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Microfluidic devices — Interoperability requirements for dimensions, connections and initial device classification

Dispositifs microfluidiques — Exigences d'interopérabilité concernant les dimensions, les connexions et la classification initiale des dispositifs

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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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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 48, *Laboratory equipment*.

This first edition of ISO 22916 cancels and replaces IWA 23:2016, which has been technically revised.

The main changes are as follows:

— the content of IWA 23 was transferred into a standard for the first time;

— the terms and definitions have been removed in the present document and it refers mainly to ISO 10991;

— the rationale behind technical decisions in IWA 23 have been removed from the present document;

— the geometrical pitch dimensions are included in Clause 4;

— the device classification is included in Clause 9;

— further information have been introduced in the present document.

NOTE   IWA 23 initiated the standardization effort in microfluidics and presented mainly the terms and definitions, the geometrical pitch rationale and dimensions and the device classification rationale and proposal.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document was developed in response to microfluidics community demand for minimum specifications for interoperability of microfluidics components, since most of the microfluidics products are produced internally with custom dimensions and characteristics.

Microfluidics based diagnostics have been shown over the years to be viable alternatives to conventional macroscale analysis systems, and in some applications provide analytical capabilities which are not possible using macroscale systems. Hence, exploitation of microfluidics will play an important role for next generation of medical devices. However, there are many (potential) applications for microfluidics, and also many technologies and materials being used. This diversity is a problem when it comes to combining microfluidic components. Researchers do not want to spend much time on side issues like correct connection of tooling; they also want to use chips from different suppliers without needing to change their whole experimental setup; and they want their developed products to go as smoothly as possible into production. Providers of analytical services do not want their limited laboratory space cluttered with a multitude of incompatible instruments. Chemical engineers want easy interconnection between pumps, sensors and reactors, and finally, operational managers want a second source for their products. In short interoperability and therefore standardizing the interfaces between them is important.

Another essential requirement for interoperability is standardization of testing. Testing may be partly very application specific, but there are also tests that are to be used cross application, cross technology and cross material; for instance leakage test, burst pressure tests and flow throughput tests. The test protocol is developed considering the material of the chips, the temperature and pressure range of operation. From studies of the products on the market a number of application classes with specific temperature and pressure ranges have been defined, that will provide the boundary conditions for the tests to be developed. Ultimately, these tests will lead to quicker access to the market.

Microfluidic devices — Interoperability requirements for dimensions, connections and initial device classification

1 Scope

This document specifies requirements for the seamless integration with other microfluidic components and systems to facilitate the process of designing new microfluidic devices (e.g. microfluidic chips, sensors, actuators, connectors).

This document is applicable to devices in the field of "microfluidics" needing microfluidic interconnections.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

ISO 10991, *Micro process engineering — Vocabulary*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 10991 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

4 General dimension tolerances

Table 1 and Table 2 present the recommended general dimension tolerances regarding port pitches, chip thicknesses and port dimensions respectively for top connections and for side connections. In the tables and in the document *n* is an integer ≥1.

Table 1 — Key parameters for top connections

Dimensions in millimetres

Parameters	Nominal value	Minimal value	Maximal value	Tolerance
Reference point	(0; 0)			
Distance of the first hole from the reference point (except for microplate compatibility)	(3; 3)			±0,15
Minimal distance of any hole from any side of the chip		3		
Port pitch	$n \times 1,5$			±0,10
Distance between rows of ports	$n \times 1,5$			±0,10
Port diameter for 1,5 mm grid		0,4	0,7	
Port diameter for 3 mm grid		0,4	2,0	
Port diameter for 4,5 mm grid		0,4	3,5	
Tight tolerance of outer chip dimension (desired)				±0,05
Lower tolerance of outer chip dimension				±0,15

Table 2 — Key parameters for side connections

Dimensions in millimetres

Parameters	Nominal value	Minimal value	Maximal value	Tolerance
Reference point	(0; 0; 0)			
Distance of the first hole from the Z axis	3			±0,15
Port pitch	$n \times 1,5$			±0,10
Total chip thickness	0,8	0,7	0,9	±0,10
	1	0,9	1,1	±0,10
	1,1	1,0	1,2	±0,10
	1,4	1,3	1,5	±0,10
	1,8	1,65	1,95	±0,15
	2	1,80	2,20	±0,20
	4	3,60	4,40	±0,20
Tight tolerance of outer chip dimension (desired)	$n \times 15$	15	30	±0,05
Lower tolerance of outer chip dimension				±0,15

5 Chip reference point and topology

5.1 Chip topology

The chip is a flat microfluidic device. Figure 1 describes the names for each side of the chip.
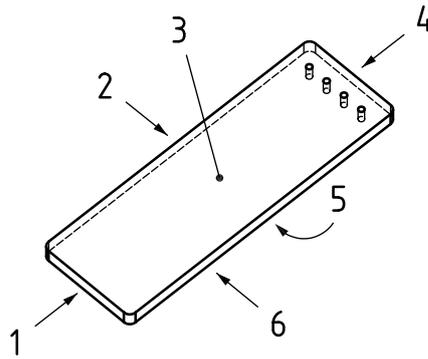
Key

1 lower side
2 left side
3 top
4 upper side
5 bottom
6 right side

**Figure 1 — Schematics showing top, bottom and sides of a chip**

5.2 Naming of the chip

The name of a rectangular (or square) chip shall contain information about the length and the width, defining an X-axis and a Y-axis. The X-axis shall be the direction with most of the fluidic connections. Then, the name of the chip shall contain $X \times Y$ with the correct values.

EXAMPLE   For a component of 15 mm by 30 mm with fluidic connections along the short length, the name of the chip contains at least 15 × 30. For example, "rectangular chip 15 × 30".

5.3 Reference point

The reference point is the intersection of the X-axis and the Y-axis. With the X-axis pointing from left to right, the reference point is at the top left of the chip as described in Figure 2.
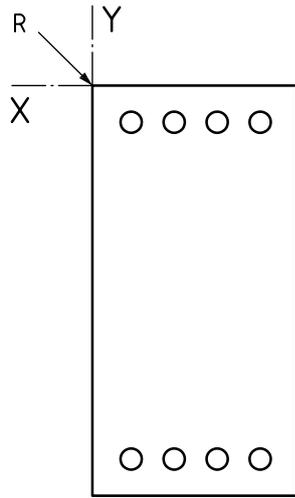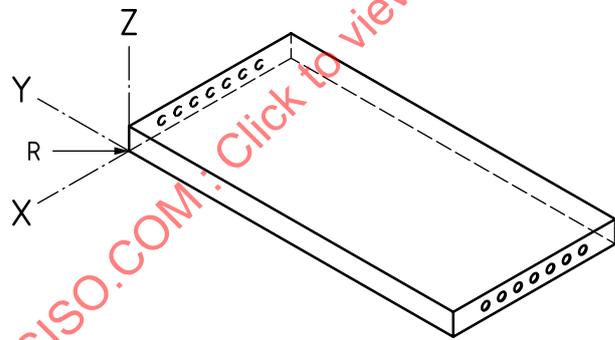
Key

X   X-axis

Y   Y-axis

R   reference point for top or bottom connections

Figure 2 — X-axis, Y-axis and R

In the case of side connections, the Z-axis shall also be taken into account. The bottom side is positioned on the X-Y plane. Figure 3 presents the reference point R for side connections.

a) Isometric view
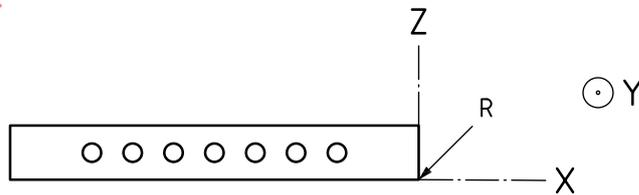
b) Upper side view

Key

X   X-axis

Y   Y-axis

Z   Z-axis

R   reference point for side connections

Figure 3 — X-axis, Y-axis and R

When a chip has rounded corners, the intersection of the extensions of X-axis and Y-axis shall be used as the reference point.

6 Microfluidic chip dimensions

6.1 Chip thickness

When made of glass, the microfluidic chip shall have a thickness compatible with existing standard wafer thicknesses since they are readily available and cheaper and no polishing is required. Moreover, standard wafers have an excellent surface quality, which has a positive influence in manufacturability and yield.

When made of polymer, the microfluidic chip should have a thickness between 1 mm and 3 mm and the microfluidic film shall have a thickness between 100 μm and 250 μm.

NOTE 1   The thickness is of relevance for side connection (see Clause 8).

NOTE 2   The usual thicknesses for bottom layer, t_1, and top layer, t_2, are given in Table 3.

Table 3 — Usual thicknesses for bottom layer, t_1, and top layer, t_2

Dimensions in millimetres

		Top layer thickness t_2							
		0,2	0,4	0,5	0,7	0,9	1,0	1,1	2,0
Bottom layer thickness t_1	0,2				0,9			1,3	
	0,4		0,8		1,1				
	0,5			1,0					
	0,7	0,9	1,1		1,4			1,8	
	0,9					1,8			
	1,0						2,0		
	1,1	1,3			1,8			2,2	
	2,0								4,0

The feasibility of the specific design and application should be checked regarding the compatibility of a device with a 't_1' layer thickness thinner than 0,4 mm. The recommended minimum thickness for t_1 and t_2 is 0,4 mm but it also depends on the type of connector available.

6.2 Outer chip dimensions for microplate compatibility

To be compatible with microplates format[2], the microfluidic chip should have the outer dimensions given in Table 4 and illustrated in Figure 4. The distance (A; B) of the first hole from the reference point depends on the number of wells[3].

Table 4 — Outer chip dimensions for microplate compatibility

Dimensions in millimetres

Length	Width
127,76 ± 0,25	85,48 ± 0,25

Dimensions in millimetres
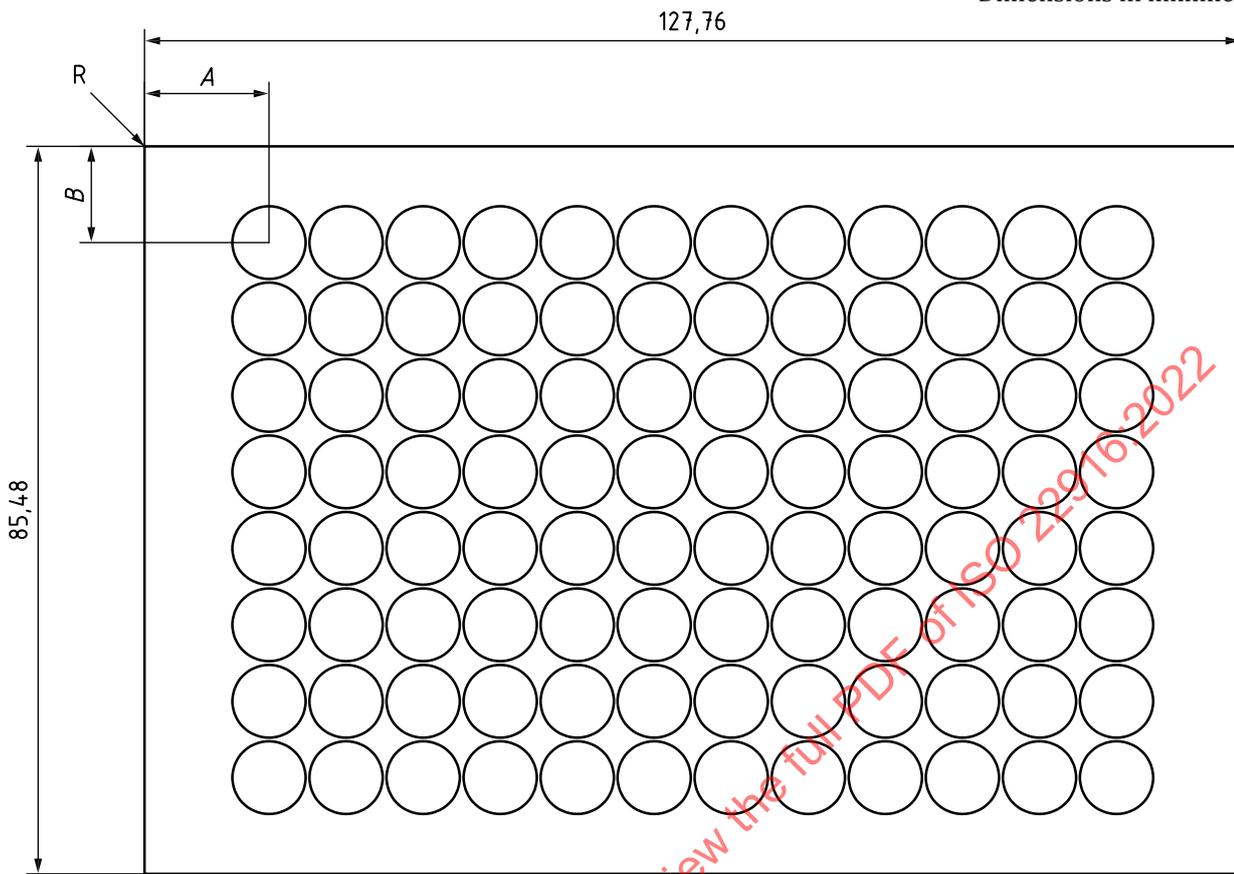
Key

A   distance between centre of first port to the reference point along X-axis

B   distance between centre of first port to the reference point along Y-axis

R   reference point

Figure 4 — Microplate footprint (example with a 96 wells multiplate)

6.3   Outer chip dimensions for microscope slide compatibility

The microfluidic chip should be rectangle with the outer dimensions given in Table 5.

Table 5 — Outer chip dimensions for microscope slide compatibility

Dimensions in millimetres

Format	Length	Width
Simple	$26 \, ^{+0}_{-1}$	$76 \, ^{+0}_{-1}$
Double	$52 \, ^{+0}_{-1}$	$76 \, ^{+0}_{-1}$

A slide format that fits best to the grid of 1,5 mm, which is therefore the 25,5 mm × 75,0 mm slide format, is recommended, see Table 6.

**Table 6 — Outer chip dimensions for microscope slide and 1,5 mm compatibility**

Dimensions in millimetres

Format	Length	Width
Normal size	25,5 ± 0,5	$75\ ^{+0}_{-1}$
Double size	$51\ ^{+0}_{-1}$	$75\ ^{+0}_{-1}$

NOTE   These dimensions ensure compatibility with standard microscope slides according to ISO 8037-1.

## 6.4   Outer chip dimensions close to credit card format

A microfluidic chip with a size close to a credit card shall have outer dimensions of 84 mm × 54 mm to fit with the 1,5 mm grid. Figure 5 and Figure 6 present examples of microfluidic chip to the credit card format in two different configurations: connections along the width (see Figure 5) and along the length of the chip (see Figure 6).

Dimensions in millimetres

Key
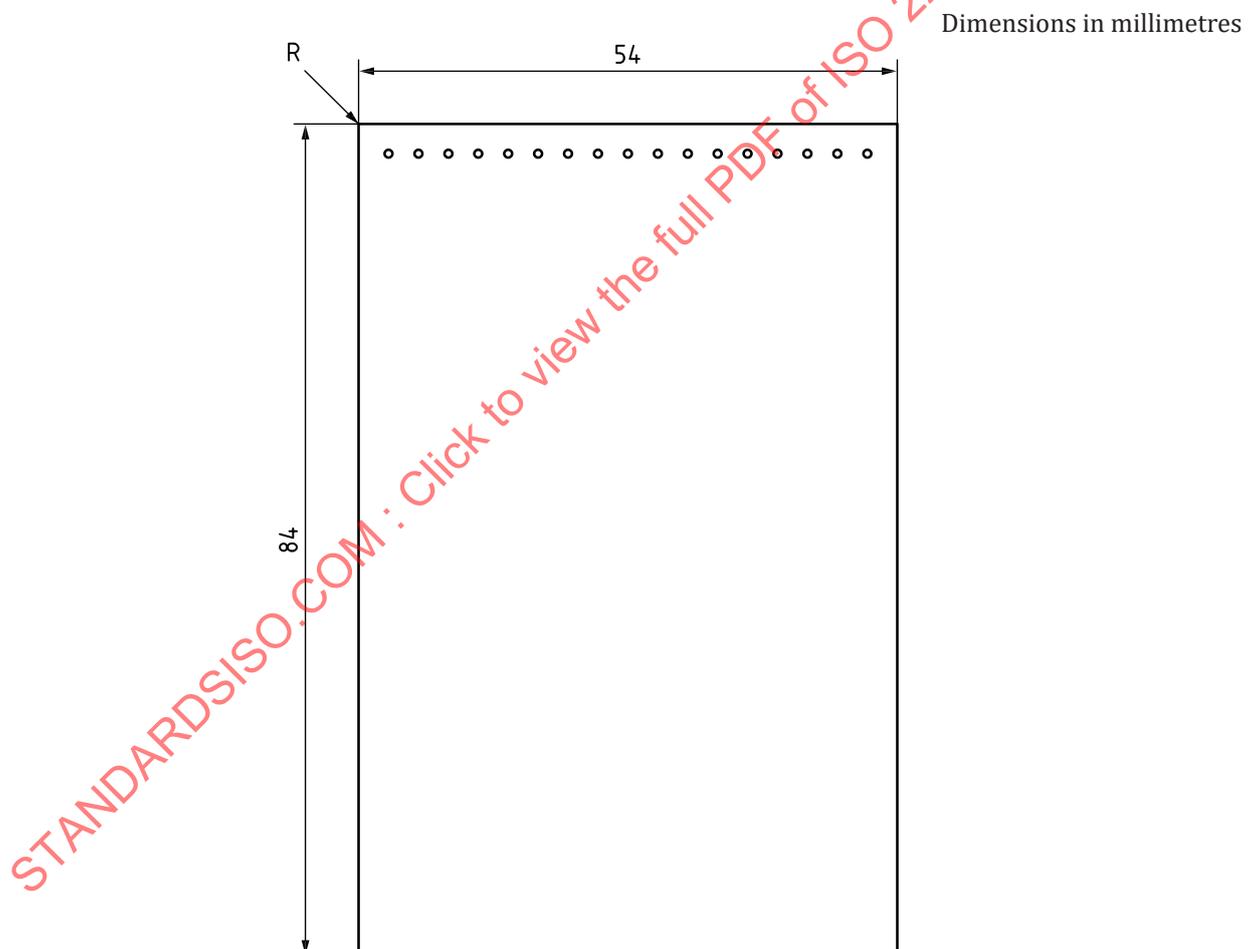
R   reference point

Figure 5 — Microfluidic chip on the credit card format, with holes along the width (3 mm pitch)

Dimensions in millimetres

Key
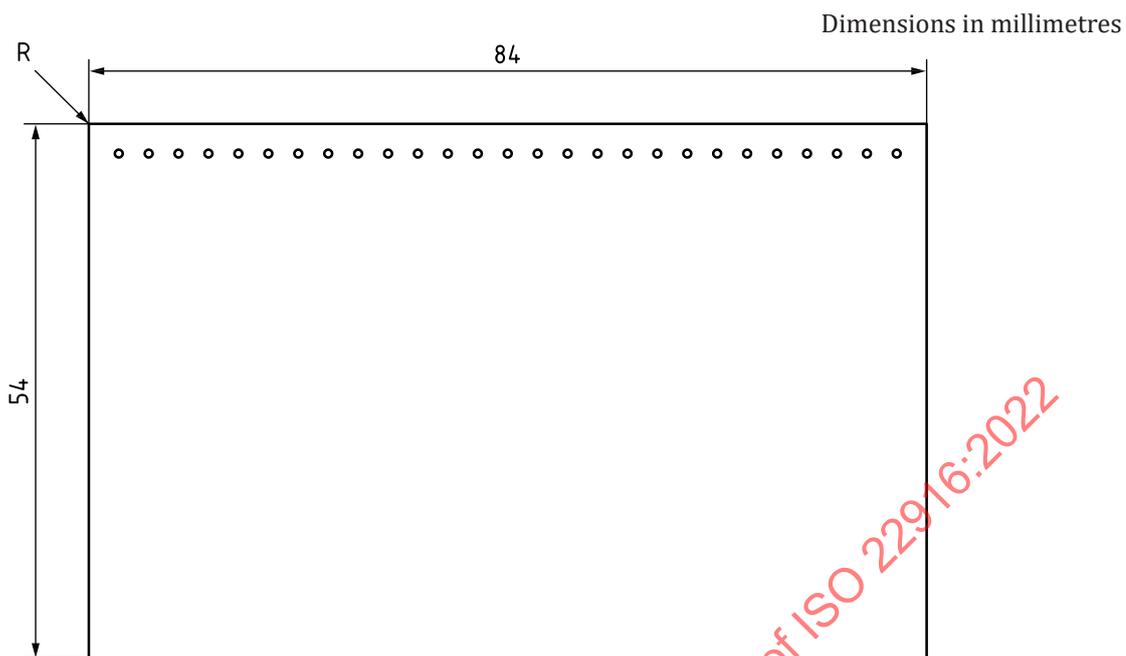
R   reference point

Figure 6 — Microfluidic chip on the credit card format, with holes along the length (3 mm pitch)

6.5 Microfluidic building blocks

A microfluidic building block shall have outer dimensions as a multiple of 15 mm. Figure 7 gives an example of a 15 mm × 15 mm microfluidic building block with a 3 mm port pitch.

Dimensions in millimetres

Key
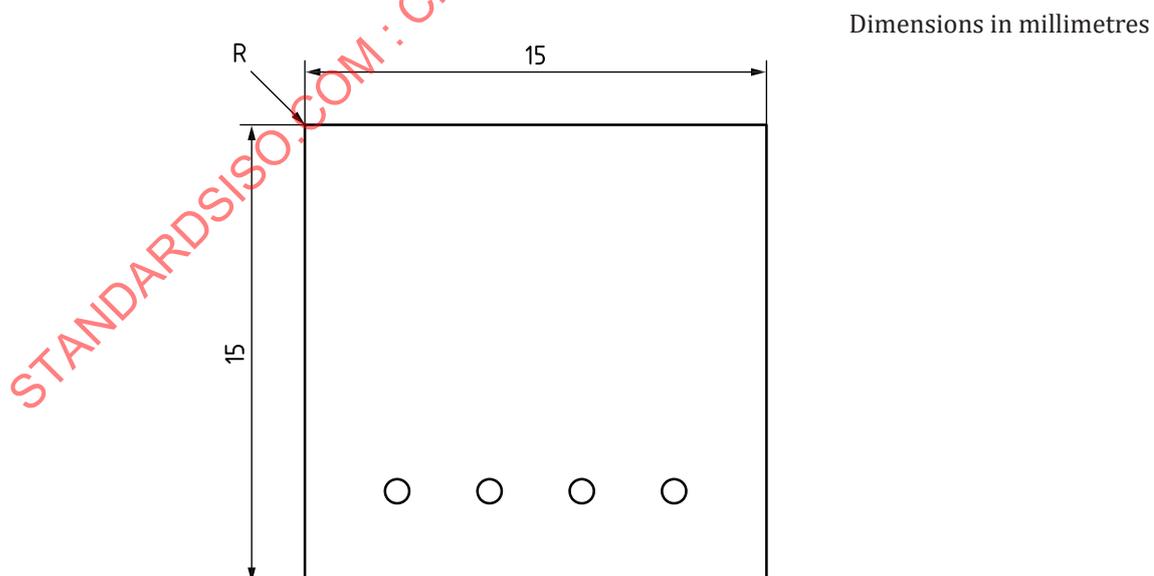
R   reference point

Figure 7 — 15 mm × 15 mm microfluidic building block (3 mm pitch)

Other examples of microfluidic building blocks outer dimensions are: 15 mm × 30 mm; 30 mm × 15 mm; 15 mm × 45 mm; 45 mm × 15 mm.

7 Microfluidic top connections

7.1 General

Microfluidic top connections address design requirements for microfluidic chips that are intended to be inter connected to top or bottom side of the chip, depending on the connector used.

The user shall address the port pitch, the port diameter, the distance between ports and edges, and the port nomenclature to ensure compatibility with interconnected microfluidic devices.

The way to address the required functionality is not specified by this document due to the wide range of existing, or yet to be developed, solutions.

7.2 Port pitch

In case of multiple microfluidic connections defined as fluidic inlet or fluidic outlet, the pitch between two ports shall be a multiple of 1,5 mm indifferently in X-axis or in Y-axis. This configuration defines a grid of lines and columns. The lines are parallel to the X-axis and the columns are parallel to the Y-axis. A 3 mm pitch is considered as the nominal value for standard microfluidic chips.

NOTE 1   MiniLuer connectors usually use 4,5 mm pitch.

NOTE 2   The 4,5 mm pitch is compatible with the microplate format (384 wells).

NOTE 3   The 9 mm pitch is compatible with the microplate format (96 wells).

7.3 Port diameter

The port diameter may follow the relation between port pitch and port diameter according to Table 7.

Table 7 — Relation between ports pitch and port diameter

Dimensions in millimetres

Port pitch	Minimum port diameter	Maximum port diameter
1,5	0,4	0,7
3	0,4	2
4,5	0,4	3,5

NOTE 1   Table 7 is the result of consensus of manufacturing and designing industries.

In order to ensure other properties (e.g. leak free, blocking, loaded volume) additional requirements may be considered.

7.4 Distance between ports and edges

In case of a minimum pitch of 1,5 mm, the centre of a fluidic port shall be at a minimum distance of 3 mm from all edges of the chip as shown in Figure 8.

In case of a smaller pitch (0,75 mm), e.g. for a silicon chip, the centre of a fluidic port shall be at a minimum distance of 1,5 mm from all edges of the chip.

7.5 Port nomenclature

The lines name shall be a letter in alphabetical order from the reference point.

The columns name shall be a number starting at 1 from the reference point.

Figure 8 presents an example of nomenclature with a grid of 1,5 mm: ports A1, A3 and C2 on a 1,5 mm grid.

Dimensions in millimetres
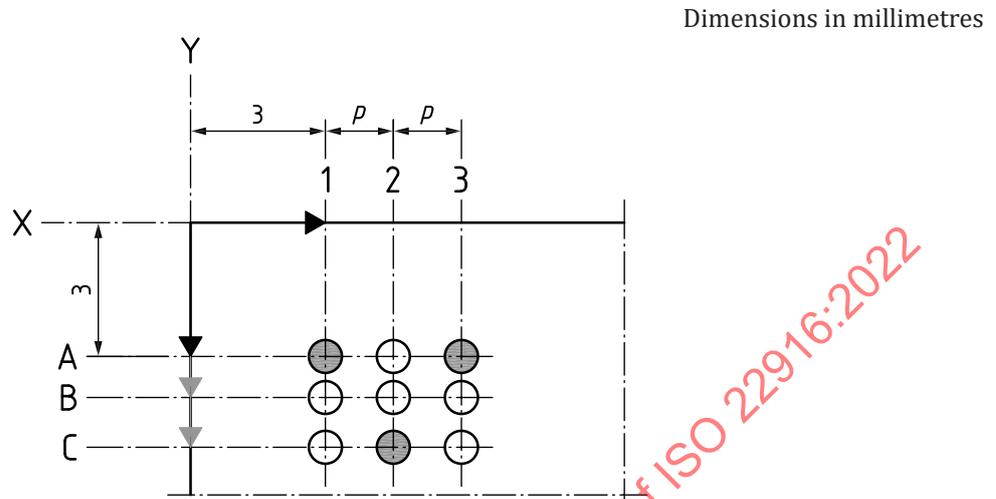
Key

X   X-axis

Y   Y-axis

A   ports line 1

B   ports line 2

C   ports line 3

p pitch

Figure 8 — Nomenclature of a microfluidic chip

In the case of a 0,75 mm grid, the position of the port A1 shall be at a distance of (1,5 mm, 1,5 mm) of the reference point.

7.6   Interfacing area

In order to achieve leak free microfluidic connection between a chip and a connector, it is recommended to define a 6 mm × 6 mm square with centre port in the middle of that square. Structures that create obstructions on the surface and structures that create holes, dents, etc. in the surface (except the portholes itself) are prohibited in this zone. Figure 9 presents examples of exclusion zones around portholes for a chip of 15 mm × 15 mm.
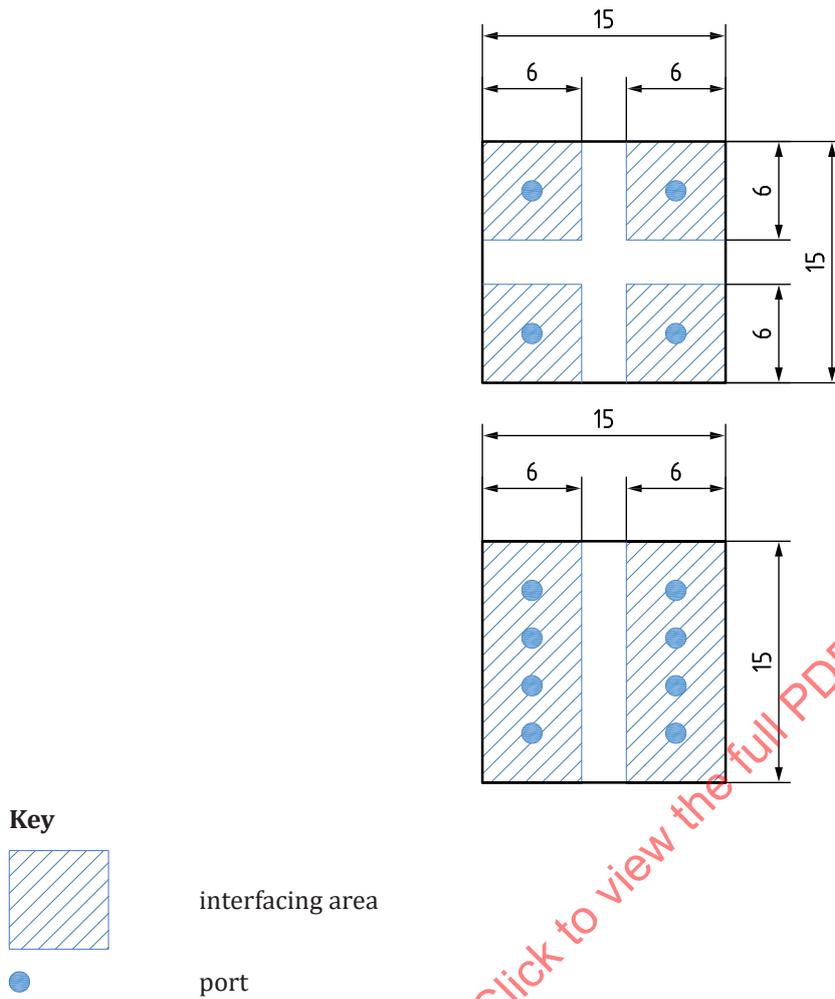
Dimensions in millimetres

Key

⬜ interfacing area

🔵 port

Figure 9 — Exclusion zones around portholes for a 15 mm × 15 mm chip

7.7 Clamping zone

If a sensor or actuator chip (or any other chip) is attached to a circuit board with clamping, it should be taken care that a strip of 1 mm wide at the opposite side of the chip (e.g. top side in case of bottom connections) is reserved for clamping purposes. This area should be free of obstructing structures. Figure 10 presents the clamping zone for a 15 mm × 15 mm microfluidic building block.