Office de la Propriété Intellectuelle du Canada
Un organisme d'Industrie Canada

Canadian Intellectual Property Office
An agency of Industry Canada

CA 2895990 A1 2014/06/26

(21) 2 895 990

(12) DEMANDE DE BREVET CANADIEN
CANADIAN PATENT APPLICATION

(13) A1

(86) Date de dépôt PCT/PCT Filing Date: 2013/12/16
(87) Date publication PCT/PCT Publication Date: 2014/06/26
(85) Entrée phase nationale/National Entry: 2015/06/19
(86) N° demande PCT/PCT Application No.: US 2013/075349
(87) N° publication PCT/PCT Publication No.: 2014/099760
(30) Priorité/Priority: 2012/12/21 (US61/745,025)

(51) Cl.Int./Int.Cl. *A61B 8/12* (2006.01)

(71) Demandeurs/Applicants:
MAI, JEROME, US;
HANCOCK, ANDREW, US

(72) Inventeurs/Inventors:
MAI, JEROME, US;
HANCOCK, ANDREW, US

(74) Agent: SMART & BIGGAR

(54) Titre : IMAGERIE A ULTRASONS POURVUE D'UNE DENSITE DE LIGNE VARIABLE
(54) Title: ULTRASOUND IMAGING WITH VARIABLE LINE DENSITY

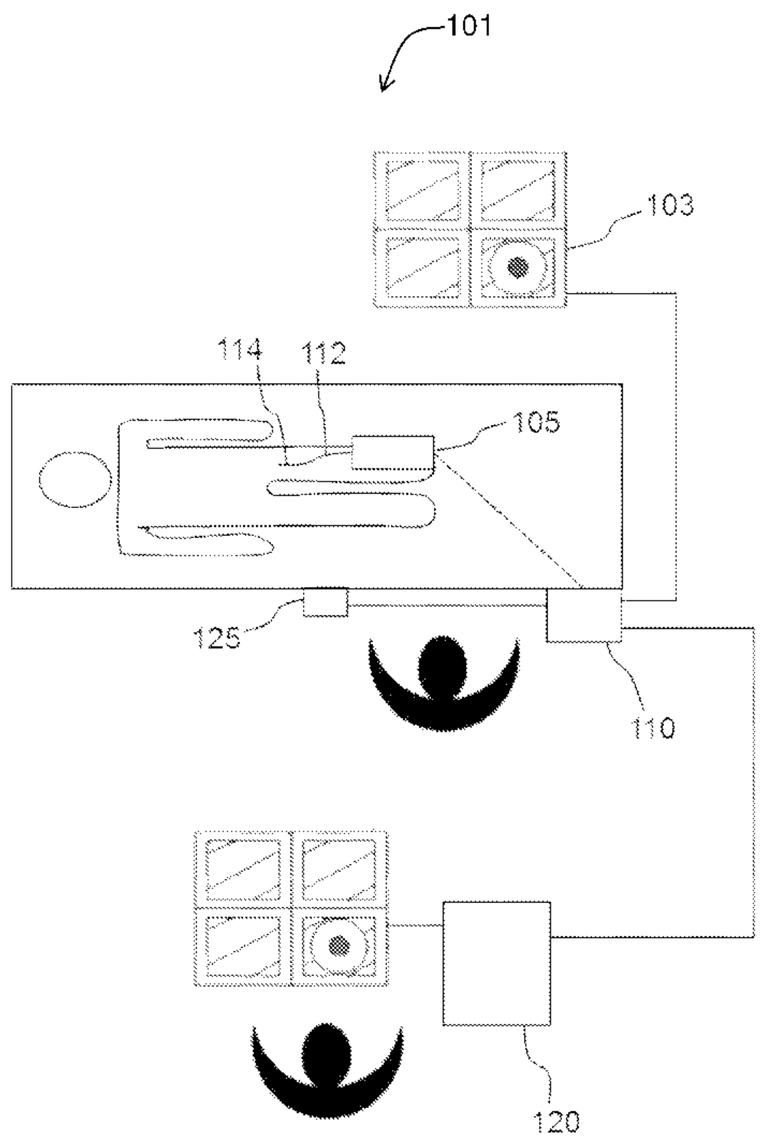

FIG. 1

(57) Abrégé/Abstract:
The invention generally relates to intravascular ultrasound imaging and to systems and methods to improve line density and image quality. The invention provides an intravascular imaging system that uses a clock device to provide a set of trigger signals for each revolution of the imaging catheter and capture various patterns of scan lines for each set of trigger signals. The system can be operated to capture two scan lines of data for each trigger signal thereby doubling scan line density compared to existing systems. The clock device can be provided by hardware, such as a rotary encoder, that is configured to define a maximum number of trigger

CA 2895990 A1 2014/06/26
(21) 2 895 990
(13) A1

(57) Abrégé(suite)/Abstract(continued):
signals that the module can provide per rotation of the catheter.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
26 June 2014 (26.06.2014)

WIPO | PCT

(10) International Publication Number
WO 2014/099760 A1

(51) International Patent Classification:
A61B 1/00 (2006.01) *A61B 5/00* (2006.01)
A61B 1/06 (2006.01) *A61B 6/00* (2006.01)
A61B 1/07 (2006.01) *A61B 8/00* (2006.01)

(21) International Application Number:
PCT/US2013/075349

(22) International Filing Date:
16 December 2013 (16.12.2013)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/745,025 21 December 2012 (21.12.2012) US

(72) Inventors; and
(71) Applicants : **MAI, Jerome** [US/US]; 405 Safflower Place, West Sacramento, CA 95691 (US). **HANCOCK, Andrew** [US/US]; 3621 Faberge Way, Sacramento, CA 95826 (US).

(74) Agents: **MEYERS, Thomas, C.** et al.; Brown Rudnick LLP, One Financial Center, Boston, MA 02111 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM,

[Continued on next page]

(54) Title: ULTRASOUND IMAGING WITH VARIABLE LINE DENSITY

(57) Abstract: The invention generally relates to intravascular ultrasound imaging and to systems and methods to improve line density and image quality. The invention provides an intravascular imaging system that uses a clock device to provide a set of trigger signals for each revolution of the imaging catheter and capture various patterns of scan lines for each set of trigger signals. The system can be operated to capture two scan lines of data for each trigger signal thereby doubling scan line density compared to existing systems. The clock device can be provided by hardware, such as a rotary encoder, that is configured to define a maximum number of trigger signals that the module can provide per rotation of the catheter.

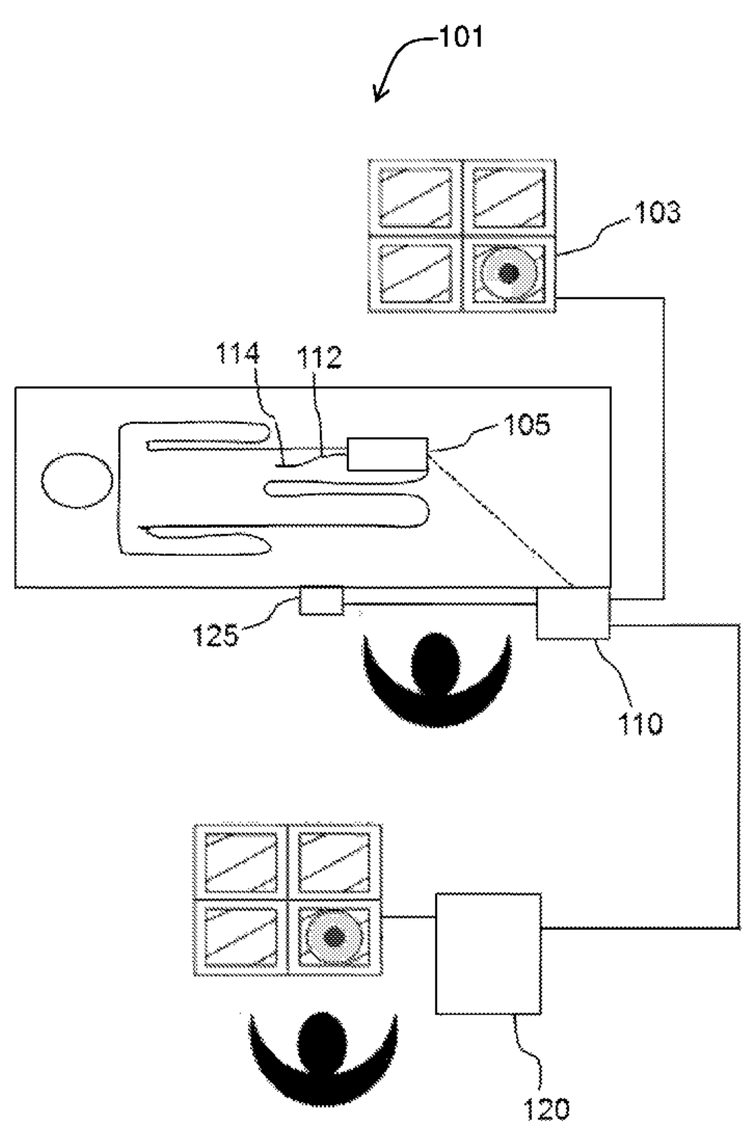

FIG. 1

WO 2014/099760 A1

WO 2014/099760 A1

TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

ULTRASOUND IMAGING WITH VARIABLE LINE DENSITY

Cross-Reference to Related Application

This application claims the benefit of, and priority to, U.S. Provisional Application Serial No. 61/745,025, filed December 21, 2012, the contents of which are incorporated by reference.

Field of the Invention

The invention generally relates to intravascular ultrasound imaging and to systems and methods to improve line density and image quality.

Background

A vulnerable plaque is a kind of plaque on an artery wall characterized by a core layer of dead tissue covered with a very thin fibrous cap. This fibrous cap is prone to rupture, releasing bits of the dead tissue into the bloodstream. This material can then flow to the brain or heart and cause a stroke or a heart attack. Vulnerable plaques are identified in autopsies but existing medical imaging systems do not all provide good enough resolution to faithfully identify the thin structures involved.

Intravascular ultrasound (IVUS) is used to study arterial plaques. Typical IVUS systems use a long, thin catheter with an ultrasonic transducer at the tip. The catheter is inserted into a patient's arteries and rotated to capture a series of lines of image data. One rotational set of those lines can be composed into a 2D display giving a cross-sectional view of the artery. However, since the catheter rotates in an organic environment, subject to non-uniform stresses, the rotational speed is variable. As a result, if the system fires a series of scan lines at regular time intervals, there will not be any intrinsic grouping of scan lines into rotational sets. Instead, systems include a mechanical device that fires each scan line at a specific rotational position.

One such device is a rotary encoder. The hardware inside of a rotary encoder creates on distinct electrical signal per step of rotation. Because the hardware provides steps in powers of two, existing rotary encoders provide, for example, 512 or 1024 steps per revolution. IVUS systems are wired so that each step provides the electrical impulse that fires the transducer. To increase scan line density requires redesigning a system or making a new system to operate with

a higher density rotary encoder. However, the problem is compounded by the recognition that rotary encoders can only have so many steps. Too many, and the electronics will not be able to faithfully detect each step speeds typical of IVUS systems.

Summary

The invention provides an intravascular imaging system that uses a mechanical device to provide a set of trigger signals for each revolution of an imaging catheter and that capture patterns of scan lines for each set of trigger signals.

The system can be operated to capture two scan lines of data for each trigger signal thereby doubling scan line density compared to existing systems. Increased scan line density allows for operations that provide high quality, high-resolution images. For example, a high density of adjacent scanlines can be averaged, which greatly improves the signal-to-noise ratio, and thus the final resolution, of the image. Adjacent scan lines can be captured at different frequencies, which can aid in discriminating among blood and different tissue types. Different frequencies allows for the use of a fundamental frequency and one or more of its harmonics, i.e., harmonic imaging, which can improve resolution, reduce spurious artifacts, and improve SNR. Since an imaging system can capture very high resolution images of the tissue surrounding the catheter, the system can be used to view very delicate structures within a patient's arteries. Thus, systems and methods of the invention have the potential to be used in medical diagnostics for identifying very fine structures and possibly diagnosing such conditions as vulnerable plaque before those conditions become symptomatic.

In certain aspects, the invention provides a method for intravascular imaging that includes introducing an ultrasonic transducer into a vessel, the transducer being disposed at a distal portion of a catheter and using a module operably coupled to a proximal portion of the catheter to rotate the transducer and to provide a plurality of trigger signals. Each trigger signal triggers a first sequencer operation and a second sequencer operation.

The module may include a clock device, such as a rotary encoder, in which hardware is configured to define a maximum number of trigger signals that the module can provide per rotation of the catheter. The method provides for performing a number of sequencer operations per rotation greater than the maximum number of trigger signals provided by the clock device. Each sequencer operation can include stimulating the transducer to transmit an ultrasonic signal

into the vessel, using the transducer to receive a backscattered signal from the vessel, or both. In some embodiments, the first sequencer operation involves ultrasonic imaging at a first frequency and the second sequencer operation involves imaging at a second frequency. In certain embodiments, the first sequencer operation involves only sending an ultrasonic signal and the second sequencer operation involves sending and receiving, e.g., to detect harmonics or interference from the sent signals. The first sequencer operation may be used to acquire a scanline with a short pulse and the second sequencer operation to acquire a scanline with a long pulse. Where the clock device includes hardware defining a maximum number of trigger signals that can be provided per full rotation of the catheter, methods include capturing a number of A lines of data per rotation of the catheter greater than the maximum number of trigger signals.

In related aspects, the invention provides a system for intravascular imaging. The system includes an ultrasonic catheter, a control system connected to the catheter, a rotary encoder operable to produce a plurality of rotary encodes per each 360° rotation of the catheter, and a processor in communication with the rotary encoder configured to issue varying patterns of transmit triggers in response to each plurality of rotary encodes.

In other aspects, the invention provides a system for intravascular imaging that uses an ultrasonic transducer disposed at a distal portion of a catheter and a module operably coupled to a proximal portion of the catheter. The system rotates the transducer and to provides a plurality of trigger signals. In response to each trigger signal, a processor triggers a plurality of sequencer operations. Preferably, the module includes a clock device such as a rotary encoder with hardware that defines a maximum number of trigger signals that the module can provide per rotation. The system can perform a number of sequencer operations per rotation greater than the maximum number of trigger signals provided by the rotary encoder.

In other aspects, the invention provides a method for intravascular imaging that proceeds by introducing an ultrasonic transducer into a vessel, the transducer being disposed at a distal portion of a catheter and using a module operably coupled to a proximal portion of the catheter to rotate the transducer 360° and to produce a plurality of trigger signals. For each trigger signal, a plurality of A lines of data are captured.

Brief Description of the Drawings

FIG. 1 shows a diagram of an exemplary IVUS system.

FIG. 2 depicts a control unit.

FIG. 3 illustrates the keypad of a control unit.

FIG. 4 presents a schematic diagram of a computer component of an IVUS system.

FIG. 5 diagrams a circuit board of the system.

FIG. 6 shows a relationship among signals of components of the invention.

FIG. 7 diagrams a sequence of events according to certain embodiments.

FIG. 8 diagrams capturing two lines per encode according to certain embodiments.

FIG. 9 diagrams a sequence for harmonic imaging according to certain embodiments.

FIG. 10 shows a sequence for interleaved imaging.

FIG. 11 illustrates firing unlike transmits per each encode.

FIG. 12 depicts firing multiple unlike transmits across a plurality of encodes.

FIG. 13 shows the use of separate encodes for transmit and receipt.

Detailed Description

The invention provides systems and methods by which intravascular imaging can be performed with high line density, varying frequencies of scan lines, and patterns of scan lines other than one scan line per rotary encode.

FIG. 1 shows a diagram of an exemplary IVUS system 101 according to certain embodiments of the invention. An operator uses control station 110 and optional navigational device 125 to operate catheter 112 via patient interface module (PIM) 105. At a distal tip of catheter 112 is an ultrasonic transducer 114. Computer device 120 works with PIM 105 to coordinate imaging operations. Imaging operations proceed by rotating an imaging mechanism via catheter 112 while transmitting a series of electrical impulses to transducer 114 which results in sonic impulses being sent into the patient's tissue. Backscatter from the ultrasonic impulses is received by transducer 114 and interpreted to provide an image on monitor 103. System 101 is operable for use during diagnostic ultrasound imaging of the peripheral and coronary vasculature of the patient. System 101 can be configured to automatically visualize boundary features, perform spectral analysis of vascular features, provide qualitative or quantitate blood flow data, or a combination thereof. Systems for IVUS suitable for use with the invention are discussed in U.S. Pat. 6,673,015; U.S. Pub. 2012/0265077; and U.S. RE40,608 E, the contents of which are incorporated by reference in their entirety for all purposes. Systems for IVUS are discussed in

U.S. Pat. 5,771,895; U.S. Pub. 2009/0284332; U.S. Pub. 2009/0195514 A1; U.S. Pub. 2007/0232933; and U.S. Pub. 2005/0249391, the contents of each of which are hereby incorporated by reference in their entirety. It will appreciated that methods of the invention are operable with phased array IVUS, which can be performed using an imaging catheter with a lumen therethrough. The trigger signals described herein can be applied to individual ones of the ultrasonic transducers in a phased-array IVUS array. Phased array IVUS is described in U.S. Pub. 2013/0150716 to Stigall, the contents of which are incorporated by reference. A rotary encoder (discussed in more detail herein) can be used to drive a signal around an array in series, even where the phased array itself does not rotate.

Operation of system 101 employs a sterile, single use intravascular ultrasound imaging catheter 112. Catheter 112 is inserted into the coronary arteries and vessels of the peripheral vasculature under angiographic guidance. Catheters are described in U.S. Pat. 7,846,101; U.S. Pat. 5,771,895; U.S. Pat. 5,651,366; U.S. Pat. 5,176,141; U.S. Pub. 2012/0271170; U.S. Pub. 2012/0232400; U.S. Pub. 2012/0095340; U.S. Pub. 2009/0043191; U.S. Pub. 2004/0015065, the contents of which are incorporated by reference herein in their entirety for all purposes. System 101 may be integrated into existing and newly installed catheter laboratories (i.e., “cath labs” or “angiography suites”). The system configuration is flexible in order to fit into the existing catheter laboratory work flow and environment. For example, the system can include industry standard input/output interfaces for hardware such as navigation device 125, which can be a bedside mounted joystick. System 101 can include interfaces for one or more of an EKG system, exam room monitor, bedside rail mounted monitor, ceiling mounted exam room monitor, and server room computer hardware.

System 101 connects to the IVUS catheter 112 via PIM 105, which may contain a type CF (intended for direct cardiac application) defibrillator proof isolation boundary. All other input/output interfaces within the patient environment may utilize both primary and secondary protective earth connections to limit enclosure leakage currents. The primary protective earth connection for controller 125 and control station 110 can be provided through the bedside rail mount. A secondary connection may be via a safety ground wire directly to the bedside protective earth system. Monitor 103 and an EKG interface can utilize the existing protective earth connections of the monitor and EKG system and a secondary protective earth connection from the bedside protective earth bus to the main chassis potential equalization post. Monitor

103 may be, for example, a standard SXGA (1280 × 1024) exam room monitor. System 101 includes control system 120 to coordinate operations.

Computer device 120 generally includes one or more processor coupled to a memory. Any suitable processor can be included such as, for example, a general-purpose microprocessor, an application-specific integrated circuit, a massively parallel processing array, a field-programmable gate array, others, or a combination thereof. In some embodiments, computer 120 can include a high performance dual Xeon based system using an operating system such as Windows XP professional. Computer 120 may be provided as a single device (e.g., a desktop, laptop, or rack-mounted unit, or computer 120 may include different machines coupled together (e.g., a Beowulf cluster, a network of servers, a server operating with a local client terminal, other arrangements, or a combination thereof). A computer according to the invention generally includes a processor coupled to memory and one or more input/output (I/O) devices. A processor generally refers to a computer microchip such as the processor sold under the trademark CORE I7 by Intel (Santa Clara, CA).

Memory generally includes one or more devices for random access, storage, or both. Preferably, memory includes a tangible, non-transitory computer readable medium, and may be provided by one or more of a solid state drive (SSD), a magnetic disc drive (aka, “a hard drive”), flash memory, an optical drive, others, or a combination thereof.

An I/O device may include one or more of a monitor, keyboard, mouse, touchscreen, Wi-Fi card, cell antenna, Ethernet port, USB port, light, accelerometer, speaker, microphone, drive for removable disc, others, or a combination thereof. Preferably, any combination of computer in system 501 may communicate through the use of a network, which may include communication devices for internet communication, telephonic communication, others, or a combination thereof.

Computer device 120 may be configured to perform processing on more than one image modality (e.g., in parallel). For example, computer 120 may operate with real time intravascular ultrasound imaging while simultaneously running a tissue classification algorithm referred to as virtual histology (VH). The application software can include a DICOM3 compliant interface, a work list client interface, interfaces for connection to angiographic systems, or a combination thereof. Computer device 120 may be located in a separate control room, the exam room, or in an equipment room and may be coupled to one or more of a custom control station, a second control

station, a joystick controller, a PS2 keyboard with touchpad, a mouse, or any other computer control device.

Computer device 120 may generally include one or more USB or similar interfaces for connecting peripheral equipment. Available USB devices for connection include the custom control stations, optional joystick 125, and a color printer. In some embodiments, computer 120 includes one or more of a USB 2.0 high speed interface, a 10/100/1000 baseT Ethernet network interface, AC power input, PS2 jack, potential equalization post, 1 GigE Ethernet interface, microphone & line inputs, line output VGA Video, DVI video interface, PIM interface, ECG interface, other connections, or a combination thereof. As shown in FIG. 1, computer device 120 is generally linked to control station 110.

FIG. 2 shows a control station 110 according to certain embodiments. Control station 110 may be provided by any suitable device, such as a computer terminal (e.g., on a kiosk). In some embodiments, control station 110 is a purpose built device with a custom form factor. A slide out keyboard is located on the bottom for manual text entry. Control station 110 may be designed for different installations options. The station can be placed directly on a desktop surface. With the optional bedside mounting kit, control station 110 can be affixed directly to the bedside rail. This mounting kit is slipped over the rail and fixed in place by tightening two hand screws. Control station 110 can include a standard four hole VESA mount on the underside to allow other mounting configurations. Control station 110 may provide a simple-to-use interface with frequently-operated functions mapped to unique switches. Control station 110 may be powered from, and may communicate with, computer 120 using a standard USB 1.1 interface. The system may include a control panel 115. In some embodiments, multiple control panels 115 are mounted in both the exam room and/or the control room. A control station for use with the invention is discussed in U.S. Pat. 8,289,284, the contents of which are incorporated by reference in their entirety for all purposes.

FIG. 3 shows an control panel 115 of control station 110 according to certain embodiments. Frequently-operated functions are mapped to contact closure switches. Those dome switches are covered with a membrane overlay. The use of dome switches provides a tactile feedback to the operator upon closure. Control panel 115 may include a pointing device such as a trackball to navigate a pointer on the graphical user interface of the system.

Control panel 115 may include several screen selection keys. The settings key is used to change system settings like date and time and also permits setting and editing default configurations. The display key may be used to provide enlarged view for printing. In some embodiments, the print key prints a 6 × 4 inch photo of the current image on the screen. Control panel 115 may include a ringdown key that toggles the operation of ringdown subtraction. A chroma key can turn blood flow operations on and off. The VH key can operate the virtual histology engine. A record, stop, play, and save frame key are included for video operation. Typically, the home key will operate to display the live image. A menu key provides access to measurement options such as diameter, length, and borders. Bookmark can be used while recording a loop to select specific areas of interest. Select (+) and Menu (-) keys are used to make selections.

In some embodiments, the system includes a joystick for navigational device 125. The joystick may be a sealed off-the-shelf USB pointing device used to move the cursor on the graphical user interface from the bedside. System 101 may include a control room monitor, e.g., an off-the-shelf 19" flat panel monitor with a native pixel resolution of 1280 × 1024 to accept DVI-D, DVI-I and VGA video inputs.

Control station 110 is operably coupled to PIM 115, from which catheter 112 extends. Catheter 112 includes an ultrasound transducer 114 located at the tip. Any suitable IVUS transducer may be used. For example, in some embodiments, transducer 114 is driven as a synthetic aperture imaging element. Imaging transducer 114 may be approximately 1 mm in diameter and 2.5 mm in length. In certain embodiments, transducer 114 includes a piezoelectric component such as, for example, lead zirconium nitrate or PZT ceramic. The transducer may be provided as an array of elements (e.g., 64), for example, bonded to a Kapton flexible circuit board providing one or more integrated circuits. This printed circuit assembly may rolled around a central metal tube, back filled with an acoustic backing material and bonded to the tip of catheter 114. In some embodiments, signals are passed to the system via a plurality of wires (e.g., 7) that run the full length of catheter 112. The wires are bonded to the transducer flex circuit at one end and to a mating connector in PIM 105 at the other. The PIM connector may also contains a configuration EPROM. The EPROM may contain the catheter's model and serial numbers and the calibration coefficients which are used by the system. The PIM 105 provides the patient electrical isolation, the beam steering, and the RF amplification. PIM 105 may

additionally include a local microcontroller to monitor the performance of the system and reset the PIM to a known safe state in the event of loss of communication or system failure. PIM 105 may communicate with computer device 120 via a low speed RS232 serial link.

FIG. 4 describes components of computer device 120 according to certain embodiments. Computer device 120 may include a motherboard 129 that includes an IVUS signal generation and processing system. The signal generation and processing system may comprises an analog printed circuit assembly (PCA) 131, an digital PCA 133, one or more filter modules, and a VH board 135. Analog PCA 131 and digital PCA 133 are used to excite transducer 114 via catheter 112 and to receive and process the gray scale IVUS signals. The VH board 135 is used to capture and pre-process the IVUS RF signals and transfer them to the main VH processing algorithm as run by a computer processor system (e.g., dual Xeon processors). PIM 105 is directly connected to the analog PCA 131. A computer system that includes a computer, such as one like that depicted in FIG. 4, can be configured to perform the signal processing of the invention. Exemplary signal processing and systems therefore are discussed in U.S. Pat. 8,298,147; U.S. Pat. 8,187,191; U.S. Pat. 6,450,964; U.S. Pat. 5,485,845; U.S. Pub. 2012/0220874; U.S. Pub. 2012/0184853; and U.S. Pub. 2007/0232933, the contents of which are incorporated by reference herein in their entirety.

FIG. 5 provides a schematic of analog PCA 131 and digital PCA 133 according to certain embodiments of the invention. Analog PCA 131 is shown to include amplifier 141, band pass filter 145, mixer 149, low pass filter 153, and analog-to-digital converter (ADC) 157. (Here, the system is depicted as being operable to convert the transducer RF data to “In-Phase” and “Quadrature” (IQ) data. According to this embodiment, ADC 157 is 12-bits wide and converts the IQ data to a dual digital data stream.) Analog board 131 further includes an interface module 161 for PIM 105, as well as a clock device 169.

Digital PCA 133 is depicted as having an acquisition FPGA 165, as well as a focus FPGA 171, and a scan conversion FPGA 179. Focus FPGA 171 provides the synthetic aperture signal processing and scan conversion FPGA 179 provides the final scan conversion of the transducer vector data to Cartesian coordinates suitable for display via a standard computer graphics card on monitor 103. Digital board 133 further optionally includes a safety microcontroller 181, operable to shut down PIM 105 as a failsafe mechanism. Preferably, digital PCA 133 further includes a PCI interface chip 175. It will be appreciated that this provides but

one exemplary illustrative embodiment and that one or skill in the art will recognize that variant and alternative arrangements may perform the functions described herein. Clock device 169 and acquisition FPGA 165 operate in synchronization to control the transmission of acquisition sequences.

In certain aspects, clock device 169 provides a source of trigger signals and acquisition FPGA 165 triggers firing sequences that collect scan lines of data.

FIG. 6 describes events that may happen in synchrony under coordination of system 101. As shown in FIG. 6, the horizontal axis represents time, while vertical space is used to depict different things that occur simultaneously. Clock device 169 provides a series of trigger signals, here labeled "ROTENC". A processor such as acquisition FPGA 165 uses a module, here labeled SSEQ, to call firing sequencers. Two firing sequencers are depicted, here labeled FSEQ1 and FSEQ2, respectively. Each firing sequence (FSEQ) includes an operation that begins by sending a transmit trigger (here labeled TX_TRIG). The transmit trigger (e.g., a signal sent by acquisition FPGA 165) causes transducer 114 to be excited by an analog impulse and thus to interrogate the patient's tissue with an ultrasonic pulse. Each sequencer operation may typically include acquisition commands (shown as ACQEN, TRANS, and ACTRL) that follow the transmit trigger (although alternative sequencer operations, discussed below, may be performed). Thus, each set of acquisition commands within the sequencer operations provides new lines of data to system 101.

It will be noted that FIG. 6 depicts signal forms as binary states over time (e.g., of a type capable of being sent by devices such as rotary encoders), and the combination of signals can be used (e.g., by acquisition FPGA 165) to order the progression of sequencer operations. For example, FSEQ1 can be ordered to occur only after SSEQ has gone high and ROTENC has been high at least once. FSEQ2 can depend on SSEQ going high a second time, which can be programmed to occur after a wait step after FSEQ1's acquisition commands go low.

The preferred timing of the commands may relate to the operational properties of imaging catheter 112 as well as to the properties of sound. In typical intravascular imaging operations, one "frame" generally refers to one set of data that provides a cross-sectional view of the artery. A catheter that rotates at 1800 RPM makes 30 complete rotations per second. Thus, each frame of data is collected in one thirtieth of a second. Existing, prior art systems used a

clock device to provide a fixed number of event triggers for each frame of data acquisition. Prior art systems used the event triggers to fire a ultrasonic impulse and capture a line of data.

Some systems use rotary encoders. Rotary encoders include one or more conductive or optical rings that are encoded around the perimeter with a binary on/ off state. For example, a conductive encoder may include copper on half of the ring and plastic on another half. An optical encoder may include an opaque disk with punch-outs that allow an optical signal to go across. Since each ring could encode binary information (on or off; conductive or not; light or dark), and since rotary encoder include a plurality of rings, the number of steps around a full rotation that a rotary encoder can detect is a power of two. The simplest rotary encoder may have two or four steps. Rotary encoders with, for example, 512 or 1024 steps are used. One step of a rotary encoder represents the smallest angular offset that the encoder is physically capable of discriminating. Thus, for example, a 512 step rotary encoder mounted on an imaging catheter is only capable of providing a unique signal, or event trigger, for each 360/512 degrees of rotation (e.g., 0.703 degrees/step). In prior art imaging systems, the number of event triggers from the clock device 169 defines the line density of each image scan. If the system included a 512 step rotary encoder, the system produced 512 lines per frame of image data. Additionally, it is understood that rotary encoders with too many steps do not provide reliable fidelity in imaging systems.

Here, as shown in FIG. 6, systems and methods of the invention provide a sequencer operation performed by a processor that uses a trigger event from clock device 169 to trigger more than one sequencer operation and thus fire more than one ultrasound pulse into tissue for each trigger from the clock.

In some embodiments, increasing the line density includes adjusting the scan depth. For example, if catheter 112 rotates 30 × per second, then each rotation requires (1/30) seconds, or 0.0333 seconds. If transducer 114 transmits an ultrasonic pulse at a baseline frequency of 512 per each rotation, then the transmissions will be separated by a baseline period of (0.0333/512) seconds, or about 65 microseconds (μs). If the speed of sound in blood and tissue is taken to be 1,560 m/s—or 1.56 mm/μs—then each ultrasonic pulse will be able to travel a distance, by d=rt, of 1.56 mm/μs × 65 μs, which gives about 100 mm. Given that ultrasonic imaging requires the sound to make a round trip, and given that the hardware requires a little bit of time for transmitting the electronic signal and coordinating the operations, the exemplary system would

be able to image to a baseline depth of almost about 50 mm, e.g., about 30 to about 40 mm. In certain embodiments, doubling the line density halves the time between transmissions (i.e., 2× frequency → 0.5× period) and allows scanning to about half the baseline depth, e.g., to about 15 to about 20 mm. However, doubling the scan line density can greatly improve image quality by increasing resolution, decreasing signal-to-noise ratio (SNR), or a combination thereof.

In some embodiments, scanning depth is not limited and a computer processor (e.g., acquisition FPGA 165) receives backscattered ultrasound impulses from the immediately previous transmission as well as from one or more prior transmission and decodes the overlapping or interfering signals using, e.g., interferometric processing techniques such as fast Fourier transform. Additionally or alternatively, in other embodiments such as those discussed below, system 101 is operated such that a firing sequence operation includes operations other than just one transmit and one receive per firing sequence operation.

FIG. 7 provides a high-level block diagram of use of system 101 to trigger a plurality of sequencer operations for each of a plurality of trigger operations. As shown in FIG. 7, clock device 169 issues a firing trigger periodically. For example, if clock device 169 is a 512-step rotary encoder and catheter 112 of system 101 rotates at 1800 RPM, then each trigger will be a rotary encode separated by a period of about 65 μs. In this illustrative example, the period of a rotary encoder step is the minimum amount of catheter rotation that the system is capable of physically coordinating a signal with through the use of clock device 169. Acquisition FPGA 165 responds to each trigger signal by firing three firing sequences. Each firing sequence includes a transmit (Tx) trigger and a receive (Rx) trigger. Each transmit trigger causes transducer 114 to issue a pulse of ultrasonic energy and each receive trigger causes transducer 114 to operate for a period (e.g., about 1/6 of 65 μs) to receive backscattered ultrasonic signals and relay those received signals to focus FPGA 171. Here, each rotary encode is depicted as resulting in three firing sequencer operations. However, other operations are provided.

FIG. 8 illustrates use of a clock device 169 to provide two sequencer operations for each firing trigger. As shown in FIG. 8, each sequencer operation includes a transmit (Tx) trigger and a receive (Rx) trigger, as discussed above.

FIG. 9 shows a pattern of use of system 101 for harmonic imaging. As shown in FIG. 9, each rotary encode causes first one transmission, then another, followed by a receipt. Here, the adjacent transmissions may include sound at harmonic frequencies. For example, a first Tx may

define one frequency, and the subsequent Tx may include sound at the first harmonic of the one frequency. Through this methodology, tissue can be examined at higher order frequencies.

FIG. 9 also illustrates a pattern of use for pulse inversion imaging. Pulse inversion imaging could be used to boost the image signal and improve resolution. Each transmit could be at the same frequency, but the first begins with a positive amplitude and the second begins the a negative (e.g., in phase or not). Thus a transducer 114 could be used to send a pulse train, and the received signal (at Rx) will be based on the whole train. For neighboring acquisitions, different pulse trains can be used, and those can be added or averaged (e.g., at focus FPGA 171).

FIG. 10 illustrates use of system 101 for interleaved imaging. Here, each trigger signal is used to trigger a firing sequencer operation that is different than the prior firing sequencer operation. In one embodiment, this provides A lines that alternate in frequency. For example, if every other A line is at 20 Hz with the rest being at 60 Hz, the different frequencies can be used simultaneously to easily discern both the luminal border (e.g., the blood/ tissue boundary) and the medial-advential border (e.g., defining a perimeter of an adverse plaque). Accordingly, operating system 101 according to a pattern described by FIG. 10 can provide an estimate of arterial % occlusion in a single IVUS scan.

FIG. 11 depicts an additional or alternative approach to interleaved imaging. Here, each trigger signal is used to fire two sequencing operations, each of which includes a different transmission (e.g., different frequencies as discussed above). Methods and systems of the invention have particular application in increasing IVUS bandwidth as shown, for example, in FIG. 11. Bandwidth refers to a difference between upper and lower cutoff in spectrum (e.g., in MHz). Where a single transmit occurs at, for example, 40 MHz, the full bandwidth may range from about 30 MHz to about 50 MHz If Tx1 and Tx2, as shown in FIG. 11, are at different frequencies, a total bandwidth may be increased. This may have particular application in Doppler imaging, pulsed Doppler, and Doppler-based flow analysis. Doppler flow analysis typically involves sending a pulse in a direction in which velocity is of interest (e.g., along a vessel) and detecting a Doppler shift in the backscatter. Since embodiments of the invention allow for transmissions at multiple frequencies, very sensitive flow velocity profiling may be provided.

FIG. 12 shows an embodiment in which each and every sequencer operation is different than each of the others. This may provide progressive spectrum scanning in which, for example, each A line is operated at an incremented frequency to aid in discovering an optimal frequency

for a subsequent operation, to aid in device calibration, or to aid in advanced harmonics research. Embodiments such as the one depicted in FIG. 12 may provide very broad bandwidth IVUS imaging with far-reaching applications in Doppler analysis.

FIG. 13 diagrams an application of systems and methods of the invention to harmonic imaging. Here, each firing trigger is shown being associated with different sequencer operations. The first firing trigger is used to fire three sequencer transmit operations. Each sequencer transmit operation involves exciting transducer 114 with an ultrasonic pulse of a different frequency. As depicted here, the first transmit operation includes an ultrasonic pulse at a frequency that defines a fundamental frequency. The second ultrasonic pulse is transmitted at a harmonic (e.g., the first harmonic) of the fundamental frequency. The third ultrasonic pulse is transmitted at some higher order harmonic of the fundamental frequency. Then, the second firing trigger triggers a firing sequencer operation that comprises primarily a receipt operation, causing transducer 114, catheter 112, and acquisition FPGA 165 to operate to "listen" to the harmonic imaging backscatter signal.

As described above, clock device 169 and acquisition FPGA operate to provide system 101 with a module that drives rotation of catheter 112 while providing a plurality of trigger signals and each trigger signal can be used to trigger various patterns of firing sequencer operations. Systems and methods of the invention provide the ability to have different types of fast sequencer acquisition from one rotational encode to the next or within a rotational encode. In some embodiments, variable sequencer acquisitions allow for harmonic imaging. One important contribution of the inventive systems and methods includes the location of a proximal causes of firing sequencer operations out of clock device 169 (e.g., SSEQ in FIG. 6 can be provided by acquisition FPGA 165, or—in certain embodiments—by a dedicated FPGA not depicted here). This contribution uncouples the pattern of firing sequencers from the rotary encodes. In some embodiments, this is performed by new structure in which proximal triggers to transmit operations come from a timing element within a microprocessor in reaction to a timing signal from a clock device. For example, if the rotary encode period is 65 μs, despite some overall non-uniform rotational velocity of catheter 112, the rotary encode period provides a foundation of timing accuracy and the microprocessor timing element will perform operations with position-time precision. For example, if a microprocessor timing element causes a first step to occur at each rotary encode and a second step to occur 32.5 μs after each rotary encode, then even a non-

uniform rotational velocity of catheter 112 will not interfere with fidelity of a set of scan lines (e.g., even if catheter 112 rotates at ±25% of an intended 1800 RPM with a 512 step rotary encoder, then the steps timed by the microprocessor timing element will provide scan lines that are, at most, 0.53° displaced). Since the microprocessor timing is handled on-chip, the system provides the benefit that components can be independently upgraded. For example, if a field-deployed system is to be later changed by replacing any of the processers (e.g., as depicted in FIG. 5), the new processor needs simply to be programmed in accordance with the microprocessor timing element. Moreover, if a manufacturer is to change a product line (e.g., introduce the use of an accelerated processor in digital PCA 133), since the timing methods described herein can be handled on-chip, a full suite of new hardware components need not be introduced. In fact, the systems and methods of the invention are suited for increasing line density in an existing system without replacing a timing device 169 and may be beneficially and conveniently implemented during servicing or replacement of a processor.

As used herein, the word "or" means "and or or", sometimes seen or referred to as "and/or", unless indicated otherwise.

Incorporation by Reference

References and citations to other documents, such as patents, patent applications, patent publications, journals, books, papers, web contents, have been made throughout this disclosure. All such documents are hereby incorporated herein by reference in their entirety for all purposes.

Equivalents

Various modifications of the invention and many further embodiments thereof, in addition to those shown and described herein, will become apparent to those skilled in the art from the full contents of this document, including references to the scientific and patent literature cited herein. The subject matter herein contains important information, exemplification and guidance that can be adapted to the practice of this invention in its various embodiments and equivalents thereof.

What is claimed is:

1. A method for intravascular imaging, the method comprising:

introducing an ultrasonic transducer into a vessel, the transducer being disposed at a distal portion of a catheter;

using a module operably coupled to a proximal portion of the catheter to provide a plurality of trigger signals; and

triggering a first sequencer operation and a second sequencer operation with each trigger signal.

2. The method of claim 1, wherein the module comprises a rotary encoder comprising hardwire configured to define a maximum number of trigger signals that the module can provide per rotation.

3. The method of claim 2, further comprising performing a number of sequencer operations per rotation greater than the maximum number of trigger signals provided by the rotary encoder.

4. The method of claim 1, wherein performing a sequencer operation comprises stimulating the transducer to transmit an ultrasonic signal into the vessel.

5. The method of claim 1, wherein performing a sequencer operation comprises using the transducer to receive a backscattered signal from the vessel.

6. The method of claim 1, wherein the first sequencer operation comprises ultrasonic imaging at a first frequency and the second sequencer operation comprises ultrasonic imaging at a second frequency.

7. The method of claim 1, wherein the first sequencer operation consists of sending an ultrasonic signal into the vessel and the second sequencer operation comprises sending and receiving a second ultrasonic signal.

8. The method of claim 1, wherein the first sequencer operation comprises acquiring a scanline with a short pulse and the second sequencer operation comprises acquiring a scanline with a long pulse.

9. The method of claim 1, wherein the module comprises hardware defining a maximum number of trigger signals that can be provided per a rotation of the transducer, the method further comprising capturing a number of A lines of data per rotation of the catheter greater than the maximum number of trigger signals.

10. An intravascular imaging system comprising:

a catheter with an ultrasonic transducer;

a control system connected to the catheter;

a rotary encoder disposed at the control system and operable to produce a plurality of rotary encodes per each 360° rotation of the rotatory encoder; and

a processor in communication with the rotary encoder configured to issue varying patterns of transmit triggers in response to each plurality of rotary encodes.

11. A system for intravascular imaging, the system comprising:

an ultrasonic transducer disposed at a distal portion of an intravascular imaging instrument;

a module operably coupled to a proximal portion of the intravascular imaging instrument, the module operable to provide a plurality of trigger signals; and

a processor operable to trigger a first sequencer operation and a second sequencer operation in response to each trigger signal.

12. The system of claim 11, wherein the module comprises a rotary encoder comprising hardwire configured to define a maximum number of trigger signals that the module can provide per rotation.

13. The system of claim 12, further configured to perform a number of sequencer operations per rotation greater than the maximum number of trigger signals provided by the rotary encoder.

14. The system of claim 11, wherein performing a sequencer operation comprises stimulating the transducer to transmit an ultrasonic signal into the vessel.

15. The system of claim 11, wherein performing a sequencer operation comprises using the transducer to receive a backscattered signal from the vessel.

16. The system of claim 11, wherein the first sequencer operation comprises ultrasonic imaging at a first frequency and the second sequencer operation comprises ultrasonic imaging at a second frequency.

17. The system of claim 11, wherein the first sequencer operation consists of sending an ultrasonic signal into the vessel and the second sequencer operation comprises sending and receiving a second ultrasonic signal.

18. The system of claim 11, wherein the first sequencer operation comprises acquiring a scanline with a short pulse and the second sequencer operation comprises acquiring a scanline with a long pulse.

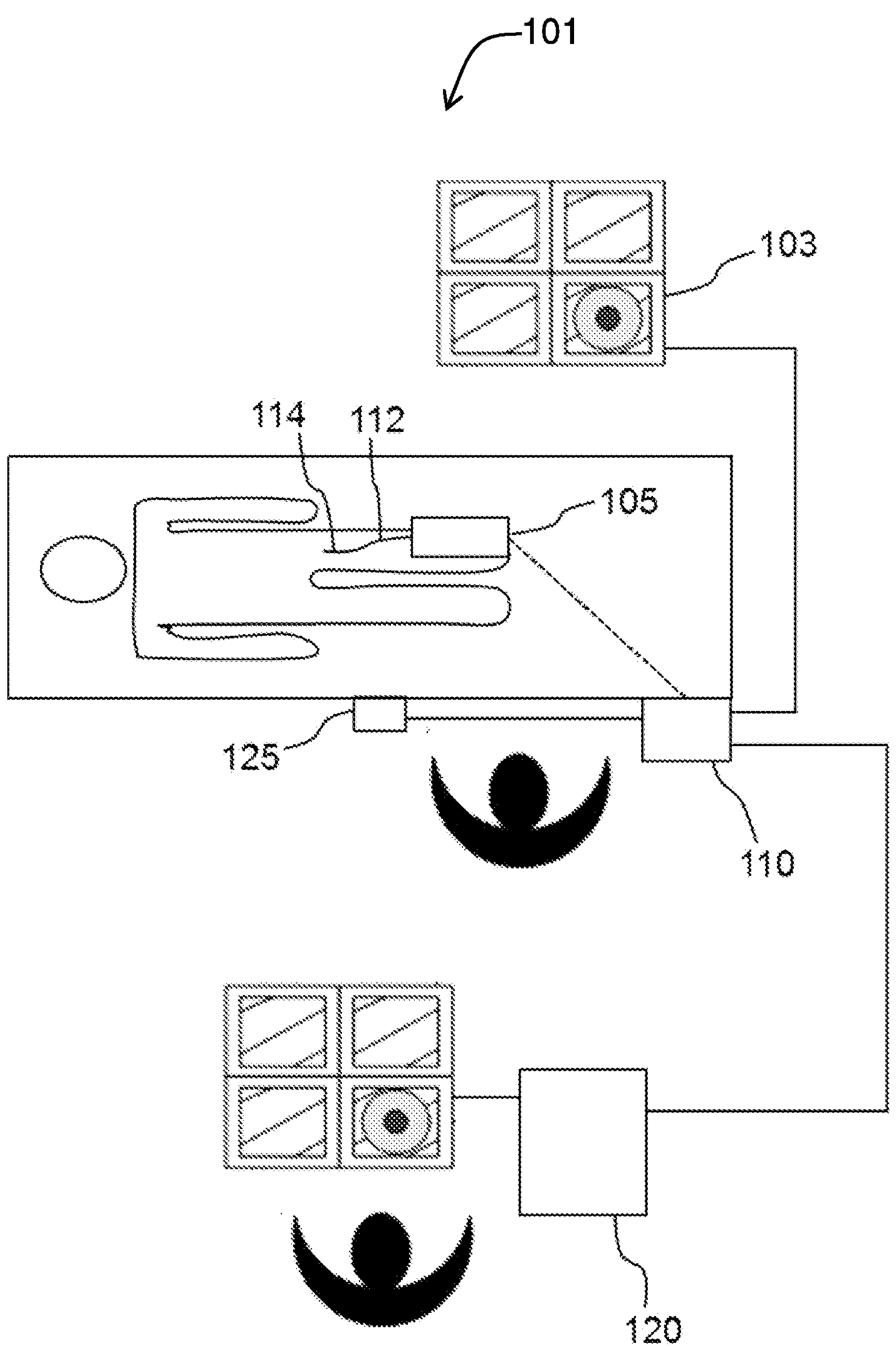

FIG. 1


110

FIG. 2

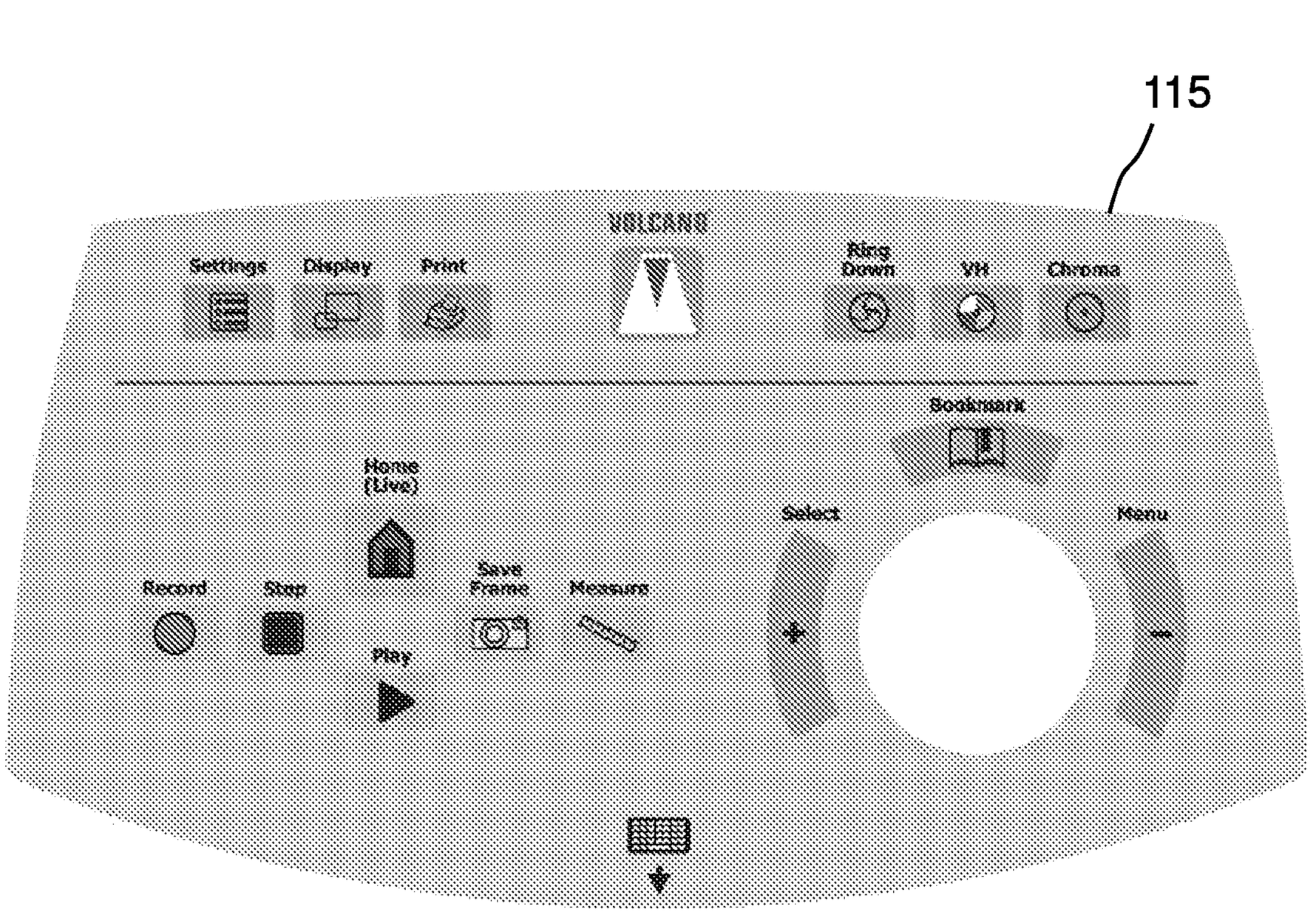
115
VOLCANO
Settings
Display
Print
Ring Down
VH
Chroma
Bookmark
Home (Live)
Select
Menu
Record
Stop
Save Frame
Measure
Play

FIG. 3

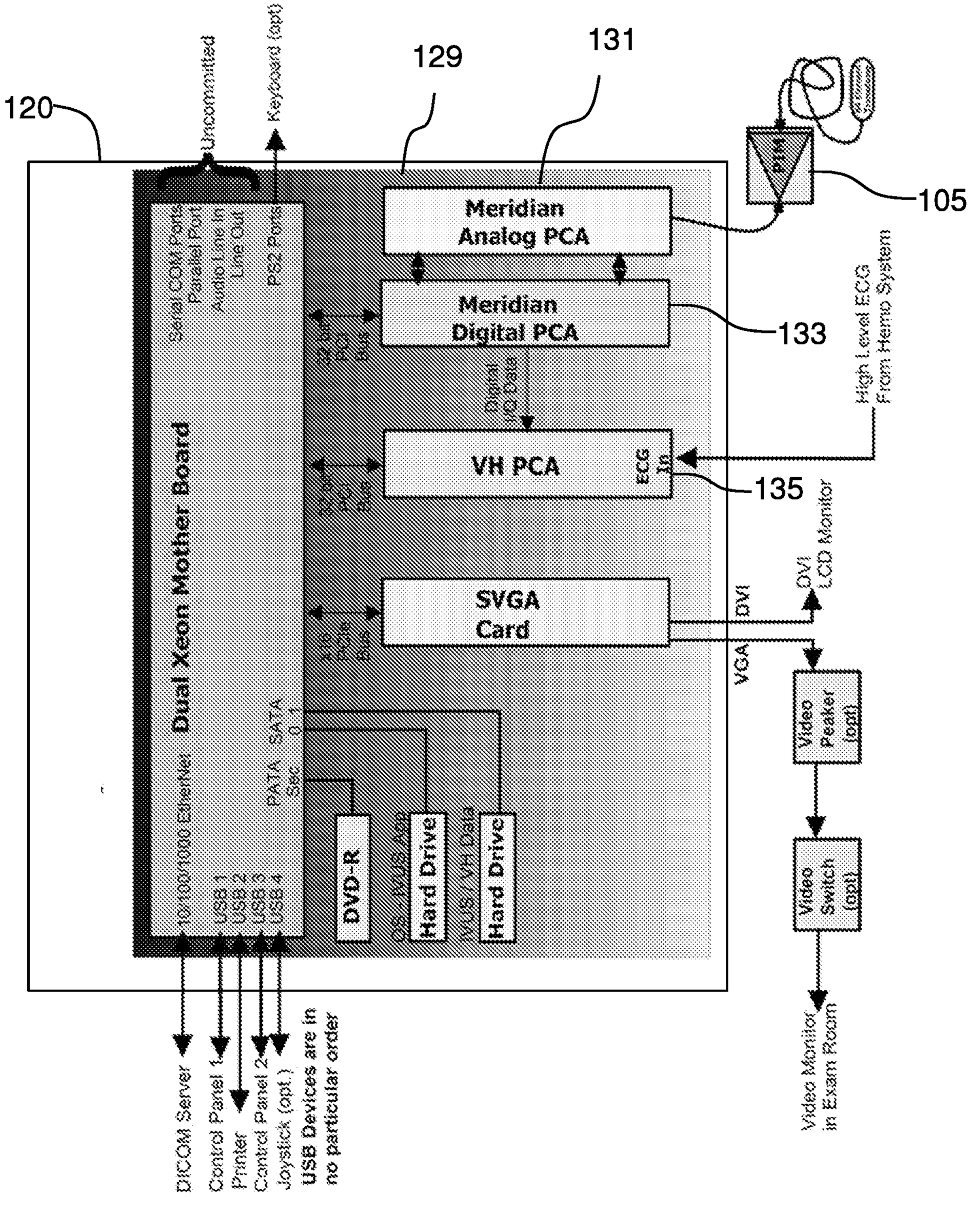
120
129
131
105
133
135
Meridian Analog PCA
Meridian Digital PCA
VH PCA
SVGA Card
Dual Xeon Mother Board
High Level ECG From Hemo System
DVI LCD Monitor
VGA
Video Peaker (opt)
Video Switch (opt)
Video Monitor in Exam Room
DICOM Server
Control Panel 1
Printer
Control Panel 2
Joystick (opt.)
USB Devices are in no particular order
DVD-R
Hard Drive
Hard Drive

FIG. 4

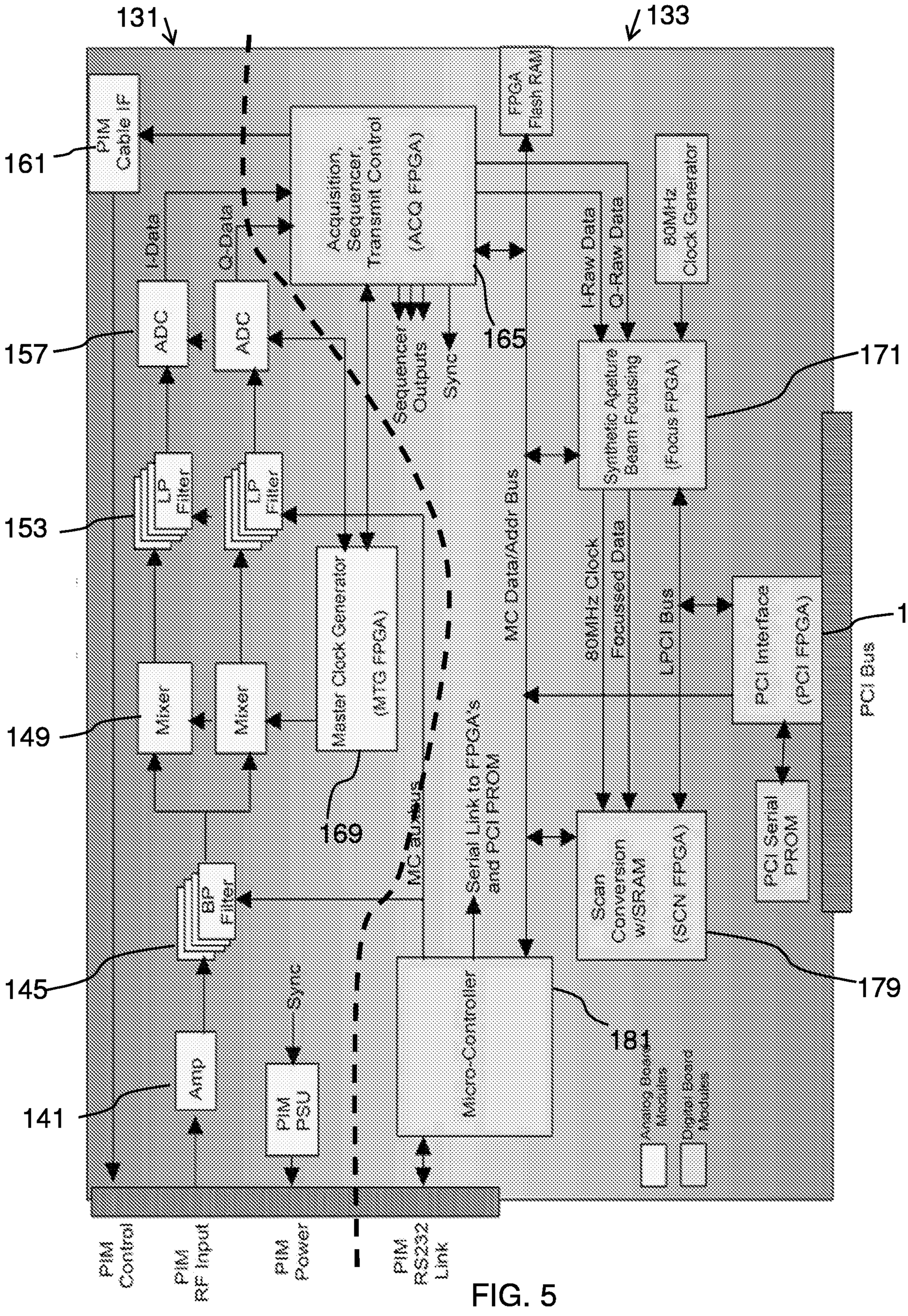
131
133
161
PIM Cable IF
FPGA Flash RAM
Acquisition, Sequencer, Transmit Control (ACQ FPGA)
I-Data
Q-Data
80MHz Clock Generator
157
ADC
ADC
165
Sequencer Outputs
Sync
I-Raw Data
Q-Raw Data
153
LP Filter
LP Filter
Synthetic Aperture Beam Focusing (Focus FPGA)
171
Clock Generator (MTG FPGA)
MC Data/Addr Bus
80MHz Clock
Focussed Data
LPCI Bus
175
PCI Interface (PCI FPGA)
149
Mixer
Mixer
169
MC address
Serial Link to FPGA's and PCI PROM
PCI Serial PROM
PCI Bus
BP Filter
Scan Conversion w/SRAM (SCN FPGA)
179
145
Sync
Micro-Controller
181
Amp
141
PIM PSU
Analog Board Modules
Digital Board Modules
PIM Control
PIM RF Input
PIM Power
PIM RS232 Link

FIG. 5

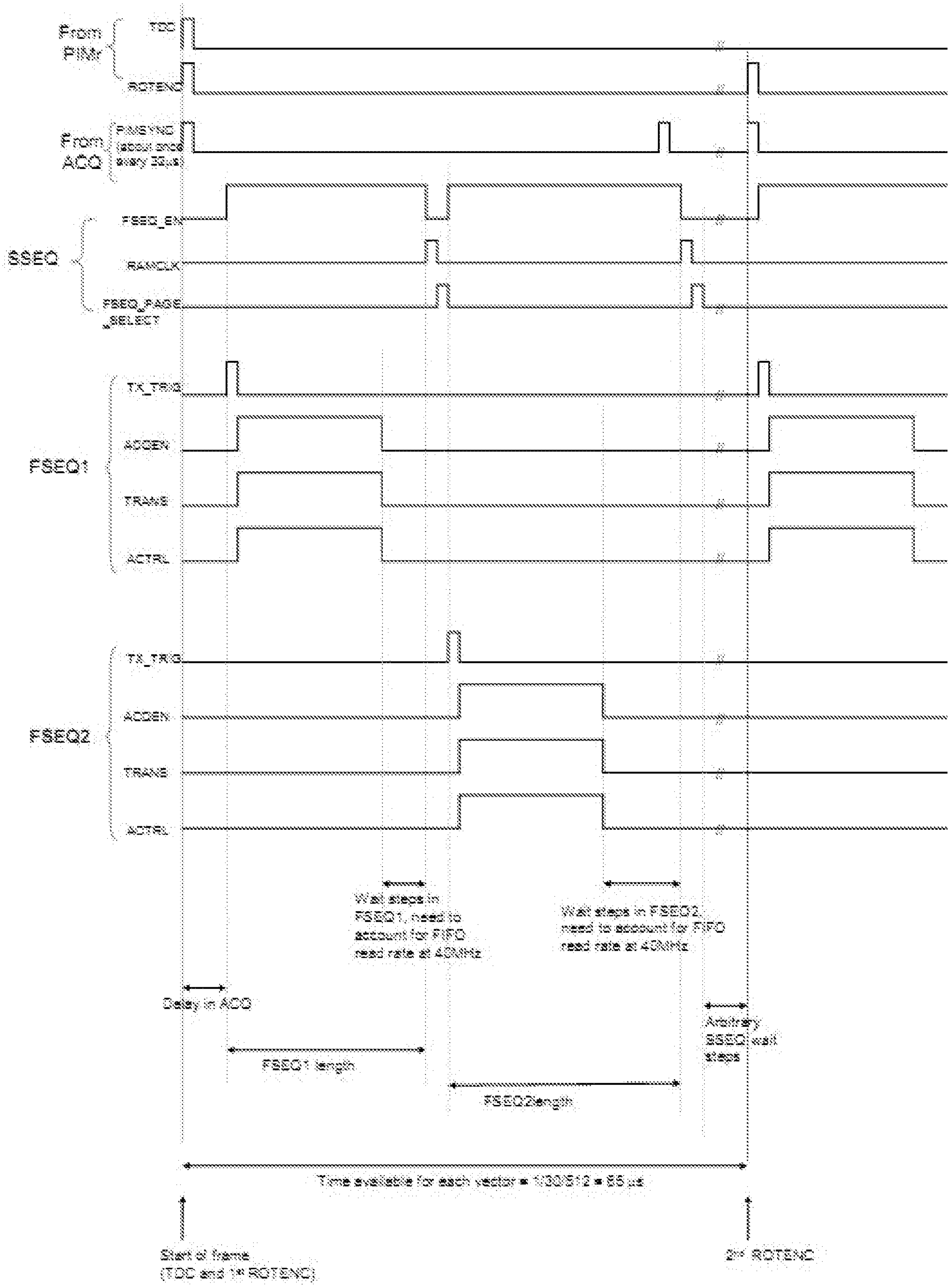
From PIMr
TDC
ROTENC
From ACQ
PIMSYNC (about once every 32us)
SSEQ
FSEQ_EN
RAMCLK
FSEQ_PAGE _SELECT
FSEQ1
TX_TRIG
ACQEN
TRANS
ACTRL
FSEQ2
TX_TRIG
ACQEN
TRANS
ACTRL
Wait steps in FSEQ1, need to account for FIFO read rate at 40MHz
Wait steps in FSEQ2, need to account for FIFO read rate at 40MHz
Delay in ACQ
Arbitrary SSEQ wait steps
FSEQ1 length
FSEQ2length
Time available for each vector = 1/30/512 = 65 µs
Start of frame (TDC and 1st ROTENC)
2nd ROTENC

FIG. 6

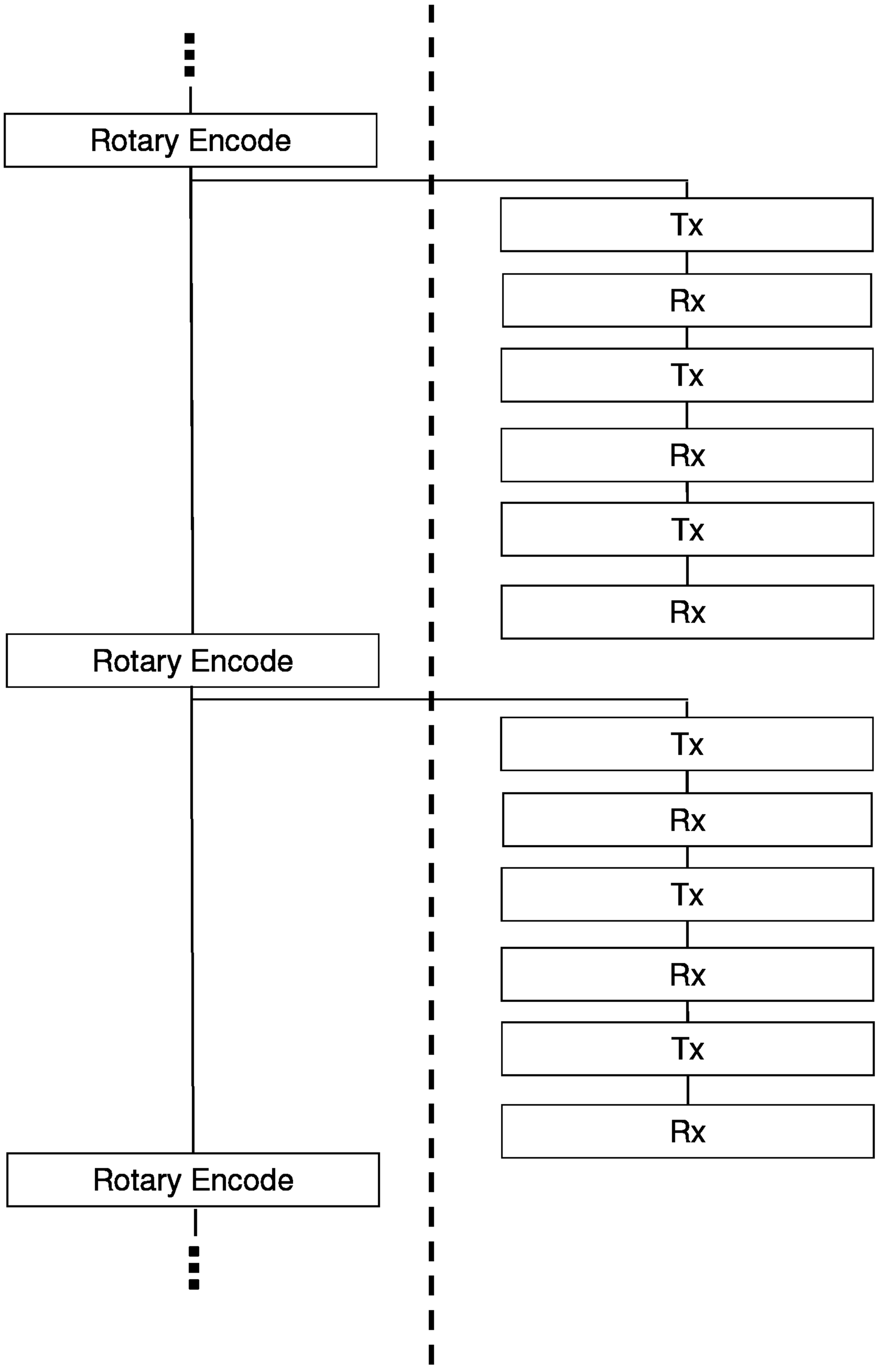
Rotary Encode
Tx
Rx
Tx
Rx
Tx
Rx
Rotary Encode
Tx
Rx
Tx
Rx
Tx
Rx
Rotary Encode
Tx
Rx
Tx
Rx
Tx
Rx

FIG. 7

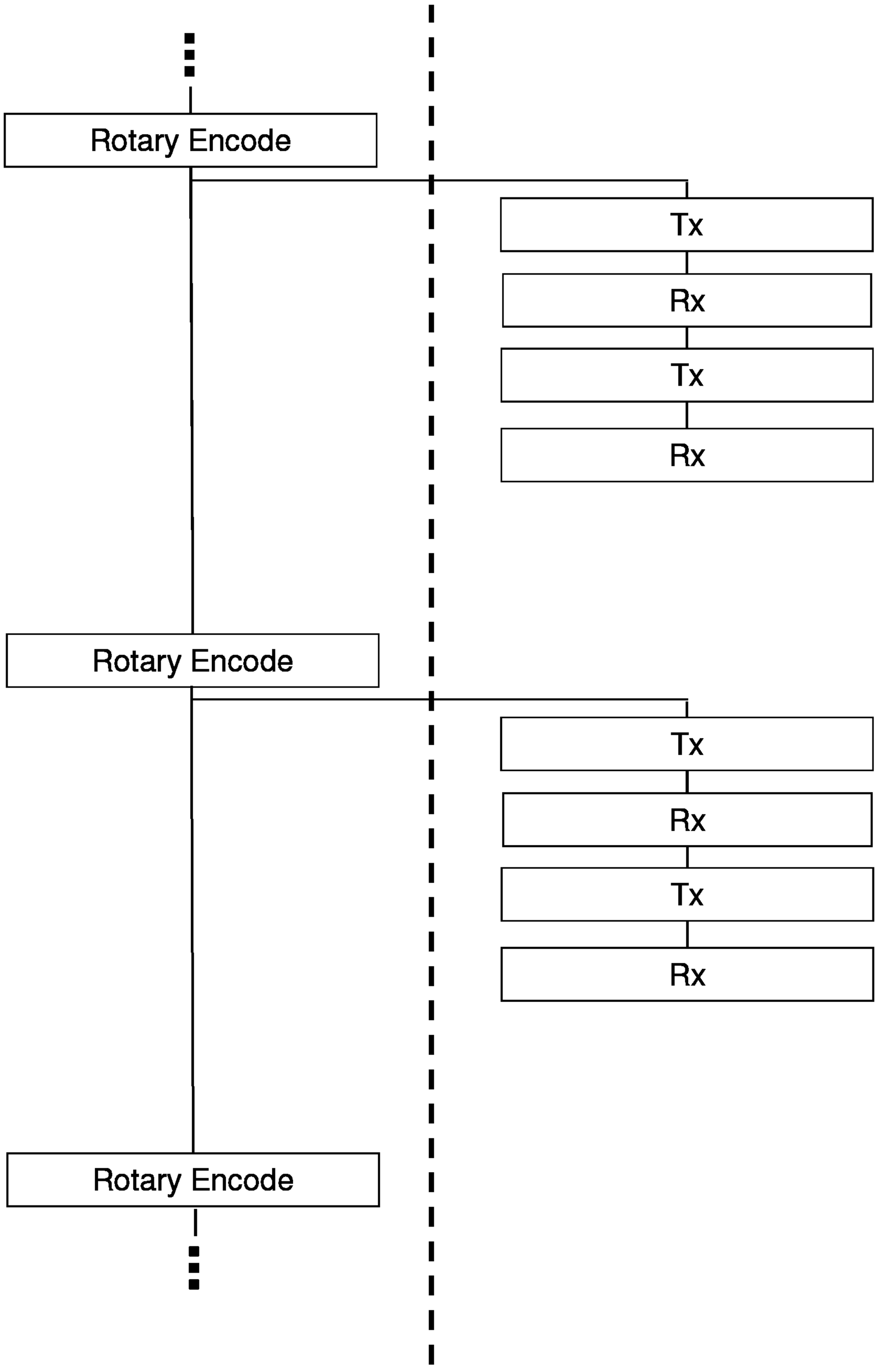
Rotary Encode
Tx
Rx
Tx
Rx
Rotary Encode
Tx
Rx
Tx
Rx
Rotary Encode

FIG. 8

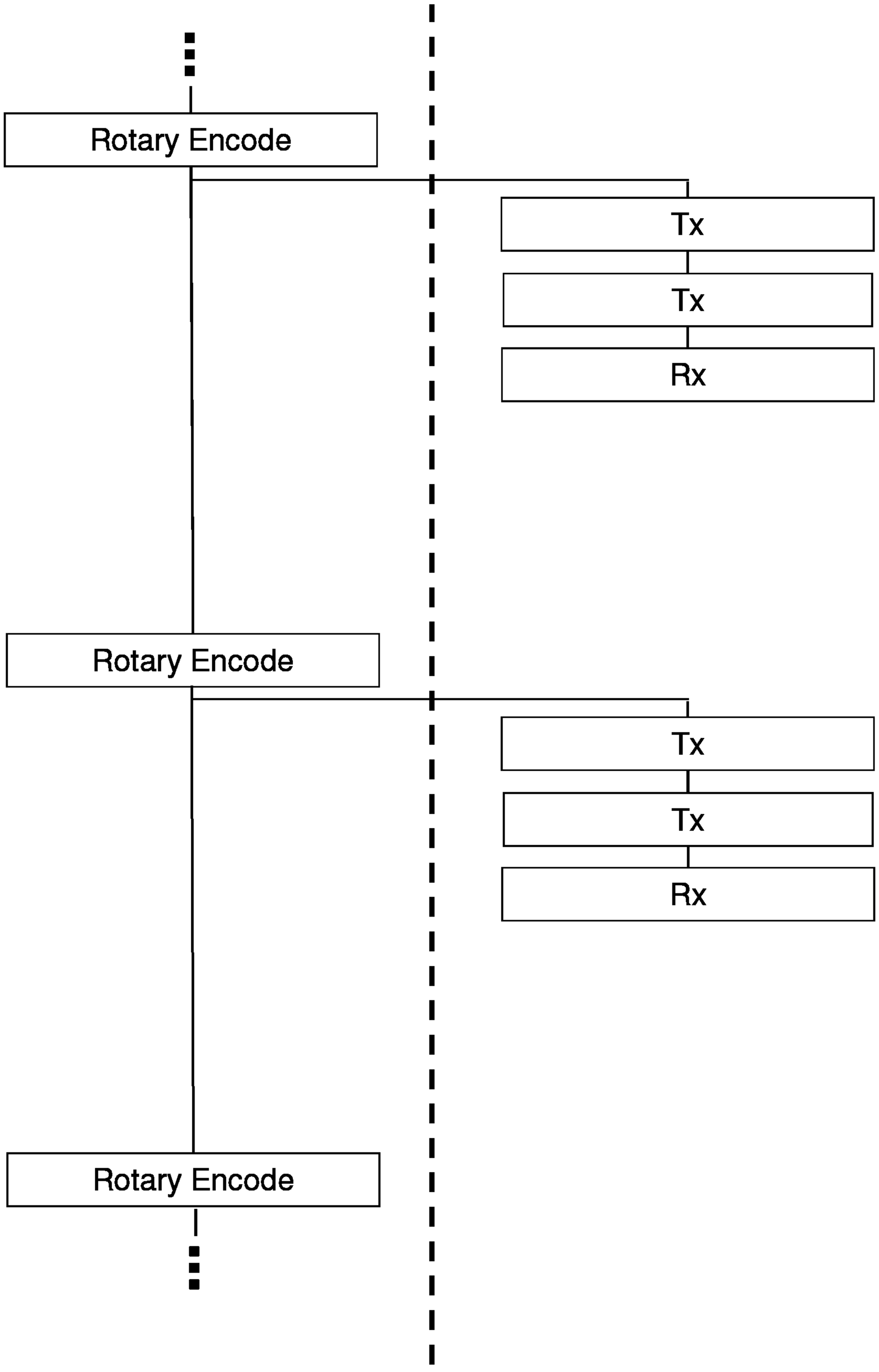

FIG. 9

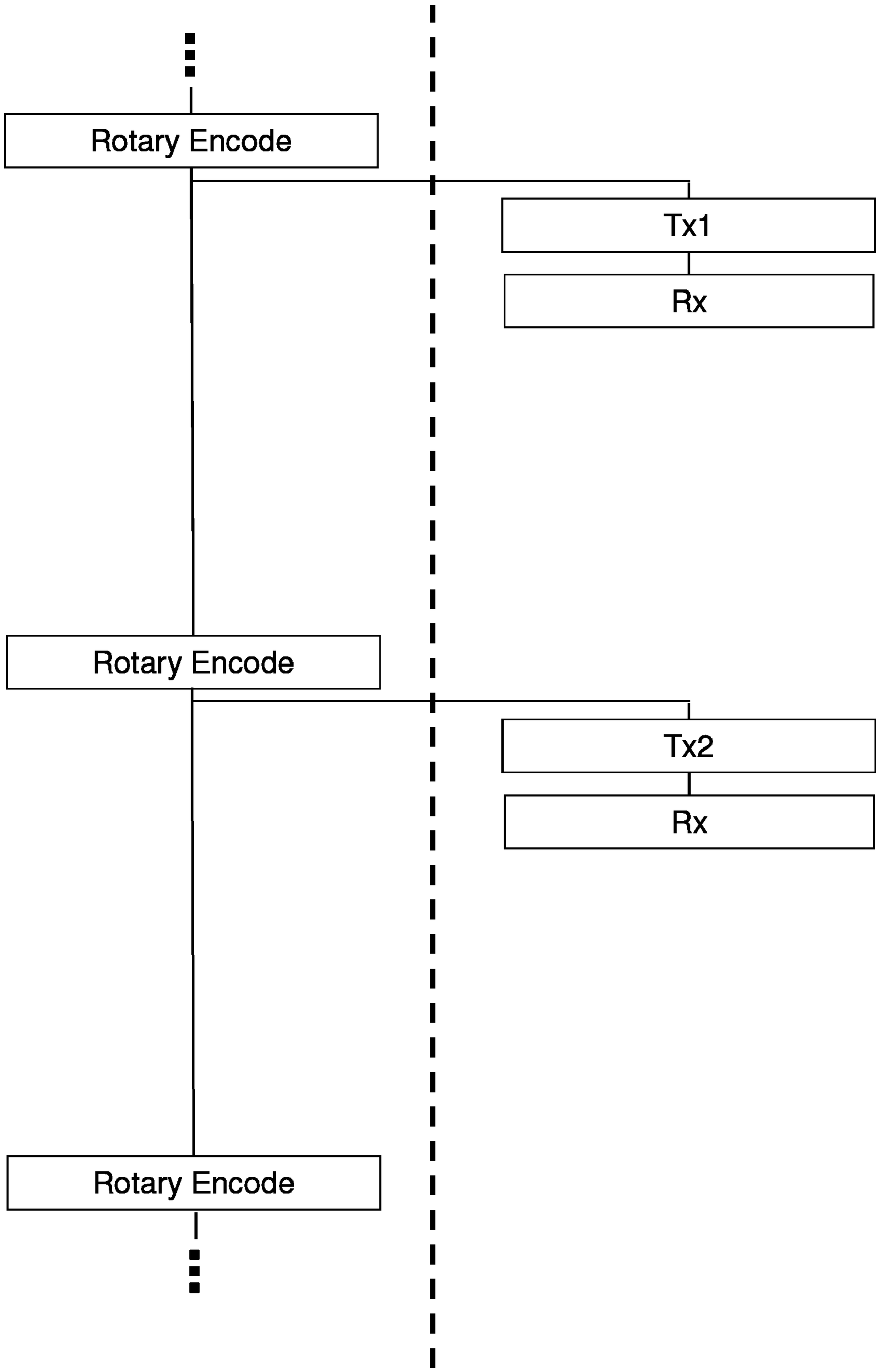

FIG. 10

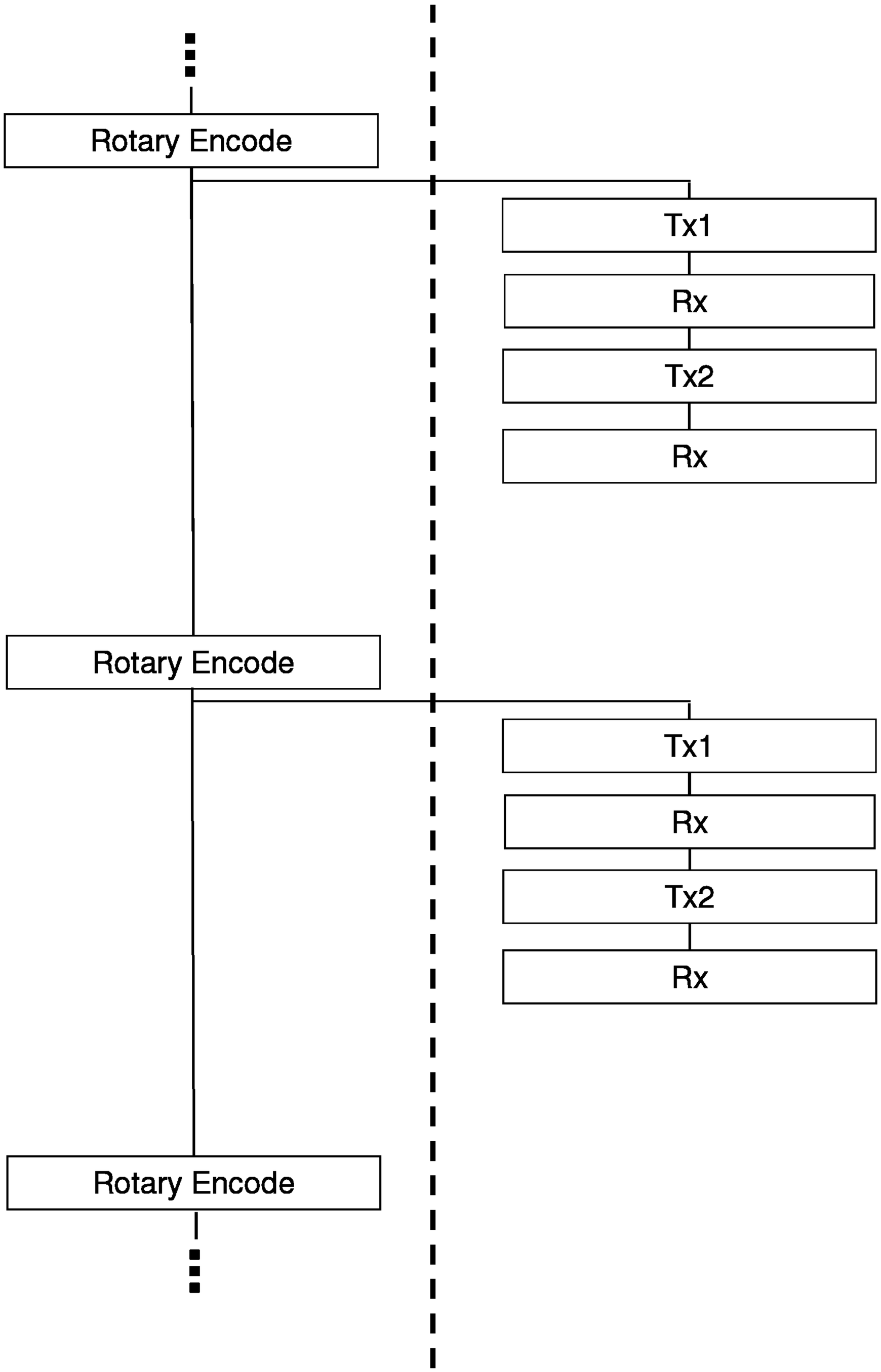
Rotary Encode
Tx1
Rx
Tx2
Rx
Rotary Encode
Tx1
Rx
Tx2
Rx
Rotary Encode

FIG. 11

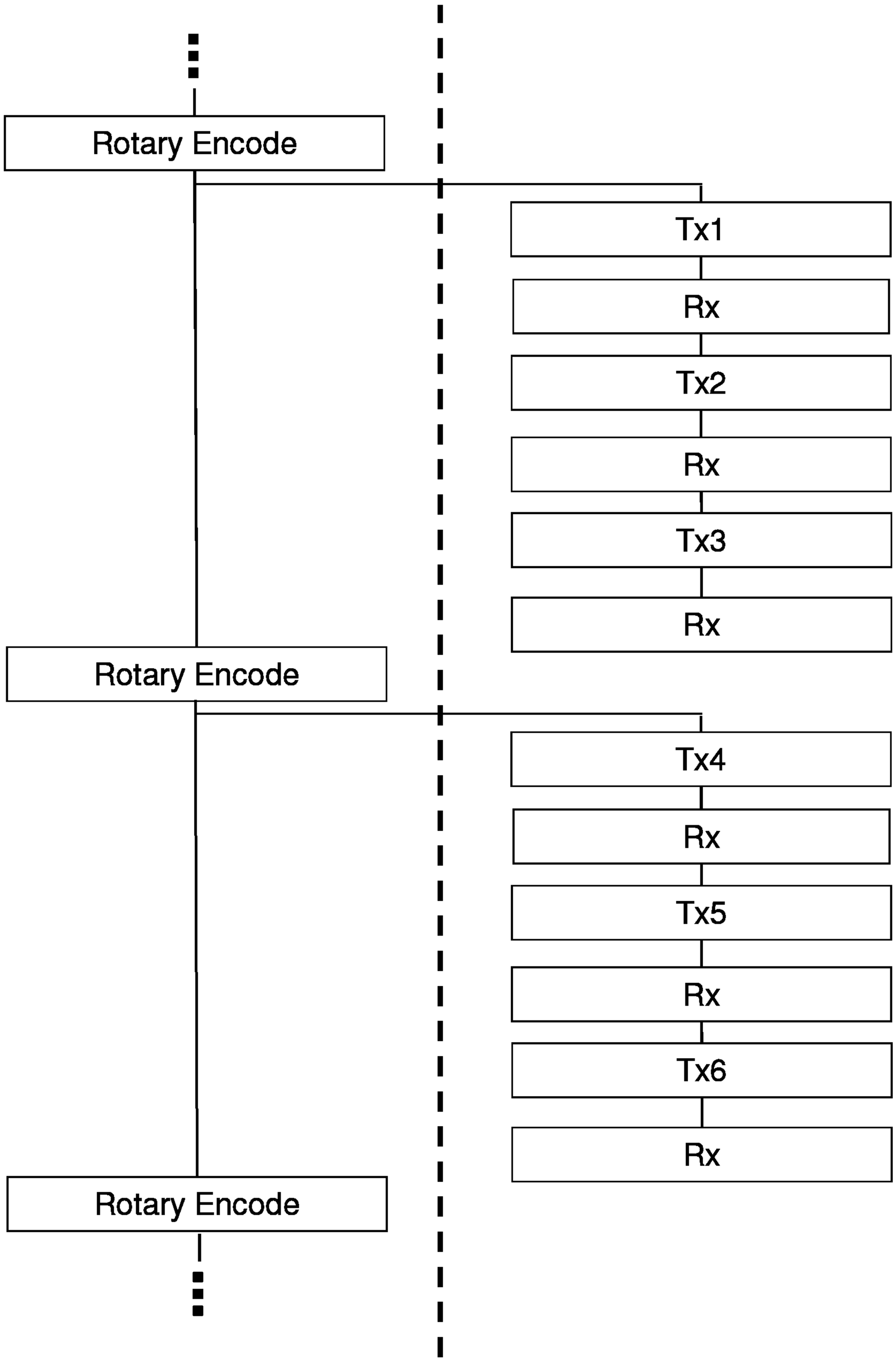
Rotary Encode
Tx1
Rx
Tx2
Rx
Tx3
Rx
Rotary Encode
Tx4
Rx
Tx5
Rx
Tx6
Rx
Rotary Encode

FIG. 12

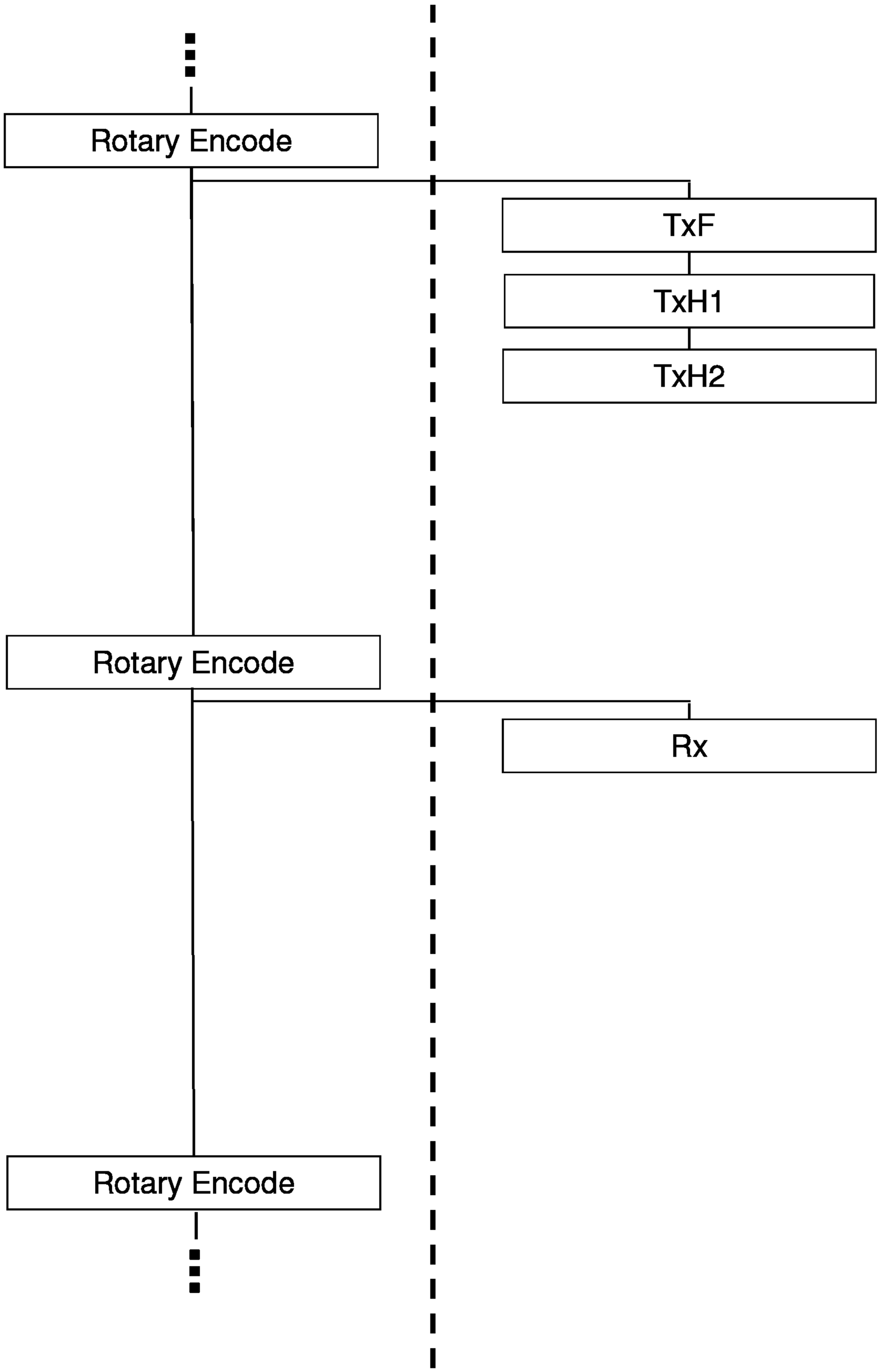

FIG. 13

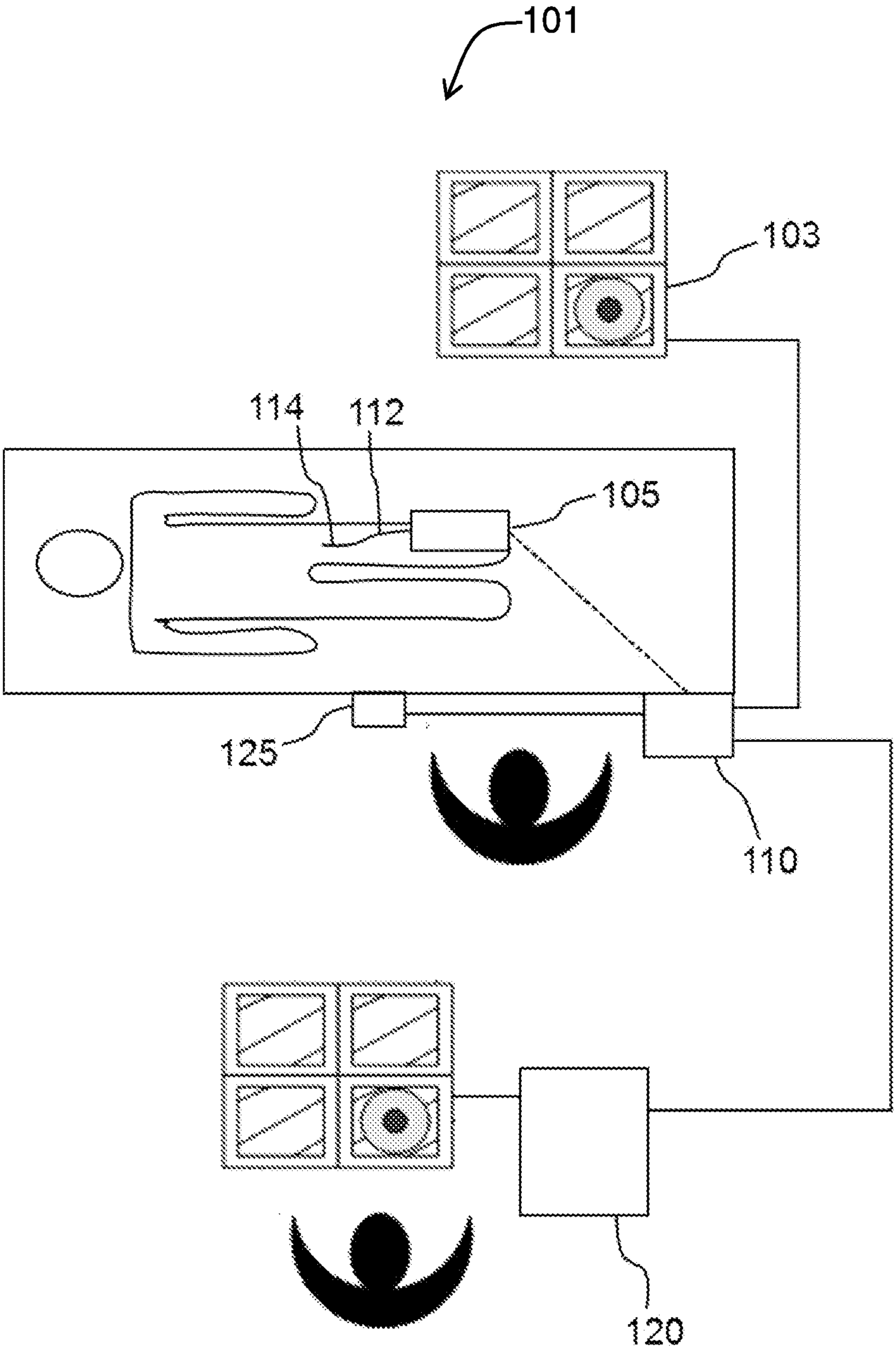

FIG. 1