



**SLOVENSKI STANDARD**  
**oSIST prEN 17746:2021**  
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**Elektronske cigarete in e-tekočine - Ugotavljanje doslednosti pri dovajanju nikotina v določenem zaporedju vdihavanja pri eni e-cigareti**

Electronic cigarettes and e-liquids - Determination of nicotine delivery consistency over defined puff sequences within a single e-cigarette

Elektronische Zigaretten und Liquids für elektronische Zigaretten - Bestimmung der Konsistenz der Nikotinabgabe über definierte Puffsequenzen innerhalb einer einzelnen E-Zigarette

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**ICS:**

65.160

Tobak, tobačni izdelki in oprema

Tobacco, tobacco products and related equipment

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**en**

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EUROPEAN STANDARD  
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**prEN 17746**

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ICS 65.160

English Version

## Electronic cigarettes and e-liquids - Determination of nicotine delivery consistency over defined puff sequences within a single e-cigarette

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 437.

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EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

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## European foreword

This document (prEN 17746:2021) has been prepared by Technical Committee CEN/TC 437 “Electronic cigarettes and e-liquids”, the secretariat of which is held by AFNOR.

This document is currently submitted to the CEN Enquiry.

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**prEN 17746:2021 (E)****1 Scope**

This document specifies the method for the determination of nicotine delivery consistency of a single electronic cigarette [1].

This document:

- defines the equipment to be used specifies the preparation of the e-cigarette samples for testing;
- specifies the aerosol generation process;
- specifies the analytical method;
- specifies the determination of the test result.

**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.

EN 17375, *Electronic cigarettes and e-liquids — Reference e-liquids*

ISO 20768, *Vapour products — Routine analytical vaping machine — Definitions and standard conditions*

ISO 24199,<sup>1</sup> *Vapour products — Determination of nicotine in vapour product emissions — Gas chromatographic method*

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**3 Terms and definitions**

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For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological 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****electronic cigarette**

product, that vaporises e-liquid to generate an inhalable aerosol carried by air drawn through the device by the user

Note 1 to entry: Electronic cigarette is also referred to as e-cig, vapour product, personal vapouriser or ENDS/ENNDS.

Note 2 to entry: Electronic cigarette differs from tobacco products in that they do not contain tobacco.

**3.2****e-liquid**

base liquid, which may or may not contain nicotine and/or additives, intended for transformation into an aerosol by an electronic cigarette

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<sup>1</sup> Under preparation. Current stage is: ISO/DIS 24199:2021.

**3.3****vaped until exhaustion**

aerosol generation via puffing machine until a pre-determined endpoint

**3.4****open system**

electronic cigarette where the user fills a reservoir with e-liquid

**3.5****aerosol collected mass**

ACM

mass of aerosol collected on an aerosol trapping system from the operation of a vapour product by a routine analytical vaping machine after a defined number of puffs

Note 1 to entry: Routine analytical vaping machine is described in ISO 20768.

**3.6****vaping**

action of generating an aerosol with an airflow from an electronic cigarette

**3.7****aerosol**

system of colloidal particles suspended in gas by the use of an e-cigarette

Note 1 to entry: Vapour is a generally accepted (but scientifically incorrect) term for aerosol.

**3.8****nicotine**

(S)-3-(1-methyl-2-pyrrolidinyl)pyridine conforming to the Chemical Abstracts Service nomenclature under No CAS: 54-11-5

**3.9****clearomizer**

e-liquid reservoir with in-built atomizer

**3.10****e-liquid cartridge**

e-liquid container that can be loaded directly into an e-cigarette, which can be disposable

**3.11****device**

assembly which consists of electronic cigarette components, intended to vaporise an e-liquid

**3.12****coil**

resistive component of the atomiser

Note 1 to entry: Made of metal, ceramic, or other resistive materials.

**3.13****sequence**

defined number of puffs for aerosol generation

**prEN 17746:2021 (E)****4 Principle**

The test specimens are vaped until exhaustion (of battery or liquid) on a routine analytical vaping machine with simultaneous collection of sequences of aerosol collected mass. If used, the consistency of the laboratory vaping process and subsequent analytical procedures are controlled by using a standardized clearomizer or a reference clearomizer together with a standardized e-liquid as specified in EN 17375. The aerosol collected mass is used for the subsequent determination of nicotine. The determined amount of nicotine per sequence can be used for the statistical determination of nicotine delivery consistency.

**5 Apparatus**

Use the apparatus as defined by the ISO method for nicotine determination in aerosol. As long as this standard is not published, use the items listed in Annex A.

**6 Sampling**

The sample should contain products taken from different parts of the population. Make up the test sample required for the test by randomly selecting products from the different parts of the population represented in the laboratory sample.

**7 Generation of aerosol collected mass for determination of consistency of nicotine delivery**

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**7.1 Sample preparation for analytical vaping**

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**7.1.1 General**

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At least 5 devices are needed.

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For the determination of the required numbers of puff per sequence 2 devices are needed

For the determination of the consistent nicotine delivery a minimum of three un-used replicates of the product have to be tested.

It is recommended to prepare at least two more products in the same way for redundancy in case any problems occur during testing.

**7.1.2 Disposable products**

For testing disposable products, a fresh product shall be taken from an un-opened pack.

**7.1.3 Rechargeable Products**

For any products equipped with rechargeable batteries ensure that the battery is fully charged following the instructions for use.

**7.1.4 Refillable Products**

For any products with the e-liquid supplied in pre-filled e-liquid cartridges a new e-liquid cartridge shall be taken from an un-opened pack and inserted into the product following the instructions for use.

Any products designed for individual filling (open systems) shall be filled with the type of e-liquid specified in the device's instructions for use. If no specific e-liquids or e-liquid characteristics are specified, one of the standard liquids as specified in EN 17375 shall be used. The device shall be filled to its maximum level following the instructions for use.



## 7.2 Preliminary tests before vaping

The following tests shall be performed prior to the vaping process:

- a) check the device for any leakages (CEN/TS 17287:2019) [2];
- b) make sure that the battery works;
- c) for manually filled devices note the amount of liquid filled to the nearest 0,1 ml;
- d) the product shall be primed in accordance with its instructions for use. If no specific instructions are provided, the first 5 puffs shall be puffed to waste prior to the first weighing of the device;
- e) weigh the filled device prior to vaping to the nearest 1 mg.

## 7.3 Vaping and collection of aerosol collected mass

### 7.3.1 Vaping plan

Products with a fixed power setting are to be tested as they are. Products with adjustable power settings have to be tested as recommended by the instructions for use or if not available, with feasible minimum and maximum power setting. Every test shall be replicated using a second product.

### 7.3.2 Collection of the aerosol

Collection of aerosol and determination of nicotine in the aerosol, shall be performed in accordance with ISO/DIS 24199, *Vapour products — Determination of nicotine in vapour product emissions — Gas chromatographic method*.

As long as the international standard for the determination of nicotine in the aerosol of e-cigarettes is not yet published, it is recommended to follow the Coresta recommended method No.84 for this purpose [3].

### 7.3.3 Setting up the vaping machine

If necessary, replace any protective filters on the machine. Switch on the machine and allow it to warm up on automatic cycling for at least 20 min.

With the machine warmed up, check that the puff volume, the puff duration and the puff period on each channel are in accordance with the standard conditions given in ISO 20768. Adjust the machine if necessary.

### 7.3.4 Procedure for vaping run

#### 7.3.4.1 General

Insert the products to be tested into the product holders. Avoid any leaks or deformations. Any products found to have obvious defects shall be discarded and replaced by prepared spare products.

Ensure that the products are positioned correctly so that the axes of the mouthpiece coincide with the axes of the ports. If available or needed adjust the position of each product support and push button activator, following the user instructions given by in the vaping machine manual.

#### 7.3.4.2 Determination of sequence size

Start the vaping process as described in ISO 20768. After 20 puffs stop the vaping process, remove the aerosol trap. Weigh the device to the nearest 1 mg and based on the differential with the pre-vaping weight, estimate the device aerosol delivery. The number of puffs per sequence are chosen based of the expected amount of aerosol from the device and taking into account the aerosol collection method and the analytical method for nicotine. A recommendation is given in Table 1.

**Table 1 — Determination of number of puffs per sequence**

Per puff delivery of aerosol collected mass	Recommended # of puffs/sequence
≤ 15 mg/puff	20
> 15 mg/puff, ≤ 30 mg/puff	10
> 30 mg/puff	5

Discard the aerosol trap used for the pre-test from further analysis and replace it by a freshly prepared one (gloves shall be worn). Adapt the number of puffs to be captured in the aerosol trap.

#### 7.3.4.3 Vaping run

Prepare a new device in accordance to the mentioned procedure. Re-start the vaping process with the identified number of puffs per sequence. Replace the aerosol trap after every sequence by a freshly prepared one.

Immediately after removing from the machine, weigh the aerosol traps to the nearest 1 mg. Note the result and seal the traps with suitable caps. Calculate the differential weight between the loaded and unloaded trap. Repeat the procedure until the conditions for tank refill as indicated in the instructions for use are exceeded. If there are no related instructions, then repeat until more than 75 % of the weight of added e-liquid has been consumed as per device mass loss. The last sequence has to be discarded. If the battery exhausts before this point is being reached, fully re-charge the battery and continue the test. The related sequence needs to be discarded as well as the last sequence during which the 75 % of mass loss has been determined. Note the number of valid sequences and keep the traps sorted in regards.

Also weigh the device to the nearest 1 mg before and after any sequence. Calculate the differential weight and the ratio of the device mass loss to the captured aerosol mass for the individual sequence. Unusually high ratios are an indication of device leakage or other issues that invalidate the result for that sample. Therefore, if this ratio represents a statistical outlier for at least 2 sequences, the test shall be repeated with a new product.

### 7.4 Determination of nicotine

For the determination of nicotine follow the procedure given by the related ISO or EN standard (ISO/DIS 24199). As long as no international standard (ISO or CEN) for the determination of nicotine in the aerosol of e-cigarettes is published, it is recommended to follow Coresta Recommended Method No.84 for this purpose [3]. Analyse the captured aerosol of all non-discarded sequences.

### 7.5 Determination of nicotine delivery consistency

For the calculation of nicotine delivery consistency, the deviation of the nicotine content of each single analysed sequence compared to the determined mean value of all analysed sequences related to each tested device shall be calculated and reported as well as the maximum deviation and the standard deviation.

**NOTE** To determine acceptability criteria for the measured nicotine delivery consistency, the different sources of variability that affect the test result need to be taken into account. This will include not only the variability of the analytical test method, but also knowledge of what is a reasonable variation in device performance given the current state of vaping product technology.