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A 96-Channel Electrophysiology Catheter with Integrated Read-Out ASIC and Optical Link

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***Abstract* — This paper describes a realization of an electrophysiology (EP) catheter with 96 electrodes which requires no electrical wiring to the outside by relying on an optical link for both power supply and data communication. The catheter tip is constructed from a liquid crystal polymer (LCP) material. It features 96 gold electrodes, which are uniformly arranged along an expandable basket. An integrated ASIC amplifies, filters and digitizes the EP signals and establishes communication to a data processing unit outside the patient's body. The optical interface consists of a conventional multi-mode fiber and a single blue LED inside the catheter. The external unit used to generate optical power, establish communication and perform data post-processing comprises a laser module, optics, and electrical components. The catheter is designed to capture EP signals in the range of 600 µVpp to 20 mVpp in a frequency range between 8 Hz and 120 Hz.**

***Clinical Relevance* — The proposed EP catheter can be used for cardiac arrhythmia interventions by a parallel spatial mapping of a high count of electrophysiology signals from inside the atrium.**

I. Introduction

The treatment of atrial fibrillation (AF) requires a recording or mapping of cardiac atrial activation, for which two types of electrophysiology (EP) catheters are commonly used: conventional catheters with only a few electrodes at their tip, and, since recently, basket catheters which mechanically expand and conform to the atrial wall in order to bring numerous electrodes in contact with the tissue at the same time. However, both of these solutions bear significant disadvantages. EP catheters with less electrodes require sequentially scanning through different points within the atrium, rendering full-scale spatial mapping time-consuming if not prohibitively unpractical. In contrast, basket catheters allow for a fully parallel spatiotemporal mapping, which greatly reduces the surgery duration. However, each electrode has to be wired through the catheter shaft to an external data acquisition unit, thereby increasing the shaft diameter and introducing unwanted stiffness.

To address these shortcomings, we present a first demonstrator EP catheter featuring a flexible basket made of liquid crystal polymer (LCP) and the feasibility to capture up to 96 signals simultaneously. Signals are measured and digitized within the catheter itself by an integrated mixed-signal ASIC, thereby also improving the signal quality due to the minimized wiring length and associated parasitic effects. An optical link, which requires only a single optical fiber through the catheter shaft, is used both to power the ASIC and to provide a bidirectional communication link. Thanks to the optical link, the external unit can be placed far away from the patient without degenerating the signal quality.

II. Overall Catheter System

The EP catheter system consists of four main components: the basket at the catheter tip, the catheter shaft with optical fiber link, the handle and the external electro-optical unit, see Figure 1. The basket catheter is made of LCP and equipped with a single blue LED, two capacitors and a mixed-signal CMOS ASIC, which is placed face down on the top of the LCP using an anisotropic conductive film bonding process (ACF) [1]. 96 electrode pads are uniformly arranged along eight LCP splines and electrically connected to the input pads of the mixed-signal ASIC. The electrodes' surfaces are gold-plated to improve the contact resistance to the tissue. The capacitors and blue LED are attached and electrically connected to the proximal end of the LCP via soldering. The LED is mated to a multi-mode fiber to establish the optical connection.

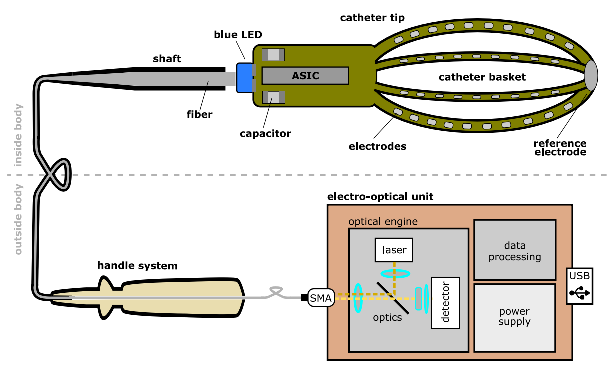

Figure 1: Overall catheter system. Mechanical steering parts of the shaft are omitted for clarity.

The latter, in turn, is routed through the catheter shaft together with the stainless-steel wires for mechanical control. The

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catheter handle connected to the shaft provides a mechanism to open, close and steer the catheter, and passes the multi-mode fiber to the external electro-optical unit. The latter includes an opto-electrical interface, a power management unit and a microcontroller for data processing.

III. EP Catheter Design

A. Basket Tip and Electrode Arrangement

The basket is made from a single 4-layer LCP substrate, which is divided into two distinct sections. One of them contains the basket splines onto which the 0.4 mm^2, gold-plated electrodes are placed. Each spline is equipped with a total of 12 electrodes at a 2.4 mm pitch, as well as a reference electrode at their distal ends. After the assembly (see Sec. III B), the reference electrodes of each spline will be electrically connected. The lower end of the splines is left empty as that area is less likely to have direct contact to the heart tissue. The length of the basket is 25 mm which yields a maximum inflation diameter of 20 mm. The length of the basket is a trade-off between electrode density, mapping area and maneuverability (Figure 2). The base of the basket contains the electrical components such as the chip, LED and a capacitor. A rectangular cut-out is added to simplify the folding process. As soon as the basket is folded into shape, the LED is located at the neutral axis of the catheter tube. This minimizes the forces on the LED and the fiber when the basket is deflected.

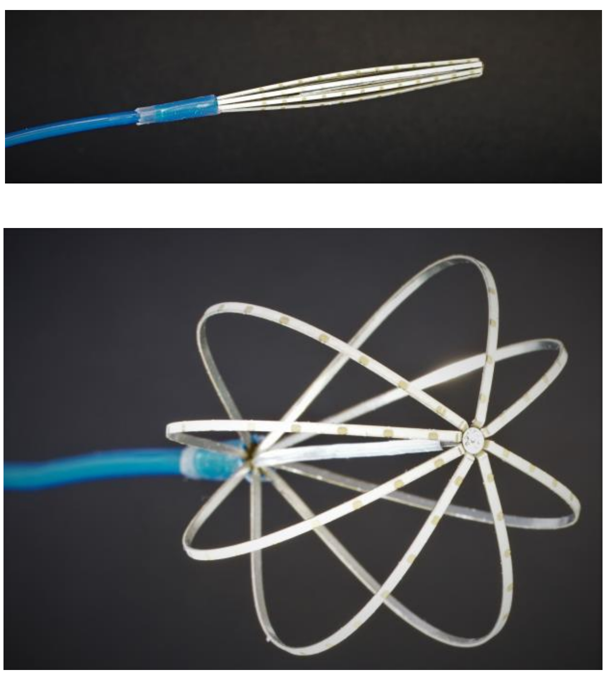

Figure 2: The catheter basket in closed (top image) and opened configuration (bottom image).

One of the main reasons why LCP is used as the substrate material for the catheter tip is that it is a thermoplastic polymer which can be permanently formed under moderate temperature and pressure. The melting temperature of LCP (> 285 °C) is above the peak reflow temperature for lead-free solder, hence standard assembly techniques can be used. The ASIC is bonded onto the substrate via ACF bonding applied with gold stud bumps and the LED and capacitors are assembled using a solder reflow process. Both the capacitors and the ASIC are assembled onto the bottom side of the substrate to increase the available area for the pull wire. A quartz optical fiber is glued onto the LED via EPOTEK301 for its low optical absorption. After the assembly of the electronic components, the substrate is heated by hot air and then formed into shape for fitting into the catheter tube. The formed LCP substrate remains its shape matching the catheter tube diameter after cooling down to room temperature.

B. Integration of Catheter Components and Shaping

After the assembly of all electrical components, the basket tip is shaped (Figure 3). The basket splines are joined together at their tips, a pull wire is connected and the resulting tip is covered with a silicon tube to reduce the sharpness and obtain an atraumatic cap. The basket is then integrated into a standard OSYPKA braided tube with a length of 110 cm. This tube is then connected to the handle. There, the pull wire for inflation and deflation of the basket is connected to a slider system so that the user can inflate and deflate the basket. Another pull wire for deflecting/steering the basket is connected to a second cylindrical slider (Figure 4). Pushing down on this slider will deflect the basket. Finally, the catheter connects to the electro-optical unit via a single SMA905 connector.

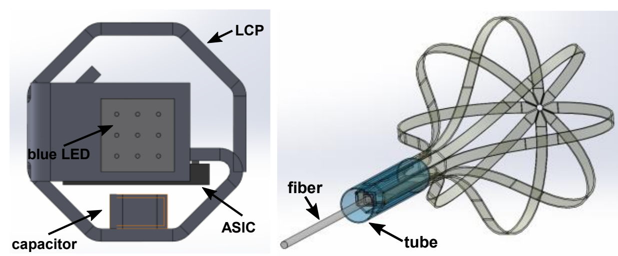

Figure 3: (left) Cross-section of the catheter tip, showing the formed LCP substrate with the assembled components. The catheter tube has a diameter of 7 french units (2.33 mm). (Right)

Figure 4: Slider system of the catheter.

IV. Optical Link

The optical link facilitates both power delivery and a bidirectional data transport by means of light only [3]. A schematic overview of the optical link is given in Figure 5.

Light from a semiconductor laser at a wavelength of approximately 405 nm is coupled into a multi-mode optical fiber at the proximal end of the catheter. The laser beam illuminates the blue LED through the fiber and, thereby, produces an electrical current that powers the ASIC at the distal end of the catheter. Data can be transmitted to the ASIC by modulating the laser power. At the same time, given the right input impedance of the circuit, the blue LED will also emit light due to a process called photo-induced electroluminescence [3]. It does so at a longer wavelength than the absorbed laser light, in our case at approximately

450 nm. The emitted light is coupled into the fiber and transmitted back to a photodiode at the proximal side of the fiber. By modulating the electrical load attached to the LED, the back-emitted power at 450 nm is modulated, which allows sending data from the ASIC to the electro-optical unit. During such a transmission, the laser power has to be held constant in order to avoid interference with the transmitted data. Therefore, the ASIC cannot receive and send data at the same time and thus a time-multiplexed communication protocol was implemented.

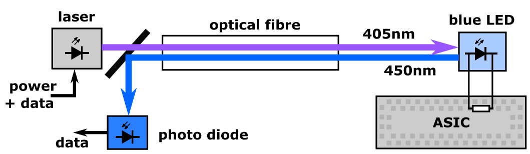

Figure 5: The optical link for power and data transport.

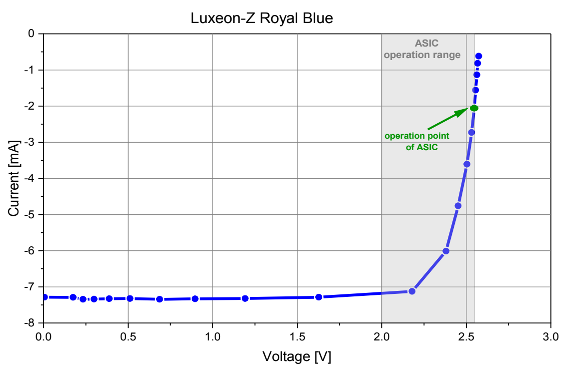

Figure 6: IV-curve of Lumileds Luxeon-Z Royal Blue LED, emitting at 446 nm and excited by 38 mW 405 nm laser light (Sanyo DL-LS5017). Observed power conversion efficiency is 42%. The operation region of the ASIC is between 2.0V and 2.6V.

A. Physics and Photovoltaics

We employ a commercial blue LED (Lumileds Luxeon-Z Royal Blue), acting as (i) photovoltaic cell, converting the optical power from a violet, 405 nm laser diode (Sanyo DL-LS5017) into electrical power, and (ii) for modulating the photon-induced LED electroluminescence by varying the electrical load connected to the LED. The underlying mechanism of photo-induced electroluminescence (PEL) in GaN/GaInN LED devices is well known in the literature [4]. After having been created by light absorption, electron-hole-pairs are either separated and provide a current flow through the load, or relax to the band edges and recombine, thereby emitting light corresponding to the intrinsic band gap of the LED's semiconductor material. At that, the rate of recombination depends on how quickly the charges are separated, i.e., how much current is drawn by the load. This LED proves to be a very efficient means for power delivery and data transmission. Upon excitation of the LuxeonZ LED with 405 nm laser light, optical to electrical power conversion with conversion efficiencies up to 42% has been realized (Figure 6), providing sufficient power to drive an ASIC connected to the LED. Another major advantage of using such a GaN based LED is the relatively large bandgap, providing voltages well above the driving voltage of a silicon-based ASIC.

Data can be sent to the ASIC by modulating the laser current, which in turn modulates the voltage drop across the blue LED. This can be measured by the ASIC and translated into a bit sequence, as long as a sufficiently high averaged optical power is maintained in order to keep the ASIC in a stable operation condition.

Similarly, the back-link from the ASIC to the external unit utilizes a binary modulation scheme, in which "0" is represented by less, and a logical "1" by more back-emitted light, respectively. In Figure 7, the electroluminescence output of the LED at 450 nm is depicted at a constant 405 nm power of 48 mW while modulating the load resistance between 1.88 kΩ and 9.34 kΩ.

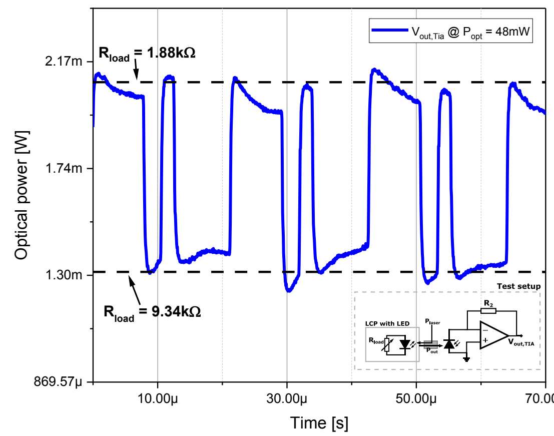

Figure 7: Modulation of the LED electroluminescence by changing the load resistance from 1.88 kΩ to 9.34 kΩ. LED Electroluminescence is measured with a transimpedance amplifier, which is connected to the PIN photodiode of the electro-optical unit.

B. Setup of External Opto-Electrical Interface

The electro-optical unit and its electronics are electrically connected to the optical engine to control the laser diode and readout the photo diode's signals. The components of the optical engine are shown in Figure 8. The collimator lens couples the laser light into the fiber, the dichroic beam splitter separates the 405 and 450 nm beam the and the 450 nm modulated signal is detected with a PIN photo diode.

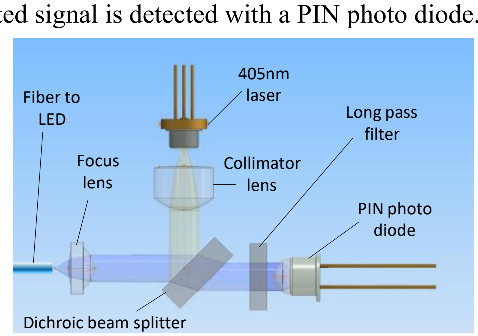

Figure 8: The components of the optical engine.

A dichroic beam splitter is used since it reflects light at a lower wavelength while transmitting light at higher wavelengths. Thus, the light which is sent back from the LED at 450 nm is first collimated by the focus lens and passes through the dichroic beam splitter towards the detector, a PIN

photodiode. The long pass filter in front of the photodiode blocks any short wavelength stray light from the laser.
The coupling efficiency of the laser beam into the fiber is typically between 75% and 90% depending on the fiber type. Figure 9 depicts a photo of the assembled prototype of the optical engine.
The optical engine contains also a mechanical light lock that blocks the laser light when the fiber connector is not fixed in the optical engine housing for eye safety reasons.

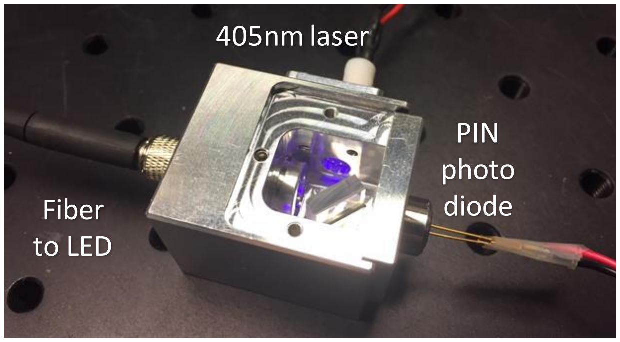

Figure 9: Prototype of the optical engine.

V. EP SIGNAL RECORDING AND COMMUNICATION SCHEME

The ASIC is realized in the 180 nm high-voltage CMOS technology, occupies an area of 4.35 mm x 1.4 mm and a thinned down thickness of 200 µm to fit optimally on top of the catheter LCP. The main functionality of the ASIC contains the following:

- fully-differential amplification and band-pass filtering of 96 analog electrical EP signals,
- digitization of 96 electrical signals,
- power harvesting and voltage regulation using a connected blue LED,
- bidirectional communication via the optical link.

The ASIC contains a power management unit (PMU) and an internal clock generator for autonomous operation. The PMU generates a regulated 1.8 V supply voltage and a power-on-reset circuit to ensure correct startup. Each signal input on the ASIC is connected to one electrode pad of the basket.
A micrograph of the ASIC is presented in Figure 10.

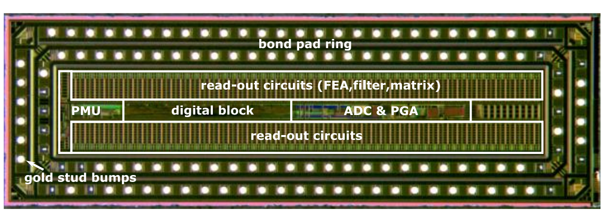

Figure 10: Micrograph of the mixed signal EP ASIC.

A. *Electrical Signal Recording and Data Processing*

A fully differential front-end amplifier stage (FEA) is implemented 97 times on the ASIC in order to amplify and filter EP signals (Figure 11). The reference electrode is freely selectable by choosing one FEA-stage as reference input by closing its switch S_0. The electrode inputs allow the amplification of the EP signal within a range of 600 µVpp to 20 mVpp and to suppress DC offsets (the high pass corner is set to f_{HP}=8 Hz). The FEA amplification can be changed stepwise to 0 dB, 3.5 dB, 7.8 dB and 13.0 dB. Furthermore, each front-end amplifier is followed by a low-pass filter stage with a corner frequency of f_{LP}=120 Hz to improve signal quality and to satisfy with the Nyquist sampling theorem. Each FEA-stage contains buffers with connected switches to build a 97:2 switching matrix. Channels can be sequentially selected at a maximum sampling frequency of 1 kHz per channel. Further signal amplification with up to 40 dB is achieved by a programmable gain amplifier (PGA). The digitization of the signals is performed by a 10-bit SAR-ADC.

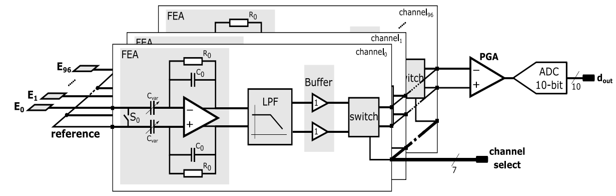

Figure 11: Analog signal chain of the ASIC.

B. *Power and Communication Circuit*

As explained in section IV, the blue LED generates an unstabilized voltage between 2.0 V and 2.5 V, depending on the external laser power. The ASIC itself needs a stabilized voltage of 1.8 V in order guarantee proper operation. Therefore, an on-chip linear voltage regulator (LDO) is implemented using one external connected capacitor C_{ext} to stabilize the internal ASIC voltage (Figure 12). The ASIC is designed to start operating at a minimum supply voltage of 2 V and a current of I_{supply} = 2.1 mA.
Data transmission of the catheter is achieved by changing the resistance on the ASIC that acts as the load to the blue LED. The resistance of the load n_0 can be changed by the internal ASIC logic, depending on the required back-emitted power for transmitting data (Figure 12). The total electrical power consumption is then composed of the constant ASIC power P_{ASIC} and the variable power P_{load}, which combines the power $P_{load,TX}$ for data transmitting and power $P_{load,H}$ in order to give some headroom for a stable catheter operation. Thus, the minimum required power is

$$P_{min,catheter} = P_{ASIC} + P_{load,TX} + P_{load,H}. \quad (1)$$

Configuration data are sent to the catheter by modulating the laser power between different power levels. The resistor network n_1 is used to measure the voltage drop at the blue LED and capture the modulated signal. The TX/RX stage shown in Fig. 12 ensures proper operation of the bidirectional communication link.

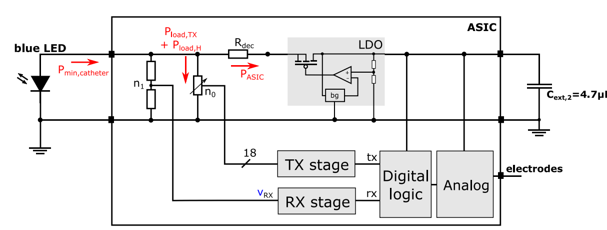

Figure 12: Communication and power circuit of the ASIC.

VI. TESTING OF ELECTRICAL READOUT PERFORMANCE

The electrical signal amplification of the ASIC's readout circuit was measured with an input signal of 7.07 mVrms and a frequency of 80 Hz, which is applied to channel 9. The processed analog signal is measured via an analog test pin (Figure 13). The calculated input referred noise is 69.4 µV in a frequency range between 1 Hz and 120 Hz.

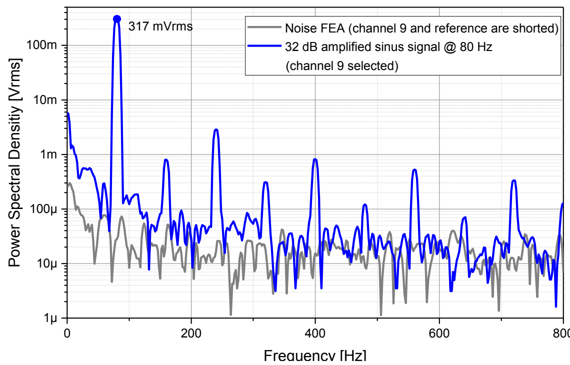

Figure 13: Measured noise and signal amplification of the ASIC's readout circuit.

Next, a human heart ECG signal with a maximum amplitude of 10 mVpp is applied to show the functionality of the complete signal chain, which proofs the function of the signal amplification, filtering, sampling and digitization (Figure 14).

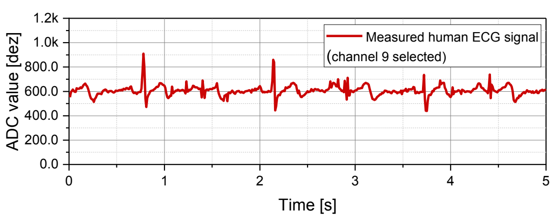

Figure 14: Measurement of a human ECG signal, which is applied to electrode 9 of the ASIC.

VII. TESTING OF OPTICAL PERFORMANCE

The optical test aims to verify proper start-up behavior of the ASIC as well as functionality of the optical communication link. The implemented optical link does not allow receiving and transmitting data at the same time. Therefore, a time-multiplexed communication protocol is used to avoid communication errors. The sequence consists of eight data identifier packets, which are sent by the ASIC after successful power-up. In between these data packets, the user can send data via power modulation. If no changes of the settings are requested, sampled data of all channels are automatically sent in the order from channel 0 to channel 95.

(Figure 15: laser power is provided (top figure); with sufficient laser light, the ASIC turns on and generates a correct supply voltage (middle figure); identifier code and data, which verifies the optical link from ASIC to outside (bottom figure)).

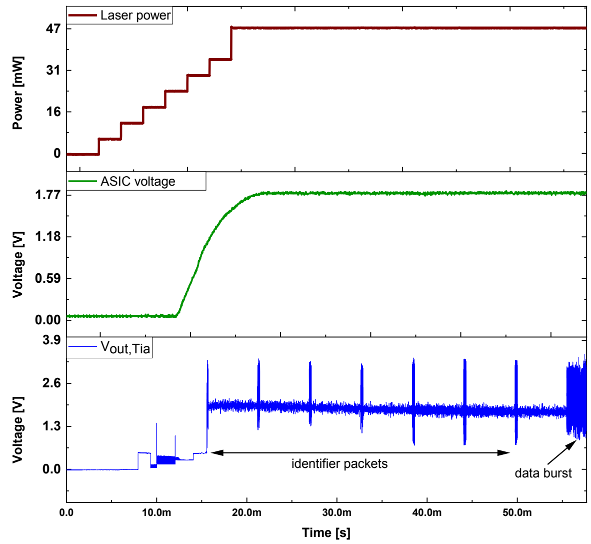

Figure 15: Start-up sequence of the catheter.

VIII. CONCLUSION

We present the first 96-channel EP prototype catheter with optical link in order to measure efficiently electrophysiology signals of the human atrium to treat atrial fibrillation. Signals are captured at the tip of the catheter with the help of an integrated mixed-signals ASIC. The optical link is used to transfer bidirectionally data and to deliver power to the catheter. Further investigations will cover the integration of only non-magnetic materials and thus allowing the catheter to work in an MRI- instead of CT-environment.

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