
Elektronske cigarete in e-tekočine - Ugotavljanje konsistentnosti porazdelitve nikotina v določenem zaporedju vdihavanja pri več e-cigaretah enakega tipa

Electronic cigarettes and e-liquids - Determination of nicotine delivery consistency over defined puff sequences of a number of e-cigarettes of identical type

Elektronische Zigaretten und Liquids für elektronische Zigaretten - Bestimmung der Konsistenz der Nikotinabgabe über definierte Zugsequenzen einer Anzahl von E-Zigarette identischen Typs

Cigarettes électroniques et e-liquides - Détermination de la constance de délivrance de la nicotine lors de séquences de bouffées définies avec plusieurs e-cigarettes identiques

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Elektronische Zigaretten und E-Liquids - Bestimmung der gleichmäßigen Abgabe von Nikotin über definierte Zugsequenzen einer Anzahl von E-Zigaretten identischen Typs

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European foreword

This document (EN 17634:2023) has been prepared by Technical Committee CEN/TC 437 “Electronic cigarettes and e-liquids”, the secretariat of which is held by AFNOR.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2023, and conflicting national standards shall be withdrawn at the latest by November 2023.

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EN 17634:2023 (E)

1 Scope

This document specifies a method for the determination of nicotine delivery consistency between e-cigarettes (devices, consumables and combinations).

This document:

- defines the equipment to be used;
- specifies the preparation of the samples for testing;
- specifies the aerosol collection process;
- specifies the analytical method.

Suitable sampling procedures are described for obtaining results from within a single production batch, as well as for sampling across batches.

The method in this document does not seek to demonstrate whether there is consistency between puffs generated at the start or nearer the end of a tank fill or battery charge. The latter is the aim of a separate method under development, EN 17746 *Electronic cigarettes and e-liquids — Determination of nicotine delivery consistency over defined puff sequences within a single e-cigarette* [1]. Two separate methods have been developed to determine consistency of nicotine delivery, pending regulatory clarity on the Tobacco Products Directive's requirement to “deliver nicotine doses at consistent levels” [2].

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*

EN ISO 24197, *Vapour products — Determination of e-liquid vaporized mass and aerosol collected mass (ISO 24197)*

EN ISO 24199, *Vapour products — Determination of nicotine in vapour product emissions — Gas chromatographic method (ISO 24199)*

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

3 Terms and definitions

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/ui>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1 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.

3.2**clearomizer**

e-liquid reservoir with in-built atomizer

3.3**coil**

resistive component of the atomiser

Note 1 to entry: Coils are made of metal, ceramic, or other resistive materials.

3.4**electronic cigarette****e-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 vaporizer or ENDS/ENNDS.

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

3.5**e-liquid**

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

3.6**e-liquid cartridge**

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

3.7**e-liquid vaporized mass**

EVM

mass of e-liquid transferred from the vapour product to the aerosol

3.8**identical e-cigarettes**

e-cigarettes made according to the same technical specifications and with the same brand and model name

3.9**nicotine**

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

3.10**open system**

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

3.11**sequence**

defined number of puffs for aerosol generation

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3.12

vaping

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

4 Principle

Average nicotine delivery from the first two puff sequences of a fully charged and filled electronic cigarette is measured and compared against the average of the nicotine deliveries measured from the same puff sequences from several samples of the same electronic cigarette. The aim is to demonstrate consistency between products.

The test e-cigarettes are vaped on a routine analytical vaping machine that meets the requirements of ISO 20768, with collection of sequences of aerosol. 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 collected aerosol is used for the subsequent determination of nicotine. The determined amount of nicotine per sequence is used for the statistical determination of nicotine delivery consistency. EN ISO 24197 and EN ISO 24199 shall be used.

5 Apparatus

Use the apparatus as defined by EN ISO 24199.

6 Sampling of test e-cigarettes

Measurements for the determination of the consistent nicotine delivery shall be performed across a sample size of at least 10 electronic cigarettes (devices, consumables or combinations). If the purpose of the testing is to obtain data on the consistency of nicotine delivery within a production batch, or across several production batches, the samples shall be randomly taken from the production batch(es).

7 Generation and collection of aerosol

7.1 E-cigarette preparation for analytical vaping

7.1.1 General

For the overall protocol for the determination of the consistent nicotine delivery, at least 12 test e-cigarettes are needed: 2 for the determination of the required number of puffs and 10 for the determination of the consistent nicotine delivery as per Clause 6. It is recommended to prepare at least 2 more e-cigarettes in the same way for redundancy in case any problems occur during testing.

7.1.2 Disposable e-cigarettes

For testing disposable e-cigarettes, a fresh e-cigarette shall be taken from an unopened pack.

7.1.3 Rechargeable e-cigarettes

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

7.1.4 Refillable e-cigarettes

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

Any e-cigarettes designed for individual filling (open systems) shall be filled with the type of e-liquid specified in the e-cigarette's instructions for use. If no specific e-liquids or e-liquid characteristics are specified, one of the standard e-liquids as specified in EN 17375 shall be used. The e-cigarette 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 e-cigarette for any leakage;
- b) make sure that the battery works;
- c) for manually filled e-cigarettes note the amount of e-liquid filled (in mg);
- d) the e-cigarette 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 e-cigarette;
- e) weigh the filled e-cigarette prior to vaping to the nearest 1 mg.

7.3 Vaping and collection of aerosol

7.3.1 Vaping plan

E-cigarettes with a fixed power setting shall be tested as they are. E-cigarettes with adjustable power settings shall be tested using the settings recommended by the instructions for use. If multiple settings are recommended, the maximum and minimum recommended power settings shall be tested. If the e-cigarette is intended for use with various coils, as indicated in the instructions for use, each combination of e-cigarette and coil shall be tested separately. If the instructions for use do not provide recommended power settings, the maximum and minimum feasible power settings shall be used. Testing for consistency of nicotine delivery shall be performed for each applicable power setting and e-cigarette - coil combination using at least 10 test e-cigarettes. ist-en-17634-2023

7.3.2 Preparation for vaping run

Prepare and attach aerosol traps to the vaping machine following the procedure described in EN ISO 24199. Set up the vaping machine in accordance with the manufacturer's instructions for use. Puff volume, puff duration and the puff period settings shall be in accordance with the standard conditions given in ISO 20768.

7.3.3 Procedure for vaping run

7.3.3.1 General

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

Ensure that the e-cigarettes 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 e-cigarette support and push button activator following the user instructions in the vaping machine manual.

EN 17634:2023 (E)**7.3.3.2 Determination of sequence size**

Perform this procedure for two e-cigarettes. Puff 20 puffs to waste. Weigh the e-cigarette to the nearest 1 mg and based on the differential with the pre-vaping weight, estimate the e-liquid vaporized mass (EVM). The number of puffs per sequence are chosen based on the average estimated EVM 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 estimated EVM	Recommended number of puffs/sequence
≤ 5mg/puff	50
> 5 mg/puff, ≤ 15 mg/puff	20
> 15 mg/puff, ≤ 30 mg/puff	10
> 30 mg/puff	5

Adapt the number of puffs to be captured in the aerosol trap.

7.3.3.3 Vaping run

The determination of nicotine delivery consistency is done using the first two sequences of puffs for each single e-cigarette.

Immediately after removing the aerosol trap from the machine, weigh it to the nearest 1 mg. Note the result and seal the trap with suitable caps. Calculate the differential weight between the loaded and unloaded trap. Also weigh the e-cigarette to the nearest 1 mg. Calculate the differential weight between the e-cigarette weight before and after the vaping into the second trap.

Repeat the procedure for the remaining test e-cigarettes.

Calculate the ratio of the EVM to the captured aerosol mass for each of the test e-cigarettes. If this ratio represents a statistical outlier based on published data or historical in-house experience, this suggests there were issues with the vaping that could invalidate the results. As long as this applies to no more than 2, out of 10 of the e-cigarettes, results from these outlier e-cigarettes need not be included in the evaluation described in 7.4. Instead, results from any additional e-cigarettes that were run as per 7.1.1, can be used and a justification included in the report, describing the procedure applied to establish whether samples were statistical outliers.

7.3.4 Determination of nicotine

The determination of nicotine shall follow the procedure described in EN ISO 24199. Analyse the captured aerosol of all e-cigarettes.

7.4 Determination of nicotine delivery consistency

For the determination of nicotine delivery consistency, the deviation of the nicotine content of any single analysed trap compared to the determined mean value of all analysed traps related to one e-cigarette shall be calculated.

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 e-cigarette performance given the current state of vaping product technology.