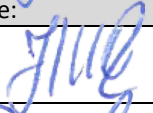
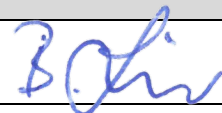


Document Type:	DMR 03-001	Technical Documentation - SpiroTrue H		
	Basic UDI-DI:	42516796-001-WR		
Document name:	SpiroTrue H – Technical specification			
Document ID number:	BPM-TS-080130-101-NR-R10	Revision:	10	
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Approved by:	Title/Position:	Effective Date (YYYY-MM-DD):	Signature:
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This document is the transfer file of BPM-TS-080130-001-NR-R9 from DHF 03-001 to DMR 03-001

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	Basic UDI-DI:	42516796-001-WR		
Document name:	SpiroTrue H – Technical specification			
Document ID number:	BPM-TS-080130-101-NR-R10		Revision:	10
			Status:	Release

1. Purpose

The purpose of this document is to provide an overview of the revisions/change log of document, as technical specification, for the product(s) mentioned and to support the Design Review Control (DRC) team by documents control.

2. Product data

Product name	Product version	Product REF	UDI-DI (GTIN-14)	Basic UDI-DI
SpiroTrue	H	1030132000	2 42516796 0156 6	42516796-001-WR
SpiroTrue	H (2m)	4030131003	2 42516796 0163 4	42516796-001-WR

3. Summary

The product specific requirements and applicable regulatory and safety standards related to the product design (technical specifications) are listed into Design Inputs SpiroTrue-H (Doc.ID Nr: BPM-DI-071112-001-NR-R4)

The information of the technical specification had been reviewed and approved by DRC team.

Annex

- SpiroTrue H - Technical specification

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	Basic UDI-DI:	42516796-001-WR			
Document name:	SpiroTrue H – Technical specification				
Document ID number:	BPM-TS-080130-101-NR-R10			Revision:	10
				Status:	Release

SpiroTrue®H

Disposable flow sensor used to measure the airflow in the breathing system of the patient for use with Hamilton ventilators.



Sensor technical data:

- Measuring principle: differential pressure measurement
- Flow range: 0 to 180 L/min
- Accuracy: ± 25 ml/s or $\pm 20\%$ (whichever is greater) of sensor signal, uncalibrated (manufacturing tolerances)
- Designed in accordance with Annex I of 93/42/EEC and (EU)2017/745(MDR)
- Quality control acc. to: DIN EN ISO 13485
- Materials: Data on request only.
- Sensor weight: $\leq 9,5$ g (without sensor tube)
- Dead space: ≤ 10 mL (functional)
- Resistance: $<0,03$ cmH₂O/(L/min) in the range of 0 to 100 L/min;
 $<0,04$ cmH₂O/(L/min) across the entire range;
- Connections:
 - Sensor: 15M/15M - DIN EN ISO 5356-1
 - ISO Adaptor: 15F/22M – 15F/22M, DIN EN ISO 5356-1
- Biocompatibility evaluation: DIN EN ISO 10993-1 and DIN EN ISO 18562-1. Further data on request.
- Non-sterile packaged

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Recommended operating conditions:

- Temperature: 10°C to 40°C
- Relative humidity: 5 to 95%, non-condensing
- Atmospheric pressure: 700hPa to 1060hPa

Recommended storage conditions:

- Temperature: -20°C to 50°C
- Humidity (r.H.) : 5% to 95%
- Atmospheric pressure: 700hPa to 1060hPa
- Storage period: ≤ 3 years (unopened, away from direct sunlight)

Compatibility:

- SpiroTrue®H is compatible with Hamilton single use flow sensor PN: 279331

Notes:

- The flow sensor must be calibrated within the basic device (ventilator) prior to patient use.
- The flow sensor calibration must be performed in accordance with the instructions for use of basic device (ventilator). Observe the selected gas/gas-mixture type.
- A preoperational device system check must be performed according to the instructions for use of basic device (ventilator) prior to patient use.
- Alignment, operation and sensor change must be carried out in accordance with the relevant device-specific instruction manual considering the hospital's infection control regulations.

Ordering information:

- REF 1030132000 – Box of 6pcs: SpiroTrue H with 2m±0,05m double PVC tube, incl. hook and adaptor

Ordering information for SpiroTrue H as component for Manufacturers of OEM Breathing Systems:

- REF 4030131003 – 1pcs SpiroTrue H with 2m±0,05m double PVC tube.
Packed in PE Bag 20pcs/Bag; 200pcs/Box

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