

INTERNATIONAL STANDARD



**Semiconductor devices –
Part 18-3: Semiconductor bio sensors – Fluid flow characteristics of lens-free
CMOS photonic array sensor package modules with fluidic system**



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INTERNATIONAL
ELECTROTECHNICAL
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SEMICONDUCTOR DEVICES –

**Part 18-3: Semiconductor bio sensors – Fluid flow characteristics
of lens-free CMOS photonic array sensor package modules
with fluidic system**

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The text of this International Standard is based on the following documents:

FDIS	Report on voting
47E/682/FDIS	47E/690/RVD

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

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INTRODUCTION

The IEC 60747-18 series on semiconductor bio sensors is composed of the following parts:

- IEC 60747-18-1 defines the test method and data analysis for calibration of lens-free CMOS photonic array sensors
- IEC 60747-18-2 defines the evaluation process of lens-free CMOS photonic array sensor package modules
- IEC 60747-18-3 defines the fluid flow characteristics of lens-free CMOS photonic array sensor package modules with fluidic system

The IEC 60747-18 series includes subjects such as noise analysis, long-term reliability tests, test methods for lens-free CMOS photonic array sensor package modules under patchable environments, test methods under implantable environments, etc.

The International Electrotechnical Commission (IEC) draws attention to the fact that it is claimed that compliance with this document may involve the use of patents given in several subclauses as indicated in the table below. These patents are held by their respective inventors under license to SOL Inc.:

KR1020170125673	[SOL]	METHOD FOR EVALUATING FLUID FLOW CHARACTERISTICS OF LENS-FREE CMOS PHOTONIC ARRAY SENSOR PACKAGE MODULE WITH FLUIDIC SYSTEM	Subclause 4.4 Clause 5, 6
PCT/KR2017/011031	[SOL]	METHOD FOR EVALUATING FLUID FLOW CHARACTERISTICS OF LENS-FREE CMOS OPTICAL ARRAY SENSOR PACKAGE MODULE HAVING FLOW CHANNEL	Subclause 4.4 Clause 5, 6
US/16338064	[SOL]		

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SEMICONDUCTOR DEVICES –

Part 18-3: Semiconductor bio sensors – Fluid flow characteristics of lens-free CMOS photonic array sensor package modules with fluidic system

1 Scope

This part of IEC 60747 specifies the fluid flow characteristics of lens-free CMOS photonic array sensor package modules with fluidic system for bio analysis. This document includes the measurement set-up, measurement and calculation at initial state flow, criteria of the fluidic system for quality assurance, measurement and calculation at steady-state flow, and test report.

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.

IEC 60747-18-1:2019, *Semiconductor devices – Part 18-1: Semiconductor bio sensors – Test method and data analysis for calibration of lens-free CMOS photonic array sensors*

IEC 60747-18-2¹ –, *Semiconductor devices – Part 18-2: Semiconductor bio sensors – Evaluation process of lens-free CMOS photonic array sensor package modules*

3 Terms and definitions

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

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

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

3.1

lens-free CMOS photonic array sensor package modules with fluidic system

device composed of the lens-free CMOS photonic array sensor, middle layer, user light (first light source, second light source), its own dark box and fluidic system on or over the sensor

SEE: Figure 1.

Note 1 to entry: Lens-free CMOS photonic array sensor package modules with fluidic system are extensively utilized in bio-diagnostic devices, healthcare devices, lens-free microscopes, and patchable/implantable medical devices as shown in Figure 1.

¹ Under preparation. Stage at the time of publication: IEC/RFDIS 60747-18-2:2019.

Note 2 to entry: The sensing environments of such a lens-free CMOS photonic array sensors are typically different from those of general-purpose image sensors which are normally mounted with an external lens in module housings.

Note 3 to entry: The first light source (first user light) and second light source (second user light) are described in Figure 1 of IEC 60747-18-2:–.

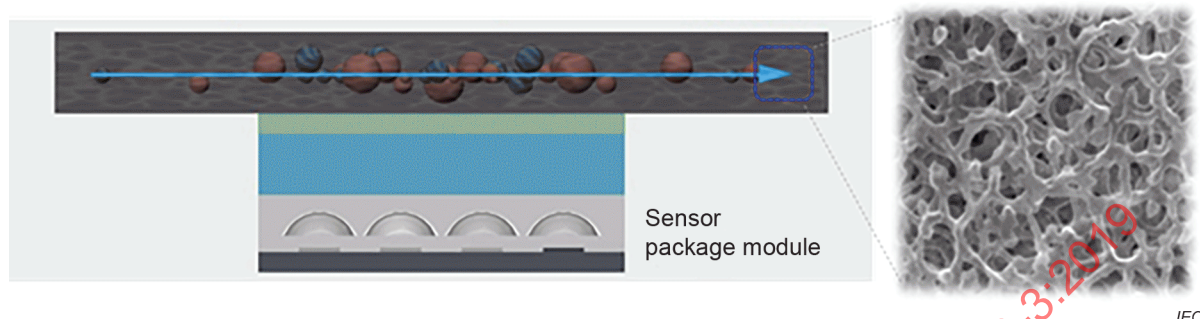


Figure 1 – Example of lens-free CMOS photonic array sensor package modules with fluidic system of porous media

3.2

linearity

ability of a pixel of an array sensor to provide an output having a linear relationship with an input light power

[SOURCE: IEC 60747-18-1:2019, 3.3]

3.3

Reynolds number

Re

quantity of dimension 1 characterizing the flow of a fluid in a given configuration characterized by a specified length l , defined by $Re = \frac{\rho \times v \times l}{\eta} = \frac{v \times l}{\nu}$, where the fluid is described by its mass density ρ , speed v , dynamic viscosity η , and kinematic viscosity ν

Note 1 to entry: The Reynolds number characterizes the relative importance of inertia and viscosity in a fluid flow.

Note 2 to entry: When the Reynolds number is less than a critical value Re_{crit} , laminar flow is stable. For higher values of Re , laminar flow becomes unstable. The critical value depends on the configuration.

Note 3 to entry: In case of a fluid flowing through a circular tube with diameter d , the specified length is $l = d$, and the critical value of the Reynolds number is $Re_{crit} \approx 2\,300$.

[SOURCE: IEC 60050-113:2011, 113-03-36]

4 Measurement setup

4.1 General

The lens-free CMOS photonic array sensor package module with fluidic system is shown in Figure 2 as an example. The fluidic system can be a paper-based membrane strip, gel matrix with pore and microchannel (with forced flow or capillary flow) for biological detection. A Reynolds number equation is employed to optimize the measurement condition of the sensor to avoid spatial distortion caused by motion blur that is the apparent streaking of rapidly moving objects in the sensor output value (overlapping exposure for two frames). Here the velocity of the fluid is a major parameter that needs to be tested in case other specific channel conditions are fixed. Using this velocity parameter obtained from the test based on Reynolds equation, the specific sensor condition that minimizes the motion blur phenomenon can be determined.

4.2 Measurement system

All measurements shall be performed under the standard conditions, according 4.2 of IEC 60747-18-1:2019, as shown in Figure 2 and Figure 3. All items mentioned in 4.2 of IEC 60747-18-1:2019 shall also be also defined.

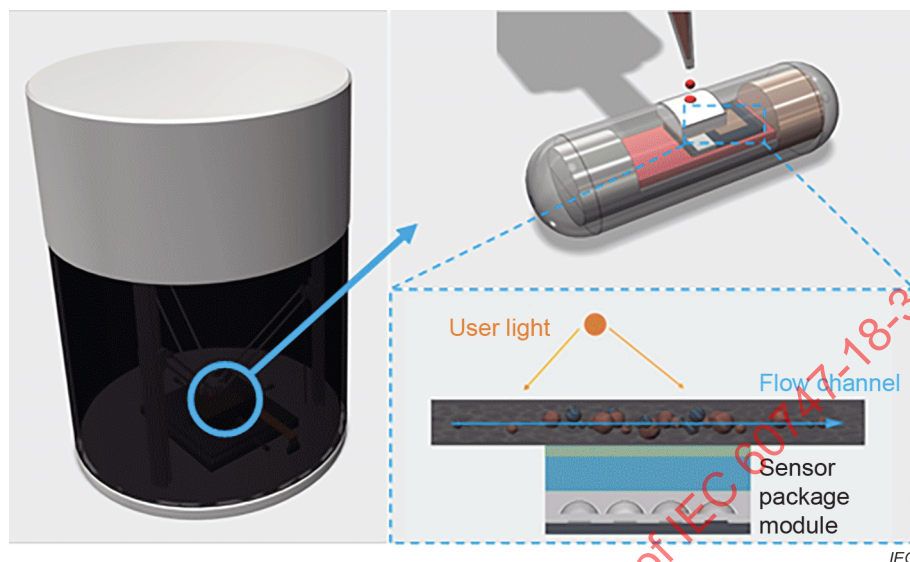


Figure 2 – Example of measurement setup for lens-free CMOS photonic array sensor package module with fluidic system

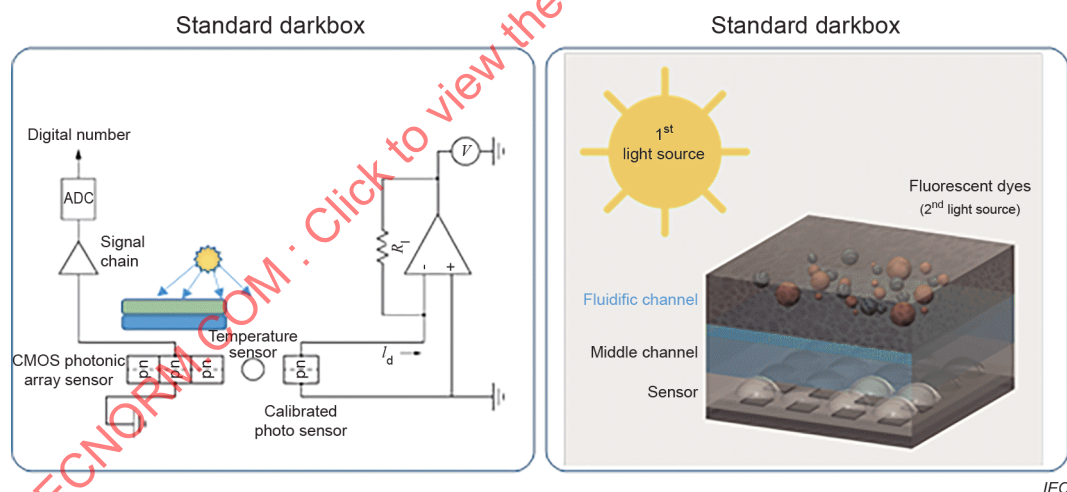


Figure 3 – Example of photoelectric measurement schematics

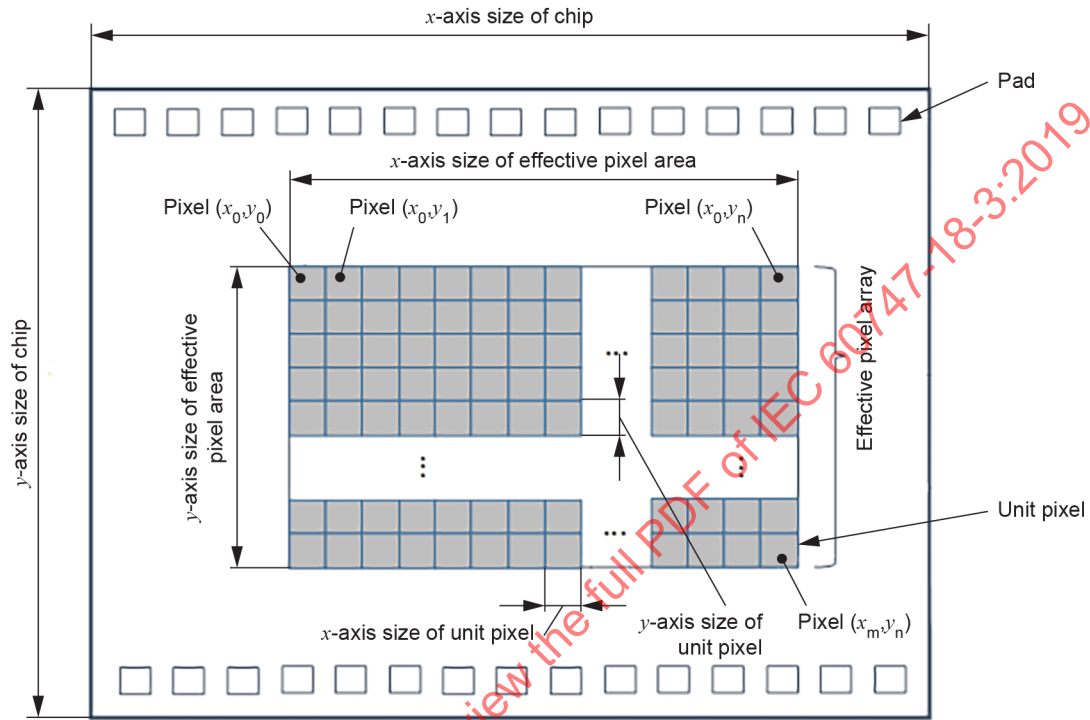
The photoelectric characteristics of lens-free CMOS photonic array sensor package modules with fluidic system can be measured using the measurement system shown in Figure 3 during fluid flow.

4.3 Measurement parameters of sensor

The measurement parameters listed below shall be specified and included in the test report. Some of the parameters are shown in Figure 4:

- unit pixel size of sensor
- effective pixel area of sensor

- effective pixel array (number)
- shutter type (global, rolling)
- exposure time
- frame time (frame-to-frame interval)
- line time (line-to-line interval)
- sensor orientation (horizontal, vertical)



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Figure 4 – Example of measurement parameters of sensor

4.4 Evaluation process

The fluid flow characteristics for bio-analysis can be performed on the lens-free CMOS photonic array sensor package modules with fluidic system via the measuring light signals. The evaluation process can be carried out in accordance with Figure 5.

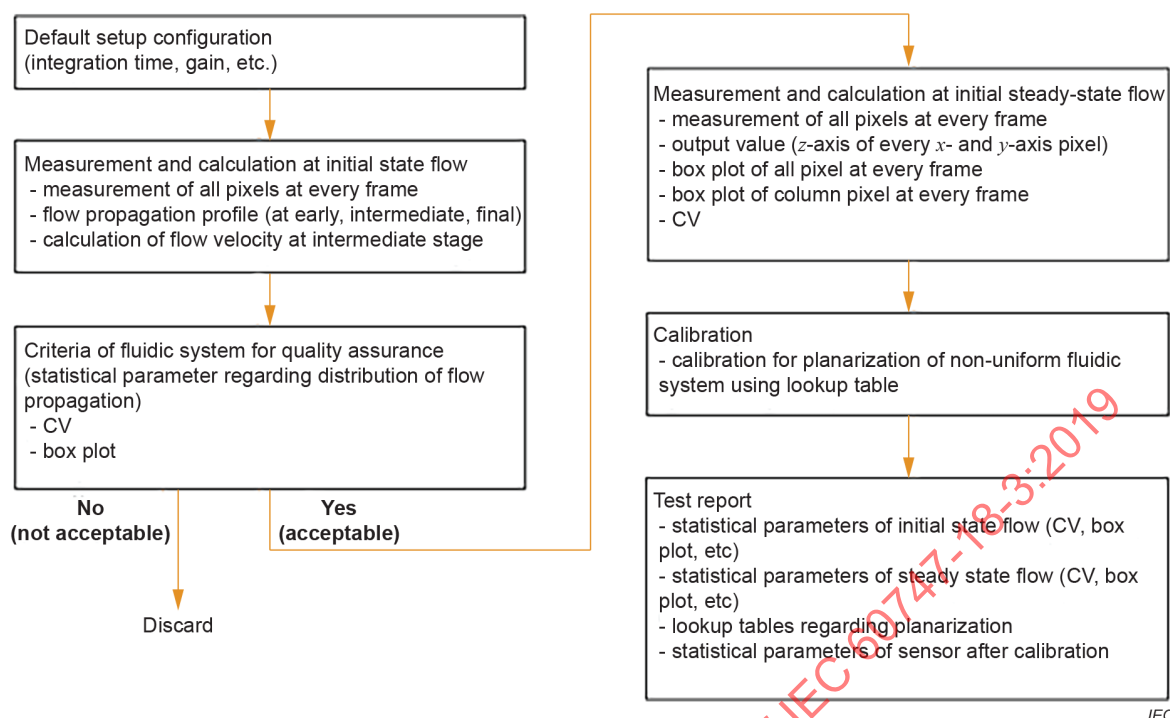


Figure 5 – Evaluation process of fluid flow characteristics of lens-free CMOS photonic array sensor package modules with fluidic system

5 Measurement and calculation at initial state flow in fluidic system

5.1 General

The characteristics of fluids (e.g., buffers and serum) for biological analysis in a fluidic system can be performed on the lens-free CMOS photonic array sensor package modules with fluidic system. For instance, the effective area of the sensor is composed of a fixed number of pixel arrays. In this device, when the sample flow reaches the reaction sensing area, each pixel begins to measure the light (e.g., fluorescence signal) produced from the light source material (e.g., fluorescence dyes) that is contained in the fluid. In this case, depending on the character of the stationary matrices (e.g., distribution of pore size and defect in gel or paper matrix) a flow velocity at the respective sampling volume varies, which influences the light signal distribution in the flow direction.

The qualitative inspection of the fluidic system can be made in the initial state flow. The results of the inspection become the reference for qualification. By measuring the distribution and the velocity of the fluid, the qualification can be evaluated using statistical methods. There are three methods for calculating the velocity of traveling fluid depending on the shutter system: the global shutter system, vertical rolling shutter system and horizontal rolling shutter system.

In the overall shutter system, the granularity of time required for calculation of flow velocity can be limited by the frame time, and this can be the limiting factor to the accurate measurement of flow. In addition, the system cannot measure or estimate the flow propagation before the early stage and after the final stage at the initial state flow. Therefore, the flow at the early and final stage shall not be counted in the calculation of the flow velocity (the flow at the intermediate stage shall be the appropriate sample to measure and calculate the flow velocity at the initial state flow).

In the rolling shutter system, the exposure interval (line time) between each line exists but it is a small value compared to the frame time, so that the value can be either neglected or considered in the calculation of the fluid traveling time. The perpendicular component of the propagation of fluid is not considered in the flow velocity. The flow velocity shall be determined at the pixel in which the fluid arrives and the output code of the corresponding pixel exceeds the threshold value. When the number of corresponding pixel is greater than the number of frames, the flow velocity can be calculated by interpolating the flow velocity in between the previous pixel and current pixel. The flow velocity shall be calculated for all pixels whose output code exceeds the threshold value.

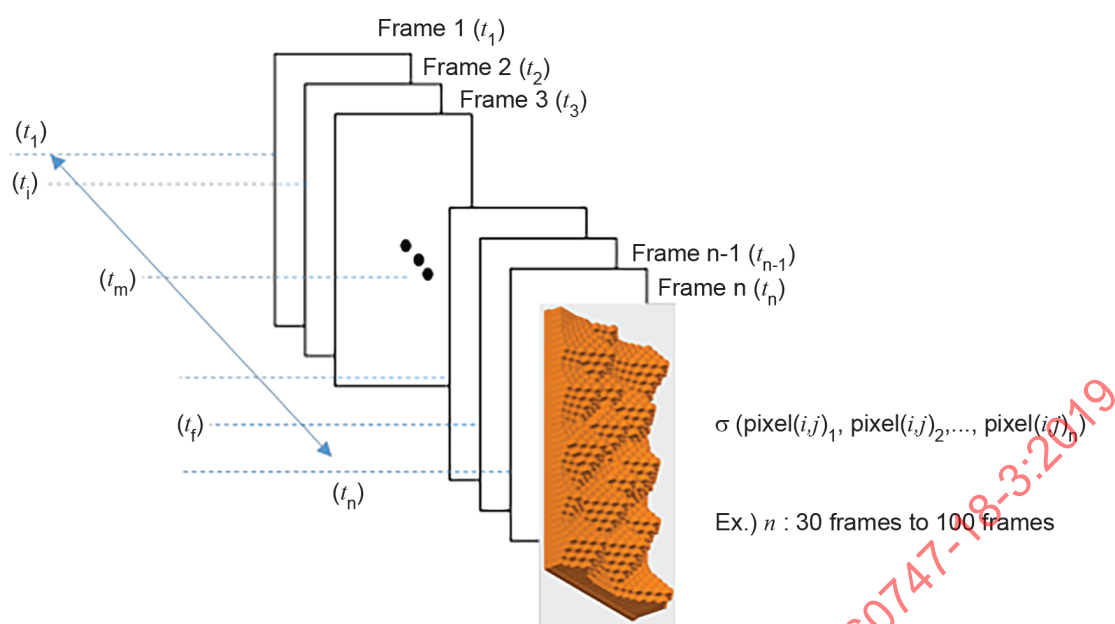
The pass and fail of system shall be determined by using the mean and standard deviation of flow velocity. Reynold's number in 3.3 can be applied to determine the reliability of the measurement and the characteristics of the sample (fluid and strip) after the calculation of flow velocity. The processing time for the system is required to detect and display the flow from each pixel whose output code exceeds the threshold value. However, the processing time is considered equal at every pixel and therefore can be neglected.

5.2 Measurement and calculation of the flow propagation characteristics

When the data is measured at every frame shown in Figure 6, the two-dimensional flow propagation profile shall be analysed by the following procedure and as shown in Figures 7 to 9:

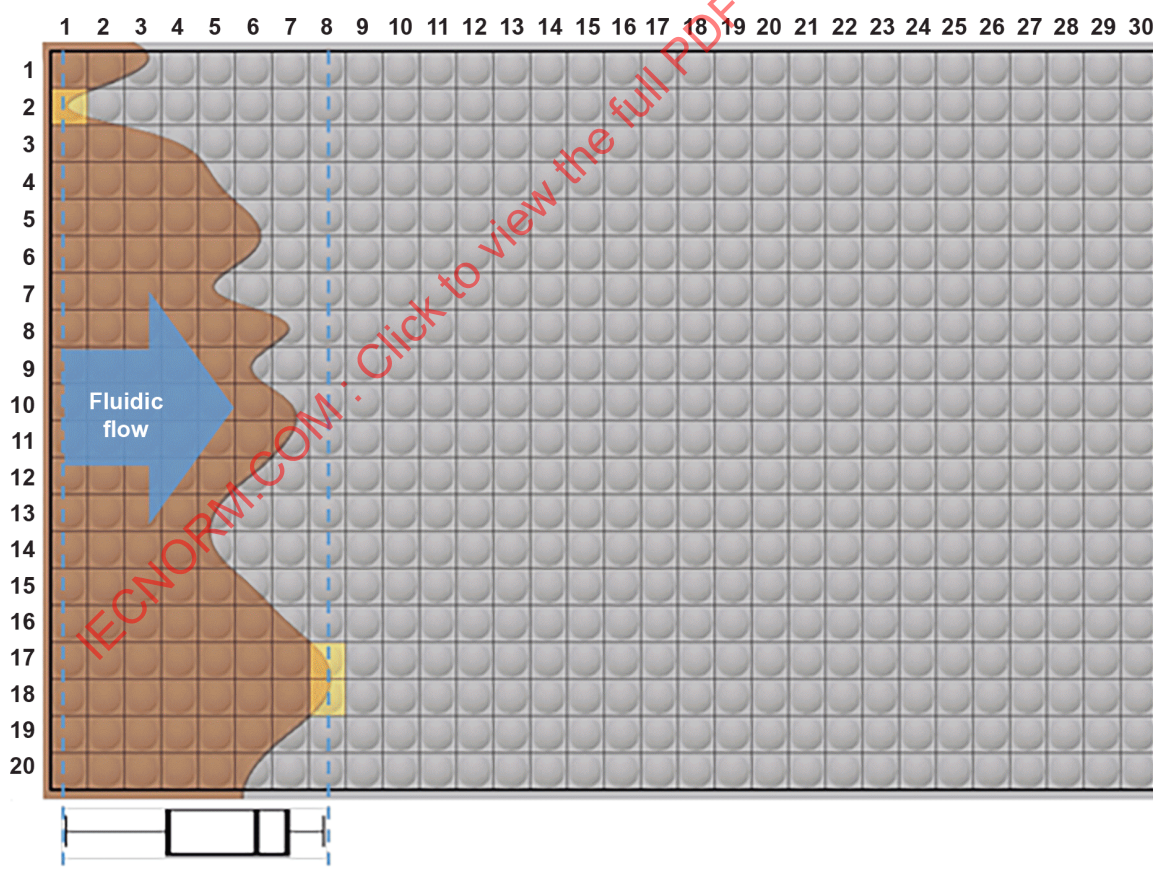
- 1) initial conditions can be determined when the last pixel starts the light signal detection;
- 2) all light signals detected from whole pixels are obtained at the same time;
- 3) the box plot for each row is created according to 3.4 of IEC 60747-18-1:2019;
- 4) The coefficient of variance (CV) can also be determined from the mean and standard deviation according to the flow propagation profile.

The fluid flow propagation profile can be changed as the flow proceeds through the channel due to the character of stationary matrices, which are continuously monitored by the sensor at each pixel and analysed with the identical statistical method as described above. The fluid flow propagation profile shall be performed in at least three different states; the early stage (such as in Figure 7), the intermediate stage (such as in Figure 8) and the final stage (such as in Figure 9) of the initial state flow. The statistical parameters of the initial state flow (CV, boxplot, etc.) shall be included in the test report.



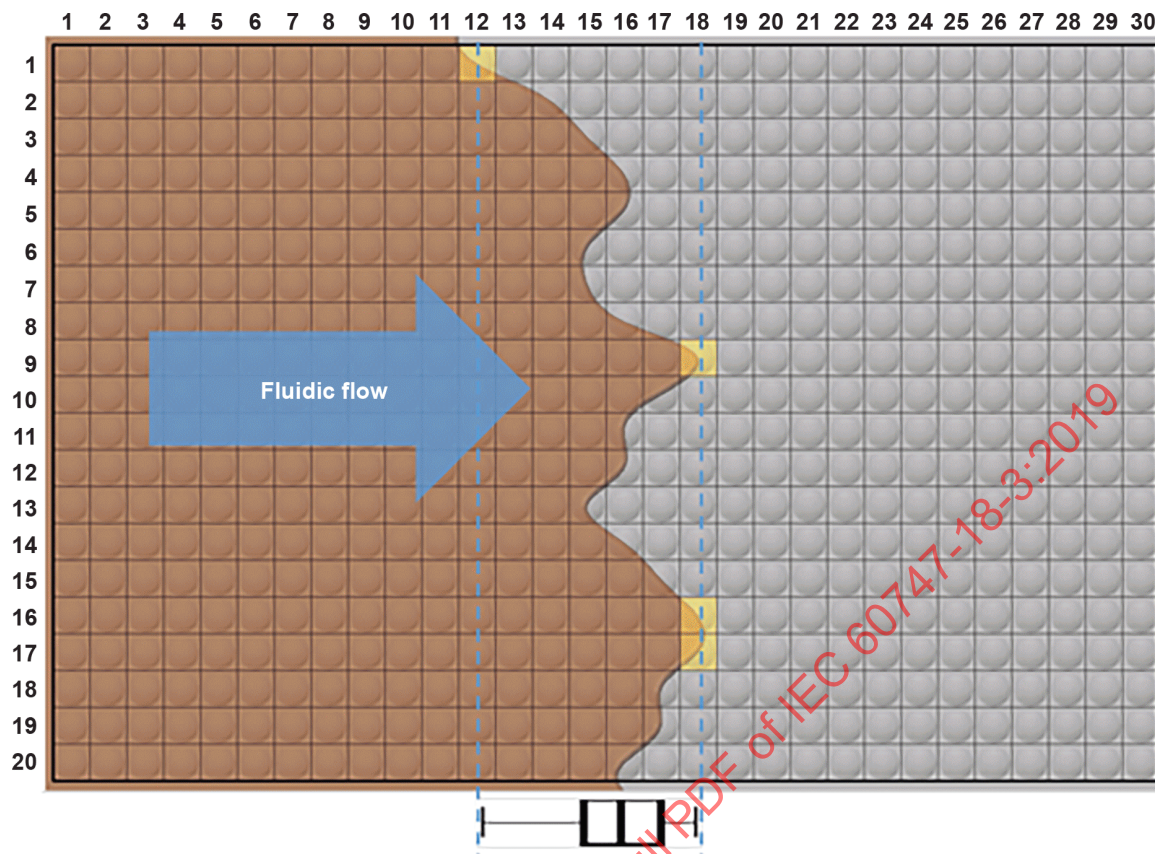
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Figure 6 – Example of frame capture performed at every frame



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Figure 7 – Flow propagation profile in the early stage of the initial state flow



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Figure 8 – Flow propagation profile in the intermediate stage of the initial state flow

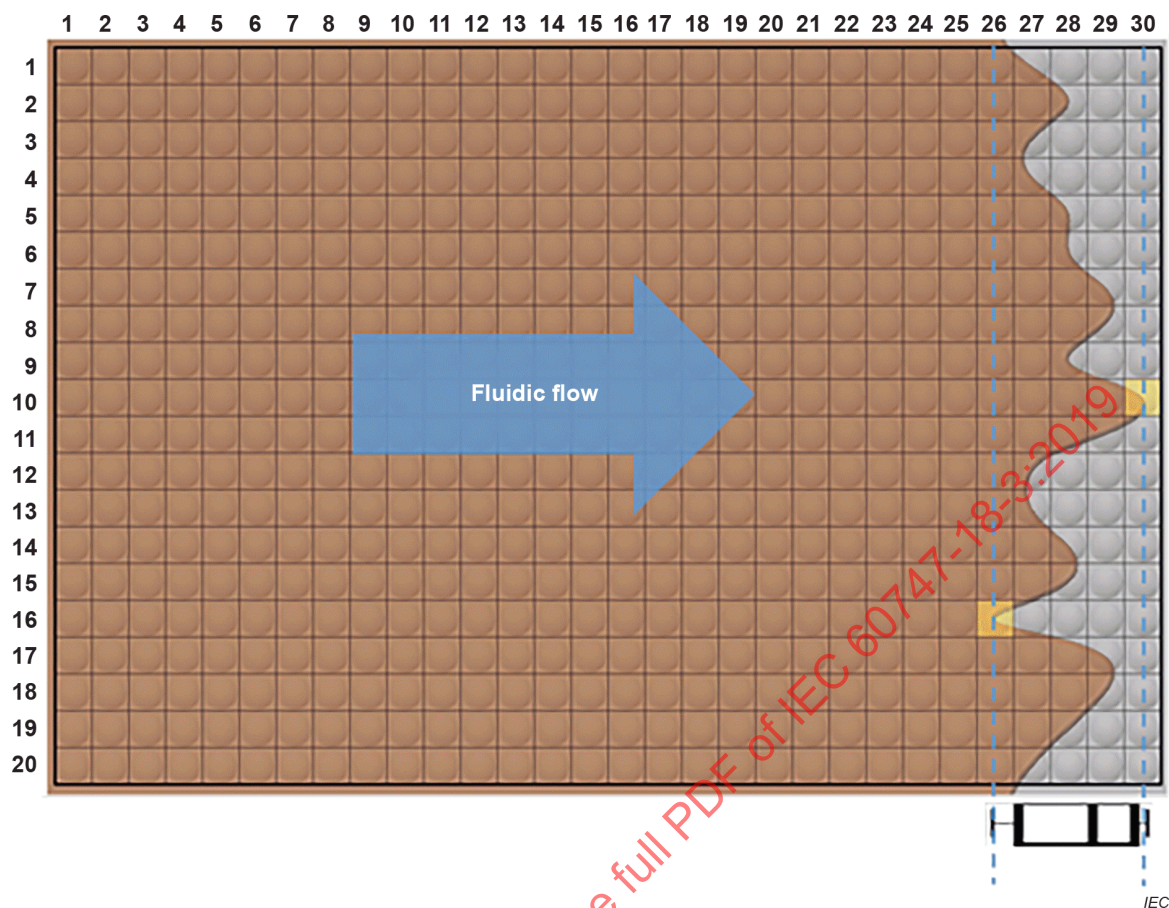


Figure 9 – Flow propagation profile in the final stage of the initial state flow

5.3 Calculation of horizontal flow velocity for global shutter system

In a global shutter system, all the pixels are exposed simultaneously, and the direction of flow is horizontal. An example of this system is shown in Figure 10. The horizontal flow velocity in the global shutter system can be calculated as follows:

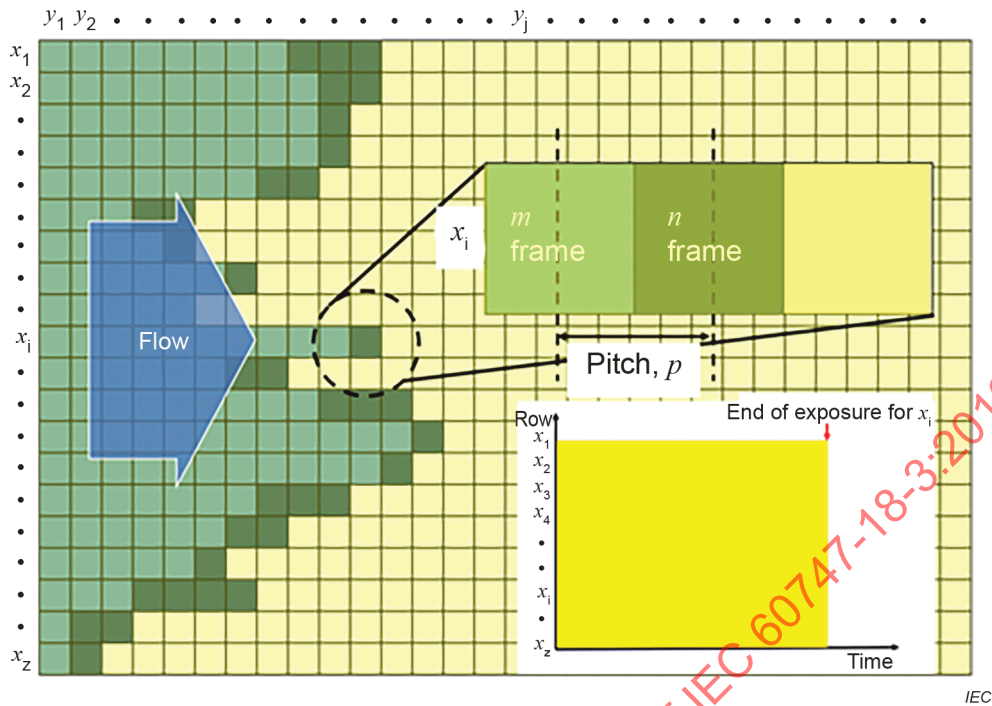


Figure 10 – Example of exposure and horizontal flow in global shutter system

- 1) When the system reads all the output values of the pixel at the m^{th} frame ($m \geq 1$), the position of the last pixel which exceeds the threshold value, c , can be defined as Q_{ij} , where i and j correspond to the i^{th} row and j^{th} column.
- 2) When the system reads all the output values of the pixel at the n^{th} frame ($n > m$), the position of the last pixel which exceeds the threshold value, c , can be defined as Q_{ik} ($k > j$), where i and k correspond to i^{th} row and k^{th} column. The pitch between neighbouring pixels can be defined as p .
- 3) The travel distance of flow, S_{G_i} , the travel time of flow, T_{G_i} , and the flow velocity in the global shutter system, V_{G_i} , can be described as follows (the threshold value for the pixel output shall be the reference to determine the existence of the flow at the pixel and be individually defined by the manufacturer):

$$S_{G_i} [\text{m}] = (Q_{ik} - Q_{ij}) \times p$$

$$T_{G_i} [\text{s}] = \frac{n - m}{FPS}, \text{ (FPS is Frames Per Second)}$$

$$V_{G_i} [\text{m/s}] = \frac{S_{G_i}}{T_{G_i}} = \frac{Q_{ik} - Q_{ij}}{n - m} \times p \times FPS$$

EXAMPLE

When p is $1,12 \mu\text{m}$ and the frame rate is 60 fps, the pixel (3, 2) exceeds the threshold value at the first frame and the pixel (3, 7) exceeds the threshold value at the third frame. The flow velocity is, $V_{G_i} = \{ (7-2) \times 1,12 \times 10^{-6} \} / \{ (3-1)/60 \} = 0,000 168 [\text{m/s}]$.

5.4 Calculation of horizontal flow velocity for rolling shutter system

In the rolling shutter system with horizontal fluid flow, the pixels on the same row are exposed simultaneously, and once the last row, x_z , is exposed the system repeats the exposure of the next frame from the first row, x_1 . The line time, I , between neighbouring rows is present as shown in Figure 11. Since the direction of flow is perpendicular to the direction of exposure, the line time shall not affect the flow velocity. The horizontal flow velocity in the rolling shutter system can be calculated as follows:

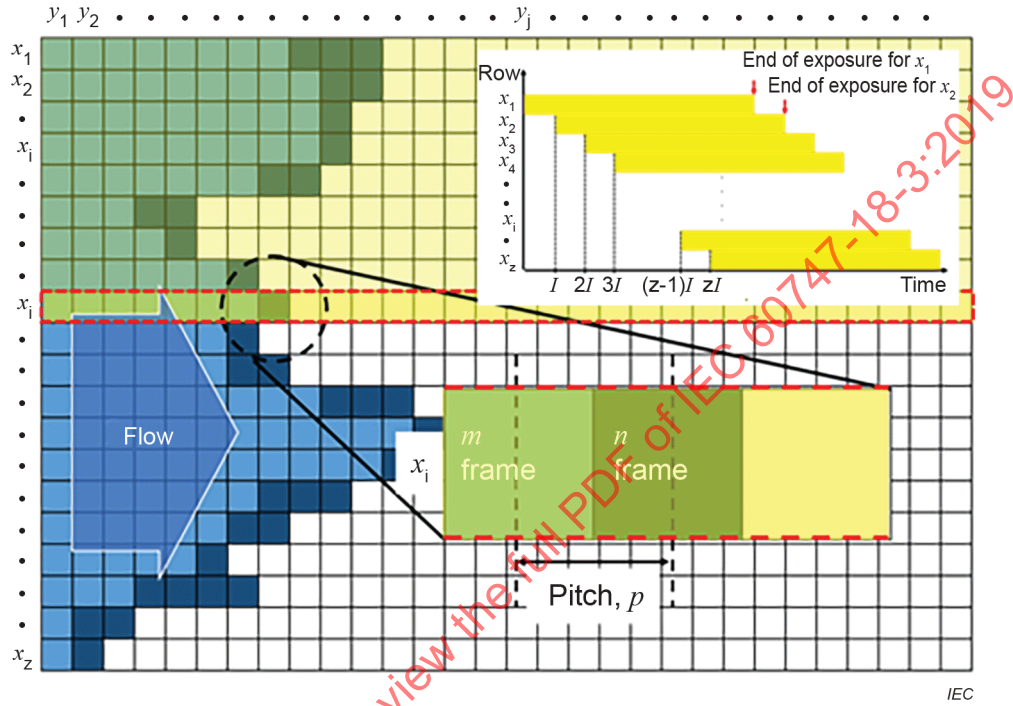


Figure 11 – Example of exposure and horizontal flow in horizontal rolling shutter system

- 1) When the system reads all the output values of the pixel at the m^{th} frame ($m \geq 1$), the position of the last pixel which exceeds the threshold value, c , can be defined as Q_{ij} , where i and j correspond to the i^{th} row and j^{th} column.
- 2) When the system reads all the output values of the pixel at n^{th} frame ($n > m$), the position of the last pixel which exceeds the threshold value, c , can be defined as Q_{ik} ($k > j$), where i and k correspond to the i^{th} row and k^{th} column. The pitch between neighbouring pixels can be defined as p .
- 3) In the rolling shutter system, the exposure start time in each row can be different due to the line time. However, the pixels on the same row are exposed simultaneously during the flow.
- 4) The travel distance of flow, S_{R-H_i} , the time of flow, T_{R-H_i} , and the horizontal flow velocity in the rolling shutter system, V_{R-H_i} , can be described as follows (the threshold value for the pixel output shall be the reference to determine the existence of the flow at the pixel and be individually defined by the manufacturer):

$$S_{R-H_i} [\text{m}] = (Q_{ik} - Q_{ij}) \times p$$

$$T_{R-H_i} [\text{s}] = \frac{n - m}{FPS}$$

$$V_{R-H_i} [\text{m/s}] = \frac{S_{R-H_i}}{T_{R-H_i}} = \frac{Q_{ik} - Q_{ij}}{n - m} \times p \times FPS$$

EXAMPLE 1

When p is $1,12 \mu\text{m}$, the frame rate is 60 fps and one-line time is $2 \mu\text{s}$, the pixel (3, 2) exceeds the threshold value at the first frame and the pixel (3, 7) exceeds the threshold value at the third frame. The flow velocity is $V_{R-H_i} = \{ (7-2) \times 1,12 \times 10^{-6} \} / \{ (3-1)/60 \} = 0,000 168 [\text{m/s}]$.

EXAMPLE 2

When p is $1,12 \mu\text{m}$, the frame rate is 60 fps and the one-line time is $2 \mu\text{s}$, the pixel (3, 2) exceeds the threshold value at the first frame and the pixel (3, 1 000) exceeds the threshold value at the third frame. The flow velocity is $V_{R-H_i} = \{ (1\ 000-2) \times 1,12 \times 10^{-6} \} / \{ (3-1)/60 \} = 0,033 532 8 [\text{m/s}]$.

5.5 Calculation of vertical flow velocity for rolling shutter system

In the rolling shutter system with vertical fluid flow, the pixels on the same row are exposed simultaneously and the pixels on different rows are exposed at different times. Once the last row, x_z , is exposed, the system starts the exposure of the next frame from the first row, x_1 . The line time, I , between neighbouring rows is present as shown in Figure 12. Since the time required to read out the flow at each line of pixels is small, the time resolution of flow is much improved. The vertical flow velocity in the rolling shutter system can be calculated as follows:

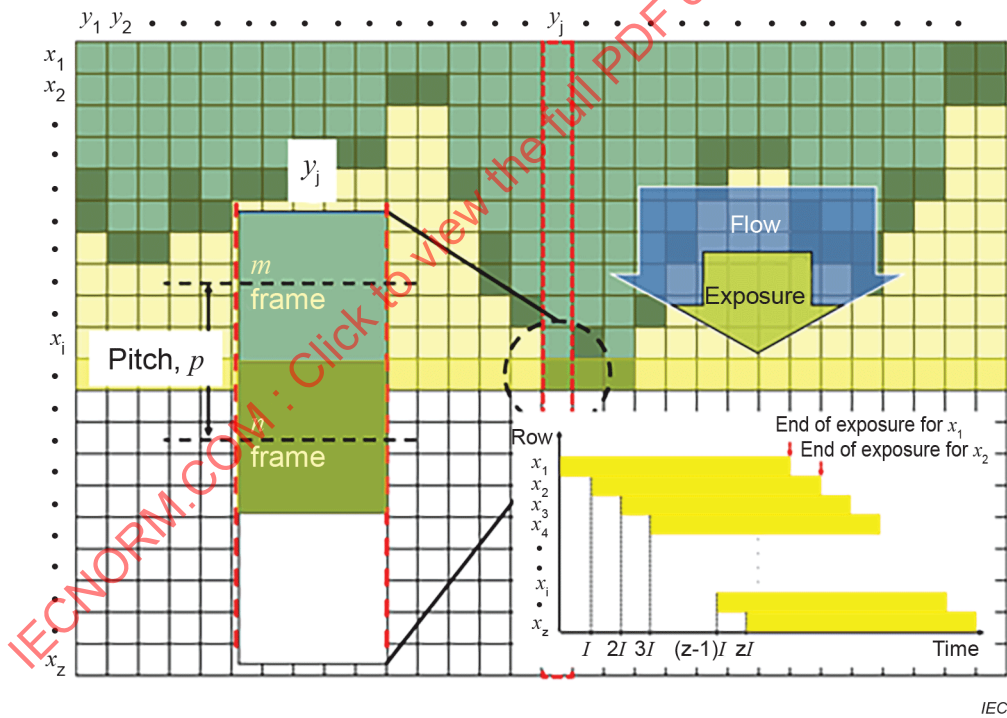


Figure 12 – Example of exposure and vertical flow in vertical rolling shutter system

- 1) When the system reads all the output values of the pixel at the m^{th} frame ($m \geq 1$), the position of the last pixel which exceeds the threshold value, c , can be defined as Q_{ij} , where i and j correspond to the i^{th} row and j^{th} column.
- 2) When the system reads all the output values of the pixel at the n^{th} frame ($n > m$), the position of the last pixel which exceeds the threshold value, c , can be defined as Q_{kj} ($k > i$), where k and j correspond to k^{th} row and j^{th} column. The pitch between neighbouring pixels can be defined as p .
- 3) In the rolling shutter system with vertical fluid flow, the direction of the flow and exposure are the same. Therefore, the line time should be considered to calculate the flow velocity.