

PBM – RoM Study

PBM (PhotoBioModulation) therapy is a safe, integrated, non-invasive and complementary treatment modality that promotes healing, reduces inflammation and reduces pain. More specifically, PBM therapy increases blood circulation and enhances nutrient and oxygen delivery, similar to an athletic warm-up, resulting in better musculature coordination and strain prevention. These benefits are relevant and applicable for dental patients receiving procedures that require sustained opening of the mouth. This *PBM – RoM Study* seeks to better understand PBM light energy's effect on masseter (jaw) muscle range of motion, using *PBM Light*. This handheld photobiomodulation device is easy to use, safe to operate and features three LEDs (Light Emitting Diodes; 630, 660 & 850 nm) which generate beneficial red and near-infrared light energy. PBM can generate immediate, positive and sometimes transient biological responses when a physical deficiency is present (injury, fatigue etc.). Reference measurements of the masseter muscle's RoM, (range of motion) will be taken before and after PBM therapy is administered. Normal jaw RoM is 45 – 55 mm.

In an effort to promote integrative treatment modalities with photobiomodulation therapy, recognizing ALD's (Academy of Laser Dentistry) mission of "...supporting the safe and effective adoption of laser therapy in oral systemic health for patient well-being," in collaboration with the PBM Foundation's mission to "...develop and promote PBM as a viable medical treatment with the purpose of operating exclusively for charitable, educational and/or scientific purposes, and with Oral IQ LLC, with the mission of promoting oral health and beyond , the following program is proposed to ALD members wishing to further these missions.

The *PBM – RoM Project* focuses on ALD member participants, sourced from ALD's 30th annual meeting in Dallas, TX. We project 100 participants with each participating professional providing readings from 10 patients, two readings per patient (pre and post-PBMT), for a total of 2000 data points. Once collected, data from the study will be independently analyzed and compiled by Shepherd University. The study involves four sites, ST6 (stomach 6) and ST 7 (stomach 7), located on the masseter muscle of each cheek. *PBM Light* will treat four sites, 2.5 mins per site (total time: 10 mins). Patient criteria: adults aged 18 – 65, excluding emergency dental patients or those experiencing pain.

In exchange for participating in the *PBM – RoM Project* (recording ROM before-and-after results from ten different patients, after signing an open invoice agreement) participants will be provided with one (1) *PBM Light* with instruction sheet and standardized measuring ruler. A blank data sheet will also be supplied. Any additional data and/or comments provided will be greatly appreciated and recognized. Acceptance of complimentary *PBM Light* unit obligates the participant to complete and return this survey to Oral IQ within 90 days, by **July 21, 2023**. *Once a fully completed study data sheet is returned, the invoice's open balance will be cleared.*



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Criteria:

- Patient Recruitment:
 - Adults aged 18-65 excluding emergency pain patients.
- Target Site: masseter muscles (stomach channels: ST6 & ST7) on both left and right side of face. 4 spots total.

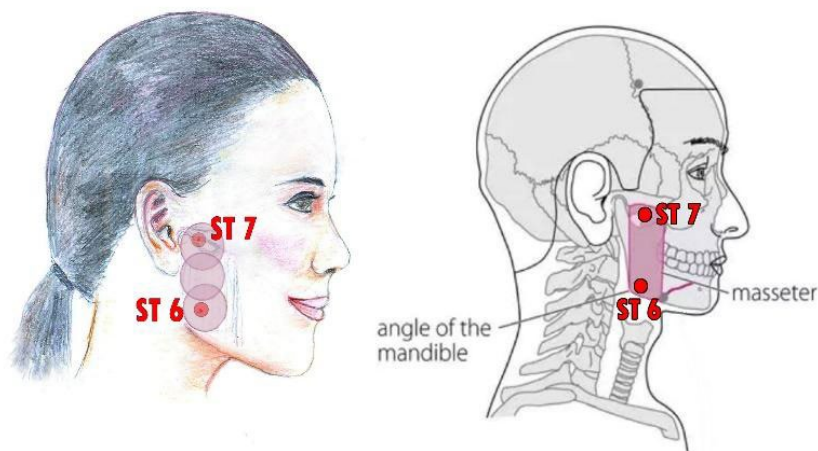
ST6 is located one finger-breadth anterior and superior to the angle of the mandible, at the prominence of the masseter muscle when the teeth are clenched.

ST7 is located in the depression of the lower border of the zygomatic arch, level with the tragus.
- Setup:

<ul style="list-style-type: none"> • <i>PBM Light</i> (Oral IQ- silver unit) • Ruler, Clear, 15 cm in length • Data Collection Sheet • Timers 	<ul style="list-style-type: none"> -Plastic barrier (sleeve for <i>PBM Light</i>) -Patient goggles -Dermal skin marker (mark ST6, ST7 spots for easy spot identification)
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Method:

After verbal consent is reviewed, locate the 4 targeted sites. Proceed to assess if any tender spot is present, palpate masseter muscle and log it on a data sheet. Have the participating patient place the protective eyewear on themselves. Cover *PBM Light* unit and Ruler in a plastic barrier for hygienic purposes. Begin with the pre-tx ROM measurement. All measurements are to be done in millimeters, with the zero-line aligned with the incisal edge of the lower central incisors. With the subject's mouth comfortably, fully open, take measurements against the subject's incisal edge of the upper central incisors. Begin ST6 treatment with *PBM Light* by using a two-and-a-half-minute timer in contact mode (tissue seal) in circular, sweeping motion. Then move up to ST7 and repeat. Proceed to do the same on the opposite side; ST6 and ST7 -total of 10 minutes PBM Light treatment. Measure post ROM.

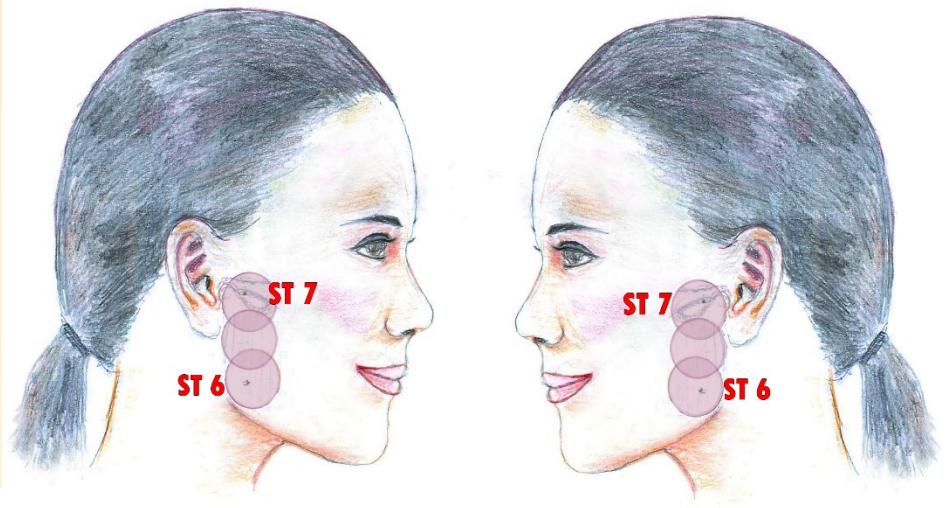


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Informed Consent:

PBM, photobiomodulation, is a safe, integrated, non-invasive and complementary treatment modality to promote healing, reduce inflammation and reduce pain. PBM therapy can increase blood circulation, nutrient circulation and oxygenation to treatment sites, similar to an athletic warm-up. Benefits include better musculature coordination, preventing further strain, important for dental procedures that require sustained opening of the mouth.

This *PBM-RoM* study targets the jaw (masseter) muscles and how PBM light interacts with these muscles. Measurements will be taken before and after PBM treatment to determine jaw range of motion, totaling ten minutes of treatment, five minutes per side. We appreciate your participation in this scientific research study! Any questions that cannot be answered by your oral health care professional can be directed to hello@theoq.shop.



*Patients must wear protective eyewear while using *PBM Light* / while receiving light therapy treatment. Each treatment point receives 2.5 mins of light therapy. Five minutes per side. Ten minutes in total.

**Video instructions available here (scan QR):*
<https://youtu.be/F5eyoUo-h48>



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Name of Healthcare Professional: _____

***Video instructions available here (scan QR): <https://youtu.be/F5eyoUo-h48>**

***Please review Method Guidelines (page 2) to ensure uniform protocol**

***Ensure PBM-ROM measurements are completed before any dental work is done. If measurements are taken at the end of the patient's visit, please make a note in the note area.**



Pt initials	Date	Age	Sex	Symptom	RoM Pre (mm)	RoM Post (mm)	Operator Initials (and notes):
1:			F / M	Y / N L / R			
2:			F / M	Y / N L / R			
3:			F / M	Y / N L / R			
4:			F / M	Y / N L / R			
5:			F / M	Y / N L / R			
6:			F / M	Y / N L / R			
7:			F / M	Y / N L / R			
8:			F / M	Y / N L / R			
9:			F / M	Y / N L / R			
10:			F / M	Y / N L / R			
			F / M	Y / N L / R			
			F / M	Y / N L / R			

****When complete, please scan and email to hello@theoq.shop with the subject line “PBM – RoM Study Submission” or mail to “Oral IQ, 460 N. Doheny Drive, Los Angeles CA 90048”**

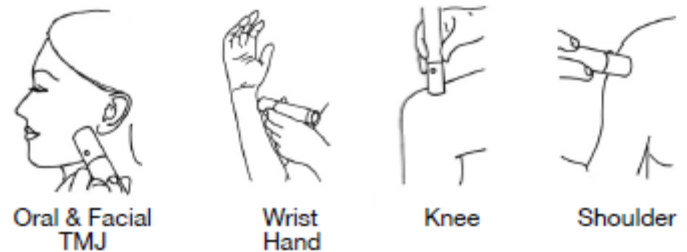
Study Submission Date: _____



PBM – RoM Study

PBM Light Specs and Quick Start Guide

PBM Light (630nm, 660nm, 850nm), with two red LED diodes and one infrared LED diode, is a safe and efficient photobiomodulation device suitable for muscle and joint preconditioning and recovery (before and after dental procedures to prevent post-op discomfort, improving chronic pain conditions etc.), for dental procedures and general physical aesthetic applications. This technology is suitable for bio-stimulating (healing and regenerating) and bio-inhibiting (pain management) tissues, and can also be used for meridian point activation.



Specifications:

- PBM Light (Stainless Steel): 26mm(w) x 120.5mm(L). 7.4oz/0.21kg
- Lens - Spot Size: 20mm
- Light Wavelength (λ): 630 nm, 660 nm, 850 nm (LED diodes)
- Power Output: 236mW
- Power Density: 75mW/cm²
- Energy Density (fluence) 5 min: skin contact: ~22.5J/ cm²
- Built-in pre-set timer: 5 minutes. All diodes turn on at same time (not selectable)
- Battery Type: Lithium-ion 18650 (rechargeable) Battery Capacity: 2500mAh
- Warranty: 12 months Lifespan: 50,000 hrs
- For hygiene purposes, wrap device in cellophane or zip-loc bag. Do not auto-clave.

FDA Class 2 light therapy device for safe, efficient treatment:

- FDA medical device category K-100213 for temporary pain relief
- CE Standard No. EN 55015:2013 + A1: 2015
- ANSI Classification: 3B (< 500mW)

Package Contents:

- PBM red light treatment device with sleeve, pouch, user manual, guide, protective eyewear
- Rechargeable battery model no. 18650 (x2) with USB battery charger

Order: www.TheOQ.shop or www.PBMTPPro.com

Contact: hello@theOQ.shop 818-925-4497