# *Evaluation of QimoMale & QimoFemale Connectors Resistance to Microbial Ingress*

## ***Context***

The use of closed system connectors has become a standard to reduce the risk of exposure of health care professional and patients against chemical and microbial contamination.
The closed system Qimo Female (Figure 1) and Qimo Male (Figure 2) have been specifically designed to meet these requirements.

The objective of this study is to evaluate the effectiveness of membranes disinfection of Qimono connectors (Qimo Male and QimoFemale) to prevent entry of microorganisms after repeated access over a period of seven days.
In order to be approved, FDA requires to perform a microbial ingress testing in clinical use conditions, for any new Closed System Transfer Device (CSTD)[1].
In that respect, Vygon entrusted the realization of this study on Qimono closed system to an independent laboratory (NAMSA, Chasse sur Rhône, France)[2]. The protocol for this test, as well as the results are presented below.

Figure 1 QimoFemale

Figure 2 QimoMale

## ***Protocol - Acceptance Criteria – Test System***

Protocol:

Several Qimo Male (product code: 7210.91) and Qimo Female (product code: 7210.02 were each inoculated with at least $10^3$ CFU of different microbial strains.
The following strains were tested:
Staphylococcus aureus (gram positive bacteria)
Staphylococcus epidermidis (gram positive bacteria)
Pseudomonas aeruginosa (gram negative bacteria)
Klebsiella pneumoniae (gram negative bacteria)

The samples were then subjected to the following steps: disinfection with a wipe of 70% IPA (isopropyl alcohol), drying, activation (connection between Qimo Male and Qimo Female), flush through the connectors with saline solution, disconnection. These steps are repeated several times a day.

After the last connection at D1/D5 and D7 and for each microorganism tested, the saline solution flushed through QimoMale connected to QimoFemale is filtered on a membrane for determination of the number of CFU at the end of the incubation time.
This procedure was repeated over a period of seven days ; a new male Qimo being used every day.

Acceptance criteria:

The actual amount deposited of each bacterial suspension on the device must be greater than the minimum limit of $10^3$ CFU.
No bacterial growth should be observed during the negative control after 48 hours of incubation.

## Results

- Counting the inoculum showed that there were at least $10^3$ CFUs deposited on each connector.
- No bacterial growth was detected on the negative controls, those not inoculated but disinfected.
- Positive controls, those inoculated but not disinfected, showed bacterial growth with the exception of 1 out of 3 devices for Pseudomonas aeruginosa and 2 out of 3 devices for Staphylococcus epidermidis.
- No bacterial growth was detected on all connectors tested for the 4 microorganisms studied.
- The bacterial reduction is always equal to or greater than 3 log.

## Discussion

The risk of Catheter Related Bloodstream Infection (CRBSI) increases with the frequency of catheter access[3]. This is why needleless connectors must prevent the entry of microorganisms after multiple handlings.

Tests have been realized simulating clinical use of both connectors QimoMale and QimoFemale, the study was conducted taking into account the following criteria:

- QimoFemale connected to Qimo Male can be used up to 4 days on IV lines, in line with Cochrane recommendation[4], without risk of CRBSI increase. The CSTD is intended to secure the end of the perfusion line and patient vascular access and can be connected/disconnected several times a day.
- Fluid transfer at each connection between QimoMale and QimoFemale replicates solution administration through the 2 connectors and the number of repeated accesses comply with standard practices for chemotherapy treatments.
- Recommendation is to swab the access with an antiseptic wipe containing 70% IPA (isopropyl alcohol) for a minimum of 5 seconds and let it dry up for at least 1 minute.

  Thanks to the conception of Qimono connectors, since each membrane are flat and thus can be easily disinfected with a pad.

## Conclusion

No bacterial growth has been observed for the test connectors under conditions described above for a period up to seven days.

In clinical use, both connectors QimoMale and QimoFemale prevent contamination of the fluid path by microorganisms.

Results of the Microbial Ingress Testing confirm that the disinfection is effective and that both QimoMale and QimoFemale prevent the entry of microorganisms after a period up to seven days.


1 Guidance for Industry and FDA Staff. Intravascular Administration Sets. Premarket Notification Submissions 510(k) (issued on: July 11, 2008)

2 Report RR_CDC15002_961_18_A1 September 4th, 2018

3 Harshal Shah, MBBS, Wendelyn Bosch, MD, Kristine M. Thompson, MD, and Walter C. Hellinger, MD. Intravascular Catheter Related Bloodstream Infection. The Neurohospitalist.2013, Vol.3.3.

4 Ullman AJ, Cooke ML, Gillies D, Marsh NM, Daud A, McGrail MR, O'Riordan E, Rickard CM. Optimal timing for intravascular administration set replacement. Cochrane Database of Systematic Reviews. 2013, Vol. Issue 9.