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(71) Applicant: **NEURO-KINESIS CORPORATION** [US/US]; 10524 S. La Cienega Blvd, Inglewood, California 90304 (US).

(72) Inventors: **SHACHAR, Josh**; 2417 22nd St., Santa Monica, California 90405 (US). **ROCKLINGER, Marc**; 12920 Walsh Ave #7, Los Angeles, California 90066 (US). **STELEA, Sorin**; 19846 Caprice Dr., Yorba Linda, California 92886 (US). **YIN, Peter**; 5172 Berryman Ave, Culver City, California 90230 (US). **SALCEDA, Elissa**; 3980 Wilshire Blvd Apt 724, Los Angeles, California 90005 (US). **BOURDAGES, Dylan**; 1135 N. Dearborn St., Redlands, California 92374 (US). **GANG, Eli**; 2633 Zorada Dr., Los Angeles, California 90046 (US).

(74) Agent: **DAWES, Daniel L.**; 5200 Warner Ave, Ste 106, Huntington Beach, California 92649 (US).

(54) Title: ROBOTICALLY CONTROLLED ELECTROPHYSIOLOGY CATHETER WITH CLOSED LOOP CONTROL

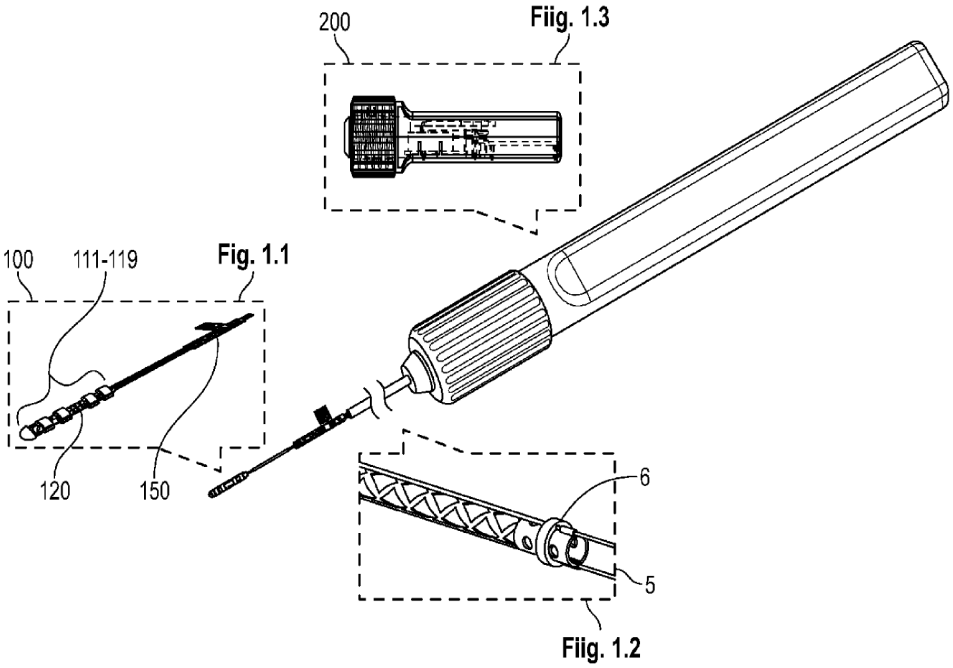

FIG. 1

(57) Abstract: The embodiments include an apparatus used in combination with a computer for sensing biopotentials and electrode contact impedance. The apparatus includes a catheter in which there is a plurality of sensing electrodes, a corresponding plurality of local amplifiers, each coupled to one of the plurality of sensing electrodes, a data, control and power circuit coupled to the plurality of local amplifiers, and a photonic device bi-directionally communicating an electrical signal with the data, control and power circuit. An optical fiber optically communicated with the photonic device. The photonic device bi-directionally communicates an optical signal with the optical fiber. An optical interface device provides optical power to the optical fiber and thence to the photonic device and receives optical signals through the optical fiber from the photonic device. The optical interface device bi-directionally communicates electrical data, control, and power signal to the computer.

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ROBOTICALLY CONTROLLED ELECTROPHYSIOLOGY CATHETER WITH CLOSED LOOP CONTROL

RELATED APPLICATIONS

[0001] The present application is a continuation in part application pursuant to 35 USC 120 of OPTICALLY COUPLED CATHETER AND METHOD OF USING THE SAME, US Pat. Appl. 16/424,202, filed May 28, 2019, and A CATHETER FOR CARDIAC AND RENAL NERVE SENSING AND MEDIATION, U.S. Pat. Appl. 17/468,460, filed Sept. 7, 2021.

[0002] The following patents, applications and patent publications, currently abandoned or issued, are related to the present application, all and each of which are incorporated herein by reference: US Pat. Pub. 2008/0249395 A1 – METHOD AND APPARATUS FOR CONTROLLING CATHETER POSITIONING AND ORIENTATION; US Pat. 8,986,214 B2 – SYSTEM AND METHOD FOR USING TISSUE CONTACT INFORMATION IN AN AUTOMATED MAPPING OF CARDIAC CHAMBERS EMPLOYING MAGNETICALLY SHAPED FIELDS; U.S. Pat. Appl. 12/475,370, entitled "Method and Apparatus for Magnetic Waveguide Forming a Shaped Field Employing a Magnetic Aperture for Guiding and Controlling a Medical Device," filed on May 29, 2009; US Pat. Pub. 2012/0316431 A1 – METHOD FOR ACQUIRING HIGH DENSITY MAPPING DATA WITH A CATHETER GUIDANCE SYSTEM, which is a continuation of U.S. Pat. Appl. Ser. No. 12/582,588, filed Oct. 20, 2009; US Pat. Appl. 2006/0116634 A1 – SYSTEM AND METHOD FOR CONTROLLING MOVEMENT OF A SURGICAL TOOL, which is a divisional of U.S. Pat. Appl. Ser. No. 10/621,196 titled APPARATUS AND METHOD FOR A CATHETER GUIDANCE CONTROLAND IMAGING, which was filed Jul. 15, 2003 which claims priority from U.S. Provisional Pat. Appl. No. 60/396,302, filed Jul. 16, 2002, titled "CATHETER GUIDANCE CONTROL AND IMAGING APPARATUS AND METHOD"; US Pat. Pub. 2012/0288838 A1 – METHOD FOR SIMULATING A CATHETER GUIDANCE SYSTEM FOR CONTROL, DEVELOPMENT AND TRAINING APPLICATIONS, which is a continuation of U.S. Pat. Appl. Ser. No. 12/582,621, filed Oct. 20, 2009; US Pat. 9,655,539 B2 – SYSTEM AND METHOD FOR TARGETING CATHETER ELECTRODES, which is a continuation of U.S. Pat. Appl. Ser. No. 12/615,176, filed Nov. 9, 2009; US Pat. 8,457,714 B2 – SYSTEM AND METHOD FOR A CATHETER IMPEDANCE SEEKING DEVICE; US Pat. Pub. 2009/0275828 A1 – METHOD AND APPARATUS FOR CREATING A HIGH RESOLUTION MAP OF THE ELECTRICAL AND MECHANICAL PROPERTIES OF THE HEART; and US Pat. Pub.

2009/0253985 A1 – APPARATUS AND METHOD FOR LORENTZ-ACTIVE SHEATH DISPLAY AND CONTROL OF SURGICAL TOOLS.

[0003] BACKGROUND

[0004] *Field of the Invention*

[0005] The invention relates to systems and methods for guiding, steering, and advancing an invasive medical device in a patient while using a sensor and fiducial markers to determine the location and orientation of the catheter.

[0006] The invention further relates to the field of medical mapping systems, namely systems and methods for guiding, steering and advancing an invasive medical device in a patient for the purpose of defining the physical boundaries and surface properties of a chamber or orifice.

[0007] The invention further relates to the systems and methods forguiding an invasive medical device within a patient for the purpose ofmapping anatomical cavities.

[0008] The invention further relates to systems and techniques for guiding, steering, and advancing invasive medicaldevices such as catheters and catheter-type devices.

[0009] The invention further relates to the systems and methods for guiding, steering and advancing an invasive medical device in a patient.

[0010] The invention further relates to the placement of catheters in contact with specific anatomical locations while optimizing the direction and orientation of tissue contact.

[0011] The invention further relates to the field of acquiring high-resolution clinical models of various properties of the heart using an invasive medical device and systems and methods for locating and tracking the invasive device.

[0012]

[0013] *2. Description of the Prior Art*

[0014] Catheterization is typically performed by inserting an invasive device into an incision or body orifice. This procedure relies on manually advancing the tip of the invasive device by pushing, rotating, or otherwise manipulating the proximal end which remains outside of the body.

[0015] The prior art approach to solving the fiducial relationship between the moving catheter tip and the heart catheter relies on manually advancing the catheter tip by pushing the proximal end of the catheter, while grossly neglecting the respiratory outputs (ribcage displacement), heart contraction, QRS synchronization, patient operating bed location, and image capture (x-ray or other imaging

modalities) to approximately move the catheter from the current Actual Position (AP) to the Desired Position (DP).

[0016] Review of the prior art and its limitations indicate the inability of the prior art solutions to account for the global orientation of the catheter tip relative to frame distortion associated with the operating table, QRS synchronization timing point, or image acquisition, where the data points (e.g., the vector space) are normalized to the patient local coordinate system.

[0017] The limitations of the prior art are characterized by the fact that the operator requires the system to define an accurate position for moving the catheter tip from actual position to its desired position in an "autopilot" regimen. The prior art cited cannot perform the task because the position and orientation of the catheter tip is influenced by more than the local coordinate system and it is dependent on many variables such as, heart dynamics, fiducial external sensor, and patient's body relative to the operating table, etc.

[0018] Therefore, there is a substantial and unsatisfied need for an apparatus and method for detecting the position and orientation of a medical tool such as a catheter or catheter-like devices for guiding, steering, advancing the position of an invasive device, for accurately controlling their position, for providing three-dimensional imaging, and for minimizing the use of x-ray or other ionizing radiation.

[0019] BRIEF SUMMARY

[0020] The preferred embodiments of the invention and its scope are best understood by first appreciating the problems, which needed to be solved in order to realize the goals or objects of the invention.

[0021] Standard diagnostic methods of identifying pacing disturbances in the electrical activity in the heart are well known. The cardiac waveform has a certain characteristic time-domain pattern and an amplitude that are considered normal and healthy. Although there are variations from on a normal distribution in the length and amplitude of electrical activity among patients of different genders and age, in general the electrical patterns are the essentially the same in shape and the time-domain characteristics, namely approximately 60 beats per minute (1Hz), and sometimes when there is exercise or pressure, up to 1.5Hz or 90 bpm. For example, an older, slower heart is typically as low as 45 bpm, a normal heart 60-70, and an young athlete of 25years is 65 bpm. Rates are typically slower in people with difference sizes, maladies, weights, and preexisting conditions.

[0022] There are two broad categorizations of cardiac disease derived from identification of the disease based on the waveform, its geometric and time-domain characteristics. The disease models are

described by the geometric and time-domain aspects of the waveform. For example, patients with a slow heart (bradycardia), and patients with a fast heart (tachycardia). These categorizations arise from disturbances in the pacing. It starts with the QRS waveform, for example, with an ectopic signal coming from sino-atrial node, which comes from the autonomic nervous system, which triggers the performance of the heart responding to a heart wave from the sino-atrial node to the HIS bundle, to the Purkinje fibers to the mitral valve and to the pulmonary vein.

[0023] There are classes of disease models such as atrial fibrillation, (AFib) such as persistent AFib, and paroxysmal AFib. There are accessory pathways in different locations, and there is VT/tachycardia, all varieties of disease models relating to abnormal pacing. An electrophysiology catheter must be able to uncover abnormal cardiac behavior from the cardiac waveform.

[0024] Unfortunately, the underlying waveforms, namely the electrical activity of the cardiac DC potential in a time-domain, are subject to additional parameters that affect the measurement, such as the nature of the contact surface, which is often critical in obtaining an accurate measurement of the cardiac signal. The signal is not emanating just from the surface of the endocardial area, like the outer layers of the inner surface of the heart, but also from the substrate, the entire thickness of the cardiac muscles. Because the cardiac signal is transmitted from its origin site, the nature of the deep cardiac tissue also affects cardiac measurement. The proximity of signal-emitting tissue varies from 2mm on the pulmonary vein to 50mm on the ventricle.

[0025] A catheter with multiple electrodes, measuring either in unipolar or bipolar configuration, picks up electrical activity on the surface of the heart, and in doing so requires an electrical contact with the heart that is substantially constant in order to accurately detect a cardiac event in a time domain that realistically represents the vectorial waveform magnitude and direction. The electrophysiologists needs to know where the cardiac wave moves to, in what space does cardiac wave move (its trajectory), and what is its amplitude. In addition, some of the clinical signals of interest range between 5-25μV in amplitude.

[0026] These signals are subject to error and noise, because the environment outside the patient, including the patient himself, can have a myriad of electrical signals that are substantially larger than the potential of interest. An example is the electrical output from the lights and hospital equipment in the operating room which is around 60Hz (50Hz in Europe). They radiate an enormous amounts of power relative to the cardiac signal at 5μV. Many of the noise characteristics are detectable because of their repeatability, and they we can be removed with a high-pass filter, low-pass filter, or other forms of analytical discrimination between signal and noise. Many of the signals of interest (5-25μV) ride on a very large signal, so noise is the leading vector in size, magnitude, and direction, compared to the signal of interest. It is like trying to scoop a specific drop of water

from a full bucket.

[0027] Using conventional filters as is used with analog electrodes, the filters are like a lawnmower, namely when you "cut the grass" you also "cut the daisies", eliminating low-performing signals of CFAE (complex fractionated atrial electrogram) which are indications of areas where scar tissues are located. Current flows around the scar tissue island, either clockwise or counter-clockwise.

[0028] The aim of our technology is how to fish the little "drop of water" that is of interest without fishing out the whole bucket of water. We must fish with a hook that is very specific. As disclosed below we can only do that if we pick the native signal, amplify it locally, digitize it so as a "digital word", it is immune to any outer analog interference, and then transmit it to the station for processing to produce a map.

[0029] Another goal is to pick up the signal in a time domain to allow us to see the entire cineography of the heart wave, like a video, so instead of having 50Hz update as the current system operates. As disclosed below we operate at 1KHz, where we are an order of magnitude higher resolution in the time domain than conventional cardiac monitors. The dynamic range has a better representation of what is happening in each fraction of a second where the events take place. Signals with a low power can be picked up, and they are captured locally in a digital word that is no longer trapped along a 1-meter-long catheter shaft, which behaves as an antenna, going to a 5-meter-long cable into a workstation which processes it. Heart performance is not measured with a fiducial representation, but is actually captured at its naturally occurring rate.

[0030] Now it can be appreciated what is required to uncover the electrical activity of the substrate tissue of the heart (which is a circuit starting from the SA node to the HIS bundle, to the Purkinje fibers and to the mitral valve. Cardiac electrical activation is more like a battery structure where there is an avalanche between ionic structure of cellular matrices that are cascading into each other on a time domain. Sometimes there is a scar tissue which creates islands which diverts the signal from its native linear propagation as defined for a normal patient. What we do by exploring the endocardial surface of the heart, especially in AFib (or the left atrium), is where there is an aberration, where the geometry and time domain variations are occurring, and then we later apply a therapeutic approach to correct it, to rewire or remodel the heart's electrical system from a spurious junction to a new rewiring by ablating and creating a path that allows the waveform to travel in a more linear fashion to achieve the time domain of a sinus rhythm, which is the ultimate goal of a therapeutic approach.

[0031] What we find out is, that in the exploration of the diagnostic phase and therapeutic phase, both are subject to a macro that is common for a common disease (such as AFib). For example, the

approach created by Haïssaguerre (1982), in his seminal paper about the relationship between pulmonary vein isolation and correction of arrhythmia, and the continuation of a therapeutic for more complex cases. For example, one correction includes where there is a roofline ablation and an isthmus line complementary ablation, which separates the pulmonary vein, the roofline and the isthmus all the way to mitral valve which creates a line of isolation that recovers a persistent AFib. There are other cases such as accessory pathways, and the strategy for each one is known. It means that there are sets of cardiac macros that physicians apply in the diagnostic and therapeutic modes. In both diagnostic and therapeutic cases, it lends itself to a specific macro.

[0032] The concept of Huygens catheter disclosed below is to solve two big issues: on the one hand, increase the resolution of the impedance microscopy to measure the potential at as low as 5μV to uncover CFAE events, and on the other hand, change the dynamic range by going from a small frequency domain of 50Hz to 1KHz (digitally). By these two steps we are able to scan and create maps that demonstrate the dynamic of the waveform magnitude and direction.

[0033] The map created subsequently represents more realistically, through cardio processing systems such as Carto, Ensite and others, two things: the combination of the location of the catheter position and orientation, and measurement of the DC potential over the surface of the heart in the time domain, while measuring the contact surface to verify consistent pressure. As disclosed below taking the ordered tuple data set of DC cardiac potential Z, position P, orientation O, contact impedance Ω and time t, <Z, P(xyz), O(xyz), Ω, t>, all relative to a standard QRS event, there is an adiabatic timer that is inherent to the patient tied to an identifiable cardiac event in the human heart and specifically to that patient.

[0034] The aberrations of geometrical displacements in the time-domain are measured against a known standard internal reference which is the heart of the patient. As we map, we record the places where we have seen an aberration, not approximately on the screen and then estimating how to return to that location as was the conventional, but by recording position and orientation, we set markers and use of the Proteus robot to reliably move the catheter specifically to these coordinate sets with a +/- 1mm margin of error, depending on the system. This lends itself to a macro-operation, where two very complex subjective sets of in the time domain are reduced to a machine language that is capable of capturing the mapped terrain with the electroanatomical activity and its definition on a three-dimensional grid, which is recognized by a robotic system that uses the loop to lock in and place the catheter in that location of interest to the physician.

[0035] A better diagnostic microscopy of the position, orientation, and DC potential of the disease is performed, and then the catheter or another surgical tool is translated and rotated back to that location with the robotic system for a therapeutic response. The physician's diagnostic approach

is reduced and recorded into a machine language, and the dexterity of the physician is turned it into a set of machine commands. In both cases, macros are interrelated into a complex loop, and that loop is then stored and reported directly into the "Cloud", which then enables the physician to maintain an understanding of future cases or progression of the disease if it reoccurs and repeats itself.

[0036] The system described herein solves these and other problems by locating the catheter tip in a robotic chamber and within the patient's body. In one embodiment, the catheter is located in the heart in the presence of dynamic motion under the QRS regiments (e.g., while undergoing the systole/ diastole cycle).

[0037] The position and orientation of the catheter is tracked in the presence of dynamical variables, such as, movement of the catheter from its actual position (AP) to its desired position (DP), the dynamics of the patient's heart during its mechanical contraction and repolarization of the heart muscle, the location of the catheter tip relative to the organ's specific anatomy, the operating table, and all the above variables relative to the orientation of the imaging modality used in viewing the organ, (e.g., ultrasonics, radar, x-ray, x-ray with different angulation AP caudal 20° etc.).

[0038] Many of the variables are relatively independent of each other such that there is no useful functional relationship between each one of the elements which define the position of the catheter so as to predicate the other variables. The operating table position, the respiratory chest positions, the movement of catheter tip from AP to DP, the heart cycle, the QRS signal, and the x-ray image orientation are relatively independent variables. One embodiment provides a correlation of these variables.

[0039] In a catherization system, the robotic guidance & control system must be capable of identifying the position and orientation of the catheter tip in order to be able to operate in closed-loop servo mode. In one embodiment, the system is used in connection with a cardiology procedure, such as, for example, an electrophysiological (EP) procedure of mapping and ablation by using the robotic guidance & control system to control, guide, and image the catheter's position and orientation.

[0040] One embodiment includes a servo closed-loop robotic guidance & control system controller where:

a. The patient's rotation relative to the catheter's tip (the tip) is independent of the transformation for finding the accurate position and orientation of the catheter's tip.

b. The location and movement of the organ (e.g., heart) relative to the operating table is

independent of the transformation for finding the accurate catheter's position and orientation.

c. The patient's position and heart orientation relative to the operating table as well as the orientation of the auxiliary imaging equipment are independent variables and can be accounted for. Without loss of generality, the system can provide an accurate catheter position and orientation under conditions noted above.

d. The system is able to provide servo closed loop control while accounting for translation and rotation of the catheter tip relative to a set of independent variables, such as the patient's orientation relative to the operating table, image acquisition orientation (e.g., AP, RAO, caudal, etc.), respiration mode, and the QRS heart dynamic (muscle contraction and repolarization).

e. The system, including the catheter position detection unit and its three dimensional vectors, the QRS synchronization unit, the fiducial alignment system, the operation console (includes the display, haptic controller, and mouse) the mapping unit, the position recording unit, the fiducial sensor, the operating table, configuration file holding the three dimensional models, a three dimensional heart model, a three dimensional torso model, a three dimensional atrial parts model) determine the position and orientation of the catheter tip under dynamic conditions as indicated in i thru iv above. The patient's organ and its specific anatomical site are synchronized to form a normalized vector field (orthogonal to the global coordinate system) further facilitating the operation of the servo closed loop.

[0041] One embodiment includes a robotic guidance & control system apparatus for determining the position and orientation of the catheter's tip under an translation or rotation of variables, relative to patient specific anatomical features such as the heart, right atrium, inferior vena cava, superior vena cava, right atrium lateral wall, His Bundle, interatrial trans-septum, heart left atrium, heart right ventricle, heart left ventricle, heart tricuspid valve, heart mitral valve, electro-cardiac signal, QRS synchronization timing point, and respiration signal, etc.

[0042] The catheter tip is detected and displayed relative to the fiducial sensor position and orientation with its orthogonal vector set: the fiducial x-axis, FX; fiducial y-axis, FY; fiducial z-axis, FZ; and fiducial position, FP.

[0043] In one embodiment, the actual catheter tip and virtual catheter tip are normalized under the global orientation transformation matrix, GO, and global position transform matrix, GP.

[0044] In one embodiment, the detection unit provides data for defining the location of the catheter tip,

forming a map and synchronizing the location to the patient's, his or her heart and specific anatomical features e.g. His Bundle, its electro-cardiac signal, and/or its QRS synchronization timing point. The catheter position and orientation is further corrected relative to respiration signal (pulmonary chest displacement).

[0045] The closed loop control system uses the ability of the imaging and synchronization module to locate, identify, and report the position and orientation of the catheter tip in three-dimensional space under dynamic conditions (e.g., heart muscle contraction and repolarization) while considering respiration distortion of the ribcage, the patient's position relative to the operating table and the specific image capture relative to the patient's organs.

[0046] The system provides an accurate position and orientation of the catheter's tip the presence of relatively independent dynamic variables. The movement of the catheter tip from its actual position AP (catheter axis, global coordinates, and catheter position, global coordinate) to its desired position DP, the movement of the catheter tip, the patient, heart and its specific anatomical features (e.g. heart left atrium) are relatively independent variables.

[0047] In one embodiment, the system is used in connection with a procedure for finding the tricuspid valve in a rotated patient.

[0048] In one embodiment, the system is used in connection with a procedure for finding the pulmonary vein in a rotated patient.

[0049] In one embodiment, the system is configured to determine the position and orientation of the catheter tip and or surgical tools while accounting for mechanical contraction of the heart muscle, its electrical excitation propagation in three dimensional space (one embodiment of a technique for computing the Laplacian cardiac electrogram and the wave equation characteristics used by the robotic guidance & control system apparatus is further described by U.S. patent application Ser. No. 11/362, 542, hereby incorporated by reference).

[0050] In one embodiment, the multiple dynamic and independent variables such as QRS complex, catheter position and orientation, and the outside fiducial markers are normalized in real time to facilitate the servo closed loop modality for controlling the movement of the catheter from AP to a DP. The actual position (AP) is mapped onto the virtual models and patient anatomy by using the global position and orientation matrices generated to account for the shifts of position and orientation of the fiducial alignment sensor caused by patient motion and ribcage displacement due to respiration. Using these matrices, the operator commands, the patient and the patient data are synchronized, and the desired position and orientation (DP), is generated as a conformal map relative to the actual catheter tip position (AP) and patient anatomy, further forming a servo

close loop modality for control, guidance and imaging of catheter tip in a human heart or other internal anatomical site of interest.

[0051] In one embodiment, a fiducial map is used to relate dimensional, anatomical and electrical elements in real time.

[0052] One embodiment includes a robotic catheter guidance and control apparatus that requires less training and less skill than prior art systems.

[0053] In one embodiment, an RF trilateralization system is used to determine the location of the tip of the catheter inside the body, thus minimizing or eliminating the use of ionizing radiation such as X-rays. Alternatively, the catheter guidance system can be used in combination with an X-ray system (or other imaging system) to provide additional imagery to the operator. Moreover, the robotic system used in the robotic catheter guidance system can also be used to locate the catheter tip to provide location feedback to the operator and the control system.

[0054] One embodiment includes a catheter and a guidance and control apparatus that can accurately, and with relative ease, allow the surgeon/operator to position the catheter tip inside a patient's body. The catheter guidance and control apparatus can maintain the catheter tip in the correct position.

[0055] One embodiment includes a catheter and a guidance and control apparatus that can steer the tip of the catheter through arteries and forcefully advance it through plaque or other obstructions.

[0056] One embodiment includes a catheter guidance and control apparatus that displays the catheter tip location with significantly reduced X-ray exposure to the patient and staff.

[0057] One embodiment includes a catheter guidance and control apparatus that is more intuitive and simpler to use, that displays the catheter tip location in three dimensions, that applies force at the catheter tip to pull, push, tum, or hold the tip as desired, and that is capable of producing a vibratory or pulsating motion of the tip with adjustable frequency and amplitude to aid in advancing the tip through plaque or other obstructions.

[0058] One embodiment provides tactile feedback at the operator control to indicate an obstruction encountered by the tip.

[0059] In one embodiment, the catheter guidance control and imaging (robotic guidance & control system) system allows a surgeon to advance, accurately position a catheter, and to view the catheter's position in three dimensions by using a detection system to locate the tip of the catheter.

[0060] In one embodiment, the detector data can be combined with X-ray imagery to produce a composite display.

[0061] In one embodiment, the detector is a system which includes an RF trilateralization system.

[0062] In one embodiment, the apparatus includes a user input device called a "virtual tip" that, in addition to being a representation of the actual or physical catheter tip advancing within the patient's body, possesses a positional relationship to the catheter tip. The virtual tip includes a haptic joystick that can be manipulated by the surgeon/operator and is also designed to deliver tactile feedback to the surgeon in the appropriate axis or axes if the actual tip encounters an obstacle. In other words, the virtual tip includes a joystick type device that allows the surgeon to guide the actual catheter tip though the patient's body. When the actual catheter tip encounters an obstacle, the virtual tip provides tactile force feedback to the surgeon to indicate the presence of the obstacle.

[0063] In one embodiment, the robotic guidance & control system apparatus uses a technique of image synchronization by using a sensor having six degrees of freedom (6-DOF), thereby allowing the formation of a stereotaxic frame of reference.

[0064] In one embodiment, the robotic guidance & control system apparatus uses numerical transformations to compute currents to be provided to various servo motors to control the catheter guidewires used to push, pull and rotate the catheter tip in an efficient manner.

[0065] In one embodiment, the robotic guidance & control system apparatus includes an RF trilateralization system and a 6-DOF sensor configured to detecting the catheter tip and moving body organs, and synchronize their motions.

[0066] In one embodiment, the robotic guidance & control system apparatus is used to perform an implantation of a pacemaker leads during an electrophysiological (EP) procedure.

[0067] In one embodiment, the robotic guidance & control system apparatus uses a detector or other sensors to measure, report and identify the location of a moving organ within the body (e.g., the heart, lungs, etc), with respect to the catheter tip and one or more fiducial markers, so as to provide guidance control and imaging to compensate for movement of the organ, thereby simplifying the surgeon's task of manipulating the catheter through the body.

[0068] In one embodiment, the operator control provides the position and orientation command inputs to a servo system that controls the catheter tip position by regulating the mechanical force applied inside the patient's body. A measurement of the actual tip position and orientation is made via sensory apparatus that includes a radar system, and the 6-DOF sensor. This measurement is used to provide feedback to the servo system and the operator interface.

[0069] In one embodiment, the servo system has a correction input that compensates for the dynamic position of a body part, or organ, such as the heart, thereby offsetting the response such that the

actual tip moves substantially in unison with the beating heart.

[0070] In one embodiment, operation of the catheter guidance system is as follows: i) the operator adjusts the physical position of the virtual tip; ii) a change in the virtual tip position is encoded and provided along with data from the detector system and a 6-DOF sensor to a control system; iii) the control system generates servo-system commands that are sent to a servo system control apparatus; iv) the servo system control apparatus operates the servo mechanisms to adjust the tension force applied to the guidewire assembly to form the necessary geometry calculated by the resident computer; v) the position of the actual robotic catheter tip within the patient's body is changed; vi) the new position of the actual catheter tip is then sensed by the detector and the position of a plurality of fiducial markers are sensed by the 6-DOF sensor, thereby allowing synchronization and superimposing of the catheter position on an image produced by fluoroscopy and/or other imaging modality; and vii) feedback is provided to the servo system control apparatus and to the operator interface; and viii) the displayed image of the actual catheter tip position in relation to the patient's internal body structures is updated.

[0071] The operator can make further adjustments to the virtual catheter tip position and the sequence of steps ii through viii are repeated. In one embodiment, feedback from the servo system control apparatus creates command logic when the actual catheter tip encounters an obstacle or resistance in its path. The command logic is used to control stepper motors which are physically coupled to the virtual catheter tip. The stepper motors are engaged as to create resistance in the appropriate directions that can be felt by the operator, and tactile feedback is thus provided to the user.

[0072] While the apparatus and method has or will be described for the sake of grammatical fluidity with functional explanations, it is to be expressly understood that the claims, unless expressly formulated under 35 USC 112, are not to be construed as necessarily limited in any way by the construction of "means" or "steps" limitations, but are to be accorded the full scope of the meaning and equivalents of the definition provided by the claims under the judicial doctrine of equivalents, and in the case where the claims are expressly formulated under 35 USC 112 are to be accorded full statutory equivalents under 35 USC 112. The disclosure can be better visualized by turning now to the following drawings wherein like elements are referenced by like numerals.

[0073] BRIEF DESCRIPTION OF THE DRAWINGS

[0074] Fig. 1 is a perspective view of the catheter tip, sheath and manually operated handle includes three views of the smart catheter electronic components and its scaffold, starting with an external side view at the top, an internal side view in the middle and an internal top view of the circuit-carrying components at the bottom. Fig. 1.1, included in an inset in Fig. 1A, is perspective view of the printed circuit board layout of the catheter tip. Fig. 1.2, included in an inset in Fig. 1A, is an enlarged perspective view of the distal end of the catheter sheath. Fig. 1.3, included in an inset in Fig. 1A, is an enlarged side transparent or internal view of the manual handle connected to the proximal end of the catheter. Fig. 1.4 is a side cross-sectional view of handle, and Fig. 1.5 is an exploded perspective view of handle. Fig. 1.6 is side transparent view of catheter tip and the opposing pair of pull wires along with a safety wire fixed to tip to insure its retention on the catheter.

[0075] Fig. 2 is a circuit block diagram of the Huygens catheter assembly depicting the distal tip subassembly containing all functional elements for the detection, amplification, digitization, multiplexing, and communication of the native signal using multiple split electrodes.

[0076] Fig. 3 is a circuit block diagram of the circuits in the catheter handle which includes the functional elements that detect contact pressure of the electrode with tissue, enabling the discerning genuine contact with the tissue from other kinds of contact conditions.

[0077] Fig. 4 is a schematic diagram of two views of geometry of the distal end of the catheter with the tip electrode, the split electrodes, and their configuration with a set of vias corresponding to the individual electrodes. A side internal view is provided above and an internal top view below. A circuit block diagram of corresponding circuitry of Fig. 2 is shown above the two internal views identifies in the figure the elements in the electrode array and in the associated circuitry as the circuitry carried by the printed circuit views shown in enlarged scale.

[0078] Fig. 5 shows two internal top plan layouts of the Huygens catheter distal electrode flex circuit, the interconnecting cable and the interface to the electronic circuit assembly, the upper plan layout is a pictorial illustration of the distal electrode flex circuit and interface and the lower plan layout is a diagrammatic depiction of the distal electrode flex circuit connected by the interconnecting cable to the interface. A block diagram of the corresponding circuitry in Fig. 2 is shown above the two internal top plan views and identifies the interconnecting cable.

[0079] Fig. 6 is a diagram of the isolation and trilateralization circuit and is identified in the circuit block diagram of Fig. 2 above the diagram.

[0080] Fig. 7.1 is a block diagram of the multiplexing circuit located proximal to the flexible printed circuit board (FPC) and Fig. 7.2 shows its physical placement on the FPC is a perspective view. In Fig. 7.3 the multiplexing circuit is identified in the circuit block diagram of Fig. 2 to the left side of the diagram.

[0081] Fig. 8.1 is a schematic circuit diagram depicting the amplification elements of the Huygens catheter with its physical location on the FPC shown in Fig. 8.2 in perspective view depiction. Fig. 8.3 identifies on the circuit diagram of Fig. 2 the corresponding portion of the circuitry.

[0082] Fig. 9.1 is a schematic circuit diagram of the A/D processing circuit for the DC voltage potential with its physical location on the FPC shown in Fig. 9.2 in perspective view. Fig. 9.3 identifies on the circuit diagram of Fig. 2 the corresponding portions of the circuitry.

[0083] Fig. 10.1 is a schematic circuit diagram of the data transmission elements with their physical location on the FPC shown in Fig. 10.2. Fig. 10.3 identifies on the circuit diagram of Fig. 2 the corresponding circuitry.

[0084] Fig. 11.1 is a block circuit diagram of the cardiac signal flow elements with their physical layout on the FPC shown in Fig. 11.2 with the wiring labels. Fig. 11.3 identifies on the circuit diagram of Fig. 2 the corresponding circuitry.

[0085] Fig. 12.1 is a circuit block diagram of communication elements used between the electrodes and the electronic circuit with their physical layout on the FPC shown in Fig. 12.2. Fig. 12.3 identifies on the circuit diagram of Fig. 2 the corresponding circuitry.

[0086] Fig. 13.1 is a schematic circuit diagram of the impedance measuring circuit with its physical layout on the FPC shown in Fig. 13.2. Fig. 13.3 identifies on the circuit diagram of Fig. 2 the corresponding circuitry.

[0087] Fig. 14.1 and 14.2 are schematic circuit diagrams of the universal asynchronous receiver-transmitter (UART) for the communication protocol and the signal integration of the cardiac signal output with its physical layout on the FPC shown in Fig. 14.3. Fig. 14.4 identifies on the circuit diagram of Fig. 2 the corresponding circuitry.

[0088] Fig. 15.1 is a schematic diagram of the power circuitry and isolation technique of the Huygens catheter with its physical layout on the FPC shown in Fig. 15.2 . Fig. 15.3 identifies on the circuit diagram of Fig. 2 the corresponding circuity.

[0089] Fig. 16 is a perspective view of the robotic navigation device without catheter loaded as shown on the left side and with catheter inserted as shown on the right side of the figure.

[0090] Fig. 17 is a perspective side view of the robotic navigation device shown some of its mechanical components.

[0091] Fig. 18 is an exploded perspective view of the robotic navigation device better displaying some of its mechanical components.

[0092] Fig. 19 is a top perspective view of the robotic navigation device.

[0093] Fig. 20 is a side plan view of the robotic navigation device with the catheter loaded in it.

[0094] Fig. 21 is a top plan view of the robotic navigation device with the catheter loaded in it.

[0095] The disclosure and its various embodiments can now be better understood by turning to the following detailed description of the preferred embodiments which are presented as illustrated examples of the embodiments defined in the claims. It is expressly understood that the embodiments as defined by the claims may be broader than the illustrated embodiments described below.

[0096]

[0097] **Detailed Description of the Preferred Embodiments**

[0098] Fig. 1 is a perspective representation of a catheter 100 employed in the Huygens Catheter as described below, with its three main subassemblies: 1) the distal end of the catheter FPC 120, 2) the overlay sheath 5, and 3) the catheter handle 200 having a kinematic mechanism therein as partially seen in Fig. 1.3 for differentially tensioning the pulley wires to deflect the catheter tip 120. The kinematic mechanism is described in more detail in incorporated applications serial nos. 16/424202 and 17/468,460, and is shown in greater detail in Figs. 1.4 – 1.6. Fig. 1.4 is a side cross-sectional view of handle 200 and Fig. 1.5 is an exploded perspective view of handle 200. Knob 202 has internal threading and threadably engages a piston 203 by means of opposing pairs of tabs 205 riding in the threading of knob 202 in order to move piston 203 longitudinally within handle 200 as knob 202 is rotated. Pull wire 7 has one end fixed within handle 200 and is coupled by a stop or other means to the proximal end of piston 203, led around pulley wheel 211, then led distally out of handle 200 to and fixed to catheter tip 120. The opposing pull wire 7 is also fixed to catheter tip 120 and is led proximally back to handle 200 where it is led through end 209 of piston 203 and fixed to handle 200. Both ends of pull wires 7 fixed to handle 200 are spring loaded to allow resilient tension to be maintained on pull wires 7. Differential tension or extension applied by piston 203 by means of knob 202 causes catheter tip 120 to be deflected or allows it to straighten. Fig. 1.6 is side transparent view of catheter tip 120 and the opposing pair of pull wires 7 along with a safety wire 213 fixed to tip 120 to insure its retention on the catheter.

[0099] The size of the sheath 5 is typically 6 or 7 French for use in the cardiovascular system and all circuitry and chips must be dimensioned to fit within the inner diameter of a catheter of that size, while still maintaining the required flexibility. Hence, the sizing and placement of rigid integrated

circuit chips and their associate wiring must be carefully thought out and the following figures shown an embodiment in which such placements or layouts can be realized. The catheter assembly includes a handle 200, a distal end flex circuit 120 carrying the sensing electrodes 111-119, a protective overlay sheath 5, enclosing the entire assembly, including a sleeve ring 6 to which a safety wire 135, shown in Fig. 1A, and a pair of pulley wires 7 are affixed. Pulley wires 7 are disposed in PTFE liners to insure lubrication and sheath 5 is coated with an inner PTFE layer and reinforced with a flexible braid. Handle 200 includes a rotatable knob 202, which selectively tensions each of the pair of opposing pulley wires 7 to deflect catheter tip 120. The proximal flex section 150 of the assembly in Fig. 1.1 includes the electronic processing unit is electrically connected via a wire bundle 140 to FPC 120. The structural as well as functional elements of the novel catheter and its intended use are detailed below.

[00100] Fig 1A includes three views of the smart catheter electronic components and its scaffold, starting with an external side view at the top, an internal side view in the middle and an internal top view of the circuit-carrying components at the bottom. These views of the catheter 100 depict the placement of the major electronic elements included in the Huygens catheter assembly. The catheter 100 provides the sensing elements, such as the set of electrodes 111-119 mounted on a distal tip 110 and attached to a flex printed circuit board (PCB) 120 to provide the necessary metrics customary in an electrophysiological study, for example the metrics provided by an electrode assembly having a spacing of 2mm between a tip electrode 111 and a first pair of electrodes 112-113, another spacing of 2mm between the first pair 112-113 and a second pair of electrodes 114-115, a spacing of 5mm between the second and a third pair of electrodes 116-117 and a spacing of 2mm between the third and a fourth and last electrode pair 118-119. These metrics are preserved to provide a standard for an electroanatomical waveform.

[00101] A safety wire 135 connects the distal tip electrode 111 to the sleeve 6. The proximal end flex circuit 150 carries the electronic assembly which enables the DC potential signal to be sensed by the electrodes 111-119, and thereafter digitized, amplified, filtered, multiplexed and transmitted via a communication protocol to the electronics in handle 200. The details of this signal flow are described in the subsequent figures. A programming flap 182 is provided for programming the digital circuits in proximal FPC 150 and is removed or cut off once the circuits have been programmed.

[00102] Fig. 2 is a circuit block diagram of the Huygens catheter assembly depicting the distal tip subassembly containing all functional elements for the detection, amplification, digitization, multiplexing, and communication of the native signal using multiple split electrodes. The block diagram of the catheter assembly depicts the distal tip 110 with its signal acquisition electrode

inputs 111-119, connected via wire bundle 140 to the proximal end flex circuit 150 to capture the sensing potential from the endocardial surface of the heart, to multiplex (multiplexers 172, 174) and amplify the signals via a set of amplification stages, digitize the amplified signals and to transmit the multiplexed, digitized, amplified native heart signal from the endocardial surfaces via a communication protocol to an external conventional mapping station (not shown).

[00103] The circuit diagram of Fig. 2 depicts the major functional elements that form the Huygens catheter, items such as the signal processing circuits comprised of a 2-1 MUX 172, an 8-1 MUX 174, an instrumentation amplifier 176, a bandpass filter 177, a level shift amplifier gain 175, a microcontroller unit (MCU) 179, programmable gain circuit 182 controlling instrumentation amplifier 179, a charge pump 183, a 3.3V low dropout regulator (LDO) 184, an RS-485 input/output circuit (I/O) 180, and universal asynchronous receiver/transmitter (UART) 185. Electrodes 111-113 are selectively used to sense contact impedance using control signals Impedance IN and OUT, and cardiac signals as described below. The sensed signals are multiplexed into an amplifier chain 176, 177 175, digitized by MCU 179 and formatted into an UART 185 protocol and line driver 180. The multiplexed digital output/input of the circuitry of Fig. 21 is presented at line driver 180 as the transmission signals TX+. TX- and input signals RX+, RX-.

[00104] -Fig. 3 is a circuit block diagram of the Huygens catheter assembly depicting the distal tip subassembly containing all functional elements for the detection, amplification, digitization, multiplexing, and communication of the native signal using multiple split electrodes. The circuit diagram depicts the handle electronic circuit containing a microcontroller 270 which maintains the communication with and control of the flex circuit 150 in Fig. 2 as well as the Impedance measuring circuit (IMC) 255 and communication protocol. The handle 200 serves multiple requirements, namely it includes an impedance circuit 255 which enables the catheter sensing element to determine whether the catheter electrodes 110 are in contact with the endocardial surfaces of the heart, or if the electrodes 110 are nested in the heart chamber and blood pool. The handle electronics of Fig. 3 includes a MCU 270 sets the priorities for communication of the signal from and to the distal and proximal electronics. The handle circuitry includes the RS-485 line driver 260, MCU 270, 3.3V LDO 272, charge pump 274, power isolator 276, signal isolator 278, UART decoder 280 and UART encoder 281. Bidirectional data and control signals, RX+, RX-, TX+, TX- are input and output from line driver 260 into and from the internal ADC and DMA of MCU 270. The impedance measuring circuit 255 is also coupling bidirectional impedance signals Impedance IN and Impedance OUT into and out of MCU 270. Data is serialized in MCU 270, formatted by UART 281 and communicated through an isolator 278 to a UART transceiver 279.

Catheter power management is also provided by the circuitry in handle 200 though LDO 272, charge pump 274, and power isolator 276.

[00105] Fig. 4 is a schematic diagram of two views of geometry of the distal end of the catheter with the tip electrode, the split electrodes, and their configuration with a set of vias corresponding to the individual electrodes. A side internal view is provided above as an internal top view below. A circuit block diagram of corresponding circuitry shown in Fig. 2 above the two internal views identifies the elements 110 in the electrode array and in the associated circuitry. In addition a temperature sensor 132 (also shown in Fig. 2) compensates for variations of temperature to control a baseline of the signal is provided. Each electrode 110 has a dedicated connection to its corresponding via except for the first ring electrode (E2). Top and bottom half-ring electrodes 114, 115 (E3-E4) on the first ring are shorted together and identified as the E2 signal, since half-ring electrodes 114, 115 (E3-E4) need to function as a bipolar pair with the nosecone electrode (E1).

[00106] Fig. 4 further depicts the elements that form the distal end of the catheter distal tip 110 which includes the nose electrode 111, electrode split-rings 112-119 mounted on flex PCB 120, connected via distal FPC pads 121-130 to the proximal end circuit 150. One of the preferred embodiments of this geometric layout includes the use of split electrodes on each of the axial layouts of the quadrupolar catheter configuration, whereby the distal most electrode pair 112-113 is able to pick up the DC potential signal from the endocardial surface as either electrode 111 or its counterpart pair 112-113 are touching the endocardial surface thereby providing a signal via the impedance measuring circuit 255 located at the handle electronic board 250, which sends an AC test current through the tip electrode 111 in combination with electrode pair 112-113 to sense impedance to determine whether the catheter electrodes 110 are in contact with the endocardial surface or situated within the blood pool in the heart chamber. Such determination is further described in detail by Fig. 13, where the usefulness and clinical value of this circuit is further described.

[00107] Fig. 5 shows two internal top plan layouts of the Huygens catheter distal electrode flex circuit, the interconnecting cable 140 and the interface to the electronic circuit assembly. The upper plan layout in Fig. 5 is a pictorial illustration of the distal electrode flex circuit and interface and the lower plan layout in Fig. 5 is a diagrammatic depiction of the distal electrode flex circuit connected by the interconnecting cable 140 to the interface. A block diagram of the corresponding circuitry of Fig. 2 shown is shown above the two internal top plan views and identifies the interconnecting cable 140. Fig 5 illustrates certain manufacturing and physical attributes of the Huygens catheter. The layout further shows the distal flex circuit 120 FPC tabs (MPAD1 – MPAD10) which are

connected to a set of vias located at the end of the distal FPC 120 by employing a 40AWG Daburn wire bundle 140. The number system describes the sequence of the electrodes and their location. Proximal FPC (MPAD1 – MPAD10) through 40AWG Daburn wires are bundled in a strand. For assembly convenience, the corresponding vias have same numbering.

[00108] Distal FPC 120 containing the electrodes with distal FPC tabs 121-130, wire bundle 140, proximal end 150, proximal FPC tabs 161-170 are shown for clarity, and their separation with the bundle of interconnecting wire 140 enables free rotation of the distal catheter tip 120 along the Y- and Z-axis for rotation and along the X-axis for translation without any limitation associated with the stiffness of the catheter shaft because of electronic circuit FPC 155 or the distal FPC 120. Both FPC 155 and FPC 120 are linked mechanically by wire bundle 140 to enable a high degree of movement along any axis.

[00109] Fig. 6 is a diagram of the isolation and trilateralization circuit shown and is identified in the circuit block diagram above the diagram. The isolation and trilateralization circuit is where conventional RF trilateralization signals to map the position of the catheter 100 are picked up from electrodes 111-119 and independently carried with a set of wires through the shaft of the catheter 100 and are transmitted to an external system, such as a conventional CARTO/EnSite NavX, where trilateralization is computed and displayed using position and orientation vector data collected from external RF patches mounted on the body of the patient according to conventional electrophysiology practice, and augmented with additional information such as impedance, DC potential, timing and temperature, and varieties of other electrical parameters as disclosed below. Fig. 6 depicts the proximal FPC 155, which receives the signals from the electrodes 111-119 provided to proximal FPC tabs 161-170 each through a Schottky protection diode 171.

[00110] Fig. 7.1 is a block diagram of the multiplexing circuit located proximal to the flexible printed circuit board (FPC) and Fig. 7.2 shows its physical placement on the FPC is a perspective view. In Fig. 7.3 the multiplexing circuit is identified in the circuit block diagram of Fig. 2. The inputs from nosecone electrode 111 in Fig. 4 and first ring electrodes (E1 & E2) 112-113 are coupled to a pair of 2-to-1 MUXs 172. These sets of electrodes have a dual-function and their use is determined by the MCU 270 located in the handle 200 which switches the use of the electrodes 112-113 for either impedance measurement (contact or non-contact of the electrodes to endocardial surface), or for DC potential measurement of the endocardial surface. The IMP_SEL pins of the 2-to-1 MUX 172 control which function these electrodes serve. The outputs of the two MUXs 172 along with the rest of 6 input signals (E3 – E8) connected to 8-to-1 MUX 174 are multiplexed to a single analog signal. Each input via from proximal FPC 161-170 (MPAD1 – MPAD8) has an ESD protection diode 173 (D3 – D10). Electrodes E1, E2, E3, E5, and E7 have

split traces that connect to the mapping station such as a conventional EnSite NavX/CARTO (not shown) for the purpose of tri-lateralization of locating signals as described in Fig. 6. Fig. 7 further depicts the distal tip 110, proximal end 150, proximal FPC tabs 161-170, Schottky diode 171, 2-1 MUX signal converter 172, protection diode 173, and 8-1 MUX 174.

[00111] Fig. 8.1 is a schematic circuit diagram depicting the amplification elements of the Huygens catheter with its physical location on the FPC shown in Fig. 8.2 in perspective view depiction. Fig. 8.3 identifies on the circuit diagram of Fig. 2 the corresponding portion of the circuitry. The amplification is provided where the multiplexed analog signals enter instrumentation amplifier 176 (MAX41400), and are referenced to the patient's right leg, where a standard bipolar recording is provided utilizing a right limb lead to enable the measurement of the potential difference between the catheter and its limb reference point. The amplifier 176 has a programmable gain set to 200x. After the initial amplification, the signal is input to a second order Butterworth lowpass filter 177 configured in a Sallen-Key topology. The filter 177 is designed to have -3dB cutoff frequency at 1KHz in order to filter out the trilateralization signals. The second stage of the operational signal amplifier 175 shifts the entire signal so that its voltage range is entirely in positive domain. Fig. 8.1 depicts the distal tip 110, proximal end 150, 8-to-1 MUX 174, Instrumentation amp 176, Butterworth bandpass filter 177, and signal amp 175.

[00112] Fig. 9.1 is a schematic circuit diagram of the A/D processing circuit for the DC voltage potential with its physical location on the FPC shown in Fig. 9.2 in perspective view. Fig. 9.3 identifies on the circuit diagram of Fig. 2 the corresponding portions of the circuitry. Fig. 9.1 illustrates the A/D processing of the DC voltage potential, where the amplified signal is input into (STM32G031Y8Y6TR) microcontroller MCU 179 where its internal ADC (not shown) converts the processed cardiac signal into digital format. The microcontroller (MCU) 179 also collects the temperature data from MPAD9. Thereafter, the MCU 179 compiles these converted digital signals and outputs in a UART format with a BAUD rate of 4Mbps. The microcontroller MCU 179 is programmed through J1 tab 182, which is removed once the component has been programmed.

[00113] Fig. 10.1 is a schematic circuit diagram of the data transmission elements with their physical location on the FPC shown in Fig. 10.2. Fig. 10.3 identifies on the circuit diagram of Fig. 2 the corresponding circuitry. Fig. 10.1 depicts the data transmission scheme, where the UART signal is processed through an RS-485 transmitter 186 and receiver 187 before sent to the handle PCB (HAN300001) 251. RS-485 transmitter 186 allows the data transmission to be done in a differential paired mode, providing immunity over EMI in a long strand of wires.

[00114] Fig. 11.1 is a block circuit diagram of the cardiac signal flow elements with their physical layout on the FPC shown in Fig. 11.2 with the wiring labels. Fig. 11.3 identifies on the circuit diagram

of Fig. 2 the corresponding circuitry. Fig. 11.1 depicts the cardiac signal flow, whereby the 40-AWG Daburn wires 205 from the tip are connected to the distal portion of handle PCB 251 (HAN300001). As shown in the assembly drawing, the via labeling for wiring connection corresponds to the tip FPCs for ease of wire assembly. From the handle 200 to the external devices, bigger diameter wires are used, resulting in bigger vias (1mm hole diameter).

[00115] Fig. 12.1 is a circuit block diagram of communication elements used between the electrodes and the electronic circuit with their physical layout on the FPC shown in Fig. 12.2. Fig. 12.3 identifies on the circuit diagram of Fig. 2 the corresponding circuitry. Fig. 12.1 illustrates the communication format between the electrodes and the electronic circuit 261, which outputs the RS-485 differential pair signals connected to vias MPAD16 to MPAD18. These signals are input into full-duplex RS-485 driver 260, where the signals are converted back to a UART format. The converted UART signals are input to the microcontroller 270 and processed.

[00116] Fig. 13.1 is a schematic circuit diagram of the impedance measuring circuit with its physical layout on the FPC shown in Fig. 13.2. Fig. 13.3 identifies on the circuit diagram of Fig. 2 the corresponding circuitry. Fig. 13.1 illustrates the impedance measuring circuit, comprising an impedance converter AD5933 254 and two operational amplifiers 256, 257. Impedance converter AD5933 254 sends a small current to MPAD19 which is communicated to the 2-to-1 MUX 172 at the proximal FPC 155. When the read signal is asserted, the impedance-reading current travels through the nosecone electrode 111 and returns to the first ring electrodes 112-113. The current returns to the handle 200 via MPAD20, and back to impedance converter AD5933 254. The calculated impedance is sent to the microcontroller (MCU) 270 via an inter-integrated circuit (I2C) communication protocol.

[00117] Fig. 14.1 and 14.2 are schematic circuit diagrams of the universal asynchronous receiver-transmitter (UART) for the communication protocol and the signal integration of the cardiac signal output with its physical layout on the FPC shown in Fig. 14.3. Fig. 14.4 identifies on the circuit diagram of Fig. 2 the corresponding circuitry. Figs. 14.1 and 14.2 illustrate the UART communication protocol and the signal integration of the cardiac signal output, where the microcontroller MCU 270 combines the digital input from the tip FPC 120 and the impedance data. The MCU 270 combines all the data and outputs the combined data via a UART protocol. To comply with medical device regulations, all signals and power must be isolated. Therefore, the UART signals are optically isolated before connecting to an external programmable logic controller (PLC). The circuit of Fig. 14.2 depicts the serial communication channel 1 265, serial communication channel 2 266, handle MCU 270, power isolator 276, and signal isolator 278.

[00118] Fig. 15.1 is a schematic diagram of the power circuitry and isolation technique of the Huygens

catheter with its physical layout on the FPC shown in Fig. 15.2 . Fig. 15.3 identifies on the circuit diagram of Fig. 2 the corresponding circuity. Fig. 15.1 shows that the power circuitry and isolation circuity of the Huygens catheter receives +5V power from PLC's USB connector 285. The voltage and ground from external PLC (not shown) is isolated before it powers the catheter 100. The 3.3V low dropout voltage regulator (LDO) 272 supplies local electronic components while the isolated +5V and the -5V that is generated from the charge pump 274 is connected to the tip FPCs. Fig. 15.3 depicts the catheter handle electronics 250, serial communication channel 1 265, serial communication channel 2 266, handle MCU 270, handle LDO 272, handle charge pump 274, power isolator 276, and power input 285.

[00119]

[00120] Proteus Robot

[00121] Fig. 16 is a perspective view of the robotic navigation device 400 without catheter 100 loaded as shown on the left side and with catheter 100 inserted as shown on the right side of the figure. Fig. 17 is a perspective side view of the robotic navigation device shown some of its mechanical components, showing the top carriage assembly 410, baseplate 420, proximal pillow block 430, distal pillow block 440, deflection-rotary drive (DRD) 450, rotary drive 452, linear translation drive (LTD) 460, angle mounting system (AMS) 470. Handle 200 is disposed in device 400. DRD 450 engages knob 202 to bidirectionally rotate it using a computer controlled electric motor and toothed belt combination to selectively deflect the catheter tip 120. DRD drive 452 uses a computer controlled electric motor and toothed belt combination to selectively rotate the body of handle 200 thereby rotating the catheter as a unit . Linear translation drive 460 uses a computer controlled linear electric motor to selectively translate the upper portion of device 400, namely pillow blocks 440 and 430 to translate handle 200 carried therein and catheter 100. The angular inclination of lower platforms 420 and 470 are varied using a scissor hinge connecting platforms 420 and 470. Fig. 18 is an exploded perspective view of the robotic navigation device better displaying some of its mechanical components, showing again the top carriage assembly 410, baseplate 420, proximal pillow block 430, distal pillow block 440, deflection-rotary drive (DRD) 450, linear translation drive (LTD) 460, angle mounting system (AMS) 470. Fig. 19 is a top perspective view of the robotic navigation device 400. Fig. 20 is a side plan view of the robotic navigation device with the catheter loaded in it. Fig. 21 is a top plan view of the robotic navigation device with the catheter loaded in it.

[00122] Many alterations and modifications may be made by those having ordinary skill in the art without departing from the spirit and scope of the invention. Therefore, it must be understood

that the illustrated embodiments have been set forth only for the purposes of example and should not be taken as limiting the scope of the invention.

[00123] Therefore, it must be understood that the illustrated embodiment has been set forth only for the purposes of example and that it should not be taken as limiting the invention as defined by the following claims. For example, not withstanding the fact that the elements of a claim are set forth below in a certain combination, it must be expressly under stood that the invention includes other combinations of fewer, more or different elements, which are disclosed in above even when not initially claimed in such combinations. A teaching that two elements are combined in a claimed combination is further to be understood as also allowing for a claimed com bination in which the two elements are not combined with each other but may be used alone or combined in other combinations. The excision of any disclosed element of the invention is explicitly contemplated as within the scope of the invention.

[00124] The words used in this specification to describe the invention and its various embodiments are to be understood not only in the sense of their commonly defined meanings, but to include by special definition in this specification structure, material or acts beyond the scope of the commonly defined meanings. Thus if an element can be understood in the context of this specification as including more than one meaning, then its use in a claim must be understood as being generic to all possible meanings supported by the specification and by the word itself.

[00125] The definitions of the words or elements of the following claims are, therefore, defined in this specification to include not only the combination of elements which are literally set forth, but all equivalent structure, material or acts for performing substantially the same function in substantially the same way to obtain substantially the same result. In this sense it is therefore contemplated that an equivalent substitution of two or more elements may be made for any one of the elements in the claims below or that a single element may be substituted for two or more elements in a claim. Although elements may be described above as acting in certain combi nations and even initially claimed as such, it is to be expressly understood that one or more elements from a claimed com bination can in some cases be excised from the combination and that the claimed combination may be directed to a sub combination or variation of a sub-combination. Accordingly, the scope of the invention is limited only by the claims and equivalents thereto.

What is claimed is:

1. An apparatus for robotically performing electrophysiological and/or renal macros in combination with a remote mapping station comprising:

a flexible catheter having a distal portion and a plurality of sensing electrodes included in the distal portion for sensing native biometric signals;

one or more multiplexers included in the distal portion of the catheter and coupled to the plurality of sensing electrodes to multiplex the biometric signals;

an amplifier circuit included in the distal portion of the catheter and coupled to the one or more multiplexers to amplify the biometric signals in the distal portion of the catheter;

a microcontroller included in the distal portion of the catheter coupled to the amplifier circuit to digitize the biometric signals and to format the digitized amplified biometric signals according to a communications protocol;

a flexible sheath coupled at a distal end to the distal portion of the catheter and including a digital communications cable and control wires;

a remote handle coupled to a proximal end of the sheath, to the digital communications cable and to the control wires, the remote handle including a kinematic mechanism coupled to the control wires to selectively deflect a distal end of the catheter including the plurality of sensing electrodes, and the remote handle including circuitry for digitizing and/or formatting the digitized amplified multiplexed biometric signals for bidirectional transmission to the remote mapping station; and

a robot engaging the remote handle for selectively deflecting the distal tip of the catheter, rotating the catheter and/or translating the catheter in response to computer commands to learn and/or execute electrophysiological and/or renal macros.

2. The apparatus of claim 1 where the distal portion of the catheter is comprised of at least a distal subportion and a separate proximal portion, the distal and proximal subportions being coupled by a flexible wiring cable, which allows relative rotation of the two subportions.

3. The apparatus of claim 2 where the distal subportion includes the plurality of sensing electrodes and the proximal subportion includes the multiplexers, amplifier circuit and microcontroller.

4. The apparatus of claim 1 where the amplifier circuit comprises an amplifier chain.

5. The apparatus of claim 4 where the amplifier chain comprises an instrumentation amplifier, an active filter coupled to the instrumentation amplifier and level shift amplifier coupled to the active filter.

6. The apparatus of claim 1 where the remote handle further comprises an impedance measuring circuit.

7. The apparatus of claim 1 where circuitry for digitizing and/or formatting the digitized amplified multiplexed biometric signals comprises a handle microcontroller.

8. The apparatus of claim 1 where circuitry for digitizing and/or formatting the digitized amplified multiplexed biometric signals comprises a power isolator and a signal isolator coupled to the circuitry carried on a printed circuit board which includes a copper free zone including the power isolator and the signal isolator isolating the circuitry from the mapping station.

9. The apparatus of claim 1 where the sensing electrodes, multiplexers, amplifier circuit and microcontroller are disposed on one or more flexible printed circuit boards included inside of the sheath having a predetermined French size.

10. The apparatus of claim 1 where the computer commands transmitted to the robot are stored and/or generated in the mapping station.

11. A method of robotically and dynamically controlling the movement of a catheter in a body organ cavity of a patient as directed by a surgeon comprising:

disposing an optical catheter into the body organ cavity under manual control by the surgeon at one or more anatomical sites in the body organ cavity as chosen by the surgeon;

recording the positions of the one or more anatomical sites in the body organ cavity as identified by the surgeon;

measuring one or more biometric signals at a corresponding one or more positions in the body organ cavity using the catheter as identified by the surgeon;

robotically moving the optical catheter in the body organ cavity on a path selected by the surgeon to the one or more anatomical sites and/or positions in the body organ cavity;

generating a map of the biometric signals from positions on the path; and

displaying the map.

12. The method of claim 11 where recording the positions of the one or more anatomical sites in the body organ cavity comprises recording the positions of the one or more anatomical sites in the body organ cavity as corrected for dynamic movement of the body organ within the patient, of cardiac movement, of respiratory movement, and of patient movement.

13. The method of claim 12 where recording the positions of the one or more anatomical sites in the body organ cavity comprises identifying selected ones of the anatomical sites and/or positions as sites or positions respectively requiring medical mediation.

14. The method of claim 13 where identifying selected ones of the anatomical sites and/or positions as sites requiring medical mediation comprises identifying a path in the body organ cavity along which medical mediation is required.

15. The method of claim 13 further comprising robotically performing a medical mediation procedure at selected ones of the anatomical sites and/or positions as sites or positions respectively.

16. The method of claim 11 where measuring one or more biometric signals at a corresponding one or more positions in the body organ cavity using the catheter as identified by the surgeon comprises measuring local cardiac or local renal signals from positions with the body organ cavity contacted by the catheter.

17. The method of claim 11 where measuring local cardiac or local renal signals from positions with the body organ cavity contacted by the catheter comprises measuring cardiac or local renal signals substantially free of any far-field signals.

18. The method of claim 11 where the optical catheter is an electrophysiology catheter and further comprising robotically and automatically performing a cardiac mediation procedure in a heart at selected ones of the anatomical sites and/or positions as sites or positions respectively as automatically guided by the generated map of the biometric //signals of the heart.

19. The method of claim 15 further comprising using artificial intelligence to analyze the generated map of biometric signals and to generate from the map a program of controlled robotic movement and operation of the catheter to automatically perform the medical mediation procedure at selected ones of the anatomical sites and/or positions as sites or positions respectively.

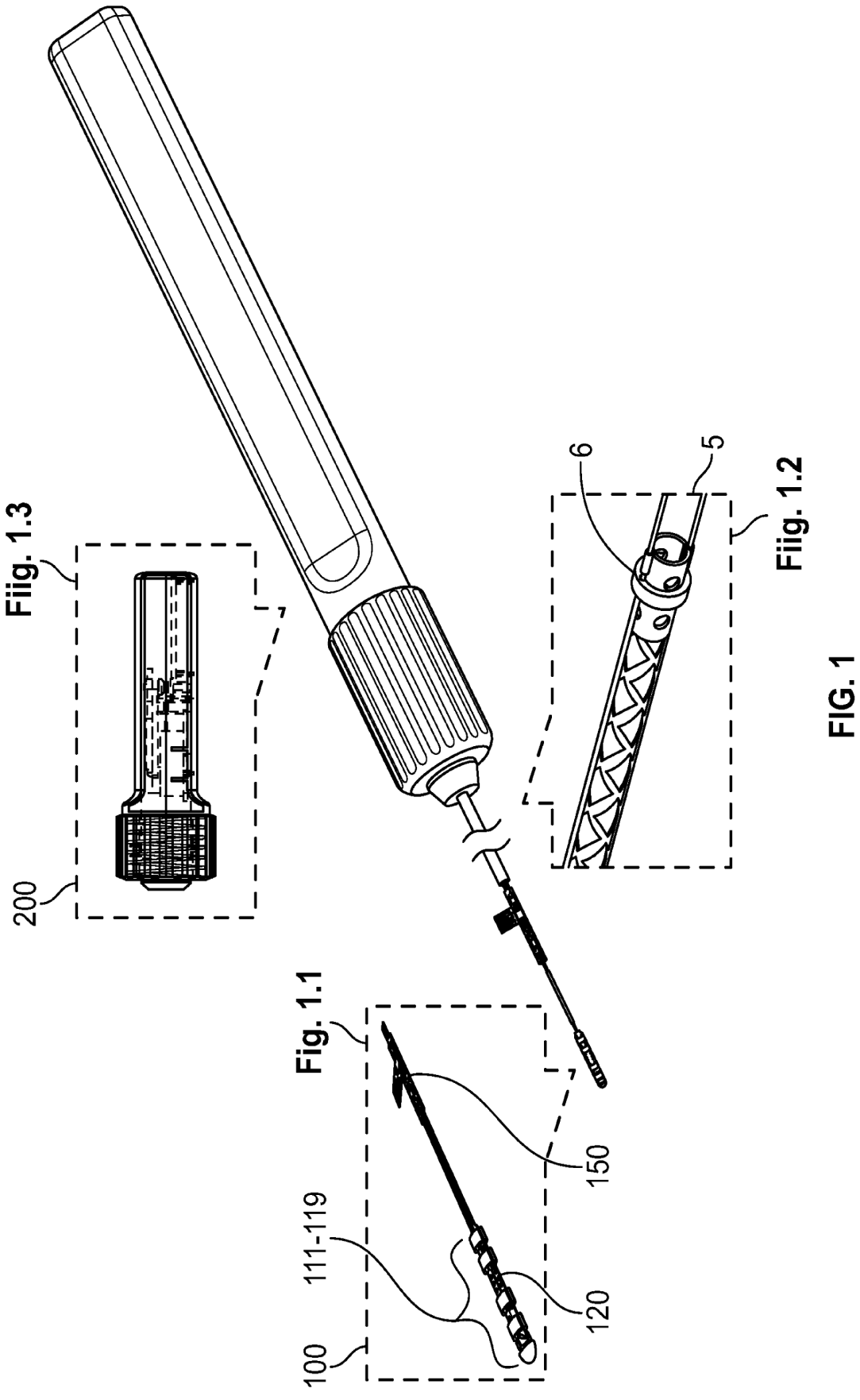


FIG. 1

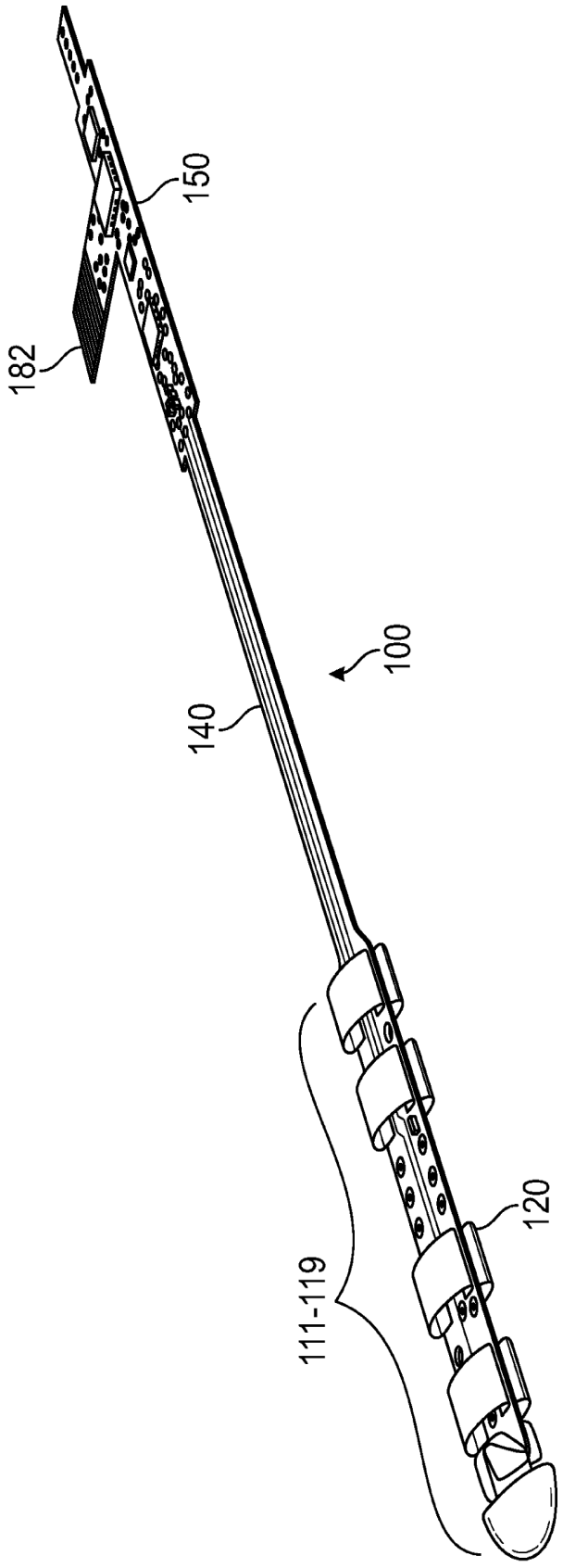


FIG. 1.1

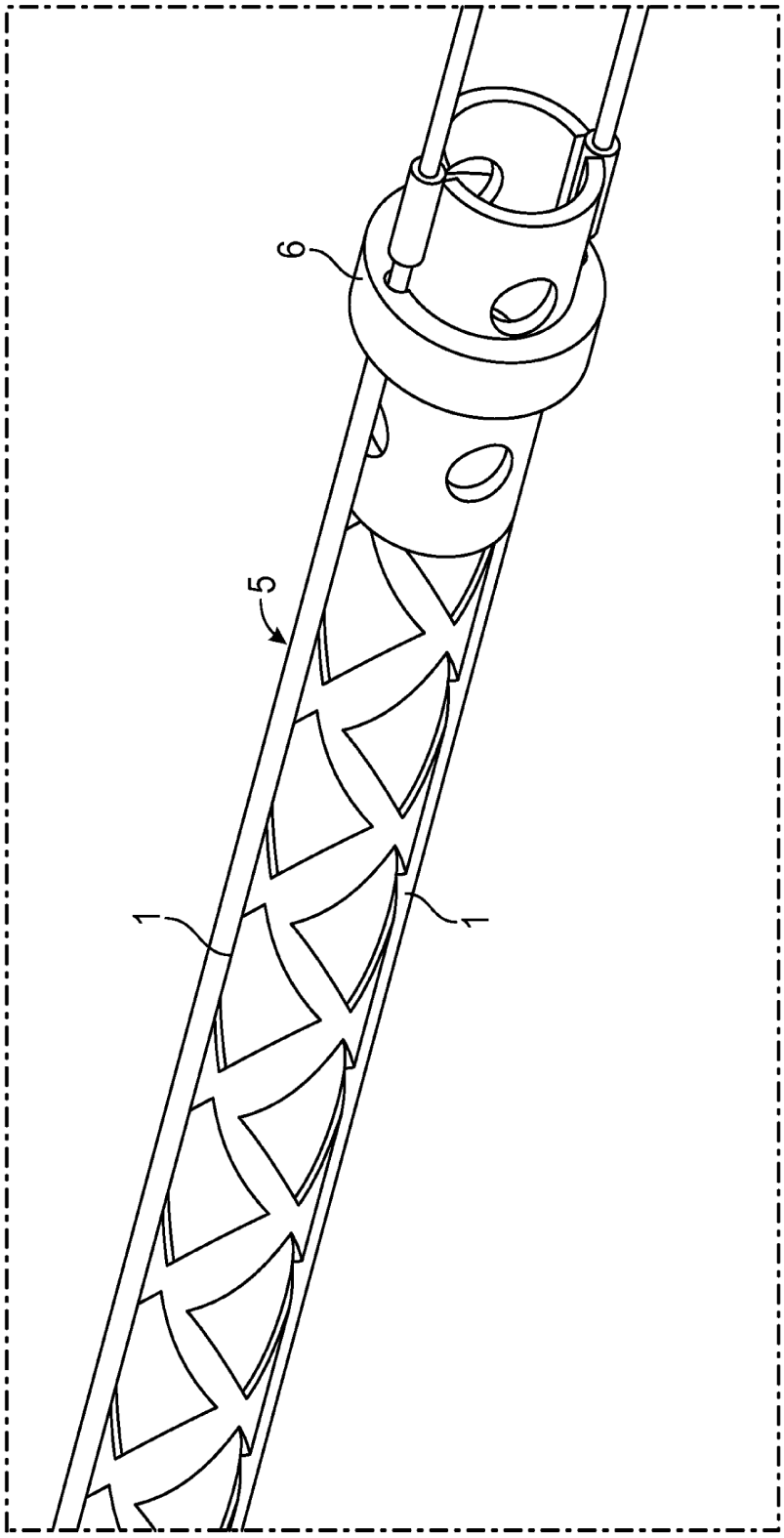


FIG. 1.2

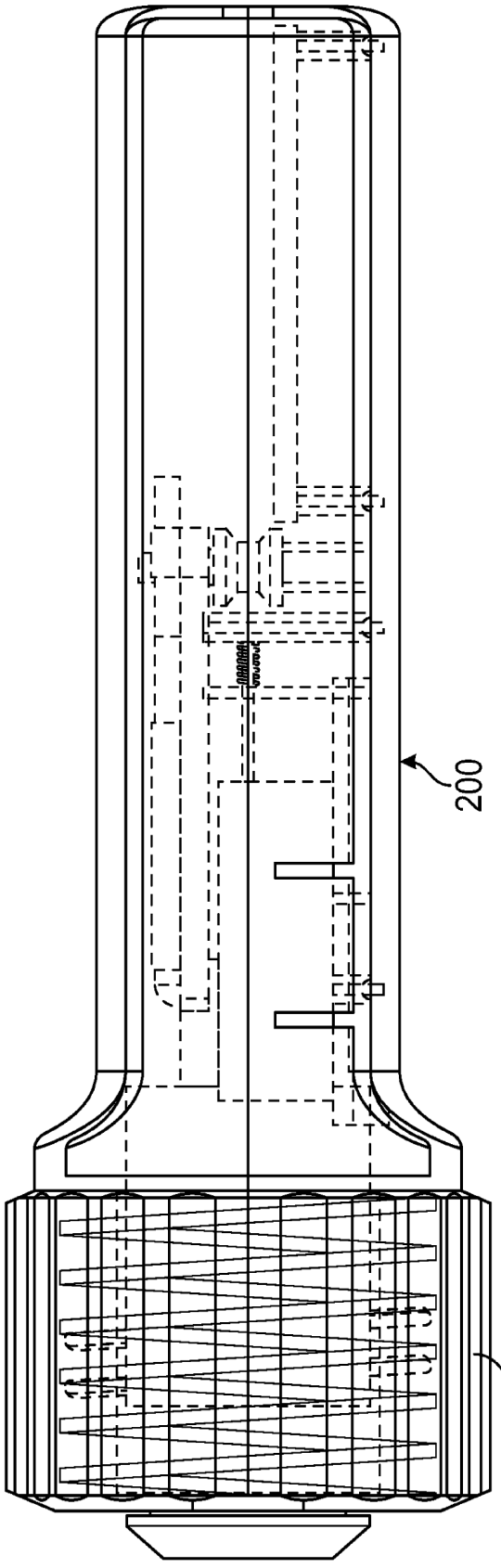


FIG. 1.3

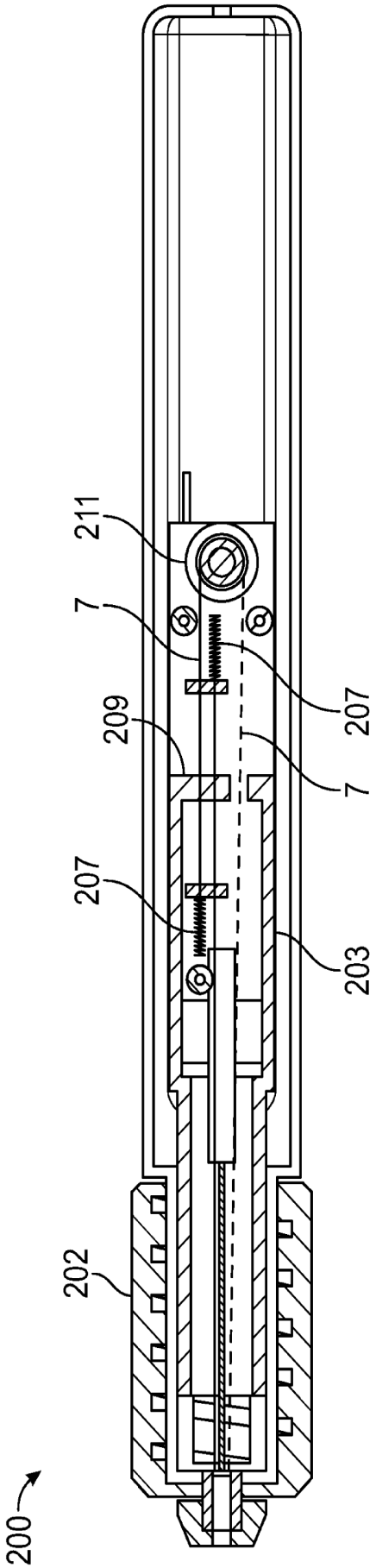


FIG. 1.4

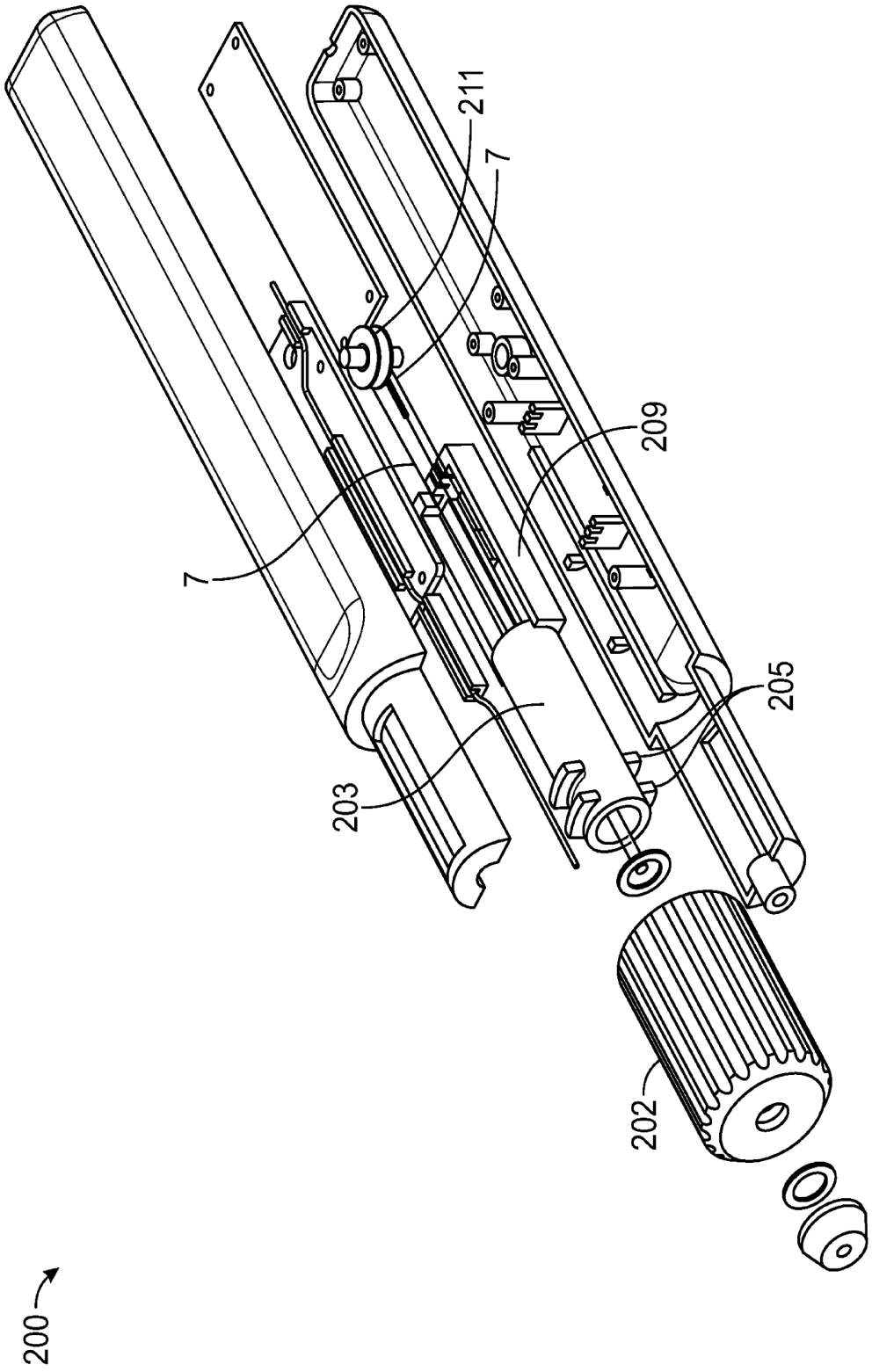


FIG. 1.5

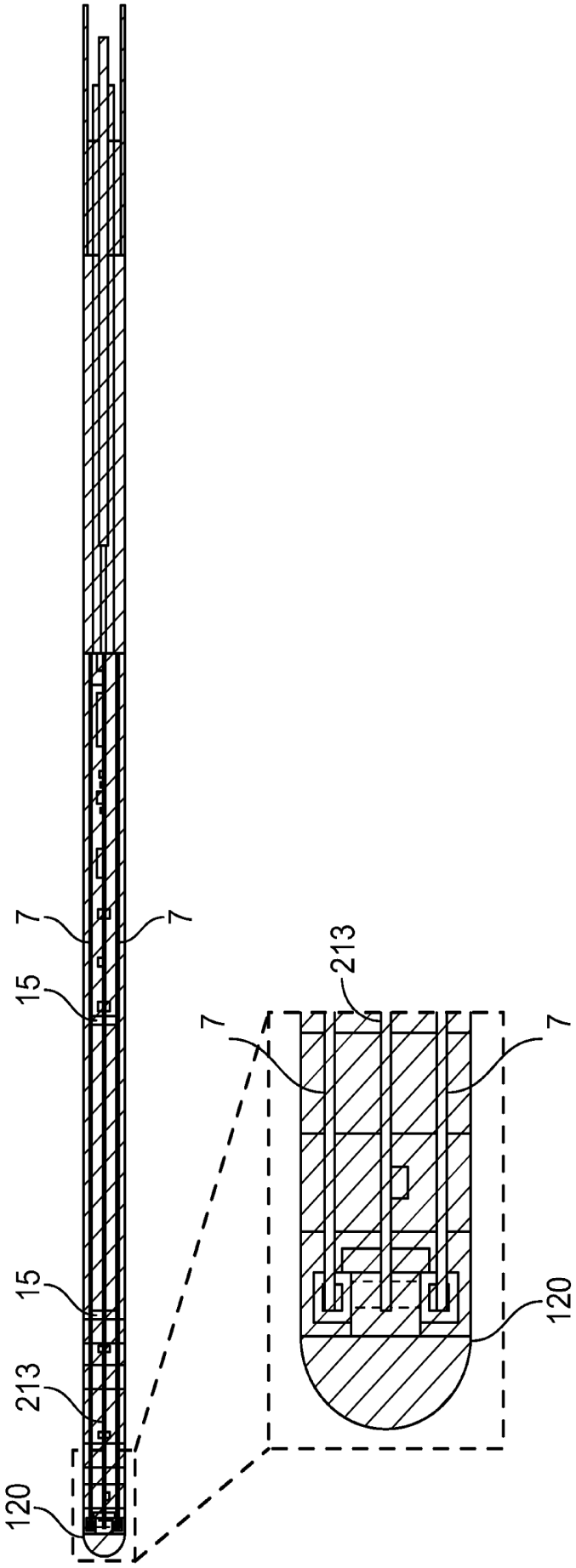


FIG. 1.6

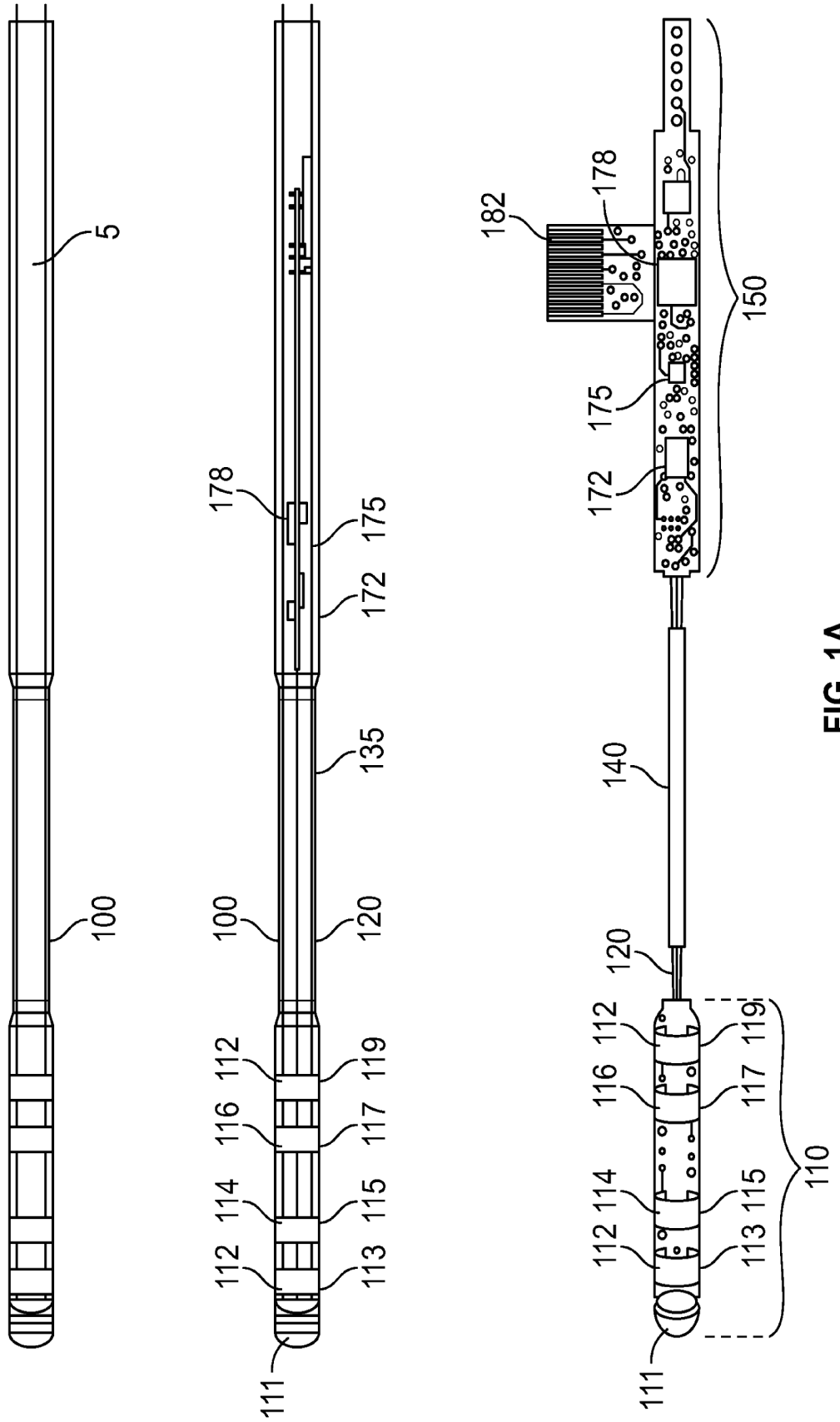

5
100
178
175
172
135
100
120
112
119
116
117
114
115
112
113
111
182
178
150
175
172
140
120
112
119
116
117
114
115
112
113
110
111

FIG. 1A

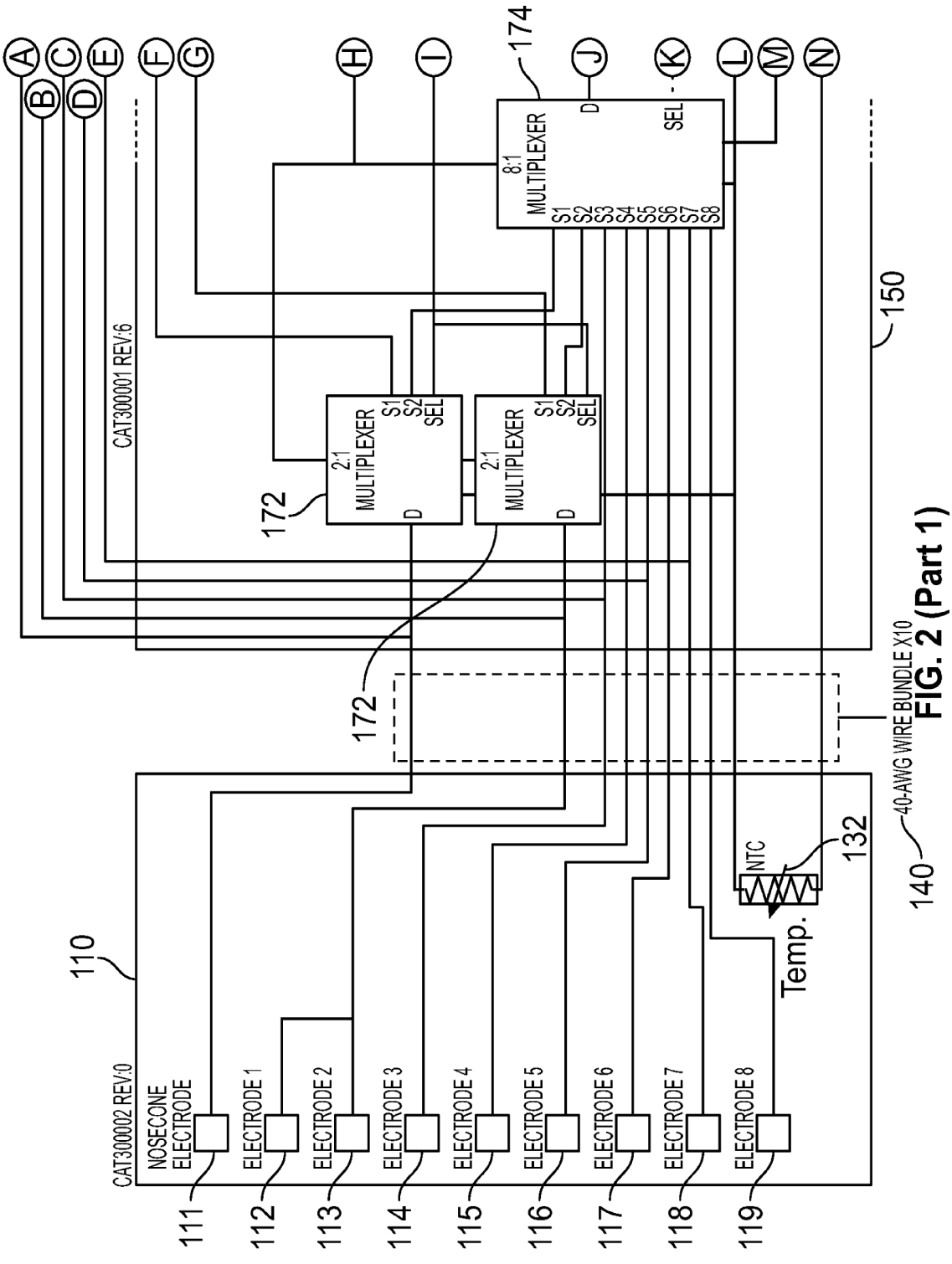

A
B
C
D
E
F
G
H
I
J
K
L
M
N
174
8:1
MULTIPLEXER
S1
S2
S3
S4
S5
S6
S7
S8
SEL
D
CAT300001 REV:6
2:1
MULTIPLEXER
S1
S2
SEL
D
172
150
172
40-AWG WIRE BUNDLE X10
140
110
CAT300002 REV:0
NOSECONE
ELECTRODE
ELECTRODE 1
ELECTRODE 2
ELECTRODE 3
ELECTRODE 4
ELECTRODE 5
ELECTRODE 6
ELECTRODE 7
ELECTRODE 8
NTC
132
Temp.
111
112
113
114
115
116
117
118
119

FIG. 2 (Part 1)

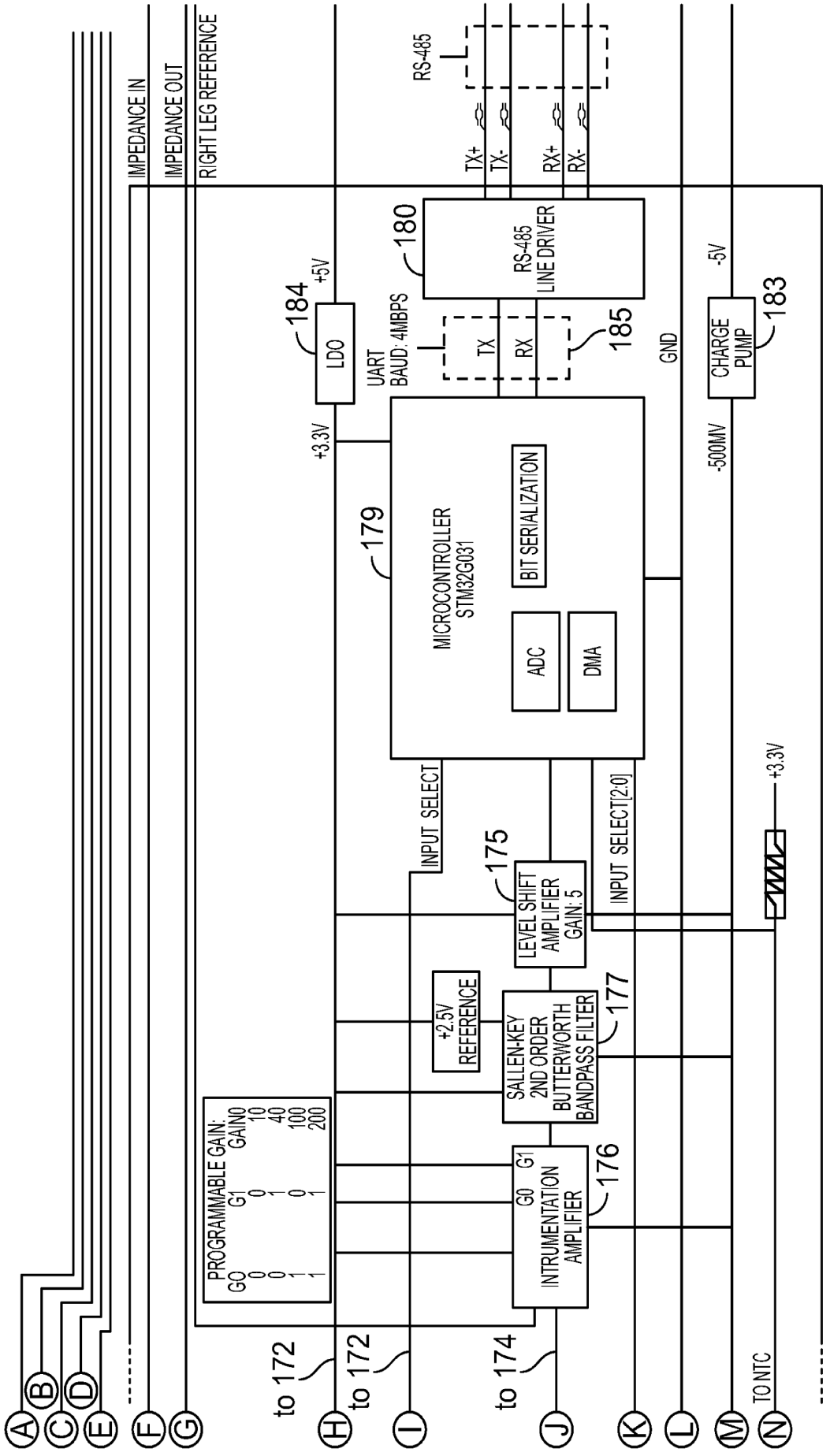

IMPEDANCE IN
IMPEDANCE OUT
RIGHT LEG REFERENCE
RS-485
TX+
TX-
RX+
RX-
180
RS-485 LINE DRIVER
184
LDO
+5V
+3.3V
UART
BAUD: 4MBPS
TX
RX
185
GND
CHARGE PUMP
-5V
183
-500MV
179
MICROCONTROLLER
STM32G031
BIT SERIALIZATION
ADC
DMA
INPUT SELECT
INPUT SELECT[2:0]
175
LEVEL SHIFT AMPLIFIER GAIN: 5
+2.5V REFERENCE
SALLEN-KEY 2ND ORDER BUTTERWORTH BANDPASS FILTER
177
INTRUMENTATION AMPLIFIER
176
G0 G1
PROGRAMMABLE GAIN:
G1 G0 GAIN0
0 0 10
0 1 40
1 0 100
1 1 200
to 172
to 172
to 174
TO NTC
A
B
C
D
E
F
G
H
I
J
K
L
M
N

FIG. 2 (Part 2)

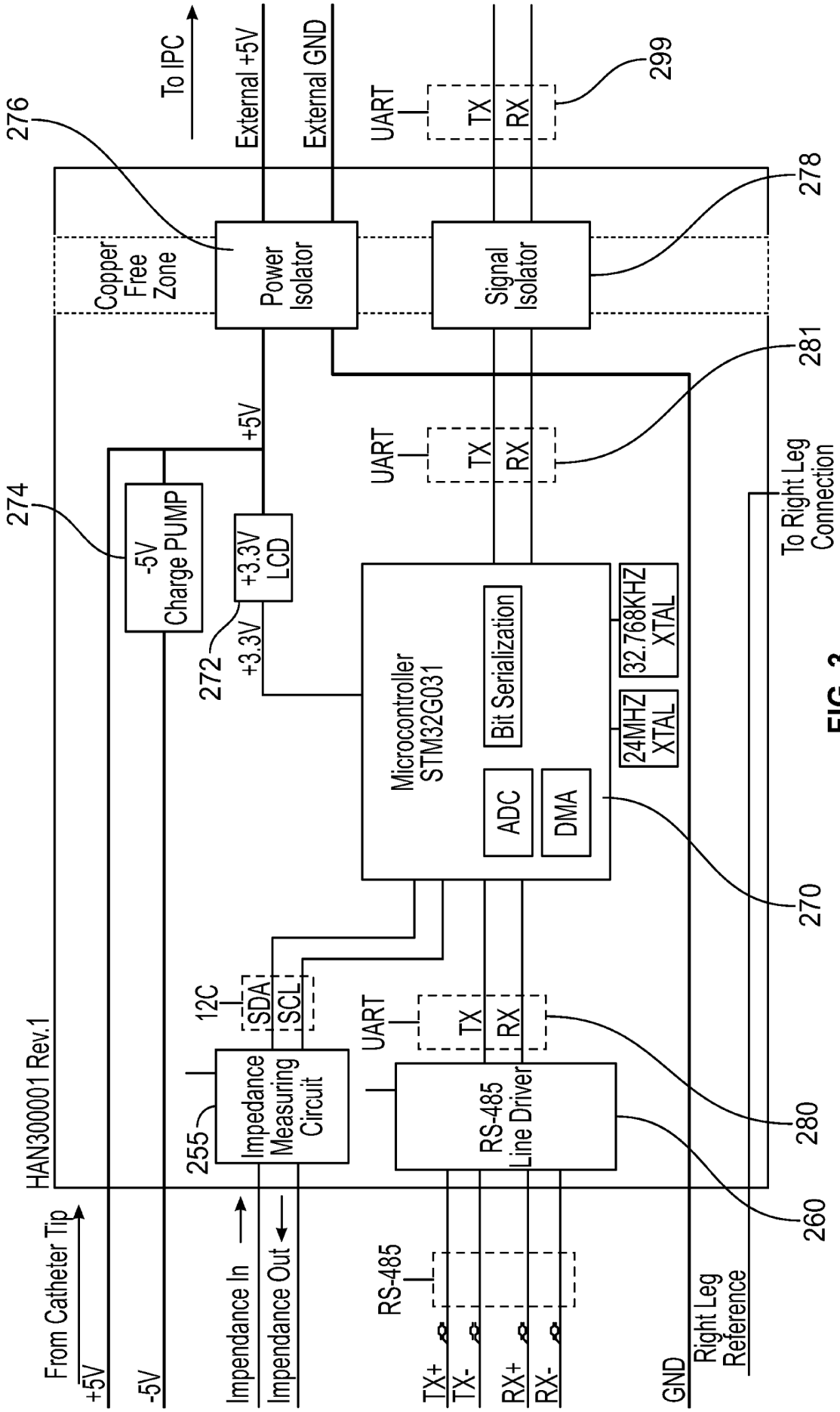

HAN300001 Rev.1
276
To IPC
External +5V
External GND
UART
TX
RX
299
278
Copper Free Zone
Power Isolator
Signal Isolator
281
+5V
UART
TX
RX
274
-5V Charge PUMP
+3.3V LCD
272
+3.3V
To Right Leg Connection
Microcontroller STM32G031
Bit Serialization
32.768KHZ XTAL
24MHZ XTAL
ADC
DMA
270
I2C
SDA
SCL
UART
TX
RX
255
Impedance Measuring Circuit
RS-485 Line Driver
280
260
From Catheter Tip
+5V
-5V
Impendance In
Impendance Out
RS-485
TX+
TX-
RX+
RX-
GND
Right Leg Reference

FIG. 3

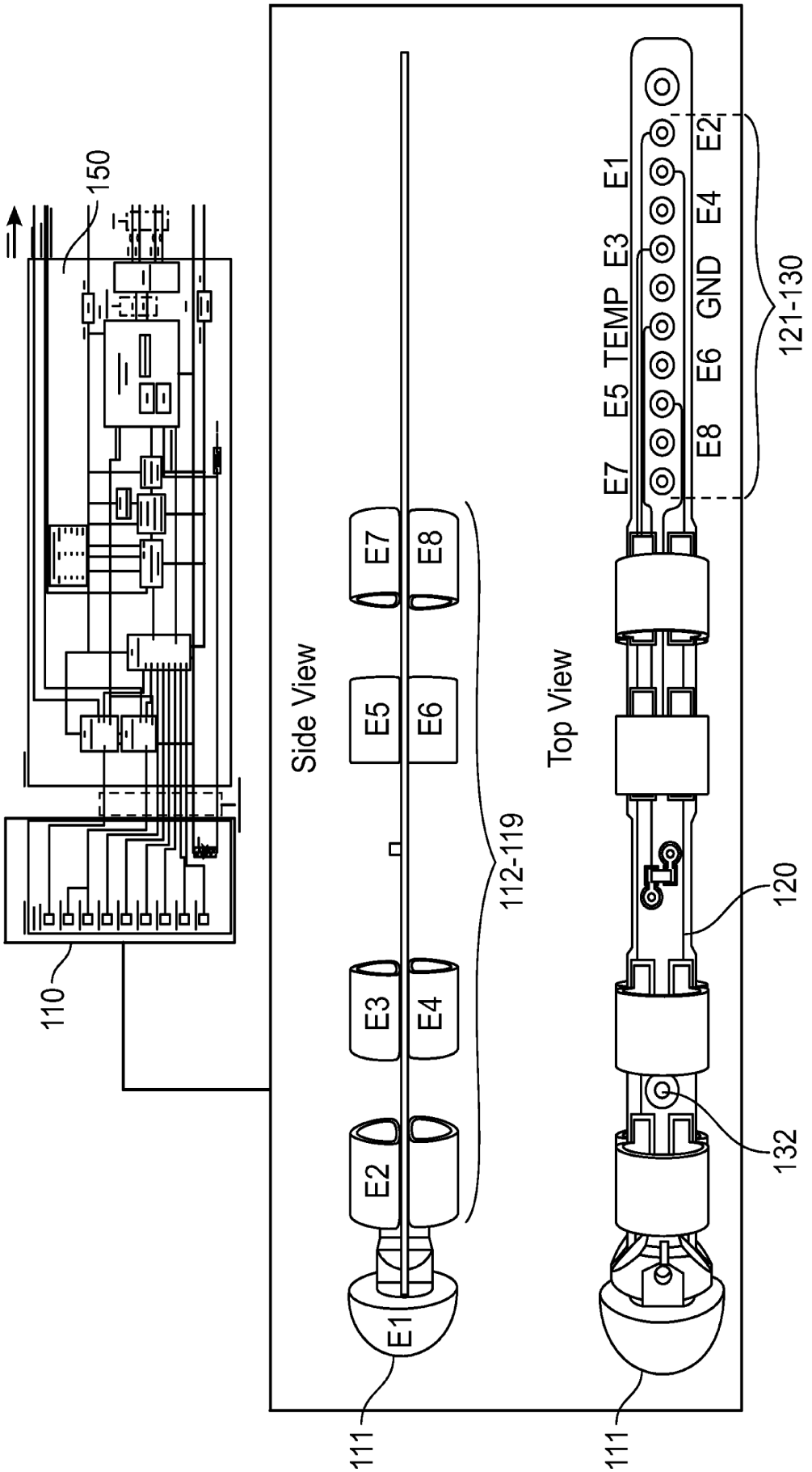

150
110
Side View
E7
E8
E5
E6
E3
E4
E2
E1
112-119
111
Top View
E1
E2
E3
E4
E5 TEMP
E6 GND
E7
E8
121-130
120
132
111

FIG. 4

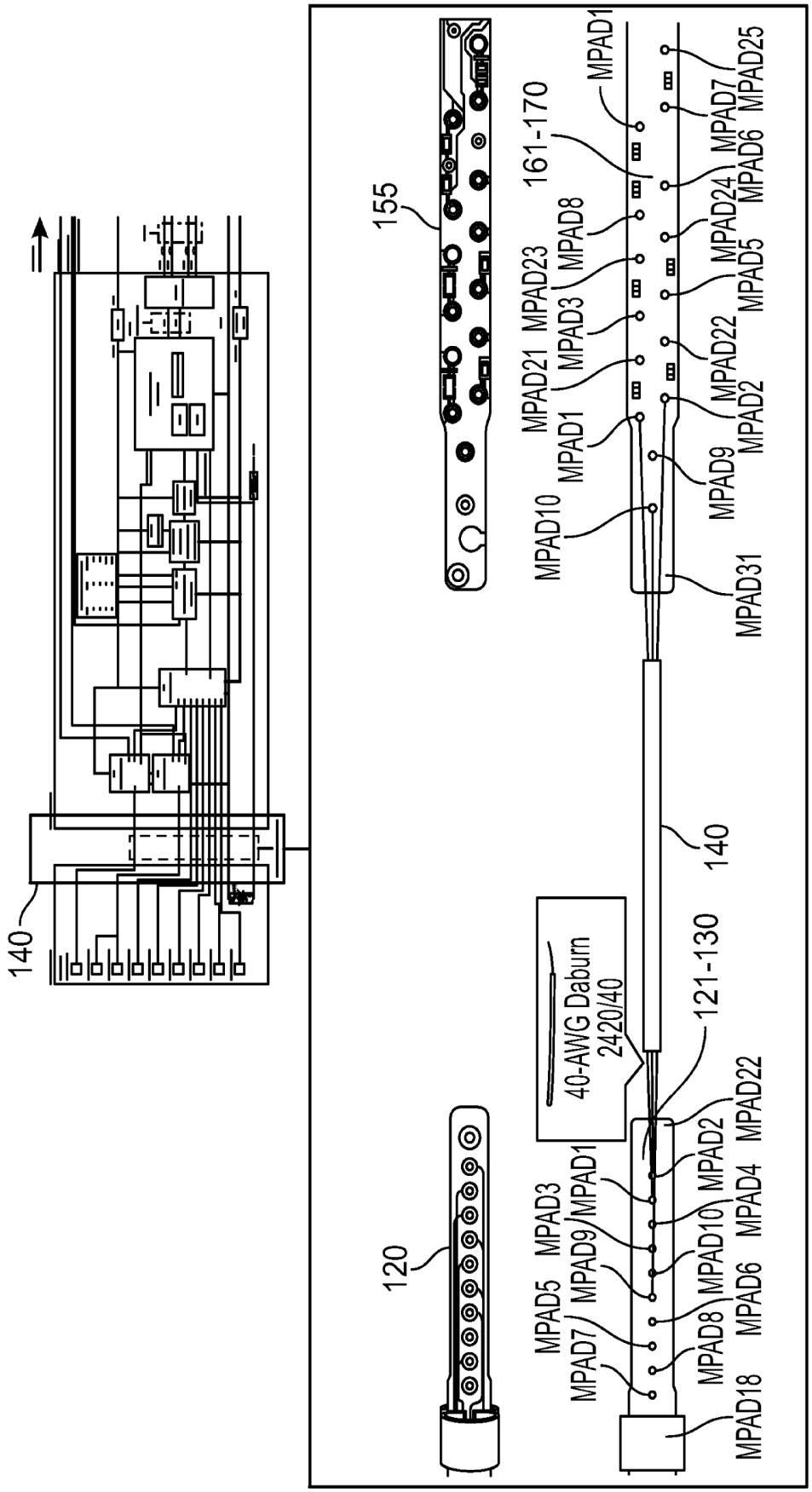

140
155
161-170
MPAD1
MPAD25
MPAD7
MPAD6
MPAD24
MPAD5
MPAD8
MPAD23
MPAD3
MPAD22
MPAD2
MPAD21
MPAD1
MPAD9
MPAD10
MPAD31
140
121-130
40-AWG Daburn
2420/40
120
MPAD22
MPAD2
MPAD4
MPAD10
MPAD6
MPAD9
MPAD3
MPAD5
MPAD1
MPAD7
MPAD8
MPAD18

FIG. 5

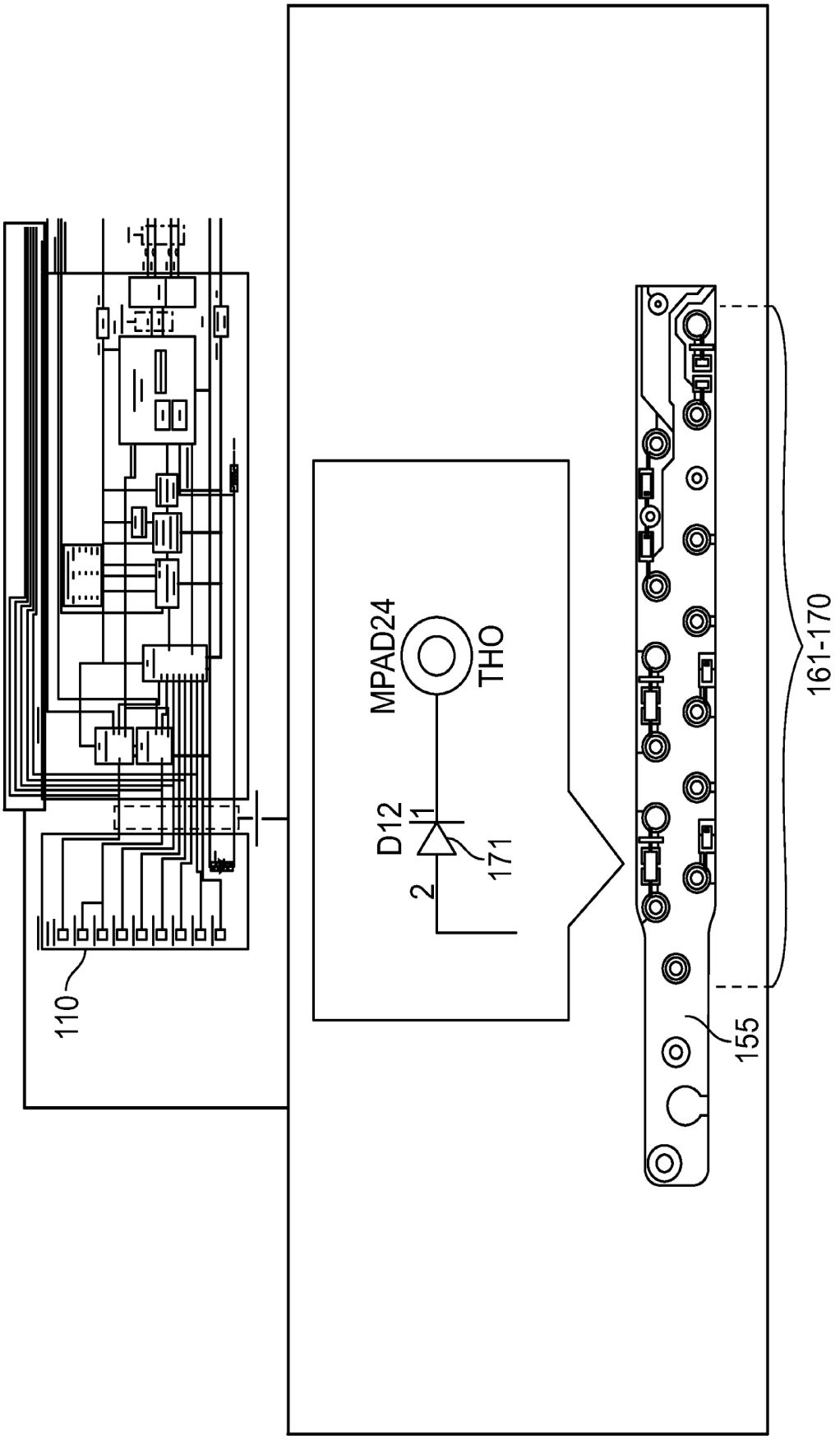


FIG. 6

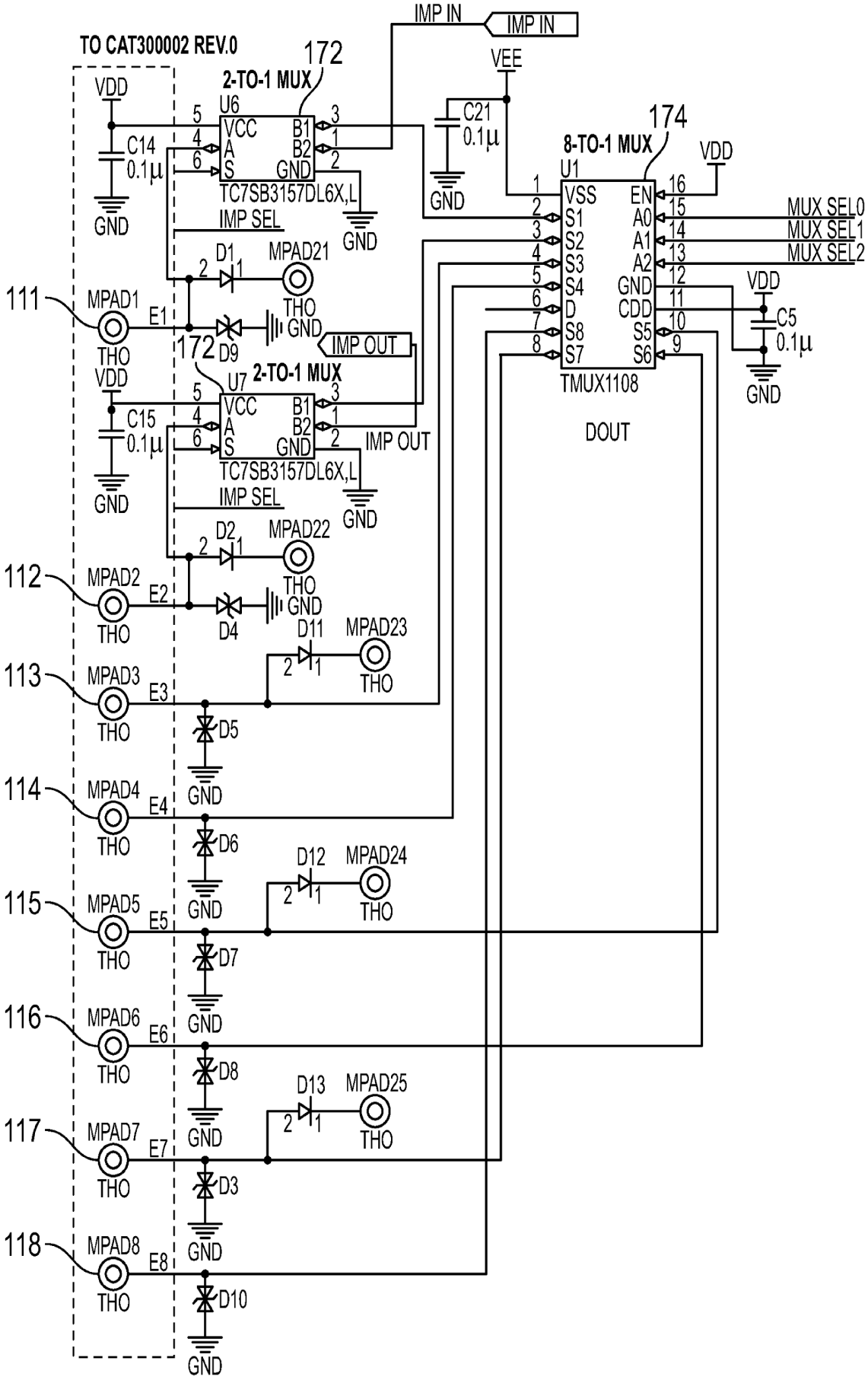

TO CAT300002 REV.0
IMP IN
IMP IN
VEE
172
2-TO-1 MUX
U6
VCC
A
S
B1
B2
GND
TC7SB3157DL6X,L
VDD
C14
0.1µ
GND
IMP SEL
C21
0.1µ
174
8-TO-1 MUX
U1
VSS
S1
S2
S3
S4
D
S8
S7
EN
A0
A1
A2
GND
CDD
S5
S6
TMUX1108
DOUT
MUX SEL0
MUX SEL1
MUX SEL2
C5
0.1µ
D1
MPAD21
THO
111
MPAD1
E1
D9
IMP OUT
U7
C15
D2
MPAD22
112
MPAD2
E2
D4
D11
MPAD23
113
MPAD3
E3
D5
114
MPAD4
E4
D6
D12
MPAD24
115
MPAD5
E5
D7
116
MPAD6
E6
D8
D13
MPAD25
117
MPAD7
E7
D3
118
MPAD8
E8
D10

FIG. 7.1

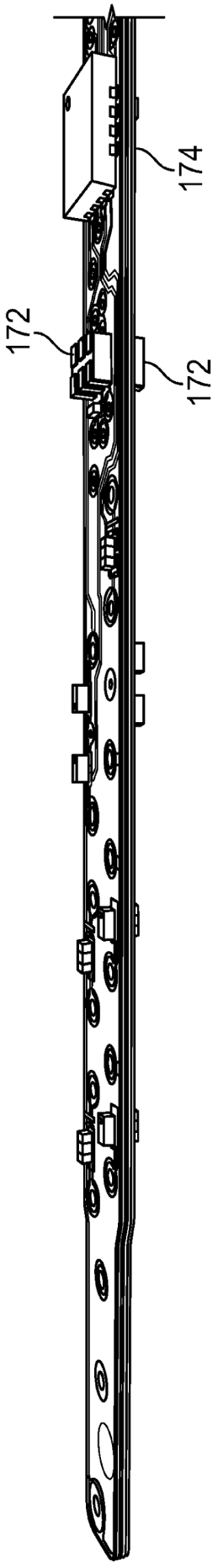


FIG. 7.2

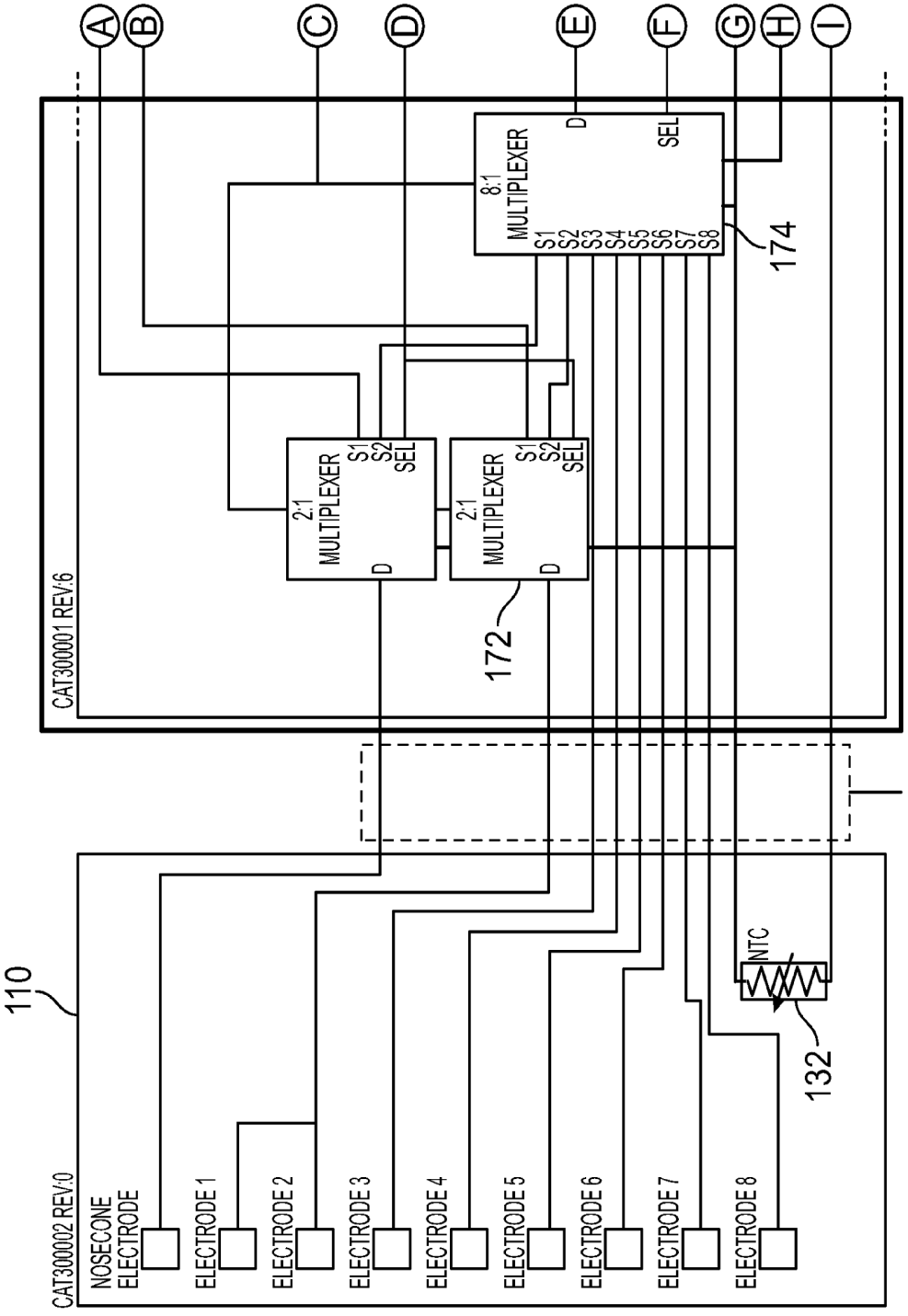

A
B
C
D
E
F
G
H
I
CAT300001 REV:6
8:1 MULTIPLEXER
S1
S2
S3
S4
S5
S6
S7
S8
D
SEL
174
2:1 MULTIPLEXER
S1
S2
SEL
D
172
40-AWG WIRE BUNDLE X10
110
CAT300002 REV:0
NOSECONE ELECTRODE
ELECTRODE 1
ELECTRODE 2
ELECTRODE 3
ELECTRODE 4
ELECTRODE 5
ELECTRODE 6
ELECTRODE 7
ELECTRODE 8
NTC
132

FIG. 7.3 (Part 1)

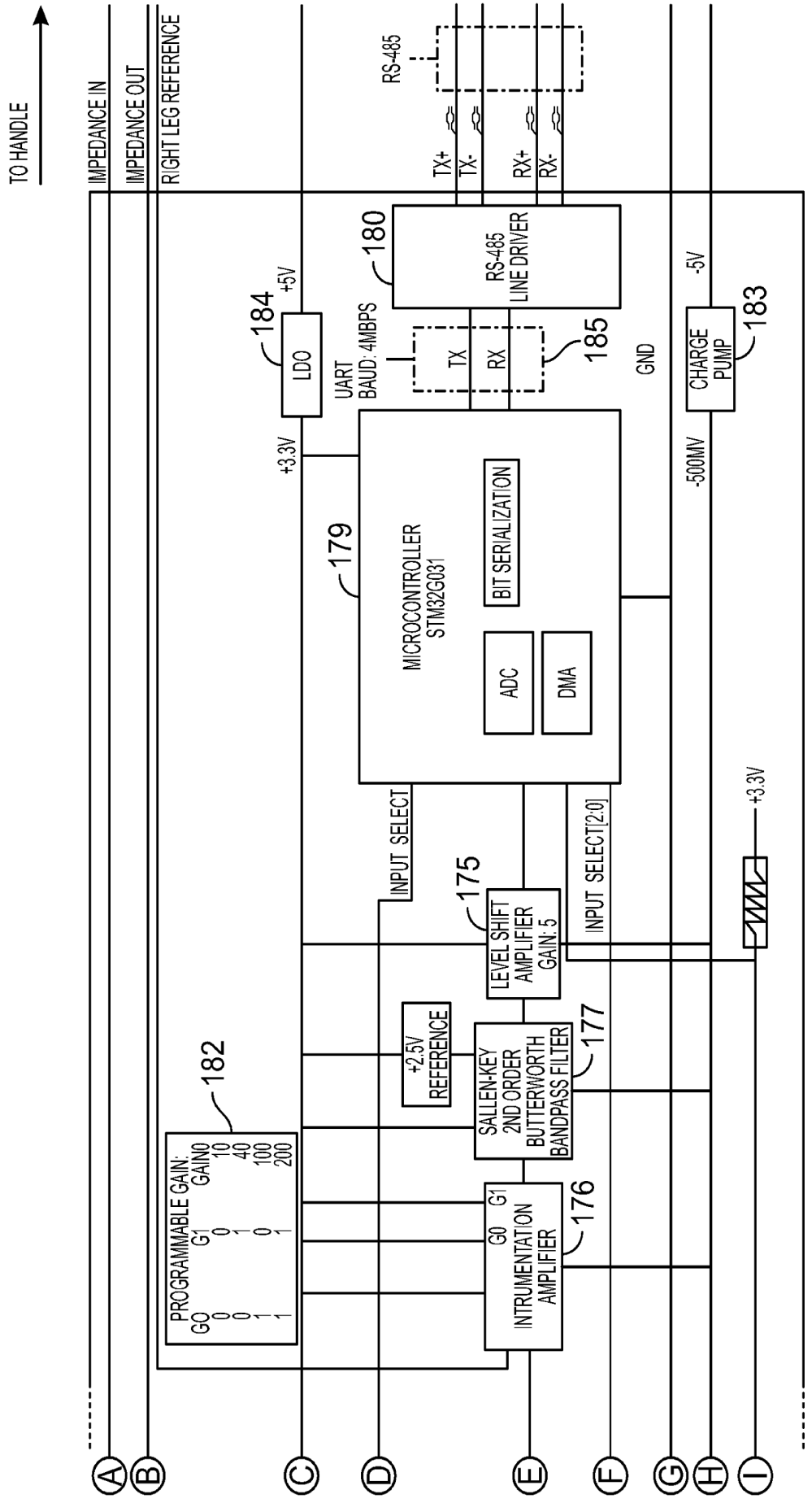

TO HANDLE
IMPEDANCE IN
IMPEDANCE OUT
RIGHT LEG REFERENCE
RS-485
TX+
TX-
RX+
RX-
180
RS-485 LINE DRIVER
184
+5V
LDO
UART
BAUD: 4MBPS
TX
RX
185
GND
CHARGE PUMP
-5V
183
+3.3V
-500MV
179
MICROCONTROLLER
STM32G031
BIT SERIALIZATION
ADC
DMA
INPUT SELECT
INPUT SELECT[2:0]
175
LEVEL SHIFT
AMPLIFIER
GAIN: 5
+2.5V
REFERENCE
177
SALLEN-KEY
2ND ORDER
BUTTERWORTH
BANDPASS FILTER
182
PROGRAMMABLE GAIN:
G0 G1 GAIN0
0 0 10
0 1 40
1 0 100
1 1 200
G0 G1
176
INTRUMENTATION
AMPLIFIER
A
B
C
D
E
F
G
H
I

FIG. 7.3 (Part 2)

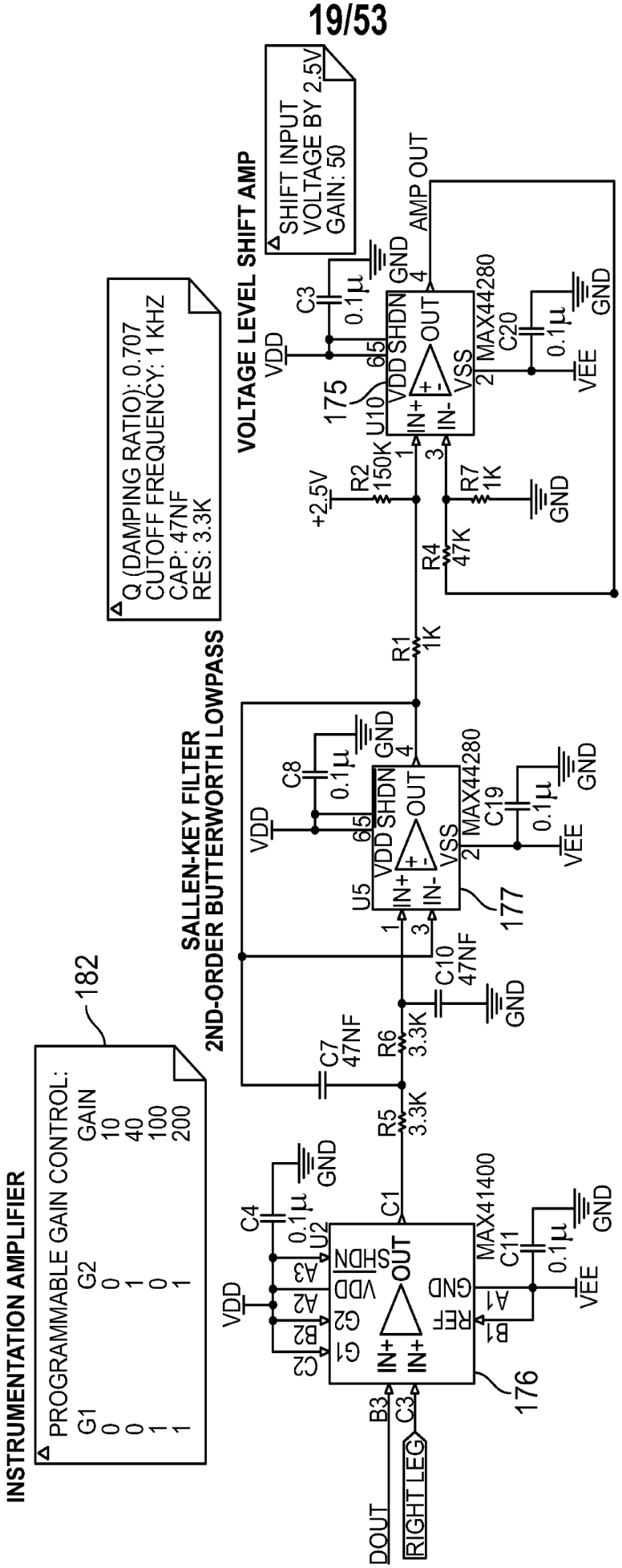

INSTRUMENTATION AMPLIFIER
PROGRAMMABLE GAIN CONTROL:
G1 G2 GAIN
0 0 10
0 1 40
1 0 100
1 1 200
182
SALLEN-KEY FILTER
2ND-ORDER BUTTERWORTH LOWPASS
Q (DAMPING RATIO): 0.707
CUTOFF FREQUENCY: 1 KHZ
CAP: 47NF
RES: 3.3K
VOLTAGE LEVEL SHIFT AMP
SHIFT INPUT
VOLTAGE BY 2.5V
GAIN: 50
AMP OUT
MAX41400
MAX44280
VDD
VEE
GND
+2.5V
DOUT
RIGHT LEG
R1 1K
R2 150K
R3 3.3K
R4 47K
R5 3.3K
R6 3.3K
R7 1K
C1
C2 47NF
C3 0.1µ
C4 0.1µ
C7 47NF
C8 0.1µ
C10 47NF
C11 0.1µ
C19 0.1µ
C20 0.1µ
U2
U5
U10
175
176
177

FIG. 8.1

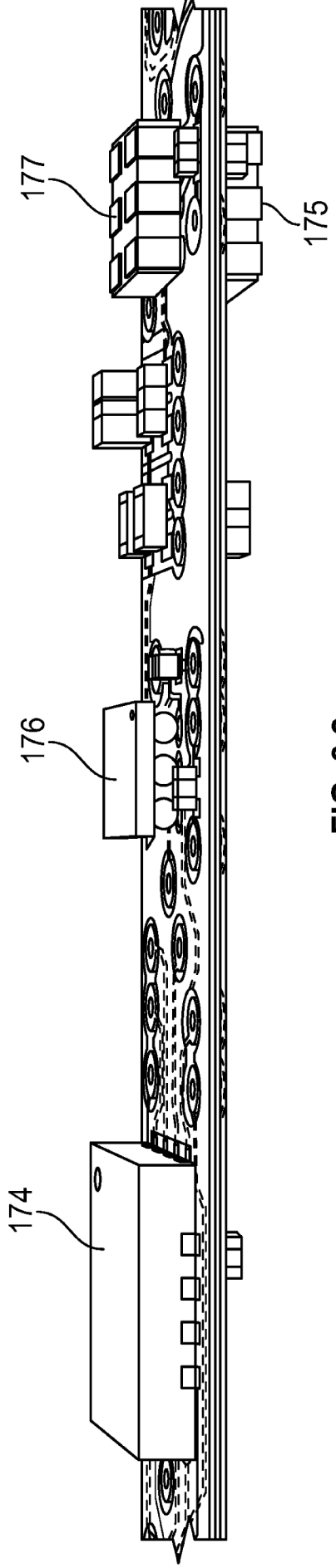


FIG. 8.2

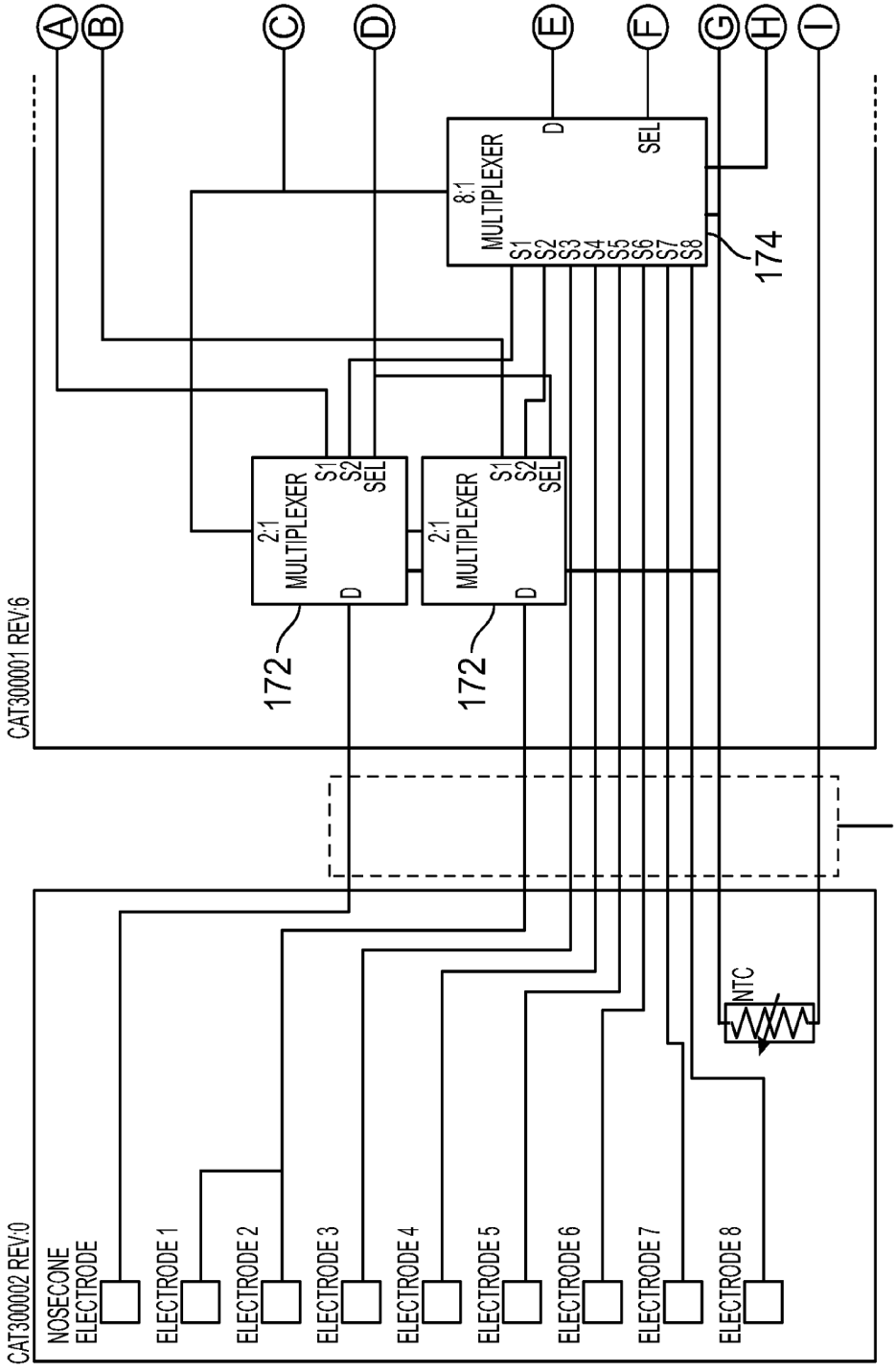

A
B
C
D
E
F
G
H
I
CAT300001 REV:6
8:1
MULTIPLEXER
D
SEL
S1
S2
S3
S4
S5
S6
S7
S8
174
2:1
MULTIPLEXER
S1
S2
SEL
D
172
172
40-AWG WIRE BUNDLE X10
CAT300002 REV:0
NOSECONE
ELECTRODE
ELECTRODE 1
ELECTRODE 2
ELECTRODE 3
ELECTRODE 4
ELECTRODE 5
ELECTRODE 6
ELECTRODE 7
ELECTRODE 8
NTC

FIG. 8.3 (Part 1)

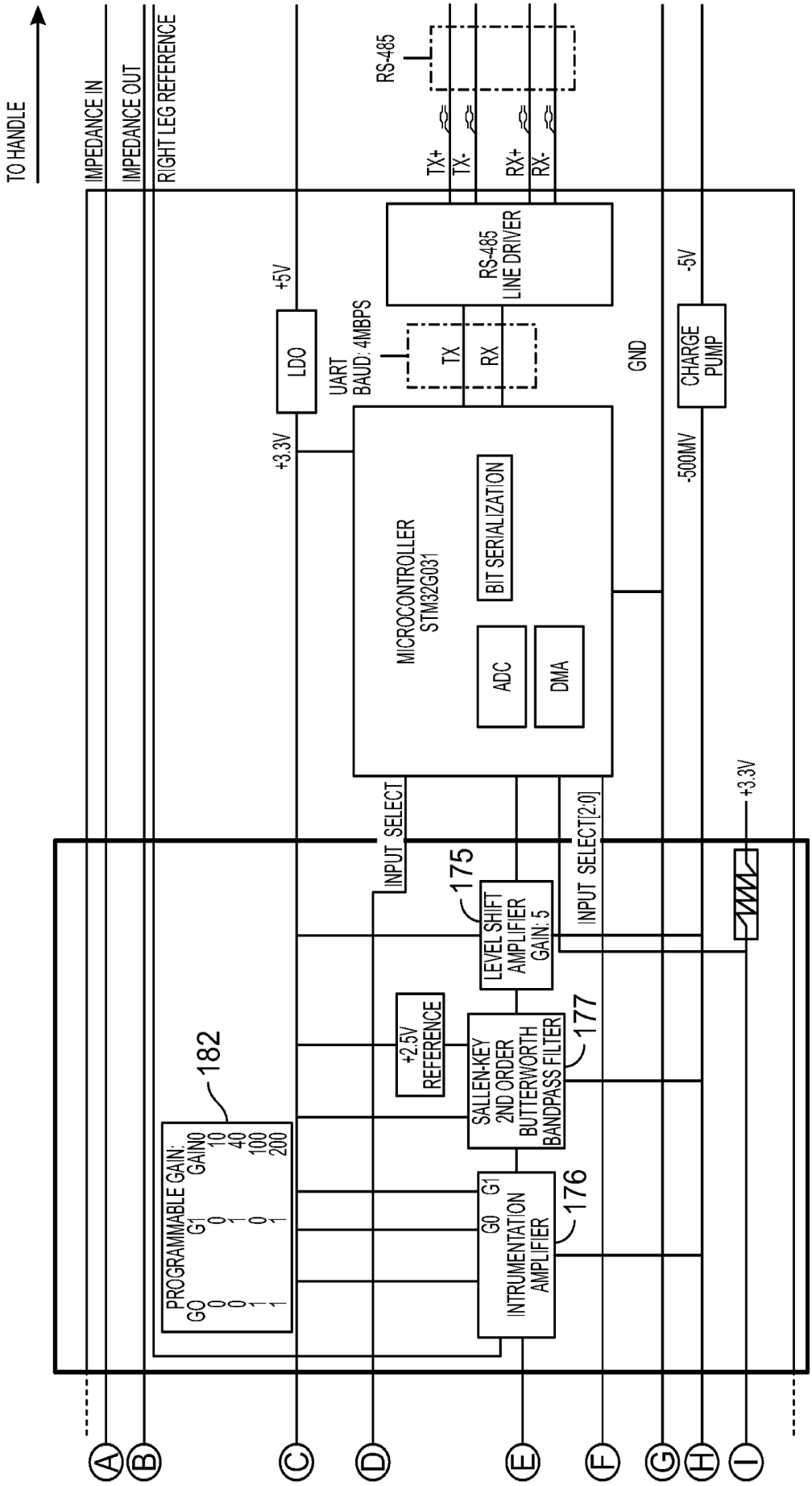

TO HANDLE
IMPEDANCE IN
IMPEDANCE OUT
RIGHT LEG REFERENCE
RS-485
TX+
TX-
RX+
RX-
RS-485 LINE DRIVER
+5V
LDO
+3.3V
UART
BAUD: 4MBPS
TX
RX
GND
CHARGE PUMP
-5V
-500MV
MICROCONTROLLER
STM32G031
BIT SERIALIZATION
ADC
DMA
INPUT SELECT
INPUT SELECT[2:0]
175
LEVEL SHIFT
AMPLIFIER
GAIN: 5
+2.5V
REFERENCE
SALLEN-KEY
2ND ORDER
BUTTERWORTH
BANDPASS FILTER
177
182
PROGRAMMABLE GAIN:
G0 G1 GAIN0
0 0 10
0 1 40
1 0 100
1 1 200
G0 G1
INTRUMENTATION
AMPLIFIER
176
+3.3V
A
B
C
D
E
F
G
H
I

FIG. 8.3 (Part 2)

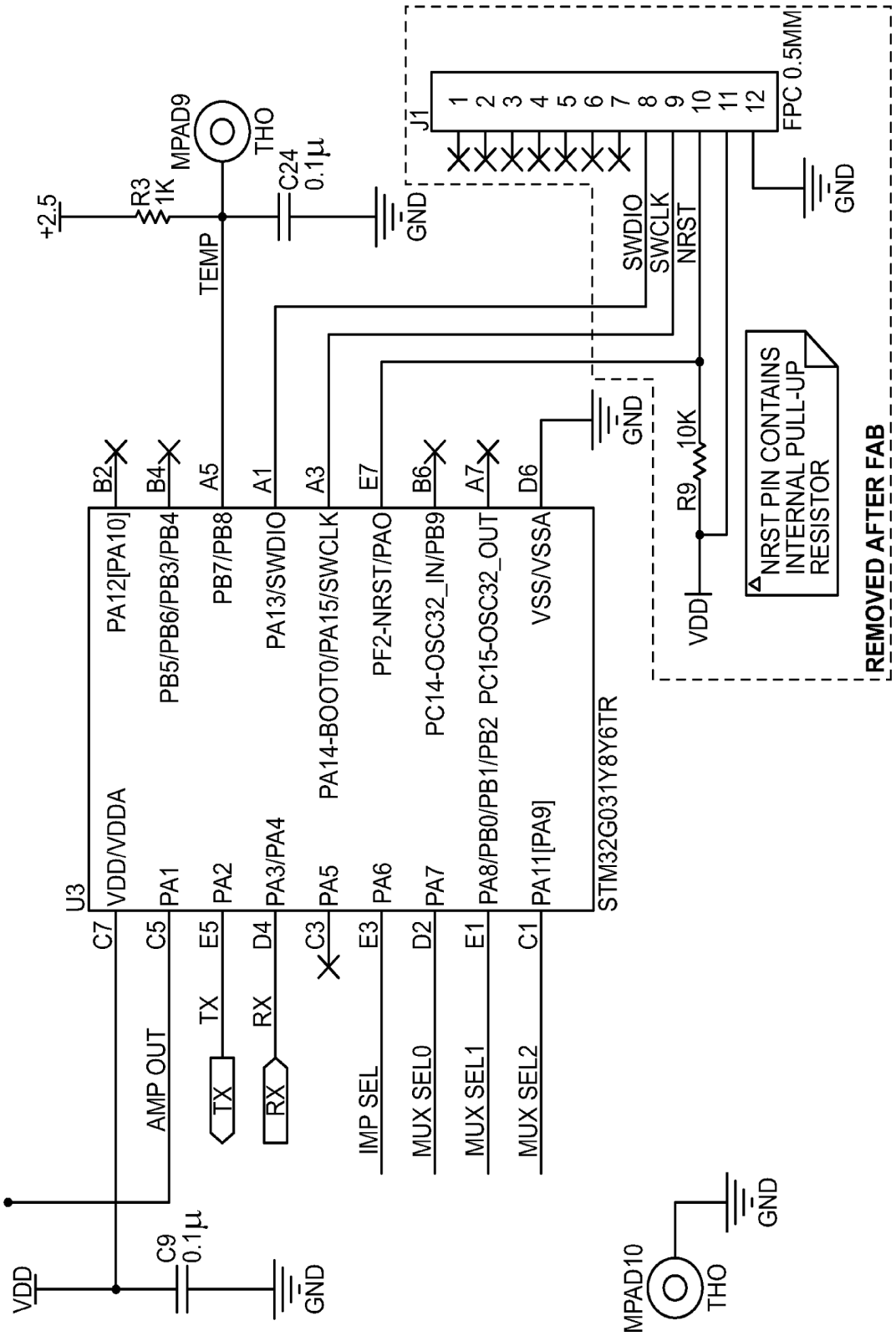

U3
STM32G031Y8Y6TR
VDD/VDDA
PA1
PA2
PA3/PA4
PA5
PA6
PA7
PA8/PB0/PB1/PB2
PA11[PA9]
PA12[PA10]
PB5/PB6/PB3/PB4
PB7/PB8
PA13/SWDIO
PA14-BOOT0/PA15/SWCLK
PF2-NRST/PAO
PC14-OSC32_IN/PB9
PC15-OSC32_OUT
VSS/VSSA
C7
C5
E5
D4
C3
E3
D2
E1
C1
B2
B4
A5
A1
A3
E7
B6
A7
D6
VDD
GND
C9
0.1µ
AMP OUT
TX
RX
IMP SEL
MUX SEL0
MUX SEL1
MUX SEL2
+2.5
R3
1K
MPAD9
THO
TEMP
C24
0.1µ
J1
FPC 0.5MM
SWDIO
SWCLK
NRST
R9
10K
NRST PIN CONTAINS
INTERNAL PULL-UP
RESISTOR
REMOVED AFTER FAB
MPAD10

FIG. 9.1

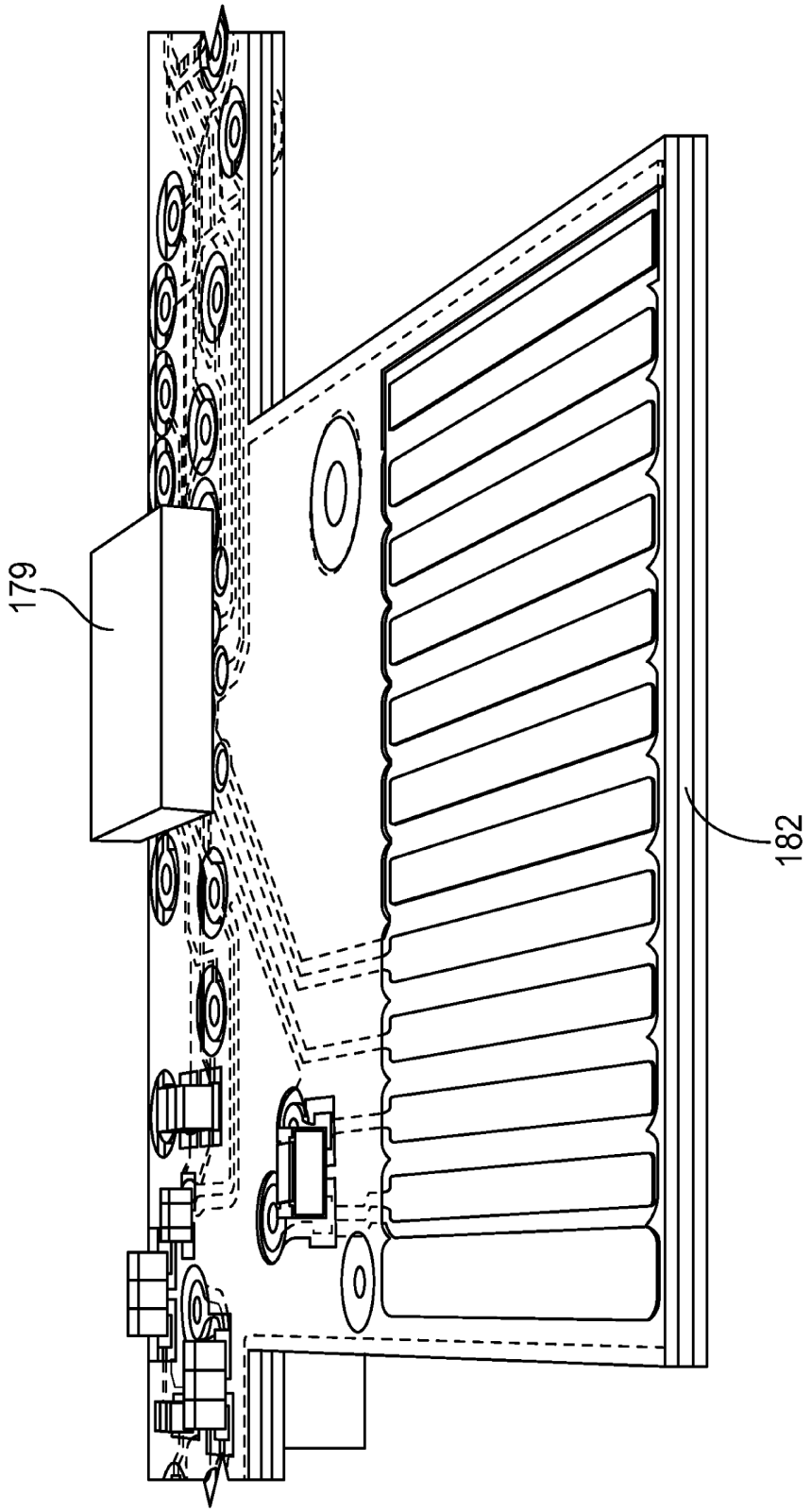


FIG. 9.2

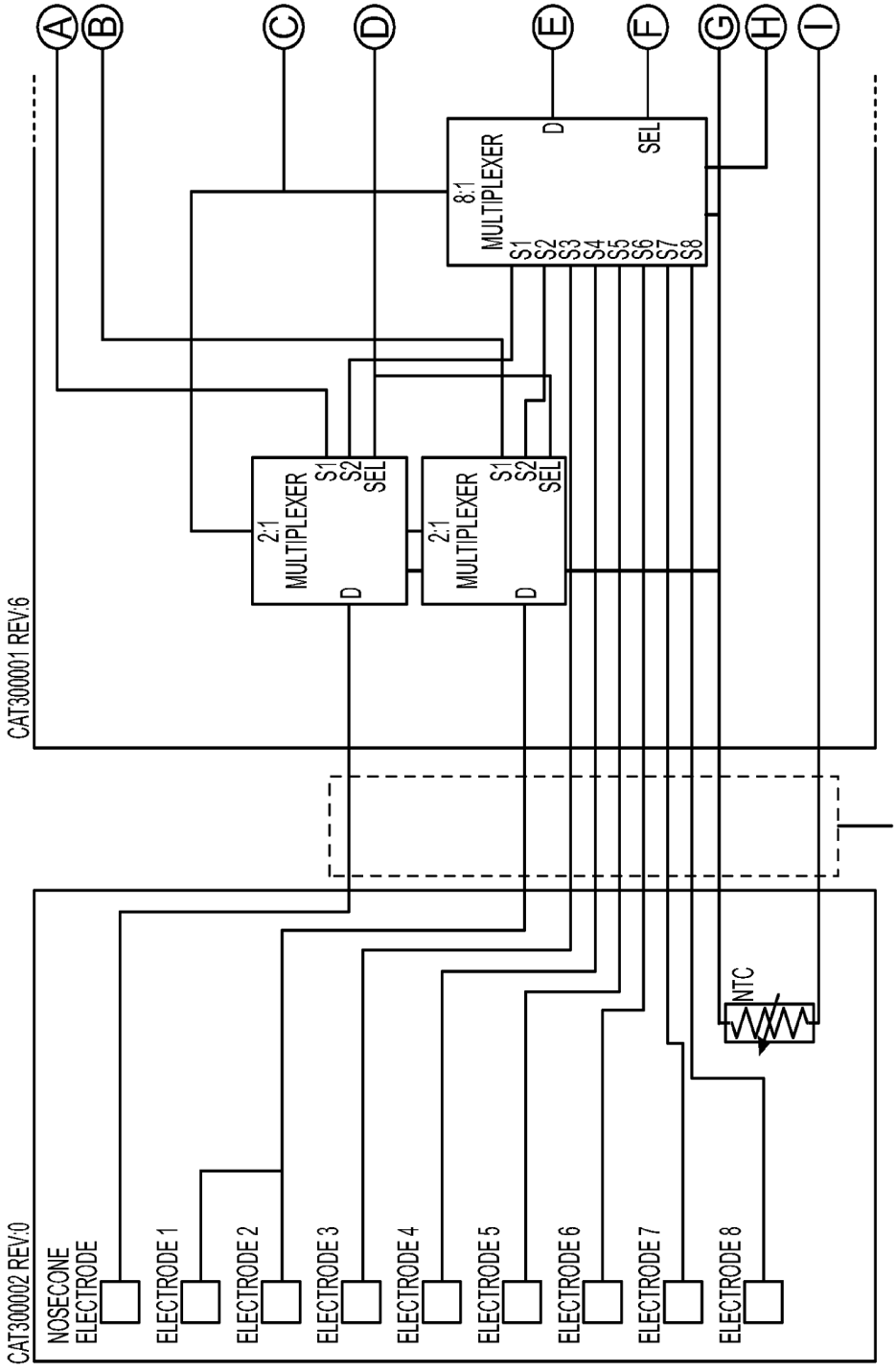

A
B
C
D
E
F
G
H
I
8:1
MULTIPLEXER
D
SEL
S1
S2
S3
S4
S5
S6
S7
S8
2:1
MULTIPLEXER
S1
S2
SEL
D
2:1
MULTIPLEXER
S1
S2
SEL
D
CAT300001 REV:6
40-AWG WIRE BUNDLE X10
CAT300002 REV:0
NOSECONE
ELECTRODE
ELECTRODE 1
ELECTRODE 2
ELECTRODE 3
ELECTRODE 4
ELECTRODE 5
ELECTRODE 6
ELECTRODE 7
ELECTRODE 8
NTC

FIG. 9.3 (Part 1)

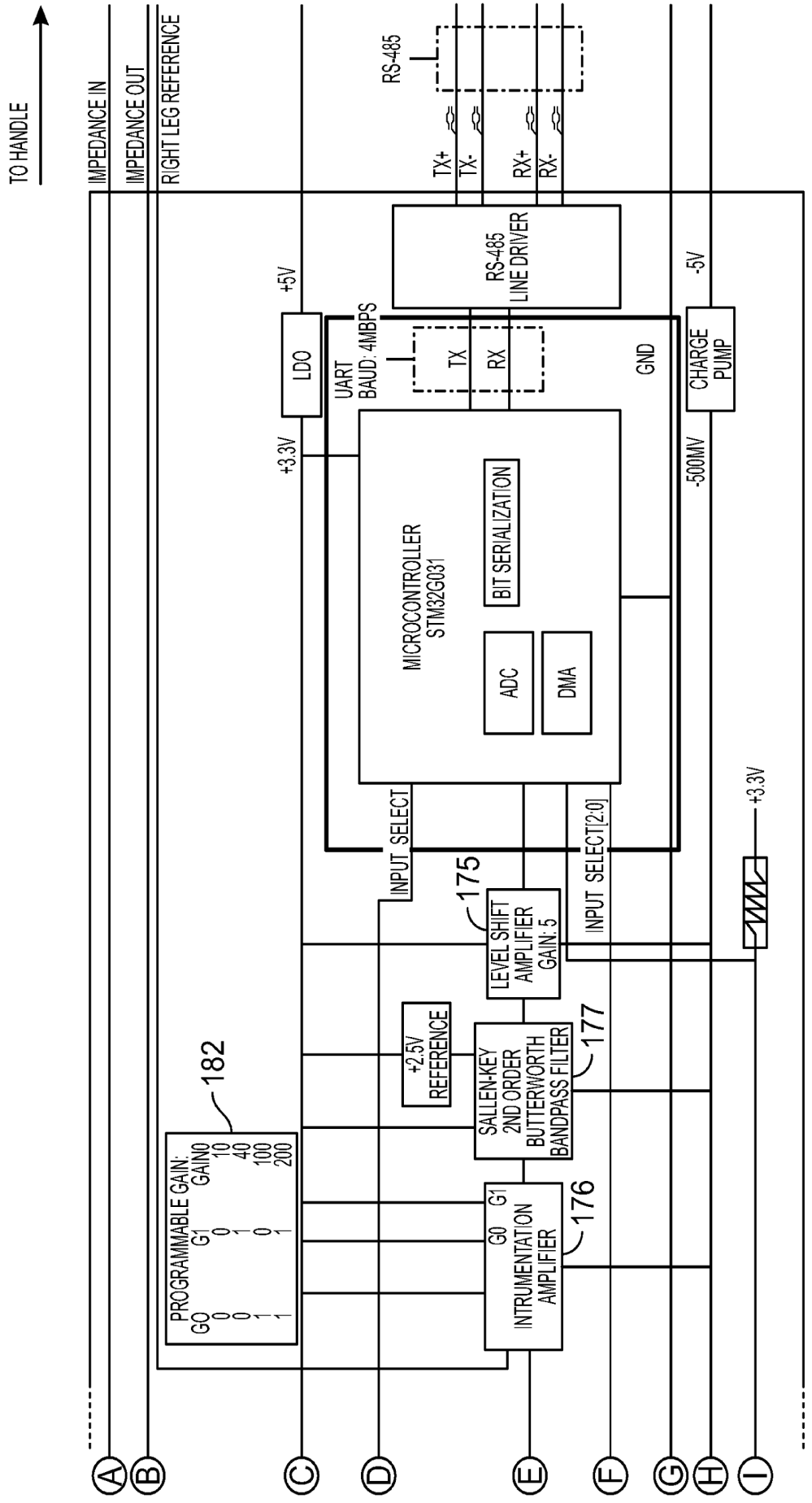

TO HANDLE
IMPEDANCE IN
IMPEDANCE OUT
RIGHT LEG REFERENCE
RS-485
TX+
TX-
RX+
RX-
RS-485 LINE DRIVER
+5V
LDO
+3.3V
UART
BAUD: 4MBPS
TX
RX
GND
-5V
CHARGE PUMP
-500MV
MICROCONTROLLER
STM32G031
BIT SERIALIZATION
ADC
DMA
INPUT SELECT
INPUT SELECT[2:0]
175
LEVEL SHIFT
AMPLIFIER
GAIN: 5
+2.5V
REFERENCE
177
SALLEN-KEY
2ND ORDER
BUTTERWORTH
BANDPASS FILTER
182
PROGRAMMABLE GAIN:
G0 G1 GAIN0
0 0 10
0 1 40
1 0 100
1 1 200
176
G0 G1
INTRUMENTATION
AMPLIFIER
A
B
C
D
E
F
G
H
I

FIG. 9.3 (Part 2)

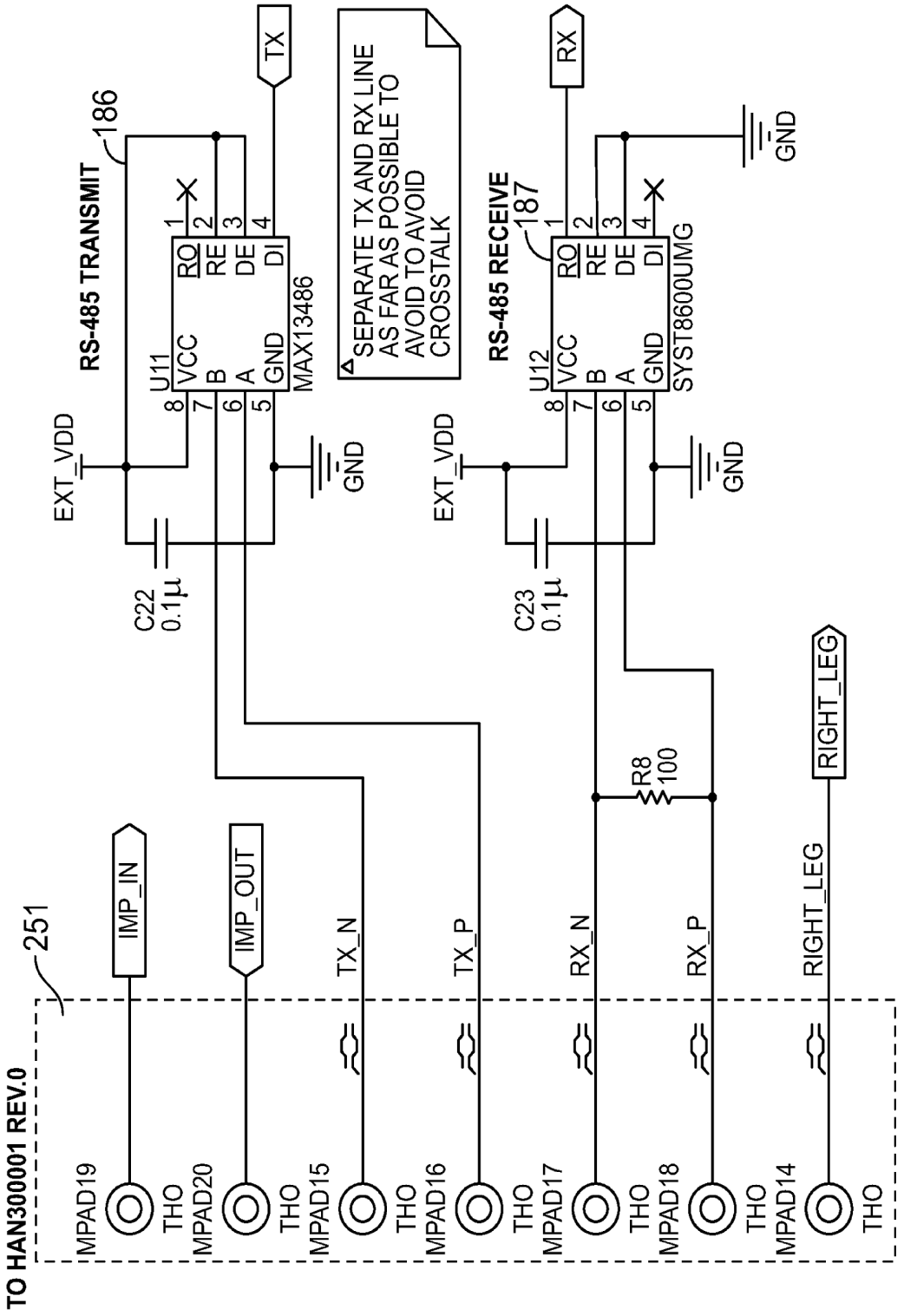

TO HAN300001 REV.0
251
MPAD19
THO
MPAD20
THO
MPAD15
THO
MPAD16
THO
MPAD17
THO
MPAD18
THO
MPAD14
THO
IMP_IN
IMP_OUT
TX_N
TX_P
RX_N
RX_P
RIGHT_LEG
R8
100
RS-485 TRANSMIT
186
U11
MAX13486
VCC
B
A
GND
RO
RE
DE
DI
TX
RX
EXT_VDD
GND
C22
0.1µ
C23
0.1µ
SEPARATE TX AND RX LINE AS FAR AS POSSIBLE TO AVOID TO AVOID CROSSTALK
RS-485 RECEIVE
187
U12
SYST8600UMG

FIG. 10.1

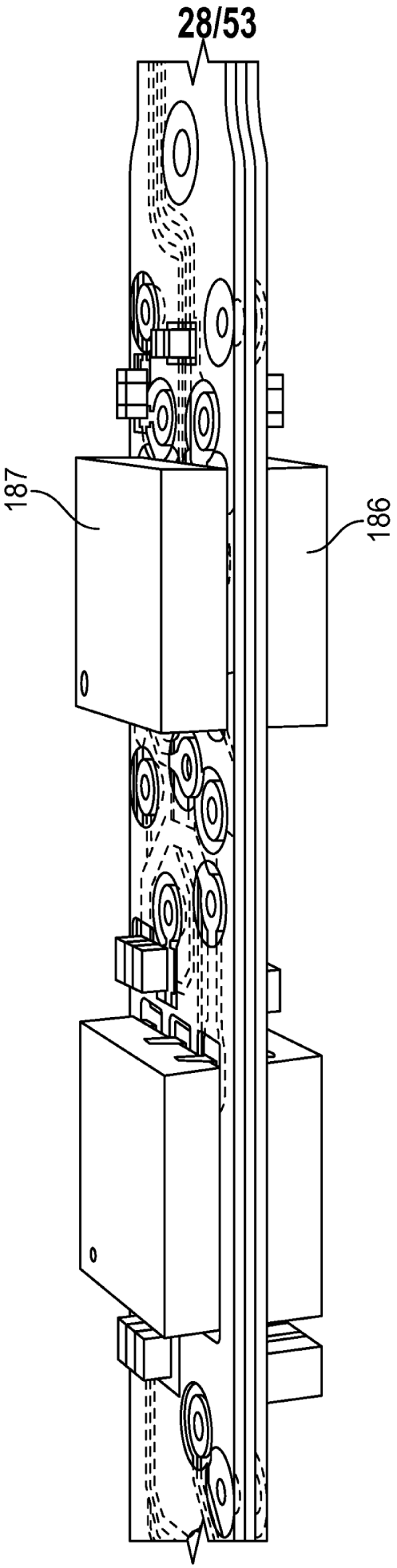


FIG. 10.2

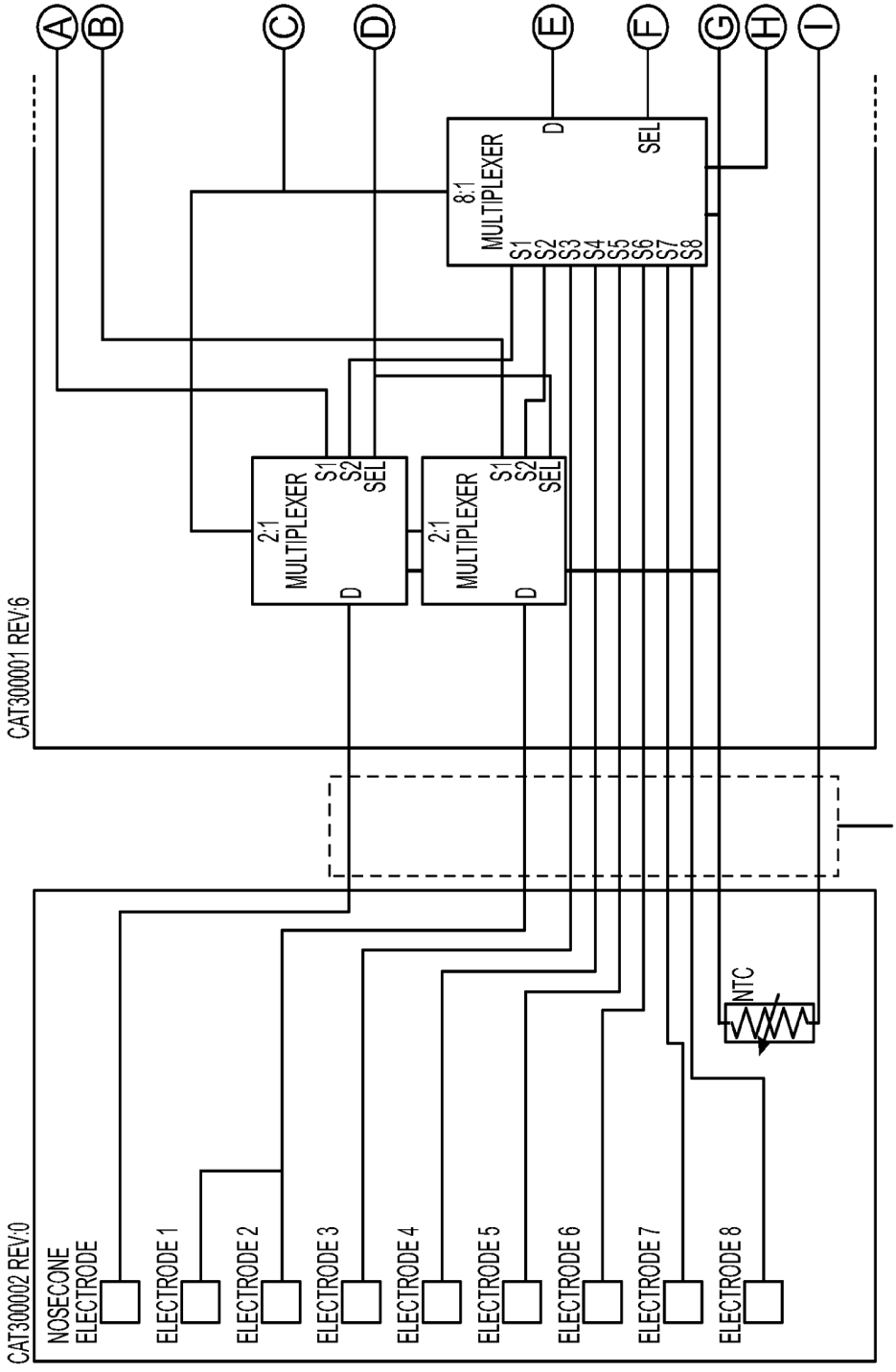


FIG. 10.3 (Part 1)

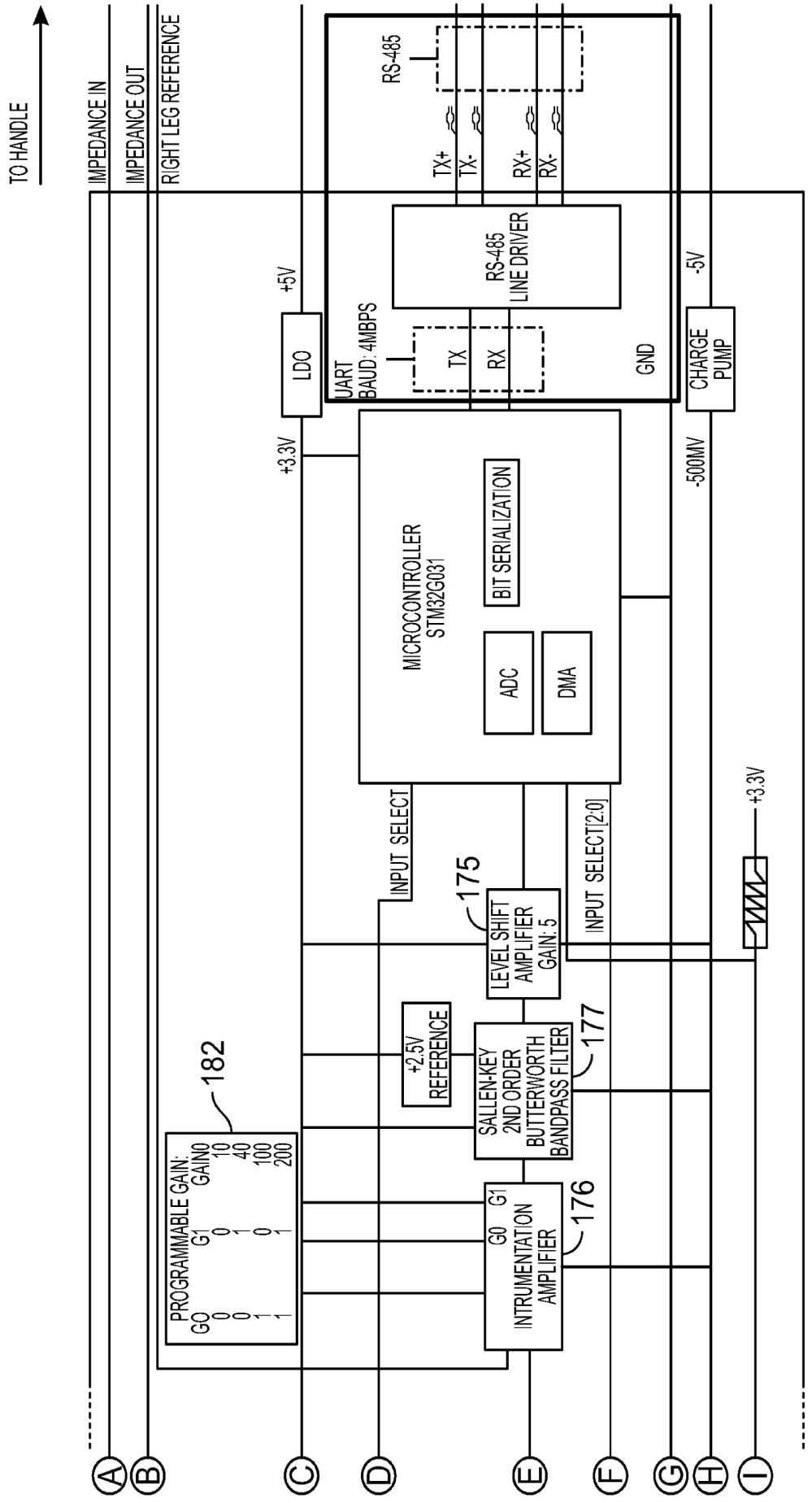


FIG. 10.3 (Part 2)

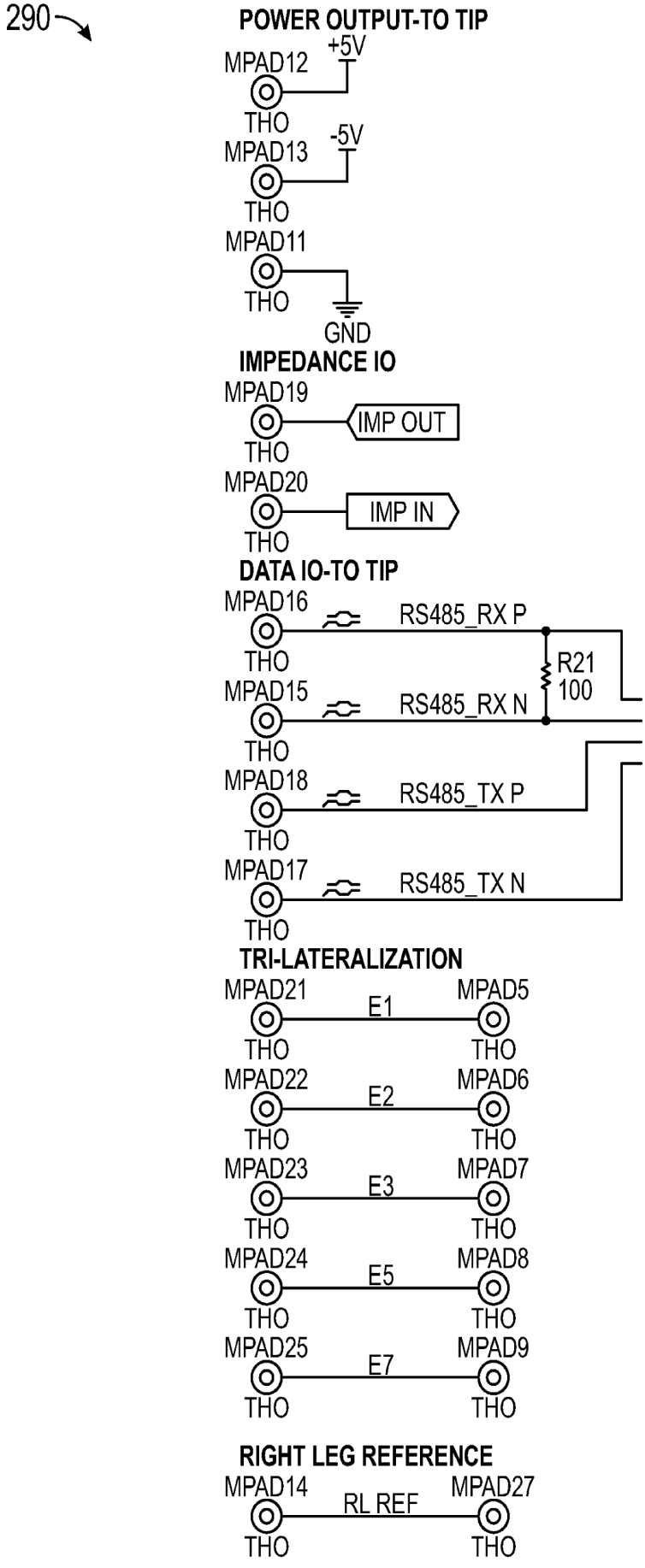

290
POWER OUTPUT-TO TIP
MPAD12
+5V
THO
MPAD13
-5V
THO
MPAD11
THO
GND
IMPEDANCE IO
MPAD19
IMP OUT
THO
MPAD20
IMP IN
THO
DATA IO-TO TIP
MPAD16
RS485_RX P
THO
R21
100
MPAD15
RS485_RX N
THO
MPAD18
RS485_TX P
THO
MPAD17
RS485_TX N
THO
TRI-LATERALIZATION
MPAD21
E1
MPAD5
THO
THO
MPAD22
E2
MPAD6
THO
THO
MPAD23
E3
MPAD7
THO
THO
MPAD24
E5
MPAD8
THO
THO
MPAD25
E7
MPAD9
THO
THO
RIGHT LEG REFERENCE
MPAD14
RL REF
MPAD27
THO
THO

FIG. 11.1

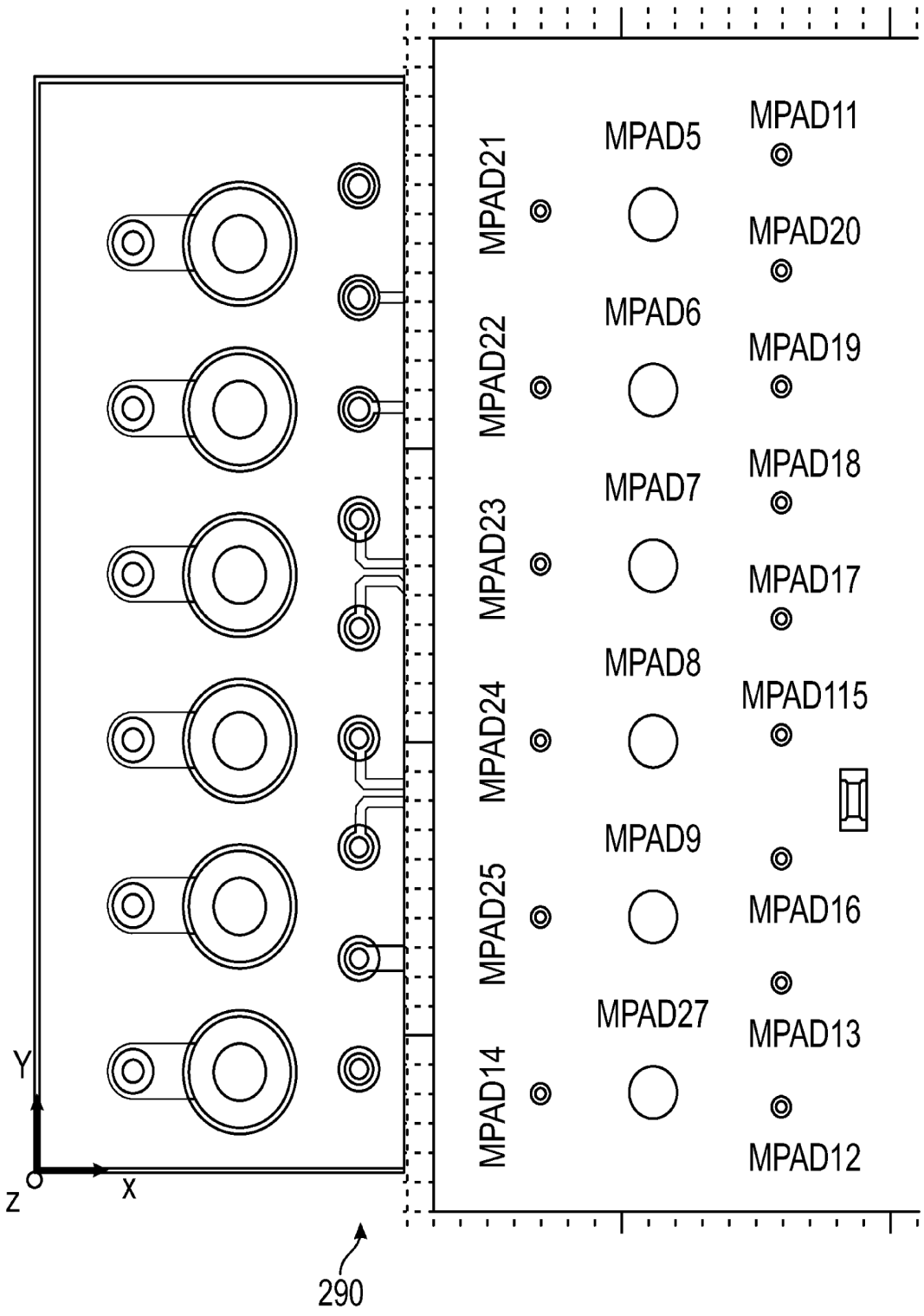

MPAD21
MPAD5
MPAD11
MPAD20
MPAD22
MPAD6
MPAD19
MPAD23
MPAD7
MPAD18
MPAD17
MPAD24
MPAD8
MPAD115
MPAD25
MPAD9
MPAD16
MPAD14
MPAD27
MPAD13
MPAD12
Y
Z
X
290

FIG. 11.2

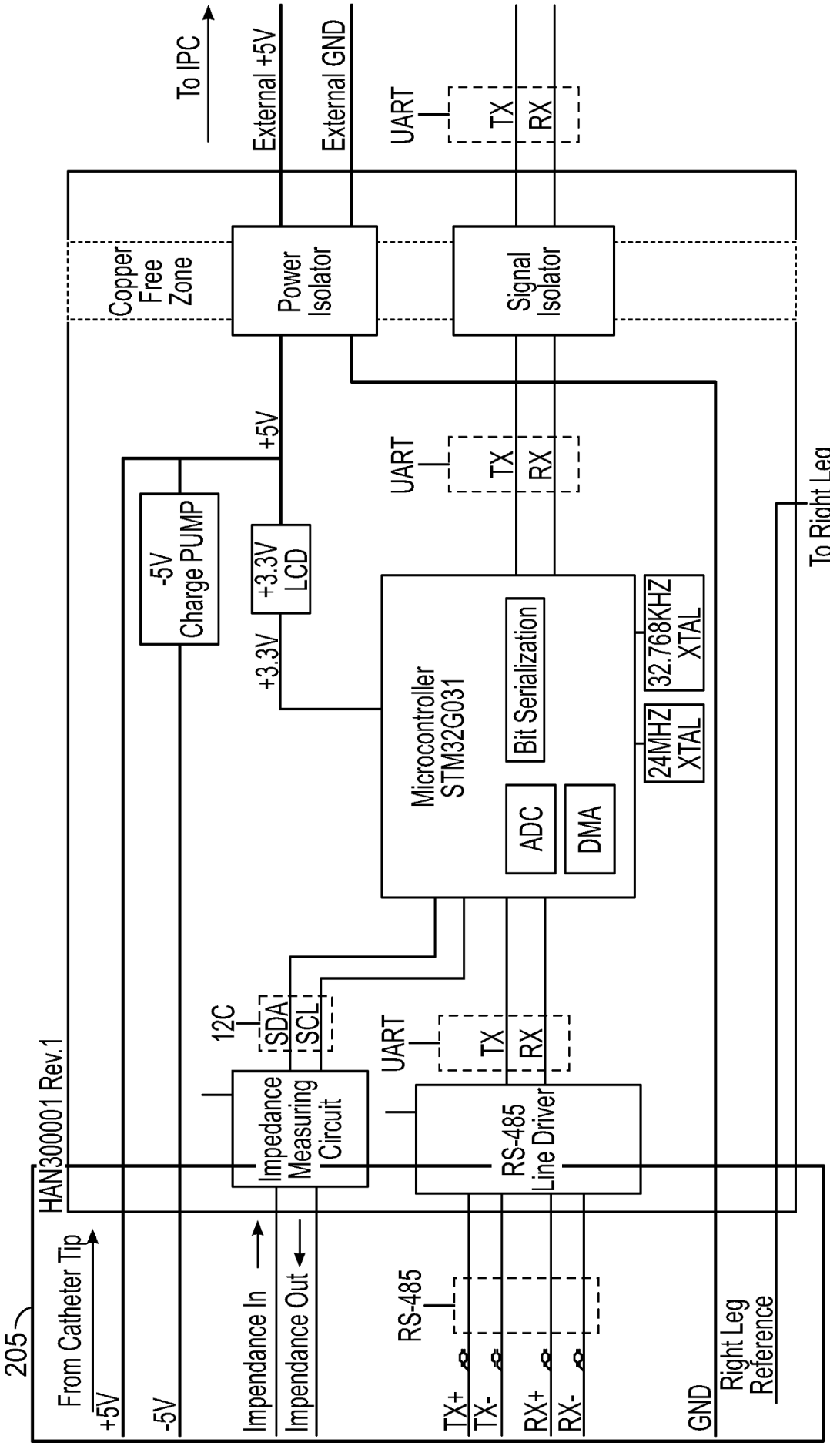

205
HAN300001 Rev.1
From Catheter Tip
+5V
-5V
Impedance In
Impedance Out
RS-485
TX+
TX-
RX+
RX-
GND
Right Leg Reference
12C
SDA
SCL
Impedance Measuring Circuit
UART
TX
RX
RS-485 Line Driver
-5V Charge PUMP
+3.3V LCD
+3.3V
+5V
Microcontroller STM32G031
Bit Serialization
ADC
DMA
24MHZ XTAL
32.768KHZ XTAL
Copper Free Zone
Power Isolator
Signal Isolator
To IPC
External +5V
External GND
To Right Leg Connection

FIG. 11.3

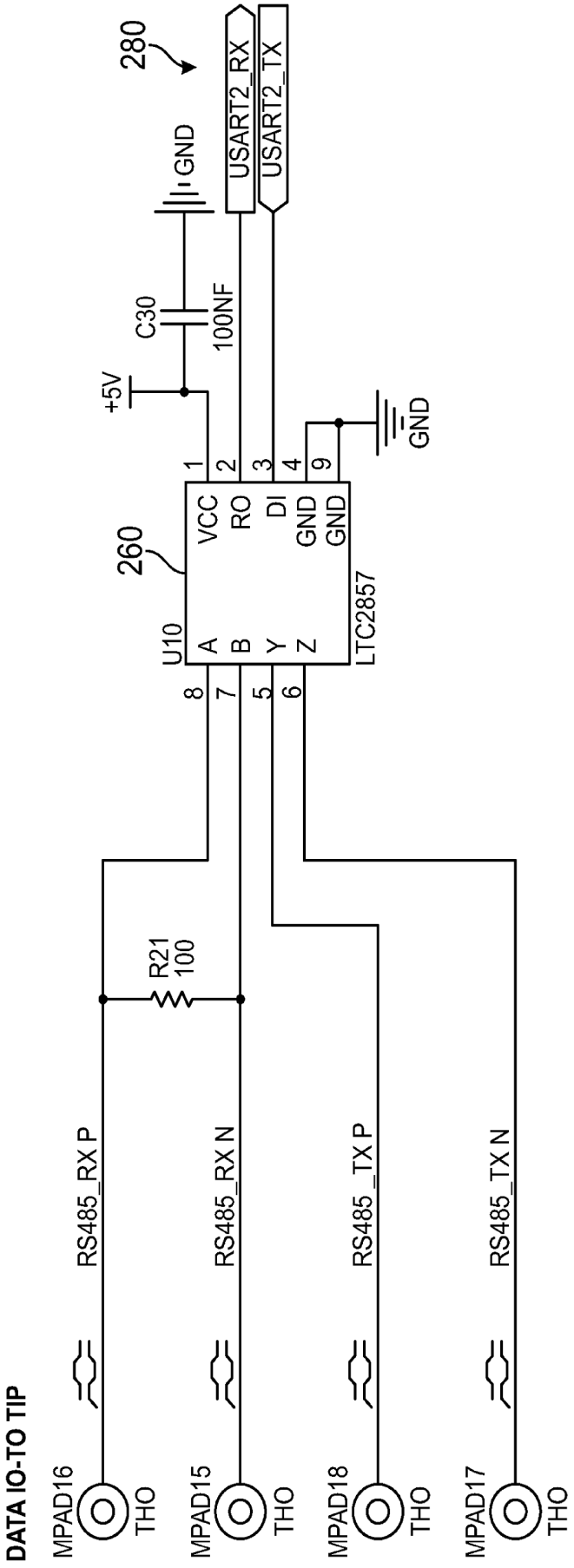
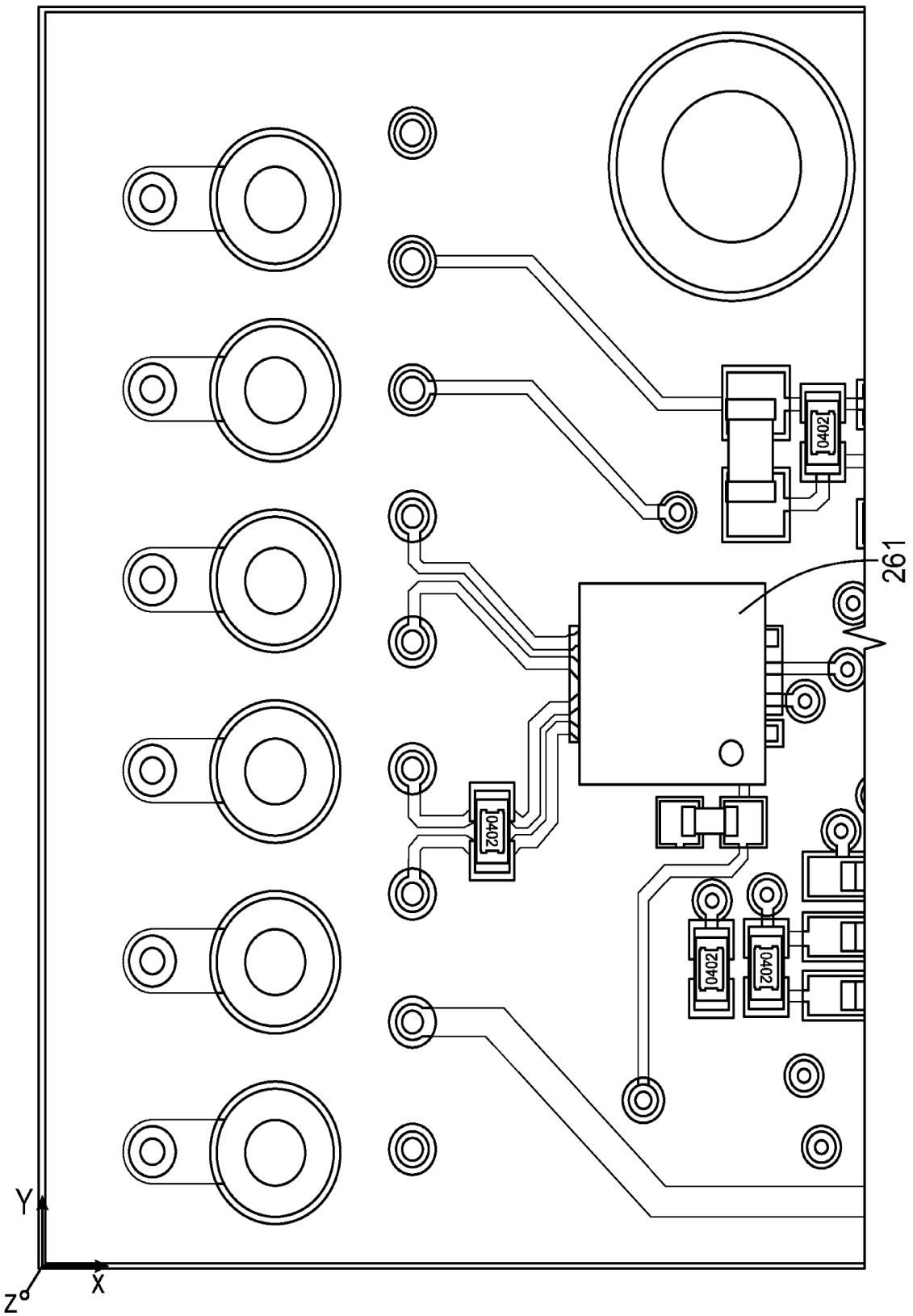

280
USART2_RX
USART2_TX
GND
C30
100NF
+5V
GND
260
U10
VCC
RO
DI
GND
GND
A
B
Y
Z
LTC2857
1
2
3
4
9
8
7
5
6
R21
100
DATA IO-TO TIP
MPAD16
THO
RS485_RX P
MPAD15
THO
RS485_RX N
MPAD18
THO
RS485 _TX P
MPAD17
THO
RS485_TX N

FIG. 12.1

FIG. 12.2



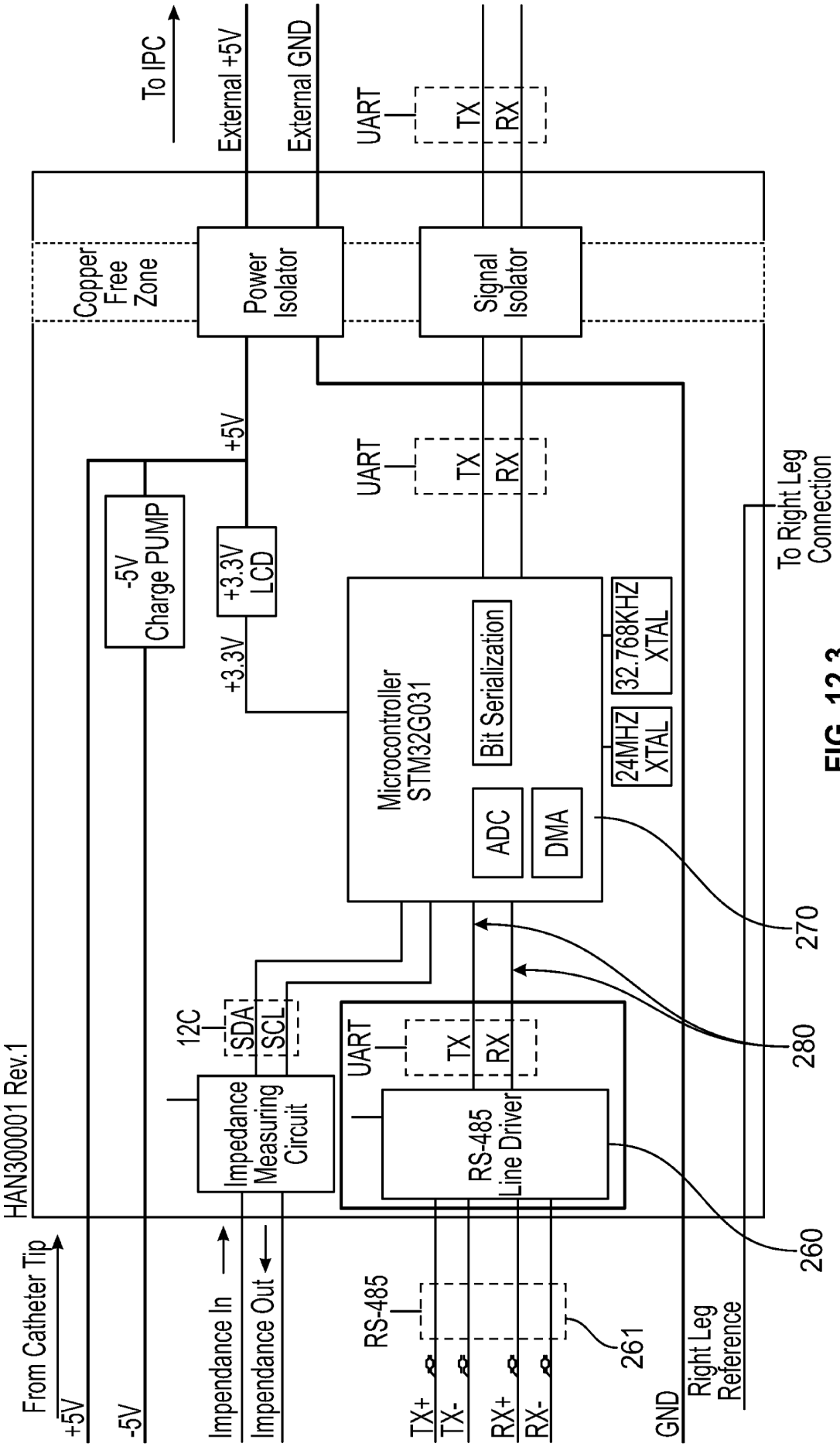

To IPC
External +5V
External GND
UART
TX
RX
Copper Free Zone
Power Isolator
Signal Isolator
+5V
-5V Charge PUMP
+3.3V LCD
+3.3V
Microcontroller STM32G031
Bit Serialization
ADC
DMA
24MHZ XTAL
32.768KHZ XTAL
To Right Leg Connection
270
280
260
261
12C
SDA
SCL
Impedance Measuring Circuit
RS-485 Line Driver
HAN300001 Rev.1
From Catheter Tip
+5V
-5V
Impendance In
Impendance Out
RS-485
TX+
TX-
RX+
RX-
GND
Right Leg Reference

FIG. 12.3

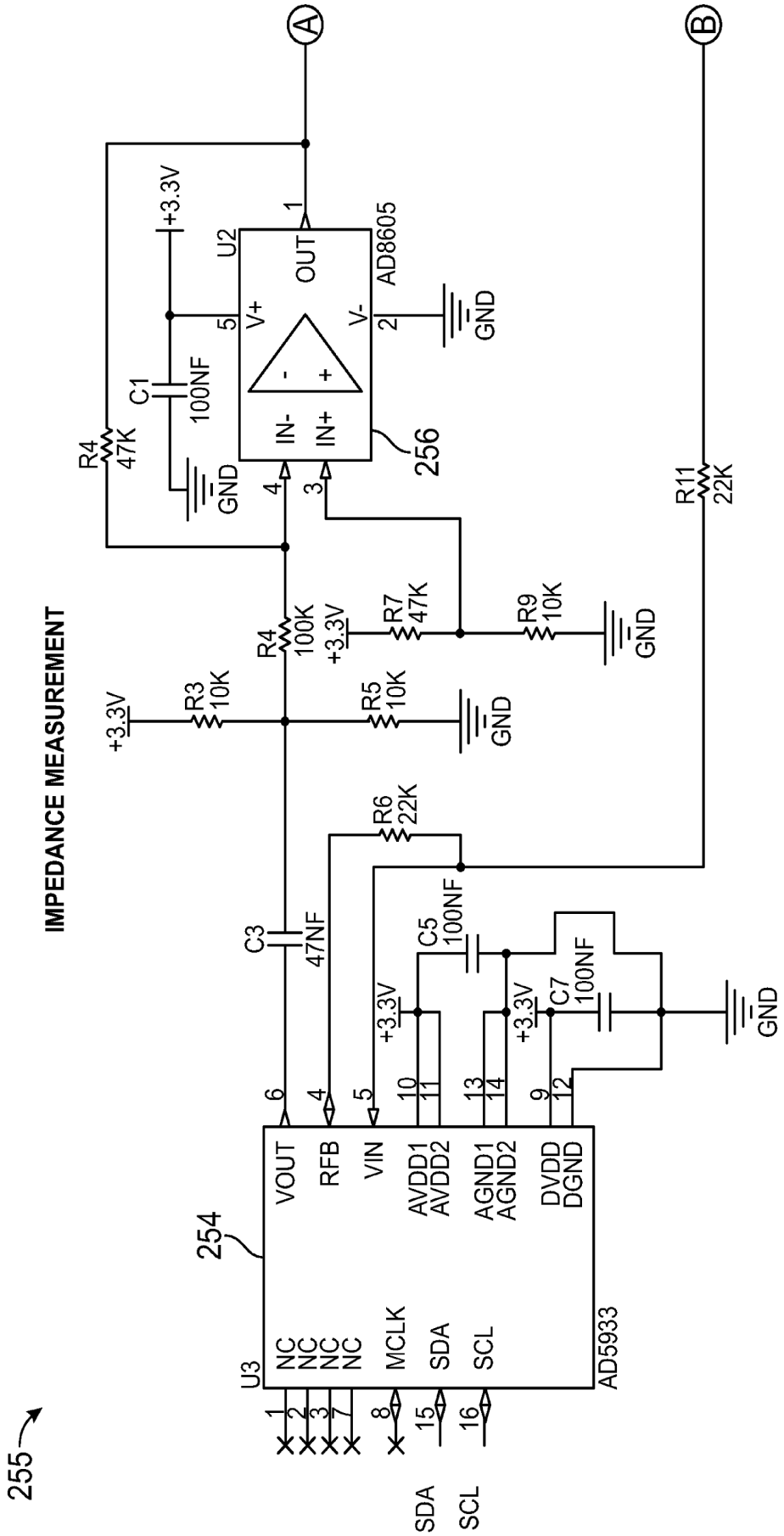


FIG. 13.1 (Part 1)

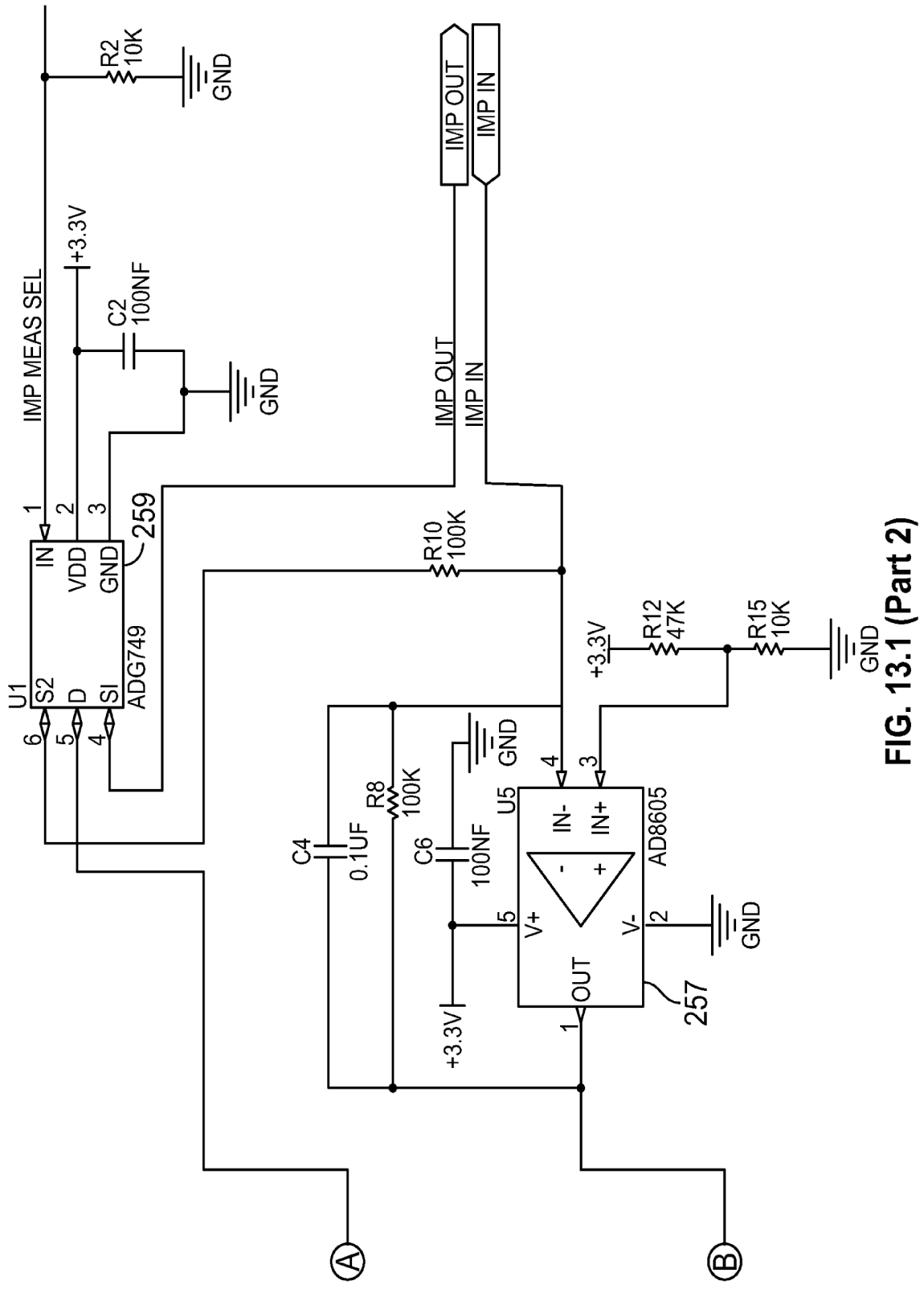


FIG. 13.1 (Part 2)

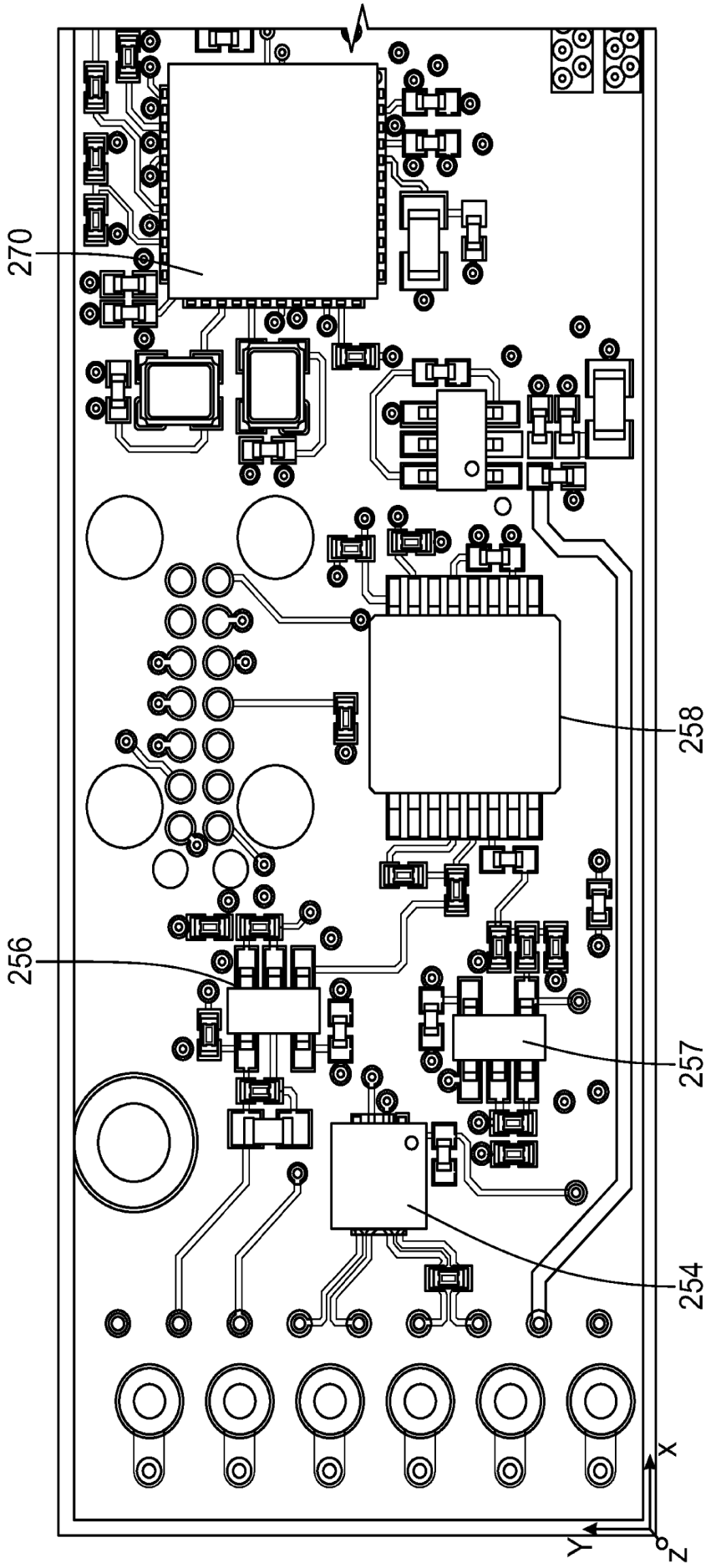


FIG. 13.2

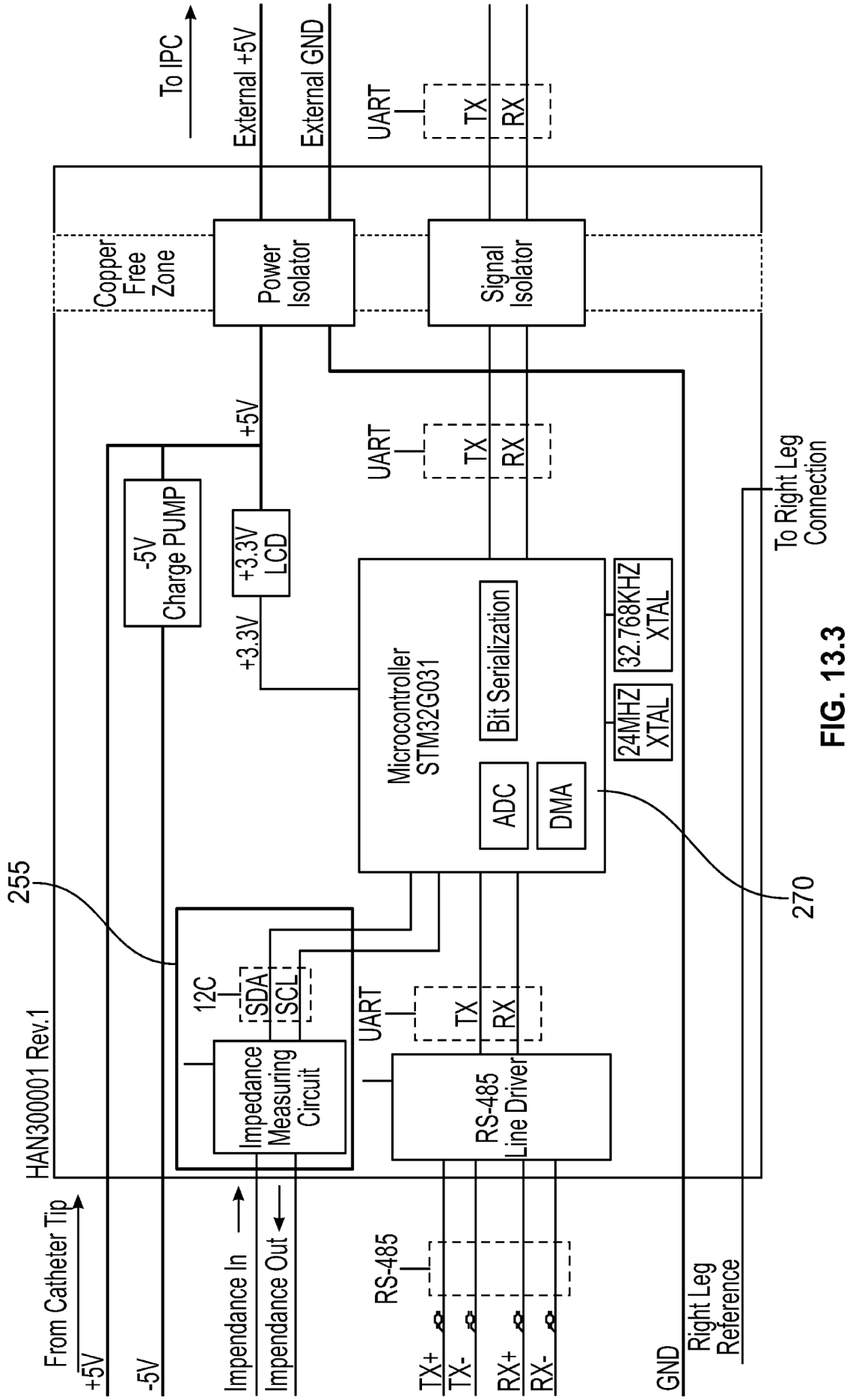

To IPC
External +5V
External GND
UART
TX
RX
Copper Free Zone
Power Isolator
Signal Isolator
+5V
-5V Charge PUMP
+3.3V LCD
+3.3V
Microcontroller STM32G031
Bit Serialization
ADC
DMA
24MHZ XTAL
32.768KHZ XTAL
To Right Leg Connection
255
270
HAN300001 Rev.1
12C
SDA
SCL
Impedance Measuring Circuit
RS-485 Line Driver
From Catheter Tip
+5V
-5V
Impendance In
Impendance Out
RS-485
TX+
TX-
RX+
RX-
GND
Right Leg Reference

FIG. 13.3

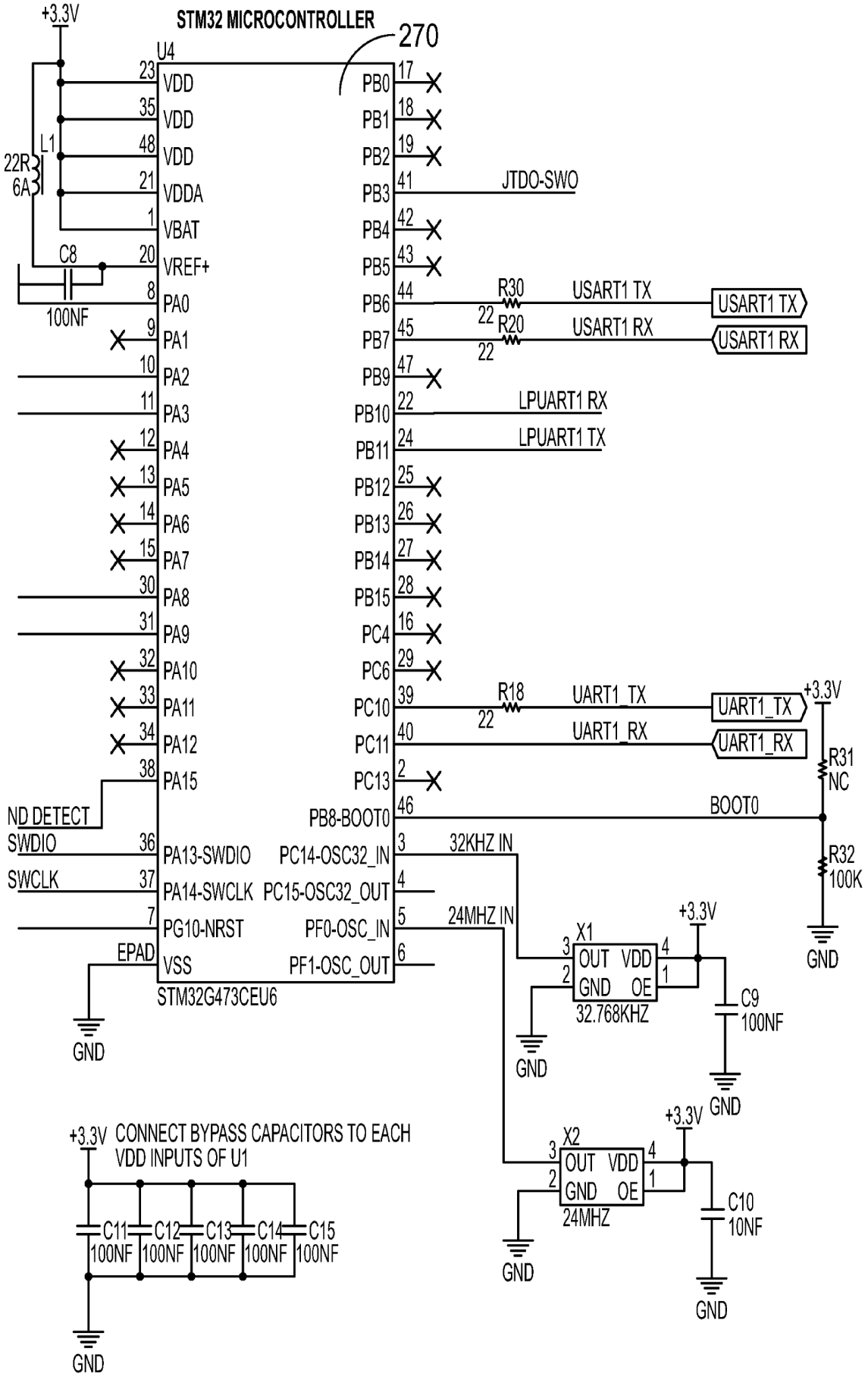

STM32 MICROCONTROLLER
270
U4
+3.3V
VDD
VDDA
VBAT
VREF+
PA0
PA1
PA2
PA3
PA4
PA5
PA6
PA7
PA8
PA9
PA10
PA11
PA12
PA15
PA13-SWDIO
PA14-SWCLK
PG10-NRST
VSS
STM32G473CEU6
PB0
PB1
PB2
PB3
PB4
PB5
PB6
PB7
PB9
PB10
PB11
PB12
PB13
PB14
PB15
PC4
PC6
PC10
PC11
PC13
PB8-BOOT0
PC14-OSC32_IN
PC15-OSC32_OUT
PF0-OSC_IN
PF1-OSC_OUT
EPAD
GND
L1
22R
6A
C8
100NF
JTDO-SWO
R30
22
USART1 TX
R20
22
USART1 RX
LPUART1 RX
LPUART1 TX
R18
22
UART1_TX
UART1_RX
R31
NC
R32
100K
BOOT0
ND DETECT
SWDIO
SWCLK
32KHZ IN
24MHZ IN
X1
OUT VDD
GND OE
32.768KHZ
C9
100NF
X2
24MHZ
C10
10NF
CONNECT BYPASS CAPACITORS TO EACH VDD INPUTS OF U1
C11 100NF
C12 100NF
C13 100NF
C14 100NF
C15 100NF

FIG. 14.1

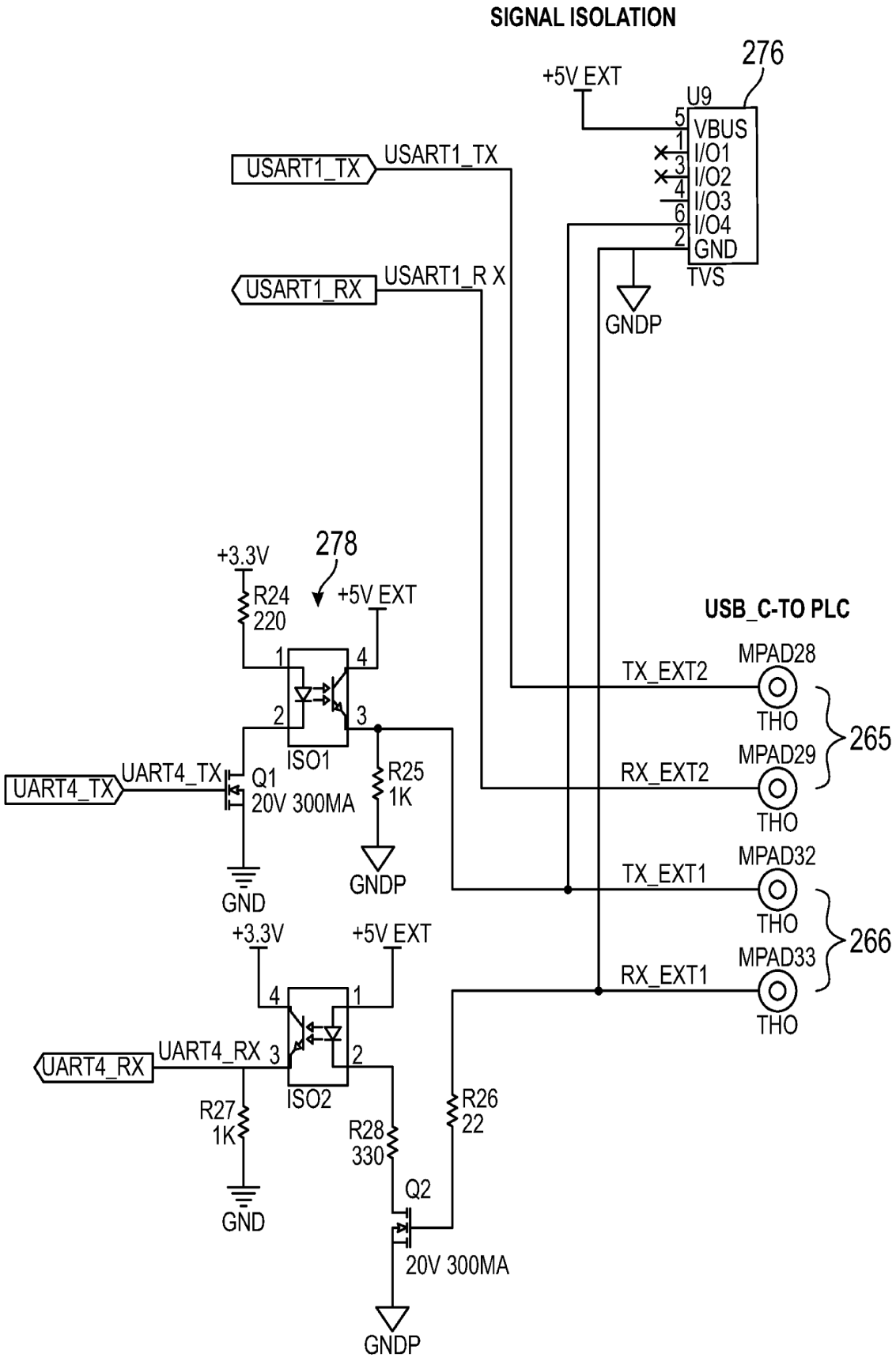

SIGNAL ISOLATION
276
+5V EXT
U9
5 VBUS
1 I/O1
3 I/O2
4 I/O3
6 I/O4
2 GND
TVS
USART1_TX
USART1_TX
USART1_RX
USART1_R X
GNDP
278
+3.3V
R24
220
+5V EXT
1
4
2
3
ISO1
UART4_TX
UART4_TX
Q1
20V 300MA
R25
1K
GND
GNDP
USB_C-TO PLC
MPAD28
TX_EXT2
THO
265
MPAD29
RX_EXT2
THO
MPAD32
TX_EXT1
THO
266
MPAD33
RX_EXT1
THO
+3.3V
+5V EXT
4
1
UART4_RX
UART4_RX
3
2
ISO2
R27
1K
GND
R28
330
R26
22
Q2
20V 300MA
GNDP

FIG. 14.2

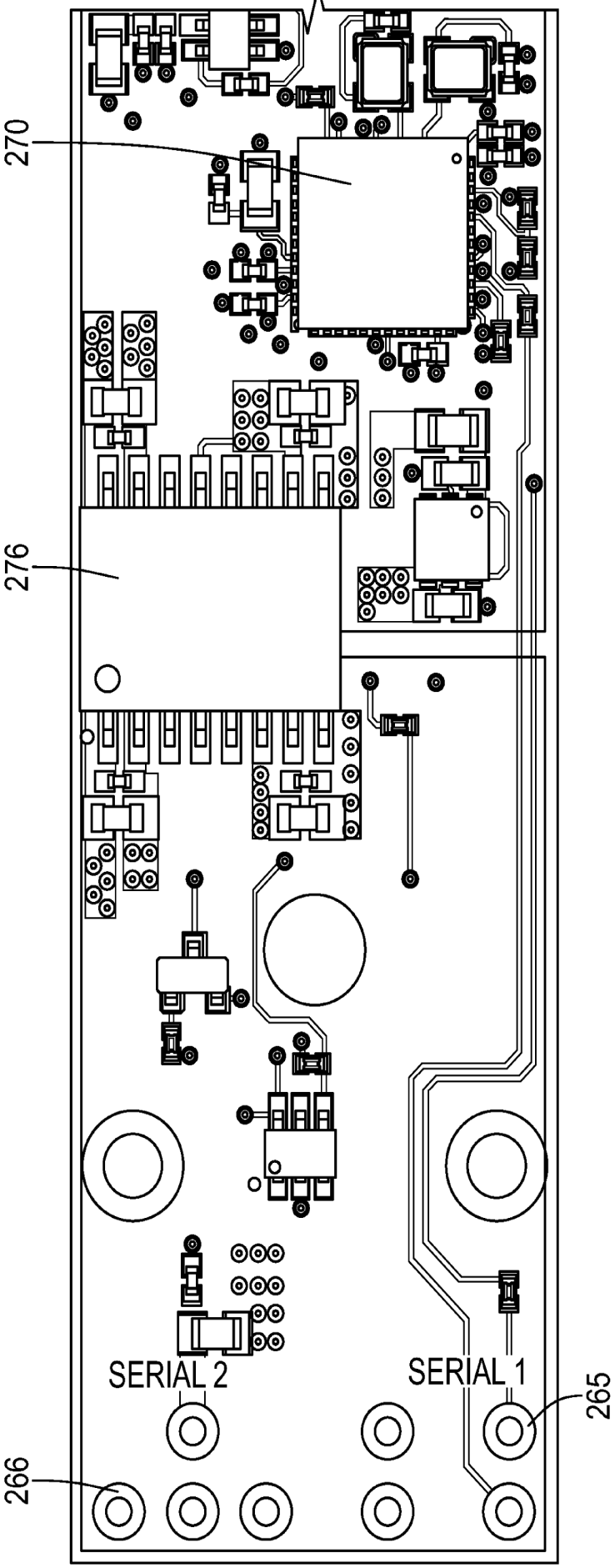


FIG. 14.3

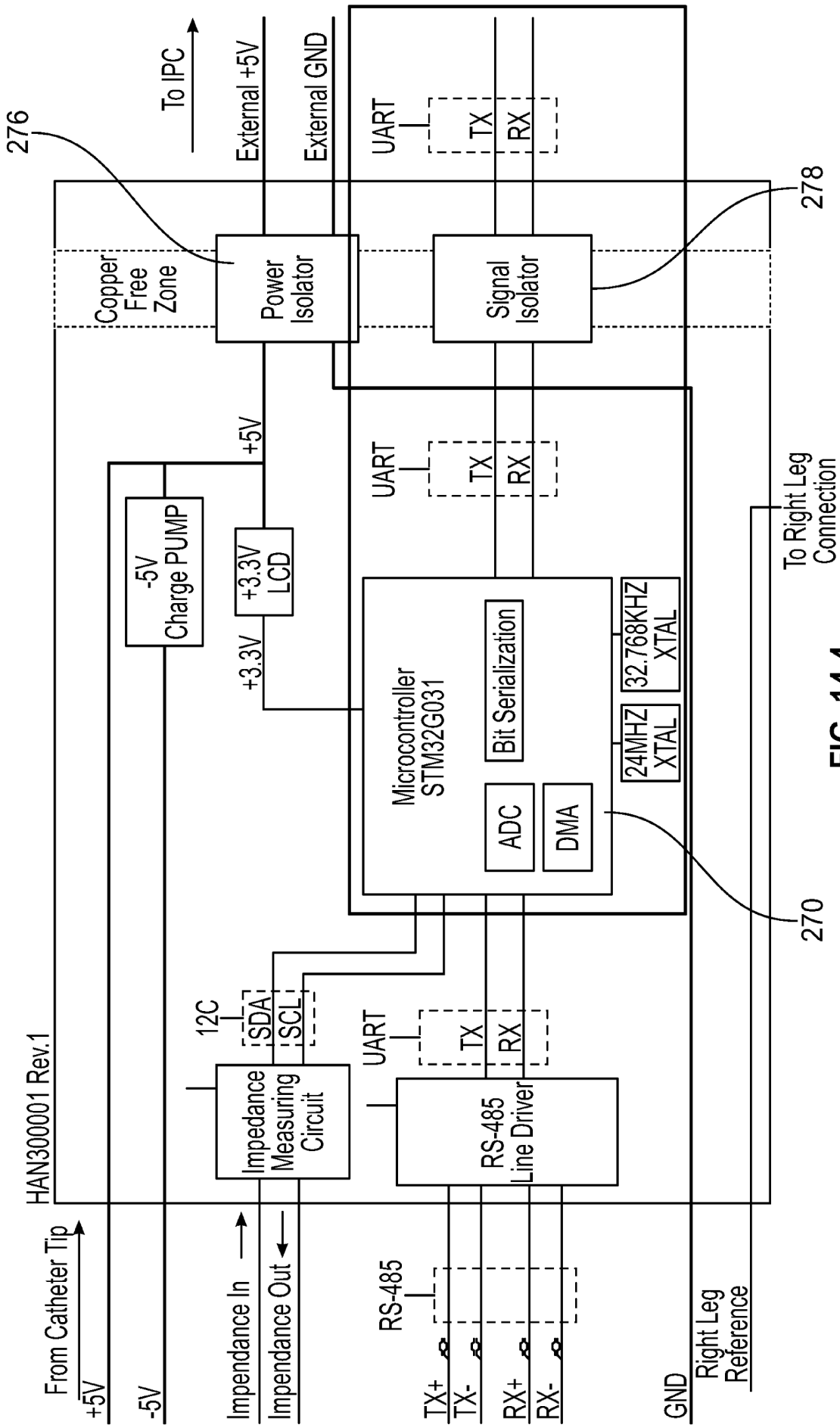

276
To IPC
External +5V
External GND
UART
TX
RX
278
Copper Free Zone
Power Isolator
Signal Isolator
+5V
-5V Charge PUMP
+3.3V LCD
+3.3V
UART
TX
RX
To Right Leg Connection
Microcontroller STM32G031
Bit Serialization
32.768KHZ XTAL
24MHZ XTAL
ADC
DMA
270
12C
SDA
SCL
UART
TX
RX
HAN300001 Rev.1
Impedance Measuring Circuit
RS-485 Line Driver
From Catheter Tip
+5V
-5V
Impendance In
Impendance Out
RS-485
TX+
TX-
RX+
RX-
GND
Right Leg Reference

FIG. 14.4

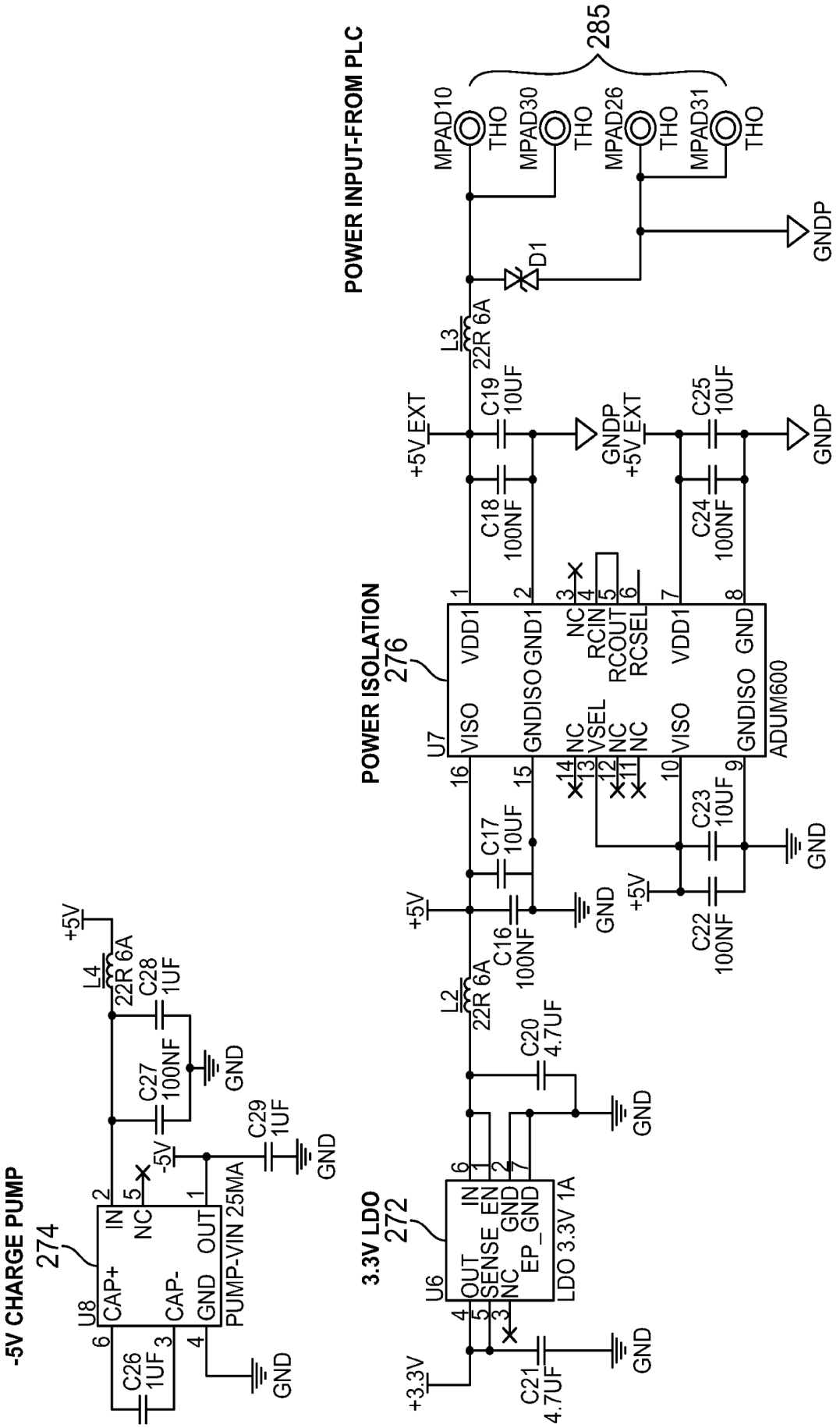

POWER INPUT-FROM PLC
285
MPAD10
THO
MPAD30
THO
MPAD26
THO
MPAD31
THO
D1
GNDP
L3
22R 6A
+5V EXT
C19
10UF
C18
100NF
GNDP
+5V EXT
C25
10UF
C24
100NF
GNDP
POWER ISOLATION
276
U7
VISO
VDD1
GNDISO
GND1
NC
RCIN
RCOUT
RCSEL
NC
VSEL
NC
NC
VISO
VDD1
GNDISO
GND
ADUM600
+5V
C17
10UF
C16
100NF
GND
+5V
C23
10UF
C22
100NF
GND
L2
22R 6A
C20
4.7UF
GND
3.3V LDO
272
U6
OUT
SENSE
NC
IN
EN
GND
EP_GND
LDO 3.3V 1A
+3.3V
C21
4.7UF
GND
-5V CHARGE PUMP
274
U8
CAP+
CAP-
IN
NC
OUT
GND
PUMP-VIN 25MA
C26
1UF
+5V
L4
22R 6A
C28
1UF
C27
100NF
GND
-5V
C29
1UF
GND

FIG. 15.1

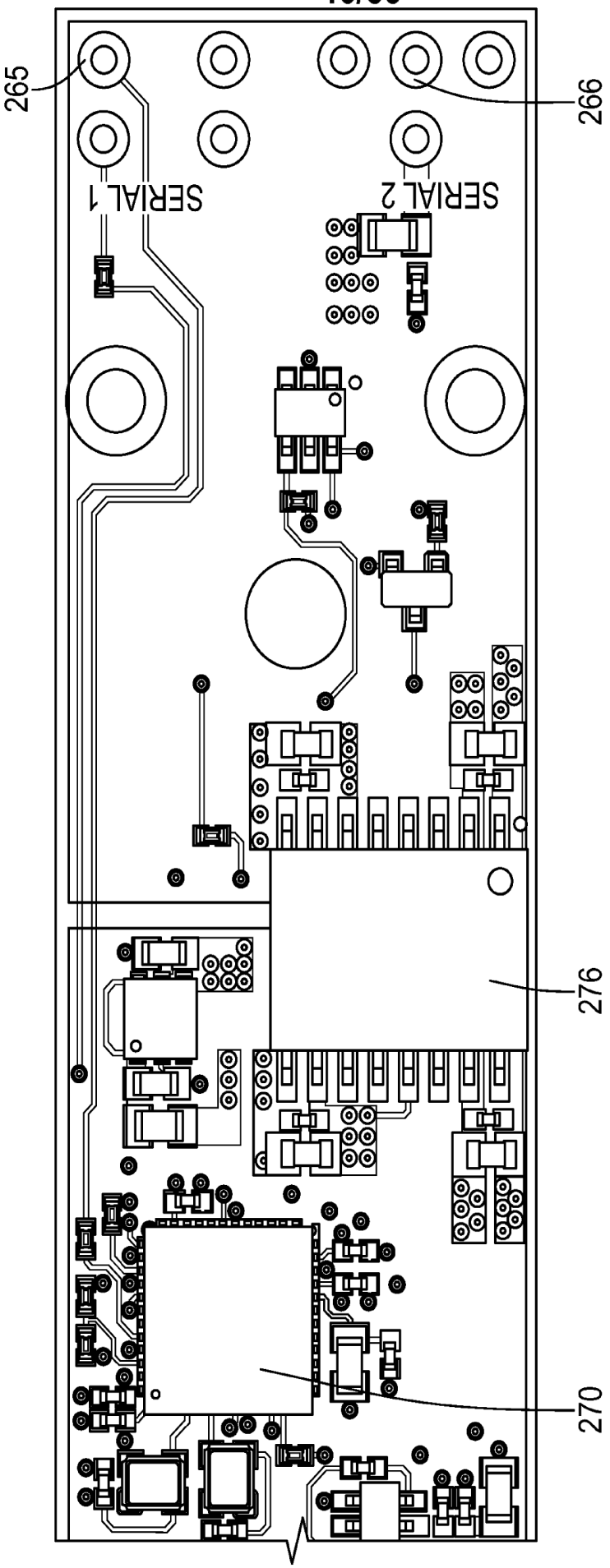


FIG. 15.2

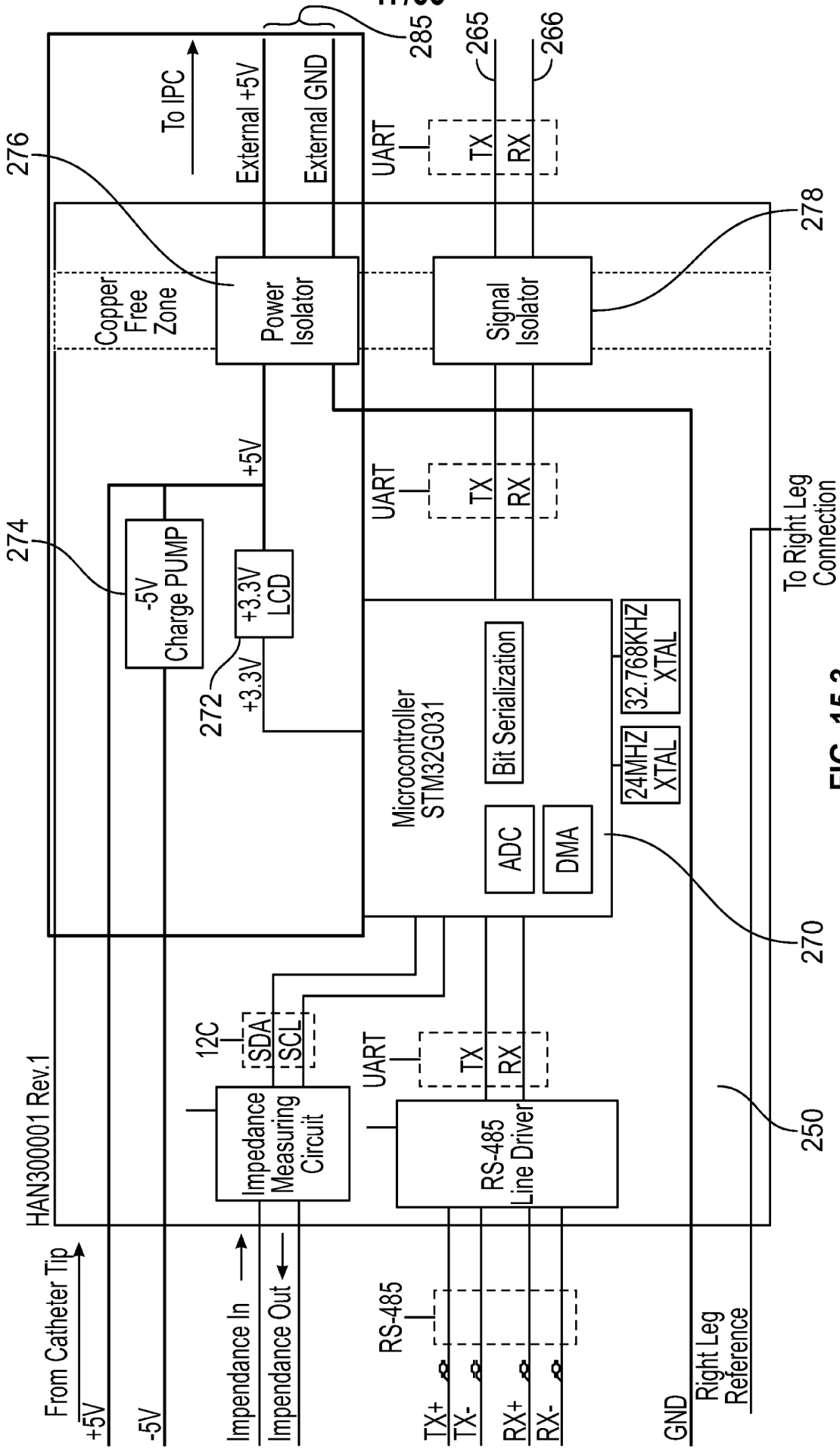

HAN300001 Rev.1
From Catheter Tip
+5V
-5V
Impendance In
Impendance Out
RS-485
TX+
TX-
RX+
RX-
GND
Right Leg Reference
12C
SDA
SCL
Impedance Measuring Circuit
UART
TX
RX
RS-485 Line Driver
250
270
Microcontroller STM32G031
Bit Serialization
ADC
DMA
24MHZ XTAL
32.768KHZ XTAL
To Right Leg Connection
-5V Charge PUMP
+3.3V LCD
+3.3V
+5V
272
274
276
278
Copper Free Zone
Power Isolator
Signal Isolator
To IPC
External +5V
External GND
285
265
266

FIG. 15.3

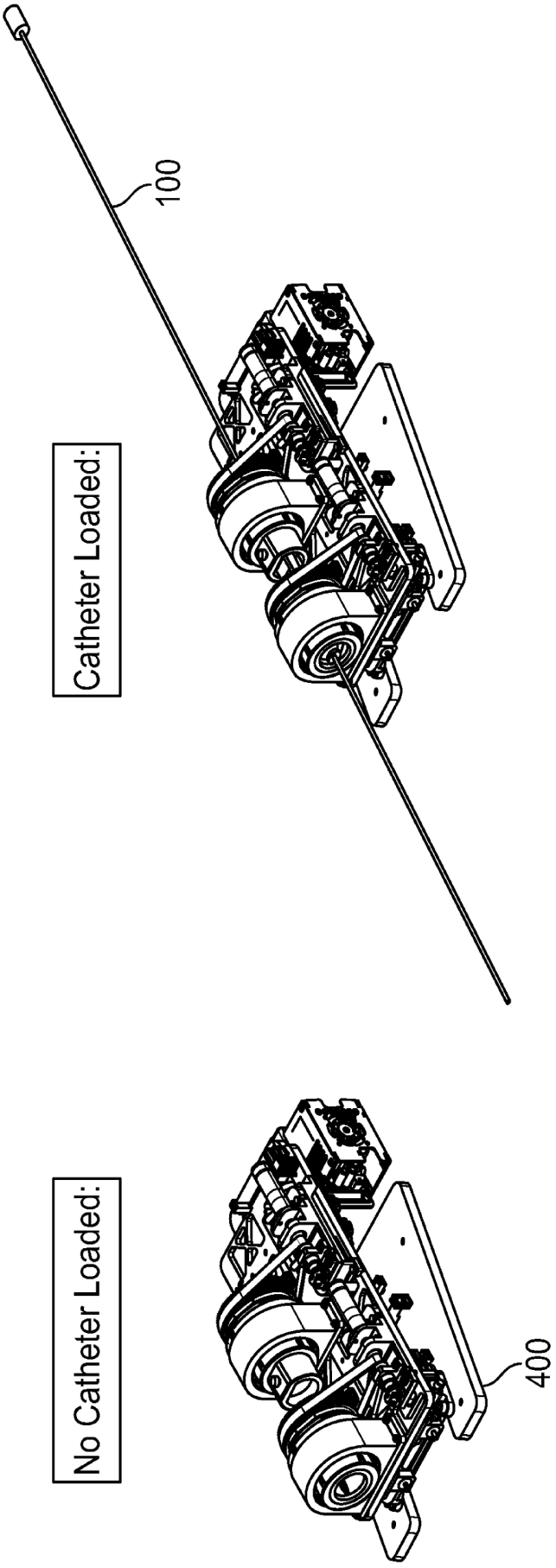


FIG. 16

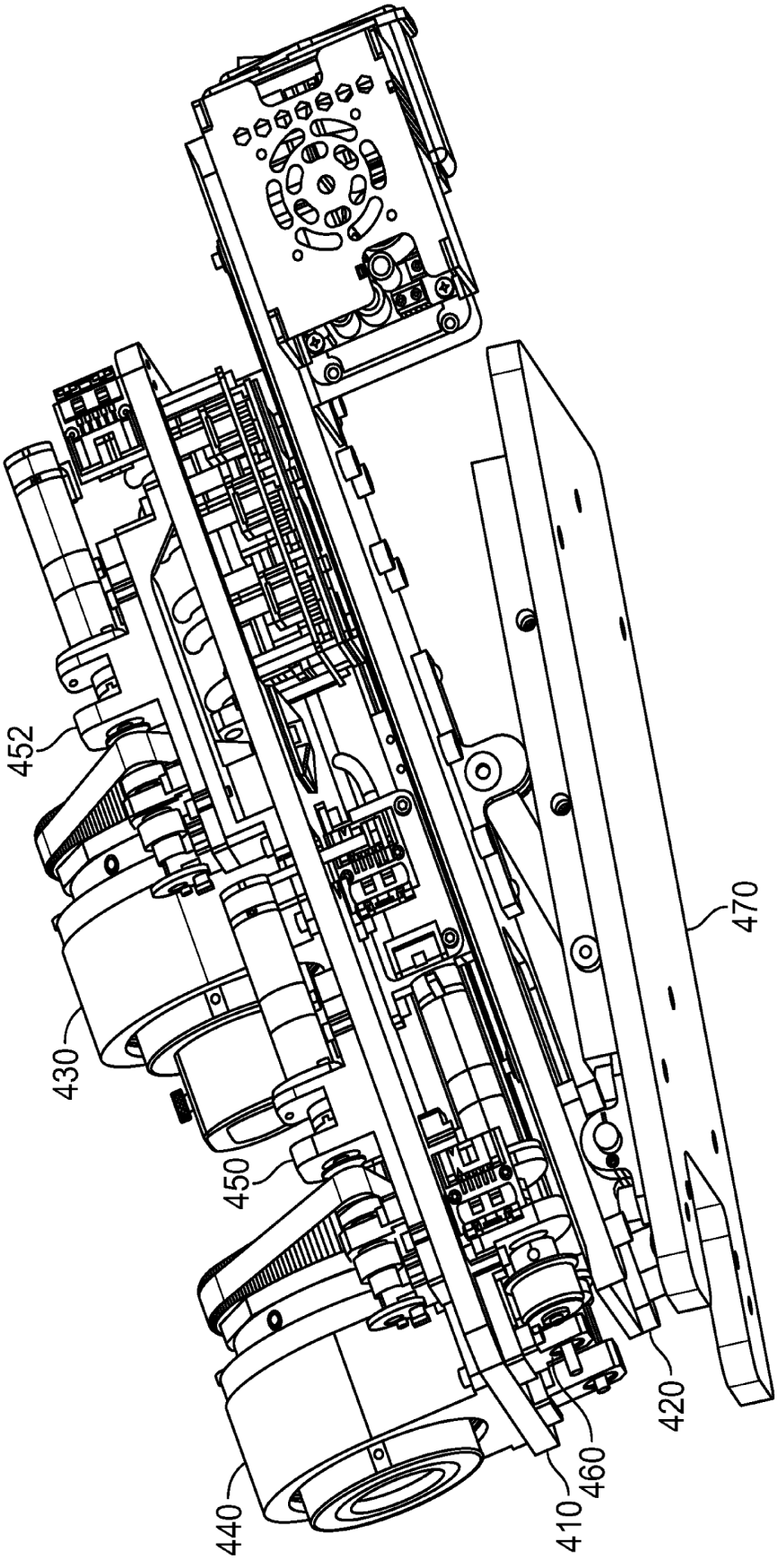


FIG. 17

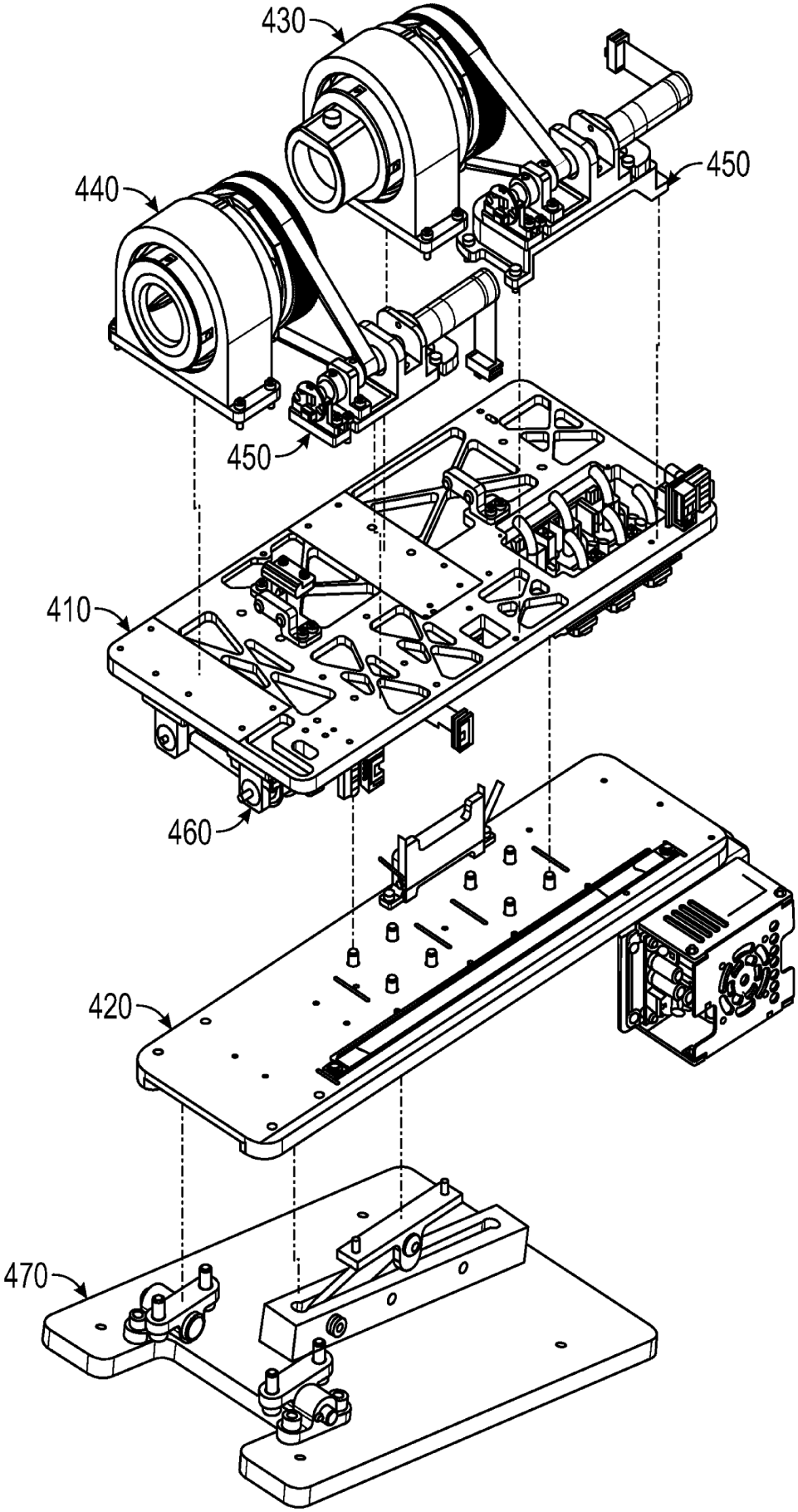


FIG. 18

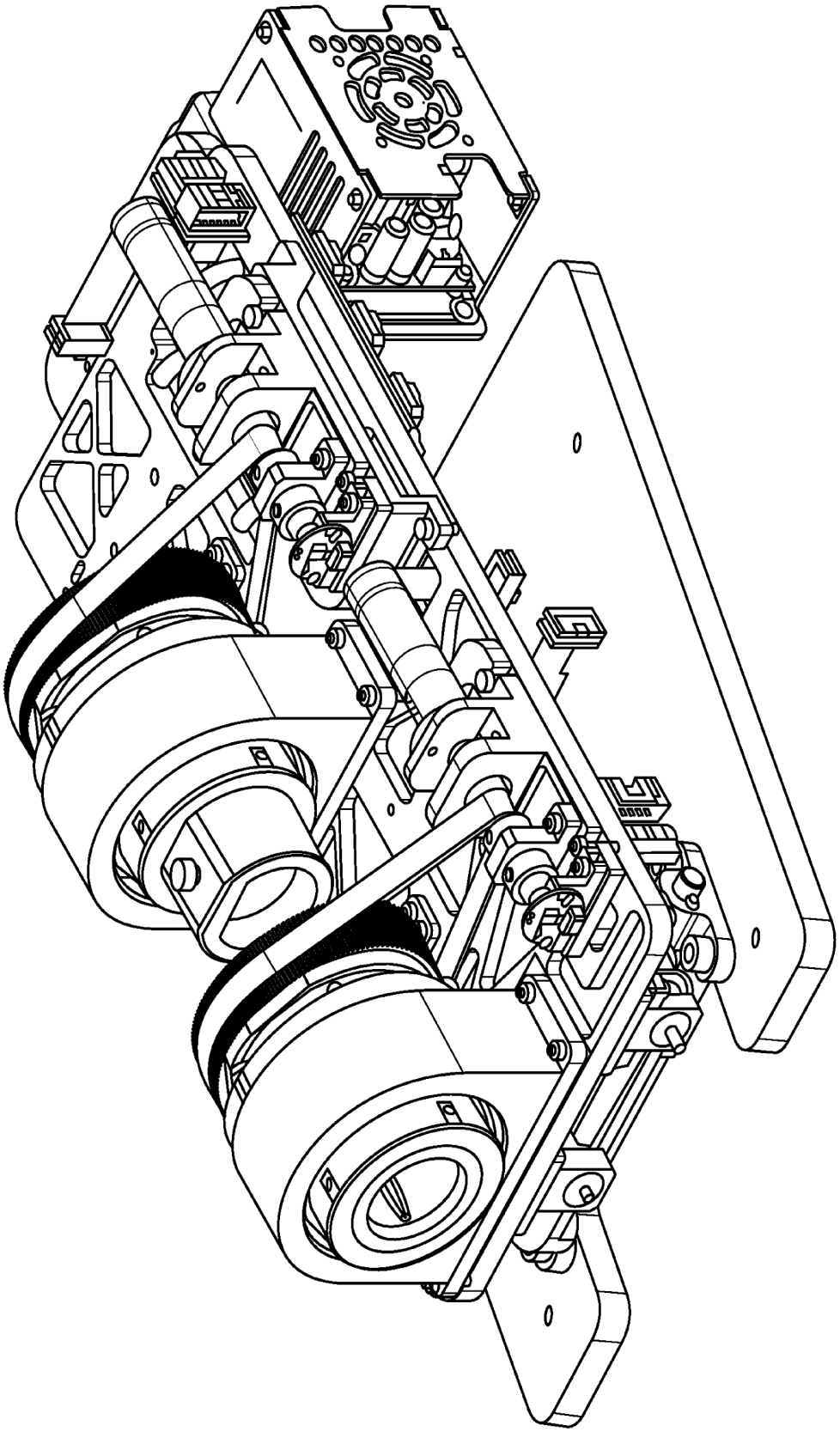


FIG. 19

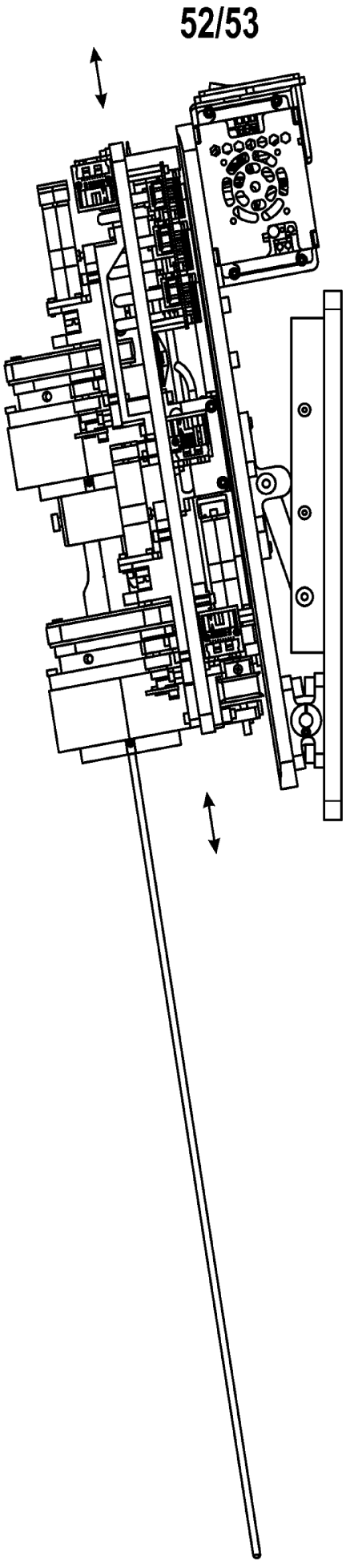


FIG. 20

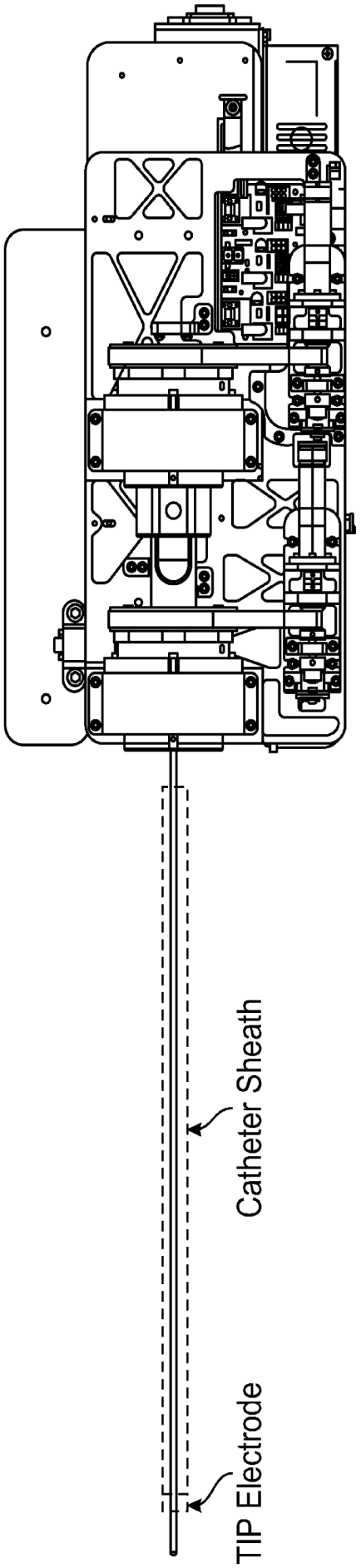


FIG. 21

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US22/30399

A. CLASSIFICATION OF SUBJECT MATTER

IPC - INV. A61B 18/14; A61B 5/053; A61B 5/06; A61B 34/20; A61B 34/32; A61B 34/35 (2022.01)
ADD. A61B 34/37 (2022.01)

CPC - INV. A61B 18/1206; A61B 5/053; A61B 18/1492; A61B 34/20; A61B 34/30; A61B 34/73
ADD. A61B 5/062; A61B 5/068; A61B 34/76; A61B 2018/00303; A61B 2018/00357; A61B 2018/00577; A61B 2018/00666

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2018/0078300 A1 (ST. JUDE MEDICAL, ATRIAL FIBRILLATION DIVISION, INC.) 22 March 2018; See figures 1, 2A; paragraphs [0005], [0041-0043], [0047-0048], [0054-0057], [0079], [0082], [0096]	1-10
A	WO 2021/084476 A1 (NAVIX INTERNATIONAL LIMITED) 06 May 2021; See entire document for additional information	1-10
A	WO 2021/165882 A2 (NAVIX INTERNATIONAL LIMITED) 26 August 2021; See entire document for additional information	1-10

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
08 September 2022 (08.09.2022)	OCT 13 2022
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Shane Thomas Telephone No. PCT Helpdesk: 571-272-4300

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US22/30399

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
-***-Please See Supplemental Page-***-

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-10

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US22/30399

-***-Continued From Box No. III: Observations where unity of invention is lacking-***-

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-10 are directed toward an apparatus for robotically performing electrophysiological and/or renal macros in combination with a remote mapping station comprising: a flexible catheter having a distal portion and a plurality of sensing electrodes; a remote handle including a kinematic mechanism coupled to control wires to selectively deflect the catheter.

Group II: Claims 11-19 are directed toward a method of robotically and dynamically controlling the movement of a catheter in a body organ cavity of a patient as directed by a surgeon comprising: disposing an optical catheter into the body organ cavity; recording the positions of the one or more anatomical sites in the body organ cavity; generating a map of the from positions on the path.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I include an apparatus for robotically performing electrophysiological and/or renal macros in combination with a remote mapping station comprising: a flexible catheter having a distal portion and a plurality of sensing electrodes included in the distal portion for sensing native biometric signals; one or more multiplexers included in the distal portion of the catheter and coupled to the plurality of sensing electrodes to multiplex the biometric signals; an amplifier circuit included in the distal portion of the catheter and coupled to the one or more multiplexers to amplify the biometric signals in the distal portion of the catheter; a microcontroller included in the distal portion of the catheter coupled to the amplifier circuit to digitize the biometric signals and to format the digitized amplified biometric signals according to a communications protocol; a flexible sheath coupled at a distal end to the distal portion of the catheter and including a digital communications cable and control wires; a remote handle coupled to a proximal end of the sheath, to the digital communications cable and to the control wires, the remote handle including a kinematic mechanism coupled to the control wires to selectively deflect a distal end of the catheter including the plurality of sensing electrodes, and the remote handle including circuitry for digitizing and/or formatting the digitized amplified multiplexed biometric signals for bidirectional transmission to the remote mapping station; and a robot engaging the remote handle for selectively deflecting the distal tip of the catheter, rotating the catheter and/or translating the catheter in response to computer commands to learn and/or execute electrophysiological and/or renal macros, which are not present in Group II.

Group II include a method of robotically and dynamically controlling the movement of a catheter in a body organ cavity of a patient as directed by a surgeon comprising: disposing an optical catheter into the body organ cavity under manual control by the surgeon at one or more anatomical sites in the body organ cavity as chosen by the surgeon; recording the positions of the one or more anatomical sites in the body organ cavity as identified by the surgeon; measuring one or more biometric signals at a corresponding one or more positions in the body organ cavity using the catheter as identified by the surgeon; robotically moving the optical catheter in the body organ cavity on a path selected by the surgeon to the one or more anatomical sites and/or positions in the body organ cavity; generating a map of the biometric signals from positions on the path; and displaying the map, which are not present in Group I.

The common technical features of Groups I and II are robotically; catheter; biometric signals.

These common technical features are disclosed by US 2018/0078300 A1 to ST. JUDE MEDICAL, ATRIAL FIBRILLATION DIVISION, INC. (hereinafter 'ST. JUDE'). ST. JUDE discloses robotically (the manipulation system is robotically operated; paragraph [0005]); catheter (electrode catheter; paragraph [0042]); biometric signals (measuring impedance of the tissue; paragraphs [0043], [0083], [0086]).

Since the common technical features are previously disclosed by the ST. JUDE reference, the common features are not special and so Groups I and II lack unity.