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Tobacco heating systems — Definitions and standard conditions for aerosol generation and collection —

Part 1: Electrically heated tobacco products (eHTPs)

Systèmes de chauffage du tabac — Définitions et conditions normalisées pour la génération et la collecte d'aérosol —

Partie 1: Produits de tabac chauffés électriquement (PTCe)

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Foreword

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This document was prepared by Technical Committee ISO/TC 126, *Tobacco and tobacco products.*

A list of all parts in the ISO 5501 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Tobacco heating systems (THS) are designed to heat a tobacco substrate, to produce a nicotine-containing aerosol without the combustion of the tobacco substrate. A THS is a combination of a heated tobacco product (HTP) and a tobacco heating device (THD). The HTP part of the THS is a product containing a tobacco substrate that is designed to be heated and not combusted.

With the emerging development and commercialisation of HTPs, there are a number of different approaches to heating the HTP, categorised as electrically, aerosol and carbon, HTPs; eHTP, aHTP and cHTP, respectively (see ISO 6080).

This document has been developed to define and specify the requirements for an electrically heated tobacco product (eHTP) puffing regime in order to generate and collect aerosol for subsequent analytical measurement in a robust and reproducible manner.

No machine puffing regime can represent all human use behaviour, so dependent on the testing requirement it might be appropriate to test eHTPs differently according to their design, or under conditions of different intensity to reflect the range of human behaviour.

Machine testing is useful to characterize emissions for device development and regulatory purposes and may be used as inputs for product hazard assessment; however, it is not intended to be nor is it valid as a measure of human exposure or risk.

NOTE This document is a reference document for ISO standards on tobacco heating systems (e.g. ISO 5501). Regulation and standardisation are independent from each other, and standardisation does not pre-empt regulation.

Tobacco heating systems — Definitions and standard conditions for aerosol generation and collection —

Part 1: Electrically heated tobacco products (eHTPs)

1 Scope

This document:

— defines the parameters and specifies the standard conditions for the routine analytical generation and collection of aerosol from electrically heated tobacco products (eHTPs);

— specifies technical requirements for the routine analytical puffing machine for eHTP generation and collection of aerosol, termed as "machine" in this document, conforming with the standard conditions stated within Clause 4.

This document does not specify aerosol trapping nor subsequent sample preparation and analytical method of components in the trapped aerosol or the gas phase.

This document is also applicable to products other than those defined in 3.15 if a specific method references this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3402, *Tobacco and tobacco products — Atmosphere for conditioning and testing*

ISO 6080, *Tobacco heating systems — Vocabulary*

3 Terms and definitions

For the purposes of this document, the following terms and definitions given in ISO 6080 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
conditioning temperature
temperature at which the electrically *heated tobacco products (eHTPs)* (3.15) are kept before being subjected to test

3.2
test atmosphere
atmosphere to which the tobacco heating system (THS) is exposed throughout the test

3.3
pressure drop
static pressure difference between the two ends of a pneumatic circuit when it is traversed by an air flow under steady conditions as described in ISO 7210

Note 1 to entry: Although the pressure drop of a device or a pneumatic circuit is defined for a specific set of reference parameters to describe its physical properties, the device can be used for measurements under conditions other than the reference parameters.

[SOURCE: ISO 20778:2018, 3.4]

3.4
puff duration
interval of time, measured in seconds, during which the port of the machine is pneumatically connected to the suction mechanism

[SOURCE: ISO 20778:2018, 3.6]

3.5
puff volume
volume leaving the eHTP and passing through the aerosol trap

3.6
puff frequency
number of puffs in a given time

[SOURCE: ISO 3308:2012, 3.10]

3.7
puff profile
flow rate measured over the time span of the puff at the port of the machine, typically depicted graphically as a function of time

[SOURCE: ISO 20778:2018, 3.11]

3.8
puff number
number of puffs collected from an eHTP

3.9
THS holder
device for connecting the THS to the port of the machine during aerosol generation and collection

3.10
aerosol trap
device for collecting the aerosol from an eHTP which is necessary for the determination of specified analytes

3.11
port
aperture of the suction mechanism through which a puff is drawn and to which is attached an aerosol trap

[SOURCE: ISO 3308:2012, 3.16]

3.12
compensation
ability to maintain constant puff volumes and puff profiles when the pressure drop at the port changes

Note 1 to entry: In practice, a change of the pressure drop is introduced by the connection of the test product to the machine or the inclusion of an aerosol trap.

[SOURCE: ISO 3308:2012, 3.18]

3.13
clearing puff
puff taken immediately after the THS has been removed from the *THS holder* (3.9) of the machine

[SOURCE: ISO 3308:2012, 3.23]

3.14
termination of collection
termination of the connection of the THS to the suction mechanism after completion of the requested number of puffs

3.15
electrically heated tobacco product
eHTP
product containing a tobacco substrate that is designed to be heated with an electrical tobacco heating device (THD) without combustion of the tobacco substrate in order to produce a nicotine-containing aerosol

Note 1 to entry: eHTP category includes products that:

— are the heated tobacco product (HTP) part of a tobacco heating system (THS);

— contain a tobacco substrate that is encapsulated or wrapped in paper or other material;

— are designed to be used with an electrical tobacco heating device (THD) that:

  — applies indirect resistive, inductive or other electrical method of heating of the tobacco substrate;

  — designed to prevent combustion of the tobacco substrate;

  — are battery powered.

Note 2 to entry: eHTP category may include products that have:

— a puff count and/or use duration that is limited by either the design of the heated tobacco product (HTP) or tobacco heating device (THD) hardware/software.

Note 3 to entry: eHTP category does not include products that are designed to have:

— combustion of any material including tobacco; or that are

— electrically heated waterpipe tobacco products; or

— electrically heated loose-leaf tobacco products.

Note 4 to entry: See NOTE in the Introduction.

Note 5 to entry: An ISO standard or a revision of this document, which provides a test method for analysing tobacco heating systems to support the assessment if combustion occurs is under development within ISO/TC 126.

[SOURCE: ISO 6080:2024, 3.2.1]

4 Standard conditions

4.1 Machine pressure drop

The whole of the flow path between the port of the eHTP aerosol collection system and the suction mechanism shall offer the least possible resistance, and its pressure drop shall not exceed 300 Pa.

4.2 Puff duration

The standard puff duration shall be (2,00 ± 0,02) s.

4.3 Puff volume

The standard puff volume shall be (55,0 ± 0,6) ml determined at the port of the machine in series with a pressure drop device of (1 000 ± 50) Pa.

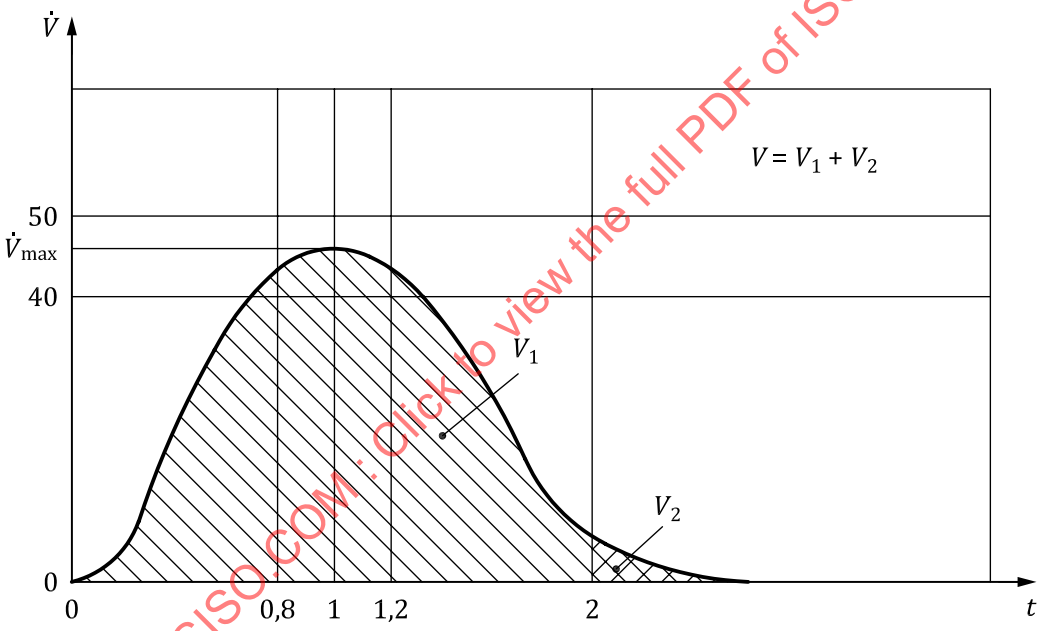
4.4 Puff frequency

The standard puff frequency shall be one puff starting every (30,0 ± 0,5) s.

4.5 Puff profile

The puff profile shall be measured with an impedance of (1 000 ± 50) Pa, as specified in 4.3. It shall be shaped as shown in Figure 1 (known as bell-shape profile) with a maximum between 0,8 s and 1,2 s from the start of the puff. The increasing and decreasing parts of the profile shall not have more than one point of inflection each. The maximum flow rate shall be between 40 ml/s and 50 ml/s. At no point shall the direction of flow be reversed.

The standard puff volume V, with $V = V_1 + V_2$, measured in series with a pressure drop device of (1 000 ± 50) Pa shall be (55,0 ± 0,6) ml. In one puff duration not less than 95 % of the puff volume shall leave the mouth end of the eHTP (V_1).



Key

$\dot{V}$ volumetric flow, ml/s

t time, s

NOTE Puff profile (idealized) according to ISO 20778:2018, 4.4.

Figure 1 — Puff profile (idealized)

4.6 Puff number

Each individual puff shall be counted and recorded until the collection process is terminated. The machine shall be capable of taking a predetermined number of puffs or allowing operator termination. Refer to 5.10 and 5.11 for initiation and termination of puffing.

5 Specification of the machine

5.1 General

The machine shall conform with the standard conditions (see 4.1 to 4.6).

5.2 Operating principle and puff profile

5.2.1 The machine shall include a device to draw a fixed volume of air (puff) through the THS.

5.2.2 The machine shall produce a bell shape puff profile (see 4.5). A schematic diagram is shown in Figure 1.

5.2.3 The machine shall be switched on and allowed to warm up on automatic cycling for at least 20 min. With the machine warmed up, check that the puff volume on each channel is in accordance with the standard conditions (see 4.3).

5.3 Reliability and compensation

5.3.1 The machine shall contain devices to control the puff volume, the puff duration, and the puff frequency.

5.3.2 The machine shall possess the mechanical and electrical reliability necessary to meet the standard conditions regarding these parameters (see 4.1 to 4.6) for prolonged periods of testing.

5.3.3 The machine shall be capable of sufficient compensation.

When the machine has initially been set to give a puff volume of (55,0 ± 0,6) ml without a pressure drop device, a reduction of no more than 2,5 ml shall be observed when the machine is tested with a pressure drop device of 2 kPa.

5.3.4 The machine shall be capable of taking one or more clearing puffs after the termination of collection as needed in regard to the requirements of analytical methods to measure the aerosol components.

5.3.5 Each port should have its own puff counter.

5.4 THS holder

5.4.1 The design of the THS holder is such that it shall connect the THS to the port of the machine in a leak-free manner and cover 9,0 mm, with a range of 8,0 mm to 9,5 mm, from the mouth end of a THS. It shall be impermeable to air and HTP aerosol.

NOTE For samples with a diameter between 4,5 mm and 9 mm the cigarette holder described in ISO 3308 can be used without the neoprene washer.

5.4.2 The product orientation should be horizontal. Some products or analytical methods may require a product orientation other than horizontal. In this case, this should be noted in the reporting documents.

5.5 Aerosol traps

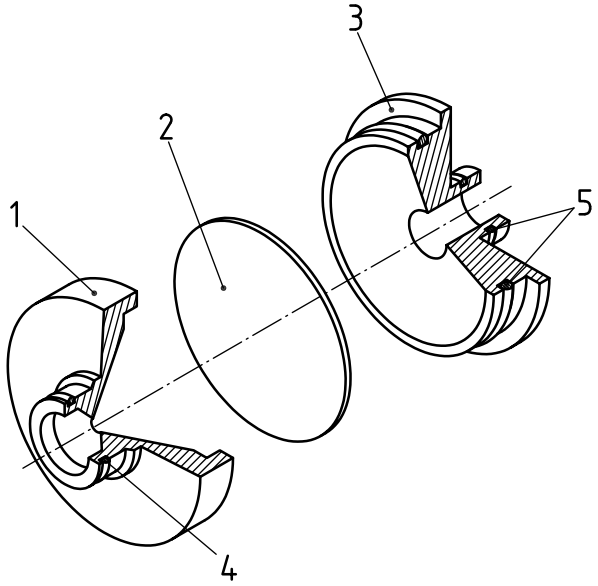
5.5.1 When the machine is used for collecting aerosol, a trap shall be fitted between the suction source and the THS. The type of trap will depend on the purpose for which the aerosol is being collected. The efficiency

of aerosol collection by the trap shall be specified in the analytical method. When a filter trap is used for collecting aerosol, it should be comprising the following.

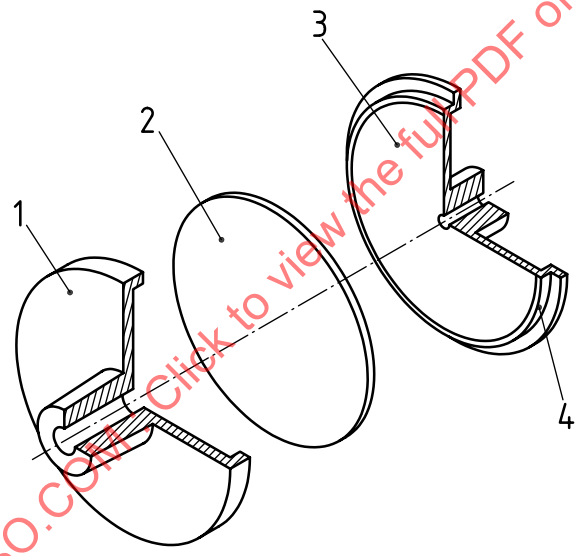
a) Airtight filter holder and end caps made of a non-hygroscopic and chemically inert material, able to contain a filter disc of glass fibre material 1 mm to 2 mm thick. The rough filter surface shall face the oncoming aerosol. Different designs of aerosol trap can meet this requirement. Depending on the amount of aerosol collected, filter pads with a diameter of 44 mm and 92 mm can be used but other sizes are also available. Two examples are given in Figure 2.

b) Filter material which shall retain at least 99,9 % of all particles having a diameter equal to or greater than 0,3 µm of a dioctyl phthalate aerosol at a linear air velocity of 140 mm/s. The pressure drop of the filter assembly shall not exceed 900 Pa at this air velocity. The content of binder shall not exceed 5 % as mass fraction. Polyacrylate and polyvinyl alcohol (PVA) have been found to be suitable binders for this material.

5.5.2 The filter assembly shall be capable of quantitatively retaining the aerosol produced by the THS without loss.



a)



b)

Key

1 GF holder front
2 filter pad
3 GF holder back
4 "O"-ring seal
5 "O"-ring seals

NOTE Examples of glass fibre filter (GF) aerosol traps (schematic) according to ISO 20778:2018, 5.4.7.

Figure 2 — Examples of glass fibre filter (GF) aerosol traps (schematic)

5.6 Sample conditioning and handling

5.6.1 The eHTPs shall be temperature equilibrated in sealed packs for a minimum of 48 h and a maximum of 10 d at a conditioning temperature of (22 ± 1) °C**.** This period may be changed if the testing laboratory is able to demonstrate that there is no statistically significant influence on yields.

NOTE THDs are stored according to the manufacturer's instructions.

5.6.2 eHTPs shall be removed from the pack immediately prior to testing, in order to avoid absorption of environmental moisture by the tobacco substrate which can influence aerosol yields.

5.6.3 eHTPs removed from open packs may be kept in sealed containers for a maximum of 4 h; after this time, they should no longer be regarded as suitable for testing and should be discarded. This period may be extended if the testing laboratory is able to demonstrate that there is no statistically significant influence on yields.

5.7 Test atmosphere

The test atmosphere shall be applied as described in ISO 3402.

5.8 THD preparation

Battery state of charge can influence aerosol generation and composition. THDs should be charged, stored and cleaned according to manufacturer's instructions and/or study testing protocol prior to commencement of testing.

5.9 Vent blocking

Vent blocking should be applied to eHTPs only if (a) ventilation holes in the product "filter" section can be occluded in normal use and (b) vent blocking does not compromise the operation of the THS.

When vent blocking of the filter ventilation holes is required, this may be accomplished by two approaches:

a) A modified sample holder which fully occludes the ventilation holes.

b) The ventilation holes are sealed with tape: a 10 mm to 20 mm wide cellophane tape shall be applied around the entire circumference of the eHTP with a small overlap, with the tape not extending beyond the mouth end or any part of the consumable which can enter the heating section of the device.

5.10 Initiation of collection

If the THD has a preheating cycle, then the THD should be activated and complete its preheating cycle, prior to commencing puffing and aerosol collection. When the THD indicates the completion of the preheating cycle (e.g. LED indication or haptic feedback), puffing and aerosol collection should be immediately initiated.

5.11 Termination of collection

Typically, a THD has a defined session length/heating cycle duration or puff count and indication by LEDs and/or haptic feedback on completion of the session/heating cycle. If completion of the session/heating cycle occurs at the same time as a puff is taken, puffing and aerosol collection should be terminated after this puff. If the completion of the session/heating cycle does not occur at the same time as a puff being taken, then an additional puff should be taken prior to termination of the aerosol collection.

If the heating duration is known in advance through prior testing or information provided to the user (e.g. product information leaflet) then the appropriate predetermined number of puffs may be set on the machine.

EXAMPLE 1 A device has a preheating cycle of 20 s, followed by a 300 s session/heating cycle.

The completion of the preheating (20 s) and start of the session/heating cycle is signalled by LED indication. At this point, the puffing cycle is initiated. With the first puff being taken at t=0 and then at 30 s puff intervals