

## **Informed Consent to Participate in an Observational Study**

**Study title:** BI-SENSES: Validation of nasal versus frontal placement of the SedLine® sensor through processed electroencephalography in adult patients undergoing general anesthesia. A Prospective cohort study

**Sponsor:** Masimo Corporation

**Primary Investigator:** Dr. Boris Tufegdzcic

**Consent Version:** 1.0 **Consent Date:** 15.03.2019.

**Study Coordinator:** Dr. Boris Tufegdzcic

After hours phone contact: Dr. Boris Tufegdzcic +971-52-247-0672

You are being invited to participate in a research study. The aim of the study is to understand whether the alternative position of the sensors for assessing the depth of anesthesia during surgery can be used as a safe alternative. The purpose of this document is to provide a written summary of the discussion and exchange of research information you had with the research team. It is also for use as a reference during the study.

### **Please note:**

- **You are being asked to participate in a research study**
- **Ask as many questions as needed so you can make an informed decision**
- **Carefully consider the risks, benefits, and alternatives of the study**
- **Your decision to participate is completely voluntary and will have no effect on the quality of your medical care if you choose not to participate. You can also withdraw from the study at any time**

## **1. INFORMATION ON THE RESEARCH**

### **Why is the observational study being done?**

Assessment of the depth of anesthesia is part of the standard monitoring in our institute. It provides us several essential data that are in the patient's interest: preventing the presence of consciousness during surgery, adequate use of medication during surgery, and predictable waking of the patient after intervention.

With this study, we want to understand whether an alternative sensor application is possible when a standard position is not acceptable.

### **Why are you being asked to participate in this study?**

You are an adult older than 18 years of age and are scheduled to have a surgery.

### **What is involved if you decide to take part in this observational study?**

On the day of surgery, 5 minutes before administering you the general anesthesia, both sensors will be set to their intended positions. A standard sensor will be at the forehead and an alternative sensor will be over the nasal bridge. Both sensors will be removed after removal of the breathing tube.

The study does not have any impact on your safety, as the placement of the sensor is a painless and safe procedure that is standard in everyday anesthetic work.

You will not need any additional visits to the hospital.

The studies described are for research purposes only. It is not the purpose of these studies to look for or provide you with any medical information or diagnoses relating to your present condition or any other disease or illness. Therefore, you will not receive results from these research studies.

## **2. ALTERNATIVES**

### **What are the alternatives to participation in the observational study?**

If you choose not to participate in the trial, you will continue to receive standard care and it will not affect your treatment otherwise.

### **3. RISKS**

#### **What are the risks of participating in the observational study?**

This study does not present greater than minimal risk for patient.

### **4. BENEFITS**

#### **What are possible benefits of participating in the research?**

We believe that the knowledge to be gained will benefit future patients in terms of correct position of the sensors for assessing the depth of anesthesia during neurosurgical procedures when the standard position is not possible.

### **5. COSTS**

#### **Are there any costs to you if you participate in this study?**

The research study services are being done only because you are participating in this research study and **will be paid for by Cleveland Clinic Abu Dhabi** and will not be billed to you or your health insurance plan.

### **6. COMPENSATION**

#### **Are there any payments to you if you participate in this study?**

There is no payment for the participation in the research.

### **7. RESEARCH RELATED INJURY**

#### **What will happen if you are injured as a result of taking part in the research?**

There is minimal risk of injury in regards to this study.

### **8. PRIVACY AND CONFIDENTIALITY**

#### **What will happen to your information that is collected for this research?**

Cleveland Clinic Abu Dhabi has rules and procedures to protect information about you.

The research team working on the study will collect information about you. This includes your health information, data collected for this research study and personal identifying information including your name, address, date of birth and other identifying information.

We will make sure the personal information in your medical record is kept private in secured files.

Information shared with our outside research center will be de-identified of all personal information. If this study is published, no personal information will be used.

## 9. CONFLICT OF INTEREST

### Do the researchers or institution have any conflicts of interest relating to this study?

No one of the Investigators conducting this study serve as paid speakers, consultants to advisory committee members for the company that is paying for this research or a company that makes products used in this study. These financial interests are within permissible limits established by the Cleveland Clinic Conflict of Interest Policy.

## 10. QUESTIONS

### Who do you call if you have any questions or problems?

- You may contact Boris Tufegdzcic mob: +971-52-2470672
- IRB Contact Information: 02 501 9000 ext. 48432

## 11. VOLUNTARY PARTICIPATION

### What are your rights as a research participant?

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Withdrawing from the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to withdraw from the study you should discuss with your study doctor your decision to ensure a safe withdrawal.

## 12. SIGNATURES

*I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form does not waive any of my legal rights. I understand that a copy of this consent will be provided to me. By signing below, I agree to take part in this observational study.*

\_\_\_\_\_  
Printed name of Participant

\_\_\_\_\_  
Participant Signature

\_\_\_/\_\_\_/\_\_\_  
Date

### Statement of Person Conducting Informed Consent Discussion

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

\_\_\_\_\_  
Printed name of person obtaining consent

\_\_\_\_\_  
Signature of person obtaining consent

\_\_\_/\_\_\_/\_\_\_  
Date