Qimono® successfully passes Customized NIOSH Testing in Administration

Performed by Biopharma Stability Testing Laboratory Limited (BSTL) - Nottingham, UK[1]

CONTEXT

In 2015, the NIOSH (National Institute for Occupational Safety and Health), released a protocol to evaluate the efficiency of CSTD (Closed System Transfer Devices)[2]. This protocol gives a methodology for the evaluation of vapor containment for CSTD's, using IPA (Isopropyl Alcohol) as challenge agent. In order to evaluate Qimono connectors, Vygon has designed a customized protocol[3] simulating an IV perfusion, in accordance with 2015 NIOSH protocol.

1/ OBJECTIVE

The objective of this testing, was to demonstrate the containment performances of three different connections in administration of Hazardous Drugs, based on the NIOSH original protocol.

Solution of 70% IPA was chosen to test liquid, aerosol and vapor release during the simulation of an IV perfusion.
3 configurations of perfusion line connections were tested:

- QimoMale® with QimoFemale®
- Luer Lock Male Connector with Chemoclave® (ICU Needle Free Connector - NFC)
- Luer Lock Male Connector with Luer Lock Female Connector: "open system"

2/ PROTOCOL

Material and Method

The 2015 draft NIOSH protocol uses 1 ppm value as threshold for successful containment. Thus, for the described customized NIOSH experiment, a 1 ppm quantifiable performance threshold was selected to represent the threshold for successful containment.

Material

NIOSH Chamber

Figure 1 shows the BSTL chamber, which is a replica of NIOSH test chamber.
Only "connector's parts" of the perfusion line are present in the NIOSH chamber during the test.

Figure 1: **BSTL Chamber**

IPA detectors:

Two detectors are used to report released values of IPA with a detection level of parts per billion (ppb), which is far below the acceptance criteria of 1ppm.

The configuration tested are presented on Table 1 below.

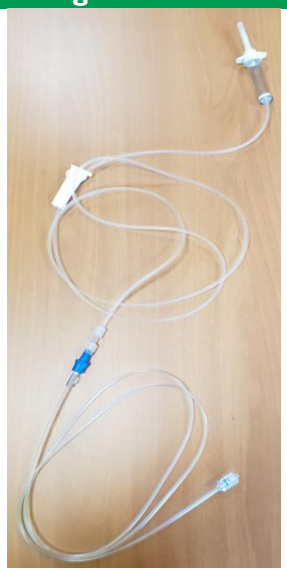
Configuration 1	Configuration 2	Configuration 3
		
Perfusion line with Qimono® connectors	Perfusion line with Luer + Chemoclave® connector	Perfusion line without specific connector
		
QimoFemale® connected to QimoMale®	Chemoclave® connected to Open Luer Lock Male (LLM)	Open Luer Lock Female (LLF) connected to Open Luer Lock Male (LLM)
		
Proximal end of the vascular access - QimoFemale®	Proximal end of the vascular access – Chemoclave®	Proximal end of the vascular access – Open Luer Lock Female (LLF)

Table 1 : Detail of the 3 configurations tested

3/ RESULTS

Negative control:

The configuration tested for the negative control is the open Luer connection where the IPA solution is replaced by 0.9% saline.
Release values detected on negative control are below the LOQ (Limit Of Quantification) of 1ppm and are considered as "background".

Positive control (configuration 3):

The configuration tested for the positive control is the open Luer connection with IPA. It is used to check if the IPA detector shows measurable release.

Results:

The results of the study with IPA presented in the Table 2 below, show background corrected mean values rise in IPA level, 30 min and 1 h after disconnection of the perfusion line.

Connection configuration	Mean Values in IPA Level after 30min in ppm	Mean Values in IPA Level after 1 hour in ppm
1 QimoMale® & QimoFemale®	0.82	0.98
2 Luer + ChemoClave®	5.77	9.41
3 Luer + Luer	27.77	35.88

Table 2 : Mean Values IPA release results

According to the Figure 2 below, we note that an average value of less than 1 ppm of IPA is released at the disconnection of Qimono connectors, and this mean of rise in IPA level remains under 1ppm even 1 hour after disconnection.

The 1 ppm IPA level is reached faster with the full open Luer option (configuration 3).

We can also note that securing only vascular access is not efficient to guarantee a safe connection (configuration 2).

The best configuration is obtained with the full secured Qimono connectors (configuration 1).

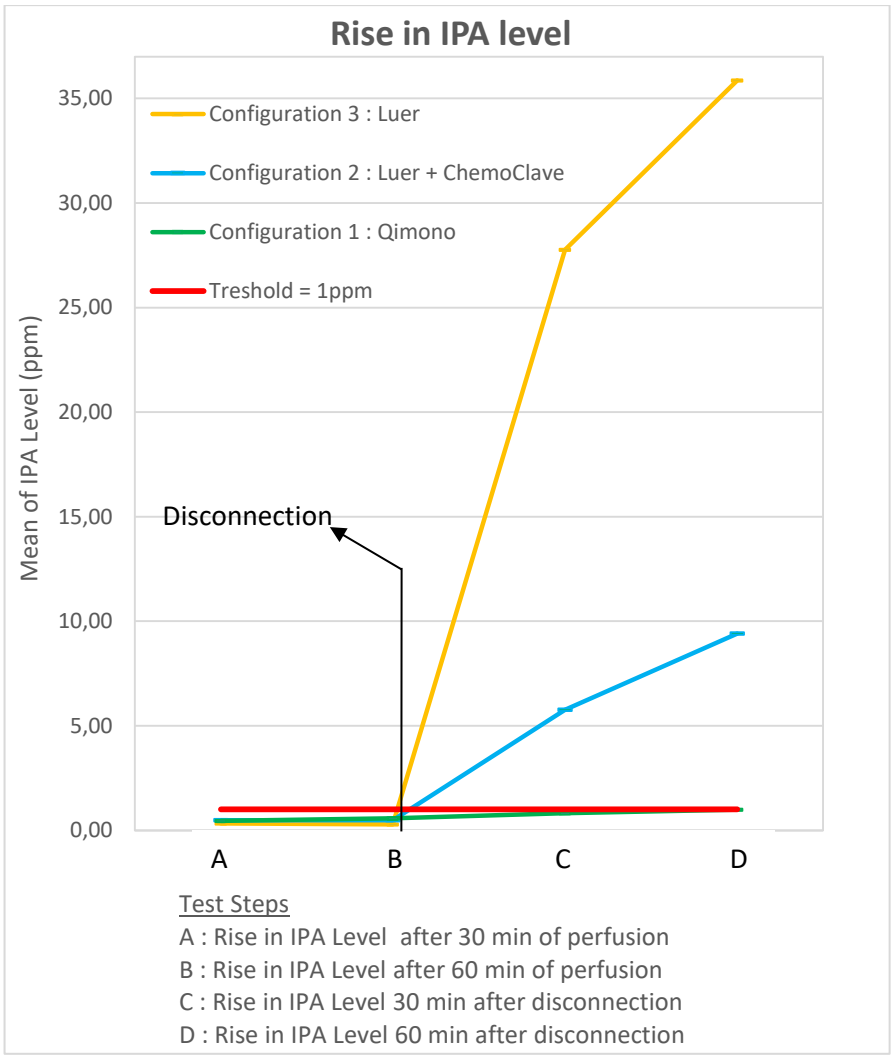


Figure 2 : Mean Values IPA release results

4/ Discussion

With Qimono® connectors, values of IPA released after disconnection are below the 1 ppm threshold. With Luer + ChemoClave® (configuration 2) and with open Luer connections (configuration 3), values of IPA released after disconnection are well above 1 ppm.

5/ Conclusion

There are two main conclusions regarding this Testing.

1) Qimono® connectors passes the customized protocol in accordance with original 2015 draft NIOSH, using the IPA as challenge agent and based on the LOQ of 1ppm. Both Luer + ChemoClave® and Open Luer connection did not pass this protocol acceptance criteria.

2) The totally secure Qimomale® & Qimofemale® connection gives better protection to healthcare workers than Luer + ChemoClave® or Open Luer connection. It prevents from any exposure to cytotoxic drugs during the full administration process, from perfusion to disconnection of the IV line.
Qimono® connectors (QimoMale® and QimoFemale®) give benefits with a safety factor of 10 compare to Luer + ChemoClave® and a safety factor of 37 compare to open Luer, while using these connectors during an administration procedure.

1 - Vygon Report RR_CDC15002_312_19_A1
2 - NIOSH 2015. A vapor containment performance protocol for closed system transfer devices used during pharmacy compounding and administration of hazardous drugs. National Institute for Occupational Safety and Health (NIOSH)
https://www.cdc.gov/niosh/docket/review/docket288/pdfs/a-vapor-containment-performance-protocol-for-closed-system-transfer-devices.pdf
3 – Vygon Protocol RP_CDC15002_420_19