

To whom it may concern

Ihre Zeichen

Unsere Zeichen

Tel. (0 56 61) 71-0

Fax (0 56 61) 75-0

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Blood transfusion using Infusomat Space and Infusomat fmS

Dear Ladies and Gentlemen,

Blood transfusion with peristaltic finger pumps is a well established medical technique to administer blood in form of human whole blood or human packed red cells (PRC).

In an in-vitro lab test with human blood (whole blood/packed red cells, Flow rate 950 ml/h) according to DIN EN ISO 10993-1, 1099-4, 10993-8, 1099-12 and DIN EN ISO 17025 the influence of Infusomat Space and Infusomat fmS (peristaltic finger pumps) on the blood quality was evaluated after passing the pump 1, 3, 5, 7 and 10 times. Only the 1st pump passage is clinical relevant, since in routine application the blood transfusion is passing the pump only once (the 3rd, 5th, 7th and 10th was only for scientific reasons).


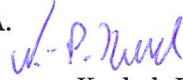
The test showed results as follows:

- *Red blood cells (RBC) counts* (human whole blood and packed red cells (PRC)) are not significantly influenced by this transfusion technique with Infusomat Space and Infusomat fmS.
- The value of *leucocytes and thrombocytes* decreased down to 92% amount versus the 100% baseline data. The observed reduction of the leucocyte number is most probably due adhesion to foreign surfaces (e.g. bags, tubes made of plastic).
- *Platelet factor 4 level (PF4, as a marker of platelet activation)* is increased (factor two after one pump passage). This is a well known effect in human whole blood transfusion and not only a specific problem of using infusion pumps.
- PRC showed more *haemolysis* than human whole blood. The level of free haemoglobin after one pump passage of human whole blood is within the clinical accepted tolerance level. The level of free haemoglobin for human packed red cells is higher. This effect was also reported for gravity transfusion technique.

As regards their effects on human blood cells and following the clinical recommendations/guidelines for blood transfusion, peristaltic finger pumps (Infusomat Space/Infusomat fmS) can be used safely in clinical practice.

With kind regards

B. Braun Melsungen AG

ppa. 
Ute Brauer, MD
Chief Medical Officeri.A. 
Norman Kachel, PhD
Head of Scientific Affairs