PROJECT: SEAM10		NUMBER: TN – S04 – 0001
DATE (YY/MM/DD): 13/01/25	AUTHOR NAME: Lowell Misener	

1. PURPOSE

Transcutaneous Electrical Nerve Stimulators (TENS) and surface skin electrodes are used as a combined device to provide pain relief. The AAMI has created a standard (AAMI NS4:1986/(R)2009) that establishes the safety and performance requirements for the Stimulator device. The standard clearly indicates that these guidelines exclude the leads/electrodes and that at the time there was insufficient data to generate an electrode safety and performance standard. This technical note will use the AAMI NS4:1986/(R)2009 as a basis for establishing some impedance test criteria for manufacturers/researchers of the TENS electrodes to aid in the development of acceptance limits.

2. REFERENCES / DOCUMENTS

1. Transcutaneous Electrical Nerve Stimulators AAMI NS4:1986/(R)2009
2. Disposable ECG Electrodes ANSI/AAMI EC12:2000
3. Linzer, M., & D.M. Long. Transcutaneous neural stimulation for relief of pain. IEEE Trans Biomed Engr BME-23(4): 341-345, 1976.
4. Robinson, D.A. The electrical properties of metal micro-electrodes. *Proceedings IEEE* 56: 1065-1071, 1968.
5. Alistair Boyle and Andy Adler, Impact of Electrode Area, Contact Impedance and Boundary Shape on EIT Images, Systems and Computer Engineering, Carleton University, Ottawa, ON, Canada

3. DESCRIPTION

<u>Key TENS Stimulator Boundaries</u>

As part of (1), the safety aspects were defined. Importantly, as the focus was on energy transmission, the limits are defined in terms of per pulse electrical charge (Q in micro-Coulomb's - uC). Mathematically, this is the electrical current pulse height (I in Amperes) multiplied by the duration (t in seconds) the pulse is on.

$Q(C) = I(A) * t(sec)$ Note that uC are the scaled unit that is used.

A review of the efficacy, safety and typical device maximum outputs yields three important limits:

- **3uC** - is the minimum charge found to alleviate pain (3)
- **18uC** - is the maximum charge found to alleviate pain (3)
- **25uC** - maximum practical charge output from commercial stimulators also considered as part of (1) when developing the modified formula for setting the maximum charge based on pulse width.

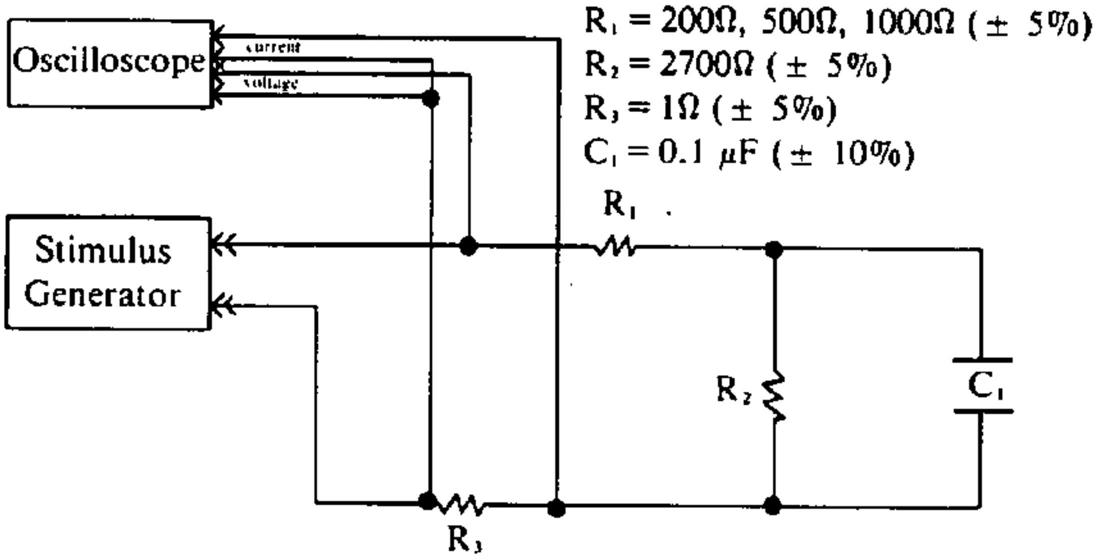
These limits can then be considered for discrete impedance testing for TENS electrodes as limits for *minimum usage* (3uC), *maximum usage* (18uC) and *worst case usage* (25uC). Also considering from an engineering test stand point, if you also apply a standard safety factor of 1.4 to the maximum usage to define the worst case usage, you end up with of 25.2uC and supports the above worst case usage condition.

Note that for new TENS electrodes, impedance for short duration tests should be independent of the input charge level. The impact of the charge level on impedance would be seen over a long timeframe.

<u>Selecting TENS Electrode Impedance Acceptance Limits</u>

While absolute limits cannot be practically defined as they not only depend on the manufacturing process, but also the physical size; below represents a series of rules that can help define these acceptance impedance limits.

An impedance model for the skin/electrode pair interface (4) was used in (1) as part of the load test requirements for the TENS stimulators.



R2 and C1 represent the skin interface and R1 is the electrode pair. Two limits were cited in (1) where 200 ohm represented a lower impedance electrode pair and 500 ohms represents a higher impedance electrode pair of a 5cmx5cm. Note that these impedances represent 2 electrodes in series, hence the single electrode impedance is half of these limits (100 and 250 ohms respectively). Note that this assumes the electrode pair behaves as a linear resistor.

Note that since the TENS electrode impedance is inversely proportional to the surface area, the impedance should be initial expressed as a unit impedance area:

Low Unit Impedance = 100ohms*(5x5)cm^2 = **2500 ohms cm^2** OR **5000 ohms cm^2** per pair
High Unit Impedance = 250ohms*(5x5)cm^2 = **6250 ohms cm^2** OR **12500 ohms cm^2** per pair

Within a family of TENS electrodes, with the only difference being surface area, high and low impedances can be calculated for each simply by dividing these by the TENS electrode surface area (in cm^2).

Note that these two Unit Impedances represent typical values as defined in the literature and should be used as a reference only. Statistical lot testing should be performed to establish these number for the TENS electrode in question. The suggestion is that one type be tested and then apply surface area properties to remaining electrodes in the family of TENS electrodes. An example of how to derive pass/fail based on low and high values for test data are:

Ex: 0 ohms ***to*** AVG(Low + High) = **PASS**,
AVG(Low + High) ***to*** (High + (High - AVG(Low + High)) = **Marginal PASS** - may require additional testing or inspections
Greater than (High - AVG(Low + High)) = **FAIL**

Also note that in actual use, TENS electrodes are used in pairs. As such, testing can be performed with a pair of TENS electrodes connected gel-to-gel, as is done for ECG electrodes (2), but noting that the *per-electrode* impedance is **half** of the recorded value for the pair.

Test Durations

As TENS electrodes have an expected use life, testing for impedance variation as a function of the anticipated use life is important - especially for qualification of a new or modified product (eg new gel formulations).

Long term testing performed in the EC12 standard (2), the bias test applies a current to an electrode pair and monitors the resulting change in residual voltage over the expected duration of use or 8 hours, whichever is greater.

Duration testing of TENS electrode test the performance of the conductive medium (eg gel). Over time, the Stimulator current can breakdown/modify the medium properties, potentially causing the impedance to rise over the established pass/fail limits. For any given input pulse, the larger the surface area, the more spread out the charge, and hence the "wear" impact of the pulse in reduced.

Establishing the actual Test duration is actually based on the smallest surface area. For a fixed pulse charge and frequency, the test duration for the smallest TENS electrode would be the manufacturers expected duration. For subsequent larger electrodes, the test duration is extended by the ratio of the surface area:

Test Duration = Manu-life duration * (Test Electrode Area / Smallest Electrode Area)

If the manufacturer defines a number of reuses, use a typical session time of 60 min.

3. TEST PROGRAM SUGGESTIONS

3.1 New/Modified Product Qualification (single or paired electrodes)

Test Setup 1 - Establish High Unit Impedance alert limit:

1. Based on your quality system, select (X) TENS electrodes for testing
2. Run short term tests (less than 30 sec) @ 3uC (eg 10mA for 300usec) 50Hz

The following sample data was gathered using 32 TENS electrodes to demonstrate options of establishing the upper alert impedance:

56.20	71.50	84.70	132.70
62.20	72.00	87.70	148.70
62.70	74.20	90.00	163.20
66.20	77.70	92.50	168.50
66.70	78.70	97.20	179.70
68.20	79.00	106.20	200.00
68.50	79.70	113.20	212.50
70.00	83.50	119.50	241.70

3. Approach 1: For a practical determination, use the average of the highest 25% to set the High Impedance. For the sample population above, this is 181 Ω.

4. Approach 2: Determine the standard deviation and mean of the entire sample population. Add 3 standard deviations to the mean for an upper acceptance limit that would incorporate 99.7% (3sigma). For the sample population the upper 3sigma alert limit is 254 Ω.

5. Approach 3: Using the CONFIDENCE function in Microsoft Excel and establishing a confidence interval of 99% (alpha = 0.01). For the sample population the upper alert limit is determined to be 128 Ω.

6. Use the upper alert limit determined by one of the above methods to set the PASS? lower value on the SEAM10.

7. **Note:** The Standard Unit Impedance for the TENS electrodes are a function of the electrode surface area. Determine the mean impedance and multiply by the samples surface area to get Ω sq inch (or equivalent unit of measure). You can then determine the upper alert limit for all size electrodes by dividing the Standard Unit Impedance by the surface area of the sample under investigation.

Test Setup 2 - Long Duration Qualification Testing:

1. Based on your quality system, select (X) TENS electrodes for testing - must be the smallest in the "family" of electrodes.

2. Run long-term tests @ 25uC (100mA for 250usec) 50Hz - minimum of 2 impedance measurements (beginning and end) with the last measurement used to determine product PASS/FAIL disposition.

3. Once you have your sample population data you can proceed to determine an upper acceptance limit for duration testing using one of the approaches in Test Setup 1.

4. **Note:** The Standard Unit Impedance for the TENS electrodes are a function of the electrode surface area. Determine the mean impedance and multiply by the samples surface area to get Ω sq inch (or equivalent unit of measure). You can then determine the upper alert limit for all size electrodes by dividing the Standard Unit Impedance by the surface area of the sample under investigation.

Upper Specification Limit Determination

Since an international standard for TENS Electrodes does not exist at this time, determination of an absolute upper specification limit can be difficult. CALM Technologies has reviewed the available guidance and safety documents and has calculated a practical upper specification limit that could be employed.

Per AAMI NS4: 1986/R2009, Transcutaneous Electrical Nerve Stimulators, the committee limited the output charge to be 25 µC. The threshold for cardiac excitation is linear over the range of pulse widths between 0.5 and 5 ms (B3.2.2.2 Safety Consideration, AAMI NS4: 1986/R2009). 0.5 ms (500 µs) is the upper limit of the SEAM10 TENS Tester and can be used as a worst case safety consideration. Also considering the lowest voltage stated for a shock hazard creating a fatal risk to be 30V under low skin resistance conditions (ie not dry skin) assumed to be created with the Gel-skin interface of a TENS electrode (McGraw-Hill Electronics Pocket Reference 3rd Edition; Edward Pasahow, 2000). An instantaneous current of 50 mA (25uC/0.5msec) can be created under these conditions, resulting in the upper safety limit for a TENS electrode to be **600 Ω**. In comparison, this limit is close to the upper test load limit of 500 Ω set for TENS stimulator efficacy testing in AAMI NS4: 1986/R2009.

3.2 Product Lot Acceptance (one set per lot)

1. Based on your quality system, select (X) TENS electrodes for testing
2. Run long-term tests @ 18uC (50mA for 360usec) 50Hz - minimum of 2 impedance measurements (beginning and end) with the last measurement used to determine PASS/PASS?/FAIL to the upper acceptance limit and upper specification limit determined in section 3.1.

3.3 Manufacturing Inspection Test (assembly line quick tests)

1. Run short term tests (less than 30 sec) @ 3-18uC range at 50Hz
2. Single impedance test measurement to establish PASS/PASS?/FAIL to the upper acceptance and specification limit determined in section 3.1.