Quantitative Sensory Testing Procedures

RC completes at Baseline Week 4 and Months 6, 18, & 36 Clinic Visits.
RC also completes at **ATLASI** Visits 61 & 67 and **ATLASII** Visits 71 & 77.

QST pre-procedure diagnostic questions

1d. Please confirm the Participants *dominant* thumb: ❑₁ Right ❑₂ Left

1. Artificial fingernails status and history for **MAST** procedures

Please see the QST MOP section regarding artificial fingernails and review with the Participant *prior to completing MAST procedures*.

  a. Participant has artificial fingernails ❑₁ Yes ❑₀ No ❑₉₉ NA

   i. If *Yes*, Participant agrees to continue wearing artificial fingernails for the full duration of the MAPPII SPS Study ❑₁ Yes ❑₀ No ❑₉₉ NA

  b. Has Participant *started* wearing artificial fingernails since previous clinic visit QST procedures? ❑₁ Yes ❑₀ No ❑₉₉ NA

   If *Yes*, *skip MAST procedures*. Data analysis will not be possible.

  c. Has Participant *discontinued* wearing artificial fingernails since previous clinic visit QST procedures? ❑₁ Yes ❑₀ No ❑₉₉ NA

   If *Yes*, *skip MAST procedures*. Data analysis will not be possible.

2. Peripheral neuropathy for **MAST** & **Conditioned Pain Modulation** procedures

Please see the QST MOP section regarding peripheral neuropathy and review with the Participant *prior to completing MAST and CPM procedures*.

  a. Participant has peripheral neuropathy in **hands** which would interfere with **MAST** results. ❑₁ Yes ❑₀ No

   If *Yes*, *skip MAST procedures*.

  b. Participant has peripheral neuropathy in **fee**t which would interfere with **Conditioned Pain Modulation** results. ❑₁ Yes ❑₀ No

   If *Yes*, *skip CPM procedures*.

  c. Participant reports sensory abnormalities in either the hands or the feet but does not have diagnosed upper or lower extremity neuropathy, respectively. ❑₁ Yes ❑₀ No

   i. If **Yes**, please describe these abnormalities in the space below, but conduct all QST procedures as normal.

_____

_____

_____

3. Open wounds on feet for **Conditioned Pain Modulation** procedures

Please see the QST MOP section regarding open wounds on feet and review with the Participant *prior to completing CPM procedures*.

  a. Participant has open wound(s) on **non-dominant** foot requiring **dominant** foot to be used for CPM testing. ❑₁ Yes ❑₀ No

  b. Participant has open wound(s) on **both feet** requiring CPM testing to be skipped at this visit. ❑₁ Yes ❑₀ No

Quantitative Sensory Testing Procedures

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Section I: Generalized Mechanical Sensitivity (MAST Test)

4. Was MAST familiarization protocol conducted (testing non-dominant thumb)? ❑₁ Yes   ❑₀ No
   If **No**, please confirm why the non-dominant thumb was not tested.

   If *Yes*, please leave the section below blank and proceed to **Q.#5**

   a. Non-dominant thumb is malformed, significantly injured, or missing requiring dominant thumb to be used for MAST familiarization. ❑₁ Yes   ❑₀ No

   b. Participant has peripheral neuropathy in non-dominant thumb requiring dominant thumb to be used for MAST familiarization. ❑₁ Yes   ❑₀ No

   c. Other (please specify) _____ ❑₁ Yes   ❑₀ No

5. Were the MAST test procedures completed (testing dominant thumb)? ❑₁ Yes   ❑₀ No

   If *No*, please confirm why the MAST procedures were not completed.

   If *Yes*, please leave the section below blank and proceed to **Q.#6.**

   a. Participant declined MAST procedures ❑₁ Yes   ❑₀ No

   b. Participant's thumb too large ❑₁ Yes   ❑₀ No

   c. Participant's hand too small ❑₁ Yes   ❑₀ No

   d. Equipment/Technical Malfunction ❑₁ Yes   ❑₀ No

   e. Other (please specify) _____ ❑₁ Yes   ❑₀ No

6. Was the Participant's dominant thumb tested? ❑₁ Yes   ❑₀ No
   If **No**, please confirm why the dominant thumb was not tested.

   a. Dominant thumb is malformed, significantly injured, or missing requiring non-dominant thumb to be used for MAST procedure. ❑₁ Yes   ❑₀ No

   b. Participant has peripheral neuropathy in dominant thumb requiring non-dominant thumb to be used for MAST procedure. ❑₁ Yes   ❑₀ No

   c. Other (please specify) _____ ❑₁ Yes   ❑₀ No

7. Was MAST test procedure data successfully recorded to the MAST equipment and uploaded to the central MAST database? ❑₁ Yes   ❑₀ No   ❑₉₉ NA

   Please record *99/NA* if MAST procedures were not completed.

   Please complete **Q.#7a.** below if **Q.#7** is *No* and MAST data was not successfully recorded and/or uploaded.

   a. Reason MAST data not recorded and/or uploaded:

   _____

Quantitative Sensory Testing Procedures

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Section II: Segmental/Regional Mechanical Sensitivity (Algometer Test)

8. Was the **Algometer Familiarization Protocol** conducted? ☐₁ Yes ☐₀ No

   If **Algometer Familiarization Protocol** was **NOT** completed, please confirm reasons below

   a. Participant declined procedure ☐₁ Yes ☐₀ No

   b. Procedure too painful/uncomfortable ☐₁ Yes ☐₀ No

   c. Other (please specify) _____ ☐₁ Yes ☐₀ No

9. Were **ALL** Segmental/Regional Mechanical Sensitivity procedures completed? ☐₁ Yes ☐₀ No

   If **Q.#9** is **No**, please confirm which procedures were completed, which procedures were not completed, and reasons for procedures not completed.

   a. **Dominant forearm** (control) procedures completed? ☐₁ Yes ☐₀ No

      i. 2 kg   __ __ __ (0 – 100)   ☐₉₉ **Not done**

      ii. 2 kg   __ __ __ (0 – 100)   ☐₉₉ **Not done**

      iii. **4 kg**   __ __ __ **(0 – 100)**   ☐₉₉ **Not done**

      iv. 2 kg   __ __ __ (0 – 100)   ☐₉₉ **Not done**

      v. **4 kg**   __ __ __ **(0 – 100)**   ☐₉₉ **Not done**

      vi. **4 kg**   __ __ __ **(0 – 100)**   ☐₉₉ **Not done**

      vii. **Calculated mean of 3 ratings of 2 kg to be generated by Biostatistics.**

      viii. **Calculated mean of 3 ratings of 4 kg to be generated by Biostatistics.**

   If **Dominant forearm** procedures were **NOT** completed, please confirm reasons below

      ix. Procedure stopped early ☐₁ Yes ☐₀ No

      x. Procedure too painful/uncomfortable ☐₁ Yes ☐₀ No

      xi. Other (please specify) _____ ☐₁ Yes ☐₀ No

Quantitative Sensory Testing Procedures

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b. **Suprapubic** procedures completed? $\Box_1$ Yes $\Box_0$ No

   i. 2kg __ __ __ (0 – 100) $\Box_{99}$ **Not done**

   ii. 2kg __ __ __ (0 – 100) $\Box_{99}$ **Not done**

   iii. *4*kg *__ __ __ (0 – 100)* $\Box_{99}$ **Not done**

   iv. 2kg __ __ __ (0 – 100) $\Box_{99}$ **Not done**

   v. *4*kg *__ __ __ (0 – 100)* $\Box_{99}$ **Not done**

   vi. *4*kg *__ __ __ (0 – 100)* $\Box_{99}$ **Not done**

   vii. *Calculated mean of 3 ratings of 2 kg to be generated by Biostatistics.*

   viii. *Calculated mean of 3 ratings of 4 kg to be generated by Biostatistics.*

If – **Suprapubic** procedures were *NOT* completed, please confirm reasons below

   ix. Bladder pain/discomfort too severe for procedures $\Box_1$ Yes $\Box_0$ No

   x. Procedure stopped early $\Box_1$ Yes $\Box_0$ No

   xi. Procedure too painful/uncomfortable $\Box_1$ Yes $\Box_0$ No

   xii. Other (please specify) _____ $\Box_1$ Yes $\Box_0$ No

c. **Pressure Pain Threshold –** Trapezius threshold familiarization completed? $\Box_1$ Yes $\Box_0$ No

   i. Threshold 1 - Left __ __ . __ (kg) $\Box_{99}$ **Not done**

   ii. Threshold 2 - Right __ __ . __ (kg) $\Box_{99}$ **Not done**

   iii. Threshold 3 - Left __ __ . __ (kg) $\Box_{99}$ **Not done**

   iv. Threshold 4 - Right __ __ . __ (kg) $\Box_{99}$ **Not done**

   v. *Calculated mean of 4 ratings to be generated by Biostatistics.*

If **Pressure Pain Threshold – Trapezius** (control) procedures were *NOT* completed, please confirm reasons below

   vi. Procedure stopped early $\Box_1$ Yes $\Box_0$ No

   vii. Procedure too painful/uncomfortable $\Box_1$ Yes $\Box_0$ No

   viii. Other (please specify)_____ $\Box_1$ Yes $\Box_0$ No

Quantitative Sensory Testing Procedures

RC completes at Baseline Week 4 and Months 6, 18, & 36 Clinic Visits.
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Section III: Temporal Summation (PinPrick Test)

10. Was the **Temporal Summation Familiarization Protocol** conducted? ☐₁ Yes ☐₀ No

   If **Temporal Summation Familiarization Protocol** was *NOT* completed, please confirm reasons below

   i. Participant declined procedure ☐₁ Yes ☐₀ No

   ii. Procedure too painful/uncomfortable ☐₁ Yes ☐₀ No

   iii. Other (please specify) _____ ☐₁ Yes ☐₀ No

11. Were *ALL* **Temporal Summation** procedures completed? ☐₁ Yes ☐₀ No

   If **Q.#11** is **No**, please confirm which procedures were completed, which procedures were not completed, and reasons for procedures not completed.

   a. **Dominant Forearm (256 mN stimulator)** procedures completed? ☐₁ Yes ☐₀ No

      i. Rating 1a – Single Stimulus __ __ __ (0 – 100) ☐₉₉ **Not done**

      ii. Rating 1b – 10 Stimuli __ __ __ (0 – 100) ☐₉₉ **Not done**

      iii. Rating 2a – Single Stimulus __ __ __ (0 – 100) ☐₉₉ **Not done**

      iv. Rating 2b – 10 Stimuli __ __ __ (0 – 100) ☐₉₉ **Not done**

      v. Rating 3a – Single Stimulus __ __ __ (0 – 100) ☐₉₉ **Not done**

      vi. Rating 3b – 10 Stimuli __ __ __ (0 – 100) ☐₉₉ **Not done**

      vii. Calculated WUR (mean of a.ii, a.iv.,a.vi. / mean of a.i., a.iii., a.v.) to be generated by Biostatistics.

      viii. After-sensation rating 15 s __ __ __ (0 – 100) ☐₉₉ **Not done**

      ix. After-sensation 30 s __ __ __ (0 – 100) ☐₉₉ **Not done**

   If **Dominant Forearm (256 mN stimulator)** procedures were *NOT* completed, please confirm reasons below

      x. Procedure stopped early ☐₁ Yes ☐₀ No

      xi. Procedure too painful/uncomfortable ☐₁ Yes ☐₀ No

      xii. Other (please specify) _____ ☐₁ Yes ☐₀ No

Quantitative Sensory Testing Procedures

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b. **Suprapubic (256 mN stimulator)** procedures completed? ☐₁ Yes ☐₀ No

   i. Rating 1a – Single Stimulus   __ __ __ (0 – 100) ☐₉₉ **Not done**

   ii. Rating 1b – 10 Stimuli   __ __ __ (0 – 100) ☐₉₉ **Not done**

   iii. Rating 2a – Single Stimulus   __ __ __ (0 – 100) ☐₉₉ **Not done**

   iv. Rating 2b – 10 Stimuli   __ __ __ (0 – 100) ☐₉₉ **Not done**

   v. Rating 3a – Single Stimulus   __ __ __ (0 – 100) ☐₉₉ **Not done**

   vi. Rating 3b – 10 Stimuli   __ __ __ (0 – 100) ☐₉₉ **Not done**

vii. Calculated WUR (mean of b.ii, b.iv.,b.vi. / mean of b.i., b.iii., b.v.) to be generated by Biostatistics.

   viii. After-sensation rating - 15 s   __ __ __ (0 – 100) ☐₉₉ **Not done**

   ix. After-sensation rating - 30 s   __ __ __ (0 – 100) ☐₉₉ **Not done**

If **Suprapubic (256 mN stimulator)** procedures were ***NOT*** completed, please confirm reasons below

   x. Procedure stopped early   ☐₁ Yes   ☐₀ No

   xi. Procedure too painful/uncomfortable   ☐₁ Yes   ☐₀ No

   xii. Other (please specify) _____   ☐₁ Yes   ☐₀ No

IV. Conditioned Pain Modulation

12. Were ***ALL*** **Conditioned Pain Modulation** procedures completed?   ☐₁ Yes   ☐₀ No

If **Q.#12** is **No**, please confirm which procedures were completed, which procedures were not completed, and reasons for procedures not completed.

   a. ***Note: Original Q.#12a. section removed per confirmation from QST working group.**

   b. **Test Stimulus Calibration**

      i. Initial Pain40 pressure   __ __ . __ __ (kg)

      ii. Initial Pain40 pre-test rating   __ __ __ (0 – 100)

      iii. Final adjusted Pain40 Pressure   __ __ . __ __ (kg) ☐₉₉ **N/A**

      iv. Final adjusted Pain40 pre-test rating   __ __ __ (0 – 100) ☐₉₉ **N/A**

      v. Number of adjustments required   __ __   ☐₉₉ **N/A**

Quantitative Sensory Testing Procedures

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c. **Test Stimulus Alone (30-s, dominant thumb, Pain40 pressure)** procedures completed? ❑$_1$ Yes ❑$_0$ No

    i. Rating 1 - 10 s __ __ __ (0 – 100) ❑$_{99}$ **Not done**

    ii. Rating 2 - 20 s __ __ __ (0 – 100) ❑$_{99}$ **Not done**

    iii. Rating 3 - 30 s __ __ __ (0 – 100) ❑$_{99}$ **Not done**

> *iv. Calculated mean of 3 test stimulus ratings to be generated by Biostatistics.*
>
> *v. Calculated Pressure Summation (c.iii. - c.i.) to be generated by Biostatistics.*

If **Test Stimulus Alone (30-s, Pain40 thumb pressure)** procedures were *NOT* completed, please confirm reasons below

    vi. Procedure stopped early ❑$_1$ Yes ❑$_0$ No

    vii. Procedure too painful/uncomfortable ❑$_1$ Yes ❑$_0$ No

    viii. Other (please specify) _____ ❑$_1$ Yes ❑$_0$ No

d. **Test Stimulus + Neutral Conditioning Stimulus (60-s, 32 °C neutral foot bath, non-dominant foot)** procedures completed? ❑$_1$ Yes ❑$_0$ No

    i. Ratings of Neutral Conditioning Stimulus (foot bath)

        1. Rating 2 - 10 s __ __ __ (0 – 100) ❑$_{99}$ **Not done**

        2. Rating 3 - 25 s __ __ __ (0 – 100) ❑$_{99}$ **Not done**

        3. Rating 4 - 60 s __ __ __ (0 – 100) ❑$_{99}$ **Not done**

> *4. Calculated mean of 3 ratings to be generated by Biostatistics.*

    ii. Ratings of Test Stimulus (thumb)

        1. Rating 1 – 40 s __ __ __ (0 – 100) ❑$_{99}$ **Not done**

        2. Rating 2 – 50 s __ __ __ (0 – 100) ❑$_{99}$ **Not done**

        3. Rating 3 – 60 s __ __ __ (0 – 100) ❑$_{99}$ **Not done**

> *4. Calculated mean of 3 test stimulus ratings to be generated by Biostatistics.*

If **Test Stimulus + Neutral Conditioning Stimulus (60-s, neutral foot bath)** procedures were *NOT* completed, please confirm reasons below

    iii. Procedure stopped early ❑$_1$ Yes ❑$_0$ No

    iv. Procedure too painful/uncomfortable ❑$_1$ Yes ❑$_0$ No

    v. Other (please specify) _____ ❑$_1$ Yes ❑$_0$ No

Quantitative Sensory Testing Procedures

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e. **Painful Conditioning Stimulus Calibration**

    i. Initial hot water temperature: (°C)   __ __ . __ (°C)

    ii. Initial hot water rating   __ __ __ (0 – 100)

    iii. Final adjusted water temperature (46.5 °C max)   __ __ . __ (°C)   ❑$_{99}$ **N/A**

    iv. Final adjusted rating   __ __ __ (0 – 100   ❑$_{99}$ **N/A**

    v. Number of adjustments required   __ __   ❑$_{99}$ **N/A**

    vi. Was the immersion circulator repositioned to provide direct water flow onto foot?   ❑$_1$ Yes   ❑$_0$ No

f. **Test Stimulus + Painful Conditioning Stimulus (60-s, hot foot bath, non-dominant foot)** procedures completed?   ❑$_1$ Yes   ❑$_0$ No

    i. Ratings of Painful Conditioning Stimulus (foot bath)

        1. Rating 2 - 10 s   __ __ __ (0 – 100)   ❑$_{99}$ **Not done**

        2. Rating 3 - 25 s   __ __ __ (0 – 100)   ❑$_{99}$ **Not done**

        3. Rating 4 - 60 s   __ __ __ (0 – 100)   ❑$_{99}$ **Not done**

        4. Calculated mean of 3 ratings to be generated by Biostatistics.

    ii. Ratings of Test Stimulus (thumb)

        1. Rating 1 – 40 s   __ __ __ (0 – 100)   ❑$_{99}$ **Not done**

        2. Rating 2 – 50 s   __ __ __ (0 – 100)   ❑$_{99}$ **Not done**

        3. Rating 3 – 60 s   __ __ __ (0 – 100)   ❑$_{99}$ **Not done**

        4. Calculated mean of 3 test stimulus ratings to be generated by Biostatistics.

If **Test Stimulus + Painful Conditioning Stimulus (60-s, hot foot bath)** procedures were ***NOT*** completed, please confirm reasons below

    iii. Procedure stopped early   ❑$_1$ Yes   ❑$_0$ No

    iv. Procedure too painful/uncomfortable   ❑$_1$ Yes   ❑$_0$ No

    v. Other (please specify) _____   ❑$_1$ Yes   ❑$_0$ No

g. ***CPM Magnitude*** *(calculated variables)*

    i. *Neutral (Sham) Conditioning (d.ii.4. – c.iv.)* __ __ __ *(0 – ±100)* ***to be generated by Biostatistics.***

    ii. *Painful Conditioning (f.ii.4. - c.iv.)* __ __ __ *(0 – ±100)* ***to be generated by Biostatistics.***

    iii. *CPM relative effect (f.ii.4. – d.ii.4)* __ __ __ *(0 – ±100)* ***to be generated by Biostatistics.***

13. Comments: _____

_____

_____