Response to van Boxtel *et al.*, 'Testing errors in measuring the effective orifice diameter as a new sizing parameter of surgical valve prostheses'

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We are grateful to Drs. van Boxtel and Ebels for their interest in our paper (1,2). Upon careful study of the concerns raised in the letter, we feel there seems to be a misunderstanding of both the methodology and the intent of our paper.

The letter states that "*The purpose of the study was to determine whether the effective orifice diameter (ID-effective) could be derived from the EOA [effective orifice diameter] measured under steady flow conditions in a repeatable and reproducible manner as described in the ISO Publicly Available Specification (PAS) 7020:2023 [hereafter 'the specification'].*" This is factually incorrect. Our study was designed, conducted, and completed before the release of the specification and formed the basis of the method for determining the "effective orifice diameter" parameter described in the specification. Our paper was meant to communicate the methodological background underpinning the specification's development, which was why it referenced the specification. We stated in the "Introduction" section of our paper that "*there was not a published, validated method for obtaining the effective orifice diameter. Thus, the Working Group embarked on an effort to develop a validated method.*" Had our study been based on International Organization for Standardization (ISO) PAS 7020:2023 as the letter claims, we would not have been able to make this statement because the methodology described in ISO PAS 7020:2023 would have been considered published and validated. Further, we stated clearly in the "Methods" section of our paper that "*each laboratory was instructed to follow Annex I … of ISO 5840-1:2021 in performing the tests*", which recommends that "*[s]teady flow testing for heart valve substitutes should be conducted in a straight tube having an internal*

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diameter of 35 mm" (3). Thus, our results accurately reflect following the clearly stated test methodology from Annex I of ISO 5840-1:2021.

The letter further states that "*the results were published without warning the reader about their flawed nature*" and suggests that "*this study should be repeated whilst adhering to the PAS 7020 and a revision of the study should be published.*" This is a misunderstanding of the intent of our paper. We pointed out in the "Discussion" section of our paper that "*the main purpose of the round-robin study was not to determine the actual effective orifice diameters of the valve models tested but to develop a valid methodology for determining the effective orifice diameters*" and that "*[m]anufacturers will need to complete testing in accordance with ISO PAS 7020:2023.*" In fact, some manufacturers have already shipped valves with additional sizing information printed on the unit container boxes in accordance with ISO PAS 7020:2023, while other manufacturers are in the process of completing the testing required.

In summary, the intent of our paper and the test methodology are clearly defined; testing followed the stated methodology without deviation; and the reported results are consistent with the method used and meet the stated purpose of the paper.

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Footnote

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