

JB00002-2022

Breath Alcohol Detector Verification System

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Breath Alcohol Detector Verification System



アルコール検知器協議会
Japan Breath Alcohol
Testing Consortium

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Foreword

The Japan Breath Alcohol Testing Consortium was established on April 8, 2015.

The Consortium is the only domestic industry organization created by companies who are involved in manufacture and marketing of breath alcohol detectors. It aims to raise the status of the industry by improving the technology and quality of breath alcohol detectors and raising awareness about them, while working together with various related governmental agencies and other organizations to eradicate drunk driving and other alcohol-related problems.

In recent years, fatal and serious injury accidents caused by drunk driving have become a major social problem. To prevent seriously dangerous driving, in 2006, the criminal law stipulating the vehicular manslaughter crimes was revised to strengthen the penalties for drunk driving. In May 2011, for the commercial transportation industry, use of breath alcohol detectors at roll call became a legal requirement in addition to visual checking etc. to check whether alcohol has been consumed by drivers. Today, increase of health hazards due to excessive drinking is also a serious problem. Excessive consumption of alcohol raises the risk of lifestyle diseases and may lead to acute alcohol poisoning and alcoholism. In these situations, the role of breath alcohol detectors is becoming increasingly important.

The breath alcohol detector market is expanding year by year by introducing commercial products for health management and industrial products for alcohol detection conducted by transportation businesses. As more breath alcohol detectors are adopted for various commercial and industrial uses, it has become a problem that some consumers and companies who purchase them are not well-informed or well-trained to use them correctly.

With the need for establishing the verification system to certify manufacturers and distributors who have a quality control system and meet a certain quality level, by conducting research on national and international standards and survey on quality standards of the member companies, the Consortium established and started a trial operation of the tentative version of the “Voluntary Standard of Breath Alcohol Detector Verification System (J-BAC Mark System) <Draft>” in July 2016.

The tentative version of the standard is not strictly binding but intended to provide easy-to-understand criteria for consumers and companies and propose marketing guidelines that require breath alcohol detector providers to give proper instructions about their products. It specifies only 3

technological requirements and if not improved, it may be regarded as ineffective in the world.

To prevent wrong knowledge and wrong use of alcohol concentration criteria and breath alcohol detectors in all scenarios including retail, business, commercial, and industrial uses, the Consortium decided to create a more general and fair system that can cover a wide range of technological requirements to meet applications and purposes under various Japanese laws and regulations and can facilitate independent testing by external organizations. To this end, the Consortium has augmented the standard by elaborating the content that were simplified in the tentative version.

The Consortium is aiming to earn the trust of consumers and other industries by fulfilling their responsibility to continuously announce, maintain, and operate the verification system from an independent and fair standpoint.

In addition, by incorporating the trends of international technical standards and device certification systems into the verification system, it prevents itself from being a bottleneck of international trading. It also promotes competition for technological innovations among member companies and international leading manufacturers to energize the industry and raise its status.

As stated in the membership rule, Article 2 and Article 3, our effort to raise the status by establishing the verification system is essential to eradicate drunk driving and other alcohol-related problems.

For details, refer to the membership rule of the Japan Breath Alcohol Testing Consortium, Article 2 (Purpose) and Article 3 (Activity).

About This Document

Chapter 1 Breath Alcohol Detector Verification System

Chapter 2 Requirements that Should Be Satisfied by Applicants and Certified Providers

Chapter 3 External Organization's Audit and Technical Standard Test

[Document Numbering Rule]

JB	X	X	X	X	X	-	X	X	X	X
JB	0	0	0	0	0	-	20XX			
JB	Document category		Serial number (3-digit)			Hyphen	Revision year			
JB	00 Main document		Serial number 001 -			Hyphen	20XX			
JB	10		Serial number 001 -			Hyphen	20XX			
JB	20 (TBD)		Serial number 001 -			Hyphen	20XX			
JB	90 Appendix		Serial number 001 -			Hyphen	20XX			

[Document Content]

Standard Number	Document Title	Major Underlying International Standard
JB10001	Breath Alcohol Detector Technical Standard Document	EN15964, EN16280
JB20001	Breath Alcohol Detector Technical Standard Document (TBD)	EN15964, EN16280

Chapter 1 Breath Alcohol Detector Verification System

1.1 Purpose of the System

The system is intended to facilitate correct use and application of breath alcohol detectors in society.

1.2 Scope of the System

- 1) The system has been established by the Japan Breath Alcohol Testing Consortium.
- 2) Only regular members of the Japan Breath Alcohol Testing Consortium are eligible to apply for examination under the system and their application is voluntary.
- 3) The system is not meant to obstruct particular manufacturing or marketing activities.
- 4) Information related to the system (information about the system, technical standards, certified devices, etc.) is made public on the Japan Breath Alcohol Testing Consortium's website.

1.3 Terms and Definitions (For Overall Verification System)

1.3.1 Main Document

Refers to this document.

1.3.2 Technical Standard Document

Technical standard documents referred to with the JBXXXXX-XXXX numbers specified in this document.

1.3.3 Verification System

The verification system is composed of the main document and the technical standard documents. It is a comprehensive system that involves the application procedure, technical standards, testing method, initial audit, recertification audit, control and maintenance of the certification mark, scope of responsibility, disclaimers by the Japan Breath Alcohol Testing Consortium and external organizations, application forms, and all relevant documents.

1.3.4 JB Mark

The applicant is allowed to use the mark as certification that their device has satisfied all of the technical standards and other requirements specified by the system. The JB mark consists of a "JB logo and a standard number". For how to use it, refer to Chapter 2 in the main document.

1.3.5 Applicant

Regular members of the Japan Breath Alcohol Testing Consortium as defined in its membership terms, Article 4, who are legal entities involved in manufacturing or marketing.

1.3.6 Certified Device Provider

Providers who handle the device certified under the verification system. Certified device providers shall adhere to the maintenance and operation rule of the verification system.

1.3.7 External Organization's Audit

Document examination or on-site examination (including collecting target device samples) conducted by an external organization in response to a submitted application. An external organization conducts an initial audit, surveillance audit (document examination only), and recertification audit.

1.3.8 Technical Standard Document JB10002-2022

"Chapter 3 Breath Alcohol Detector Technological Requirements" in the voluntary standard issued in 2016.

1.3.9 Technical Standard Document JB20001-XXXX (TBD)

This technical standard contains the content of the "Breath Alcohol Detector Verification System (J-BAC Mark System)" standard and other essential performance specifications of breath alcohol detectors. The standard refers to the European standard of EN16280 (Breath alcohol test devices for general public - Requirements and test methods) and EN15964 (Breath alcohol test devices other than single use devices - Requirements and test Methods) and incorporates the content of related Japanese laws and regulations.

While JB10002-2022 contains only 3 test items, i.e., (1) MPE, (2) reproducibility, and (3) interfering components, this standard contains the drift test, temperature test, expiratory volume test, drop test, and low-voltage test as well.

1.3.10 Manufacturer

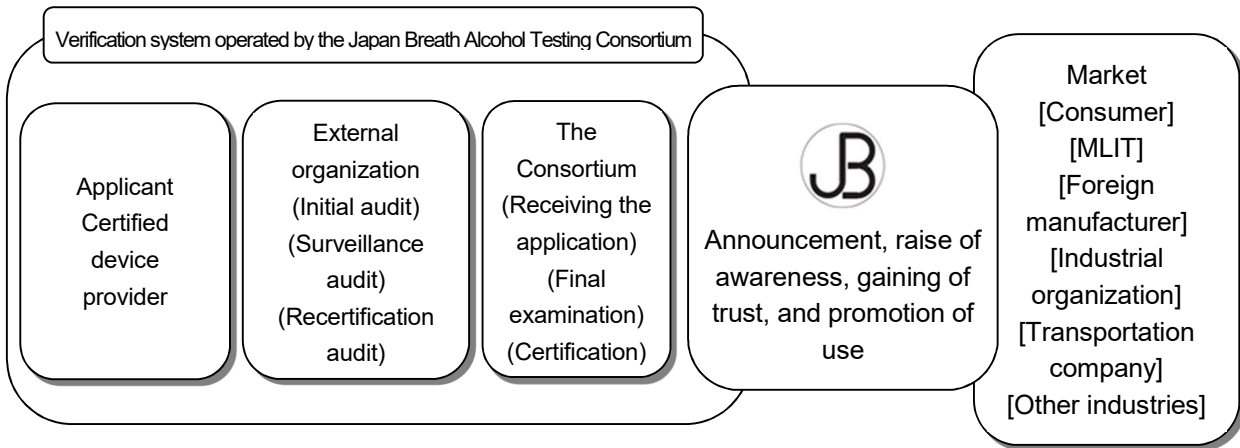
Legal entities who are a brand owner of breath alcohol detector or their associated companies responsible for designing, manufacturing, packaging, and labelling breath alcohol detectors whether they conduct such processes by themselves or by outsourcing them.

1.4 Position of the Verification System

Stakeholders of the verification system are member companies, the Consortium, external

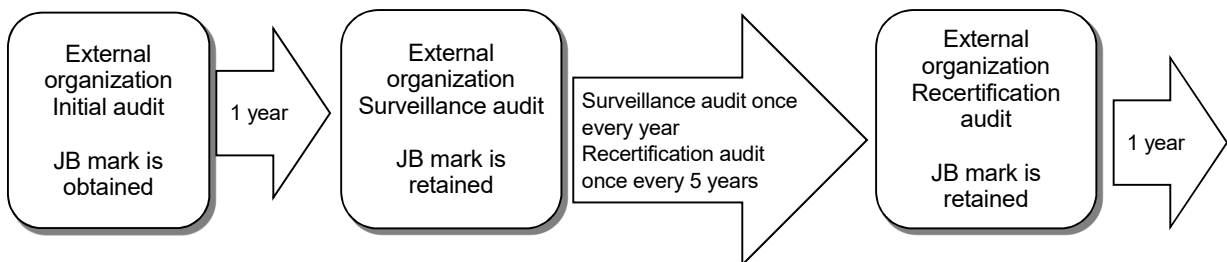
organizations, and the market.

They are involved in the system from 4 different standpoints: the applicant, approver, auditor, and user of the system and certified device. In principle, the system (including the testing procedures, results, and examination methods) should be independent, fair, open, and transparent. It is expected to grow while focusing on independency, fairness, and transparency and gaining the trust of the market.



1.5 External Organization’s Audit

The verification system adopts the independent audit process conducted by external organizations. The audit process has the phases of initial audit, surveillance audit, and recertification audit. Devices that passed the initial audit can retain the JB mark only by passing the surveillance audit or recertification audit.



1.6 Applicable Products

The following apply to the products subject to the system.

- 1) The system is intended for breath alcohol detectors that are or planned to be distributed in the market.
- 2) The system applies to measuring breath and not to directly collecting blood and analyzing blood concentration.
- 3) The system applies to any shape, use environment, application, recording method, breath collection method, and detection principle.

Below is the guidance table for applicants. Applicants can check in advance the category of their product and whether it is applicable.

Guidance Table

No.	Classification	Category (Self-Reported)	Applicability	
1	Classification by distribution	Post-market	Yes	
		Pre-market (still in development)	Yes	
2	Classification by measured substance	Breath	Yes	
		Breath (disposable)	Yes	
		Blood	No	
3	Features specific to the device	Shape	Large	Yes
			Small	Yes
		Use environment	Stationary	Yes
			Portable	Yes
			In-car	Yes
			Indoor use	Yes
			Outdoor use	Yes
		Application	Self-check	Yes
			Employee check	Yes
			Policing	Yes
		Recording method	Recordable	Yes
			Unrecordable	Yes
		Breath collection method	Non-contact blowing	Yes
			Blowing through mouthpiece (into the device)	Yes
			Blowing into the bag	Yes
		Detection principle	Semiconductor gas sensor	Yes
			Electrochemical sensor (fuel cell type)	Yes
			Catalytic combustion sensor	Yes
			NDIR	Yes
			Biosensor, QCM	Yes

The terms of classifications 1 to 3 in the guidance table are based on those commonly used in

the commercial market. They are useful for applicants to quickly determine whether their product is applicable or not.

If the product does not fall under any classification in the table and it is difficult to determine whether it is applicable, consult the Japan Breath Alcohol Testing Consortium.

1.7 JB Mark

The JB mark is a clear indication as a combination symbol consisting of a JB logo and a standard number.



 JB20001 - 2017

How to use it on a product, package, and technical and business documents is described in Chapter 2.

Graphical specifications of the JB mark will be provided by the Japan Breath Alcohol Testing Consortium after the product is certified.

Adhere to the following when displaying and using the mark.

I Basic Japanese laws and guidelines related to labelling

- ◆ Consumer Affairs Agency
- ◆ Act against Unjustifiable Premiums and Misleading Representations

II Penal rules applied to members of the verification system

Manufacturers shall bear sole responsibility for their product conformity as far as they are a JB mark holder.

The Japan Breath Alcohol Testing Consortium or any external organization shall not be subject to penalty or involved in a lawsuit on behalf of manufacturers.

Applicants or certified providers will be warned of breach if their improper use of a JB mark assigned by the verification system is identified. In serious cases, applicants or certified providers will be struck off as they are regarded to fall under the membership rule, Article 4-8, "Expulsion" (refer to the attachment).

1.8 Announcing Information about the Verification System Public

People can obtain all information about the verification system at any time by accessing the documentation about the system on the Japan Breath Alcohol Testing Consortium website.

The documentation about the entire verification system is made public in the following reasons:

- 1) To ensure that purchasers and the market can access the list of certified devices and the detailed reasons of certification, and
- 2) To raise the status of the industry by disseminating the fact that there are proven technical standards harmonized with international standards for breath alcohol detectors.

1.9 Announcing the Certified Devices

The list of the certified devices is available on the Japan Breath Alcohol Testing Consortium website.

Chapter 2 Requirements that Should Be Satisfied by Applicants and Certified Providers

The Japan Breath Alcohol Testing Consortium member companies participating in the verification system shall ensure that the breath alcohol detector specifications they provide are true.

2.1 Understanding Laws and Regulations Applicable to Alcohol Detection

The Japan Breath Alcohol Testing Consortium member companies participating in the verification system should understand the background and details of the current Japanese laws and regulations underlying the main document and technical standard documents.

2.2 Rule about Breath Alcohol Detector Marketing Guidelines

Applicants for this certification shall ensure that 14 items specified, in addition to formal descriptions of the specifications and operating method based on the specifications, are included in the instruction manual. For details, refer to Form 2.

2.3 Requirements about the Quality Assurance System

2.3.1 Product Quality Assurance System

Applicants shall provide the necessary information in the application form (Form 2) about the origin and manufacturing factory of the product concerned, the quality assurance system, and the traceability system, in accordance with the quality management documents and work manuals. Considering confidentiality, it is not an obligation to disclose confidential matters such as subcontractors. However, since the verification system requires an on-site examination (as described in Chapter 3), applicants shall specify a physical site (final testing (shipment) site) where the final product quality can be assessed. Such a physical site shall be in Japan.

2.3.2 Identification and Traceability

Applicants shall ensure traceability of the breath alcohol detector concerned in the market. The product concerned shall be uniquely identifiable in the market and traceable with its time of manufacture, time of shipping inspection, and final site of manufacture or shipment.

2.3.3 Controlling the Monitoring and Measuring Instruments

Applicants shall specify and maintain the instruments (calibration instrument, air blower, alcohol simulator, monitoring instrument, etc.) and materials (dry gas, ethanol, and water) that may affect the performance and quality of the product.

2.3.4 Monitoring and Measuring the Product

Typical breath alcohol detectors are made up of an alcohol sensor and parts other than it. Manufacturing them may be outsourced. “Calibration” and “precision adjustment” processes, which are important during manufacturing breath alcohol detectors, and manuals for such processes may also be outsourced. “Monitoring for acceptance between processes” and “Monitoring for acceptance at final inspection” regarding the product concerned shall be conducted by applicants.

2.3.5 Controlling Nonconforming Products

To prevent products not conforming to the product requirements from being used or delivered accidentally, organizations shall separate and control them properly. They shall document the procedure for treating and controlling nonconforming products as well as the responsibilities and rights associated with them. If applicable, organizations shall treat nonconforming products in one or more of the following ways.

a)	Taking an action to remove the detected nonconformity.
b)	An authorized person or (if applicable) a customer gives permission to use, release, or accept the products as an exception.
c)	Taking an action to prohibit the intended use or application.
d)	Taking an appropriate measure against actual and potential impacts caused by the non-conformity if non-conforming products are found after delivery or start of use.

2.4 Accountability of Manufacturers to Distributors

If the applicant is a manufacturer and the product is distributed through multiple channels including tier 1 and tier 2, the manufacturer should explain to the distributor about the marketing guidelines described in 2.2 at the time of concluding a sales agreement or business partnership agreement.

2.5 Product Requirements

Applicants can apply for certification under the following two technical standards in the verification system.

I JB10002-2022, Separate document, Breath Alcohol Detector Technical Standard Document

II JB20xxx-xxxx, Separate document, Breath Alcohol Detector Technical Standard Document (TBD)

2.6 Instruction Manual

An instruction manual shall contain the 14 items specified in the marketing guidelines.

2.7 Marking Requirements

2.7.1 General Requirements

Certified device providers under the verification system shall be responsible for marking a JB logo on their products. The Japan Breath Alcohol Testing Consortium and certified providers shall cooperate to ensure clarity for consumers, purchasers, and users, eliminate disadvantages to them, and protect them. They shall also work on preventing unauthorized use or counterfeit of the mark by members or non-members. Replication and display of the mark and logo without prior permission by the Japan Breath Alcohol Testing Consortium is strictly prohibited.

2.7.2 Using the Mark on Products

The JB mark shall contain the technical standard number and the time of certification.



2.7.3 Using the Mark in Documentation

Certified device providers can display the statement of certification or the JB mark on the product, promotional brochure, catalog, and other public documents to differentiate the certified device from the other devices.

Certified device providers shall submit the documents that contain a direct or indirect statement on the JB mark whenever requested by the Japan Breath Alcohol Testing Consortium.

2.7.4 Laws Related to Consumers and Representations

Certified device providers shall adhere to the following Japanese laws.

- ◆ Consumer Affairs Agency

◆ Act against Unjustifiable Premiums and Misleading Representations

2.8 Certification Criteria

Among the applied devices, those satisfying the following requirements can pass the examination (certification).

- 1) Satisfying the criteria of the “Breath Alcohol Detector Marketing Guidelines” described in 2.2.
- 2) Satisfying the requirements related to the quality assurance system.
- 3) Passing the on-site audit conducted by an external organization.
- 4) Passing the confirmation test specified in the technical standard document.

2.9 Procedure for Changing the Specifications

Applicants shall submit the Specification Change Notice (Form 4) to the technical committee chairperson if they made a specification change that may impact the operation and purpose of purchasers.

	Content	Change Level	Submission of the Specification Change Notice
1	Change in the marketing guidelines	Minor	No
2	Important change in the marketing guidelines	Change in key items that may impact the operation and purpose	Yes
3	Change in technical requirements	Minor	No
4	Important change in technical requirements	Change in key items that may result in performance change	Yes

Notes on the change level:

Minor: Change in the product color, appearance, etc. that gives no impact on the precision

Change in key items that may impact the operation and purpose and change in key items that may result in performance change: Change in the precision of alcohol detection, indication of the result, product life, or interfering components

For any specification change requiring device evaluation regarding technical requirements, follow 3.4 below.

2.10 Revoking the Certification

If the certified device falls under any of the following and the technical committee determines that doing so is appropriate, the Japan Breath Alcohol Testing Consortium may cancel the certification and remove the device from the certified device list upon notice to the member concerned.

- 1) Falsification of data at the time of application was found
- 2) False descriptions in the application form were found
- 3) Exaggerated claims were made about the certified device
- 4) A specification change notice was not submitted
- 5) Improper use of the certification mark
- 6) Intentional misleading about marked (certified) products and unmarked (conforming) products
- 7) False descriptions in the website, catalog, etc. were found
- 8) The member was expelled

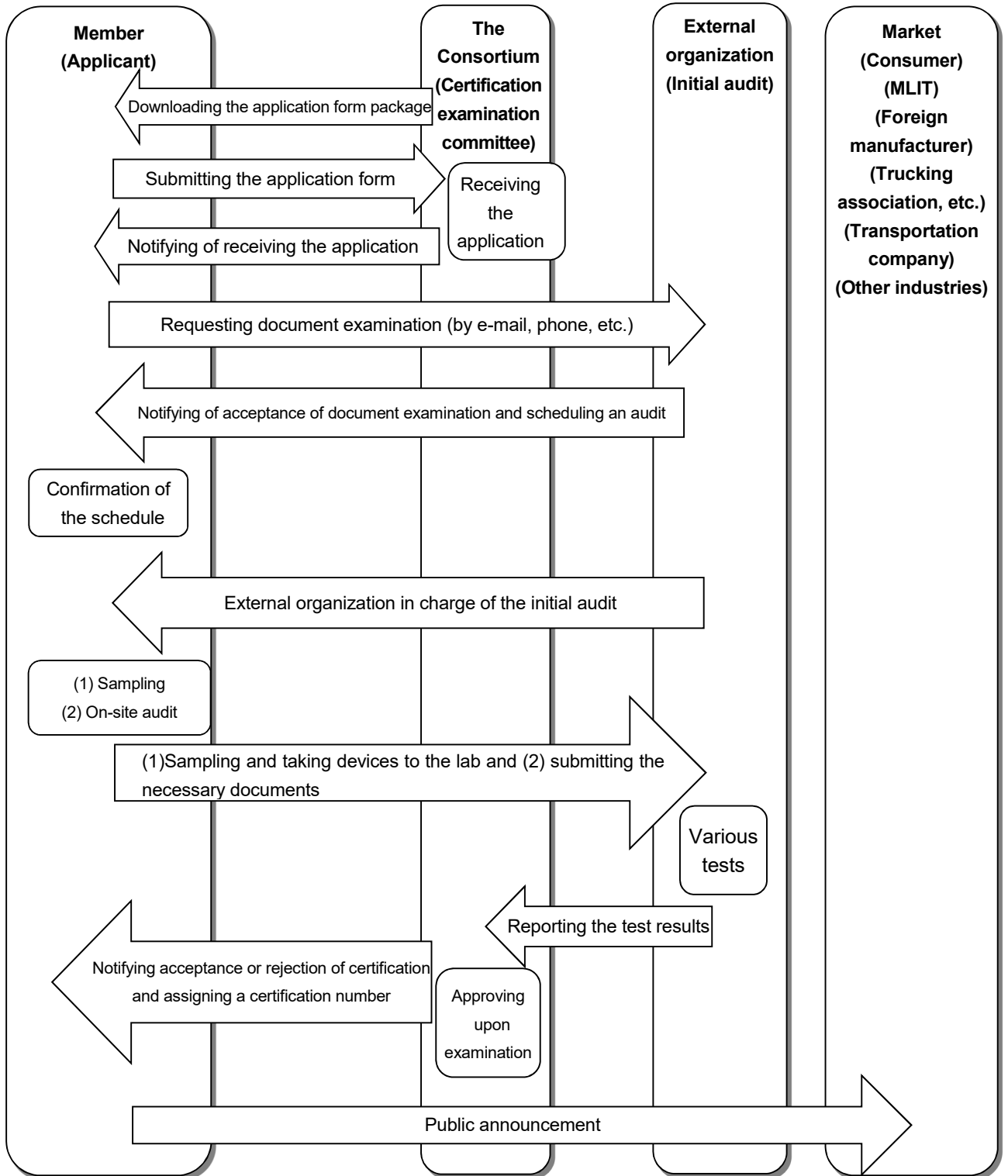
2.11 Disclaimer

The system is intended to raise the status of the breath alcohol detector industry by enhancing manufacturers and distributors to disclose the specifications, purpose, and quality criteria of the product to the market. The mark indicates approval (certification) on the product model and not on individual devices in the market. Any problems associated with the certified device should be addressed by the provider concerned and the Japan Breath Alcohol Testing Consortium and external organizations shall not be liable for them.

Chapter 3 External Organization’s Audit and Technical Standard Test

3.1 Initial Verification Process (Application~Initial Audit~Certification Notification~Announcement)

Below is the overall workflow.



- 1) An applicant downloads the application form from the membership page on the Japan Breath Alcohol Testing Consortium website (<https://j-bac.org/>), fills the necessary fields and submits the form to the Japan Breath Alcohol Testing Consortium.
- 2) The Japan Breath Alcohol Testing Consortium examines the content of the application form and notifies the applicant that the application has been received.
- 3) The applicant requests an external organization to conduct document examination. (Contact of external organization: CERI)
- 4) The external organization conduct document examination and notifies of acceptance or rejection. In case of acceptance, they schedule an audit.
- 5) After the audit schedule is confirmed by the applicant, the external organization visits the audit site and conduct the on-site audit by referring to the submitted documents (the quality assurance system document, manual, etc.).
- 6) During the on-site audit, the external organization collects samples of the device subject to the technical standard conformity test and take them to their lab.
- 7) The external organization conducts tests on the samples.
- 8) After completing the audit, the external organization sends the test result report to the Japan Breath Alcohol Testing Consortium.
- 9) The Japan Breath Alcohol Testing Consortium holds an examination committee for examination.
- 10) The Japan Breath Alcohol Testing Consortium notifies the applicant of the examination result. They assign a certification number in case of acceptance.
- 11) The applicant becomes a certified device provider and obtains the license to use a JB mark upon receiving the acceptance notification.
- 12) The applicant can publicly announce the certification in accordance with the rules regarding certified device providers, the verification system, and JB marks.

3.2 How to Make Application

Applicants obtain Forms 1 to 8 among the certification related documents on the Japan Breath Alcohol Testing Consortium website below, fill necessary fields, and submit them.

Certification related document	Japan Breath Alcohol Testing Consortium's website
Submission destination	Technical committee chairperson

Below are the certification related documents.

Form 1	Examination Application Form (Common to Initial, Surveillance and Recertification)
Form 2	Conformity Statement
Form 3	JB10 Test Conditions
Form 4	Submission of the Specification Change Notice
Form 5	Cancellation Notice
Form 6	Document Examination Result
Form 7	OEM Notice
Form 8	JB20 Test Conditions(TBD)

Applicants (for initial certification and recertification) ensure that all materials specified in the application forms are ready and then submit them to the technical committee chairperson. Application by mail is not acceptable. The submitted documents shall be signed (PDF).

3.3 Certification Examination Committee

The certification examination committee is set up under the technical committee and its members are assigned by the technical committee chairperson.

3.3.1 Activities of the Certification Examination Committee

The examination committee of the Japan Breath Alcohol Testing Consortium is responsible for the following activities.

- 1) Determination of acceptance of the application
- 2) Determination of acceptance of the application for the same model and the application for OEM model
- 3) Examination of the test result report issued by an external organization

3.3.2 Notes on Application

- 1) It normally takes about 3 months from document examination (marketing guidelines examination) by an external organization to issuance of the test result report although it may vary depending on the application conditions. The acceptance notice issued by the Japan Breath Alcohol Testing Consortium will be sent by e-mail to the contact address given at the time of application submission. It will not be sent by mail.
- 2) For examination, submission of additional materials or demonstration may be requested if necessary.

- 3) The application cost is all borne by the applicant.
- 4) No objection to the result by the applicant is accepted.
- 5) The examination committee and an external organization do not have a discussion (consultation) prior to or during the examination.

3.4 Collecting the Target Device Samples

For the device subject to the technical standard conformity test, an external organization responsible for the test will collect samples at the factory (place of shipment) upon agreement of the applicant at the time of the initial audit, recertification audit, and any specification change requiring device evaluation regarding the technical requirements. The applicant shall notify its relevant department about sampling to help the external organization complete it smoothly. The number of samples is specified in the relevant technical document. The applicant should ensure that no breakage occurs while the external organization is transporting the product.

3.5 Roles of External Organizations

External organizations play the following roles in accordance with the technical standard documents.

- (1) Examination of the application documents (marketing guidelines, instruction manual, etc.) submitted by the applicant
- (2) On-site audit
- (3) Testing of the breath alcohol detector samples collected during the on-site audit

3.6 Handling Non-conformities to the Criteria

An external organization notifies the applicant of non-conformities to the criteria if they occur during the conformity test. Upon discussion with the applicant, if the non-conformities are not attributable to the external organization, not due to a wrong procedure, improper material handling, etc., the external organization rejects the device and then ends the test.

If the applicant needs completion of the remaining part of the test, upon separate discussion, the external organization may continue the test.

3.7 Test Result Report

An external organization creates the test result report with no delay after the audit and submits it to the Japan Breath Alcohol Testing Consortium (the examination committee).

3.8 Surveillance Audit

Certified device providers shall apply for and undergo a surveillance audit every year. If they are not willing to retain the certification, they shall submit a cancellation notice. If they do not apply for a surveillance audit or submit a cancellation notice within the prescribed period, the certification may be forcibly cancelled.

If the device fails a surveillance audit, it loses the license to use a JB mark.

3.9 Surveillance Audit Processes

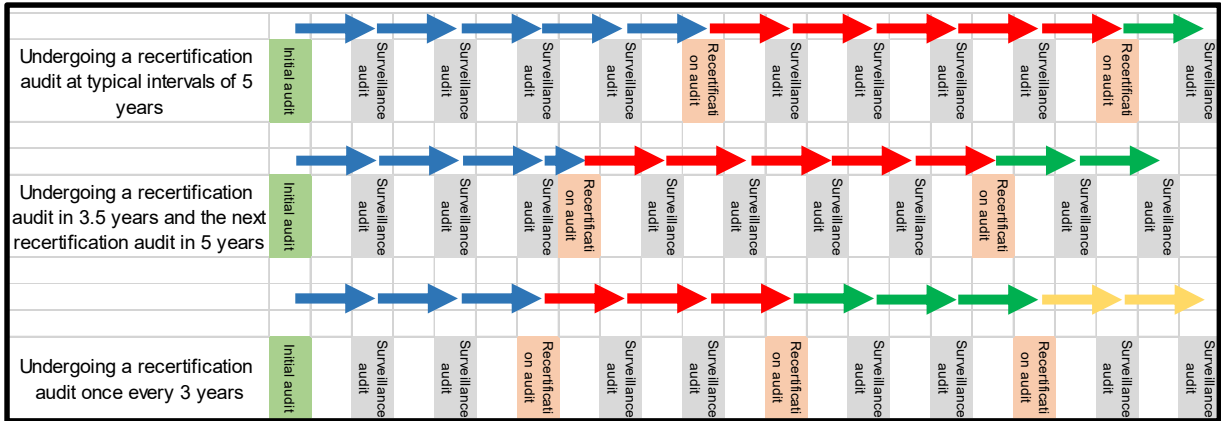
- 1) A certified device provider submits application documents to the Japan Breath Alcohol Testing Consortium about 3 months before the end of the current license period so that the surveillance audit on the device can end by the expiration date.
- 2) "Specification Change Notices" issued after the previous examination, if any, shall be attached.
- 3) The Japan Breath Alcohol Testing Consortium checks if the application form is complete without flaw and notifies the applicant of the check result.
- 4) An external organization conducts examination on the documents (marketing guidelines) submitted by the applicant.
- 5) After notifying of acceptance of document examination, the external organization schedules an on-site audit upon discussion.
- 6) After the surveillance audit, the external organization creates a test result report with no delay and submits it to the Japan Breath Alcohol Testing Consortium (the examination committee).

3.10 Recertification Audit

Certified device providers shall undergo a recertification audit within 5 years from the date of certification. If they undergo a recertification audit within 4 years from the date of certification, the next license period is 5 years from the date of recertification.

If they are not willing to retain the certification, they shall submit a cancellation notice. If they do not apply for a recertification audit or submit a cancellation notice within the prescribed period, the certification may be forcibly cancelled.

If the device fails a recertification audit, it loses the license to use a JB mark.



3.11 Recertification Audit Processes

- 1) A certified device provider submits application documents to the Japan Breath Alcohol Testing Consortium about 3 months before the end of the current license period so that the recertification audit on the device can end by the expiration date.
- 2) “Specification Change Notices” issued after the previous examination, if any, shall be attached.
- 3) The Japan Breath Alcohol Testing Consortium checks if the application form is complete without flaw and notifies the applicant of the check result.
- 4) An external organization conducts examination on the documents (marketing guidelines) submitted by the applicant.
- 5) After notifying of acceptance of document examination, the external organization schedules an on-site audit upon discussion.
- 6) After the recertification audit, the external organization creates a test result report with no delay and submits it to the Japan Breath Alcohol Testing Consortium (the examination committee).