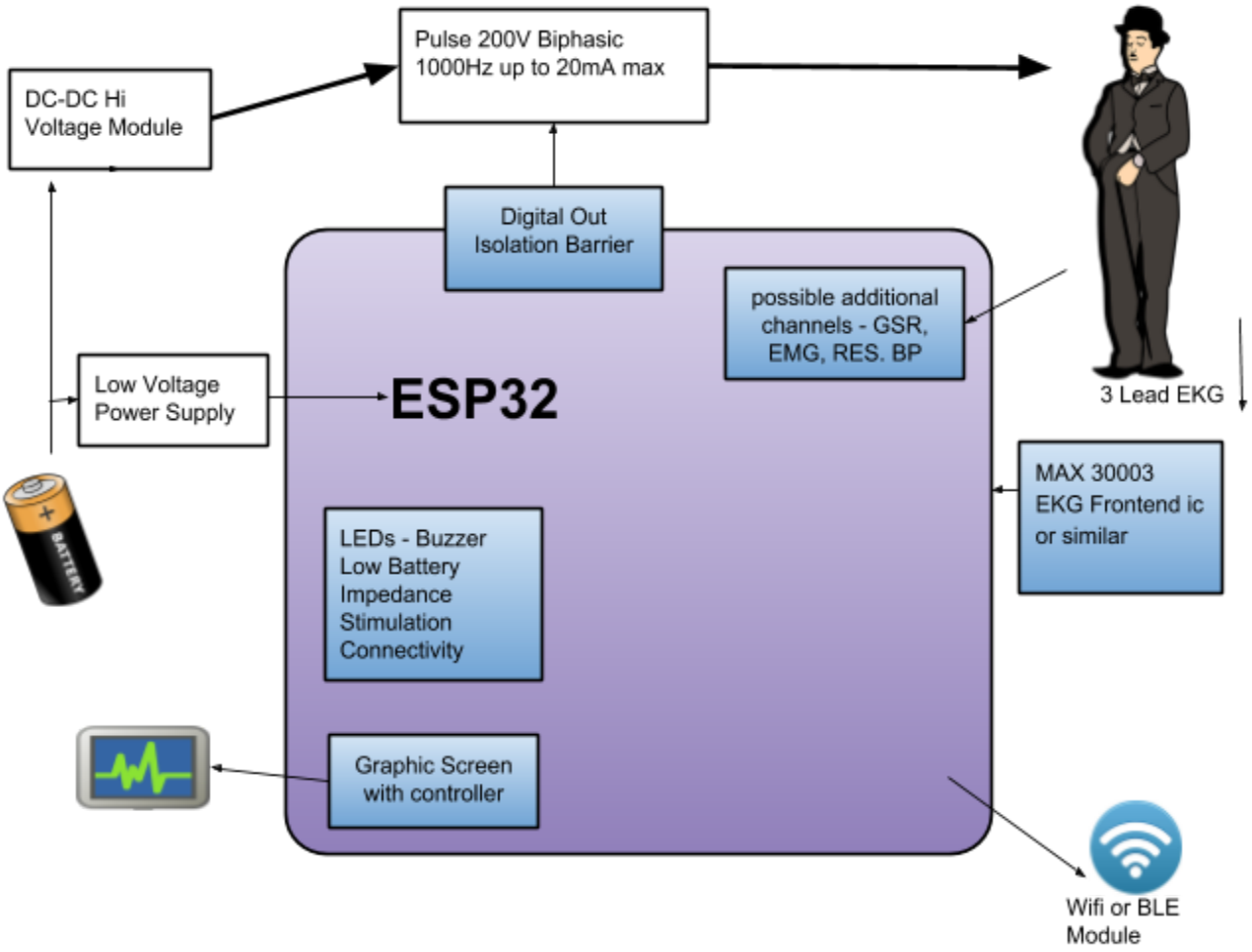
Block Diagram



DEVICE DETAIL

A battery operated EMG/ECG triggered standalone electrical stimulator capable of sending bursts (trains) of constant current (bipolar symmetrical rectangular waveform) pulses up to 20 mA, at 10kOhm impedance, at frequencies variable from 100 to 2,000 Hz.

General

1. Stimulation is to the ring finger and thumb – 2 electrodes.
2. Standard fail-safes and medical isolation. As a safety precaution, hardware high current detection circuit to shut down the high voltage supply and halt the treatment in progress should an unexpected high current occurs.
3. An isolation amplifier to read actual current delivered and flags if the electrode Impedance increases so the system cannot meet the power requirements.
4. Capture and save the ECG signal, the stimulation parameters, and mark the stimulation point and amplitude.
5. Add other input channels that can be captured in real time and synced such as blood pressure, skin conductance, respiration …
6. Display – ECG, Event, TT, DT, HTT, frequency, heart rate, IBI, TimeOn, TimeOff, repeat #, stim light, Impedance, trigger light, high current light.
7. Web server interface to capture and display EMG and Stimulus data, initiate sessions, set variables and parameters, and save patient and session information.

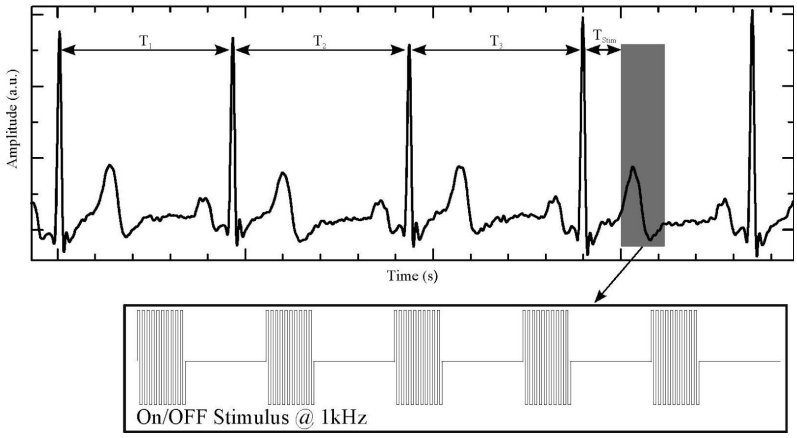
Pulse trigger

1. Put the ECG electrodes on the body so as to capture the heart muscle contractions (ECG signal) - finger and thumb for the right medial nerve..
2. Average of the last four RR intervals (IBI - interbeat interval), and predict the next peak, assuming a constant heart rate call this Tpeak. Tpeak is used to define the stimulation point after the EKG peak.
4. Two potential stimulation time points:
   a. Systolic - TPeak + 0.2 · IBI, or
   b. Diastolic - TPeak + 0.8 · IBI - .2 and .8 are 2 variable settings (0-1)
5. Intrinsic delays from hardware and software should be subtracted.
6. Time periods of less than 200 mSec should be ignored (equivalent to 300 BPM), to eliminate annoying double R-wave signals.

Rating - Done twice and averaged before each stimulation session

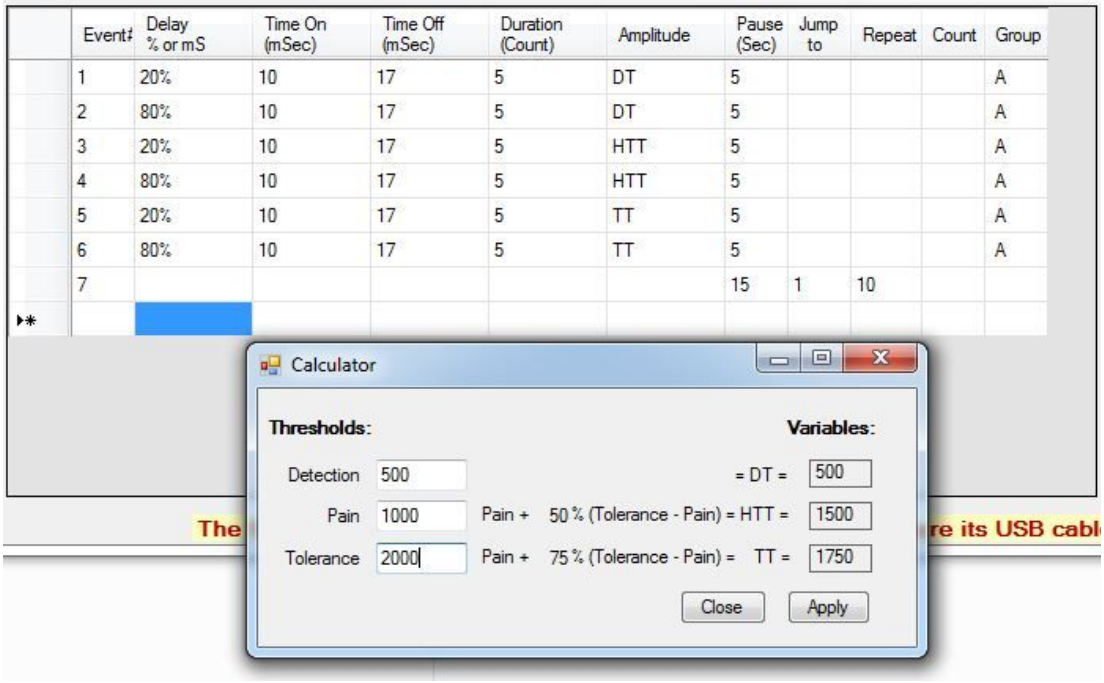
Therapist stimulates with the device - start at a 200μA pulse train and increase in 200μA increments to set the DT, Pain, and Tolerance values, which then get used for the treatment.

Stimulation Table



Single pulse train

	Event#	Delay % or mS	Time On (mSec)	Time Off (mSec)	Duration (Count)	Amplitude	Pause (Sec)	Jump to	Repeat	Count	Group
	1	20%	10	17	5	DT	5				A
	2	80%	10	17	5	DT	5				A
	3	20%	10	17	5	HTT	5				A
	4	80%	10	17	5	HTT	5				A
	5	20%	10	17	5	TT	5				A
	6	80%	10	17	5	TT	5				A
	7						15	1	10		



Pulse trains

1. An event is one line of the table.
2. Delay (After the pulse trigger) variable 0-100% of Tpeak.
3. Event pulse train length (TimeOn) variable 5-100 mSec, no stimulus time (TimeOff) variable 0-1000 mSec.
4. Amplitude variable - 3 levels - DT (detection threshold), HTT (Pain + 50% * (Tolerance – Pain)), TT (Pain + 75% * (Tolerance – Pain)) 0-100% each.
5. Number of passes of each event (Count) 0 variable -100.
6. Time break after each Event (Line in table) (Pause) variable 0-100 Sec.

7. Longer break after each Table completes (TableRepeatPause – i.e. Event 7) variable 0-500 Sec.
8. Number of table repeats (TableRepeat) variable 0-100.
9. Randomize which of the Events (Lines in the table)(i.e. 1-6) occurs first, randomize which of the remaining 5 that occur, … , until all of the events have occurred.
10. Frequency variable 100 to 2,000Hz – positive pulse width 50-500µSec
11. Table may have up to 20 events (rows)

Validation Fields/Initial parameters

Patient Data

TT - generally 600 - 20,000 µA tolerance threshold
Pain - generally 400 - 8,000 µA pain threshold
DT - generally 200 - 2,000 µA sensitivity (detection) threshold
Token - Alphanumeric - 32 place
Ratings PreA, PreB, Post 0-10 - Integers in microAmps

Last Session Data

Last SBP - 80 - 300 mmHg
Last DBP - 40 - 200 mmHg
Last BRS - 0 - 80 mmHg
Last DT, Pain, TT - microAmps

Additional Channels

Blood Pressure - Analog or Digital signal
GSR - 2 lead analog - 2 electrodes
EMG - 2 lead analog - 2 electrodes
fNIR - 4 channel 2 oprodes

Stimulation Data

StimFreq - 1000 (Device frequency at 27 mSec = 37)
Sensory - 0 - DT - sensory threshold
ToleranceHTT - 75% - times (TT - Pain) + Pain - calculated
PainHT - 50% - times (TT - Pain) + Pain - calculated
PulseStart (Delay) - .2 or .8 20%/80% of IBI after EKG peak - train start point -
PulseTimeOn - 10 Amount of time in mSec that is stimulated
PulseTimeOff - 17 Amount of time in mSec that is off
PulseCount - 5 Number of pulses in a pulse train
PulseAmplitude - 0, PercentHTT, PercentHT
PulsePause - 5 Time in seconds before next row (pulse train) in the table
TableRepeatPause - 15 Seconds pause before the table (6 rows) repeat
TableRepeat - 10 Number of times the table (6 rows) repeats
MoodleConfirm - Therapist, Patient, SAC, plus Flag - 0,1,2 0 is default, 1 means simulation, 2 means diagnosis only - no stimulation

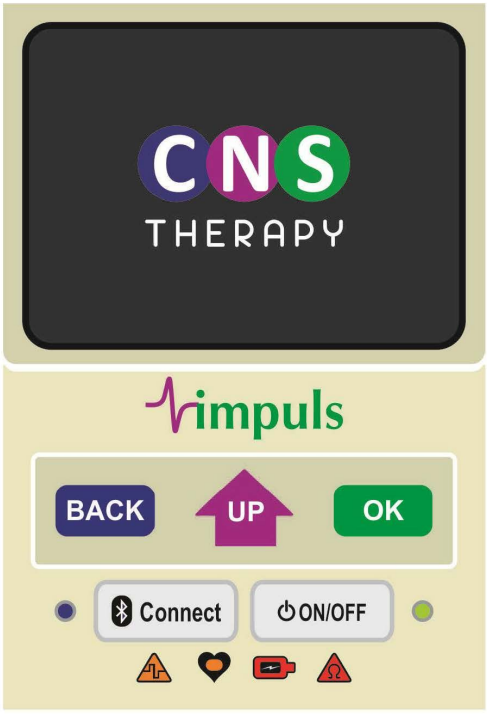
Device should also have an on/off/emergency off switch and power light. Low battery, impedance too high, cable unplugged would flash on the screen, self-test circuit. The EKG/ECG, Stimulation Cable, and other channels shall have different plugs, so that they cannot be inserted into the wrong place.

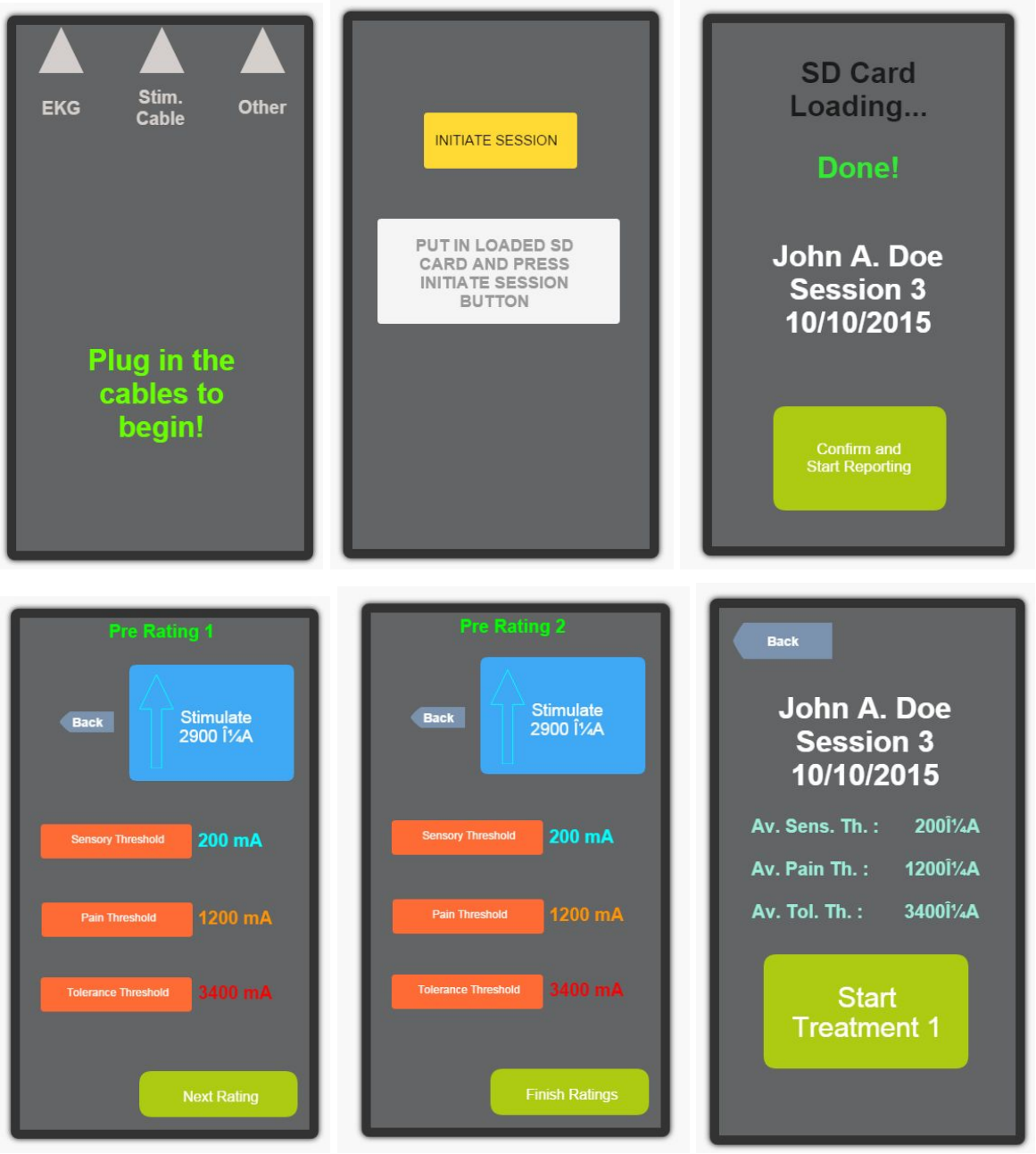
1. Screen 2 should first show some form of “connecting” (perhaps with a loading circle) which is then replaced with a completion message (for example “Done!”) on successful Connect (if the Connection is not available or of the device has no setup therapist/patient stimulation sessions, the message should be help, “please check - no stimulation sessions have been initiated, and try again.”). After showing the completion message, the screen should then show 1) Name of Patient, 3) Name of therapist, 4) Session number and 5) Date/time.
2. In relation to screens 4, 5, 8, 9, 12 and 13, upon a push of the UP button, the device should increase the amount of stimulation amperage by 200μA (per push) and then deliver the new stimulation value. The button should show the NEXT stimulation value (what it will increase to)[1]. The “Sensory Threshold”, “Pain Threshold” and “Pain Tolerance” buttons, upon pushing the OK button, should record the CURRENT amperage and display it out next to the button and change color. Upon pushing the “Tolerance Threshold” OK button, the device should immediately lock both the increase of electricity and the administration of electricity by the device (further pushing the UP button has no effect). The “Back” button should go back one step.
3. In relation to screens 6 and 10, the back button restarts the ‘report cycle’ (goes back to screen 4 and 8 respectively). The average “Sensory Threshold”, “Pain Threshold” and “Pain Tolerance” values should be calculated using the numbers gained in the previous ‘report cycle’ – 4 and 5, 8 and 9, 12 and 13. The 4-5 averages are used as parameters for the first treatment session and the 8-9 values are used for the 2nd treatment session.
4. After the ratings, the OK button starts the ~8 min treatment cycle.
5. Device sends EKG and other data to a cloud DB and receives session authorization.
6. Medical look to packaging.
7. Buttons should have a positive feel to them and have to be pushed with some force - not just touched or touch screen
8. Continuous BP digital-in and other channels optional input.

[1] Note that the rating stimulation protocol is just the first line (Event 1) of the table at the given amplitude.

DEVICE UI

One suggestion only:




EKG
Stim. Cable
Other
Plug in the cables to begin!
INITIATE SESSION
PUT IN LOADED SD CARD AND PRESS INITIATE SESSION BUTTON
SD Card Loading...
Done!
John A. Doe
Session 3
10/10/2015
Confirm and Start Reporting
Pre Rating 1
Back
Stimulate 2900 Î¼A
Sensory Threshold
200 mA
Pain Threshold
1200 mA
Tolerance Threshold
3400 mA
Next Rating
Pre Rating 2
Back
Stimulate 2900 Î¼A
Sensory Threshold
200 mA
Pain Threshold
1200 mA
Tolerance Threshold
3400 mA
Finish Ratings
Back
John A. Doe
Session 3
10/10/2015
Av. Sens. Th. : 200Î¼A
Av. Pain Th. : 1200Î¼A
Av. Tol. Th. : 3400Î¼A
Start Treatment 1


John A. Doe
Session 3
10/10/2015
Treatment In Progress
Emergency Abort
Done!
Treatment 1
John A. Doe
Session 3
10/10/2015
Go to 2nd Rating
Rating 1
Back
Stimulate 2900 µA
Sensory Threshold
200 mA
Pain Threshold
1200 mA
Tolerance Threshold
3400 mA
Next Rating
Rating 2
Back
Stimulate 2900 µA
Sensory Threshold
200 mA
Pain Threshold
1200 mA
Tolerance Threshold
3400 mA
Finish Ratings
Back
John A. Doe
Session 3
10/10/2015
Av. Sens. Th. : 200Î¼A
Av. Pain Th. : 1200Î¼A
Av. Tol. Th. : 3400Î¼A
Start Treatment 2
John A. Doe
Session 3
10/10/2015
Treatment In Progress
Emergency Abort

PROCESSES

Proposed Device Processes:

- Device ON button is pushed
- Device sends url query to Impulse DB to find Therapist, Patient and SAC.
    - http://elearning.wikiangels.com/login/token.pHp?username=********&password=********&service=localservice
    - Token is received - no token and the user is not authorized
    - Device reads stimulation parameters and writes any blog (bio-physical) data in memory from and to Impulse DB (through the Dreamfactory API)
- Connect light goes from blinking to green
- Therapist Starts Rating (Pre1) - patient ratings (pre1, pre2, and post), DT, Pain and TT are determined twice and averaged.
    - For each session (and patient) the amplitude (μA) detection/sensitivity (DT), pain onset (Pain), and tolerance threshold (Tolerance-TT) is captured in Rating procedure.
    - Therapist pushes the UP button and gives a stimulus - which starts at 200μA and increases in 200μA increments and captures (pushes OK) the DT, Pain, and Tolerance values, which then get used for the treatment.
    - Rating pulse train is the same as for the Stimulation
- Therapist start 1st stimulation
- Therapist 2nd Rating (Pre2)
- Therapist starts 2nd stimulation
- Therapist 3rd Rating (Post)
- Collects biometric data and sends it to Cloud DB in blog files