

1) Background:

Micro-current biofeedback (MB) devices are non-invasive medical devices used by physicians, therapists and chiropractors to manage acute, postoperative and chronic pain. It simulates the body's own bioelectric system, promotes natural healing and relieves various symptoms of pain. The technology relies on generating micro-current output directed directly to specific types of nerve endings, which can be formulated to treat pain and medical conditions neurotransmitters.

2) Description:

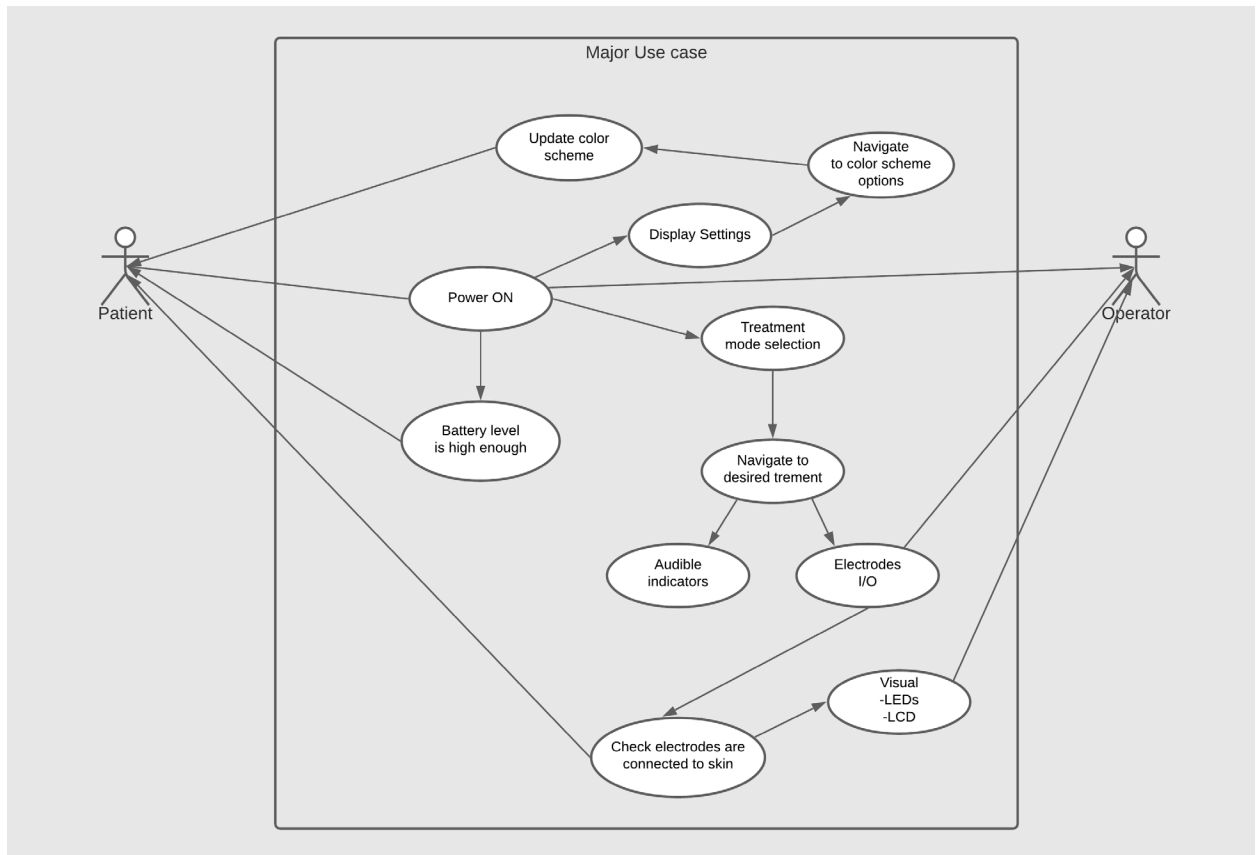
The device has following components:

1. Microprocessor: Modulates electrical signals through electrodes directly exposed to the skin to communicate with the peripheral nervous system to achieve the purpose of therapeutic intervention.
2. Power level Selection (up/down): increase and decrease frequency.
3. Visual Indicator (display): LCD or LED screen displays the user graphic interface and displays instructions.
4. Audible indicator (speaker): Announce a specific beep as a notification device.
5. Treatment mode (selection switch): Pre-defined program, including micro-current frequency and specific time settings. Each procedure is carried out for a specific medical condition.
6. Indicators: display informational indicators such as error and success codes.
7. Electrodes: These contain the output circuit that sends out modulated micro-current pulses through the patient's skin, Pulse generator and Detector/receiver for detecting nerve endings conducted to the patient's skin.
8. USB interface: Connect external electrodes for treatment that cannot be completed by internal electrodes.

3) Use cases:

Basic Use Case(UC-1):

Use Case Diagram:



Use Case -1(UC-1):

Actors: Patient and Operator.

Pre-condition: Device must be on, and electrodes are connected to patient's skin properly.

Description:

1. The Operator can control the power of the device by switching it on and off.
2. The Operator proceeds by selecting the treatment mode suitable for patient and time duration is settled by keeping the consent of the patient.
3. The electrodes will detect the patient's nerve as the device is placed over patient's body. The device then continues treatment reaching optimum electrical characteristics.
4. Audible indicators are used to hear or demonstrate the detected tissues, these are the physical buttons up/down on the device.

Alternatives:

- In the case of the battery level running low or for any type malfunction, the device must be changed or replaced.

Post condition:

The patient's diagnosis has been completed successfully.

Use Case Diagram:

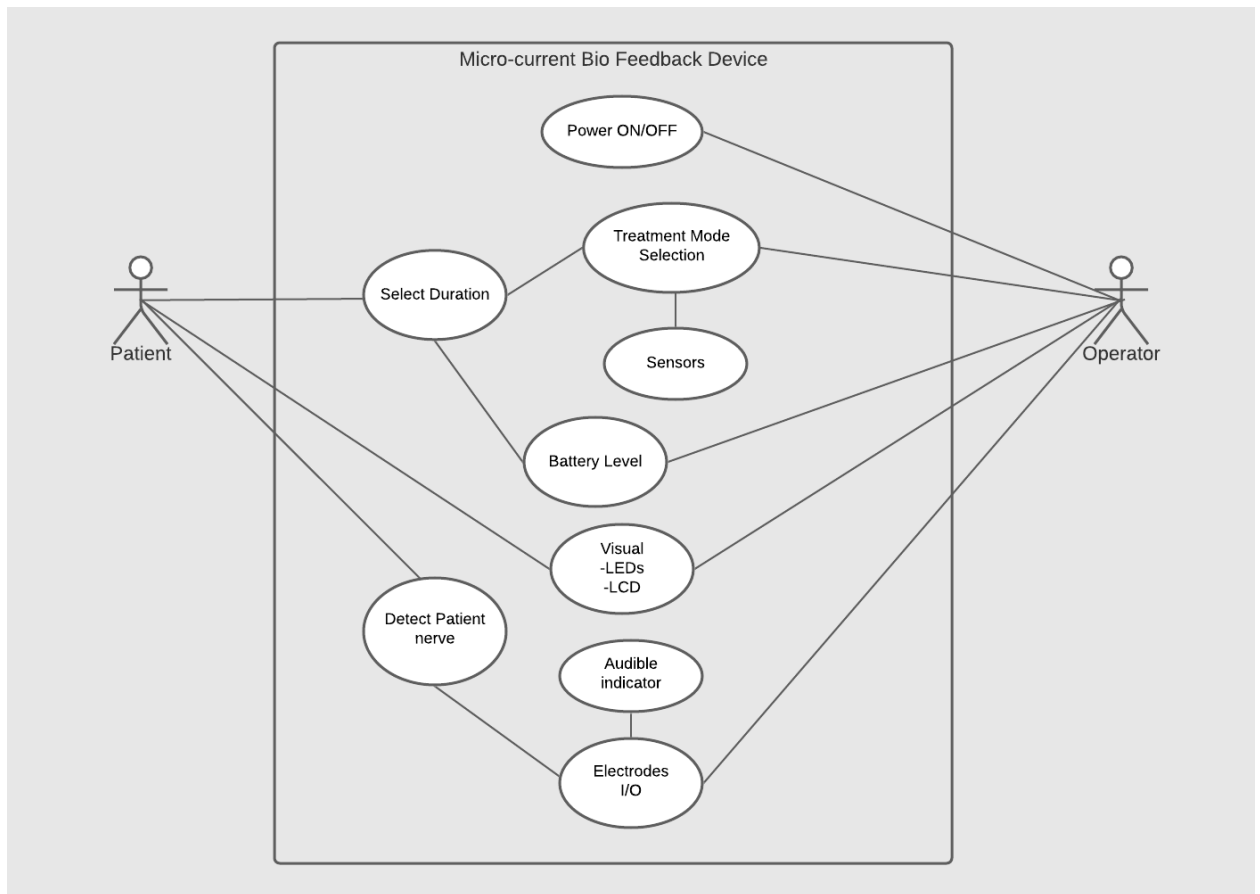


Figure 1: UC1 Micro-current Bio Feedback Device:

Use Case -2(UC-2):

Actors: Patient

Pre-conditions: The device must be powered on.

Description:

1. Power on the device.
2. Navigate through menu on display by buttons and select the desired treatment mode.
3. Electrodes are to be checked if they are connected properly to skin.
4. Increase volume to hear beep as electrodes detect tissues.
5. Plug in USB of main screen into USB interface.

Post condition: The desired treatment mode is selected.

Use Case Diagram:

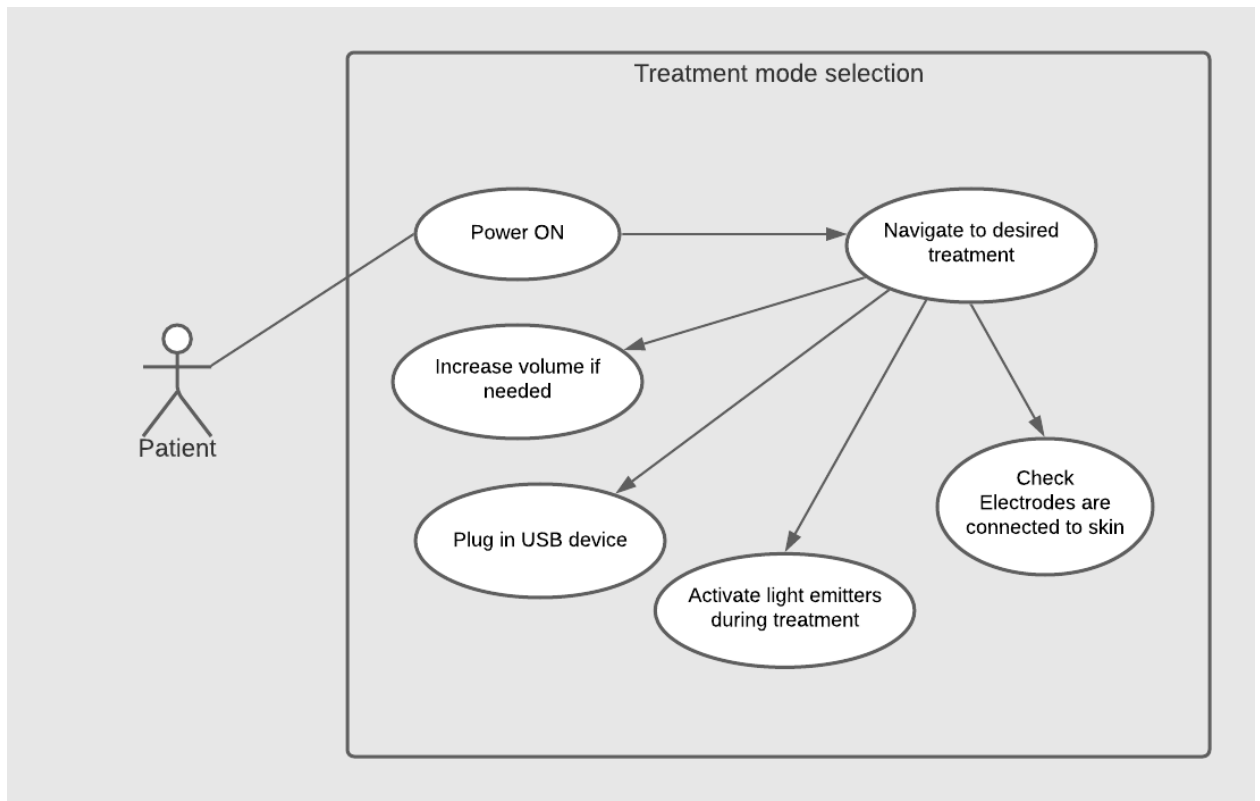


Figure 2: UC2 Treatment mode selection:

Use Case -3(UC-3):

Actors: The Operator.

Pre-conditions: The main screen should be available and working via USB.

Description:

1. Power on the device.
2. Check the battery level is high enough.
3. Check and set the USB interface with main screen using USB cable.

Alternatives:

- Check the main screen have USB facility and working properly or change it.

Post-conditions:

The USB interface is working properly and shows visual output on the main screen.

Use Case Diagram:

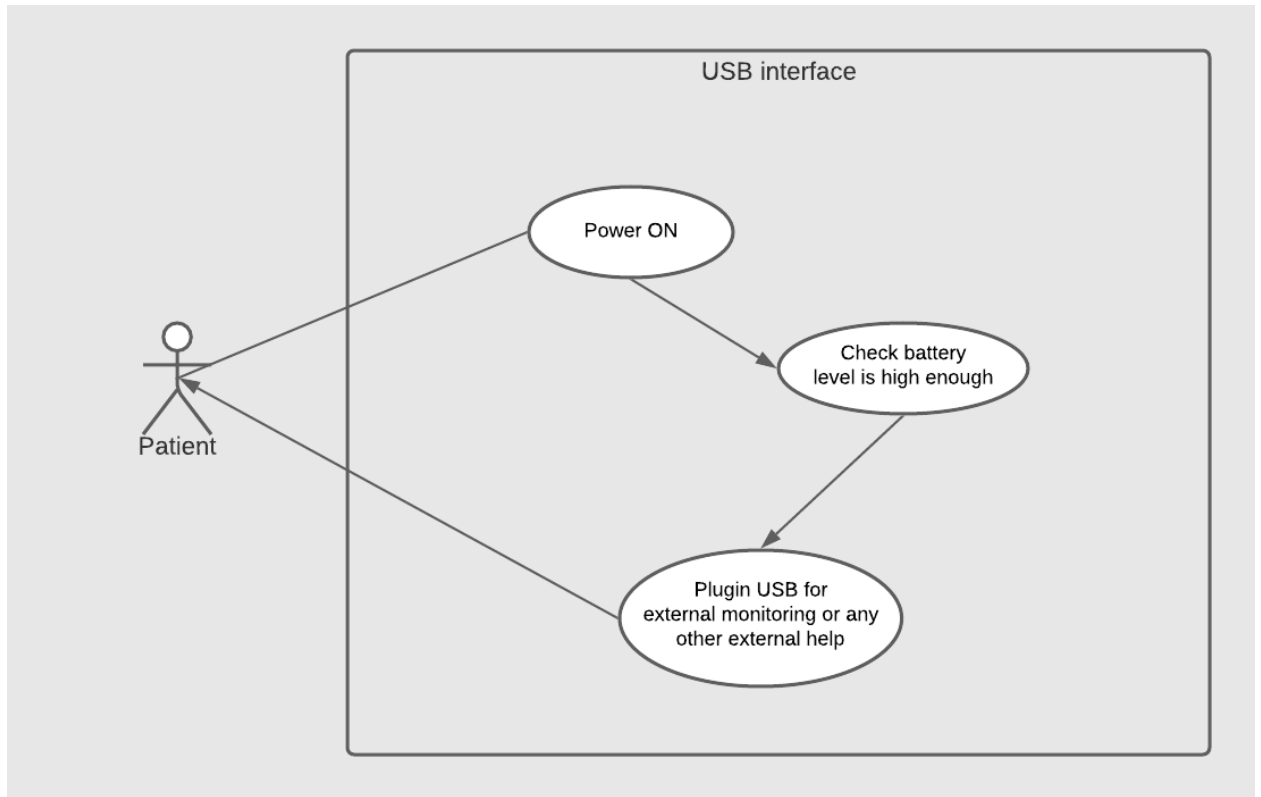


Figure 3: UC3 USB interface:

Use Case -4(UC-4):

Actors:

Patient.

Pre-conditions:

Patient should know how to navigate through display change settings.

Description:

- a) If patient feels the display color scheme isn't visually appealing, he/she can change the display by:
- b) Navigate to the Settings menu using the traversal buttons.
- c) Once in the settings traverse to the color selection.
- d) Change the color scheme accordingly based on the available colors for the device.

Post-condition: The display changes to the desired display settings as it is set by the patient.

Use Case Diagram:

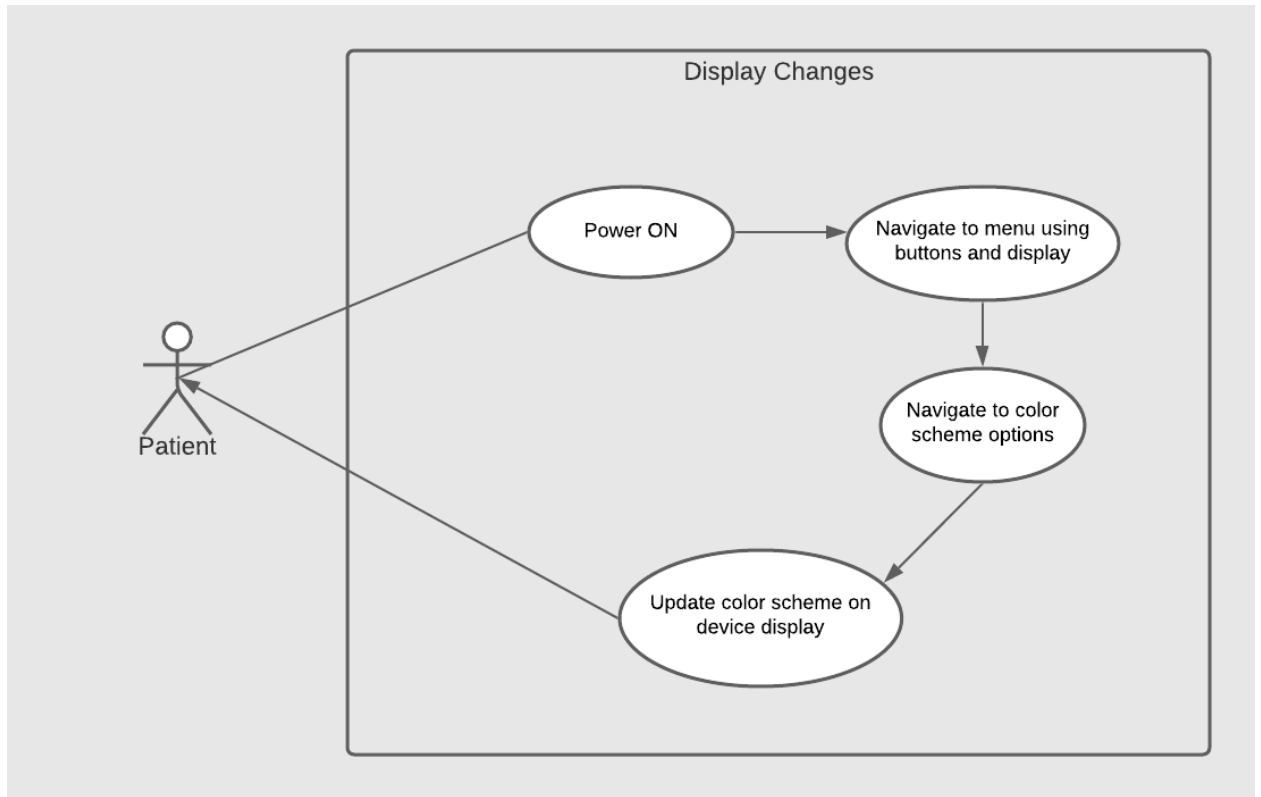


Figure 4: UC4 Display changes:

Use Case -5(UC-5):

Actors: The operator

Pre-conditions: Electrodes should be properly connected to patient's skin

Description:

- a) Detect the patient's nerve; The electrodes of the device have three states, which change according to the signals received from its detector/receiver.
- b) Unorganized state: the detector is in idle mode, in this mode, the signal voltage is 204 volts.
- c) First contact state: The detector immediately detects when the electrode is first placed on the 114-volt reactive tissue signal.
- d) Treatment status: The device will continue treatment until it reaches the optimal electrical frequency set on the selected treatment program or manually adjusted by the operator.

Alternatives:

- Check whether electrodes need to be replaced, or properly attached.

Post-conditions:

Device beeps, which signals that electrodes are properly connected and working as desired.

Use Case Diagram:

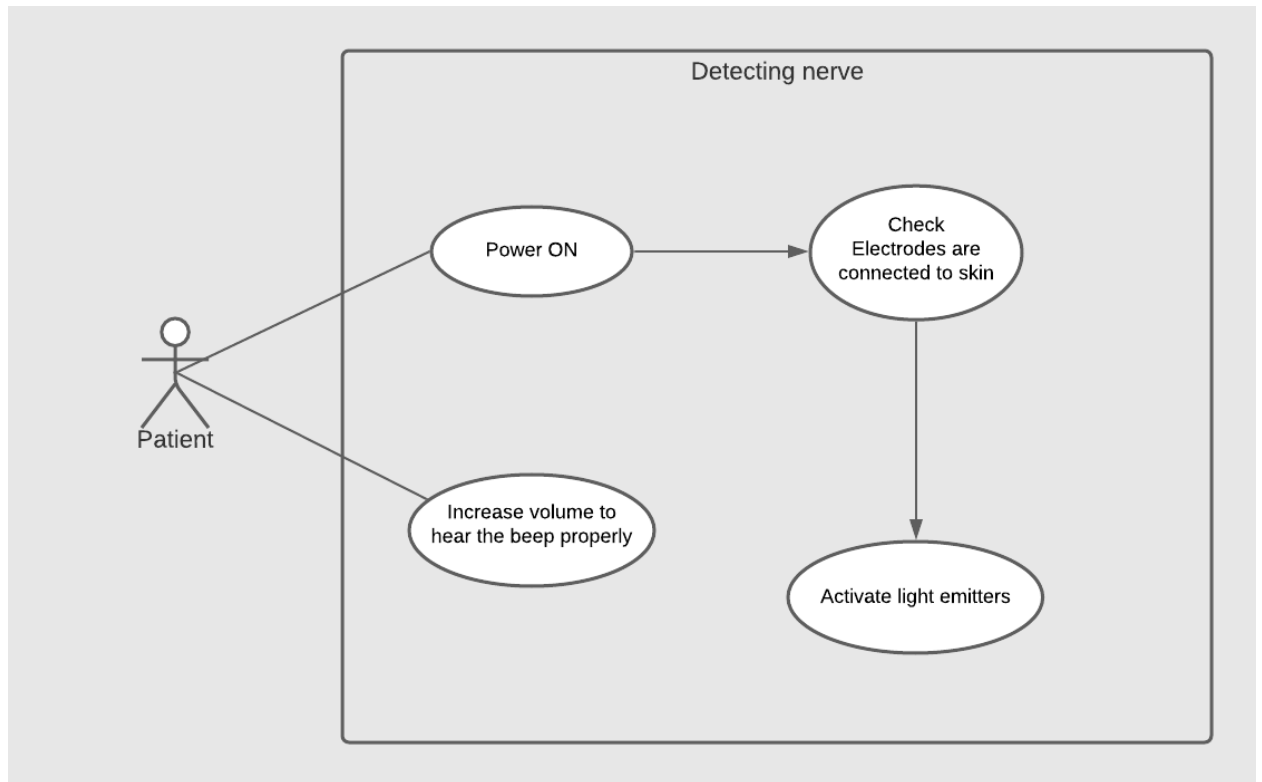


Figure 5: UC5 Detecting nerve