUI, the K_{dev} 430 will preferably be printed on a label which should be affixed to the external packaging of the device 470, its documentation, or on the device itself, to be removed following initiation. In contrast, smart-local devices 415 and bridge devices 420 as defined herein have a GUI and can thereby make their device keys 430 available by way of an external label (as with dumb-

local devices), or through the devices' GUIs. Because K_{dev} is the only piece of information that an attacker would need to know in order to gain access to a telemetry node device from an unauthorized BAN, it is important to keep K_{dev} as private as possible. For smart-local devices 415 and bridge devices 420, it would clearly be more secure if devices keys K_{dev} were only stored in on-board memory/storage 435 or 455, and available solely by way of the devices' GUIs, requiring interaction with the device's GUI, as opposed to being printed on the outside of the device.

While device keys such as K_{devB} 430 are preferably hard-programmed into dumb-local devices 470 (including in flash memory 435), device keys need not be for smart-local devices 415 and bridge devices 420. Accordingly, in certain embodiments of the present invention, device-key privacy for smart-local devices 415 and bridge devices 420 can be maximized if device keys are randomly generated each time that they are needed. Using freshly-generated random numbers for device keys, thereby requiring that the device keys are made viewable by way of a GUI, offers smart-local devices 415 and bridge devices 420 extra immunity from hijacking (i.e., unauthorized use or access) in that the probability distribution of possible device keys is effectively uniform (up to the uniformity of the pseudorandom-number generator) each time that a new device key is generated. This means that an attacker 475 trying to guess a device key 430 would need to start her search over each time that a new device key 430 is generated. Accordingly, in certain embodiments of the invention, freshly-generated random numbers will be used to generate device keys for smart-local devices 415 and bridge devices 420. A block cipher may be used to secure all messages – those messages keyed with the BAN key as well as those keyed with the device key. For example, a block cipher affording strong security without undue overhead may be 128-bit AES. If the device key is shorter than the length of the block cipher, then the device key may be repeated and concatenated to itself as many times as needed in order to reach the length of the block cipher argument.

Figure 5 shows the network key propagation protocol of Figure 4 in pseudo-protocol notation. This protocol describes how the BAN key is to be securely communicated from in-vitro devices in a BAN 400 (bridge devices 420 and smart-local devices 415) to other in-vitro devices in the BAN 400 (either bridge devices 420, smart-local devices 415, and dumb-local devices 470). The device receiving the BAN key, in

this case Bob 110, must be able to visually provide the human operating the device delivering the BAN key (in this case Alice 410) an in-vitro device such as a bridge, smart-local, or dumb-local device, with the receiving device's 110 device key K_{dev} 430, as well as the receiving device's ID number 440. Initially, Bob 110 receives a "deliver BAN-key" session request 210 from Alice 410. Alice 410 and Bob 110 must initially initiate a telemetric communication session 215 where Bob 110 provides Alice 410 with a freshly-generated random number, Q_B , as with message 425 in Figure 4. According to certain embodiments of the present invention, smart-local devices 415 and bridge devices 420 are responsible for securely delivering the BAN key, if they have it, to other eligible devices in the BAN 400 (all dumb-local devices 470 and/or other smart-local devices 415 and/or other bridge devices 420). Accordingly, the following protocol is in place to allow for secure and wireless delivery of the BAN key to eligible BAN 400 devices.

As shown in Figure 5, a "deliver BAN-key" session request 210, which is initiated by the device delivering the BAN key (Alice 410), first consists of establishing an unsecured communications session 215 with the device receiving the BAN key (Bob 110). Once Alice 410 and Bob 110 have established a telemetry session, Bob 110 also needs to send Alice 410 a freshly generated 64-bit pseudo-random number, Q_B via message 215.

An additional and extremely powerful method of preventing device hijacking can be realized if the firmware in smart-local devices 415 and bridge devices 420 refuses incoming "BAN-key delivery" commands 210 unless the human user places the smart-local device 415 or bridge device 420 into an "accept a new BAN-key" mode. The requirement of human intervention in the acceptance of a new BAN-key could be implemented in dumb-local devices 470 with the addition of a dedicated physical button or switch on the dumb-local device 470.

An additional and extremely powerful method of preventing device hijacking can be realized if the firmware 435, 455 in smart-local devices 415 and bridge devices 420 refuses incoming "BAN-key delivery" commands unless a human user in proximity to the device places the smart-local or bridge device into an "accept a new BAN-key" mode. This idea of requiring human intervention in the acceptance of a new BAN-key could also be realized in dumb-local devices 470 with the addition of a physical button or switch (such as a recessed "reset" button) on the dumb-local device 470. While requiring human

interaction to accept a new BAN-key practically eliminates any possible device hijacking (provided that the attacker does not achieve physical contact with the device), other attacks on the BAN-key delivery protocol are possible, as described herein, and are addressed by other embodiments of the invention.

In the last step of the BAN key delivery protocol of Figures 4 and 5, Bob 110 may transmit a message 465 to Alice 410, secured with K_{BAN} , thus confirming that the key-delivery protocol succeeded. This confirmation signal could be passed up to the application layer and then communicated to the human user as a “delivery successful” notification in the form of a visual and/or acoustic signal.

Bridge devices 420 and smart-local devices 415 of the present invention can in certain embodiments reset BAN keys, thereby also resetting session keys, as described below. For example, at the instruction of a patient or physician, bridge devices 420 and smart-local devices 415 can deliver BAN keys to local devices 415, 470, and/or to other bridge devices 420 by using the receiver's device ID and device key. In certain embodiments of the instant invention, smart local devices 415 can generate BAN keys regardless of whether there are implanted or bridge devices 420 in the BAN. In general, the only time that a BAN key needs to be updated is when a device that has the BAN key is lost or stolen. In certain embodiments according to the present invention, BAN keys would only need to be updated with a frequency on the order of hundreds of years to avoid being compromised, based on current attacker processing power.

Because of networking resource constraints, in certain embodiments of the present invention, a common secret key will be shared by all devices in a particular body-area network (BAN). The BAN key, K_{BAN} , will be used to secure all communications within the BAN. Within a BAN, a telemetry session may be established as follows: On the command of any device initiating a telemetry session, the shared BAN key, along with freshly generated and shared random numbers contributed by all BAN members wishing to communicate in the current telemetry session, are distilled into a session key, K_{ses} , which is used to secure all messages communicated in the BAN for the duration of the telemetry session. Once the telemetry session is closed, the current session key is discarded.

In order to open a communications session between nodes, initially an unsecured exchange takes place between the communicating devices, e.g., by means of a handshake, session request/accept, or other session initiation protocol. Preferably incoming and outgoing packet lengths are fixed, and moreover, in certain embodiments according to the present invention, the physical-layer hardware is set up to expect these packet lengths—shorter or longer packets may accordingly be flagged and rejected as “bad.” An instance of the relevant cipher to be used must be available. One of various suitable encryption standards for use with the present invention is the FIPS-approved 128-bit AES block cipher (FIPS PUB 197). Encryption may be suitably performed in the “counter mode” (CTR mode) of AES. Message freshness may be checked through use of token-like nonces (i.e., single-use pseudorandom numbers). Also in certain embodiments, message integrity will be maintained, for instance by use of the “cipher-block-chaining message-authentication-code mode” (CBC-MAC mode) of AES. In the telemetry security system of the present invention, pseudorandom numbers must be generated from time to time, as discussed herein. We may refer to so-called pseudorandom numbers (as opposed to truly random numbers) to be technically precise when referring to computer-generated numbers, in that the computer-generated numbers are in fact deterministic. However, the pseudorandom numbers are preferably derived from sufficiently complex or varied states or subsidiary functions that the overall function behaves for observable purposes as a stochastic process overall. It will be appreciated that the actual value of the number is immaterial, the number may be used, in certain embodiments, as a seed for a cipher, message authentication function, or even the generation of another pseudorandom number. Because the actual value of the number is immaterial as regards the function of the pseudorandom number, the value of the number may be said to be arbitrary, which herein is intended to be generally synonymous with “aleatory.” In general, wherever the present invention calls for the use of pseudorandom number, the functionality may be replaced by, e.g., an alternate pseudorandom number generator, or a hardware-generated random number according to alternate embodiments of the present invention. In certain embodiments, the FIPS-approved AES block cipher specification described above provides for the implementation of a NIST-recommended pseudorandom-number generator (PRNG) based on the ANSI X9.31 specification (appendix A.2.4), which is

suitable for typical embodiments of the present invention. This specific embodiment of the ANSI X.9.31 PRNG specification uses the AES block-cipher (FIPS PUB 197).

Embodiments of this type generate PRNG pseudorandom numbers 128 bits at a time.

Figures 6 through 9 depict data flow diagrams of pseudorandom number generator functions according to certain embodiments of the present invention. Figure 6 depicts a data flow diagram of the first step of the random number generator of Figure 9, according to embodiments of the present invention. In certain embodiments, generation of a 128-bit pseudo-random number (PRN) is implemented using the AES block-cipher, as specified in ANSI X9.31, providing adequate security and privacy in light of anticipated attacker processing power, without undue overhead. As an initial matter, 128-bit random numbers K_R 610 and R_0 are available to the PRNG. K_R 610, the PRNG key, does not change and is always loaded into the *key_i* input 615 of the block cipher 620 by way of a 128-bit register. R_0 is the PRNG's secret and random initialization-vector which is updated with the new and current PRN ($R_1, R_2, \dots$) every time the PRNG generates a 128-bit random number. Both K_R 610 and the current R may be stored in memory or secure local storage as they are required for the generation of any new pseudorandom numbers.

In this embodiment, generation of every $(i+1)^{th}$ PRN proceeds as follows: The block cipher 620 (in this example, 128-bit AES) is used to encrypt a nonce 625 using K_R 610 as the key input 615, as depicted in Figure 6. The nonce 625, which could, for example, consist of the node's current real-time clock value, may be loaded into the 128-bit *data_i* input 630 of the block cipher 620 by way of a 128-bit register. (If the real-time clock is longer than 128 bits, then the least-significant 128 bits of the real-time clock may be used.) If the real-time clock is shorter than 128 bits, the most-significant bits of the nonce 625 may be padded with zeros such that the number of zeros plus the number of real-time clock bits equals 128. Whether or not the real-time clock is used to generate the nonce 625 the intermediate value *data_o* 635 outputted from the block cipher 620 may be called V_1 640 herein.

Figure 7 depicts a step subsequent to that of Figure 6 in an embodiment of a pseudorandom number generator according to the instant invention. As depicted in Figure 7, intermediate value V_1 640 is XORed with the current R 710 (R_0 for the first random number, or R_i for the $(i+1)^{th}$ random number). This 128-bit value, $V_1 \oplus R_i$, 625 may then

be encrypted with the block cipher 620. Specifically, K_R 610 may be loaded into the *key_i* input 615 of the block cipher 620, for example from a 128-bit register. Following that, $V_1 \oplus R_i$ 625 may be loaded into the *data_i* input 630 of the block cipher 620 by way of another 128-bit register. Intermediate value V_2 720 is the *data_o* output 635 of the block cipher 620.

Figure 8 depicts a step subsequent to that of Figure 7 in an embodiment of a pseudorandom number generator according to the instant invention. In this embodiment, the 128-bit intermediate values V_1 640 and V_2 720 are XORed together and encrypted with the block cipher 620. Specifically K_R 610 is loaded into the *key_i* input 615 of the block cipher 620 by way of a 128-bit register. The $V_1 \oplus V_2$ 625 result is loaded into the *data_i* 630 input of the block cipher 620 by way of another 128-bit register. The output *data_o* 635 of the block cipher 620 contains the new PRN, R_{i+1} 810. In the event that further 128-bit PRNs are needed, the RNG process may be repeated using a new nonce 625 (the current real-time clock data, for example) and using the newly updated PRN R_{i+1} 810. If no additional random numbers are required, then R_{i+1} is to be stored in memory for the generation of future PRNs in future sessions. The PRNG key, K_R 610, may be stored in memory or secure local storage.

To summarize, the generation of the PRNG key preferably proceeds as follows, as depicted in Figure 9. If the block cipher is represented by the function $E(\text{data}_i; \text{key}_i) = \text{data}_o$, where E represents the AES function 620, with the relevant arguments to the function and *data_i* 630 and *key_i* 615 (with $i \geq 0$), then the algorithm can be summarized according to 3 steps of nested or iterative processing through the block cipher:

Step 1. V_1 640 = $E(\text{nonce } 625; K_R \text{ } 610)$

Step 2. V_2 720 = $E(V_1 \text{ } 640 \oplus R_i \text{ } 710; K_R \text{ } 610)$

Step 3. R_{i+1} 810 = $E(V_1 \text{ } 640 \oplus V_2 \text{ } 720; K_R \text{ } 610)$. Combining all three of the above steps gives $R_{i+1} = E(E(\text{nonce}; K_R) \oplus E(R_i \oplus E(\text{nonce}; K_R); K_R); K_R)$,

In certain embodiments of the instant invention, the PRN generation is allocated use of a 128-bit AES block-cipher 620 and modulo-2 addition functionality, three 128-bit registers to buffer the block-cipher, access to the real-time clock or another nonce 625 source, and storage space for two 128-bit numbers, R_i 710 and K_R 610. Of these, the storage space for R_i and K_R , may be unavailable to other aspects and functions of the

invention. Preferably, two 128-bit random numbers may be “installed” into a module implementation of the present invention, e.g., in production. One of these random numbers (K_R 610) may be permanent and the other, R_0 710, may preferably be updated every time a new pseudorandom number is generated.

A secure telemetry session according to the present invention is preferably to be initiated whenever one or more communicating devices request a secure session. Setting up a secure communications session is a two-step process, by which all communicating devices are provided the same session key, K_{ses} . In step one, all communicating devices take turns announcing a previously generated pseudo-random number, e.g., a 64-bit random number, called R_x , where “x” indexes the different devices. As described above and depicted in Figures 6 through 9, in certain embodiments pseudo-random numbers are generated at the end of the previous secure communications session so that they are immediately available for the next secure session. The generation of these pseudo-random may preferably take place according to the disclosure herein, but other methods of generating pseudo-random numbers or hardware-generated random numbers may be substituted in accordance with the present invention.

Following the announcement of the previously generated random number, the next step provides for the establishment of a secure session, and requires that all communicating devices calculate a common session key (K_{ses}) which will subsequently be used to secure data traffic for the duration of the secure session. K_{ses} is calculated independently but identically by each device using a cipher, such as a block cipher. The 128-bit AES block cipher is suitable for typical embodiments of the present invention.

Figure 10 is a data flow diagram of the generation of a session key according to embodiments of the present invention. The common session key may be derived from the previously-established BAN key, K_{BAN} , and all of the communicating nodes random numbers $\{R_1, R_2, R_3, \dots\}$. In certain embodiments, K_{ses} may be calculated by loading K_{BAN} into the “key input” 615 to the block cipher 620 and loading the devices’ random numbers 1010 into the “data in” 630 of the block cipher 620. This may be accomplished by firmware control in certain embodiments of the present invention. Specifically, the first two devices’ 64-bit random numbers are to be concatenated to a 128-bit number which is then loaded into the “data in” 630 of the block cipher 620. If there are only two

devices wishing to establish a secure session, then the 128-bit output 635 of the block cipher 620 is the session key, Kses. If there are more than two devices wishing to communicate securely within a single session, then the output 635 of the block cipher 620 is then XORed (i.e., modulo-2 added) to the next two devices' 1020 concatenated 128-bit (2×64-bit) random number before again entering the "data in" 630 of the block cipher 620 and getting processed as above. The application of the cipher (here, 128-bit AES) to the XOR-derived value 635 is preferably repeated as many times as is needed to get through all of the devices' random numbers, where the final output 635 of the block cipher 620 is Kses 1030. In the event that there are an odd number of devices to be included in a secure session, an "empty" slot in the 128-bit concatenation may be filled with 64 zeros. At the conclusion of the secure-communications session, the ephemeral Kses 1030 may be "deleted" and a new session key 1030 is calculated at the beginning of each new secure telemetry session, as provided.

As described, the securing of information in certain embodiments may be based on ciphers, including by the use of block ciphers, for example, used in their counter (CTR) mode. In this way, the block cipher may be applied to streams in that the block cipher generates a keyed, pseudo-random keystream which is then XORed against the plaintext in order to generate encrypted text (or, at the recipient node, applied against the ciphertext to generate plaintext to effect decryption). Figure 11 shows the data flow of the CTR-mode encryption and decryption of a message according to embodiments of the present invention. As depicted, the shared session key 1030 is loaded into the *key_i* input 615 of the block cipher 620 by way of a 128-bit register; the session key 1030 may be loaded into the register from memory or storage (after being calculated at the initiation of a secure session as discussed above). A 128-bit nonce (i.e., a number used only once) 1110 is loaded into the *data_i* input 630 of the block cipher 620 by way of another 128-bit register.

Figure 12 shows the data structure of a nonce register according to embodiments of the present invention. In this embodiment, the most significant eight bytes 1210 of the 128-bit nonce 1110, as shown in Figure 12, are actually an eight-byte up-counter 1210, while the lower six bytes of that counter 1215 are initiated with the least-significant six bytes [i.e., bits 47 through 0] of the instigating device's random number Rx 1220. It will

be appreciated that the random number Rx 1220 was contributed to the generation of the session key 1030 of Figure 10. Every time that a telemetry packet according to the present invention is received or transmitted in a secure session, the value of the counter 1210 is incremented. The next nonce byte 1225 (just below the eight-byte counter 1220) contains the *mode bit* 1230, bit “m” 1230 in Figure 12. This bit may be set to logical zero when the nonce is being used for CTR-mode encryption/decryption; the mode bit is to be set to logical one when the nonce is being used for message integrity, as described herein. The seven-bit field below the mode bit, the *block-number* field 1240, is to be reset to logical 0000000 at the start of every packet and incremented on the generation of each 128-bit block of keystream material to be used for encryption/decryption within that packet. If, for example, each telemetry packet required 300 bits of keystream material for encryption/decryption, then the first 128 bits of keystream would be generated using 0000000, the second 128 bits would be generated using 0000001, and the third 128 bits would be generated using 0000010 (incrementing by 1, noting that in an example where 300 bits of keystream material are required per packet, only 44 of the last 128 bits of keystream material would be needed). The remaining seven bytes of the 128-bit nonce 1110 (the least-significant seven bytes 1240), may preferably be permanently set to logical zero.

Rather than or in addition to synchronized timestamps to help prevent replay attacks, in certain embodiments of the present invention, message freshness and user authentication is provided by calculating a new session key Kses 1030 at the start of every secure telemetric session, the new session key 1030 being a function of the contribution of random numbers generated by each of the participants in the secure session. With regard to intra-session replay attacks, however, a further freshness mechanism may be provided—in this case, the devices in a secure session should never allow the counter in their local copy of the session nonce to be reset to a value lower than its current value. In the event that a telemetry communications session is interrupted or for some other reason needs to be “reset” or resynchronized within the underlying communications protocol, it might be necessary for the current session nonce to be announced in order for devices in a secure session to resynchronize. An attacker could conceivably attempt to exploit such a situation by trying to reset other session participants’ nonces to a previous value, thereby

allowing the attacker to replay old messages that used the previous nonce value. In this way, the session nonce acts as something of a network token. If nonce counters only increase, no old message will ever have a legitimate nonce, as past intra-session messages have an earlier nonce, provided that no more than 2^{64} packets are communicated in a single secure session, which is unlikely.

As depicted in Figure 11, in embodiments of the present invention, encryption and decryption are preferably performed by executing a bitwise modulo-2 addition (XOR) between the 128-bit output bus, *data_o* 635 of the block cipher 620, and 128-bit blocks of data 1115, taken from the payload plaintext for encryption, and from the payload ciphertext for decryption. In certain embodiments of the present invention, packet headers are not encrypted.

Figure 13 shows a data structure for a telemetry packet 1300 according to an embodiment of the present invention. Each of the 128-bit message blocks 1115 may be XORed 1120 with a different output 635 of the block cipher 620, e.g., message block m_1 1310 of Figure 13 is to be XORed with keystream block (i.e., the 128-bit block leaving the *data_o* bus 635 of the block cipher 620) s_1 , message block m_2 (the next 128-bits of packet 1320) is to be XORed with s_2 , etc. As previously stated, a different nonce 1110 is to be used in the generation of each keystream block 635. In certain embodiments, the same nonce 1110 is never used twice within the same session; accordingly, when the eight-byte nonce counter 1210 reaches its maximum value (0xFFFFFFFFFFFFFFFF), the secure session may be terminated, with a new session key collectively calculated. In this embodiment, the number of telemetry packets that can be communicated using a single session key is from 2^{64} (corresponding to the case where the least-significant six bytes of the instigator's random number is 0x0000000000000000) to $2^{64} - 2^{48}$ (corresponding to the case where the least-significant six bytes of the instigator's random number is 0xFFFFFFFFFFFFFFFF). In base10, these numbers are 1.84467×10^{19} and 1.84464×10^{19} , respectively, thus it will be appreciated that these packet numbers are unlikely to ever be reached in practice.

In a secured network, e.g. a TDMA structure, preferably devices will increment their nonce counters regardless of whether or not the devices actually broadcasts during

their allocated window, in order to maintain secure communications during a period of non-transmission, during which time the device may power-down its radio in order to conserve energy. On power up, the device has kept track of the session nonce, and will still be able to power-up later and communicate securely. Alternatively, the “master” or “beacon” of a telemetry network session could broadcast, unsecured, the current nonce counter every time it starts a new “round” within the network session.

In certain embodiments of the present invention, MACs will be calculated on and appended to each telemetry packet. Also in certain embodiments of the invention, one packet size and structure is used. One possible embodiment for such packet structure is depicted in Figure 13. As shown, a packet 1300 according to the present invention may consist of a 42-bit (5.25 byte) header 1310, a 30-byte payload 1315, and a 3-byte MAC 1320.

In certain embodiments of the invention, a block-cipher (e.g., 128-bit AES) may be used in the CBC-MAC mode to generate a keyed hash-value (the message authentication code, or MAC) of the plaintext of a message, which as depicted in Figure 13, is to be appended at 1320 to an encrypted form of that message 1315 upon transmission. On reception of these packets 1300 and their appended MACs 1320, the receiver may decrypt the packet payloads 1315, calculate the MAC on their decrypted packets, and compare the calculated MAC value they derived from the received payload 1315, to the MAC value 1320 received as appended to the instant packet 1300. If the MACs match, the packet 1300 is accepted. Naturally if the MACs conflict, then the packet 1300 is to be discarded or re-requested. If MACs 1320 are calculated and appended onto each packet 1315 according to the present invention, MACs 1320 may be used in place of the packet-wise CRC in telemetry systems of the prior art. To the extent that certain packets will be sent unsecured, as detailed variously herein, in addition an unkeyed integrity-check mechanism (like a CRC) may be applied. This integrity check could be realized through the use of a hardware CRC or alternatively, by using CBC-MAC with a publicly-known key and nonce (e.g., by using 0x00000000000000000000000000000000 for both).

While in this embodiment using a MAC 1320, the length of packet payloads 1315 (i.e. the portion of the packet which is to be encrypted) is 30 bytes, (thus requiring a nonce register block-number field 1235 of only 1 bit, the nonce register block-number field 1235

may be fixed at seven bits to provision for future telemetry schemes which might permit the use of longer packet payloads as long as 4096 bytes using the same nonce register structure 1110.

In a CBC-MAC generation/verification algorithm according to a representative embodiment of the present invention depicted in Figure 14, initially, the shared session-key 1030 (the same one used for CTR-mode encryption/decryption) is loaded into the *key_i* input 615 of the block cipher 620 by way of a 128-bit register 1430. The *data_i* input 615 of the block cipher 620 may be loaded with a concatenation 1435 of the 97 most-significant bits of the nonce (truncating the block-number field as necessary) and up to the first 31 bits of the plaintext packet (typically consisting of header information). The mode bit 1230 of the nonce-register 1110 may be set to logical one. In a typical embodiment, regardless of whether the CBC-MAC algorithm is being used for MAC generation or MAC verification, CBC-MAC processing is to be done on the decrypted form (i.e., message plaintext) of each packet. In this embodiment, accordingly the received packets must be decrypted before their MAC can be verified.

The output (*data_o*) 635 of the first block-cipher 620 in Figure 14 may be bitwise XORed to the next 128-bits following the plaintext concatenated to the 97 bit nonce at 1435. The result of this XOR is then loaded into input 630 of the second block-cipher 1440. The output 635 of the second block-cipher 1440 is then XORed with the last 128-bits of packet plaintext from 1315 of packet 1300 (zero padded as necessary), and then processed by the third block-cipher 1445. In this embodiment, as the bit sum of a packet header and packet payload is ≤ 287 bits, no further rounds of CBC-MAC are required as the MAC is the 128-bit output (*data_o*) of the third block. In the event that a MAC were needed on longer packets according to an alternative embodiment of the present invention, additional plaintext blocks could be processed by XORing and passing the output through additional block ciphers 620. Generally, for m blocks of plaintext, m XOR/block-cipher rounds 630 would be required, where the *data_o* output 635 of the last block cipher would be the MAC 1450. Note that while three block-cipher cores 620, 1440, 1445 are depicted in Figure 14, in certain embodiments only one core will actually be implemented in hardware; in practice, the XOR output will be routed to *data_i* input 630 of the first block

cipher 620. The three cores 620, 1440, 1445 shown in Figure 14 are meant only to illustrate the CBC-MAC algorithm.

As depicted in Figure 14, in certain embodiments of the present invention, only the least-significant 24 bits (bits 23 through 0) of the CBC-MAC output 1450 will be appended onto the end of the processed packet 1300 as MAC 1320, which does not compromise the underlying cryptographic strength of the CBC-MAC function (e.g., 128-bits, as in this case).

Each device participating in a secured session will preferably increment its respective session nonce counter 1210 on the transmission and reception of every packet 1300. In this manner, because only one device in a secure-session is transmitting at a time, the nonce increment acts as a proxy token, thus ensuring that multiple devices cannot transmit simultaneously. Because in certain embodiments, telemetry packets are relatively long, nodes could conceivably lose nonce synchronization amongst a BAN group in certain circumstance. Where supported by the underlying communications protocol, in certain embodiments of the instant invention, the devices may periodically include their current plaintext nonces in frame headers to provide a nonce-synchronization check. In typical embodiments, nonce synchronization may generally be recovered by always including the current nonce 1110 in NACK packets, or through whatever native recovery techniques that exist in the underlying communications protocol. Preferably, all devices adhere to the rules that a) the counter within their copy of the session nonce should be at least as large as any nonce they that receive in a maintenance message and b) a new session key must be calculated when the nonce counter reaches 0xFFFFFFFFFFFFFFFF, no nonce will be used twice, thus assuring message freshness, as described further herein.

Preferably, encryption/decryption should be applied to telemetry packet payloads 1315, rather than headers 1310. This embodiment of the invention tends to minimize both the known-plaintext available to an attacker, as well as the length of the required keystream. Furthermore, this gives the block-cipher time to compute and buffer keystream material while the packet headers 1310 are propagating through the physical-layer hardware. While in certain embodiments of the present invention, a single block-cipher core 620 (e.g., AES block cipher) will be used to implement both ciphering and MAC functions, this preferably will be effected by first generating and storing enough

keystream material, using CRT mode, for an entire packet's worth of payload data 1315, rather than alternating CTR mode with CBC-MAC mode per block at runtime. Once encrypted/decrypted 128-bit blocks are available, the CBC-MAC mode will be used successively to generate/verify the MAC. Figure 15 illustrates a proposed hardware layout for the AES-based mixed use of CTR and CBC-MAC modes for packets according to an embodiment of the present invention (≤ 32 -byte payload).

Generally, a hardware implementation of a node according to the current invention requires one instance of the 128-bit AES block cipher (and corresponding dedicated 128-bit registers) and keep-alive or non-volatile storage for the 128-bit BAN key. Because the session nonce consists solely of the instigating device's random-number contribution to the session key (Rx), all devices in a secured network know the session nonce without the need for any additional transmissions. As shown in Figure 15, single block cipher 620 is used to process either keystream (via input 1510) or CBC-MAC input (via input 1515) to data_i input 630. The output 635 of block cipher 620, register 1515, is XORed with plaintext 1525 to encrypt plaintext data 1525.

In certain embodiments of the invention, an unkeyed integrity check will still be used to the extent that packets will need to be communicated unsecured (like the packets which are used to open a session and share random numbers). This integrity check may be implemented through, for example, the use of a hardware CRC or perhaps by using CBC-MAC with a publicly-known secret key and nonce (like 0x00000000000000000000000000000000 for both).

Keystream material is generated and stored in first and second keystream registers, 1510 and 1515, respectively. Once the keystream material in the second keystream 1515 register is used up, first keystream register 1510 parallel loads into the keystream register 1515. The first plaintext block is stored in the register 1520, and the resulting first MAC block following block-cipher processing 620, is stored in the first keystream register 1510 (once its keystream material is emptied into second keystream register 1515). The first MAC block is XORed with the second block of plaintext from 1525 and put through the block cipher 620. The least-significant 24 bits of the final MAC 1530 is then appended to the encrypted data 1315 of Figure 13.

In a wireless telemetry system according to the present invention, typically communications sessions between in-vivo and in-vitro devices can be initiated, executed, and closed entirely wirelessly, as disclosed herein. Therefore, it is important to prevent unauthorized and/or malicious parties to communicate with implanted devices or other nodes of the BAN, as discussed. However, it will be appreciated that there may arise situations in practice where unauthorized in-vitro devices (such as physician programmer appliances, emergency-response equipment) and their users (unauthorized in the sense that they do not have access to an implant's secret key, but having a patient's express or implied consent or direction to access the patient's BAN) still need to communicate with an implanted device. Such situations may arise, for example, in emergency situations where a patient is undergoing a critical, and even life-threatening physiological event, whether or not caused by the implant itself. For example, the patient may conceivably be unconscious and without identification materials. Situations may also arise where full authentication, according to aspects of the invention as described above, is not feasible due to excessive inconvenience where authentication according to the protocols above is prohibitive or infeasible. For example, a patient may have traveled a great distance to a physician appointment, but upon arrival, found that he or she has forgotten or mislaid his or her smartcard, or other materials necessary to permit an in-vitro node to communicate with the implant, or the patient may have forgotten his or her authenticating password. In these situations, a "backdoor," i.e. a method of interfacing with an IMD BAN node (but, in representative embodiments, without any way to derive the node's secret device key K_{dev}), may permit legitimate access to the node in a manner that circumvents, on a limited basis, the security protocols of a system according to the invention; thus avoiding the inconvenience of rescheduling a patient's appointment, or in true emergency situations, enabling critical care to a patient.

In one embodiment of the invention, a convenient backdoor mechanism may be provided that would operate wirelessly, for example, over some distance, for example, as a wireless protocol. In certain embodiments of the instant invention, however, the backdoor would not be wireless, and equipment able to open the backdoor may be widely available (and accordingly, would be easy for an attacker to acquire). Accordingly, the backdoor in certain embodiments would not be implemented in a manner such that the security of all

node devices sharing the key would be irrevocably compromised upon the acquisition of a node device by an attacker who is motivated for whatever reason to compromise the relative secrecy of the backdoor key. Therefore, in certain embodiments of the present invention in which a wireless backdoor is implemented, preferably only a limited amount of functionality of the entire implant or node (e.g., Alice 115) is operable upon communication of the backdoor key. For example, in certain implementations in which a wireless backdoor is available, wireless backdoors may be used solely to put implants in their respective quiescent (i.e., “stand-by”) modes. More specifically, a pacemaker, for example, may go into a 60bpm mode, while an implantable cardioverter defibrillator or neural stimulator or drug pump could be put into a therapy-suspension mode by means of the wireless backdoor.

Referring to Figure 16, in certain embodiments of the instant invention, a “physical” backdoor 1610, i.e., a method of access not using a wireless communications channel 120, is provided. In these embodiments, access to the BAN node 115 without authentication is effected only by physical contact (or close proximity) between the device seeking backdoor access 110, and the node to be accessed 115 and/or its patient (in the case of an implanted device). This may be implemented by the use of a near-field magnetic sensor, such as a Hall-effect sensor or magnetic reed switch, in certain BAN nodes 115. Preferably, this sensor 1610 does not effect a communications channel per se, but rather is used solely to put the module in an open mode where equipment can communicate with the implant(s) or other node, without the authentication requirements called for by embodiments of the invention (as described above). Alternatively, the backdoor may initiate means of near-range telemetry such as magnetic telemetry, in which the proximity actually enables use of a communication channel.

Also in certain embodiments, once the emergency equipment 110 closes the communications session, the backdoor 1610 would close, i.e., the open communications channel would be closed down, and further communications to the device 115 would require the applicable authentication information, for example as provided herein, or alternately the establishment of another backdoor communications session. The effect of the use of this backdoor may be compared to the recessed reset button of a wireless network appliance, such as a wireless router. While the reset may allow aspects of the

wireless router to be changed by a remote third party, the state is not provided without a physical action at the device. This physical access to the device is taken as a proxy for administrative authorization to administer changes to the device or node.

The backdoor may also be used as a preferred means of extracting K_{BAN} from an IMD for the purposes of delivering that K_{BAN} to other devices in the BAN. The backdoor may also be used to request that an IMD transmit an ephemeral K_{BAN} (a locally generated random number to be temporarily used as the K_{BAN}) which is only valid for the duration of that telemetry session. In implementations where backdoor access can result in the wireless transmission of K_{BAN} or an ephemeral K_{BAN} , it may be the case that added credentials are required in order for the IDM to transmit the K_{BAN} , with respect to those credentials needed to recover an ephemeral K_{BAN} . Such credentials may include activation of a proximity switch for an extended period of time, e.g., 10 seconds, where recovery of an ephemeral K_{BAN} might be authorized on activation of the same proximity switch for only three seconds.

The backdoor 1610 to the IMD 115 may be embodied as follows: Initially, Alice 115 and Bob 110 open a communications session over insecure channel 120 by exchanging IDs (ID_A , ID_B) via messages 1615 and 1620. Bob 110 then, via insecure channel 120, asks Alice 115 to power-up her backdoor circuitry 1610, that otherwise would be turned off and would not respond to any external event such as the proximity of a magnet, for example--when off, the backdoor may be said to be "locked." Once the backdoor circuitry 1610 is on, thus "unlocking" the backdoor 1610, Bob 110 may physically open Alice's backdoor by means such as a magnetic switch or Hall-effect sensor, as described above. Preferably, if the backdoor 1610 is not physically opened before a pre-defined time-out, Alice 115 will automatically power down her backdoor circuitry 1610, relocking the backdoor 1610 to avoid attacks where proximity to the host patient is available to the attacker.

Following the opening of the backdoor 1610, Alice 115 will reduce her RF transmission power (thereby reducing the effective transmission range of the signal) and then send Bob 110 K_{BAN} 1625 by via message 1630, whereupon Alice 115 promptly powers down her backdoor circuitry 1610. In representative embodiments, no request by

Bob 110 for the BAN key is necessary, as the request for the BAN key is implicit in the initiation of the backdoor protocol.

Figure 17 depicts a pseudo-protocol and data flow for an emergency access protocol according to the embodiment of Figure 16. As indicated in Figure 17, a bridge device 110 can obtain a BAN key by means of a backdoor session request 1710. Following the backdoor session request 1710, the two nodes establish an unsecured telemetry session at 215. Bridge device 110 may then request 1715 that backdoor circuitry 1610 be powered up. In response, IMD 115 powers up its backdoor circuitry 1610 at 1720, and at 1725 confirms to bridge device 110 that backdoor circuitry 1610 is powered up. Bridge device 110 may then activate the powered-up backdoor 1610 by means of proximity to the magnetic switch, Hall-effect sensor, or other proximity-based switch comprising the backdoor 1610; indicated by 1730.

Upon the opening 1730 of the backdoor 1610, IMD 115 realizes that the backdoor has been opened by the proximate node 110 as indicated at 1735, and subsequently transmits at 1625 the BAN key over the insecure telemetry channel 120. In certain embodiments, bridge device 110 may transmit confirmation of the receipt of the BAN key at 1730, however in typical embodiments the IMD 115 promptly powers down backdoor 1610 upon sending of the BAN key, and another request 1715 for the opening of the backdoor will be required.

There are a variety of situations where it is advantageous for a given device or node within the BAN to transmit data to another node without initiating a fully secure telemetry session according to the above security parameters. For example, the BAN may include one or more nodes that are transmit-only type sensors that are unable to establish a secure two-way link. Other devices, such as a patient activator, could transmit data that could be acted upon immediately. Thus, embodiments of the present invention provide for securing a wake-up packet that includes data and for a limited amount of secure subsequent communications. In this context, the fully secure protocol will be referred to as establishing general security and the less onerous protocol will be referred to as wake-up security or the like.

Figure 18 is a diagram depicting in block form a secured wake-up packet 2000 as generated by an authorized device (e.g., Alice 115) within the BAN. The wake-up packet

2000 may also include other data not illustrated, such as an ID of Alice 115, an ID of the node that is to receive the packet, among other things. In short, the wake-up packet includes 4 bytes of unencrypted data 2010, a 3 byte MAC 2020, and a 3 byte MCTR 2030. The MCTR is a 3 byte message counter value associated with a specific device that is stored within each device in the BAN and incremented each time that specific device authors a new secure wake up packet. Each device within the BAN maintains a value of MCTR in always on memory for every device within the network. If a new device is added to the BAN then all values of MCTR are reset. The MCTR value is not encrypted in the wake-up packet 2000. In addition to maintain a MCTR value; each device in the BAN includes a receptor bitmap which is a one byte value used to identify each device as intended recipient(s).

The generation of the MAC 2020 along with the tracking of the value for MCTR provides security to the protocol. Upon receipt, an authorized receiving device (e.g., Bob 110) evaluates the MCTR value 2030. If inappropriate, the message is ignored. If appropriate, the MAC is then decoded. If authenticated, the data 2010 is utilized; if not, the data is ignored. In one embodiment, no further exchanges other than ACK/NACK messages are permitted. In another embodiment, once the wake-up packet is authenticated, each node is permitted to transmit a limited amount of data (e.g., one frame) without requiring the initiation of general security

Figure 19 depicts the generation of the MAC 2020 by executing the AES block cipher 2090 (and as previously shown and described). The “nonce” register of the AES block cipher 2090 is loaded with a data set 2045. The data set 2045 includes the sender’s ID (ID_{sender}) as the most significant 6 bytes; the sender’s current MCTR value ($MCTR_{\text{sender}}$) as the next three bytes; the next 4 bytes are the data to be transmitted and the last byte is the receptor bitmap indicating the intended recipient(s). The BAN key 2100 is also input into the AES block cipher 2090. From the resultant output 2110 of the AES block cipher 2090, the least significant three 3 bytes of data are designated as the MAC 2020.

Figure 20 is a flowchart of a process for generating and sending a secure wake-up packet. In this example, “Alice” 115 intends to communicate a data packet to “Bob” 110. Alice 115 generates or acquires 4 bytes of data (e.g., Alice’s sensor data; a command of a

patient activator, etc.) 2200. Alice 115 reads 2210 the current value of MCTR from memory and populates 2220 the AES block cipher 2090 as described with respect to Figure 19. The MAC is obtained and Alice 115 composes 2240 the wakeup packet 2000 that includes the 4 bytes of data; the MAC; and the MCTR value. Preferably each device within the BAN has designated permissible transmission times. Alice 115 transmits 2250 the composed message during an appropriate time window. As a new secure wake-up message has been composed, Alice 115 increments the MCTR 2260.

Assuming the message is properly received, Alice 115 may receive 2270 an ACK message from the recipient. If an ACK message is expected and not received or if other errors occur, Alice 115 may retransmit the same message (2250) without generating a new MAC and without incrementing the MCTR. When the ACK is received by Alice 115 a native mode session is established 2280. In one embodiment, this simply means that the session is terminated 2290 in that Alice has successfully transmitted the data and received (if appropriate) an ACK message. In an alternative configuration, establishing 2280 a native mode session permits each device in the BAN engaged in the session to transmit a limited amount of data, e.g., one frame. Thus, as indicated in dashed lines Alice 115 transmits 2300 an additional frame data. Each device in the native session is permitted to transmit, thus Alice 115 may receive 2310 a frame of data from another device in the BAN. ACK/NACK messages are permitted 2320 and the session is then terminated.

In this manner, the wake-up packet is secured and a small amount of data is transmittable without establishing general security. If there is a need to transmit larger amounts of data, then the general security protocol is implemented as previously described.

Figure 21 is a flowchart of a process that a receiving node, e.g., Bob 110, employs upon receipt of potential secured wake-up message. Bob 110 receives 2400 the message and identifies 2410 the sender. This may occur based upon the network timeslot allocated for transmission to e.g., Alice 115, or based upon other identification means. In any event, Bob 110 identifies that it is Alice 115 purportedly sending the message and that Bob 110 is an intended recipient. Bob 110 extracts 2420 the MCTR value from the transmitted message and compares 2430 to an MCTR value Bob 110 has stored for Alice 115 in memory. If at step 2440, the received MCTR value is smaller than the value Bob 110 has

stored for Alice, the message is ignored 2450. If the MCTR value is greater than the stored value, Bob 110 will temporarily assume 2460 that the received MCTR is correct and proceed utilizing the received value. Similarly, if the received MCTR value is equal to the stored value, Bob 110 proceeds to the next step.

In either case, the received MCTR is utilized to calculate a MAC in the same manner as Alice 115 with the AES block cipher 2090. The MAC value calculated by Bob 110 is compared 2480 to the MAC value received by Bob 110. If the MAC values do not match, the message is ignored 2490. If the MAC values do match, then Bob 110 enters a native mode 2500 and accepts 2510 the data accordingly. Bob 110 updates 2515 the MCTR value related to Alice 115. This will effectively result in an incremental value added of the MCTR value transmitted by Alice 115. Optionally, Bob 110 may secure and transmit 2520 an ACK/NACK message. The session is then terminated 2530.

In an alternative embodiment, each node that entered the native mode 2500 is able to transmit an additional frame of data. Thus, Bob 110 may transmit 2540 to Alice 115 an additional amount of data and likewise Alice 115 may transmit 2550 an additional frame of data 2550. The session key is defined by a portion of the MAC output in order to assure inter-session freshness. Each node is permitted to send appropriate ACK/NACK messages 2520 and the session is then terminated 2530. The packets and frames are secured as previously described with respect to general security, with the exception that the AES_out 2110, BAN key 2100 is utilized instead of K_{ses} and the least significant three bytes of the nonce counter are initiated with the MCTR value, the next most significant two bytes utilize the least significant two bytes of the MCTR value and the most significant byte is initiated with zeros.

Data privacy (encryption) can optionally be applied to the four bytes of user data before transmission. Encryption, and subsequent decryption, can be realized by XORing the four user bytes with a four byte keystream (just as is done for native-mode communications). The four byte keystream could come from unused bytes of 2110, or they could come from another execution of the block cipher using a different nonce value known to both Alice and Bob.

Various embodiments of the invention have been described and are intended to be exemplary and not limiting. Portions of the subject matter disclosed may be combined in

embodiment not explicitly set forth while remaining within the spirit and scope of the invention.

CLAIMS:

1. In a telecommunications network having at least a first and second node, a method of transmitting actionable data in a secured telemetry wake-up packet from the first node to the second node, the method comprising the steps of:

generating a message authentication code using a predefined protocol within the first node;

obtaining a current counter value from a memory of the first node indicative of a number of wake-up transmissions authored by the first node;

determining an identification of the second node; and

composing a transmittable wake up message for the second node include the message authentication code, the current counter value and a predetermined amount of actionable data; and

transmitting the wake-up message.

2. The method of claim 1, wherein the message authentication code is generated with a 128 bit block cipher.

3. The method of claim 2 wherein generating the method authentication code further comprises:

inputting an identifier indicative of the first node into an input register of the block cipher;

inputting the current counter value into the input register;

inputting the actionable data into the input register;

inputting a receptor identification value indicative of the second node into the imputer register;

proving a network key to the block cipher; and

generating an output value from the block cipher at least a portion of which forms the method authentication code.

4. The method of claim 1, further comprising receiving an acknowledgement message from the second node.

5. The method of claim 1, wherein successful transmission of the wake-up message including actionable data initiates a native mode telemetry session, whereby any node in the native mode may send an ACK/NACK message upon receipt of the wake-up packet.

6. The method of claim 5, further comprising terminating the native mode session without permitting any additional data exchanges.

7. The method of claim 5, further comprising:
 permitting each node engaged in the native mode session to send a single data packet of a predetermined and each node may send an ACK/NACK message;
 terminating the native mode session without permitting any additional data exchanges.

8. The method of claim 1, further comprising:
 receiving the wake-message at the second node;
 identifying the sender of the wake-up message;
 extracting the current counter value from the wake-up message;
 comparing the current counter value to a first node counter value stored within a memory of the second node;
 utilizing the comparison as a first mechanism to assess message validity;
 extracting the message authentication code from the wake-up message;
 calculating a first node message authentication code utilizing first node data in a block cipher accessible by the second node;
 comparing the first node message authentication code with the message authentication code extracted from the wake up message as a second mechanism to assess message validity; and
 accepting the actionable data from the wake-up message if both the first and second mechanisms indicating message validity.

9. The method of claim 8, wherein the first mechanism to assess message validity further comprises:

ignoring the wake-up message if the current counter value is less than the first node counter value stored in the memory of the second node;

advancing to the second mechanism and utilizing the first node counter value if the first node counter value is equal to the current counter value; and

advancing to the second mechanism and utilizing the current counter value if the current counter value is greater than the first node counter value.

10. The method of claim 9, further comprising replacing the first node counter value with the current counter value in the memory of the second node if the current counter value is greater than the first node counter value and the second mechanism indicates message validity.

11. The method of claim 9, further comprising incrementing the first node counter value in the memory of the second device if the second mechanism indicates message validity.

12. The method of claim 9, further comprising entering a native mode telemetry session if the second mechanism indicates message validity, wherein the second node is permitted to send an ACK message.

13. The method of claim 12, further comprising terminating the telemetry session without permitting addition data exchange.

14. The method of claim 12, further comprising allowing the receipt of a single additional data transmission from each node in the native telemetry mode; permitting the transmission of a single data transmission from the second node; and sending and receiving ACK/NACK messages prior to termination of the native telemetry mode.

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15. A telecommunications network having at least a first and second node including transmitting actionable data in a secured telemetry wake-up packet from the first node the second node comprising:

means for generating a message authentication code using a predefined protocol within the first node;

means for obtaining a current counter value from a memory of the first node indicative of a number of wake-up transmissions authored by the first node;

means for determining an identification of the second node; and

means for composing a transmittable wake up message for the second node include the message authentication code, the current counter value and a predetermined amount of actionable data; and

means for transmitting the wake-up message.

16. The network of claim 15, wherein the means for generating the method authentication code further comprises:

means for inputting an identifier indicative of the first node into an input register of the block cipher;

means for inputting the current counter value into the input register;

means for inputting the actionable data into the input register;

means for inputting a receptor identification value indicative of the second node into the imputer register;

means for proving a network key to the block cipher; and

means for generating an output value from the block cipher at least a portion of which forms the method authentication code.

17. The network of claim 16, further comprising:

means for initiating a native mode telemetry session upon successful receipt of the wake-up message;

means for permitting each node engaged in the native mode session to send a single data packet of a predetermined and each node may send an ACK/NACK message;

means for terminating the native mode session without permitting any additional data exchanges.

18. The network of claim 15, further comprising:

- means for receiving the wake-message at the second node;
- means for identifying the sender of the wake-up message;
- means for extracting the current counter value from the wake-up message;
- means for comparing the current counter value to a first node counter value stored within a memory of the second node;
- means for utilizing the comparison as a first mechanism to assess message validity;
- means for extracting the message authentication code from the wake-up message;
- means for calculating a first node message authentication code utilizing first node data in a block cipher accessible by the second node;
- means for comparing the first node message authentication code with the message authentication code extracted from the wake up message as a second mechanism to assess message validity; and
- means for accepting the actionable data from the wake-up message if both the first and second mechanisms indicating message validity.

19. The network of claim 18, wherein the first mechanism to assess message validity further comprises:

- means for ignoring the wake-up message if the current counter value is less than the first node counter value stored in the memory of the second node;
- means for advancing to the second mechanism and utilizing the first node counter value if the first node counter value is equal to the current counter value; and
- means for advancing to the second mechanism and utilizing the current counter value if the current counter value is greater than the first node counter value.

20. The network of claim 19, further comprising means for replacing the first node counter value with the current counter value in the memory of the second node if the

current counter value is greater than the first node counter value and the second mechanism indicates message validity.

21. In a telecommunications network having at least first and second nodes in communication with each other, a method of making secure at least one communication between the at least first and second nodes during a communication session, comprising the steps of:

- assigning to each node an identifier unique to each node within the network;
- assigning to each node a device key unique to each node within the network;
- assigning to the network a network key;
- establishing a communication session between the at least first and second nodes;
- providing the network key to at least the second node;
- providing the second node's identifier to the first node;
- providing to the first node the second node's device key in a manner not subject to unauthorized discovery;
- preparing a first communication comprising the first node's identifier and the second node's identifier;
- securing the first communication with the second node's device key;
- transmitting the first communication to the second node;
- decrypting at the second node the first communication using the second node's device key;
- providing the first node with the network key subject to verification that the second node's device key was used to secure the first communication; and
- securing a second communication among the at least first and second nodes using the network key.

22. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 21, wherein the provision to the first node of the second node's device key in a manner not subject to unauthorized discovery is effected by entry of the device key from a physical token.

23. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 21, wherein the step of providing to the first node the second node's device key in a manner not subject to unauthorized discovery comprises the steps of:

placing the second node's device key on a physical token; and
transferring the second node's device key from the physical token to the first node.

24. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 23, wherein in the step of providing to the first node the second node's device key in a manner not subject to unauthorized discovery, the second node's device key is stored on the physical token and the step of transferring of the second node's device key from the physical token to the first node is done electronically.

25. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 24, wherein the step of transferring of the second node's device key from the physical token to the first node electronically is done in a manner in which the first node is provided the device key in encrypted form.

26. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 23, wherein the physical token is a key fob containing at least one processor.

27. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 26, wherein the step of securing the first communication is effected by means of the at least one processor of the key fob.

28. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 23, wherein the physical token is a smartcard.

29. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 28, wherein the step of securing the first communication is effected by the smartcard.

30. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 29, wherein the second node's device key is encrypted by authentication information and stored on the smartcard.

31. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 30, where the authentication information comprises a string of password characters.

32. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 30, wherein the authentication information comprises biometric parameters.

33. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 21, wherein the network includes a medical data service network.

34. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 21, wherein at least one of the at least first and second nodes comprises an implantable medical device.

35. In a telecommunications network having at least first and second nodes in communication with each other, a method of making secure at least one communication between the at least first and second nodes during a communication session, comprising the steps of:

- assigning to each node an identifier unique to each node within the network;
- assigning to each node a device key unique to each node within the network;
- assigning to the network a network key;
- establishing a communication session between the at least first and second nodes;
- providing the network key to at least the first node;
- providing the second node's identifier to the first node;
- securely providing to the first node the second node's device key;
- transmitting from the second node to the first node a first communication comprising the first node's identifier, the second node's identifier, and the network key, wherein the first communication is secured with the second node's device key; and
- securing a second communication among the at least first and second nodes using the network key.

36. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 35, wherein the step of securing the second communication among the at least first and second nodes using the network key comprises the steps of:

- generating a session key at the first node as a function of the network key and a first arbitrary number;
- independently generating the session key at the second node as a function of the network key and the first arbitrary number; and
- using the session key to secure the second communication among the at least first and second nodes.

37. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 36, wherein the first arbitrary number is a pseudorandom number.

38. The method of making secure at least one communication between the at least first and second nodes during a communication session of claim 36, wherein the first arbitrary number is generated by a method of arbitrary number generation, comprising the steps of:

- generating a second arbitrary number at the first node;
- providing the second arbitrary number to the second node;
- generating a third arbitrary number at the second node;
- providing the third arbitrary number to the first node; and
- generating the first arbitrary number as a function of both the second arbitrary number and the third arbitrary number.

39. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 38, wherein at least one of the second arbitrary number and third arbitrary number is a pseudorandom number.

40. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 36, wherein the step of securing the second communication among the at least first and second nodes with the session key comprises the step of executing bitwise modulo-2 addition between the output of a cipher and a message comprising plaintext, wherein the output of the cipher is a function of both the session key and a first nonce that is unique within the communication session.

41. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 40, wherein the first nonce is a function of the number of discrete communications that have been transmitted between the at least first and second nodes during the communication session, and a size of the discrete communications.

42. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 41, wherein the discrete communications are packets.

43. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 42, wherein the size of the discrete communications is measured in blocks.

44. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 43, wherein the cipher is a block cipher.

45. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 44, further comprising the step of appending to each discrete communication an authentication tag derived from the discrete communication to which it is appended.

46. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 45, wherein the authentication tag is a function of the session key and the plaintext of the message being communicated.

47. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 46, wherein the authentication tag is also a function of a second nonce, wherein the second nonce is a function of the number of discrete communications that have been transmitted between the at least first and second nodes of the network during the communication session.

48. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 45, wherein the authentication tag is a function of the session key, the plaintext of the message being

communicated, and the number of discrete communications that have been transmitted between the at least first and second nodes of the network during the communication session.

49. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 45, wherein the authentication tag is the result of a hash function performed on the discrete communication to which the authentication tag is appended.

50. In a telecommunications network having at least first and second nodes in communication with each other, a method of making secure at least one communication between the at least first and second nodes during a communication session, comprising the steps of:

- assigning to each node a device key unique to each node within the network;
- assigning to the network a network key;
- establishing a communication session between the at least first and second nodes;
- providing the first node with an arbitrary number;
- providing to the first node the second node's device key in a manner not subject to unauthorized discovery;
- securing a first communication with the second node's device key and the arbitrary number;
- transmitting the first communication to the second node;
- decrypting at the second node the first communication using the second node's device key and the arbitrary number;
- upon verifying at the second node that the first communication was secured with the second node's device key and the arbitrary number, providing the first node with the network key; and
- securing a second communication among the at least first and second nodes using the network key.

51. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 50, wherein the arbitrary number is a pseudorandom number.

52. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 50, wherein the arbitrary number is generated by a computer-implemented method of arbitrary number generation, comprising the steps of:

generating a first intermediate number as a function of both a reference key and a nonce; and

generating the arbitrary number as a function of the first intermediate value, an initialization number, and the reference key.

53. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 52, wherein at least one of the reference key and the initialization number is arbitrary.

54. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 53, wherein at least one of the reference key and the initialization number is a pseudorandom number.

55. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 54, wherein the arbitrary number is a pseudorandom number.

56. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 55, wherein the arbitrary number is a function of the reference key and the result of a bitwise modulo-2 addition of the first intermediate value and the initialization number.

57. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 56, wherein the arbitrary number is generated by encrypting the result of the bitwise modulo-2 addition of the first intermediate value and the initialization number with the reference key.

58. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 57, wherein encrypting the result of the bitwise modulo-2 addition of the first intermediate value and the initialization number with the reference key is implemented using a block cipher.

59. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 52, wherein the method of arbitrary number generation further comprises the step of updating the initialization number with the arbitrary number.

60. The method of making secure the at least one communication between the at least first and second nodes during a communication session of claim 50, wherein the arbitrary number is generated by a computer-implemented method of arbitrary number generation, comprising the steps of:

- generating a first intermediate number as a function of both a reference key and a nonce;

- generating a second intermediate number as a function of the first intermediate value, an initialization number, and the reference key; and

- generating the arbitrary number as a function of the first intermediate value, the second intermediate value, and the reference key.

61. A secure wireless network comprising at least two nodes, wherein at least one of the at least two nodes comprises a programmable processor and a computer-readable storage element, wherein the computer-readable storage element contains instructions for causing the programmable processor to perform a method of arbitrary number generation, comprising the steps of:

- 54 -

generating a first intermediate number as a function of both a reference key and a nonce;

generating a second intermediate number as a function of the first intermediate value, an initialization number, and the reference key;

generating an arbitrary number as a function of the first intermediate value, the second intermediate value, and the reference key; and

securing with the arbitrary number a communication to be transmitted between the at least two nodes.

62. The secure wireless network of claim 61, further comprising a physical token, wherein at least one of the physical token and the at least two nodes comprises the programmable processor and the computer-readable storage element.

63. A medical device adapted for implantation in a living creature comprising:

a therapy-administering unit;

a power source;

a transmitter;

a receiver;

a unique device key;

a subcutaneously-operable physical switch; and

a switch-control module adapted to render the physical switch

activatable only in response to a request from a device networked with the medical device.

64. The medical device of claim 63, further comprising:

a network key adapted to secure communications within a wireless network; and

electronic memory adapted to store the network key; wherein the medical device is adapted to transmit the network key wirelessly in response to activation of the physical switch.

65. The medical device of claim 63, further comprising:
a session key; and
electronic memory adapted to store the session key; wherein the medical device is adapted to transmit the session key wirelessly in response to the activation of the physical switch.
66. The medical device of claim 63, wherein the physical switch comprises a magnetic reed sensor.
67. The medical device of claim 63, wherein the physical switch comprises a Hall-effect sensor.
68. The medical device of claim 63, wherein the physical switch comprises an accelerometer.
69. The medical device of claim 63, wherein the physical switch comprises an ultrasonic sensor.
70. The medical device of claim 63, wherein the physical switch comprises an optical detector.
71. A secure wireless network comprising at least two nodes, wherein at least one node has a physical switch, the physical switch adapted to activate only in close physical proximity to the secure wireless network, and wherein the at least one node having the physical switch is further adapted to transmit a secret key to at least one other node on the secure wireless network upon activation of the physical switch.

72. The secure wireless network of claim 71, further comprising:
a requesting device; wherein the physical switch is activated only by the close physical proximity of the requesting device to the at least one node having the physical switch relative to the area of the secure wireless network; and wherein the secret key is a network key or a session key.
73. The secure wireless network of claim 71, wherein the at least one node having the physical switch is adapted to effect in the physical switch a state where the physical switch can be activated only upon a request transmitted from another node in the secure wireless network.
74. In a wireless network secured by a telemetry security system, the wireless network having a first transmission range, a method of providing, to a non-member node without authentication information to authenticate itself to the wireless network, access to at least one member node of the wireless network, comprising the steps of:
providing the at least one member node with a physical switch adapted to be activated by physical proximity of a requesting device;
activating the physical switch of the at least one member node by placing a requesting device in physical proximity to the physical switch of the at least one member node;
in response to activating the physical switch, reducing a transmission power of the at least one member node having the physical switch, to effect a second transmission range smaller than the first transmission range;
locating the non-member node within the second transmission range;
transmitting authentication information from the at least one member node having the physical switch to the non-member node; and
authenticating the non-member node to the wireless network by provision of the authentication information to the at least one member node of the wireless network by the non-member node.

75. The method of providing access to the at least one member node of the wireless network of claim 12, wherein the physical switch comprises an accelerometer.

76. The method of providing access to the at least one member node of the wireless network of claim 74, wherein the physical switch comprises an ultrasonic sensor.

77. The method of providing access to the at least one member node of the wireless network of claim 74, wherein the physical switch comprises a magnetic reed switch.

78. The method of providing access to the at least one member node of the wireless network of claim 74, wherein the physical switch comprises a Hall-effect sensor.

79. The method of providing access to the at least one member node of the wireless network of claim 74, wherein the requesting device comprises a magnet.

80. The method of providing access to the at least one member node of the wireless network of claim 79, wherein the magnet is integrated into the non-member node.

81. The method of providing access to the at least one member node of the wireless network of claim 74, wherein the wireless network is a medical data service network.

82. The method of providing access to the at least one member node of the wireless network of claim 74, wherein the at least one member node with a physical switch adapted to be activated by the physical proximity of the requesting device is an implantable medical device.

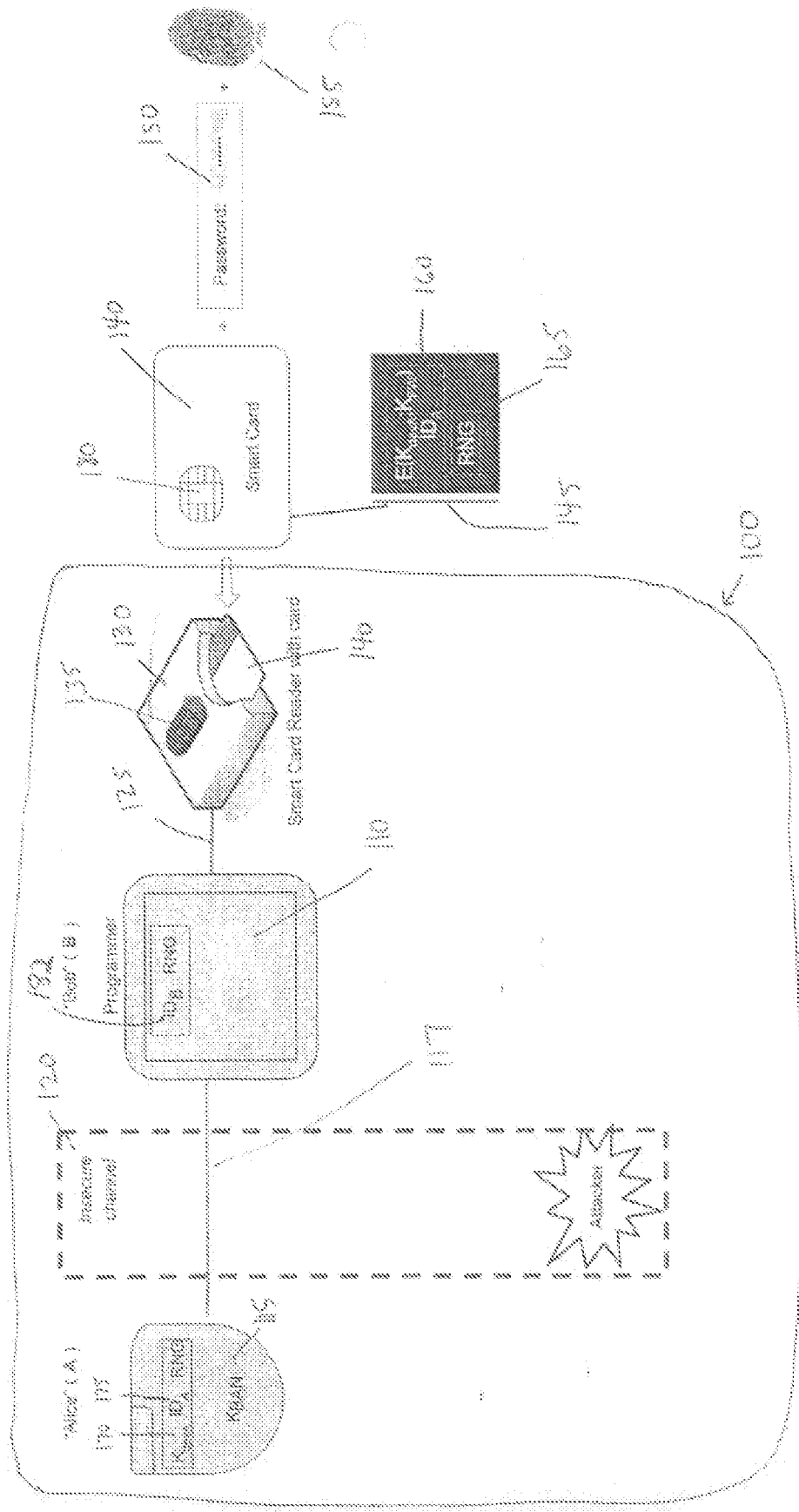
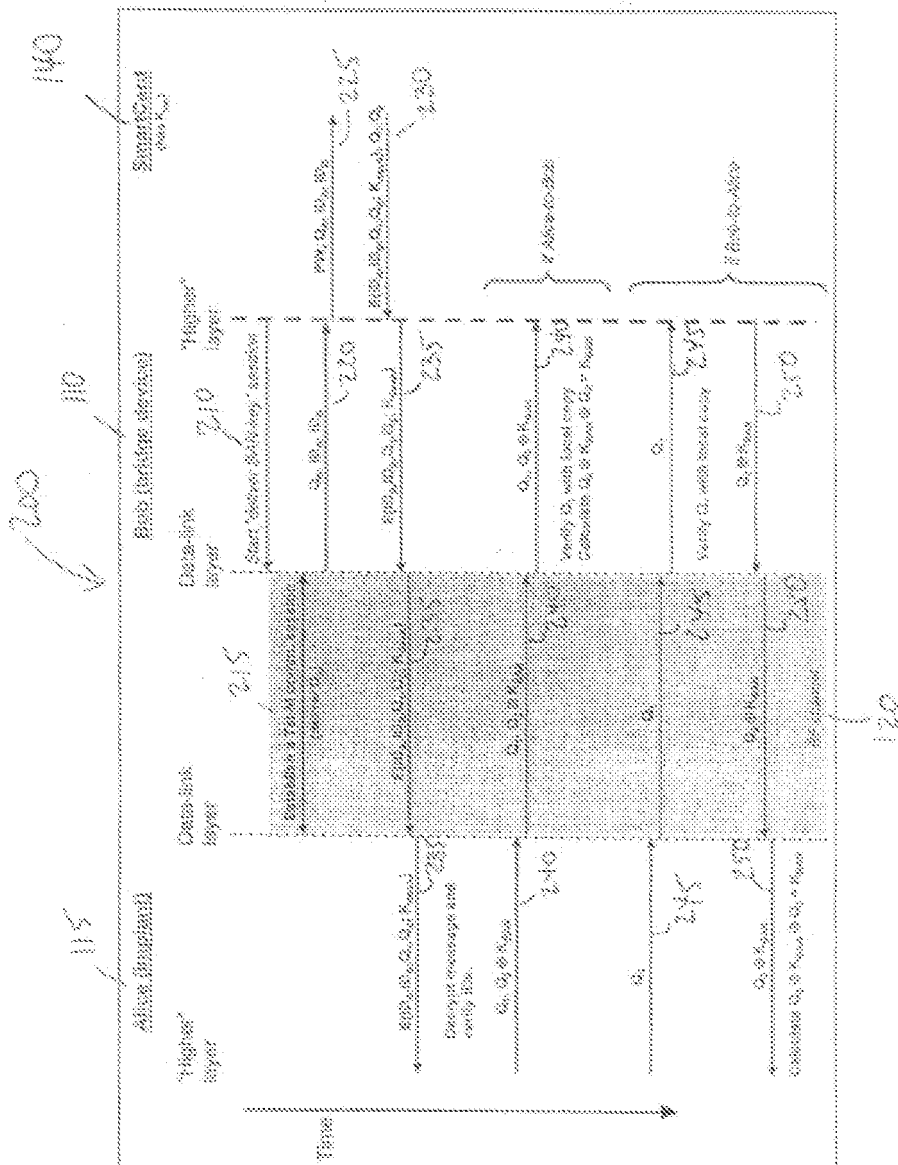


Fig. 1



45

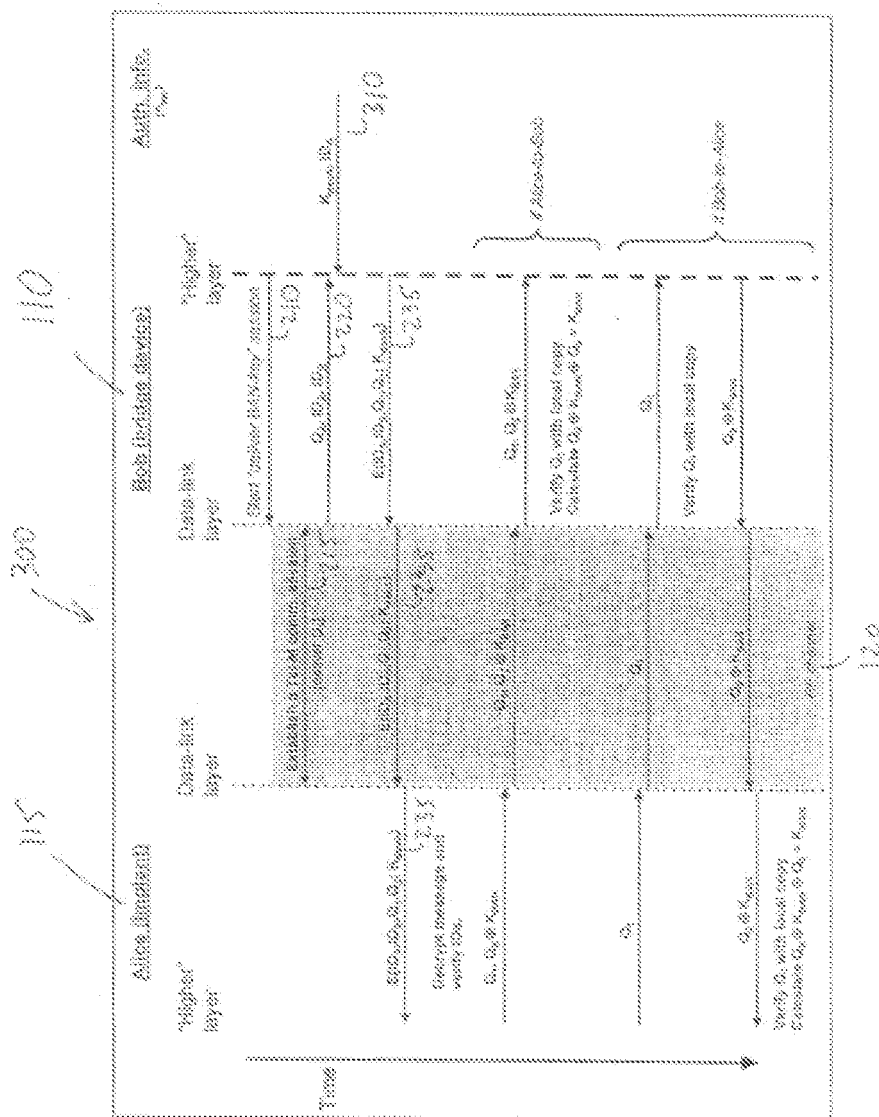
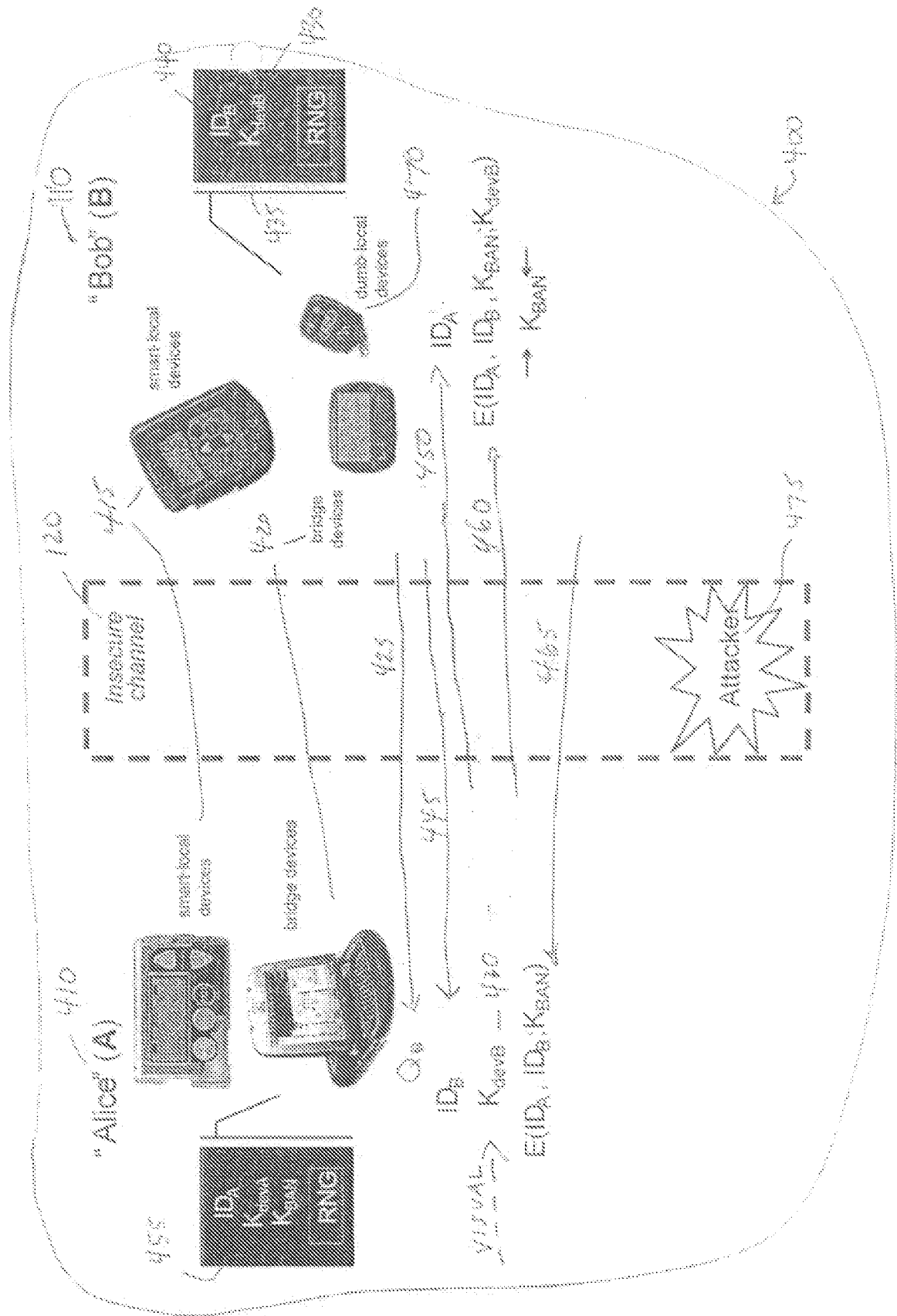


Fig. 3

Fig. 4



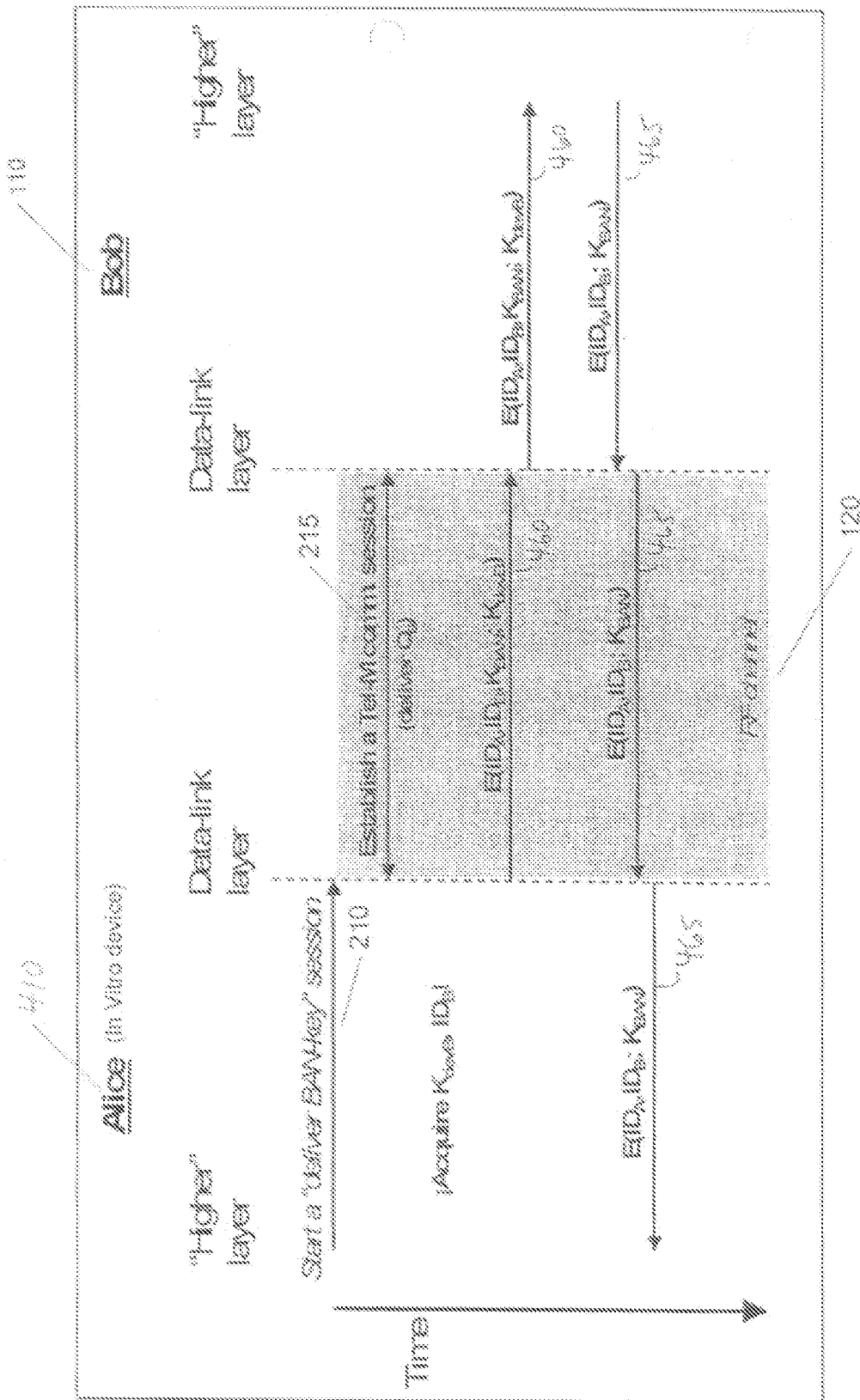


Fig. 5

Fig. 6

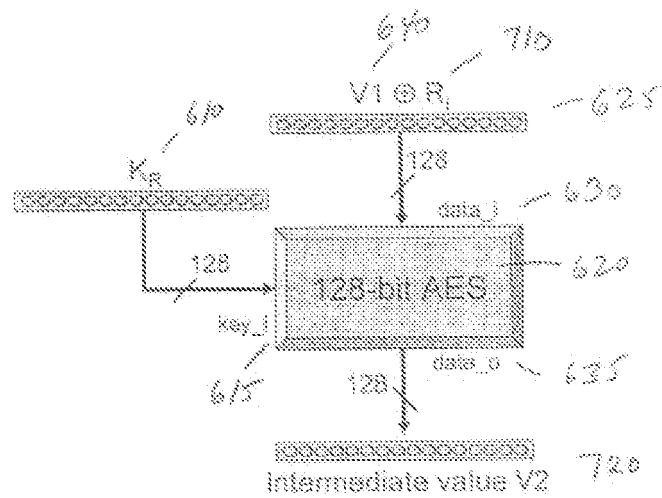
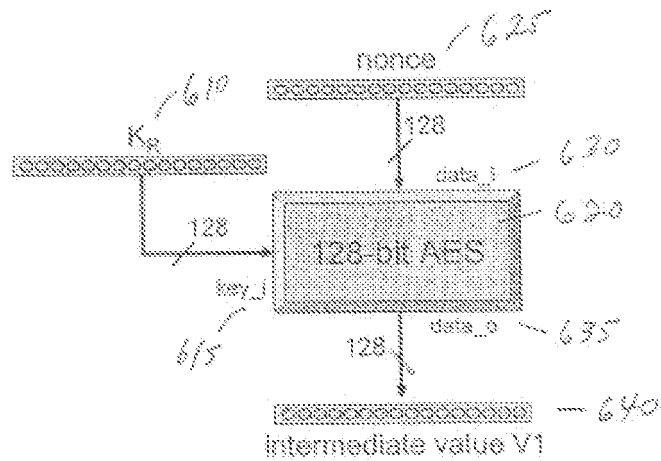


Fig. 7

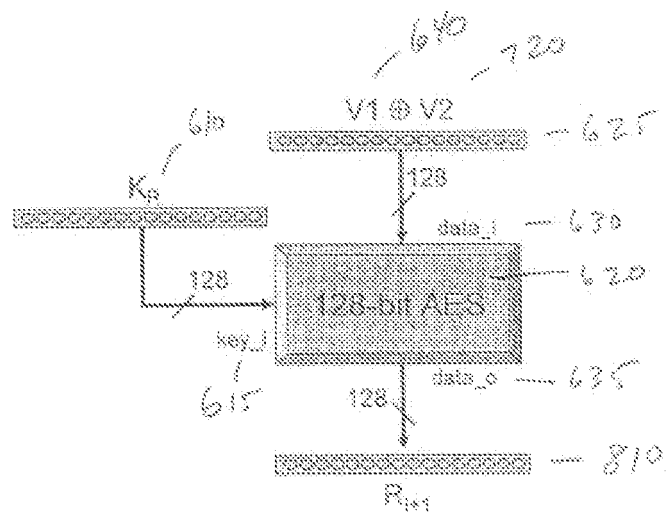


Fig. 8

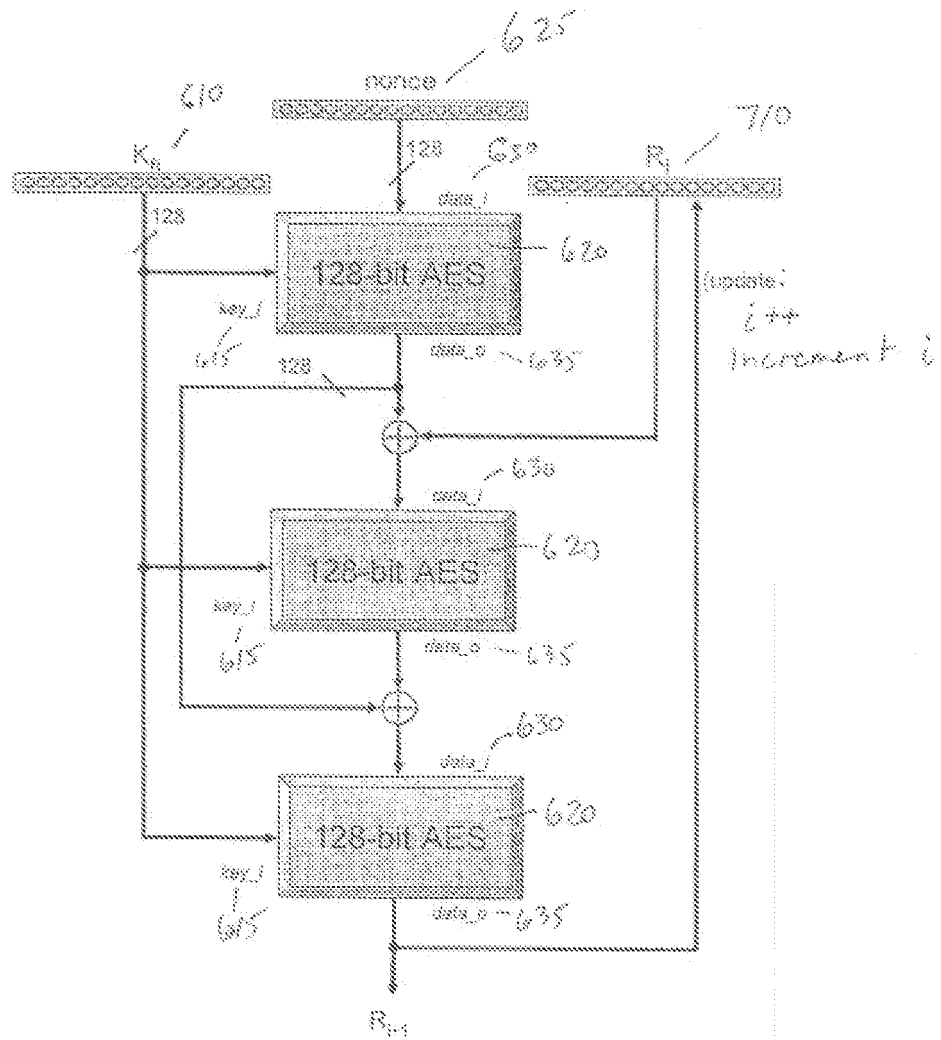


Fig 9

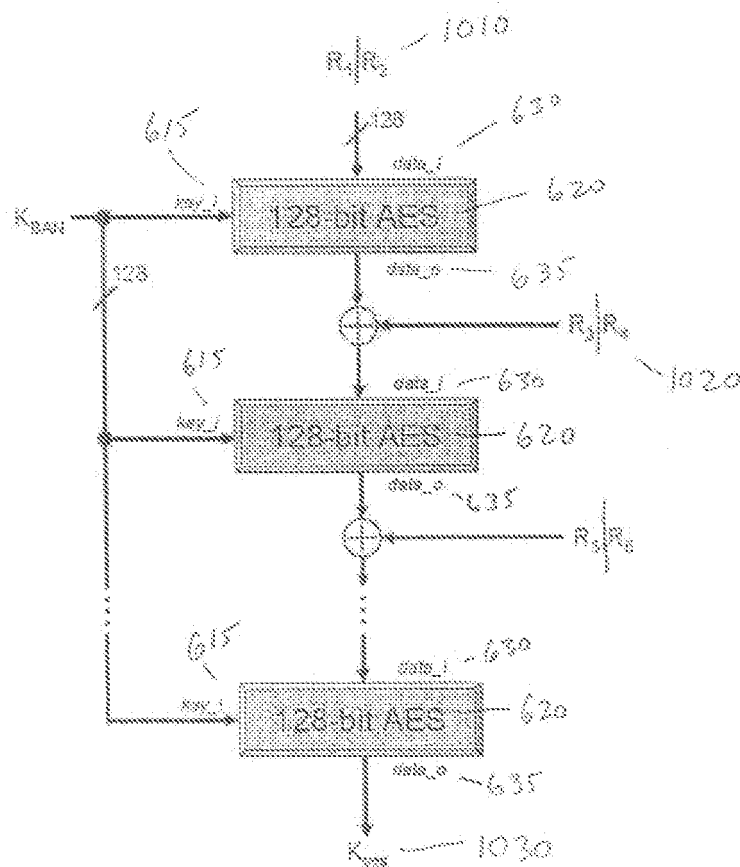


Fig 10

Fig 11

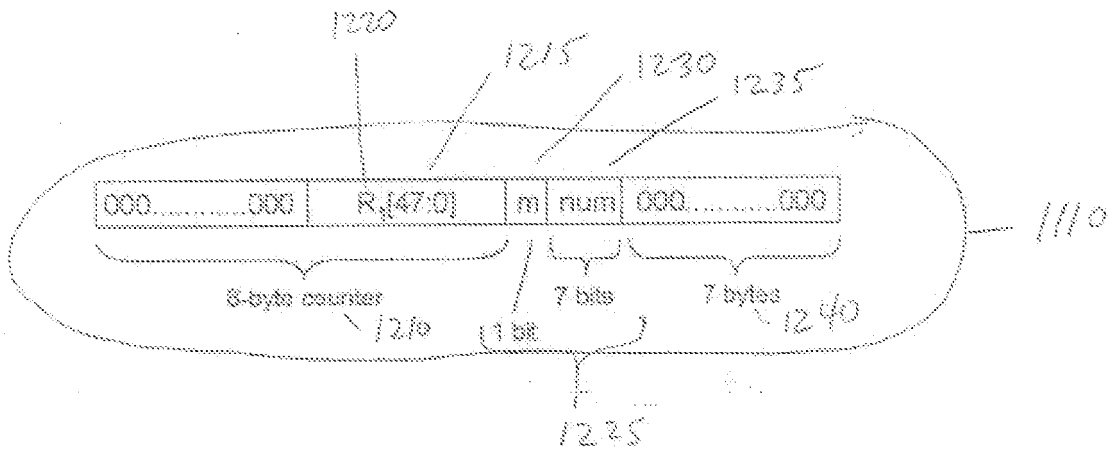
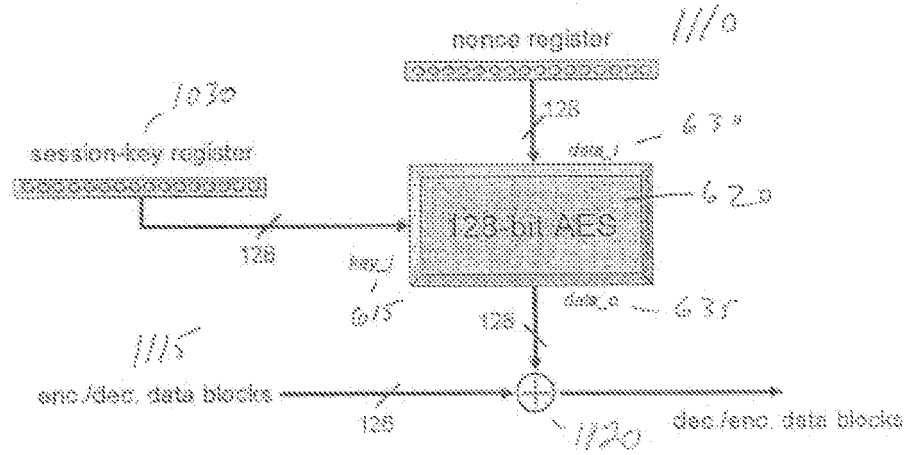


Fig 12

Fig 14

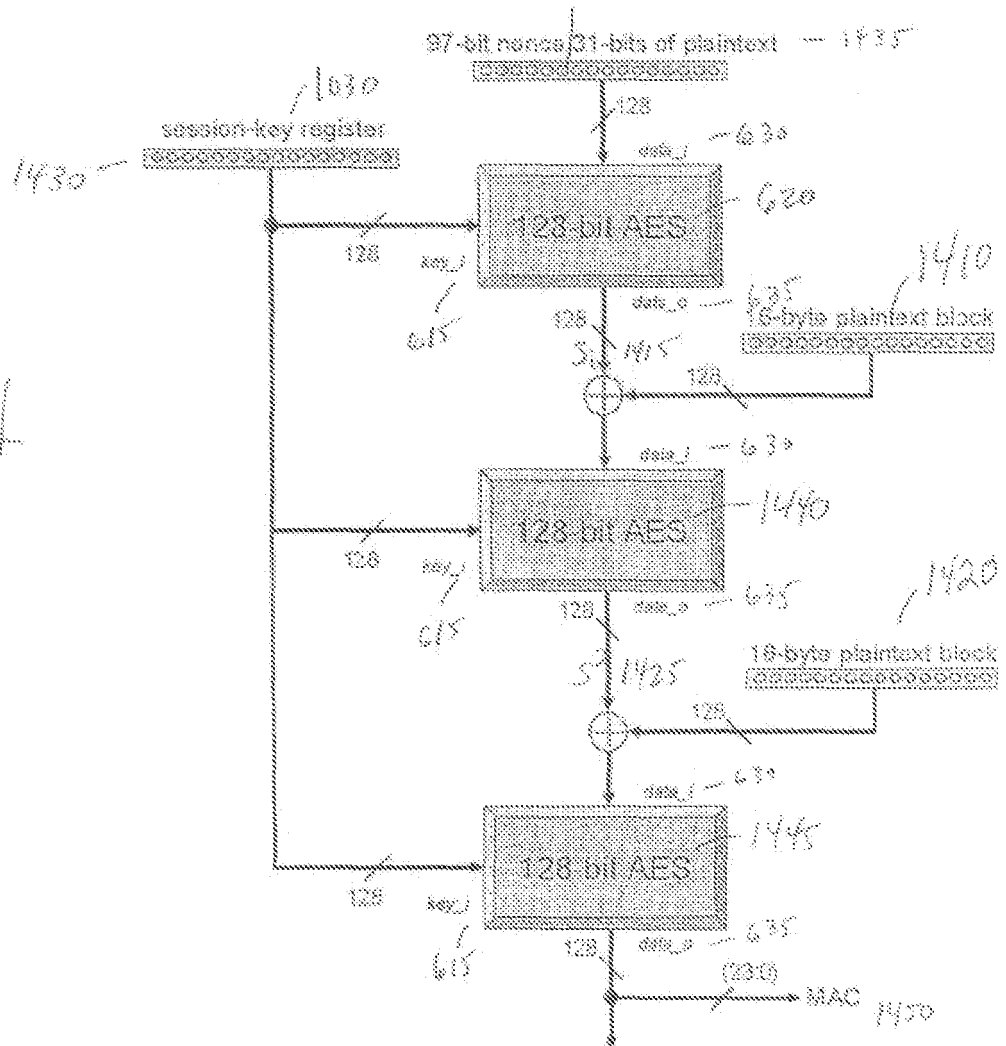
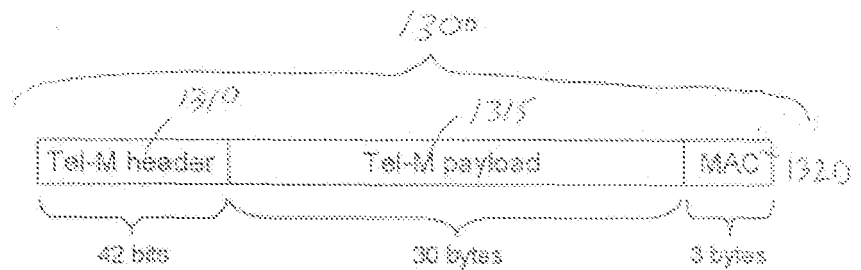


Fig 13



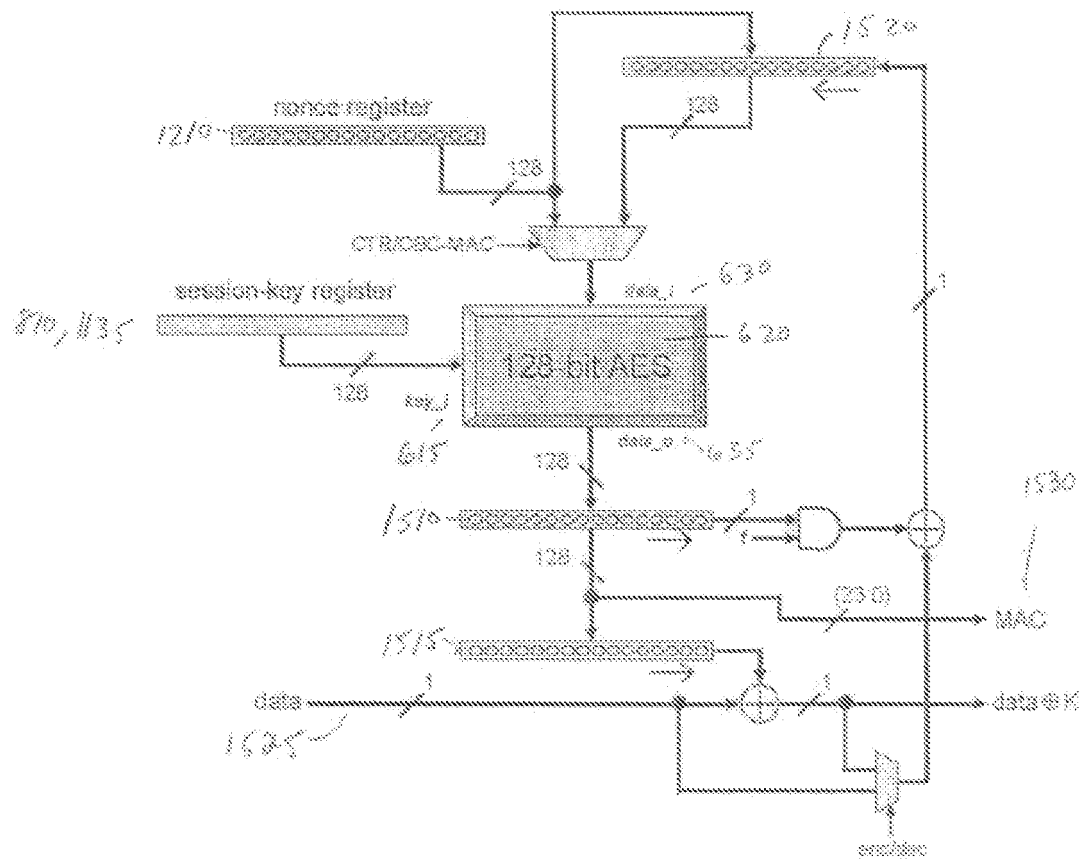


Fig 15

Backdoor - access protocol

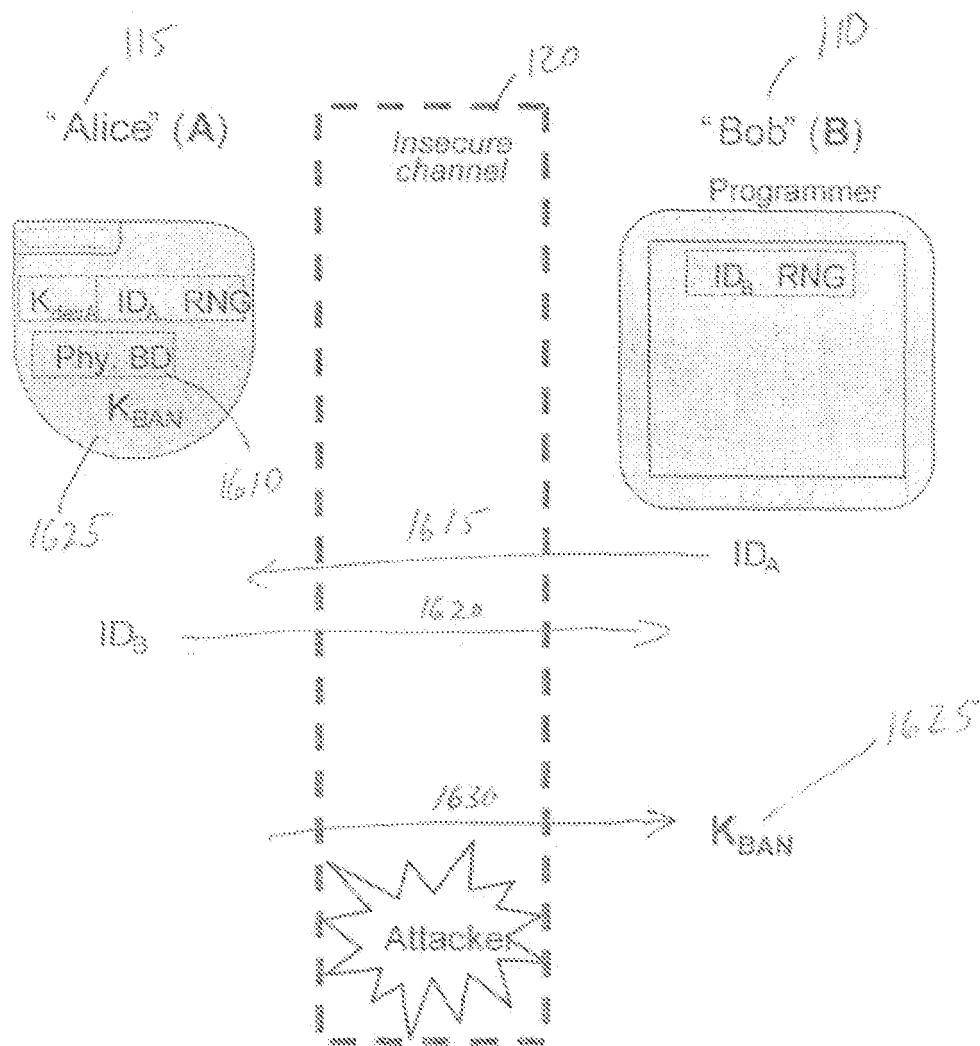


Fig 16

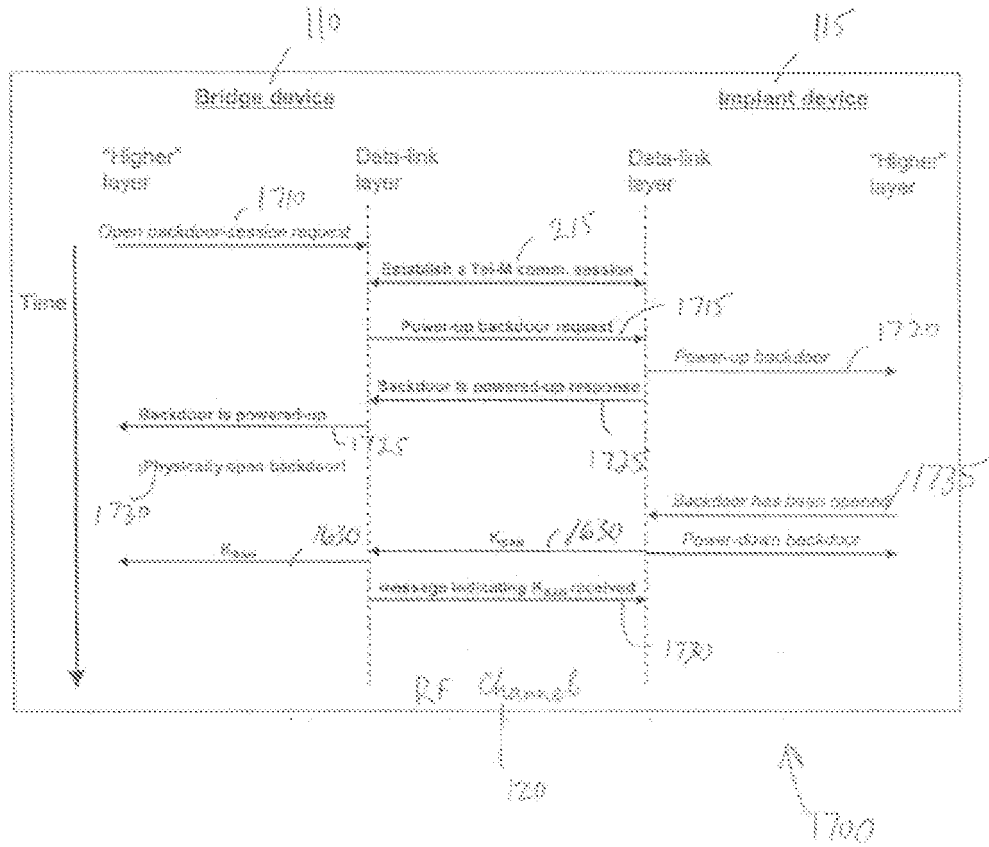


Fig 17

FIG. 18

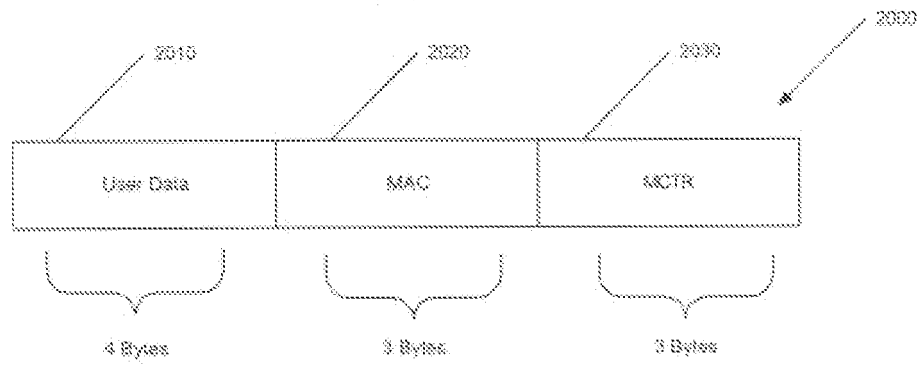


FIG. 19

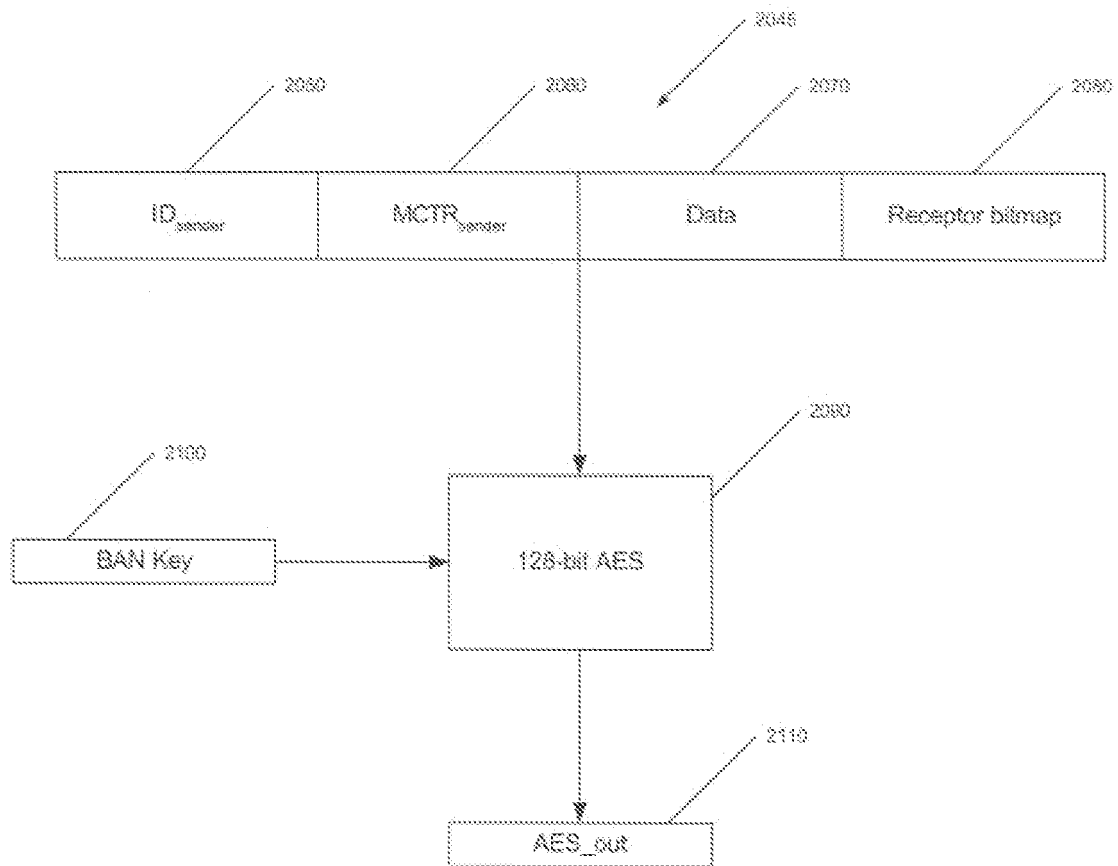


FIG. 20

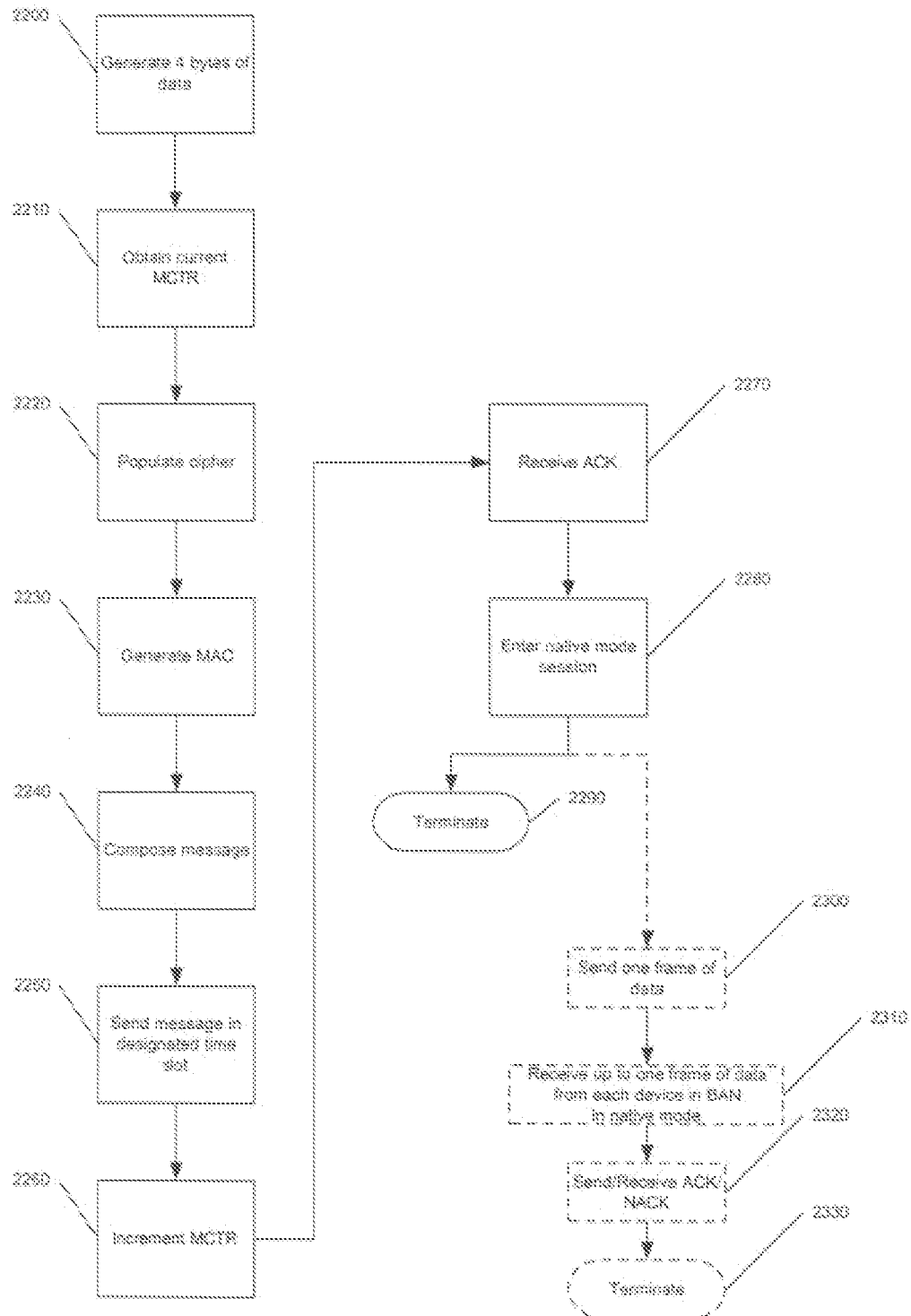
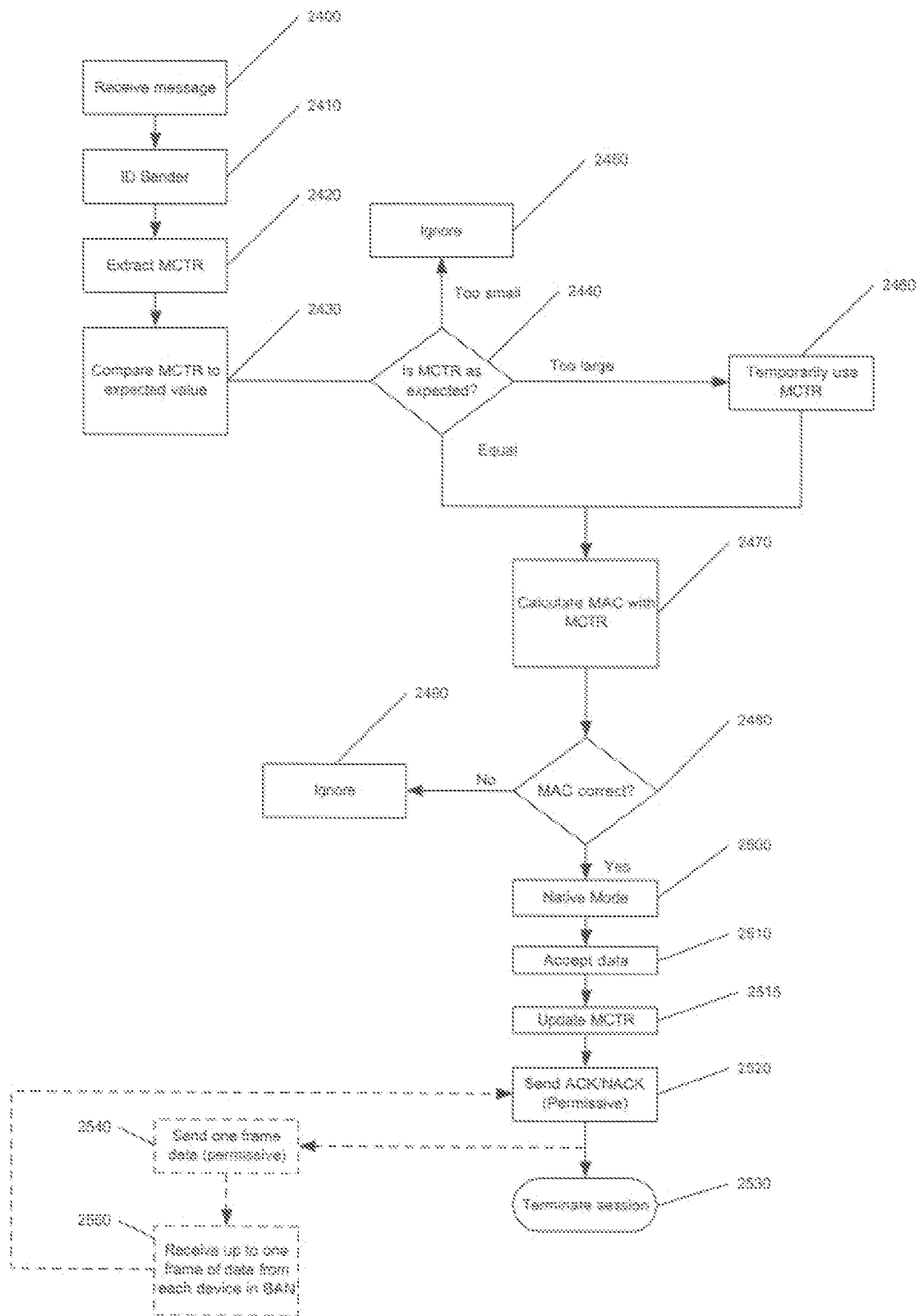


FIG. 21



专利名称(译)	安全的遥测链接		
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申请号	EP2007813921	申请日	2007-08-09
[标]申请(专利权)人(译)	美敦力公司		
申请(专利权)人(译)	美敦力公司 , INC.		
当前申请(专利权)人(译)	美敦力公司 , INC.		
[标]发明人	CORNDORF ERIC D		
发明人	CORNDORF, ERIC D.		
IPC分类号	H04L9/32 H04L9/08 A61N1/372 A61B5/00		
CPC分类号	H04L63/062 A61B5/0024 A61N1/37282 H04L9/0643 H04L9/0844 H04L9/3242 H04L63/12 H04L2209/80 H04L2209/88		
优先权	11/828940 2007-07-26 US 11/828886 2007-07-26 US 11/828898 2007-07-26 US 60/838718 2006-08-18 US 11/828867 2007-07-26 US		
外部链接	Espacenet		

摘要(译)

通信协议用于向遥测业务提供数据隐私，消息完整性，消息新鲜度和用户认证，尤其是来自体域网中的可植入医疗设备。通过使用从设备标识号和伪随机数导出的类似令牌的随机数和短暂会话密钥来提供加密，消息完整性和消息新鲜度。