INTERNATIONAL WORKSHOP AGREEMENT

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Interoperability of microfluidic devices — Guidelines for pitch spacing dimensions and initial device classification

Interopérabilité des dispositifs microfluidiques — Lignes directrices pour les dimensions d'un pas d'espacement et le classement initial de l'appareil

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Contents

Page

Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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The committee responsible for this document is the ISO/TMB, *Technical Management Board*.

International Workshop Agreement IWA 23 was approved at a workshop organized by pan European (ENIAC Joint Undertaking) project MFmanufacturing, in association with Deutsches Institut für Normung (DIN). The workshop was held in British Standards Institution (BSI), London, United Kingdom, on 19 April, 2016. The workshop resolutions and contributors are listed in Annexes A and B, respectively.

Introduction

Microfluidics technology plays an important role for next generation devices. In the last few decades, initial R& D investment in academia has led to the generation of a number of spin out companies. Most of the companies that have flourished are microfluidic foundries or suppliers of microfluidic components. However, the track record associated with the success of actual application devices has been disappointing, with only a small handful of products (such as the ink jet printer) reaching commercial success.

The concern surrounding the lack of commercialization with regards to microfluidic devices has been discussed amongst various interested parties and stakeholders within the Microfluidics Consortium (MC). MC is an ad hoc group that offers a forum for discussion amongst interested parties and stakeholders in the microfluidics community. Such discussions led to the identification of several factors that can potentially hinder commercial success of microfluidics devices. This includes the high R&D and manufacturing costs of devices currently sold into a relatively small market [13]. It has been recognized that in order to reduce costs, there is a need to bring manufacturing of microfluidic devices to the same level of maturity and industrialization as electronic devices. This meant the need to mimic some of the standardization initiatives and outputs from the electronic industry in order to not only reduce costs but at the same time increase interoperability, thus promoting plug-and-play. The standardization initiative that had begun in the MC led to the development of several internal documents, such as a guideline on how to design microfluidic devices [14]. The standardization initiative and knowledge base gained through the MC eventually led to the formation of a pan-European project MFmanufacturing consisting of 20 project partners.

In identifying what standards should be proposed, consideration must be given to current market needs and trends. This led MFmanufacturing to develop, implement and analyse a survey (of 134 respondents), in order to identify those items that are in need of standardization to ultimately enhance the commercialization of microfluidic devices. Attention was given to those items that have been identified as being of highest priority, which are

a) terminology of relevance,

b) geometrical specifications on pitch dimensions,

c) device classification.

These items are further discussed in the relevant paragraphs below.

Interoperability of microfluidic devices — Guidelines for pitch spacing dimensions and initial device classification

1 Scope

This International Workshop Agreement is a consensus document developed by the workshop participants and observers in response to the need for standardization and harmonization of pitch spacing dimension, initial device classification and terminology of relevance.

This International Workshop Agreement will serve as a guideline and is applicable to various interested parties and stakeholders in the microfluidics community.

This International Workshop Agreement

— specifies geometrical standards in relation to pitch connector dimensions of microfluidic devices,

— specifies an initial device classification rules, and

— defines terms of relevance.

2 Terms and definitions

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

2.1
classification
method of sorting into categories

[SOURCE: ISO 22935-1:2009, 3.7]

2.2
connector
component that allows one part of the set to be connected to another

[SOURCE: ISO 3826-4:2015, 3.4]

2.3
device
component or assembly of components to perform a required function

[SOURCE: ISO 10209:2012, 2.30, modified]

2.4
end-users
person or persons who will ultimately be using the system for its intended purpose

[SOURCE: ISO/IEC 19770-5:2015, 3.13]

2.5
integration
process of physically and functionally combining lower-level functional elements (hardware or software) to obtain a particular functional configuration considered to be of a much higher-level entity

[SOURCE: ISO 10795:2011, 1.117, modified]

2.6
interconnect
device used to connect two things together

2.7
interested party and stakeholders
person or organization that can affect, be affected by or perceive themselves to be affected by a decision or activity

[SOURCE: ISO 28007-1:2015, 3.6]

2.8
interoperability
characteristic of providing an intended function in coordination with other components, the characteristic of sharing information with other system functions or components to provide additional functionality

[SOURCE: ISO 22902-1:2006, 3.1.42]

2.9
microfluidics
handling of fluids in technical apparatus having internal dimensions in the range of micrometres up to a few millimetres

[SOURCE: ISO 10991:2009, 2.5, modified]

2.10
miniaturization
making things on a smaller or miniature scale

2.11
pitch
mean distance between corresponding features in a regular array of features on a surface

[SOURCE: ISO 18115-2:2013, 5.106]

2.12
plug and play
denoting or relating to software or devices that are intended to work perfectly when first used or connected, without reconfiguration or adjustment by the user and thereby enable automatic configuration

[SOURCE: ISO/IEC/IEEE 21451-4:2010, 3.1.31, modified]

2.13
reliability
capability of a device to function without a failure in all specified conditions

[SOURCE: ISO 16972:2010, 3.158]

2.14
verification
confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

[SOURCE: ISO 14025:2006, 3.9]

3 Geometrical pitch specifications

3.1 General

One of the main outputs of the survey is to address the need for geometrical specifications associated with connectors that will ultimately support an increasing trend towards highly integrated complex devices (that may require connections to electrical or optical elements) and miniaturization [15]. Interestingly, this output from the MFmanufacturing survey coincided with the result of an earlier finding from a survey conducted by Semiconductor Equipment and Materials International (SEMI). The SEMI survey (of 85 respondents) also concluded the need for industry to cater for complex and highly integrated devices. It is important to highlight that although the two surveys have reached the same conclusion, the SEMI survey focused on Micro- Electro- Mechanical Systems (MEMS)/sensors rather than microfluidics [16].

In order to support the drive towards highly integrated complex microfluidic based devices, geometrical specifications associated with pitch positions must be considered. Much of the early discussions within MFmanufacturing started in evaluating what has been done with regards to this. Figure 1 summarizes potential possibilities in relation to port pitch spacing dimensions.

Dimensions in millimetres

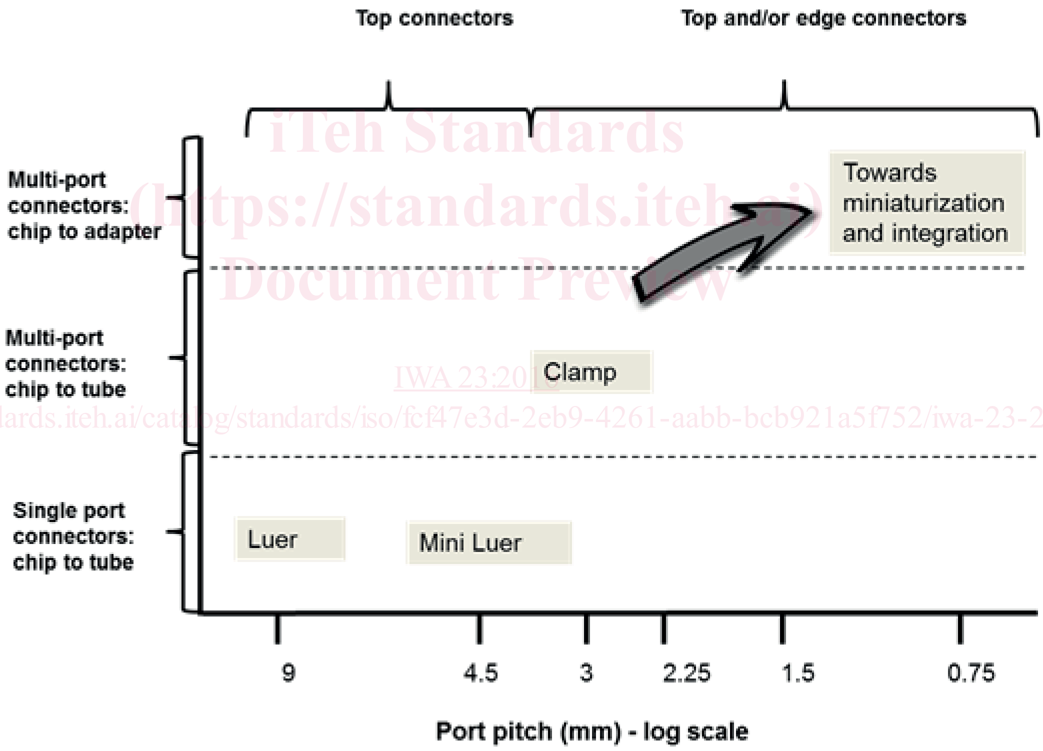


Figure 1 — Port pitch dimension possibilities

Figure 1 clearly shows for the purpose of integration and miniaturization, the trend towards smaller pitches must be realized. In further defining the geometrical specifications for pitch, several factors must be taken into consideration to include the need to:

a) adapt to what the majority of microfluidic manufacturers and users are currently using, such as existing standards already found in laboratory equipment [17];

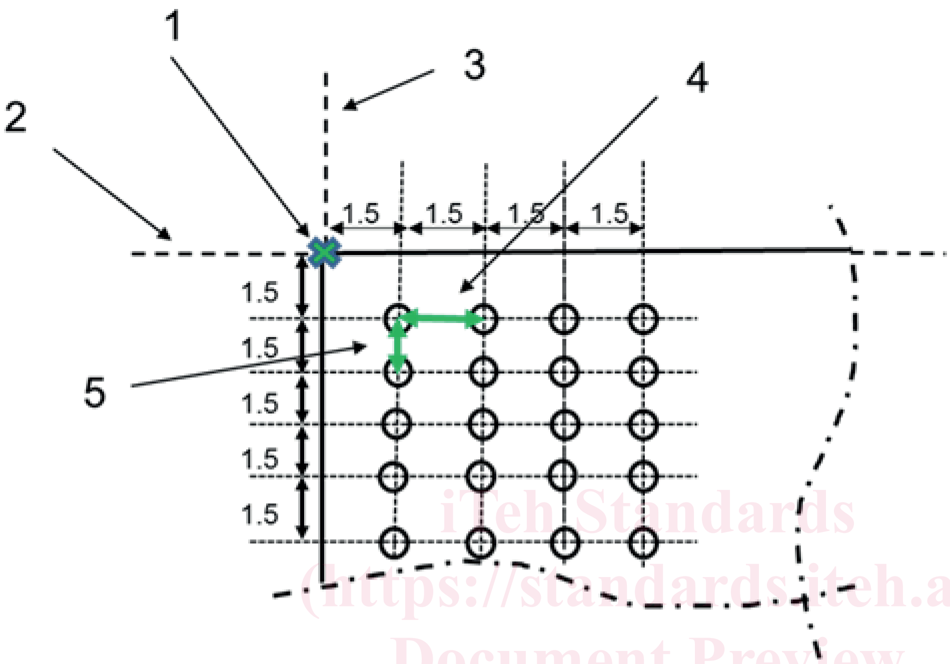
b) have a reliable leakage-free fluidic connections using the currently available multiport connection technologies.

3.2 Geometrical specifications on pitch dimensions

The purpose of this Clause is to specify the geometrical connector pitch dimensions for microfluidic devices.

Designs of microfluidic devices shall be based on a metric multiple pitch concept of $n \times 1{,}5$ mm, where $n \geq 1$. An example layout for the $n \times 1{,}5$ mm grid is shown in Figure 2.

Dimensions in millimetres



Key

1 reference point

2 *x*-axis

3 *y*-axis

4 distance between the centres of two ports on the *x*-axis

5 distance between the centres of two ports on the *y*-axis

Figure 2 — Top view (of top or bottom connections) that shows possible port pitch positions based on the $n \times 1{,}5$ mm grid, where n is an integer ≥ 1

The following considerations should be taken into account in relation to the use of the $n \times 1{,}5$ mm grid concept:

a) only the positions of the ports are prescribed;

b) all prescribed pitch positions in the 1,5 mm grid need not to be used in a design;

c) designation of port pitches shall be independent of the fabrication process and supplier.

If the above criteria are not reached, then the pitch dimensions in the design cannot be considered as standard.

The standard geometrical specifications need not apply if microfluidic chip is of the same size as normal microtitre plate and microscope slides.

