PROCEDURE FOR GENERATION AND TESTING OF MAINSTREAM TOBACCO HEATING SYSTEM (THS or IQOS) AEROSOL USING A LINEAR SMOKING MACHINE
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1 Introduction

Cigarette smoke is produced when the tobacco in a cigarette burns at temperatures in excess of 600°C. At such high temperatures, the tobacco is burned to ash and generates smoke that contains thousands of chemicals, including high levels of harmful and potentially harmful constituents (HPHCs) which are widely recognized to be the most likely causes of smoking-related diseases.

The Tobacco Heating System (THS or IQOS, its commercial name), on the other hand, heats tobacco without burning it (combusting) to generate a nicotine-containing aerosol with significantly lower levels of HPHCs. HPCHs levels can be measured by collecting the aerosol from IQOS, using a commercial linear smoking machine. This document provides a detailed description of how the device should be used in this context and step by step instructions for collecting the aerosol of IQOS using a commercial linear smoking machine.

1 Scope

This document describes the accessories and the procedures for generating and collecting the IQOS aerosol for the purposes of testing.

Mechanical aerosol generation can be performed according to ISO or other smoking regimes (e.g. Health Canada Intense) with the exception of the following requirements which cannot be fulfilled for technical reasons:

- Air velocity control (air flow) is essentially irrelevant as there is no tobacco combustion involved.
- The butt length requirement is not applicable, as the stick is not consumed, and its length remains unchanged after usage.
- There is no ignition of the HeatStick by an external lighter.
- The puff count will depend on the puffing frequency, driven by the total heating time of the system which is fixed at 6 minutes. According to this, 12 puffs can be reached when the THS operates under intense puffing regime (55/2/30) but it is limited to 6 puffs when the aerosol

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4 ISO 3308:2012 Routine analytical cigarette-smoking machine – Definitions and standards conditions
generation is performed under ISO puffing regimen (35/2/60). However, the total number of puffs will depend on the timing of the first puff; for example, a delay in the activation of the puffing regime could result in the device producing only five puffs under ISO.

2 Description of the Method

2.1 Principle

Each IQOS device is an autonomous instrument that can be used independently. An activation bar may be used to activate more than one IQOS device simultaneously when using a linear smoking machine. In the absence of an activation bar, each IQOS can be activated manually, but in this situation, we strongly recommend that testers limit the number of devices to ensure simultaneous activation.

In both cases, a consumable *Heat Stick* is inserted into the tobacco heating device, and throughout the aerosol generation process, the *Heat Stick* remains in contact with a heating blade located inside the THD.

2.2 IQOS components

<table>
<thead>
<tr>
<th>Tobacco Heating Device (THD)</th>
<th><img src="image1.png" alt="Image" /></th>
</tr>
</thead>
<tbody>
<tr>
<td>The THD and consumable <em>Heat Sticks</em> (THS)</td>
<td><img src="image2.png" alt="Image" /></td>
</tr>
<tr>
<td>Holder Cap</td>
<td><img src="image3.png" alt="Image" /></td>
</tr>
<tr>
<td>Charger</td>
<td><img src="image4.png" alt="Image" /></td>
</tr>
</tbody>
</table>
2.3 Accessories for mechanical aerosol generation

Most of the accessories indicated below have been designed and developed by Philip Morris International for use with a linear smoking machine. These accessories are not commercially available for the time being but technical information, engineering drawings, and accessories themselves can be provided upon request.

<table>
<thead>
<tr>
<th>Accessory</th>
<th>Image</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adaptor plate (aluminium)</td>
<td><img src="image1.png" alt="Image" /></td>
</tr>
<tr>
<td>Adaptor bracket (plexi-glass)</td>
<td><img src="image2.png" alt="Image" /></td>
</tr>
<tr>
<td>THS bracket</td>
<td><img src="image3.png" alt="Image" /></td>
</tr>
<tr>
<td>Alignment tool</td>
<td><img src="image4.png" alt="Image" /></td>
</tr>
<tr>
<td>Activation bar⁵:</td>
<td><img src="image5.png" alt="Image" /></td>
</tr>
</tbody>
</table>

⁵ The activation bar allows the simultaneous activation of the THS on a linear smoking machine when a maximal capacity of the smoking machine is used (up to 20 smoking ports). However, activation can also be done manually by operators but, in this case, we strongly recommend that testers limit the number of devices to ensure simultaneous activation.
2.4 Aerosol generation procedure

Linear smoking machines should be operated following recommendations from suppliers and/or local procedures. The recommended number of HeatSticks per port varies depending on the puffing regimen selected:

- ISO puffing regimen (35/2/60): Five HeatSticks per port
- Intense puffing regimen (55/2/30): Three HeatSticks per port

The aerosol collection must start after the end of the pre-heating phase (20 seconds).

2.4.1 Preparation of IQOS before use

- Ensure that THD is correctly cleaned before use (refer to chapter 2.5)
- Ensure the THD is fully charged by placing it in the Main Unit.
- When the THD has been inserted, close the lid. The LEDs on the Main Unit will flash for approximately 5 minutes.

Once the LED signals have gone out, the THD is ready for use.

2.4.2 Testing Procedure on the linear smoking machine

1. Fit the adaptor plate and the bracket together so that the red stopper of the adaptor plate faces the smoking port
2. Install the adaptor bracket with its plate in front of the smoking port by fitting together the bracket and the horizontal metallic rods located on both sides of the smoking port.

3. Several brackets can be installed side by side from left to right.

4. Install the adaptor bracket of the activation bar with its plate from the position 1 to 20. Except at position 5-7 and 14-16 to allow the activation of the bar by the operator (refer to picture in step 11)

5. Check, and if necessary, adjust the alignment of the smoking port by fitting the alignment tool on the adaptor plate with the red screw on the machine side. Rotate the mobile eccentric part of the smoking machine so that the tool fits exactly into the channel

6. When the alignment is adjusted, withdraw the tool and install the THS

7. Install the activation bar on the brackets without the top of the bar. Ensure that the extremities of the bar fit with the extremities of the smoking machine.
8. Insert the *HeatStick* in the THD until it touches the bottom of the THD and the filter is at the edge of the extractor. Install the THS on the bracket then place the filter inside the smoking port.

9. Repeat the operations for each smoking port to be used.

10. Install the activation bar and place the top of the bar on the THD activation switches.

11. Activate the THDs by pressing gently the top of the activation bar for 4 seconds. The LEDs on the THDs will flash for 20 seconds indicating that the pre-heating phase has started. Once the pre-heating is completed, the LEDs will stop flashing. **Wait the end of the pre-heating phase** before starting the aerosol generation cycle.
If the activation bar is not used, devices can be activated manually. Activate the THD by pressing the central start switch gently for 4 seconds. The LED will flash for 20 seconds indicating that the pre-heating phase has started. Once the pre-heating is complete, the LED will stop flashing. **Wait the end of the pre-heating phase** before starting the aerosol generation cycle.

12. Activate the aerosol generation cycle.
13. Repeat the process until the appropriate number of *HeatSticks* (based on the selected puffing regimen) are consumed. Ensure that THDs used for each new aerosol generation cycle are charged (refer to 2.4.1).

### 2.4.3 End of the aerosol collection

Clearing puffs can be drawn after removing the THD.

*After each aerosol collection run, remove the HeatStick from the cigarette holder using tweezers.*

Open the extractor and remove the HeatStick.
2.5 Cleaning the THD

Follow the procedure described below at the end of each day or after a maximum of 30 aerosol generation cycles.

1. Charge the THD battery.
2. Remove the THD Cap.
   
   **Caution:** When replacing the THD Cap, be careful to avoid touching the heating blade, which is ceramic and could break. Avoid shock and the mechanical stress.

2.5.1 THD Cap cleaning

1. Blow any dust and residual tobacco bits using industrial compressed air (if available). If necessary, use tweezers to remove remaining tobacco bits.
2. Rinse the THD Cap with running warm water (if an ultrasonic bath is available, perform steps 2.1 to 2.6 only)
   2.1 Place the THD Cap in an ultrasonic bath filled with a mix of warm water and Absolute Ethanol (EtOH) (20/80 v/v; preferred temperature = 40°C or higher) for at least 5 minutes.
   2.2 Remove the THD Cap from the ultrasonic bath.
   2.3 Wash the dirty surfaces of the THD Cap with a cotton swab.
   2.4 Rinse the THD Cap with water and then secondly with a mix of Absolute Ethanol (EtOH) and water (80/20 v/v).
2.5 Dry it (preferably in an oven for at least 4 hours at approximately 50°C).
2.6 Once completely dried, remove the THD Cap from the oven.

3. Wash the dirty surfaces of the THD Cap with a mix of Absolute Ethanol (EtOH) and water (80/20 v/v) impregnated cotton swab.

4. Rinse the THD Cap with clean water and again with a mix of Absolute Ethanol (EtOH) and water (80/20 v/v).

5. Dry it (preferably with industrial compressed air or in an oven for at least 4 hours at approximately 50°C). If none of these drying methods are available, place the THD Cap on an absorbing tissue for at least 12 hours at room temperature.

2.5.2 THD cleaning

1. Blow off the dust and residual tobacco using industrial compressed air (if available).

2. Perform a self-cleaning as described below:
   
   2.1 Place the THD Cap on the THD and Insert the THD in the Charger and close the Lid. Then press and hold the “self-clean” button for at least 4 seconds until the cleaning light starts blinking green. This means that the self-cleaning cycle has begun and will continue for a duration of 30 seconds.

3. Use a small wooden stick to remove the biggest residual pieces remaining in the THD.

4. Wash the dirty surfaces of the Holder with a cotton swab previously moistened with one or two drops of a mix of Absolute Ethanol (EtOH) and water (80/20 v/v)
5. Blow off the residual dust and tobacco bits using industrial compressed air (if available).
6. Once both parts are cleaned and dried (THD Cap & THD) remount the device by putting back the Holder Cap back in place.
7. If you observe some residual dust or tobacco bits in the Charger Lid due to the accumulation of vapours generated during the self-cleaning process, clean it with a cotton swab impregnated with a mixture of Absolute Ethanol (EtOH) and water (80/20 v/v).