

SVENSK STANDARD

SS-EN 15964:2011



Fastställt/Approved: 2011-03-09
Publicerad/Published: 2011-04-28
Utgåva/Edition: 1
Språk/Language: engelska/English
ICS: 03.160; 71.040.40

Alkoholmätare för utandningskontroll avsedd för professionellt bruk – Krav och provningsmetoder

Breath alcohol test devices other than single use devices – Requirements and test methods

This preview is downloaded from www.sis.se. Buy the entire standard via <https://www.sis.se/std-76940>

Standarder får världen att fungera

SIS (Swedish Standards Institute) är en fristående ideell förening med medlemmar från både privat och offentlig sektor. Vi är en del av det europeiska och globala nätverk som utarbetar internationella standarder. Standarder är dokumenterad kunskap utvecklad av framstående aktörer inom industri, näringsliv och samhälle och befrämjar handel över gränser, bidrar till att processer och produkter blir säkrare samt effektiviserar din verksamhet.

Delta och påverka

Som medlem i SIS har du möjlighet att påverka framtida standarder inom ditt område på nationell, europeisk och global nivå. Du får samtidigt tillgång till tidig information om utvecklingen inom din bransch.

Ta del av det färdiga arbetet

Vi erbjuder våra kunder allt som rör standarder och deras tillämpning. Hos oss kan du köpa alla publikationer du behöver – allt från enskilda standarder, tekniska rapporter och standardpaket till handböcker och onlinetjänster. Genom vår webbtjänst e-nav får du tillgång till ett lättnavigerat bibliotek där alla standarder som är aktuella för ditt företag finns tillgängliga. Standarder och handböcker är källor till kunskap. Vi säljer dem.

Utveckla din kompetens och lyckas bättre i ditt arbete

Hos SIS kan du gå öppna eller företagsinterna utbildningar kring innehåll och tillämpning av standarder. Genom vår närhet till den internationella utvecklingen och ISO får du rätt kunskap i rätt tid, direkt från källan. Med vår kunskap om standarders möjligheter hjälper vi våra kunder att skapa verklig nytta och lönsamhet i sina verksamheter.

Vill du veta mer om SIS eller hur standarder kan effektivisera din verksamhet är du välkommen in på www.sis.se eller ta kontakt med oss på tel 08-555 523 00.



Standards make the world go round

SIS (Swedish Standards Institute) is an independent non-profit organisation with members from both the private and public sectors. We are part of the European and global network that draws up international standards. Standards consist of documented knowledge developed by prominent actors within the industry, business world and society. They promote cross-border trade, they help to make processes and products safer and they streamline your organisation.

Take part and have influence

As a member of SIS you will have the possibility to participate in standardization activities on national, European and global level. The membership in SIS will give you the opportunity to influence future standards and gain access to early stage information about developments within your field.

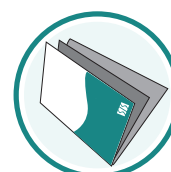
Get to know the finished work

We offer our customers everything in connection with standards and their application. You can purchase all the publications you need from us - everything from individual standards, technical reports and standard packages through to manuals and online services. Our web service e-nav gives you access to an easy-to-navigate library where all standards that are relevant to your company are available. Standards and manuals are sources of knowledge. We sell them.

Increase understanding and improve perception

With SIS you can undergo either shared or in-house training in the content and application of standards. Thanks to our proximity to international development and ISO you receive the right knowledge at the right time, direct from the source. With our knowledge about the potential of standards, we assist our customers in creating tangible benefit and profitability in their organisations.

If you want to know more about SIS, or how standards can streamline your organisation, please visit www.sis.se or contact us on phone +46 (0)8-555 523 00



Europastandarden EN 15964:2011 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN 15964:2011.

The European Standard EN 15964:2011 has the status of a Swedish Standard. This document contains the official version of EN 15964:2011.

© Copyright/Upphovsrätten till denna produkt tillhör SIS, Swedish Standards Institute, Stockholm, Sverige. Användningen av denna produkt regleras av slutanvändarlicensen som återfinns i denna produkt, se standardens sista sidor.

© Copyright SIS, Swedish Standards Institute, Stockholm, Sweden. All rights reserved. The use of this product is governed by the end-user licence for this product. You will find the licence in the end of this document.

Uppllysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS Förlag AB som även lämnar allmänna uppllysningar om svensk och utländsk standard.

Information about the content of the standard is available from the Swedish Standards Institute (SIS), telephone +46 8 555 520 00. Standards may be ordered from SIS Förlag AB, who can also provide general information about Swedish and foreign standards.

Denna standard är framtagen av kommittén för Alkoholmätare, SIS/TK 486.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

EUROPEAN STANDARD

EN 15964

NORME EUROPÉENNE

EUROPÄISCHE NORM

March 2011

ICS 03.160; 71.040.40

English Version

Breath alcohol test devices other than single use devices - Requirements and test methods

Ethylotests, autres que les dispositifs à usage unique -
Exigences et méthodes d'essais

Atemalkohol-Testgeräte zur Mehrfachverwendung -
Anforderungen und Prüfverfahren

This European Standard was approved by CEN on 29 January 2011.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.



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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents

Page

Foreword.....	4
Introduction	5
1 Scope	6
2 Normative references	6
3 Terms and definitions	7
4 Type-testing.....	8
5 Safety	8
5.1 General comments.....	8
5.2 Hygiene	8
5.3 Electrical safety.....	8
6 General specifications	8
6.1 General requirements.....	8
6.2 Maximum permissible error (MPE).....	9
6.3 Measurement range	9
6.4 Operating environmental conditions	9
6.4.1 Temperature	9
6.4.2 Humidity.....	9
6.5 Ease of use	9
6.6 Breath sampling method.....	9
6.7 Expression of results	9
6.7.1 Units of measurement	9
6.7.2 Rounding	10
6.7.3 Display	10
6.8 Adjustment	10
6.9 Start-up time.....	10
6.10 Frequency of measurement.....	10
6.11 Power supply duration	11
6.12 Data storage	11
6.13 General device functions	11
7 Metrological characteristics for testing	11
7.1 General conditions	11
7.2 Test gas characteristics.....	12
7.3 Reference conditions	12
7.4 Accuracy tests	12
7.4.1 General.....	12
7.4.2 Accuracy testing.....	13
7.4.3 Repeatability testing.....	13
7.4.4 Drift testing.....	13
7.5 Memory effects.....	14
7.5.1 Hysteresis.....	14
7.5.2 Effect of water vapour (condensation)	14
7.6 Influence factors	14
7.6.1 General.....	14
7.6.2 Operating temperature	14
7.6.3 Ambient relative humidity	15
7.6.4 Interfering substances	15
7.6.5 Influence factors exhalation parameters.....	16
7.6.6 Voltage variation (internal battery)	18

7.6.7	Power supply duration tests	18
7.7	Mechanical and climatic disturbances	19
7.7.1	General	19
7.7.2	Shock & vibration	19
7.7.3	Climatic environment	20
7.8	Electrical disturbances	21
7.8.1	General	21
7.8.2	Electrostatic discharge	22
7.8.3	Immunity to radiated electric fields	22
8	Marking	23
9	Operating instructions	23
Annex A	(informative) Example of type testing requirements	25
A.1	Additional information for compliance testing.....	25
A.2	Certification procedure	25
Annex B	(informative) Formula.....	27
Annex C	(informative) Simulated tetra immunity test	28
C.1	Test procedure – General	28
C.2	Test frequencies	28
C.3	Test limits	28
C.4	Modulation.....	28
Annex D	(informative) Software validation and verification	30
D.1	General	30
D.2	Security.....	30
	Bibliography.....	33

Foreword

This document (EN 15964:2011) has been prepared by Technical Committee CEN/TC 367 “Breath-alcohol testers”, 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 September 2011, and conflicting national standards shall be withdrawn at the latest by September 2011.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

Breath alcohol test devices are widely used in Europe in professional applications like law enforcement, promotion of traffic safety and work safety. Test results may lead to severe consequences for everybody involved. Therefore, the test results need to be reliable and acceptable.

This document contains a description of the minimum technical requirements to be met for compliance testing of multi-use breath alcohol test devices. It contains also details concerning the compliance testing and performance requirements of breath alcohol test devices as a prerequisite for approval ¹⁾.

References may also be made to sections of this document for lot-by-lot testing.

Any appropriate technology capable of providing the functionality required in this document may be used.

Breath alcohol test devices considered in this standard use mouthpieces for sampling the breath specimens.

1) European standardization does not cover those subjects that clearly belong to the domain of regulation of the Member States unless this is explicitly supported by the national authority (i.e. regulatory measures remain the competence of the various Member States).

1 Scope

This European Standard applies to breath alcohol test devices which measure the concentration of alcohol contained in an exhaled breath sample intended to be used for screening or preliminary testing. This standard specifies requirements for basic safety and performance, test methods and requirements for marking, labelling and operating instructions.

This standard gives guidelines for type approval procedure consisting of a number of technical performance tests, but excluding in vivo tests, that are carried out on devices supplied by the manufacturers.

In vivo tests, which are designed to test the ability of the device to work with real subjects, may be arranged in compliance with national requirements.

This standard is not applicable to devices covered by OIML R 126:1998 (Evidential breath analyzers) or single use testers.

Devices are designed for law enforcement.

2 Normative references

The following referenced documents are indispensable for the application 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 60068-2-1, *Environmental testing — Part 2-1: Tests — Test A: Cold*

EN 60068-2-2, *Environmental testing — Part 2-2: Tests — Test B: Dry heat*

EN 60068-2-6, *Environmental testing — Part 2-6: Tests — Test Fc: Vibration (sinusoidal)*

EN 60068-2-27, *Environmental testing — Part 2-27: Tests — Test Ea and guidance: Shock*

EN 60068-2-30, *Environmental testing — Part 2-30: Tests — Test Db: Damp heat, cyclic (12 h + 12 h cycle)*

EN 60068-2-32, *Basic environmental testing procedures — Part 2: Tests — Test Ed: Free fall*

EN 60068-2-64, *Environmental testing — Part 2-64: Tests — Test Fh: Vibration, broadband random and guidance*

EN 60068-2-78, *Environmental testing — Part 2-78: Tests — Test Cab: Damp heat, steady state*

EN 60335-2-29, *Household and similar electrical appliances — Safety — Part 2-29: Particular requirements for battery chargers*

EN 61000-4-2, *Electromagnetic compatibility (EMC) — Part 4-2: Testing and measurement techniques — Electrostatic discharge immunity test*

EN 61000-4-3, *Electromagnetic compatibility (EMC) — Part 4-3: Testing and measurement techniques — Radiated, radio-frequency, electromagnetic field immunity test*

3 Terms and definitions

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

3.1

alcohol

considered to be ethanol

3.2

breath alcohol test device

device which accepts a breath specimen, measures the concentration and indicates the level of alcohol in that breath specimen

3.3

operating state

state of the device in which it is able to take a breath specimen and determine the alcohol level in that breath specimen

3.4

normal mode

mode in which the device is ready to measure and display the level of alcohol in the breath specimen of the subject under test, either quantitatively or by preset level indication

NOTE e.g. Pass or Fail

3.5

test mode

mode in which the device displays the result of a test gas specified in this standard in numerical format

3.6

unit of measurement

concentration of ethanol expressed in milligrams of ethanol per litre of exhaled volume

NOTE Concentration in ethanol may be expressed in any other equivalent units, e.g. mg/L, µg/L or µg/100 ml.

3.7

manufacturer

natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party

3.8

MPE

maximum permissible error

extreme allowed value of measurement with respect to a test gas concentration defined in this standard

3.9

verification

testing process to establish that the breath alcohol test device is operating within the limits of the defined MPE and repeatability

3.10

adjustment

process required to correct the measurement value of the breath alcohol test device when it is found to be outside of the defined MPE

3.11

mouthpiece

hygienically wrapped part intended for single use that is fitted to the breath alcohol test device through which the subject under test provides the breath specimen

NOTE A mouthpiece is used to prevent the breath sample being mixed with ambient air and diluting the alcohol concentration.