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USER GUIDE: SAMPLING AND INTERPRETATION RESULTS.

PRELIMINARY CONSIDERATIONS:

1. Place the device OralChroma in a room, away from chemical products and laden environments that may interfere with their correct use.
2. Leave enough space between the back of OralChroma and any surface, the device needs **AT LEAST 10 CM FOR REFRIGERATED AND EVACUATE THE GAS PROPERLY.**
3. Wait until the OralChroma is in the "Ready" status, the team did not analyze any sample until you've done the warm-up.
4. **SENSITIVITY AND SPECIFICITY WILL INCREASE AS THE DEVICE IS ON.** The more time the sensors are on the better they detect CVS. It is therefore recommended connecting the equipment during the duration of the day in the clinic.
5. If there are interference gases in the environment surrounding the OralChroma, the computer automatically switches to state "Wait" to re-calibrated. Wait until the green light stops flashing and the status is "Ready" to take a measurement.
6. **DO NOT TRY TO ANALYZE GASES OTHER THAN THOSE OF ORAL CAVITY, THEY MAY DAMAGE THE EQUIPMENT.**
7. **DO NOT MAKE MEASURES IN PATIENTS THAT HAS CONSUMED ALCOHOL. IT MAY DAMAGE THE EQUIPMENT.**
8. **DO NOT CLEAN THE INJECTION NEEDLE WITH ANY DISINFECTANT SOLUTION, THEY MAY CONTAIN SUBSTANCES THAT MAYDAMAGE THE EQUIPMENT. IF FOR ANY REASON, A JUDGMENT OF DOCTOR, THE NEEDLE CAN NOT BE RE-USED, DESTROY IT (INSISTEC can replenished by order) OR USE ONLY A NON-CHEMICAL AUTOCLAVE. THIS CAN NOT GUARANTEE THAT THIS OPERATION IS SAFE.**

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Editado el 20 de Marzo de 2013 por Ángela Rico Ruiz, Odontóloga

SAMPLING GUIDE.

1. **IT IS VERY IMPORTANT THAT THE PATIENT HAS NOT CONSUMED ALCOHOL THE DAY OF THE BREATH TEST. The results would not be representative and could alter the operation of the equipment. ALSO PLEASE NOTE THE ALCOHOL CONTAINING MOUTHWASHES.**
2. **SAMPLES CAN BE TAKEN AT ANY TIME. INSISTEC RECOMMENDS MAKE THE ANALYSIS AT LEAST ONE HOUR AFTER EATING, DRINKING, SMOKING OR MAKE ORAL HYGIENE.**

   In this way the results are representative of the environmental conditions of the oral cavity for most of the day.
3. Obtaining a breath sample.
   a. Insert the syringe into the mouth with the piston fully inserted (closed).
   b. Breathe through your nose while keeping your mouth completely sealed for 30 seconds.
   c. Avoid the contact of the syringe with the tongue.
   d. Pull the piston out to fill, then empty it into the mouth, without opening it, and refill slowly with a breath sample.
4. Sample injection into the OralChroma.
   a. Clean the end of the syringe to remove saliva. **REMEMBER THAT CAN NOT BE USED DISINFECTANT SOLUTIONS TO INTERFERE IN RESULTS.**
   b. Push the plunger until the syringe contains 1 ml to purge the sample (this avoids the error mode).
   c. Inject into the input samples quickly, in less than 30 seconds.
   d. Remove the syringe with the piston tight and the needle attached.

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5. Breath samples guide.
    a. Two consecutive samples of breath are rarely identical, you can use an average.
    b. The state of the oral cavity is always changing. Consequently, the components of the breathing gas change over time. As a result, the data repeatedly to the same person also change. Moreover, since the components of the breathing gases are not uniform in the oral cavity, the position of the syringe in the mouth can change the measured values. But, please, contact INSISTEC if a very large difference occurs every time, which could be a device failure (impaired sensitivity, etc..)
    c. Use only syringes provided by INSISTEC, materials are chosen to maximize the accuracy of the measurement.
    d. Use only a breath sample for each syringe. The syringes are not reusable.

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INTERPRETACIÓN DE LOS RESULTADOS.

OralChroma identifies Oral and Internal Health Concerns. At significant levels, each of the three measured VSCs is associated with a primary issue affecting oral and internal health

- Hydrogen sulfide: oral hygiene
- Methyl mercaptan: periodontal disease
- Dimethyl sulfide: systemic diseases.

1. Hydrogen Sulfide (H2S)
    - This gas is unsolvable in blood, so that detection means originates from the oral cavity.
    - Most everyone has some H2S in breath
    - High levels predominantly associated with poor oral hygiene
    - Most H2S originates from bacteria on the tongue
    - Some H2S from plaque, gingivitis and Periodontitis

2. Methyl Mercaptan (MM)
    - This gas is unsolvable in blood, so that detection means originates from the oral cavity.
    - High levels primarily restricted to periodontal pathogens (2000ppb)
    - Periodontitis typically results in a high MM/H2S ratio (>3:1)
    - Lower levels of MM occur in conjunction with poor periodontal health and poor oral hygiene

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3. Dimethyl Sulfide (DMS)
    - It is a soluble gas in blood, so that detection can indicate both an oral and extraoral source of halitosis.
    - Originates in the digestive and respiratory systems; also from the tongue, gingival sites, and periodontal inflammation
    - Can be associated with systemic diseases, metabolic disorders and medications
    - Can also be temporarily caused by certain ingested foods and beverages

4. Cognitive Thresholds--the level at which nose detects malodor
    - H2S: 112ppb—the least smelly
    - MM: 26ppb—moderately smelly; repulsive at high concentrations (periodontitis)
    - DMS: 8ppb—the most smelly
    - Considerable threshold variation depending on research source.

5. Interpreting the measurements:
    - H2S primarily a measure of tongue coating and oral hygiene
    - MM and DMS values similar to H2S also indicative of tongue coating/oral hygiene
    - MM values > 3 x H2S values indicative of periodontitis
    - DMS can also be of digestive system and/or metabolism origin

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