PQS performance specification

WHO/PQS/E08/JI01.1
Original: English
Distribution: General

TITLE: Single-use auto-disable needle-free syringe injectors

Specification reference:	E08/JI01.1
Product verification protocol:	E08/JI01–VP.1
Issue date:	21.04.2010
Date of last revision:	New specification

Contents:

1 Scope:

This specification describes the performance requirements for needle free jet injectors that use a sterile, single-dose, auto-disabling, needle-free syringe* intended for human clinical and medical use to deliver intra-dermal (ID), and/or subcutaneous (SC), and/or intra-muscular (IM) injections. Single use and auto disabling refer to the needle free syringe/cartridge not the injector itself.

***Note:**

The dose chamber of these injection systems are completely disposable, auto-disabled after one use, and intended to be disposed after each single use. They are separable from the injection mechanism or device, and often termed a "syringe", "cartridge", "ampoule", "capsule" or "disc". In this specification the term syringe will be used.

2 Normative references:

The following referenced documents are indispensible for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies:

- EN ISO 13485:2003 Medical devices – Quality management systems – Requirements for regulatory purposes.
- IEC 60601-1 Medical Electrical Equipment – General requirements for basic safety and essential performance
- ISO 21649 Needle-free injectors for medical use – Requirements and test methods.
- ISO 7886-3 Sterile hypodermic syringes for single use – Part 3: Auto-disable syringes for fixed dose immunization.
- EN 62366 Medical devices – Application of usability engineering to medical devices.
- ISO 20282-1 Ease of operation of everyday products – Part 1: Design requirements for context of use and user characteristics.
- ISO/PAS 20282-3 Ease of operation of everyday products – Part 3: Test method for consumer products.
- Montreal Protocol: The 1987 Montreal Protocol on Substances that Deplete the Ozone Layer (as agreed in 1987)
- EU Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE).

3 Terms and definitions:

In writing: means communication by letter, fax or email.

Injector or Injection system: The mechanism or system into which the disposable syringe attaches. The injector or injection system is held by the user and provides the energy to effect the injection, along with other ergonomic, triggering, and safety components. Although normally re-usable for multiple injections, it may itself be disposable after single use.

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

Reseller: A commercial entity, licensed to act on behalf of a Legal Manufacturer, and which carries product liability and warranty responsibilities no less onerous than those carried by the Legal Manufacturer.

Auto-disable or Auto-disabling: A feature or characteristic of the syringe or device that passively and automatically activates upon administration of the intended dose to prevent subsequent re-use of the syringe. In order to avoid inadvertent or intentional re-use in the event such action is not taken, no secondary or additional action on the part of the user shall be required (adapted from ISO 7886-3).

Certification body: A government department or agency or third party organization that provides services for conformity assessment following completion of an independent assessment verification and qualification process.

Certified copies: Wherever a certified copy or certified photocopy is requested, the copy must be certified as a true copy of the original document by a person registered to practice law in the Legal Manufacturer's country of origin and must be endorsed with the legal practitioner's official stamp and signature. Self-certification is not acceptable.

4 Requirements:

4.1 General:

Needle-free jet injectors deliver a sterile, single dose of liquid medication by pressurizing the dose in a chamber from which it is ejected through a small orifice on an auto-disabling syringe with sufficient force to penetrate human tissues. It is intended for clinical use by medical personnel on humans, as well as for self-use by patients when indicated.

4.1.1 ISO standards:

Compliance with ISO standard 21649 Needle-free injectors for medical use — Requirements and test methods, First edition 01 Jun 2006, is mandatory with the exception of those clauses for which there is evidence that the requirement is not applicable to the device. In addition, the auto-disabling feature of the syringe must comply with the intent and purpose of auto-disabling as defined in ISO standard 7886-3. Specific performance requirements contained within this standard must be met, in addition to the added requirements referred to in this document.

4.1.2 Licensing requirements:

If a device is licensed in the territory of one of the founding members of the Global Harmonization Task Force (GHTF)[1], it meets the minimum quality criteria required under the PQS pre-qualification procedure (Option 1 below). If the device is *not* thus licensed, the manufacturer must be able to demonstrate that the manufacturing process meets one or more of the quality system standards listed below (Option 2).

Option 1: License in a GHTF founding member country: Domestic market clearance in any one of the five countries will indicate that the manufacturer has an acceptable quality system in place, although evidence of compliance with one or more of the quality system standards listed in Table 2 must be provided. The manufacturer must provide a certified copy[2] of their domestic market license(s) in accordance with Table 1.

Table 1 – Licensing requirements in the five GHTF founding member countries

	Australia	Canada	European Union	Japan	United States
Marketing permit/ Marketing permit/ condition	GMPALS License or CE Mark	Device license	CE mark	Device license	510k device letter

Table 2 - Acceptable quality system standards in the five GHTF founding member countries

Country	Quality system standards for medical devices	Certification body
Australia	ISO13485	Government or third party accredited by the government
Canada	ISO13485	Third party accredited by by the government
European Union	ISO13485	Notified Bodies
Japan	GMP (QS Standard for medical devices #1128)	Government
United States	QS (21 CFR part 820)	Government

Option 2: No license in a GHTF founding member country: If the device does not have Option 1 market clearance then the manufacturing process must meet one or more of the quality system standards listed in Table 2. The manufacturer must provide WHO with documentary evidence demonstrating conformity to these standards from a certification body accredited by the regulatory authorities in one of the GHTF founding member countries. The documentary evidence must take the form of certified copies of the relevant paperwork.

[1] – The founding members of the GHTF are Australia, Canada, the European Union, Japan and the United States.

[2] – Self-certification of documents is not acceptable.

4.2 Performance:

4.2.1 Auto-disable feature

The syringe must be passively and automatically rendered unusable upon the filling or delivery of the intended dose. The timing and method of the activation of the auto-disable feature may vary by design. It must not be possible to intentionally or inadvertently re-use the syringe/cartridge under the normal conditions of use.

4.2.2 Cross contamination

Parts of the device intended for patient contact shall be disposable.

4.2.3 Cycle time

The total cycle time for delivery of a dose should be comparable to or less than that of a needle/syringe and vial/ampoule cycle time.

4.2.4 Number of life time cycles

The minimum requirement is set at 20,000 cycles. Test evidence to support this claim is to be provided and specified by manufacturer.

4.3 Environmental requirements:

4.3.1 Ambient temperature range during transport and storage:

In accordance with ISO 21649: -40°C to +70°C

4.3.2 Water and dust resistance:

The injector must resist exposure to rain or otherwise accidental exposure to water, unless the use of water immersion is part of the recommended cleaning procedure.

Protection of the injector by the outer storage/carry case against water and dust penetration must not be less than rating IP55 per IEC 60529.

4.3.3 Ambient humidity range during transport, storage and use:

5% to 95% RH, non-condensing.

4.4 Physical characteristics:

4.4.1 Power source:

The device may be manually, gas or electrically powered.

4.4.2 Injector hand piece weight:

Maximum 1 kg (including syringe filled to usual dose volume), except that systems designed for mass campaigns using rapid, filling, loading, injecting, and unloading mechanisms may weigh up to 1.5 kg on the expectation that there will be frequent shift rotations of staff performing injections.

4.5 Interface requirements:

4.5.1 Disposable syringe filling:

The disposable syringe must be capable of being filled either directly or indirectly through a vial adapter or other transfer mechanism from a vaccine vial or ampoule, or from a needle.

4.6 Human factors:

4.6.1 Generally:

The device must be useable by the widest practicable range of active health workers, regardless of age, gender, size or minor disability, including long-sighted and short-sighted people without glasses, in accordance with the general principles laid out in ISO 20282-1: 2006.

4.6.2 Skill level:

It must be possible for health workers to operate the device after a hands-on training session of maximum one hour and 20 injections.

4.6.3 Handedness:

The device must be equally useable by left and right handed health workers.

4.6.4 Activation and arming force:

Compliance with the following ISO standards is required: ISO 20282-1; ISO 20282-3; and ISO 62366. The maximum force requirement for delivery should not exceed 30 N.

4.6.5 Repetitive use:

The device must be designed to reduce the risk of repetitive motion injuries and to prevent discomfort during routine use by a single operator for up to 200 cycles per day. It must be designed so that the operator's wrist can remain in a neutral position during delivery to the patient.

4.6.6 Pinch points:

Use should not result in pinching of the operator's hands.

4.7 Materials:

Ozone depleting chemicals:

During manufacture and assembly of the product any substance included in Annex A, B or C of the Montreal Protocol must not be used.

4.8 Warranty:

The product is to be covered by a replacement warranty covering the designed lifetime of the device in the event of any component failure not caused by mechanical damage.

4.9 *Servicing provision:*

The product should not require major maintenance or refurbishment through the tested cycle life, beyond general cleaning and disinfection. No disassembly for cleaning should be required. Required cleaning materials must be limited to low cost products such as bleach, quaternary ammonia, iodine and water and full cleaning instructions must be supplied by the manufacturer.

4.10 *Disposal and recycling:*

The manufacturer is to provide information to the buyer on any hazardous materials contained within the system and is to recommend in its instructions environmentally safe disposal methods, including resource recovery/recycling.

The user instructions should also stipulate that any disposable part of the system must be collected in suitable medical waste containers before treatment and that these containers should carry the international biohazard symbol (Annex 1).

4.11 *Instructions:*

Provide user and maintenance instructions in Arabic, English, French, Mandarin Chinese, Russian and Spanish and in pictorial form.

4.12 *Training:*

Training will be conducted in accordance with the device manufacturer's released procedures or protocols. It must be possible for health workers safely to operate the device after a hands-on training session lasting a maximum of one hour and 20 injections.

4.13 *Verification:*

In accordance with PQS Verification Protocol **E08/JI01-VP.1**

5 Packaging:

Disposable syringes must be packaged sterile in individual pouches or other suitable individual unit packaging. They may also be packaged with multiple syringes per pouch provided that each syringe has a cap or other means to maintain sterility after the outer package is opened. In addition, multiple sterile syringes may be packaged together in magazines for use in injection systems specifically designed for mass campaigns using rapid, filling, loading, injecting, and unloading mechanisms.

6 On-site installation:

Not applicable.

7 Product dossier:

The legal manufacturer or reseller is to provide WHO with a pre-qualification dossier containing the following:

- Dossier examination fee in US dollars.
- General information about the legal manufacturer, including name and address.
- Unique identification reference for the product type.
- Full specifications of the product being offered, covering all the requirements set out in this document, including details of product marking and traceability.
    - Certified photocopies of all type-approvals obtained for the product, including CE marking and the like.
    - Certified photocopies of the legal manufacturer's ISO 13485 quality system certification.
    - Where available, laboratory test report(s) proving conformity with the product specifications.
    - One sample of the product with a minimum of ten syringes and related disposable components.
    - Indicative cost of the product per unit, EXW (Incoterms 2000).

8 On-site maintenance:

Training to be conducted per device manufacturers instructions.

9 Change notification:

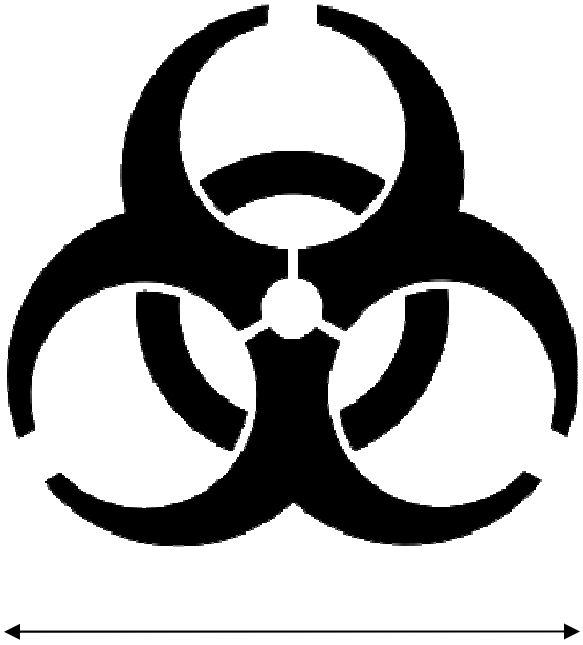
The legal manufacturer or reseller is to advise WHO in writing of any changes which affect the performance of the product after PQS pre-qualification has taken place.

10 Defect reporting:

The legal manufacturer or reseller is to advise WHO and the UN purchasing agencies in writing in the event of safety-related product recalls, component defects and other similar events.

Annex 1 – International bio-hazard symbol[3]

Colour red or black



50mm minimum
diameter

[3] Source: Laboratory biosafety manual (Third edition) World Health Organization, Geneva 2004.

Revision history:			
Date	Change summary	Reason for change	Approved