Body Fluid Transfer

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According to the World Health Organization, lymphedema affects over 250 million people worldwide. Despite this fact, the research evaluating the lymphatic system and the effectiveness of treatment has been scarce. The unfortunate result is that far too many patients are left undiagnosed and untreated and therefore have pain and suffer unnecessarily. The symptoms of lymphedema can be managed, however, with manual or mechanical lymphatic drainage. Lymphatica, a Swiss start-up, is developping the first implantable device for body fluid transfer based on a peristaltic pump magnetically coupled with a wearable controller device developed by CSEM.

CSEM developed the external devices of the Lympho Pilot in compliance with the Medical Device Regulation (MDR217/745) and according its ISO13485-certified quality system. Since the Implantable Peristaltic Pump is a Medical Device class III, the Wearable Controller Device, which influences the behavior of the Implantable Peristaltic Pump, has the same class. A Docking Station, classified as an accessory medical device class I, completes the system.

The main challenges to cope with are: (i) the magnetic coupling requirements in terms of alignment; (ii) the torque transmission; (iii) the attraction / repulsion force between the magnet in the Implantable Peristaltic Pump; the magnet in the Wearable Controller Device; (iv) the autonomy of the Wearable Controller Device versus size and weight; (v) the detection of the rotation of the rotor of the Implantable Peristaltic Pump (occlusion detection) and; (vi) the relative position of the two magnets allowing an easy placement by the patient.

Although the efficiency of the peristaltic pump is lower than 1%, the operating point of the actuator driving the magnet of the Wearable Controller Device has a direct impact on the efficiency of the overall system and therefore on the power consumption. Based on an off-the-shelf DC micromotor, the kinematic chain has to be optimized based on: (i) the medical requirements of the daily volume of fluid to be transferred, which is dependent on patient and therapy; (ii) the user requirements related to the autonomy, which must be 16 hours in the worst use case and; (iii) the technological requirements enforcing a torque of 5 mN on the rotor of the pump.

The torque to be provided to the Implantable Peristaltic Pump is modulated by the irregular friction of the rollers on the tube. This variation creates a phase shift between the two magnetic axes and then creates a modulation of the attraction / repulsion force. This dependency must be reduced as much as possible to ensure the comfort of the patient and to mitigate the risk of a potential irritation of the tissues.

The exploded view of the actuator presented in Figure 1 highlights the full kinematic chain embedded in the Wearable Controller Device. All the parts must be non-magnetic.

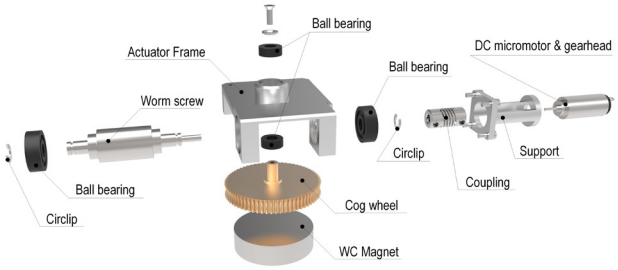

Figure 1: Magnet actuator driving of the Wearable Controller Device.

The actuator acoustic noise is one of the main constraints. Although the Wearable Controller Device is compliant with the noise requirements, after testing, one of the main source of noise resulted to be the planetary gear placed on the DC micromotor shaft. This issue has been overcome by the replacement of the aluminum coupling with a plastic tube damping the mechanical vibrations. The final design of the Wearable Controller Device is detailed in Figure 2. The battery (660 mAh) is compliant with the safety requirements for portable sealed secondary lithium cells. By design, the device cannot be used during the battery recharge, avoiding this way the risks of electrical shock for the patient.

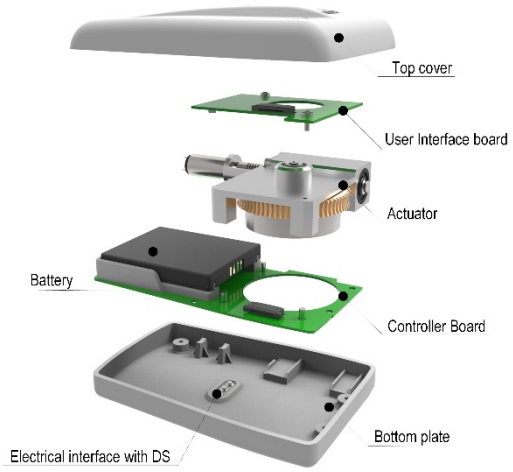

Figure 2: Exploded view of the Wearable Controller Device.

Each patient has two Wearable Controller Devices to ensure pump operation for 24/7. The Docking Station and an AC/DC Adapter compliant with the user safety and electromagnetic compatibility complete the system. Figure 3 shows the external parts of the LymphoPilot ready for clinical investigation.

Figure 3: Device developed by CSEM.

The main improvement for the final product will be the suppression of the planetary gear and the modification of the actuator with the aim of keeping the same efficiency (autonomy) with a drastic reduction of noise (objective −6 dB).

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