20 דצמבר 2007

התייחסות לתשובתו של נציג חברת דראגר ד"ר יורגן זוהייש מגרמניה.

אני, הח"מ דר' איליה פוליצ'וק, התבקשתי ע"י עו"ד קולקר בתאריך 17.12.2007 ליתן את התייחסותי למכתבו של ד"ר יורגן זוהייש אשר הובא במסגרתה של "התייחסות קצין מדור מכשור וטכנולוגיה לחוות דעת מומחים מטעם ההגנה" מאת רפ"ק דוד כתר, להלן "המכתב". מלבד המסמך הנ"ל הונחו לפניי חוות דעתם של דר' דריו ורטניק ומגר' ודים לוזנסקי "פעולת הכיול היומי המבוצעת על ידי משטרת ישראל במכשיר "דראגר אלקוטסט 7110MK III IL"", להלן "חוות הדעת" וכמו כן תגובת התביעה בתיק "מדינת ישראל נגד שלומי לפידות", אשר כוללת טפסים של ביקורת חצי-שנתית למכשיר זה. התייחסותי זו מסתמכת על הנאמר במסמכים דלעיל. אני מצהיר כי ידועים לי היטב הוראות החוק הפלילי בדבר עדות שקר בבית המשפט. דין התייחסותי זו כשהיא חתומה על ידי כדין עדות בשבועה בבית המשפט.

להלן הפרטים אודות השכלתי המקצועית ואודות עבודתי

השכלה:

2004-2003: לבתר-דוקטורט בתרמודינאמיקה באוניברסיטת מאק-גיל, מונטריאל, קנדה.
2003-1999: Ph.D. (Summa Cum Laude) בהנדסה כימית באוניברסיטת בן-גוריון בנגב.
1999-1998: M.Sc. (בהצטיינות) בהנדסה כימית באוניברסיטת בן-גוריון בנגב.
1996-1992: B.Sc. בהנדסה כימית באוניברסיטת בן-גוריון בנגב.

פרסים ומענקים:

2007: זכייה במענק מחקר מטעם הקרן לחקר הנפט (PRF) של האגודה האמריקאית לכימיה (ACS).
2003: מלגת Porjes Charitable Trust.
2002: פרס וולף על עבודת מחקר מצטיינת.
2001: מענק מטעם הלשכה הגרמנית לחילופי האקדמאים (DAAD).
2001: פרס הצטיינות של חברת אינטל.
2001: פרס טרומבקי על עבודת מחקר מצטיינת.
1999: פרס הצטיינות של המחלקה להנדסה כימית, אוניברסיטת בן-גוריון בנגב.

פרסומים:

יותר מ-30 פרסומים בכתבי-עת הבינלאומיים המובילים כגון:

Journal of Physical Chemistry (B), Physical Chemistry Chemical Physics, Industrial and Engineering Chemistry Research, Chemical Engineering Science, AIChE Journal.

שופט מאמרים ב-8 כתבי-עת בינלאומיים.

תפקיד הנוכחי:

מרצה בכיר במחלקה להנדסה כימית וביוטכנולוגיה של המרכז האוניברסיטאי אריאל. מעביר קורסים: תרמודינאמיקה 1 (תכונות של חומרים טהורים), תרמודינאמיקה 2 (תכונות של תערובות), קינטיקה ותכנון ריאקטורים וביוריאקטורים, מעבדה לקינטיקה ותכנון ריאקטורים וביוריאקטורים.

בעבר העברתי קורסים: הנדסה 3 (מעבר מסה), הנדסה 4 (תכנון ציוד למעבר מסה), מעבדה להנדסה כימית.

המחקר שלי מתמקד בהערכת התכונות של חומרים ותערובותיהם, פיתוח מודלים לשיווי משקל בין פאזות, תכנון ציוד ומכשור.

חבר באגודה האמריקאית לכימיה (ACS).

השתלמויות בחו"ל:

2005- המחלקה להנדסה כימית, אוניברסיטת טוחוקו, סאנדאי, יפן.

2002 - המעבדה להערכת התכונות התרמודינאמיות, אוניברסיטת קונספסיון, קונספסיון, צ'ילה.

2001- המכון לכימיה פיזיקאלית, אוניברסיטת קאולן, קאולן, גרמניה.

וזאת התיחסותי:

בפתח דבריו קובע ד"ר זוהייש כי מקובל להפעיל את הציוד למדידת אלכוהול בנשיפה לפי הנהלים של המטרולוגיה הרשמית במילים הבאות:

“As a common practice breath alcohol measuring devices are handled as instruments ruled by legal metrology procedures.”

אכן, מכשירי הנשיפה ורדאר הם היחידים מבין מגוון ציוד את"ן אשר קיימים לגביהם ההמלצות של הארגון הבינלאומי למטרולוגיה הרשמית, International Organization of Legal Metrology (OIML R126),

להלן "ההמלצות הבינלאומיות" (ראה נספח 1). חשוב לציין כי ישראל הינה חברה בארגון זה ומחויבת להמלצותיו [1]. לכן במקרה של מכשירי הנשיפה אין מקום לספקות ופרשנויות לגבי סטנדרטים והליכי ההפעלה אשר קיימים במקרים של מכשירים אחרים, לדוגמה הממל"ז. בין היתר, קובעות ההמלצות הבינלאומיות תקנים ברורים ומחייבים אשר מבטיחים את מיומנותה של פעולת הכיול יומי. כך דן הפרק 9.2 של ההמלצות הבינלאומיות בגז הכיול הקובע:

9.2 Characteristic reference values of the test gas

Unless otherwise specified, the test gas shall be characterized by the following parametric values:

- delivered volume: 3 L;
- total duration of injection (into breath analyzer): 5 s;
- duration of plateau of mass concentration (when injecting into the EBA): 3 s;
- carrier gas: pure air;
- gas temperature: 34 °C ± 0.5 °C;
- relative humidity of gas: at least 95 %;
- volumetric fraction of CO_2: 5 % ± 1 %;
- injected continuously and with increasing mass concentration of ethanol.

Note: Other gases may be used provided that:

- their influence on test results can be taken into consideration and corrected for (however, influences which do not exceed a quarter of the applicable mpe do not need to be corrected for);
- for dry gases, it is verified that the EBA is capable of measuring moist gases (risk of pollution of the hydraulic circuit by water);
- for cases involving dry gases in containers:
  - variations of atmospheric pressure and variations of the compressibility factor between filling and usage conditions are taken into account;
  - the quality of the containers should be taken into account to minimize contamination and a change in composition of ethanol throughout its use cycle;
- test reports shall indicate when dry gases were used and how their equivalence with moist gases was established.

(נספח 1, עמוד 12)

יש לציין כי מטרתם של התקנים הנ"ל היא להתאים את תנאי הכיול לתנאי נשיפת האדם מכול הבחינות. ככל שתנאי הכיול ונשיפת האדם שונים, כך נפגמת מהימנותן של בדיקות החשודים. אך עיון במסמכים אשר מונחים לפני מעלה מספר שאלות אשר לא מוצאות מענה. כך למשל נותר בליבי ספק לגבי ההקפדה על נפחו של הגז המוזרם אל תוך מכשיר הנשיפה וכמו כן לגבי משך הזרמתו כמתחייב בהמלצות הבינלאומיות. כי הרי פלט הכיול אשר הוצג בהתייחסותו של מר כתר איננו כולל את הנתונים הנ"ל.

בנוסף, לא ברור לי איך אופן ביצועו של הכיול היומי אשר מתואר במסמכים שהונחו לפניי מבטיח את עליית ריכוז האתנול במהלך ההזרמה. נקודה זו דורשת הבהרות נוספות. כי הרי ידוע שרק חלק מסוים של האוויר הנשוף יוצר מגע עם הדם בנאדיות ומתעשר באתנול, כאשר החלק הנותר ממלא את מה שקרוי ה"חלל האנטומי המת", למשל את קנה הנשיפה, הוא לא יוצר מגע עם הדם ואיננו מתעשר באתנול. במהלך נשיפה קודם יוצא האוויר אשר מילא את דרכי הנשימה העליונות והוא כולל מעט אתנול ורק לאחר מכן יוצא האוויר שיצר מגע עם הדם והינו אמור לייצג את ריכוז האתנול בו לפי חוק הנרי [2]. במילים אחרות, במהלך הנשיפה של אדם אשר שתה משקאות אלכוהוליים בהכרח קיימת התפלגות של ריכוזי אתנול. השוואת ההתפלגויות הנ"ל אשר אופייניות לבני אדם ואשר אמורות להתקבל במהלך הכיול ניתן למצוא בעמוד 31 של ההמלצות הבינלאומיות. מכשירי נשיפה מתוכננים לנתח את התפלגויות הריכוזים דלעיל ולחשב נכונה את הכמות של האתנול בנשיפה כולה. אך במקרה של כיול כפי שמתואר במסמכים אשר הונחו לפניי, לדעתי קיים חשש של פגיעה ביכולת זו. בדומה להתפלגות הריכוזים, מאופיינת נשיפת האדם גם בספיקות שמשתנות במהלך הזמן באופן מסוים וההמלצות הבינלאומיות מתייחסות גם לנושא זה בקבעם את משך הזמן של הספיקה הגבוה (ראה גם עמוד 32). חוששני כי אופן הביצוע של הכיול היומי אשר עומד לדיון לכאורה אינו מבטיח את תיאום פרופיל הספיקות לזה אשר אופייני לנשיפת בני אדם. בנוסף לכך, במקרה של שימוש בגז היבש דורשות ההמלצות הבינלאומיות לקבוע את התאמת התוצאות לתוצאותיו של הסימולטור הרטוב. לא הונח לפני ההגנה שום מסמך שמפרט את הנ"ל.

לדעתי הדברים טרם זכו לדיון מקצועי מעמיק אשר הינם בהחלט ראויים לו. כי הרי המצב כאשר אוכפים ומגישים כתבי אישום כנגד החשודים עם ריכוז החל מ-253 מיקרוגרם לליטר אוויר נשוף בזמן שהיצרן עצמו קובע את האי-ודאות של המדידות כי ±20 מקרוגרם לליטר [3], אינו מתקבל על הדעת. על כך יש להוסיף כי ישנם הפרסומים אשר קובעים כי האי-וודאות זו למעשה גדולה יותר (ראה למשל [4]). לדעתי טרם ההגעה למסקנות סופיות לגבי ההשלכות האפשריות של האי-התאמה לתקנים הבינלאומיים על דיוק המדידות של החשודים בשטח אין להסתפק אך ורק בתשובות של נציגי חברת דראגר. כך למשל בדיונים בביה"מ העליון של ניו-ג'רסי בפני כב' השופט King בתיק State v. Chun, אשר סיכומם פורסם זה עתה (14.11.07) [5], נתגלו סטירות בין הנטען ע"י נציג החברה לבין המציאות בנושאים כמו אופן חישוב התוצאות ואי-התלות של הבדיקה האלקטרוכימית בבדיקה ספקטרוסקופית (ראה למשל [5], עמודים 56, 57). על כך יש להוסיף כי הכיול אשר נהוג בניו-ג'רסי שונה בתכלית מהנדון בהתייחסות זו. בניו-ג'רסי משתמשים לצורך הכיול

במערכת די מתוחכמת אשר מסוגלת לענות על דרישות של ההמלצות הבינלאומיות בכל הנושאים שפורטו לעיל (ראה נספח 1, עמודים 33-37). חוששני, שבניגוד לנטען ע"י ד"ר זוהייש, אין בין ההליך של ביצוע הכיולים היומי והחצי-שנתי של משטרת ישראל לבין המטרולוגיה הרשמית ולא כלום.

בהתייחסותו לנושא של הבלונים אשר לא באים מאותו היצרן שסיפק את מכשירי הנשיפה כותב ד"ר זוהייש את הדברים הבאים:

“In industrial environment it is worldwide practice to accept certificates raised by the suppliers of calibration gases.”

אכן דברים אלה נכונים עבור הציוד התעשייתי והמעבדתי וזאת מפני שבמקרה של כשלים כאלה ואחרים במפעל או במעבדה תמיד ניתן לחזור על הבדיקות. אך במקרה של הראיות המוגשות לביה"מ לא ניתן לעשות כן. לכן הנהלים לקביעת הראיות צריכים להיות מחמירים על מנת לשלול אפשרות כלשהי לכשלים למיניהם.

בכדי לעמוד על רצינותם וחומרתם של הדברים מצרף אני להתייחסות זו את הפסקה מהרשומות של ארה"ב (Federal register) אשר דנה בהלכים הקשורים לטיפול בבלוני גז כיול של מכשירי הנשיפה (נספח 2).

ראשית כל ניתן לראות כי המסמך דורש באופן מפורש מכול יצרן אשר מעוניין לספק את בלוני הכיול לרשויות של ארה"ב את ההוראות הכוללות המידע לגבי הנהלים למניעת העיבוי, אשר יכול להתרחש במהלך שינועם וכמו כן התיקונים הנדרשים עבור הלחץ האטמוספרי. לא הונחו לפני ההגנה שום מסמכים אשר מוכיחים כי משטרת ישראל עשתה בדיקות בלתי-תלויות לתכולת הבלונים אשר קיבלה מהממלכה המאוחדת. כי הרי יתכן המצב ובו כל המשלוח יתקרר במהלך שינועו או אחסנתו והדבר מרוקן מתוכן את הכיולים החצי-שנתיים והיומיים גם יחד.

בנוסף נקבע בארה"ב כי על הוראות השימוש בבלונים לכלול גם את מידע לגבי הכשלים האפשריים אשר יכולים להיות קשורים בסוגים מסוימים של מכשירי הנשיפה. המוצרים אשר מוגשים ללא הנ"ל אפילו אינם נבדקים ע"י הרשויות של ארה"ב. במקרה שלפנינו לא הונחו לפני ההגנה מסמכים כלשהם מטעם יצרן הבלונים אשר מתייחסים לדברים הנ"ל.

בארה"ב ניתנת ליצרן בלוני הכיול הזכות לערוך בדיקות משלו של מערכת הכיול בכדי לוודא שהיא מתפקדת בתנאים הראויים. במידה ומתגלים אי-אלו כשלים, פותחות הרשויות הפדראליות בחקירה, כפי שתואר במסמך (נספח 2). במקרה שלפנינו היה מן הראוי לשאול האם נערכו בדיקות כאלה מטעם יצרן הבלונים וגם מטעם יצרן מכשיר הנשיפה. וזאת מפני שעל פניו נראה כי הכיולים אינם מבוצעים בהתאם למקובל במקרה של המכשירים אשר נועדים ליצור ראיות קבילות בביה"מ.

כך למשל, נקבע ברשומות של ארה"ב כי יש לבצע את הבדיקות במספר ריכוזים ולא בריכוז אחד כפי שמתבצע ע"י משטרת ישראל וזאת על מנת להיות מסוגלים לבנות את עקומת הכיול. יש לציין כי ללא בניית עקומה זו נפגמת מהימנותו של הכיול (ראה גם כתבה מתוך הירחון של OIML אשר מפרטת את הליכי הכיול

בפורטוגל, נספח 3). בנוסף, נקבעות במסמכים האמריקאי והאירופי גם הדרישות המפורשות לגבי האמצעים לשמירת הטמפרטורה של 34 מעלות כמתחייב בתקנים הבינלאומיים וכמו כן לגבי הצורך לחזור לפחות 10 פעמים על כול מדידה במהלך הכיול התקופתי על מנת לוודא שמתקיימת נשנות התוצאות. לא ניתן ללמוד מטופס הבדיקה התקופתית של המכשיר כמה פעמים נעשתה כל מדידה בישראל. במסמך האמריקאי מפורטים גם הליכים רבים נוספים שאין להם זכר בחומר המשטרתי אשר מונח לפנינו.

מסקנות

התייחסותי זו ניתנת בתשובה לתגובתו של נציג חברת דראגר ד"ר יורגן זוהייש מגרמניה לחוות דעתם של דר" דריו ורטניק ומגר' ודים לוזנסקי מטעם ההגנה. בתגובתו טוען ד"ר זוהייש לקיום הדרישות של התקני הארגון הבינלאומי למטרולוגיה הרשמית (OIML) בקשר להליכי הכיול של מכשיר הנשיפה מסוג "דראגר אלקוטסט 7110MK III IL". אך העיון בתקנים דלעיל מגלה חוסר התאמה בינם לבין ההליך המעשי אשר מתואר במסמכים המונחים לפניי. בנוסף לכך, ניתן לראות כי הנוהל המשטרתי לגבי פעולת הכיול לוקה בחסר בהשוואה להליכים הקבועים במדינות אחרות. בהסתמך על האמור לעיל, לפי הנתונים המונחים לפנינו אי אפשר ליחס מהימנות מעבר לכל ספק סביר לבדיקות שמבצעת משטרת ישראל לחשודים בשכרות באמצעות מכשיר הנשיפה, וקביעה זו נעשית תוך שימוש בהגדרה הזהירה ביותר, אך הנחרצת.

:ספרות

[1] The list of 59 OIML Member States.
http://www.oiml.org/dbase_members/listing.html?membership=3

[2] Henry, W. Experiments on the Quantity of Gases Absorbed by Water at Different Temperature and under Different Pressures. Phil. Trans. Roy. Soc. 93: 29-42, 1803.

[3] Dräger Alcotest 7110 Evidential. Messgenauigkeit (Precision of measurements).
http://www.draeger.com/ST/internet/DE/de/Produkte/Detection/AlcoDrug/Alcotest/Beweissicher/DragerAlcotest7110/pd_draeger_alcotest_7110.jsp

[4] Shaffner, H. T., Graw, M., Jeske, A., Schmitt, G., Goll, M., Dietz K. Die Präzision von Atemalkohol-(AAK)-Messungen mit dem Dräger Alcotest 7110 Evidential im Vergleich zur Prazision der forensischen Blutalkohol-(BAK)-Bestimmungen. (Precision of breath alcohol concentrations (BrAC) measured with the Draeger Alcotest 7110 Evidential in comparison with the precision of blood alcohol concentrations (BAC) obtained by forensic means, paper written in German). Blutalkohol, 39: 397-406, 2002.

[5] Supreme court of New Jersey. State of New Jersey v. J. H. Chun at al., Supplemental Findings and conclusions of remand court. September Term 2005. Docket No. 58,879. Published on Nov. 14 2007.
http://www.judiciary.state.nj.us/pressrel/pr071114b.htm

הנספחים:

נספח 1: ההמלצות של הארגון הבינלאומי למטרולוגיה הרשמית OIML R126 משנת 1998.

נספח 2: פסקות מתוך הרשומות של ארה"ב לגבי אפיון של גזי הכיול וביצוע פעולת הכיול למכשירי הנשיפה.

נספח 3: תפעול מכשירי הנשיפה בפורטוגל (OIML Bulletin, Vol. XLII, Nr. 2)

התייחסות זו ניתנת על ידי לשם הגשתה כראיה לבית המשפט, והריני מצהיר בזאת כי ידוע לי היטב, שלענין הוראות החוק הפלילי בדבר עדות שקר בשבועה, דין התייחסותי זו כשהיא חתומה על ידי כדין עדות בשבועה שנתתי בבית המשפט.

תאריך 20/12/07 חתימה ____________

ספרות:

[1] The list of 59 OIML Member States.
http://www.oiml.org/dbase_members/listing.html?membership=3

[2] Henry, W. Experiments on the Quantity of Gases Absorbed by Water at Different Temperature and under Different Pressures. Phil. Trans. Roy. Soc. 93: 29-42, 1803.

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http://www.draeger.com/ST/internet/DE/de/Produkte/Detection/AlcoDrug/Alcotest/Beweissicher/DragerAlcotest7110/pd_draeger_alcotest_7110.jsp

[4] Shaffner, H. T., Graw, M., Jeske, A., Schmitt, G., Goll, M., Dietz K. Die Präzision von Atemalkohol-(AAK)-Messungen mit dem Dräger Alcotest 7110 Evidential im Vergleich zur Prazision der forensischen Blutalkohol-(BAK)-Bestimmungen. (Precision of breath alcohol concentrations (BrAC) measured with the Draeger Alcotest 7110 Evidential in comparison with the precision of blood alcohol concentrations (BAC) obtained by forensic means, paper written in German). Blutalkohol, 39: 397-406, 2002.

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נספח 3: תפעול מכשירי הנשיפה בפורטוגל (OIML Bulletin, Vol. XLII, Nr. 2)

נספח 1

INTERNATIONAL
RECOMMENDATION

OIML R 126

Edition 1998 (E)

Evidential breath analyzers

Éthylomètres

OIML R 126 Edition 1998 (E)

ORGANISATION INTERNATIONALE
DE MÉTROLOGIE LÉGALE

INTERNATIONAL ORGANIZATION
OF LEGAL METROLOGY

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Foreword

The International Organization of Legal Metrology (OIML) is a worldwide, intergovernmental organization whose primary aim is to harmonize the regulations and metrological controls applied by the national metrological services, or related organizations, of its Member States.

The two main categories of OIML publications are:

- **International Recommendations (OIML R)**, which are model regulations that establish the metrological characteristics required of certain measuring instruments and which specify methods and equipment for checking their conformity; the OIML Member States shall implement these Recommendations to the greatest possible extent;
- **International Documents (OIML D)**, which are informative in nature and intended to improve the work of the metrological services.

OIML Draft Recommendations and Documents are developed by technical committees or subcommittees which are formed by the Member States. Certain international and regional institutions also participate on a consultation basis.

Cooperative agreements are established between OIML and certain institutions, such as ISO and IEC, with the objective of avoiding contradictory requirements; consequently, manufacturers and users of measuring instruments, test laboratories, etc. may apply simultaneously OIML publications and those of other institutions.

International Recommendations and International Documents are published in French (F) and English (E) and are subject to periodic revision.

This publication - reference OIML R 126, edition 1998 (E) - was developed by the OIML subcommittee TC 17/SC 7 *Breath Testers*. It was approved for final publication by the International Committee of Legal Metrology in 1997, and will be submitted to the International Conference of Legal Metrology in 2000 for formal sanction.

OIML publications may be obtained from the Organization's headquarters:

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Evidential breath analyzers

1 Scope

1.1 This International Recommendation applies to evidential breath analyzers (hereafter referred to as EBA's) which are instruments that automatically measure the mass concentration of alcohol in exhaled breath.

However, for the purpose of this Recommendation, only ethanol is considered as alcohol.

In fact, physiological phenomena associated with alcohol and, in particular, the definition of that which constitutes the offence of driving (or working, etc.) under the influence of alcohol are not within the scope of this Recommendation. Likewise the legal definition of which compounds (methanol, ethanol, propanol, etc.) constitute alcohol is not provided in this Recommendation, such considerations being established by the responsible authorities of each country.

1.2 This Recommendation does not apply to screening devices which only detect ethanol without providing a sufficiently accurate measurement (see 2.2).

1.3 The performance requirements given here apply to EBA's using currently available technology. This is not intended to restrict technical development nor exclude the use of other technologies as a means for analysis.

1.4 National authorities may require EBA's to include a specific conversion device that converts the measurement result obtained in terms of ethanol content in the exhaled breath at the measuring conditions either into physiological conditions or in terms of other quantities. This Recommendation does not cover the metrological performance of such devices.

1.5 The purpose of this Recommendation is to define the performance requirements of EBA's and the means and methods employed in testing them.

2 Applications

2.1 EBA's can be used to measure accurately and display numerically the breath alcohol mass concentration of persons (drivers, workers, etc.) who may have consumed alcohol.

2.2 Screening devices are not generally used for establishing proof of driving under the influence of alcohol but are used as detectors of alcohol in the breath.

3 Terminology

3.1 Evidential breath analyzer (EBA)

An instrument which measures the mass concentration of ethanol by analyzing deep lung air, usable for evidential purposes.

3.2 Non-portable evidential breath analyzer

An EBA intended only for use within buildings or places providing similar environmental conditions.

Note: The use of non-portable EBA's in mobile laboratories may be considered, providing adapted conditions of transport are assured.

3.3 Portable evidential breath analyzer

An EBA that may be used within or outside a building.

3.4 Deep lung air

Breath delivered from the mouth of a subject that originates from the alveoli of the lungs, normally referred to as end-expiratory breath.

3.5 Alveolar air

Air contained in the pulmonary alveoli.

3.6 Normal operation

The mode of usage which corresponds to the program of operations specified for EBA's in service.

3.7 Stand-by mode

The mode of the EBA in which only certain circuits are energized in order to conserve power and/or prolong component life, and to attain the measuring mode more rapidly than would be possible if starting from the un-powered state.

3.8 Measuring mode

The clearly marked mode in which the EBA can make measurements at the rate normally expected in service and in which it shall meet the performance requirements of this Recommendation.

Note: The measuring mode and the stand-by mode (3.7) are modes of normal operation (3.6).

3.9 Device for adjustment to a standard

A device for adjusting the EBA using, as a standard, a mixture of gases having a relative humidity of at least 90 % and a temperature of 34 °C ± 1 °C(*). The mixture of air and ethanol passes through the entire gas analysis train, starting with the mouthpiece, in the direction normally taken by exhaled air.

Note: Adjustment using a dry gas is possible provided that the difference of effect between wet and dry gases is known or can be automatically corrected.

3.10 Device for adjustment by simulation

A device for adjusting the EBA by a procedure other than that specified in 3.9, notably by the simulation of the effects of the passage of a standard mixture of gases as described in 3.9.

3.11 Adjustment-checking operation

An operation involving all relevant internal elements which verifies that the EBA is suitably adjusted.

3.12 Drift

The change in the indication which occurs during a stated period of time at a given mass concentration of ethanol in air.

3.13 Memory (residual) effect

The difference between the indications obtained with two inputs of gas of a given mass concentration, a gas of a specified higher mass concentration being injected between these two inputs.

4 Physical quantities and units of measurement

EBA's shall be capable of expressing measurement results in terms of ethanol content in the exhaled breath at measuring conditions, for example mass concentration of ethanol per unit volume.

In this Recommendation, the unit of measurement used is the milligram (of ethanol) per litre (of exhaled breath), mg/L.

5 Metrological requirements

The requirements of clause 5 are applicable to individual measurements and not to any combination of measurements of a measuring cycle.

5.1 Maximum permissible errors

5.1.1 Maximum permissible errors for pattern evaluation and initial verification

The maximum permissible errors, positive or negative, on each indication shall be:

- 0.020 mg/L for all mass concentrations less than 0.400 mg/L;
- 5 % of the measured concentration for all mass concentrations greater than or equal to 0.400 mg/L and less than or equal to 2.000 mg/L;
- 20 % of the measured concentration for all mass concentrations greater than 2.000 mg/L.

5.1.2 Maximum permissible errors for EBA's in service

The recommended values of maximum permissible errors, positive or negative, on each indication for EBA's in service are:

- 0.032 mg/L for all mass concentrations less than 0.400 mg/L;
- 8 % of the measured concentration for all mass concentrations greater than or equal to 0.400 mg/L and less than or equal to 2.000 mg/L;
- 30 % of the measured concentration for all mass concentrations greater than 2.000 mg/L.

5.1.3 Rounding

When comparing the error of an EBA with the corresponding maximum permissible error, this mpe shall

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(*) This ± 1 °C tolerance does not correspond to the uncertainty when preparing calibration gases (which is usually of 0.1 °C); it is the tolerance on the nominal temperature of calibration gases in use.

be rounded to the value of the verification scale interval.

The error of a reading indicated by an EBA may be greater than the mpe by one verification scale interval.

5.2 Repeatability

5.2.1 Estimation of the standard deviation

An estimate of the standard deviation is given by the formula:

$$s = \sqrt{\frac{\sum_{i=1}^{n} (Y_i - \bar{Y})^2}{n - 1}}$$

where:

n = the number of measurements made at a given mass concentration;

Y_i = the i^{th} indication (out of n) of the EBA for that mass concentration;

$\bar{Y}$ = the arithmetic mean of the n values.

5.2.2 Requirements

The standard deviation for all mass concentrations less than 0.400 mg/L shall be less than 0.007 mg/L.

The relative standard deviation for all mass concentrations greater than or equal to 0.400 mg/L and less than or equal to 2.000 mg/L shall be less than 1.75 %.

The relative standard deviation for all mass concentrations greater than 2.000 mg/L shall be less than 6 %.

5.2.3 Probability of compliance

The statistical probability that the EBA satisfies the requirements of 5.2.2 shall be no less than 95 % for each mass concentration.

For 20 measurements, for example, this provision would lead to EBA's being refused with an estimation of the standard deviation greater than 1.26 times the maximum permissible standard deviation.

5.3 Drift

5.3.1 Zero drift

The zero drift shall be less than 0.010 mg/L in 4 h.

5.3.2 Drift at 0.40 mg/L

5.3.2.1 Short-term drift

The drift at 0.40 mg/L shall be less than 0.010 mg/L in 4 h.

5.3.2.2 Long-term drift

The drift at 0.40 mg/L shall be less than 0.020 mg/L in 2 months.

5.4 Memory and residual effect

5.4.1 Memory effect

The memory effect shall be less than 4 % in relative value, when the test is conducted according to 9.5.1.

5.4.2 Small changes in mass concentration

The error in the result obtained with a gas having a mass concentration which is 0.10 mg/L less than that of another gas previously injected shall be less than the maximum permissible error for the lower mass concentration.

5.5 Influence quantities

When tested, the EBA shall meet the requirements with regard to the following influence quantities.

5.5.1 Influence factors in the parameters which characterize the test gases

The test methods and factor values are given in Annex A.

a) Concerning the influence of:

- delivered volume,
- duration of exhalation,
- duration of plateau, and
- carbon dioxide,

the errors in the results shall not exceed the maximum permissible errors stated in 5.1.1.

b) Concerning the influence of interruption in the flow of breath, the EBA shall not give a result.

c) Concerning the influence of ethanol in the upper respiratory tract, the national authorities may either decide that the instrument give no result, or else establish provisions concerning the use of the

EBA (for example, a label stating *"Wait at least xx minutes if the subject has drunk alcohol recently"*).

5.5.2 Physical influence factors

Concerning the following physical influence factors:

- AC supply voltage,
- supply frequency,
- DC supply voltage,
- ripple on DC voltage,
- ambient temperature,
- ambient relative humidity,
- atmospheric pressure, and
- quantity of hydrocarbons in the environment,

the methods for testing the EBA, the values of factors and the requirements are given in Annex B.

5.5.3 Physiological influence factors

Constituent parts of medicines or the products of abnormal human metabolic substances contained in solvents or industrial products, or other gases may influence the result of the measurement if present in the breath.

Annex C gives the list of interfering substances (with nominal values and maximum influences) with which EBA's shall be tested in order to verify that they meet the requirements of this Recommendation concerning physiological influence factors.

5.5.4 Physical disturbances

Concerning the following physical disturbances:

- short-time power reduction,
- parasitic voltages on the mains,
- vibrations resulting from normal conditions of transport or those corresponding to a stationary vehicle with the engine idling,
- mechanical shocks resulting from normal handling conditions,
- electrostatic discharges,
- electromagnetic fields,
- magnetic fields,
- damp heat, cyclic (for portable EBA's only),
- ambient storage conditions (for portable EBA's only),
- shaking resulting from normal conditions of transport (for portable EBA's only), and
- disturbances for portable EBA's used in the open air only,

the methods for testing the EBA, the values of disturbances and the requirements are given in Annex D.

5.6 Durability

After the EBA has been subjected to a durability test as described in 9.6, the errors in the results shall be less than the maximum permissible errors specified in 5.1.2.

6 Technical requirements

6.1 Measurement range

EBA's shall be capable of measuring all mass concentrations in the range 0.00 mg/L to at least 1.50 mg/L. In normal operation, however, the EBA may indicate 0.00 mg/L for mass concentrations equal to or smaller than 0.05 mg/L. The greatest permissible value for the upper limit of the measurement range is 3.00 mg/L.

6.2 Scale interval

The scale interval is 0.01 mg/L (scale interval of the EBA's indication) in normal operation.

During metrological testing or manual calibration it shall be possible to discriminate to 0.001 mg/L (verification scale interval of the EBA).

6.3 Display

6.3.1 The result of a measurement shall be displayed digitally by means of aligned figures. The display in normal operation shall consist of the display in metrological testing (to 0.001 mg/L) rounded down to 0.01 mg/L (e.g. a measured value of 0.427 mg/L shall be displayed as 0.42 mg/L in normal operation).

6.3.2 The height of the figures shall be equal to at least:

- 5 mm for fluorescent registering devices or devices having a luminosity recognized as equivalent;
- 10 mm in all other cases.

6.3.3 The name of the unit of measurement or its symbol shall appear in close proximity to the figures indicating the result, and the characters used shall be at least 3 mm in height.

6.4 Printing device

EBA's may be equipped with printing devices which print:

- the result of the measurement. In normal operation, the printed result shall not differ from that which is indicated by any other indicating device(s);
- the symbol of the unit in which the result is expressed.

If the symbol of the unit is preprinted, the paper shall be specially prepared for the printing device.

Printouts shall remain readable for one month, even when exposed to daylight or equivalent lighting. The printing device should include a means to check that characters are correctly printed.

The legal authority may require that a printing device be provided. It may also require that more information appear on the printed document than requested above and that measurements are not possible if paper (or other medium) is not available in the printing device.

6.5 Prohibition of display or printing

National authorities may prohibit the display or printing of results which do not represent the final measurement result.

6.6 Measuring conditions

6.6.1 The EBA shall be designed to ensure that measurements are made on samples of deep lung air.

6.6.2 When the measurement result is nil, it shall not be possible to confuse such a result with the zero indication prior to measurement. This requirement is deemed to be satisfied if, for example, the EBA indicates the various phases of the measuring cycle.

6.6.3 The EBA shall monitor the continuity of exhalation and shall give an indication if the flow of exhaled air ceases (momentarily or completely) between the beginning of the exhalation and the end of the taking of a sample, thus allowing a valid result to be obtained. A warning signal (preferably audible) shall enable the determination of continuity of exhalation.

The exhalation shall be considered interrupted if the flow is below 0.1 L/s.

6.6.4 The exhalation pressure necessary to obtain a sample of exhaled air with the mouthpiece fitted shall not exceed 25 hPa at a flowrate of 0.17 L/s.

6.6.5 The EBA shall indicate it is ready to make a measurement and shall prohibit measurement when it is not ready; these two functions shall be compatible.

6.6.6 After successful checking of correct operation according to 6.9.2, and from the moment it indicates that it is ready to receive an exhalation, the EBA shall be available for at least one minute.

6.6.7 The EBA shall provide a signal (e.g. blanking out of the indication) whenever the effect of an interfering substance exceeds the maximum influence given in Annex C.

6.7 Safety and security

6.7.1 The EBA shall be capable of being used under satisfactory hygienic conditions. It shall be possible to change the mouthpiece (see 6.16) for each measurement; mouthpieces shall be individually packaged.

6.7.2 EBA's shall conform to relevant national regulations and standards for electrical safety and, where appropriate, for compressed gases. Verification of compliance with these regulations and standards is not within the scope of this Recommendation.

6.7.3 The means by which the EBA is adjusted (particularly devices for adjusting the sensitivity and the zero position) shall not be accessible to the common operator or user.

6.7.4 The EBA shall give an indication each time the upper limit of the measurement range specified in 6.1 is exceeded in the sample. Beyond that limit, no measurement result shall be given, or the upper limit may be displayed provided that it cannot be interpreted as being valid (e.g. by displaying "greater than").

6.7.5 The means used to change from one mode of operation to another shall be inaccessible to the common operator or user of the EBA; access shall be possible only by breaking a sealing device, by entering a code, or by some other equivalent procedure.

6.8 Return to zero

6.8.1 The EBA shall incorporate a device which automatically zeros or checks the zero of the EBA at least at the beginning of each measurement.

6.8.2 The EBA shall be incapable of operation if the return to zero is not accomplished within ± 0.005 mg/L.

6.8.3 The action of returning to zero shall include a purge with ethanol-free gas (ambient air, for example). The result shall then be indicated.

6.9 Checking of correct operation

6.9.1 Checking of correct operation of the EBA comprises, in particular:

- checking that all relevant internal elements of the EBA operate correctly;
- checking that the measuring cycle is correctly performed;
- an adjustment-checking operation (3.11).

6.9.2 EBA's shall check correct operation automatically both before each measurement and after any measurement which gives a result greater than a predetermined value of the mass concentration (this value may be zero).

However, the legal authority may require the adjustment-checking operation to be performed automatically or allow this operation to be performed according to the procedure specified by the manufacturer in the EBA's user manual.

6.9.3 When an anomaly, a defect or an error signal is detected, particularly when correct operation cannot be checked, the EBA shall not give a result which may be considered valid and any further measurement shall be prevented until correct operation has been checked.

6.10 Adjustment or checking of correct adjustment

6.10.1 For purposes of maintenance and legal metrological control, it must be possible to adjust or check correct adjustment of the EBA using the standard mixture of gases under the conditions specified in 3.9. This standard mixture of gases may be contained within the EBA.

6.10.2 EBA's should, in principle, be adjusted to a standard (3.9) or adjusted by simulation (3.10) or checked to be correctly adjusted at a scale value between 0.25 mg/L and 0.50 mg/L. A different value, however, may be chosen when it has been demonstrated that such a value gives at least the same accuracy in that part of the scale.

6.10.3 When the automatic adjustment device(s) no longer allow(s) adjustment or when the automatic checking of correct adjustment no longer gives a confirmatory result, the EBA shall no longer be capable of making measurements.

6.10.4 The legal authority may require routine adjustments or routine checks of correct adjustment involving a given means, for instance dry gas in a pressure vessel or humid gas delivered by a simulator.

6.11 Warm-up time

Under reference conditions, the EBA shall be capable of attaining the measuring mode:

- 15 minutes after being switched on;
- 5 minutes after a switch from stand-by mode to measuring mode.

However if these requirements are not fulfilled, the corresponding times shall be marked on the EBA and provided in the user manual.

6.12 Measuring cycle

National authorities shall define what constitutes a measuring cycle, i.e. the set of operations which may permit the operator to conclude whether or not a person is under the effect of alcohol.

A measuring cycle may be defined in terms of:

- number of successive individual measurements;
- sequence for displaying the results;
- consideration of variations between results (particularly in relation with the effect of alcohol in the upper respiratory tract), etc.

Advisable provisions are given in Annex I.

6.13 Length of time during which the result is indicated

It shall be possible to retain the results in a readable or accessible form for at least 15 minutes. If this requirement can be met only by printing the results, the absence of paper in the printer shall prevent measurements being made.

Note: The initiation of a new measurement cycle may shorten this period.

6.14 Minimum volume

For EBA's that do not monitor maximum mass concentration during exhalation, measurements shall imply an exhalation volume equal to at least 1.5 L. This shall particularly apply to EBA's that perform a measurement after a preset volume or period of time for exhaling.

6.15 Markings

6.15.1 An EBA shall be marked indelibly and irremovably with the following information:

- pattern approval mark (after a successful evaluation of the pattern);
- manufacturer's name;
- denomination of the instrument;
- serial number;
- measurement range;
- range of ambient temperature in which the EBA may be used;
- warm-up time if the requirement in 6.11 is not fulfilled;
- length of time or the number of analyses permitted between maintenance operations (including adjustment in accordance with 3.9 described in the user manual supplied by the manufacturer).

All of this information shall be legible and grouped together on a visible part of the EBA.

6.15.2 Verification marks may be applied by means of a stamp. It is, however, recommended that national regulations provide for the replacement of these marks by a sticker attesting to the regulatory status of the EBA.

6.15.3 Although the EBA is designed to detect the presence of ethanol in the mouth, it is strongly recommended that an inscription analogous to that in 5.5.1.c be marked on the EBA, even if it fulfills the corresponding requirement. However, it may be sufficient to include this information in the user manual.

6.15.4 Instruments which use specific technology may be required to bear particular marking.

6.16 Breath sampling system

The EBA breath sampling system including the mouthpiece shall not allow the subject of the measurement to inhale contaminated air from previous usages. It shall prevent the deposition of droplets from exhaled breath in the EBA.

7 Practical instructions

If the national regulation prescribes a metrological logbook, this shall be presented with the EBA every time the latter is submitted for statutory metrological control.

The logbook, which shall carry information identifying it with the EBA, shall contain a recorded entry of every metrological operation (and results) that has been performed under statutory metrological control; it shall also contain a record of any repairs that may affect metrological characteristics or performance of the EBA.

8 Metrological controls

It is recommended that national regulations provide for the following control procedures:

- pattern approval;
- initial verification of new EBA's;
- periodic verification.

Note: Provisions applying to verification after repair are left to national regulations.

8.1 Pattern approval

8.1.1 Manufacturers shall provide the national responsible body with technical documentation and a user manual for the EBA and device for adjustment to a standard, and may provide data and other information on performance tests and calibrations that support a determination of whether the design of the EBA meets the requirements of this Recommendation.

8.1.2 The user manual shall be reviewed by the national responsible body for its completeness and clarity of operating instructions. The EBA and technical documentation shall be visually inspected in conjunction with a review of specifications provided by the manufacturer to determine that requirements 6.1 through 6.16 are met.

8.1.3 The national responsible body shall carry out the following performance tests (or where applicable may accept the manufacturer's test data) to verify that the EBA fulfills the requirements in clause 5, i.e.:

- accuracy test (maximum permissible errors, 5.1.1 and 9.3);
- repeatability test (5.2 and 9.3);
- drift test (5.3 and 9.4);
- memory effect test (5.4 and 9.5);
- influence quantities tests (5.5 and Annexes A, B, C, D and H);
- durability test (5.1.2, 5.6 and 9.6).

8.1.4 For each test the expanded uncertainty(*) (calculated with k = 2) of the composition of the test gases shall be less than one fourth of the applicable mpe.

8.1.5 The report on the examination and the tests of the EBA carried out at pattern evaluation shall contain, as a minimum, the items of information according to the format provided in Annex E. A specific form may be developed according to national preference. However, use of this *Test Report Format* is mandatory in the framework of the *OIML Certificate System*. The manufacturer shall be provided with specific comments about any test failures.

8.2 Initial verification

8.2.1 All requirements in this Recommendation may be subject to testing particularly when they are critical to the specific application.

8.2.2 It is recommended, however, that EBA's be tested systematically to verify the following:

- accuracy (9.3.1 and 5.5.1);
- repeatability (9.3.1 and 5.2);
- effect of the volume delivered (A.1);
- effect of the duration of exhalation (A.2);
- effect of the duration of the plateau (A.3).

8.2.3 The number of test gases or the number of measurements may be reduced in relation to those specified in this Recommendation.

8.2.4 The period of validity of this verification shall be specified by the national responsible body.

8.3 Periodic verification

8.3.1 Periodic verification may be confined to verification of accuracy (9.3.1 and 5.1.1 or 5.1.2 according to the national responsible body) for various conditions of injection (9.2, A.1, A.2 and A.3).

8.3.2 The number of test gases or the number of measurements may be reduced in relation to those specified in this Recommendation.

8.4 Routine tests by a user

8.4.1 The national responsible body shall provide information on methods for using EBA's for specific applications.

8.4.2 If required by the national responsible body, the operator of an EBA shall carry out a test with a reference sample in the field before and after a series of tests in the laboratory or in the field. The results of these tests shall be within the limits established by the national responsible body.

8.4.3 If required by the national responsible body, a chronological written record shall be maintained for each EBA and shall contain at least the results of all routine tests. This record may be included in the metrological logbook.

9 Test method

9.1 General

9.1.1 The apparatus used by the laboratory for testing the EBA shall deliver test gases having mass concentrations of ethanol analogous to those which evolve during an exhalation. This evolution is characterized by a plateau in the curve of mass concentration against time during the last part of the injection, the duration of which is fixed for each test.

9.1.2 The mass concentration at the plateau shall be considered to be the true value of the test mass concentration.

9.1.3 Annex F shows the general form of this evolution of mass concentration, as well as that of the evolution of flow rate during a test. Annex G gives an example of a design of a testing apparatus capable of generating the required evolutions of mass concentration and flow rate. Other apparatus that can provide equivalent performance may be used.

(*) Refer to the *Guide to the expression of uncertainty in measurement*, 1995 edition.

9.1.4 Taking into account the capabilities of the testing apparatus, the tests shall be conducted with the maximum frequency allowed by the EBA according to 6.6.5.

9.1.5 With the exception of the study of the influence of physical influence factors (see Annex B) and, where appropriate, of the study of drift, tests shall be performed under the reference conditions specified in B.2.

9.1.6 The EBA may be adjusted manually, if necessary, before testing starts. Thereafter, no adjustment shall be made until all testing is finished. This does not apply to self-calibration (semi-automatic adjustment) on command by the user as required by the manufacturer in the user manual.

9.1.7 The tests specified in this Recommendation constitute an example of a basic test procedure. If uncertainty exists as to the extent to which an EBA conforms to the requirements given in this Recommendation, other values of the test parameters may be chosen.

9.1.8 Without prejudice to the above provisions, and provided that they do not significantly influence the measurement results, the parameters that characterize the test means may be different from those specified in this Recommendation. This allows the use of simplified test means for some tests that, for example, imply transportation of these test means (mainly tests in Annexes B and D). Such means may consist in dry gases in containers or preferably wet gases generated by simple test means (e.g. the absence of CO_2 in test gases, constant mass concentration during injection). The laboratory test reports shall indicate when such alternative test means have been implemented.

Moreover, the fact must be taken into consideration that, for some of the requirements, the errors must fall within the range of maximum permissible errors whereas other requirements specify that a deviation between two values must fall within a maximum permissible deviation.

For example, when results that are provided by a simplified test means are used with and without the effect of an influence factor, the error which has been found under reference conditions shall be taken into account before comparing the effective error to the maximum permissible errors.

The effective error e can be considered as:

$$e = I_2 - I_1 + e_{ref}$$

where:

I_2 = the indication with an influence factor and with simplified test means;
I_1 = the indication without an influence factor and with simplified test means;
e_{ref} = the error of the EBA under reference conditions with the test means described in this Recommendation.

9.2 Characteristic reference values of the test gas

Unless otherwise specified, the test gas shall be characterized by the following parametric values:

- delivered volume: 3 L;
- total duration of injection (into breath analyzer): 5 s;
- duration of plateau of mass concentration (when injecting into the EBA): 3 s;
- carrier gas: pure air;
- gas temperature: 34 °C ± 0.5 °C;
- relative humidity of gas: at least 95 %;
- volumetric fraction of CO_2: 5 % ± 1 %;
- injected continuously and with increasing mass concentration of ethanol.

Note: Other gases may be used provided that:

- their influence on test results can be taken into consideration and corrected for (however, influences which do not exceed a quarter of the applicable mpe do not need to be corrected for);
- for dry gases, it is verified that the EBA is capable of measuring moist gases (risk of pollution of the hydraulic circuit by water);
- for cases involving dry gases in containers:
  - variations of atmospheric pressure and variations of the compressibility factor between filling and usage conditions are taken into account;
  - the quality of the containers should be taken into account to minimize contamination and a change in composition of ethanol throughout its use cycle;
- test reports shall indicate when dry gases were used and how their equivalence with moist gases was established.

9.3 Maximum permissible errors and repeatability

9.3.1 Compliance with maximum permissible errors and repeatability requirements should be verified at least at the following nominal scale values:

Test gas No.	Mass concentration (mg/L)
1	0.00 to 0.05
2	0.15
3	0.25
4	0.40
5	0.70
6	0.95
7	1.50
8	upper value if appropriate

9.3.2 For pattern evaluation at least 20 measurements should be made with each gas. At each mass concentration the measurements shall be made consecutively.

9.4 Drift

9.4.1 At least 10 measurements shall be made with each of test gases Nos. 1 and 4 respectively to verify compliance with 5.3. Then 10 further measurements are made, using the same gases, after the intervals specified in 5.3.2.

Other tests provided for in this Recommendation for pattern evaluation may be performed during the drift test.

9.4.2 For each gas the deviation between the mean values of the two series of measurements shall fulfill the requirements in 5.3.2.

9.4.3 During the drift tests, the influence factors shall remain stable or their variation shall be taken into account, particularly in the tests for long-term drift in the course of which, if the EBA is placed in storage, the manufacturer's instructions shall be followed.

9.5 Memory and residual effect

9.5.1 Memory effect

The EBA shall be subjected 10 times to the following cycle:

- one measurement at a mass concentration of 2 mg/L or the upper limit of the measurement range, whichever is the smaller;
- one measurement at a mass concentration of 0.40 mg/L.

For the mass concentration at 0.40 mg/L, the difference between the average of at least 10 measurements taken before this test and the average of the 10 measurements made in the second part of this test cycle shall be less than the value specified in 5.4.1.

9.5.2 Small changes in mass concentration

A gas with a mass concentration of 0.40 mg/L shall be injected at least 10 times in succession, after which a gas with a mass concentration of 0.30 mg/L shall be injected a maximum of 5 times.

The requirement in 5.4.2 shall be fulfilled.

9.6 Durability test

Test procedure:

1) The EBA, having satisfied all the other pattern approval tests, shall be placed in a chamber for 8 h in the stand-by mode. In the test chamber, the temperature shall be 40 °C, and the relative humidity 90 %.

2) Then, with the EBA's power turned off, the temperature of the chamber shall be raised to 60 °C, for 1 h.

3) When the temperature has stabilized at ambient temperature, the EBA is subjected to a sweep of frequencies of sinusoidal vibrations under the following conditions:

- range of frequencies: 10 Hz–150 Hz;
- rms acceleration: 10 m/s^2 for portable EBA's and 5 m/s^2 for non-portable ones;
- sweep on three perpendicular axes;
- rate of sweep: one octave per minute;
- number of sweep cycles (up and down): non-portable EBA: 5 on each axis; portable EBA: 20 on each axis.

4) Finally, the EBA shall be returned to the chamber in its stand-by mode and subjected to rapid variations of temperature between 0 °C–40 °C for 16 h. Condensation on the EBA shall be avoided. This operation may be performed in the following manner:

- raise the temperature to 40 °C;
- reduce the relative humidity to less than 30 %;
- change from one temperature level to the other every hour, ensuring that the ambient temperature changes from one level to the other in approximately 15 minutes.

5) After the test, at least 5 measurements are performed.

ANNEX A

INFLUENCE OF VARIATIONS OF THE PARAMETERS WHICH CHARACTERIZE THE TEST GASES

(Mandatory)

For these tests, the values of the parameters that are not specified shall be those in 9.2. The values of the parameters to be varied are specified in A.1 to A.6. Ten measurements shall be made for each test, using test gas No. 4.

A.1 Influence of delivered volume

First test: delivered volume: 1.5 L;

Second test: delivered volume: 4.5 L (with condition of A.2 for duration)

A.2 Influence of duration of exhalation

Total duration of each injection: 15 s;

Duration of plateau: 6 s.

A.3 Influence of duration of plateau

Duration of plateau: 1.5 s.

A.4 Influence of mass concentration of carbon dioxide

Mass concentration by volume of CO_2: 10 %.

A.5 Influence of interruption in the flow of breath

First test: the injection of gas normally required for the reference conditions specified in 9.2 shall be stopped 1 s after the start of injection.

Second test: the injection of gas normally required to last 15 s (see A.2) shall be stopped 6 s after the start of injection.

A.6 Test simulating the presence of ethanol in the upper respiratory tracts

The test consists in injecting a test gas providing an evolution of the mass concentration in ethanol as indicated in Annex H.

The scheme shows that the curve has a maximum and a plateau. Between this maximum and this plateau, the slope of the curve has a maximum value which is the main characteristic of the test. This maximum value of the slope shall be equal to – 0.1 $mgL^{-1}s^{-1}$ with a relative tolerance of ± 10 %.

The other characteristics of the test gas are:

• volume:	3 L;
• duration:	15 s;
• mass concentration at maximum of the curve:	0.4 mg/L.

Such a test gas can be obtained by blowing clean air through a balloon flask having a volume equal to 500 mL. The balloon contains a solution of ethanol in water whose ethanol mass concentration is equal to 1.8 g/L. The volume of the solution is 250 mL and its temperature is 34 °C.

Annex H shows a scheme of such a device.

ANNEX B

PHYSICAL INFLUENCE FACTORS

(Mandatory)

B.1 Test conditions

The effect of each influence factor shall be determined separately and influence factors not under investigation shall remain at their reference values as specified in B.2.

The effects of the various influence factors shall not be combined.

The test shall be carried out using test gas No. 4. At least 5 measurements should be made in each test condition.

When applicable the tests shall be carried out in accordance with IEC Publication 68-2-1 (cold), 68-2-2 (dry heat).

B.2 Reference conditions and rated operating conditions

The reference conditions and the extreme values of the rated operating conditions for the physical influence factors that are taken into account in the tests are given in Table 1 (see page 16).

B.3 Requirements

The errors in the results obtained at reference and rated operating conditions shall not exceed the maximum permissible errors stated in 5.1.1.

In the test at the extreme value of hydrocarbons in the environment, however, the EBA is permitted to give no result.

Battery-powered EBA's shall have a means to indicate when the voltage falls below a value specified by the manufacturer.

Table 1 Reference and rated operating conditions

Influence factor	*Reference conditions*	*Extreme values*
AC supply voltage	Nominal voltage (NV)	– 15 % of NV + 10 % of NV
Supply frequency	Nominal frequency (NF)	± 2 % of NF
DC supply voltage	Nominal voltage (NV)	– 8 % of NV + 24 % of NV (a)
Ripple on DC voltage, frequency range 40 Hz–400 Hz	0 V	amplitude 0.2 V peak to peak
Ambient temperature	19 °C–22 °C	15 °C and 35 °C for non-portable EBA's (b) 0 °C and 40 °C for portable EBA's (b)
Ambient relative humidity (RH)	Ambient RH of the laboratory	30 %–90 %
Atmospheric pressure (AP)	Ambient AP	Ambient AP – 20 kPa Ambient AP + 4 kPa
Total fraction by volume of hydrocarbons (as methane equivalent) in the environment	2×10^{-6}	5×10^{-6}

Notes to Table 1:

(a) If the EBA gives results when the voltage is outside this range of values, they shall be correct. Under-voltages may occur at any time before or during the measuring cycle with durations ranging from 2 s to that of the cycle.

(b) If the manufacturer indicates extreme ambient conditions which are more severe than these values, the tests shall be performed at the values given by the manufacturer.

ANNEX C

PHYSIOLOGICAL INFLUENCE FACTORS

(Mandatory)

EBA’s shall be tested according to the following procedure:

1) Determination of the indication for a **dry test gas** having an ethanol content of 0.4 mg/L (± 5 %), without any interfering substance.

2) Determination of the indication for the same test gas with one and only one of the interfering substances listed in Table 2, at a mass concentration also indicated in Table 2 (with the indicated tolerance on nominal value).

3) If the variation of indication is not more than the maximum influence indicated below, the EBA has passed the test for the interfering substance concerned; if the variation is more than the maximum influence and if no signal is given, the EBA has failed; if a signal is given, another test shall be made with the same interfering substance, at a mass concentration 5 times smaller; the variation shall not be more than a fifth of the maximum influence.

4) This test shall be performed at least 5 times for each of the interfering substances listed in Table 2.

Note: National authorities may decide to test the influence of other compounds.

Table 2 Interfering substances

Interfering substance	Nominal value for vapor mass concentration mg/L (± 5 %)	Maximum influence mg/L
Acetone	0.5	0.1
Acetaldehyde	0.15	0.1
Methanol	0.1	0.1
Isopropanol	0.1	0.1
Carbon monoxide	0.2	0.1
Toluene	0.2	0.1
Ethyl acetate	0.15	0.1
Methane	0.3	0.1
Diethyl ether	0.3	0.1

ANNEX D
PHYSICAL DISTURBANCES
(Mandatory)

Tests shall be performed with a single gas which shall normally be test gas No. 4. At least 5 measurements should be made in each test condition except if the test method requires otherwise.

Every time that a disturbance renders the EBA incapable of giving a result, it is advisable, to the extent that it is practicable, to retest at a reduced level of disturbance in order to verify that the results at these levels conform to the specifications.

The values of the parameters specified in this Annex shall be as near as possible to the values specified, always taking into account the characteristics of test apparatus commercially available.

Where applicable, tests shall be conducted in accordance with IEC Publications 801 (1 to 4), 68-2-6, 68-2-30 and with ISO Standard 7637 - Electrical disturbance by conduction and coupling.

- Part 1: vehicles with nominal 12 V supply voltage;
- Part 2: commercial vehicles with nominal 24 V supply voltage.

D.1 Short-time power reduction for AC mains-powered EBA's

Test method:

- The disturbances shall be applied during a measuring cycle.
- The supply voltage shall be reduced by 100 % for approximately half a mains cycle.
- The supply voltage shall be reduced by 50 % for approximately one mains cycle.
- The time interval between successive disturbances shall be at least 10 s.

Requirements:

Results obtained respectively with and without the disturbances specified above shall not differ by more than the absolute value of the maximum permissible errors in 5.1.1, or the EBA shall not give a result.

D.2 Parasitic voltages and disturbances on the mains

1) Test method for alternating current supply (see also IEC 801-4):

- The disturbances shall be applied during the measuring cycle.
- Transient voltages of each polarity shall be applied to the supply, randomly phased. The over-voltages shall be generated in common mode or in differential mode.
- The amplitude, rise time, duration and rate of repetition are specified in Table 3.

2) Test method for direct current supply:

EBA's that may be supplied from a source of direct current that is not dedicated to their exclusive use (for example, EBA's drawing power from the battery of a vehicle) shall be submitted to the following tests:

Table 3 Disturbances on the mains

Amplitude on the supply	Induced amplitude [(a)]	Rise time	Duration to half amplitude	Rate of repetition
2000 V	1000 V	5 ns	50 ns	single shot

[(a)] Inductive coupling on the control wires and data wires of the entry and exit cables between the EBA and any peripheral device.

- Disconnection of inductive loads from the supply: pulse 1 in ISO 7637-1 or 2.

  Test level: 3 or 2(*).

  The pulse is applied during the measuring cycle and repeated every 5 s. However in the case of pulse b in ISO 7637-2 the disturbance is confined to a single pulse in the course of each measurement of the measuring cycle.

- Interruption of the vehicle's circuit: pulse 2 in ISO 7637-1 or 2.
  Test level: 3 or 2(*).

  Pulses are applied continuously during the measuring cycle.
- Switching processes: pulses 3 (a and b) in ISO 7637-1 or 2.

  Test level: 3 or 2(*).

  Pulses are applied before and during the measuring cycle.

Requirement
The results of measurements obtained with and without the disturbances specified in D.2 shall not differ by more than the absolute value of the mpe, or the EBA shall not give a result when subject to disturbances.

D.3 Vibration

a) General

Test method (see also IEC 68-2-6):

The EBA shall be subjected to vibration on three axes in a swept range of frequencies of 10 Hz–150 Hz with an rms acceleration of 2 m/s^2. If resonance is observed, 5 measurements shall be made at each of the resonant frequencies. If no resonance is observed, 10 measurements shall be made at 50 Hz or 60 Hz. This test may require the removal of the EBA's casing.

Requirement
With portable EBA's, the errors in the results of measurement shall not exceed the maximum permissible errors.

With non-portable EBA's, the results obtained with and without disturbances shall not differ by more than the absolute value of the mpe, or the EBA shall not give a result.

b) Random vibrations (for portable EBA's only)

Test method

The EBA is exposed to random vibrations in the following conditions:

- It is mounted so that the gravitational force acts in the same direction as it would in normal use;
- The power is off;
- Total frequency range: 10 Hz–150 Hz;
- Total RMS level: 10 m/s^2;
- Acceleration spectral density:
  from 10 Hz to 20 Hz: 2 m^2·s^{-3};
  from 20 Hz to 150 Hz: – 3 dB/octave;

- Number of axes: 3 perpendicular axes;
- Duration per axis: 1 h.

Requirement

After the test, measurement errors shall not exceed the maximum permissible errors.

D.4 Mechanical shock

Test method

The EBA, placed on a rigid surface in the position in which it is normally used, is tilted on one bottom edge and is then allowed to fall freely onto the test surface. The height of fall given below is that of the opposite edge:

25 mm for non-portable EBA's,
50 mm for portable EBA's.

The test shall be repeated using each of the lower edges.

Requirement

After the test, measurement errors shall not exceed the maximum permissible errors.

D.5 Electrostatic discharge

Test method (see also IEC 801-2)

The EBA shall be subjected randomly, during the measuring cycle, to electrostatic discharges of 8 kV for

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(*) The normal test level is 3. However the EBA may be approved if it only fulfills level 2. In this case a mention is indicated in the pattern approval certificate.

air discharges and of 6 kV for contact discharges, from a capacitance of 150 pF discharging through a resistance of 330 Ω, with an interval between discharges of at least 10 s.

Requirement

The results of measurements made with and without the disturbances shall differ by no more than the absolute value of the mpe, or the EBA shall not give a result.

D.6 Electromagnetic field (see also IEC 801-3)

Results obtained respectively with and without disturbances shall not differ by more than the absolute value of the mpe when the EBA is exposed to electromagnetic fields of:

Frequency range:	26 MHz–1000 MHz;
Field intensity:	10 V/m;
Modulation amplitude:	80 % (1 kHz sinewave).

(See also note to D.7).

D.7 Magnetic field

The EBA shall be placed in a magnetic field of 50 Hz or 60 Hz and an intensity of 60 A/m, such as may be produced by a square coil of 50 turns, of side 1 m, carrying a current of 1 A. The results obtained respectively with and without the disturbance shall not differ by more than the absolute value of the mpe.

Note: For the tests D.6 and D.7, the fields may be applied at any time before or during the measuring cycle. It is permissible for the EBA not to give a result.

D.8 Damp heat cyclic (for portable EBA's only)

Test method

The EBA shall be exposed to cyclic temperature variation between 25 °C and 55 °C. The relative humidity shall be above 95 % during the temperature change and at 25 °C, and shall be at 93 % at 55 °C.

Condensation should occur on the EBA during the temperature rise.

The 24 h cycle consists of:

1) temperature rise during 3 h;
2) temperature maintained at 55 °C during 9 h;
3) temperature lowered to 25 °C during 3 h;
4) temperature maintained at 25 °C during 9 h.

Additional information:

• number of cycles:	2;
• power during cycles:	off;
• duration of recovery:	1 h;
• recovery temperature:	20 °C.

Requirement

After the test, measurement errors shall not exceed the maximum permissible errors.

D.9 Storage ambient conditions (for portable EBA's only)

Test method

The EBA is placed in a thermal room at temperatures and for durations as indicated below. The power is off.

Test conditions

a) Cold

• temperature:	– 25 °C;
• duration:	2 h.

b) Dry heat

• temperature:	+ 70 °C;
• duration:	6 h.

Requirement

After these two test conditions and recovery for 1 h, measurement errors shall not exceed the maximum permissible errors.

D.10 Shakes (for portable EBA's only)

This test simulates shocks in a car trunk. The EBA is placed in its reference position on a table that can generate shakes in the following conditions:

- wave shape: half-sinusoid;
- amplitude: 10 g ($g = 9.81$ m/s^2);
- duration: 6 ms;
- frequency: 2 Hz;
- number of axes: 3 perpendicular axes;
- number of shakes: 1000 for each axis.

D.11 Additional tests for portable EBA's used in open air

- downpours of water or rain water;
- dust-laden atmosphere;
- salt mist.

Under consideration

ANNEX E

TEST REPORT FORMAT

Introduction

The *Test report format* aims at presenting, in a standardized format, the results of the various tests and examinations to which a pattern of an evidential breath analyzer (EBA) shall be submitted with a view to its approval.

All metrology services or laboratories evaluating patterns of EBA's according to OIML R 126 or to national or regional regulations based on OIML R 126 are strongly advised to use this *Test report format*, directly or after translation into a language other than English or French. Its direct use in English or in French, or in both languages, is even more strongly recommended whenever test results may be transmitted by the country performing these tests to the approving authorities of another country, under bi- or multi-lateral cooperation agreements. In the framework of the OIML Certificate System for Measuring Instruments, use of the *Test report format* is mandatory.

Report No......................... OIML Recommendation No.......................... Edition (year).........................

E.1 Name and address of the testing laboratory(ies)

....

....

....

....

E.2 Location at which tests were performed (if other than the address identified in E.1)

....

....

....

....

E.3 Name and address of the manufacturer

....

....

....

....

E.4 Name and address of the applicant (if other than the manufacturer)

....

....

....

....

E.5 Identification of the pattern tested

Trade name...

Model no. ....

Serial no...

Brief description (if useful, including reference to diagrams and inscriptions)

....

....

E.6 Visual and technical examination *(see pages 25–26)*

E.7 Conclusion of tests *(see pages 27–28)*

E.8 Test method

In the case where this Recommendation indicates a recommended number of tests or recommended test values, these numbers shall be used in the framework of the *OIML Certificate System*.

The test report shall indicate what test means were used. Where test means did not conform to this Recommendation, necessary descriptions shall be developed. Where this Recommendation offers an alternative, the solution implemented shall be indicated. Any assumption or results of tests necessary to demonstrate the equivalence of results shall be given. In case of dry gases the capability of the EBA to measure moist gases shall be demonstrated.

Where simplified test means were used (see 9.1.8), the correction using the error under reference conditions shall be indicated.

Any problem observed on the EBA shall be mentioned.

Any useful information about test conditions (ambient temperature, humidity, etc.) shall be indicated.

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E.9 Example of test results sheet

According to the requirements (errors shall meet maximum permissible errors (mpe) or a maximum deviation is allowed) test results shall be indicated on different documents (see examples hereafter).

E.10 Brief statement of general conclusion as to whether the samples tested met the requirements of this Recommendation

....

....

....

....

E.11 Person(s) responsible for the testing

Signature(s) .... Date ....

Title(s) ....

EXAMINATION REPORT (E.6)

Reference to OIML R 126		Verified	Pass	Fail	Comments
Unit of measurement	4				
Measuring range	6.1				
Scale interval	6.2				
Display	6.3.1				
	6.3.2				
	6.3.3				
Printing	6.4				
Measuring conditions	6.6.1				
	6.6.2				
	6.6.3				
	6.6.4				
	6.6.5				
	6.6.6				
	6.6.7				
Safety and security	6.7.1				
	6.7.2				
	6.7.3				
	6.7.4				
	6.7.5				

Put a cross ✕ in the appropriate column(s).

Comments may be developed separately if necessary.

This Report is continued overleaf

EXAMINATION REPORT (E.6) (Cont'd)

Reference to OIML R 126		Verified	Pass	Fail	Comments
Return to zero	6.8.1				
	6.8.2				
	6.8.3				
Checking of correct operation	6.9.1				
	6.9.2				
	6.9.3				
Adjustment or checking of correct adjustment	6.10.1				
	6.10.2				
	6.10.3				
Warm-up time	6.11				
Duration of indication	6.13				
Minimum volume	6.14				
Marking	6.15.1				
	6.15.2				
	6.15.3				
	6.15.4				
Breath sampling system	6.16				

Put a cross ✕ in the appropriate column(s).

Comments may be developed separately if necessary.

CONCLUSION OF TESTS (E.7)

Reference to OIML R 126		Verified	Pass	Fail	Comments/result (1)
Accuracy	5.1.1				(1)
Repeatability	5.2				(1)
Drift	5.3.1				
	5.3.2				
Memory and residual effect	5.4.1				
	5.4.2				
Influence factors for gas 5.5.1	volume				(1)
	duration of exhalation				(1)
	duration of plateau				(1)
	carbon dioxide				(1)
	interruption				
	presence of ethanol				
Physical influence factors 5.5.2	AC supply voltage				
	supply frequency				
	DC supply voltage				
	ripple on DC voltage				
	temperature				
	humidity				
	pressure				
	hydrocarbons				

For tests marked with (1) a separate test results sheet is necessary.

For other tests, results may be directly indicated on this document for instance in the following appropriate way:

- errors from ... to ... (x measurements)
- mean deviation: ... (x measurements)

This Report is continued overleaf

CONCLUSION OF TESTS (E.7) (Cont'd)

Reference to OIML R 126		Verified	Pass	Fail	Comments/result (1)
Physiological influence factors 5.5.3 Annex C	Acetone				
	Acetaldehyde				
	Methanol				
	Isopropanol				
	Carbon monoxide				
	Toluene				
	Ethyl acetate				
	Methane				
	Diethyl ether				
Physical disturbances 5.5.4 Annex D	D.1 power reduction				
	D.2 AC parasitic				
	D.2 DC parasitic				
	D.3 vibrations				
	D.4 shocks				
	D.5 electrostatic discharges				
	D.6 electromagnetic fields				
	D.7 magnetic fields				
	D.8 damp heat cyclic				
	D.9 storage conditions				
	D.10 shakes				
	D.11 downpours of water				
	D.11 dust-laden atmosphere				
	D.11 salt mist				
Durability	5.6				

Example of test results sheet relating to maximum permissible error

Test designation

Concentration (true value)	Number of tests	Smallest error (algebraic)	Greatest error (algebraic)	Maximum permissible error	Mean error	Experimental standard deviation (esd)	Allowance for esd

Comments ....

....

....

....

Example of test results sheet relating to allowed deviation

Test designation

Concentration (true value)	Number of tests	Smallest error	Greatest error	Mean error	Reference (or initial) error	Deviation	Allowance for deviation

Comments ....

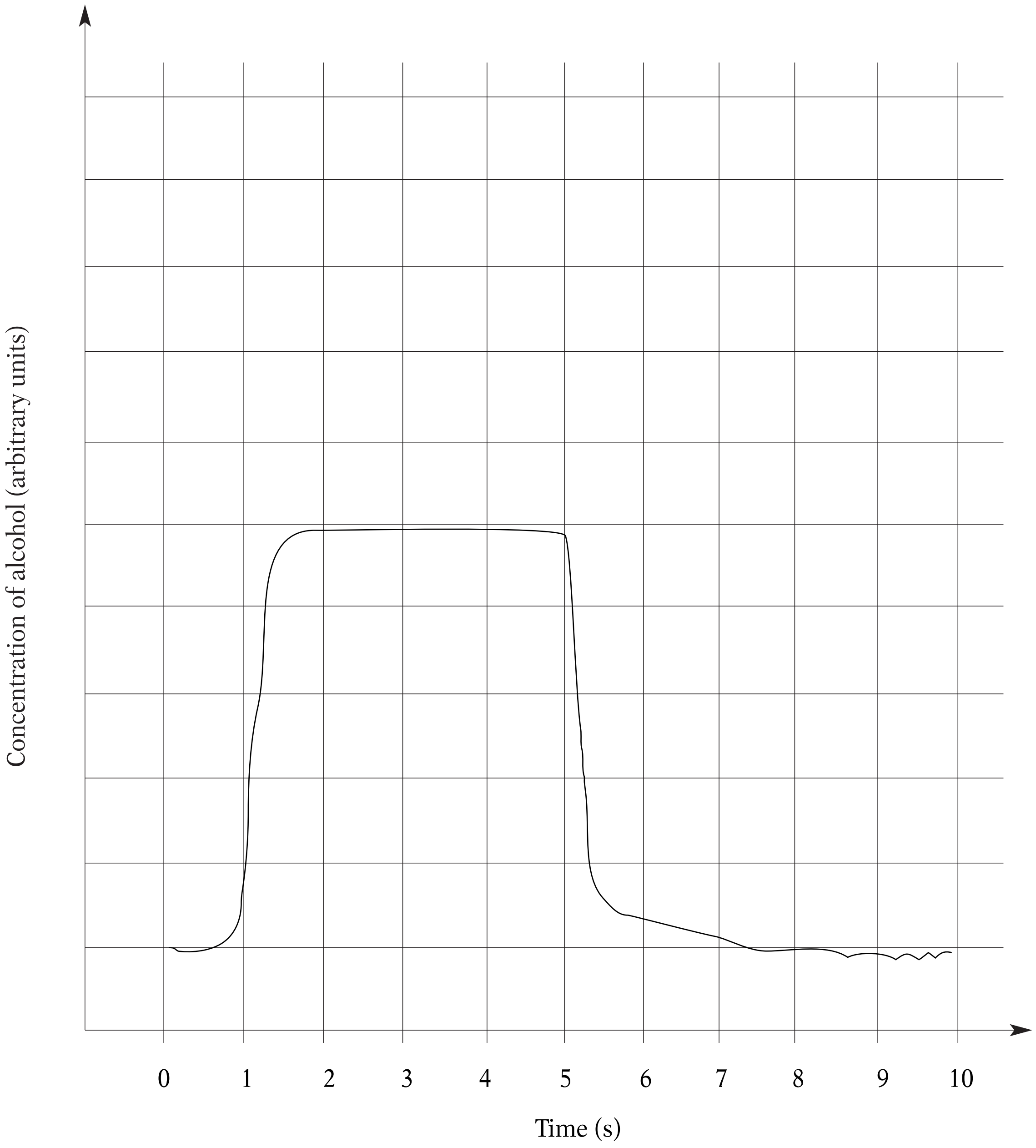
....

....

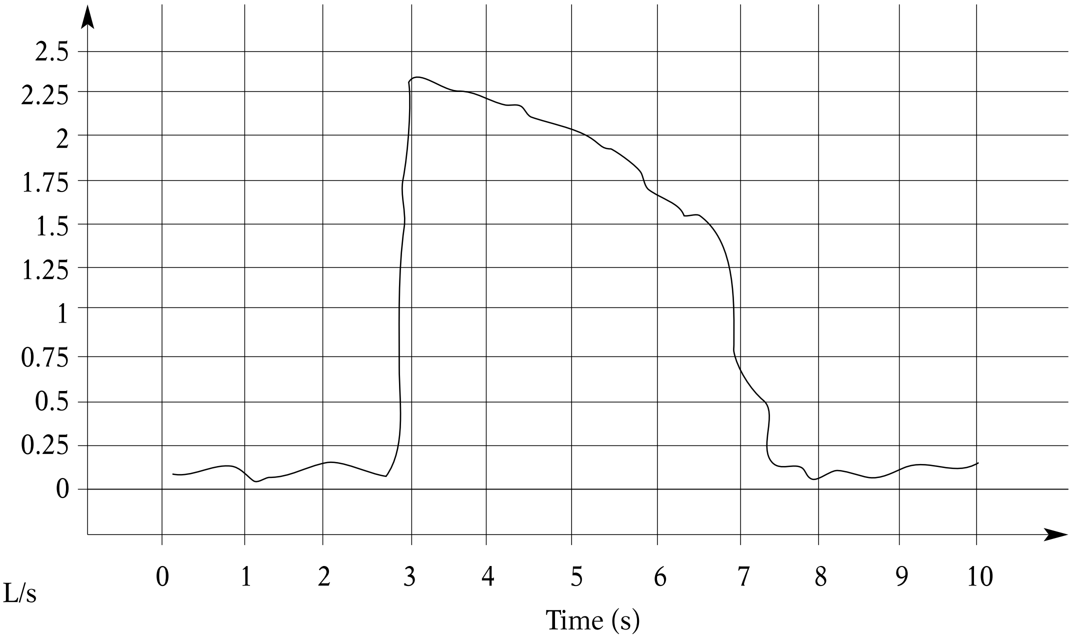
....

ANNEX F

EVOLUTION OF CONCENTRATION WITH TIME

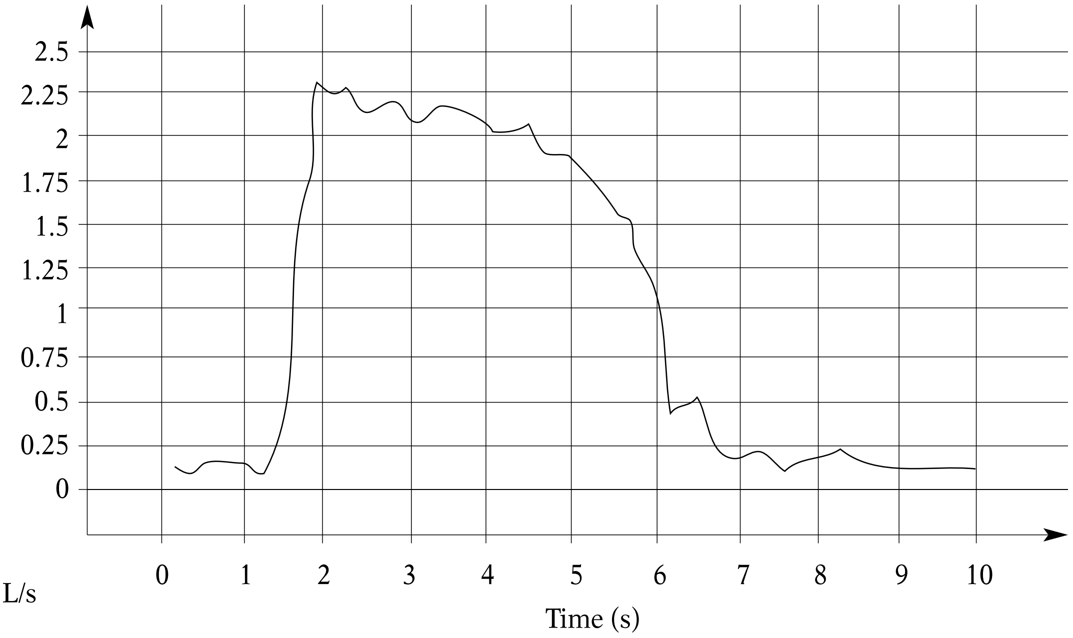


Example of the curve of the flow rate as a function of time, as obtained from a test rig (see 5.1)



max = 2.3 L/s

Example of the curve of the flow rate as a function of time, as obtained from a human exhalation



max = 2.3 L/s

ANNEX G

GENERAL EXAMPLE OF AN APPARATUS FOR TESTING EVIDENTIAL BREATH ANALYZERS

(Informative)

G.1 General

G.1.1 The testing apparatus shall deliver injections of gas corresponding to the specifications of clause 9 and of Annex A. An apparatus having components as shown in the diagrams on page 35 should meet the requirement.

G.1.2 The volume delivered is regulated by the movement of the actuator. The elastic diaphragm correctly simulates the effects of the respiratory muscles and allows the rates of exhalation to be simulated.

G.1.3 The presence of the dead volume is fundamental, rendering possible the production of an injection of gas during which the mass concentration develops in the same exponential manner as in an exhalation. By varying the dead volume and the elasticity of the diaphragm, the shapes of the curves may be changed.

G.1.4 According to the technical solutions adopted, particularly those associated with the devices to regulate the flow rate, the gas analyzer that is included can be considered as a means of checking the apparatus or as providing a standard if it is calibrated periodically.

The apparatus may be automated by using any appropriate means.

G.2 Bubble train

G.2.1 Principle

Let C_{H_2O} be the mass concentration of ethanol of an aqueous solution of ethanol. When air is bubbled through such a solution, the mass concentration C_{air} of ethanol in the air is given by Dubowski's formula$^{(*)}$:

$C_{air} = 0.04145 \times 10^{-3}\ C_{H_2O} \times \exp(0.06583t)$

where t is the temperature in °C.

For $t = 34$ °C, $C_{air} = 0.38866 \times 10^{-3}\ C_{H_2O}$.

G.2.2 Practical application

The formula of G.2.1 demonstrates that different mass concentrations in the air can be obtained by varying the mass concentration of ethanol in the water, but it is preferable to vary the proportion of air that has passed through the solution in the test gas.

The sketches on page 36 give two examples of bubble trains used in practice. By using at least two bubble flasks in series, a stable value of mass concentration at exit is achieved, allowing a fairly large number of measurements to be made.

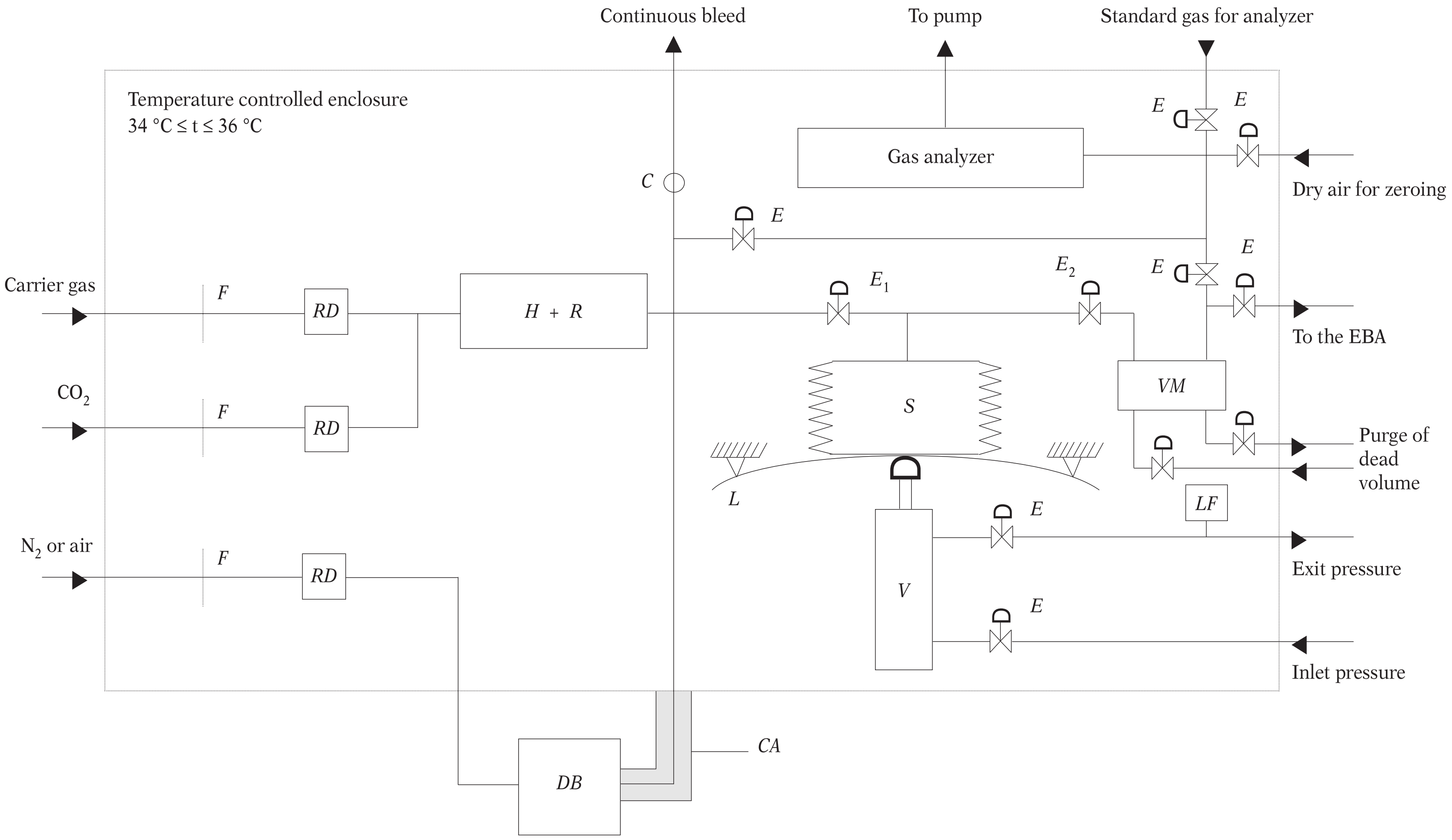
The temperature of the bath shall be held at 34 °C to within ± 0.1 °C. Temperature corrections may be applied.

(*) From *"Breath-ethanol testing: disposable breath tester"* Part 1, National Testing Information Service, USA.

Legend for the diagrammatic sketch on page 35

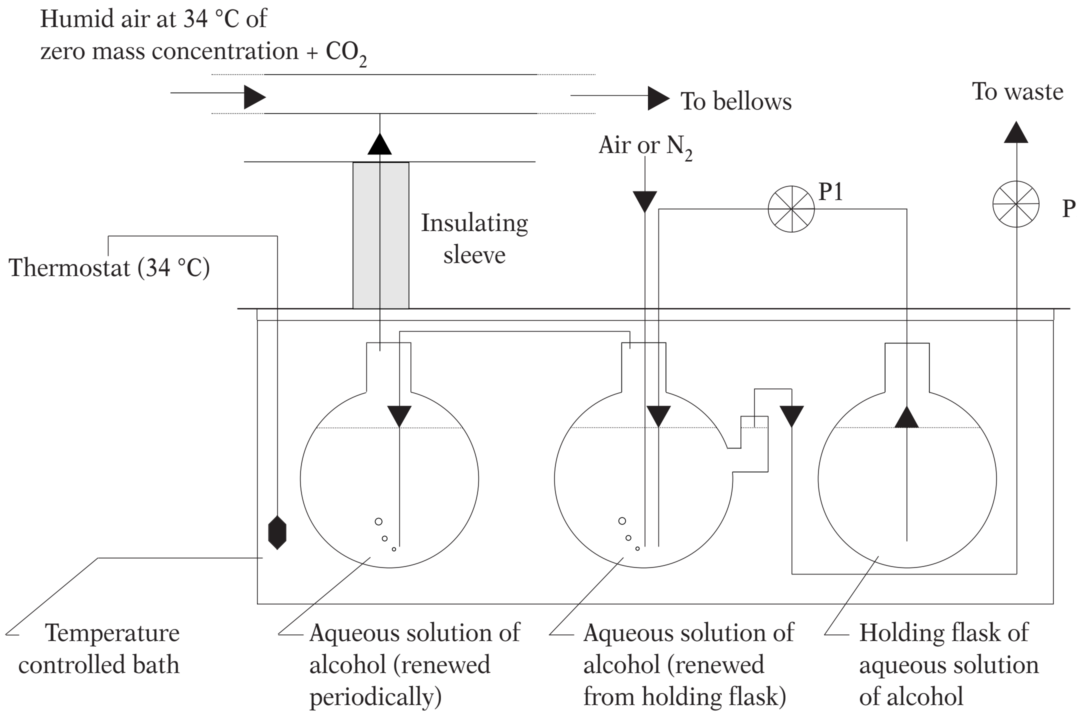
C .... non-return valve
CA .... thermal insulator
DB .... bubble train (see sketches)
E .... solenoid valve
E_1 .... solenoid valve for filling bellows (closed during exhalation)
E_2 .... solenoid valve open during exhalation
F .... filter
H .... humidifier
L .... diaphragm
LF .... flow controller
R .... temperature regulator
RD .... flow regulator
S .... bellows
V .... actuator
VM .... dead volume (to give an exponential evolution of mass concentration during an exhalation)

Diagrammatic sketch of the test rig



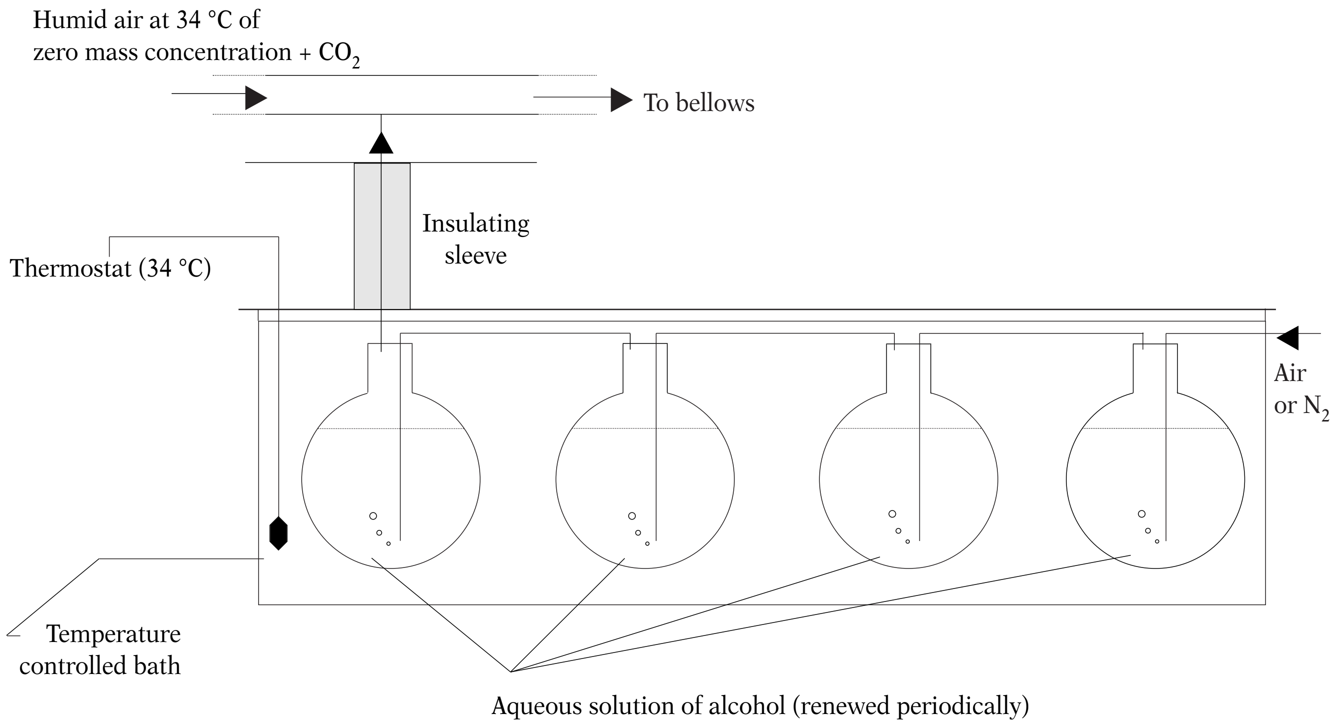
Bubble train

First example



N.B.: Pumps P1 and P2 have an identical flowrate of approximately 0.33 L/h

Second example

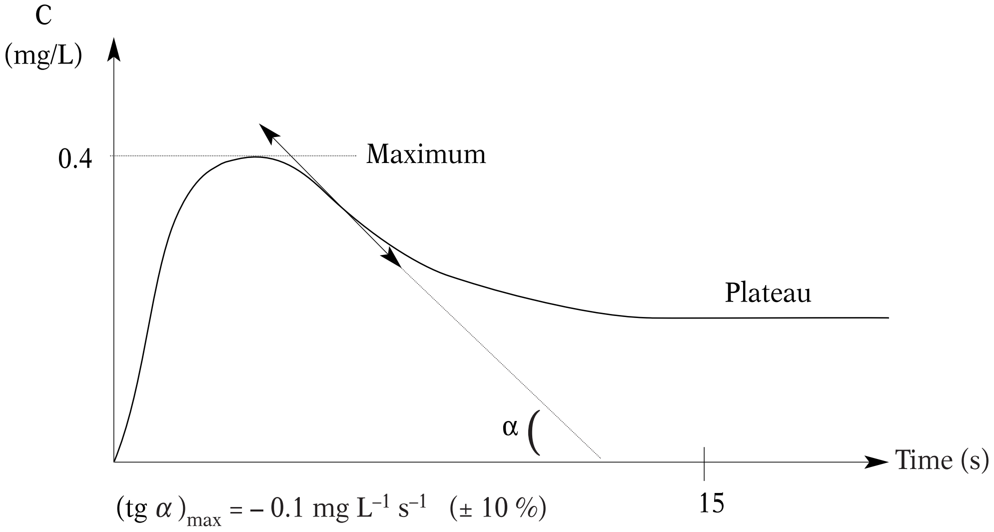


ANNEX H

TEST SIMULATING THE PRESENCE OF ETHANOL IN THE UPPER RESPIRATORY TRACTS

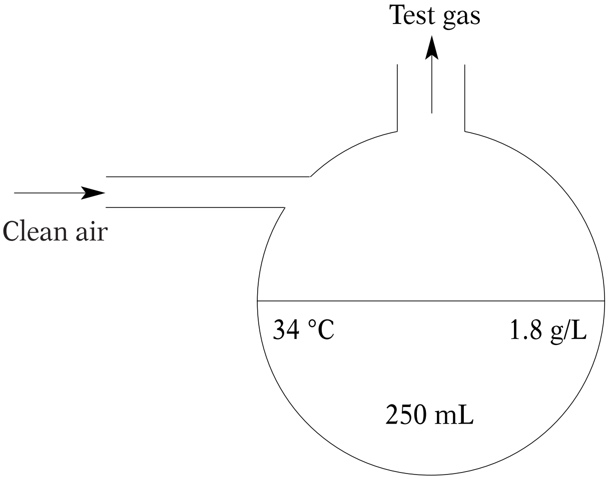
(Informative)

H.1 Evolution of concentration in time



$(\mathrm{tg}\ \alpha)_{max} = -\,0.1\ \mathrm{mg\ L^{-1}\ s^{-1}}\quad (\pm 10\ \%)$

H.2 Test balloon



Balloon volume: 500 mL

ANNEX I

ADVISABLE PROVISIONS FOR THE MEASURING CYCLE

(Informative)

Due to the physiological aspects of measuring ethanol and especially the possibility of ethanol being present in the upper respiratory tracts, the legal authority may require that EBA's fulfill the provisions in this Annex.

Where these provisions are not mandatory the legal authority should provide procedures with the aim of achieving an equivalent level of confidence in the validation of results.

Provisions are necessarily different for portable and non-portable EBA's, since by definition a portable EBA is used on the scene without delay and will therefore be more subject to the influence of ethanol in the upper respiratory tracts than a non-portable one. Although this Recommendation contains a specific test for detecting ethanol in the upper respiratory tracts, in some cases a subject's physiology is such that further provisions are necessary to ensure that accurate evidential readings may be obtained.

I.1 Provisions applicable to non-portable EBA's

I.1.1 In normal operation the measuring cycle shall involve two measurements, each corresponding to an exhalation.

I.1.2 The result of each measurement shall be delivered at the end of the measuring cycle.

I.1.3 Users should be aware that it is advisable to perform further investigations (for example, a second measurement cycle) when the difference between the two measurements of a cycle exceeds the greater of the following two values:

- 10 % in relative value of the smallest measurement, or
- 0.032 mg/L.

In such occurrences the legal authority may require that the EBA automatically either deliver a warning or invalidate the cycle.

I.1.4 Provisions I.1.1 to I.1.3 do not apply if the EBA fulfills the provisions in I.2.

I.2 Provisions applicable to portable EBA's

I.2.1 To ensure an accurate reading, EBA's shall continuously monitor the evolution of the mass concentration during an exhalation.

For application of the following provisions, they shall take into consideration the mass concentration corresponding to the plateau in the curve, and not any other mass concentration.

They shall also measure the time difference between two consecutive measurements.

It shall be possible to memorize the value that constitutes the offence of driving (or working) under the influence of alcohol, hereafter called the "legal value", taking into account the following quotient:

$$\Delta P_{ij} = \frac{\Delta C_{ij}}{\Delta T_{ij}}$$

where:

i = the measurement no. i in the cycle;

j = the measurement performed after no. i;

ΔC_{ij} = the absolute value of the difference between the mass concentrations corresponding to the plateau for measurements i and j, in mg/L.

ΔT_{ij} = the delay between measurements i and j, expressed in minutes.

Note: the decimal part of the minute shall be considered.

I.2.2 First the measuring cycle shall involve 2 measurements each corresponding to an exhalation separated in time by the larger of the following two values:

- 2 minutes, or
- the minimum time between 2 consecutive measurements.

a) Where the two results are smaller than the legal value the result of each measurement shall be delivered at the end of the second measurement.

b) Where the two results are not smaller than the legal value the quotient ΔP_{12} shall be considered by the EBA. If ΔP_{12} is greater than 15 $\mu gL^{-1}min^{-1}$ the EBA shall deliver a message such as: *"Wait 10 minutes and restart the measuring cycle"*. If ΔP_{12} is less than or equal to 15 $\mu gL^{-1}min^{-1}$ then a third measurement shall be required by the EBA, to be performed 10 minutes after the second one.

c) Where ΔP_{23} is less than or equal to 15 $\mu gL^{-1}min^{-1}$ then the smallest measurement result shall be displayed.

d) Where ΔP_{23} is greater than 15 $\mu gL^{-1}min^{-1}$ then one supplementary measurement shall be required by the EBA, to be performed within 5 to 10 minutes after the previous one.

e) Operation d) above is repeated until ΔP_{ij} is less than or equal to 15 $\mu gL^{-1}min^{-1}$, in which case the smallest measurement result shall be displayed.

I.2.3 The EBA shall check that the above delays are respected. If this is not the case, it shall stop the measuring cycle. For delays for which a tolerance is not already given, the tolerance shall be between 0 and 2 minutes only in positive value.

I.2.4 If the EBA allows measurements for other subjects to be started before the result(s) relevant to previous subjects have been displayed, any possibility of confusion of results shall be prevented.

I.3 Provisions applicable to both types of EBA

I.3.1 For legal metrology purposes, the EBA shall be capable of providing the result after each measurement when performing metrological tests.

I.3.2 Each measurement of the cycle shall always at least include:

- verification of zero adjustment and if necessary, zero adjustment before each measurement in conformity with 6.8;
- verification of correct operation of the EBA in conformity with 6.9.

I.3.3 Where it is not possible to complete the measuring cycle as defined in I.1 or I.2, it shall be possible to obtain the previous measurement result(s) upon special command after a specific period of time.

In this case, the EBA shall indicate that the measurement cycle has not been completed.

I.3.4 In normal operation, if the EBA detects a fault in the course of an exhalation (interruption, disturbance, etc.) only this exhalation shall be invalidated, *except* if the EBA detects the presence of ethanol in the upper respiratory tracts or the presence of a physiological influence factor, in which cases all the measuring cycles shall be invalidated.

I.3.5 The reproducibility of the EBA, taking into account the variations of the parameters considered in A.1, A.2 and A.3, shall be consistent with the necessity to monitor the variations in the results considered in I.2.

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require between 4–8 days and when empty the SRV would disconnect from the buoy and leave the port.

Initially it is expected that Port Dolphin would be capable of a natural gas throughput of 400 mmscfd and would eventually be capable of 800 mmscfd with a peak capacity of 1200 mmscfd by having at least one SRV regasifying and discharging at all times. The system would be designed so that two SRVs can be moored simultaneously for continuous unloading of natural gas.

Port Dolphin Energy LLC is seeking Federal Energy Regulatory Commission (FERC) approval for the onshore pipelines concurrent with this deepwater port application. As required by FERC regulations, FERC will also maintain a docket for the FERC portion of the project. The docket numbers are CP07–191–000 and CP07–192–000. The filing may also be viewed on the web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, call (866) 208–3767 or TYY, (202) 502–8659.

In addition, pipelines and structures such as the moorings may require permits under Section 404 of the Clean Water Act and Section 10 of the Rivers and Harbors Act which are administered by the Army Corps of Engineers (USACE).

Port Dolphin will also require permits from the Environmental Protection Agency (EPA) pursuant to the provisions of the Clean Air Act, as amended, and the Clean Water Act, as amended.

The new pipeline will be included in the National Environmental Policy Act (NEPA) review as part of the deepwater port application process. FERC, EPA, and the USACE among others, are cooperating agencies and will assist in the NEPA process as described in 40 CFR 1501.6; will be participating in the scoping meetings; and will incorporate the EIS into their permitting processes. Comments sent to the FERC docket, EPA or USACE will also be incorporated into the DOT docket and EIS to ensure consistency with the NEPA Process.

Construction of the deepwater port would be expected to take approximately 22 months with startup of commercial operations following construction, should a license be issued. The deepwater port would be designed, constructed and operated in accordance with applicable codes and standards.

Privacy Act

The electronic form of all comments received into the DOT docket are available to any person and may be searched by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov*.

(Authority: 49 CFR 1.66)

Dated: June 20, 2007.

By Order of the Maritime Administrator.

Daron T. Threet,

Secretary, Maritime Administration.

[FR Doc. E7–12243 Filed 6–22–07; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2007–28067]

Highway Safety Programs; Model Specifications for Calibrating Units for Breath Alcohol Testers; Conforming Products List of Calibrating Units for Breath Alcohol Testers

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Notice.

SUMMARY: This notice amends the Model Specifications for Calibrating Units for Breath Alcohol Testers (Model Specifications) by adopting an alternate test procedure for evaluating the accuracy of both wet bath and dry gas breath alcohol calibrating units infra-red spectroscopy, as proposed in the **Federal Register** on August 13, 1997 (62 FR 43416). Published with this notice is an updated Conforming Products List of Calibrating Units for Breath Alcohol Testers (CPL) of calibrating units that meet the Model Specifications. This updated CPL includes 22 new listings—8 wet bath units and 14 dry gas units.

DATES: *Effective Date:* The amendments to the Model Specifications and the issuance of the CPL become effective on June 25, 2007.

FOR FURTHER INFORMATION CONTACT: *For technical issues:* Ms. J. De Carlo Ciccel, Office of Behavioral Safety Research, NTI–130, National Highway Traffic Safety Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590; Telephone (202) 366–1694. *For legal issues:* Ms. Allison Rusnak, Office of Chief Counsel, NCC–113, National Highway Traffic Safety Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590; Telephone (202) 366–1834.

SUPPLEMENTARY INFORMATION: On August 18, 1975 (40 FR 36167), NHTSA published a standard for Calibrating Units for Breath Alcohol Testers. A Qualified Products List of calibrating units for breath alcohol testers that met the standard was first issued on November 30, 1976 (41 FR 53389).

On December 14, 1984, NHTSA issued a notice to convert the mandatory standards for calibrating units for breath alcohol testers to Model Specification for such devices (49 FR 48865) and to establish a Conforming Products List (CPL) of calibrating units meeting the Model Specifications. Calibrating units provide known concentrations of ethanol vapor for the calibration or calibration checks of instruments that measure breath alcohol (BrAC).

On December 29, 1994, NHTSA published a notice amending the Model Specifications and updating the CPL for calibrating units (59 FR 67377). The notice also proposed and sought comments about providing an alternate test procedure using National Institute for Standards and Technology (NIST) Reference Gas Mixtures for evaluating the accuracy and precision of dry-gas ethanol calibrating units. The agency amended the Model Specifications on August 13, 1997 by incorporating the NIST test procedure (62 FR 43416). In that same notice, NHTSA updated the CPL and proposed an alternate test procedure for evaluating the accuracy and precision for evaluating wet bath and dry gas calibrating units using infra-red spectroscopy.

Having received no comments regarding the infra-red spectroscopy test procedure, this notice adopts the alternate procedure for evaluating wet bath and dry gas calibrating units using infra-red spectroscopy as proposed. This notice also amends the CPL of Calibrating Units for Breath Alcohol Testers, adding 8 wet bath units and 14 dry gas units.

A. Procedures for a Product Submission

Testing of calibrating units submitted by manufacturers to these Model Specifications will continue to be conducted by the DOT Volpe National Transportation Systems Center (VNTSC). Tests will continue to be conducted semi-annually or as necessary. Manufacturers wishing to submit calibrating units for testing must apply to NHTSA for a test date (Office of Behavioral Safety Research, NTI–130, 1200 New Jersey Avenue, SE., Washington, DC 20590, Telephone (202) 366–1694). Normally, at least 30 days will be required from the date of notification until the test can be scheduled. One week prior to the scheduled initiation of the test program, the manufacturer shall deliver at least one unit of the device to be tested to: VNTSC, RTV–4F, 55 Broadway, Cambridge, MA 02142. The manufacturer shall be responsible for ensuring that the unit is operating properly. If the manufacturer wishes to submit a duplicate, backup unit, it may do so.

When a manufacturer delivers a device to be tested, it shall also deliver to VNTSC specifications and drawings that fully describe the unit and the Operator's Manual and Maintenance Manual normally supplied with purchase of the equipment. NHTSA will consider claims of confidentiality under 49 CFR Part 512.

The manufacturer shall also deliver the instructions that will accompany the device when it is sold. The instructions shall include information about the procedures to be followed to protect against possible condensation that might occur as a result of freezing during shipment and to correct for atmospheric pressure. The instructions shall also include information about any offsets that may apply to the use of a particular type of breath tester. NHTSA will examine these instructions to ensure that they provide sufficient information about these matters. Products submitted without this information will not be tested.

The manufacturer will have the right to check the calibrating unit between arrival at VNTSC and the start of the test and to ensure that the calibrating unit is in proper working condition. The manufacturer will have no access to the calibrating unit during the tests. Any malfunction of the calibrating unit that results in failure to complete any of the tests satisfactorily will result in a finding that it does not conform to the Model Specifications. If a unit fails to conform, it may be resubmitted for testing after appropriate corrective action has been taken.

On the basis of these results, NHTSA periodically will publish a CPL identifying the calibrating units that conform to the Model Specifications.

Re-testing of units will be conducted when necessary. NHTSA intends to modify and improve these Model Specifications as new data and improved test procedures become available. (The test procedures may be altered in specific instances, if necessary, to meet the unique design features of a calibrating unit). If these Model Specifications are modified, notification will be provided in the **Federal Register.** If NHTSA determines that re-testing to the modified specifications is necessary, a manufacturer whose equipment is listed on the CPL will be notified to resubmit the equipment for testing to the modified specifications only.

NHTSA reserves the right to test any unit on the CPL throughout its useful life to ensure that the unit is performing in accordance with the Model Specifications. If at any time a manufacturer plans to change the design of a calibrating unit currently on the CPL, the manufacturer shall submit the proposed changes to the NHTSA Office of Behavioral Safety Research for review. Based on this review, NHTSA will decide whether the change will require re-testing of the unit. Normally, such re-testing will be accomplished the next time testing is performed. Guidance to manufacturers on considerations governing this decision is available from NHTSA upon request.

NHTSA's Office of Behavioral Safety Research will be the point of contact for information about acceptance testing and field performance of equipment already on the list. NHTSA requests that users of calibrating units provide both acceptance and field performance data to NHTSA when such data is available. Information from users will be used to: (1) Help NHTSA determine whether units continue to perform according to the Model Specifications, and (2) ensure that field use does not indicate excessive breakdown or maintenance problems.

If information gathered indicates that a device on the CPL is not performing in accordance with the Model Specifications or demonstrates problems involving the device, NHTSA will direct VNTSC to conduct a special investigation. This investigation may include visits to users and additional tests of the unit obtained from the open market. If the investigation indicates that the units actually sold on the market are not meeting the Model Specifications, then the manufacturer will be notified that the unit may be removed from the CPL. The manufacturer shall have 30 days from the date of notification to reply.

Based on the VNTSC investigation and any data provided by the manufacturer, NHTSA will decide whether the unit should remain on the CPL. Upon resubmission, the manufacturer must submit a statement describing what has been done to overcome the problems that led to the removal of the unit in question from the CPL.

B. Infra-Red Spectroscopy

This notice incorporates into the Model Specifications an alternate procedure for evaluating wet bath and dry gas calibrating units using infra-red spectroscopy. When infra-red spectroscopy is used, the wet bath or dry gas sample to be analyzed is passed into a chamber through which infra-red radiation is transmitted. The wavelength of the transmitted radiation is chosen so that some of it is absorbed by alcohol. According to the Beer-Lambert Law of absorption of radiation,[1] the amount of energy absorbed by the sample in the chamber is proportional to the concentration of the alcohol in the sample. By measuring the amount of radiation transmitted when the sample chamber is empty and the amount transmitted when the sample is present, the concentration of the alcohol in the sample can be determined.

The agency believes that use of infra-red spectroscopy offers important advantages. First, the technique can be used to evaluate both wet bath calibrating units and dry gas calibrating units because surface interactions do not affect the analysis. Second, standards used in the evaluations can be prepared at VNTSC, eliminating the necessity of obtaining standards from an outside source.

C. Conforming Products List

The CPL, which appears as an Appendix to this notice, lists the calibrating units that have been re-tested to date at the lower BACs (*i.e.,* at 0.020, 0.040, 0.080, and 0.160) and found to conform to the Model Specifications reprinted herein. The CPL also lists devices that have not been tested at the lower BAC levels (.020, .040, .080 and .0160), but were listed on the CPL for calibrating units on the basis that they were tested and found to conform to the earlier Model Specifications (49 FR 48864) when tested at BAC levels 0.050, 0.100 and 0.150. These devices are identified on the CPL with an asterisk.

The CPL published today includes 22 new listings—8 wet bath units and 14 dry gas units. The wet bath units include: CALWAVE dt–100, submitted by Davtech Analytical Service, Canada; Model 10–4D, Model 10–4D Revision A, Model 2100 (aka: Model 210021), Model 2100 Revision A, and 590 submitted by Guth Laboratories, Inc., Harrisburg, Pennsylvania; Alcotest CU 34 submitted by National Draeger, Inc., Durango, Colorado; and Model 3402C–2K submitted by RepCo Marketing, Inc., Raleigh, North Carolina. The dry gas units[2] include: 103 ppm/108L and 270

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[1] Farrington Daniels & Robert Alberty, ''Physical Chemistry'' 3d. Ed. John Wiley & Sons, New York, 1996.

[2] The naming convention of the dry gas units added to the CPL today is illustrative of the ethanol

Continued

ppm/30L submitted by Airgas, Inc., (previously know as Gateway Airgas, Inc., A.G. Specialty Gas Co., or Acetylene Gas Co) St. Louis, Missouri; 115 ppm/34L, 115 ppm/103L, 230 ppm/34L, 230 ppm/103L, 260.5 ppm/58L, 260.5 ppm/537L, and 260.5 ppm/15L submitted by Air Liquide, CALGAZ, Cambridge, Maryland; and Scotty 28 0.040 BAC/28L, 0.045 BAC/28L, 0.080 BAC/28L, 0.100 BAC/28L, 0.105 BAC/28L submitted by Scott Specialty Gases, Inc., Plumsteadville, Pennsylvania. One device, Toxitest Model ABS120 by Federal Signal Corporation, is being removed from the CPL as it is no longer manufactured.

In consideration of the foregoing, NHTSA amends the Model Specifications for Calibrating United as set forth below.

Model Specifications for Calibrating United for Breath Alcohol Testers

1.0 Purpose and Scope

These specifications establish performance criteria and methods for testing of calibrating units which provide known concentrations of ethanol vapor for the calibration or calibration checks of breath alcohol testers. The results of this testing are intended for use in the conformance testing for the maintenance of a Conforming Products List for calibrating units.

2.0 Definitions

2.1 Conformance testing. Testing to check the conformance of a product with these model specifications in advance of and independent of any specific procurement action.

2.2 Concentration units. Blood alcohol concentration: grams alcohol per 100 milliliters blood or grams alcohol per 210 liters of breath in accordance with the Uniform Vehicle Code, Section 11–903(a)(5).[3] BrAC is often used to indicate that the measurement is a breath measurement, i.e. grams alcohol per 210 liters of breath.

2.3 Relative Standard Deviation (RSD). The ratio of the standard deviation (SD) of a series of measurements to the mean of the series expressed as a percentage:

$$RSD = (SD/Mean) \times 100 \text{ percent}$$

2.4 Standard Deviation (SD). A common indication of precision in the measurement of the concentration of a succession of N vapor samples.

$$SD = \{\text{Sum } (X_i - X_m)^2/(N-1)\}^{1/2}$$

Where:

X_i = a single measurement result;
X_m = the average of the measurements;
N = the number of measurements made in the test.

2.5 Systematic Error (SE). An indication of the accuracy of the measurement of the concentration of a succession of vapor samples.

$$SE = X_m - \text{test BrAC}$$

2.6 Least Squares Fit Calibration Curve. A Line fitted to a number of measurement pairs, one the independent value (X) and the other the dependent value (Y), over a measurement range.

The fitted line is of the form: $Y = a + bX$, where intercept, $a = Y_m - b_m$, and slope, $b = (\text{Sum}X_iY_i - NX_m) / (\text{Sum}X_i^2 - nX_m^2)$

3.0 Tests and Requirements

If the BrAC of the CU is fixed, perform the tests at the fixed BrAC; otherwise, prepare the CU for testing at 0.08 BrAC except as otherwise required in Test 1 below. Each of the tests requires 10 measurements to three decimal places using the test procedure specified in 3.1, 3.2, or 3.3, respectively. The CU will be operated according to the manufacturer's instructions. Unless otherwise specified, the tests will be performed in the absence of drafts and at prevailing normal laboratory temperature, humidity, and barometric pressure. Performance requirements are: $-0.002 \text{ BrAC} \leqq SE \leqq +0.002 \text{ BrAC}$; $RSD \leqq 2\%$

Test 1. Precision and Accuracy. Test at each specified BrAc.

Test 1.1: 0.020 BrAC
Test 1.2: 0.040 BrAC
Test 1.3: 0.080 BrAC
Test 1.4: 0.160 BrAC

Test 2. Ambient Temperature. Use a temperature chamber controllable to ± °C. Soak the CU at the specified temperature for 1 hour, being careful to prevent drafts on the device, then test at that temperature.

Test 2.1: 10 °C
Test 2.2: 30 °C

Test 3. Input Power. If the CU is powered by nominal voltages of 120 volts AC of 12 volts DC, condition the device for one half hour at the appropriate input voltage specified below, then test at that voltage. Monitor the input power with a voltmeter accurate to ± 2% full scale in the range used and re-adjust the voltage, if necessary. If the voltage is Ac, conduct test 3.1 and 3.2.

If the voltage is DC, conduct tests 3.3 and 3.4.

Test 3.1: 108 Volts/AC
Test 3.2: 123 Volts/AC
Test 3.3: 11 Volts/DC
Test 3.4: 15 Volts/DC

Test 4. Electrical Safety Inspection. Examine the CU for protection of the operator from electrical shock. Examine for proper use of input power fuses, and verify that there are no exposed male connectors at high potential. Determine that overheating does not occur during operation and that undue fire hazards do not exist.

3.1 Test Procedure (Original, wet-bath calibrating units)

Equipment and Supplies: *Gas Chromatograph* capable of complete resolution of ethanol in test samples, with heated gas sampling valve. *Water bath* thermostated at 34 °C ± 0.1 °C. *Glass Reference Sample Bottles (300 ml capacity or greater) with Stopper and Inlet and Outlet Air Hoses* (see Figure 1). Hoses should be about 1/8'' OD Teflon tubing. *Reference Ethanol Solutions* prepared using Class A glassware and American Chemical Society reagent grade ethanol or USP grade ethanol. The purity of the ethanol used shall be compared with the National Institute of standards and Technology (NIST) Standard Reference Material for ethanol. Use the value of Harger, *et al.*, for the partition ratio for concentration of ethanol in headspace to concentration in solution at 34 °C, Ka/w = 0.000393[4] to prepare two solutions which, when thermostated at 34 °C, produce headspace ethanol vapor concentrations that bracket the test BrAC by no more than ± 20%. Small Air Pump for bubbling air through reference solutions (see Figure 1).

Step 1. Prepare the Gas Chromatograph for measurement of vapor samples. Adjust instrument temperatures, gas flows, detector, and recording device for optimum response for ethanol. Prepare the CU for use according to manufacturer's instructions.

Step 2. Fill two reference solution bottles to ¾ full with above reference solutions. Insert stopper assemblies with bubble line and alcohol vapor line in place and put bottles in the water bath with water level up to the stopper. Connect air pump to bubble line. Connect alcohol vapor line to gas chromatograph sampling valve inlet fitting. Allow 1 hour for temperature equilibrium to be achieved.

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concentration in the volume of nitrogen dry gas. Concentration is expressed in parts per million (ppm) or marketed as breath alcohol concentrations (BAC) and volume is expressed in Liters(L).

[3] Available from National Committee on Uniform Traffic Laws and Ordinances, 405 Church Street, Evanston, IL 60201.

[4] RN Harger, BB Raney, EG Bridwell, MF Kitchel J. Biol. Chem. 183, 197–213 (1950). Additional data from Harger in a private communication (see 49 FR 48869).

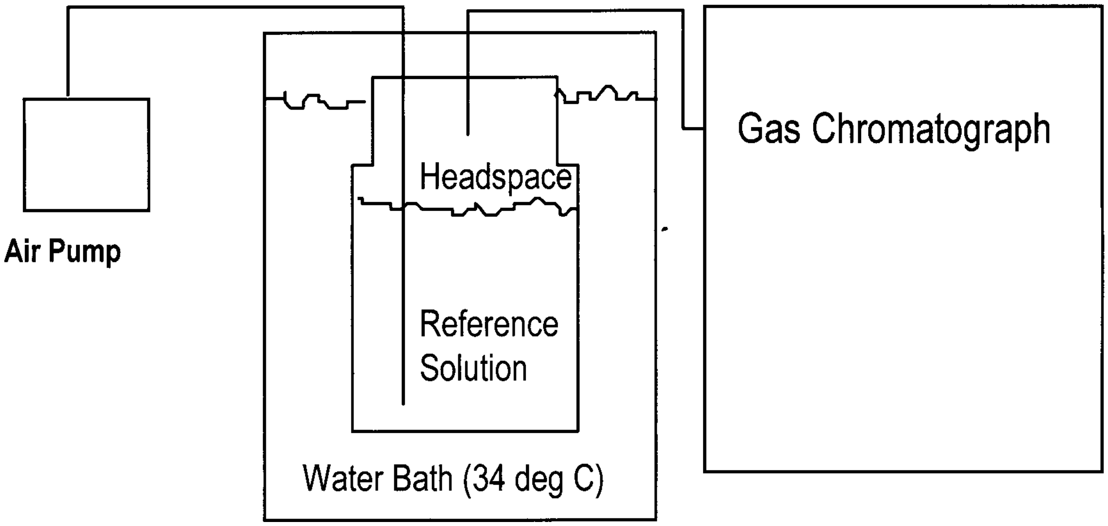
Step 3. Turn on air pump which has been pre-set to pump air through the reference solution bottle-gas chromatograph sampling assembly at a rate just sufficient to thoroughly flush the system in 10 seconds. After flushing is complete, allow the sample to relax to atmospheric pressure, then inject the reference sample onto the gas chromatograph column. In this way, obtain 5 chromatograms of one of the reference solution headspace ethanol vapors.

Step 4. Thoroughly flush the sample loop with vapors from the CU device, while avoiding over-pressurizing of the sampling system. To prevent condensation of alcohol, warm the transfer line if necessary. Allow the sample to relax to atmospheric pressure, then inject the sample onto the column. In this way, obtain 10 ethanol chromatograms using the CU device.

Step 5. Repeat step 3 using the second reference solution.

Step 6. Calculations. *Peak height to BrAC conversion factor.* For each ethanol peak obtained in Step 3 and Step 5, calculate a conversion factor for ethanol concentration by dividing the equivalent BrAC of the vapor sample by the peak height obtained for that sample. From the 10 samples, obtain the mean and the RSD of the conversion factors. If the RSD obtained fails to meet the criteria for RSD in 3.0, perform necessary troubleshooting and repeat the procedure from Step 1. Use the mean of the conversion factors to calculate the BrAC for each of the 10 ethanol peaks obtained in Step 4. Calculate the mean, the RSD, and the systematic error of the experimental BrACs.

Figure 1. Wet Bath Reference Sample Set-up. Sample lines 1/8" Teflon. The bubble line should extend at least 4 inches below surface of the solution. The length of the alcohol vapor line from the headspace to the gas chromatograph should be minimized.



3.2 Test Procedures (for dry gas calibrating units). Alternate Test Method using National Institute of Standards and Technology Reference Gas Mixtures (NISTRGMs) in place of wet bath reference samples

The following alternate method for the evaluation of dry gaseous ethanol calibration devices is presented.

Additional required material: For the alternate method for evaluation of dry gaseous ethanol calibration devices, the following will be required: Four cylinders of National Institute of Standards and Technology ethanol-in-inert gas Technical Reference Gas Mixtures (NISTRGMs) which span the BrAC range 0.01 to 0.16.

Alternate procedure for evaluation of dry gaseous ethanol calibration devices. This procedure substitutes the use of NISTRGMs in place of the wet bath reference samples when evaluating dry gas CUs.

Step A1. Connect one of the NISTRGM cylinders to the inlet of the gas chromatograph sampling valve and pass reference gas through the sampling system at a rate just sufficient to thoroughly flush the system in about 10 seconds. Allow the sample to relax to atmospheric pressure, then inject the sample onto the column. In this way, obtain 5 chromatograms of the reference gas.

Step A2. Repeat Step A1 for each of the four NISTRGM reference gas mixtures.

Step A3. Calculate the RSD of the concentration divided by peak height data obtained in Step A1 and Step A2. If the calculated RSD meets the criteria of 3.0, calculate the slope and intercept of the least squares fit calibration line for conversion of peak height to BrAC. Using the average peak height of each NISTRGM and the slope and intercept data, calculate the concentration of each NISTRGM. If the resulting concentrations are within the stated accuracy of the NISTRGM, proceed to Step A4.

Step A4. Connect the calibrating device to the inlet of the gas chromatograph sampling system and allow the calibrating device gas to flow at a rate just sufficient to thoroughly flush the sampling system in about 10 seconds. Allow the sample to relax to atmospheric pressure, then inject the sample onto the column. In this way, obtain 10 chromatograms of the calibrating device gas.

Step A5. Calculations. Using the peak height data obtained in Step A4 and intercept and slope data obtained in Step A3, calculate the BrAC for each of the 10 peak heights. Calculate the mean, RSD, and systematic error of the calculated BrACs.

3.3 Test Procedures (for dry gas or wet bath calibrating units)

This alternate procedure uses infra-red spectroscopy that is suitable for evaluating ethanol vapor samples from either wet-bath CUs or from dry-gas CUs.

3.3.1 General. This method uses the Beer-Lambert Law of absorption of radiant energy by fluids.

$I = I_o \times e^{-abc}$

Where:

I_o is the energy entering the sample chamber of a spectrophotometer containing the sample to be analyzed.

I is the energy transmitted from the sample chamber.

a is the absorptivity of the sample.

b is the radiation path length of the sample chamber.

c is the concentration of the sample in the sample chamber.

A convenient form of the Beer-Lambert law is

$\mathrm{Ln}(I_o/I) = abc$

where the term $\mathrm{Ln}(I_o/I)$, the logarithm of the ratio of incident to transmitted energy, is called the absorbance of the sample. In the procedure described below, the terms a and b are treated as a single quantity, ab, and the term c is BrAC.

3.3.2 Test Procedure.

Equipment and Supplies. *Infra-red Spectrophotometer* with sample chamber that can be heated to above 40 °C. A non-dispersive instrument with appropriate band pass filters and configured to measure breath alcohol samples, such as an infra-red evidential breath tester listed on the NHTSA Conforming Products List for evidential breath testers may be used. The detector voltage of the instrument must be accessible for measurement. The sampling hoses of the device may be altered for more convenient processing of test samples. *Water bath* thermostated at 34 °C ± 0.1 °C. *Glass Reference Sample Bottles (300 ml capacity or greater) and Stoppers with Bubble and Alcohol Vapor lines* (see Figure 2). *Reference Ethanol Solutions* prepared using Class A glassware and American Chemical Society reagent grade ethanol or USP grade ethanol. The purity of the ethanol used shall be compared with the National Institute of Standards and Technology (NIST) Standard Reference Material for ethanol. Use the value of Harger, *et al.,* for the partition ratio for concentration of ethanol in headspace to concentration in solution at 34 °C, $K_{a/w} = 0.000393$[2] to prepare two aqueous alcohol solutions which bracket the test BrAC by no more than ± 20%. A cylinder of inert *Flushing Gas*, which is optically clear in the absorption region used for measurement. This gas will be used to flush the sample chamber of the spectrophotometer and to deliver reference headspace vapors and wet bath sample vapors into the sample chamber. *Pressure regulating valve with Teflon delivery hose* for controlling flow and delivery of flushing gas.

Step B1. Prepare the spectrometer for measurement of vapor samples. Prepare the CU for use according to manufacturer's instructions.

Step B2. Fill a reference sample bottles to ¾ full with water and two reference sample bottles to ¾ full with the above reference solutions. Insert stopper assemblies ensuring that the end of the bubble line reaches to at least 4 inches below the surface of the solution, then place the bottles in the water bath with water level up to the stopper. Allow 1 hour for temperature equilibrium to be achieved.

Step B3. Connect the bubble line of the sample bottle containing water only to the flushing gas valve and the vapor line to the spectrophotometer inlet and flush the sample chamber with water vapor and obtain the detector voltage reading. Then flush the detector chamber with flushing gas only and obtain the detector reading. Repeat 2 times to obtain 3 sets of readings. If the CU being evaluated is a wet bath device, skip this step and proceed to Step B4.

Step B4. In the manner of Step B3, obtain 5 sets of detector readings using one of the reference alcohol solution bottles.

Step B5. In the manner of Step B3, obtain 10 sets of detector readings from the CU being evaluated. If the CU is a wet bath device, use the flushing gas to fill the sample chamber, operating the device according to manufacturer's instructions. If the CU device is dry gas device, fill the sample chamber according to manufacturer's instructions.

Step B6. Repeat Step B5 using the other reference alcohol solution bottle.

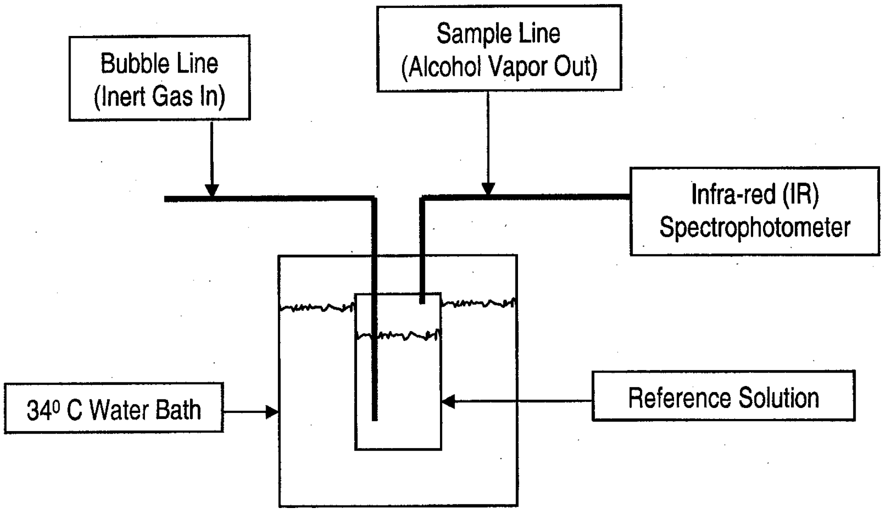
Step B7. Repeat Step B3.

Step B8. Calculations. For each measurement pair, I_o is the detector voltage obtained for the flushing gas alone in the sample chamber and I is the voltage obtained for the flushing gas with reference sample or test sample in the sample chamber corrected for water vapor absorption, i.e.; the detector voltage obtained for headspace reference samples at 0.000 BrAC. Use the average of the 6 voltage readings obtained for the water samples for the correction for water vapor absorption ($I = I_{sample} - I_{water}$). In the case of wet bath device samples, there is no correction for water vapor absorption. If the detector is biased, it will be the difference between the bias voltage and the above voltage.

Calculate the absorbance for each of the 10 reference samples. Divide each absorbance by the corresponding BrAC of the sample. Obtain the mean (which is the factor ab), SD, and RSD for the 10 ratios. If the RSD is more than 2%, troubleshoot the procedure and repeat.

Calculate the absorbance for each of the 10 CU test samples. Divide each by the ab factor to obtain the BrAC for each of the 10 CU samples. Obtain the mean, SD, RSD, and SE.

Figure 2. Equipment set-up. Bubble and sample lines 1/8" Teflon, minimized length. Depth of bubble line into reference solution at least 4". The alcohol vapor line from the headspace to the IR spectrophotometer should be minimized.



Appendix—Conforming Products List of Calibrating Units for Breath Alcohol Testers [Manufacturer and Calibrating Unit] [1]

CONFORMING PRODUCTS LIST OF CALIBRATING UNITS FOR BREATH ALCOHOL TESTERS

Manufacturers	Type of device	
	Dry gas	Wet bath
1. Airgas, Inc. (Formerly known as: Gateway Airgas, AG Specialty Gas, or Acetylene Gas Co.), St. Louis, MO		
• Ethanol Breath Alcohol Standard	X	
• 103 parts per million (ppm)/108 Liters (L)	X	
• 270 ppm/30L	X	
2. Air Liquide CALGAZ, Cambridge, MD		
• 115 ppm/34L	X	
• 115 ppm/105L	X	
• 230 ppm/34L	X	
• 230 ppm/105L	X	
• 260.5 ppm/58L	X	
• 260.5 ppm/537L	X	
• 260.5 ppm/15L	X	
3. CMI, Inc., Owensboro, KY		
• Toxitest II		X
4. Davtech Analytical Services, Canada		
• CALWAVE dT–100		X
5. Guth Laboratories, Inc., Harrisburg, PA		
• Model 34C Simulator (variations: Model 34C Cal DOJ, 34–C–FM, and 34C–NPAS)		X
• Model 3412		X
• Model 10–4 and 10–4D		X
• Model 10–4D Revision A		X
• Model 1214		X
• Model 2100 (formerly Model 210021)		X
• Model 2100 Revision A		X
• 590		X
6. Intoximeters, Inc., St. Louis, MO		
• Alco Breath Alcohol Standards*	X	
7. Lion Laboratories, Cardiff, Wales, UK (a subsidiary of CMI, Inc.)		
• AlcoCal Breath Alcohol Standard	X	
8. Liquid Technology Corp., Orlando, FL		
• Ethanol-in-Nitrogen	X	
9. Luckey Laboratories, Inc., San Bernardino, CA		
• Simulator*		X

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[1] Infra-red (IR) and fuel cell breath testers may be calibrated with either wet bath or dry gas CUs. However, it is inadvisable to use dry gas CUs when calibrating gas chromatograph EBTs.

CONFORMING PRODUCTS LIST OF CALIBRATING UNITS FOR BREATH ALCOHOL TESTERS—Continued

Manufacturers	Type of device	
	Dry gas	Wet bath
10. National Draeger, Inc., Durango, CO		
• Mark II–A		X
• Alcotest CU 34		X
11. PLD of Florida, Inc., Rockledge, FL		
• BA 500		X
12. Protection Devices, Inc., U.S. Alcohol Testing, Inc., Rancho Cucamonga, CA		
• LS34 Model 6100*		X
13. RepCo Marketing, Inc., Raleigh, NC		
• AS–1		X
• Model 3402C		X
• Model 3402C–2K		X
14. Scott Specialty Gases, Inc., Plumsteadville, PA		
• Model EBS™ Gaseous Ethanol Breath Standard	X	
• Scotty 28 0.040 BAC/28L	X	
• Scotty 28 0.045 BAC/28L	X	
• Scotty 28 0.080 BAC/28L	X	
• Scotty 28 0.100 BAC/28L	X	
• Scotty 28 0.105 BAC/28L	X	
15. Smith & Wesson Electronic Co., Springfield, MA		
• Mark II–A Simulator*		X
16. Systems Innovation, Inc., Hallstead, PA		
• True-Test MD 901*		X
17. U.S. Alcohol Testing, Rancho Cucamonga, CA		
• Alco-Simulator 2000*		X
• Alco-Simulator 61000		X

*Six instruments marked with an asterisk (*) meet the Model Specifications in 49 FR 48864 (December 14, 1984), *i.e.* instruments tested at 0.050, 0.100, and 0.150). Instruments not marked with an asterisk meet the model specifications detailed in this notice, and were tested at 0.020, 0.040, 0.080, and 0.160 BrAC.

Authority: 23 U.S.C. 402; delegations of authority at 49 CFR 1.50 and 501.

Issued on: June 25, 2007.

Marilena Amoni,

Associate Administrator for the Office of Research and Program Development.

[FR Doc. 07–3060 Filed 6–22–07; 8:45 am]

BILLING CODE 4910–59–M

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Ex Parte No. 290 (Sub–No. 5) (2007–3)]

Quarterly Rail Cost Adjustment Factor

AGENCY: Surface Transportation Board, Department of Transportation.

ACTION: Approval of rail cost adjustment factor.

SUMMARY: The Board has approved the third quarter 2007 rail cost adjustment factor (RCAF) and cost index filed by the Association of American Railroads. The third quarter 2007 RCAF (Unadjusted) is 1.197. The third quarter 2007 RCAF (Adjusted) is 0.558. The third quarter 2007 RCAF–5 is 0.531.

DATES: *Effective Date:* July 1, 2007.

FOR FURTHER INFORMATION CONTACT: Mac Frampton, (202) 245–0317. [Federal Information Relay Service (FIRS) for the hearing impaired: 1–800–877–8339.]

SUPPLEMENTARY INFORMATION: Additional information is contained in the Board's decision, which is available on our Web site *http://www.stb.dot.gov.* To purchase a copy of the full decision, write to, e-mail or call the Board's contractor, ASAP Document Solutions; 9332 Annapolis Rd., Suite 103, Lanham, MD 20706; e-mail *asapdc@verizon.net;* phone (202) 306–4004. [Assistance for the hearing impaired is available through FIRS: 1–800–877–8339.]

This action will not significantly affect either the quality of the human environment or energy conservation.

Pursuant to 5 U.S.C. 605(b), we conclude that our action will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act.

Decided: June 19, 2007.

By the Board, Chairman Nottingham, Vice Chairman Buttrey, and Commissioner Mulvey.

Vernon A. Williams,

Secretary.

[FR Doc. E7–12163 Filed 6–22–07; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

Submission for OMB Review; Comment Request—Interagency Guidance on Asset Securitization Activities

AGENCY: Office of Thrift Supervision (OTS), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review and approval, as required by the Paperwork Reduction Act of 1995. OTS is soliciting public comments on the proposal.

DATES: Submit written comments on or before July 25, 2007.

ADDRESSES: Send comments, referring to the collection by title of the proposal or by OMB approval number, to OMB and OTS at these addresses: Office of Information and Regulatory Affairs, Attention: Desk Officer for OTS, U.S. Office of Management and Budget, 725–17th Street, NW., Room 10235, Washington, DC 20503, or by fax to (202) 395–6974; and Information Collection Comments, Chief Counsel's Office, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC

נספח 3

ROAD SAFETY

Breath analyzers: Implementation of traceability in Portugal

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Instituto Portugues da Qualidade, Portugal
Helena Fino
UNINOVA, Portugal
Adriaan M.H. van der Veen
Nederlands Meetinstituut, The Netherlands

Summary

Alcohol breath analysis is used in most countries to enforce driving under the influence of alcohol (DUI) legislation. The accuracy of the "breath test" is critical to ensure the successful prosecution of DUI cases in court - this accuracy in turn directly depends on that of the calibration source used to verify the breath analyzers, and ethanol in nitrogen gas mixtures are prepared and certified for this purpose. These reference materials should be traceable to SI units in order to establish test reliability: this ensures that the results obtained during calibration/verification as well as those from breath analysis are accepted as evidence.

The objective of this paper is to outline the impact of the certification of ethanol in nitrogen gas mixtures on the verification and calibration of breath analyzers. The composition of the reference gas mixtures thus prepared can be verified by analytical reference methods such as non-dispersive infrared spectroscopy using a proper calibration method. The analysis is carried out by comparing the mixture to be certified with a set of primary reference materials (PRMs) of known composition and uncertainty.

Introduction

The abuse of alcohol is receiving more and more attention. Within the European Union it is estimated that 20 % of all fatal road traffic accidents are alcohol-related. Breath analysis was introduced in Portugal over fifteen years ago, but the authorities have only recently been granted permission to replace blood tests by breath tests. A law enforcement officer has the right to subject a driver to a breath test in the case of careless driving, an accident, or suspicion of DUI. Before the case is heard in a court of law, the suspect can request a blood test. In the case of DUI evidence, the driver has to pay all the costs involved, which has served to significantly reduce the number of blood tests requested.

Compared to blood analysis, breath tests have several advantages: they are efficient, the results are available rapidly, and the costs are low. The accuracy and reliability of breath-alcohol testing devices can be subject to debate and speculation, especially in those cases where the suspected driver's employment is at stake. Based on the experience of other EU countries, a regulation was put into force that stipulates the operational procedures as well as the requirements of the National Legal System. At first, a screening device is used as an on-the-spot analyzer by the police; if the result is positive, the driver is obliged to undergo a test with an evidential breath analyzer (EBA); thus, two types of analyzers are in use.

A portable device containing an electrochemical cell that responds to ethanol can provide initial evidence of recent drinking and blood alcohol. For these screening devices a quality assurance and quality control plan shall be designed and implemented in a such a manner that it will verify that test results differ by not more than 10 %; such screening devices should be certified by the Road Traffic Department.

The EBA adopted must be submitted to metrological control. Measuring instruments used for evidential purposes must pass pattern approval and each instrument must be submitted to initial and subsequent annual verification. Currently, the metrological requirements for analyzer performance are based on OIML specifications [1].

All evidential models approved by IPQ use the principles of IR absorption and Lambert-Beer law for quantitative analysis. The instruments measure the absorption of IR radiation at 9.4–9.5 µm, which is associated with O–H bond stretch and bending vibrations, in order to avoid interference from acetone and hydrocarbons, which can occur in poorly treated insulin dependent diabetes or during ketoacidosis. Based on the scientific work of Jones [2], the EBA must be operated at 34 °C, and the instrument uses thermostats to measure the breath temperature and to harmonize inter- and intra-individual variations. The measurements could be affected by the volume of breath discarded before sampling; to avoid this, the instruments incorporate a flow meter to monitor the breathing.

In order to carry out reliable and reproducible calibrations and metrological operations, standard operations procedures have to be approved by legal authorities. For this purpose, two types of calibration devices have been accepted: wet simulators and compressed gaseous ethanol standards in nitrogen or air. The calibrations must be traceable to the appropriate SI units.

The approved wet simulator is based on the principle reported by Dubowski [3], which employs a mixture of liquid ethanol and water maintained at a constant and outlet temperature of 34 °C. The gas phase concentration is predicted from the aqueous concentration based on Henry's Law, when ambient air is bubbled at constant flow. Critical points in the use of the wet simulator are the outlet gas concentration caused by depletion, liquid temperature maintenance, absence of monitoring concentration and lack of traceability evidence on outlet gas.

Compressed gas standards are mixtures of ethanol vapor in nitrogen or air in a pressurized cylinder. Working standards can be certified and made directly traceable to primary gravimetrically prepared standards. The stability and the homogeneity of the mixtures should be tested prior to use.

Dry standards do not have a long history and some controversy is described in the literature. The criticism is that dry gas could not resemble human breath due to the lack of moisture content. Recent work by Dubowski [3] and results from Silverman [4] with different commercial breath analyzers concluded that there is a satisfactory degree of equivalence between both types of calibration devices for those instruments. This has led to the result that the system based on ethanol-compressed gas was approved as the device for initial and subsequent verification.

The purpose of this work is to demonstrate the reliability of breath analysis in Portugal. The following parts can be identified in the system:

1) development of a suitable method to certify working standards;
2) establishment of a procedure to validate the reliability of instruments in situ;
3) definition of a realistic uncertainty budget; and
4) comparison of the results obtained during several subsequent verifications.

Certification of working standards

The validation of the composition attributed to the calibration gas mixtures can be achieved by comparison with appropriate reference gas mixtures. For this purpose, PRMs from the Nederlands Meetinstituut (NMi) have been used. These PRMs are prepared by gravimetric methods and directly linked to international standards of mass, pressure, temperature and amount of substance, which ensures traceability to international standards.

The composition of the ethanol in nitrogen working standards is verified by non-dispersive infrared spectroscopy (NDIR) in order to confirm the value of the preparations. The analysis is carried out by comparing the mixture to be certified with a set of PRMs of known composition and uncertainty.

The basic procedure can be summarized as follows:

1) Specify the analytical range of interest;
2) Specify the analytical method and measuring system to be used;
3) Design the calibration experiment;
4) Perform the calibration experiment;
5) Calculate the analysis function $x = G(y)$;
6) Determine the composition of the gas under verification (mole fraction and uncertainty); and
7) State the result of the entire analysis.

Three mixtures of ethanol in nitrogen are prepared, of nominal 217, 381, and 516 µmol/mol. A series of five primary reference materials is used for the calibration using NDIR spectroscopy. The composition of the PRMs is given in Table 1.

The NDIR spectrometer is connected to an automatic sampler, controlled by a computer program [5]. The sampler ensures the same analysis conditions for all cylinders, including pressure and mass flow control. The calibration is carried out in three runs. The NDIR-monitor is flushed 300 s before a measurement, a measurement consisting of 90 readings. The pressure is read 30 times and the mass flow is controlled during the measurement. The zero gas is nitrogen. The computer controls the measurement of the calibration mixtures and the sample cylinders.

The results have been fitted using a quadratic function of type [6]:

$$x = G(Y) = b_0 + b_1 y + b_2 y^2 \quad (1)$$

Table 1 PRMs used for calibration

Cylinder	Composition µmol/mol	U µmol/mol
Standard 1	114.1	0.9
Standard 2	223.7	1.6
Standard 3	391.3	2.8
Standard 4	512.2	3.5
Standard 5	810.0	5.0

Table 2 Results from verification (in µmol/mol)

Cylinder	Nominal	Result
Sc 5800447	217	212.3
Sc 5800445	381	382.2
Sc 5800344	516	514.2

Table 3 Uncertainty evaluation of the verification (in µmol/mol)

	Uncertainty from the analysis function					
Cylinder	Run #1	Run #2	Run #3	s_r	u_c	U
Sc 5800447	0.50	0.50	0.50	0.20	0.89	1.8
Sc 5800445	0.88	0.89	0.87	0.31	1.56	3.1
Sc 5800344	0.98	0.99	1.010	0.29	1.75	3.5

Table 4 Composition of gas mixtures, expressed in blood alcohol units and range of tolerance

Cylinder	x_{EtOH} (ppm, mol/mol)	U (ppm, mol/mol)	c_{EtOH} (mg/L)	U (mg/L)	Certified value $X \pm u(x)$	Range of tolerance
Sc 5800447	212.3	1.8	0.383	0.003	[0.379; 0.386]	[0.352; 0.413]
Sc 5800445	382.2	3.1	0.689	0.006	[0.683; 0.694]	[0.634; 0.744]
Sc 5800344	514.2	3.5	0.927	0.006	[0.920; 0.933]	[0.853; 1.001]

The results of the fit of run #1 are shown in Fig. 1 (see next page). The results of the second and third runs are very similar and the results from the verification of the three mixtures prepared are given in Table 2.

The evaluation of the main sources of uncertainty from the verification process leads to an unequivocal confidence interval for the composition of the mixtures. The main sources of uncertainty are those associated with the repeatability of the response, and the quality of the fit. The results of the uncertainty evaluation are shown in Table 3.

The compositions and the expanded uncertainties of the three mixtures are tabulated in Table 4. In order to relate the composition of the gas mixtures to the commonly used unit for expressing alcohol levels in blood (mg/L), the formula used in [2] for this conversion is:

$$c_{EtOH} = 1\,000 \; \frac{x_{EtOH} \, M_{EtOH}}{M_{N2}} \; \rho_{N2} \qquad (2)$$

where:

x_{EtOH} = the mole fraction;
c_{EtOH} = the blood alcohol concentration;
M_{EtOH} = the molar mass of ethanol;
M_{N2} = the molar mass of nitrogen gas; and
ρ_{N2} = its density at 1 bar and 34 °C.

The maximum permissible errors accepted by Portuguese legislation, for instance for periodical verification, for each of the three gas mixtures are 0.032 mg/L in absolute error for the concentration in cylinder Sc 5800447 and 8 % in relative error for the concentrations in cylinders Sc 5800445 and Sc 5800344. As can readily be seen, the confidence interval provided by the expanded uncertainty is much smaller than the range of tolerance of the breath analyzers, as it should be!

Reliability of the instruments on site

The quality control of the instruments on site must be guaranteed in order to avoid the risk of inaccurate results. The metrological features are more or less rigorous and include accuracy, linearity, hysteresis and short-term drift. Under reference conditions five concentrations are used within the range 0–800 ppm. In this case, reference gas mixtures with an uncertainty better than 1 % should be used. In the subsequent verification, the working standards with alcohol concentrations of 0, 220, 440, 660, and 800 ppm (µmol/mol) are applied for verifying linearity. For accuracy, 220 ppm and 660 ppm mixtures are used. At least 10 measurements of each gas mixture are used for repeatability. The memory effect and short-term drift are checked with the same concentration gases.

Uncertainty evaluation

Although the uncertainty concept as used in the "Guide to the expression of uncertainty in measurement" (GUM) [7] is not mentioned in OIML R 126 [1], it was

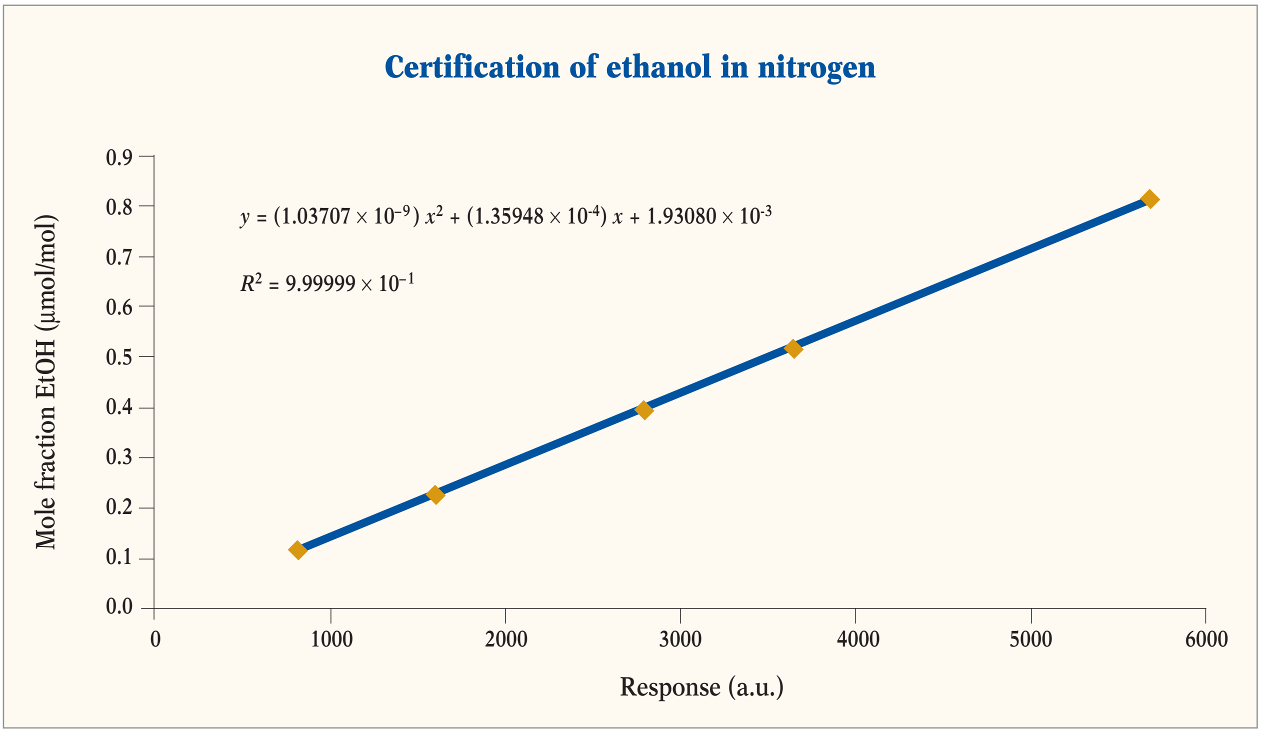

Fig. 1 Fitting results of run #1

decided to apply it just as an evaluation so that the instrument should not be rejected based on the uncertainty results. The measurement uncertainty resulting from the legal procedure was evaluated in accordance with the methodology described in the GUM, the Eurachem Guide [8] and the methodology described by ISO/TC158 [6] working groups. The expanded uncertainty U was obtained when a coverage factor k = 2 was applied. A typical excerpt of the uncertainty evaluation is shown in Table 5.

Hysteresis is assessed separately. Linearity of the device is checked by means of linear regression. The contribution from the working standard is ascertained from the uncertainty marked on the certificate.

The contributions from instrument's scale resolution and zero-setting are based on the manufacturer's specifications and a rectangular distribution is assumed. They are entered as "instrument" in Table 5. In Table 6 the measurement uncertainty at different concentrations is presented for a typical breath analyzer; these results can be regarded as representative of more than 400 instruments.

Comparison of the results obtained over several subsequent verifications

Using the same standard operational procedure during four years, all the devices were tested and the results were stored and compared in order to verify that no long-term drift can be observed. Table 7 shows the results.

Table 5 Uncertainty evaluation of an on-site tester

Variable X_i	Estimate x_i	Uncertainty	Distribution	Standard uncertainty $u(x_i)$	Sensitivity coefficient c_i	Contribution to standard uncertainty $u_i(y)$
Test	0.376	8.7×10^{-5}	Normal	8.7×10^{-5}	1	8.7×10^{-5}
CRM	0	0.004	Normal	0.0023	1	0.0023
Instrument	0	0.004	Rectangular	0.0025	1	0.0025
Result	0.376					0.007

Table 6 Results from verifying an on-site breath analyzer

Scale point (mg/L)	Maximum permissible error	Uncertainty	Scale point + observed error + U	Compliance lower limit	Compliance higher limit
0.200	± 0.032 (mg/L)	0.006 (mg/L)	0.224 (mg/L)	0.168 (mg/L)	0.232 (mg/L)
0.400	± 0.032 (mg/L)	0.007 (mg/L)	0.402 (mg/L)	0.368 (mg/L)	0.432 (mg/L)
0.678	± 8 %	0.022 (%)	0.687 (mg/L)	0.624 (mg/L)	0.733 (mg/L)
0.978	± 8 %	0.030 (%)	1.065 (mg/L)	0.900 (mg/L)	1.057 (mg/L)
1.457	± 8 %	0.050 (%)	1.457 (mg/L)	1.340 (mg/L)	1.573 (mg/L)

Table 7 Values of uncertainty during four years for the same instrument and in the same points

Scale point	1996	1997	1998	1999
0.200 mg/L	0.009 (mg/L)	0.008 (mg/L)	0.007 (mg/L)	0.010 (mg/L)
0.417 mg/L	0.007 (mg/L)	0.008 (mg/L)	0.011 (mg/L)	0.010 (mg/L)
0.700 mg/L	0.021 (%)	0.023 (%)	0.024 (%)	0.026 (%)
0.950 mg/L	0.034 (%)	0.040 (%)	0.038 (%)	0.043 (%)
1.500 mg/L	0.045 (%)	0.045 (%)	0.042 (%)	0.044 (%)

Conclusions

The methodology presented allows for transparency and validation of the methods used in legal verification. These concepts allow laboratory quality assurance and quality control to be improved without spending extra time, and is a set of tools that ensures the reliability of the measurements and provides the jurisdiction with clear evidence of reliability.

This traceability is provided through an unbroken chain of calibrations linking measurements made in one laboratory with measurements made in other places at different times. The link to other countries is established through IPQ's working standards, which are made traceable to international PRMs.

Another important consideration is the appreciation of the results for setting up compliance limits using the GUM uncertainty concept.

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