

Document Information

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Approval Route

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# Spiro-SP TrueFlow Sensor Datasheet

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## 1 Part Numbers and Customer References

Description	Quantity	ndd Order Number
Spiro-SP TrueFlow Sensor	1	2700-1SP

Table 1: Reference number – Spiro-SP TrueFlow Sensor

## 2 Contents of Package

Description	Quantity
Spiro-SP TrueFlow Sensor – Sensor device only	1
Spirette	2
Certificate of Stability	1
Spiro-Sp TrueFlow Sensor Quick Guide	1
Packaging Box	1

Table 2 – Contents of Package

### 2.1 Spiro-SP TrueFlow Sensor – Sensor device only



Figure 1: Sensor side view (Example)



Figure 2: Sensor top view (Example)



Figure 3: Sensor housing with printing (Example)



Figure 4: Sensor USB interface (Example)

Overall Dimensions:	ca. 160mm by 120mm by 70mm
Weight:	ca. 140gr (incl. Cable and Electronics)
Color of the sensor body:	PANTONE 2715
Color of the USB cable:	PANTONE 270 U
Length of the USB cable:	1.80 m

### 2.1.1 Sensor - Labelling



Figure 5: Spiro-SP TrueFlow Sensor direct marking (Computer Generated Image) (Example)

## 2.1.2 Sensor - Affixed label

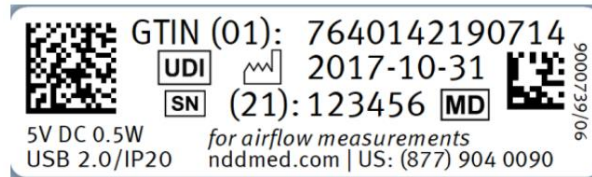


Figure 6: Affixed label - Spiro-SP TrueFlow Sensor (Example)

## 2.2 Spirette

### 2.2.1 Spirette - Product description

The Spirette is designed as a single use single patient disposable item to be used with the Spiro-SP TrueFlow Sensor. It is not possible to do use the Spiro-SP TrueFlow Sensor without using a Spirette. The Spirette is an injection molded part consisting of linear low-density polyethylene.

The Spirette has a positioning arrow. It is inserted into the Spiro-SP TrueFlow Sensor matching the positioning arrow on the sensor.

The Spirette has two windows covered with a filter membrane which allows the ultrasound signal to pass through and protects the Spiro-SP TrueFlow Sensor from contamination by human expiratory breath.

The Spirette has a mouthpiece area which has a shape optimized for use from children (from minimum 4 years) to adults (no limit).

The Spirette has a completely open inner diameter which allows to do spirometry tests with very low resistance.

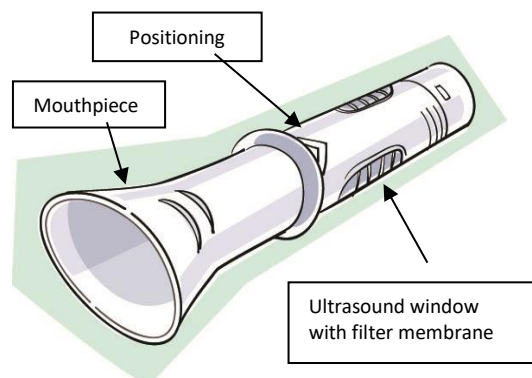


Figure 7: Spirette components

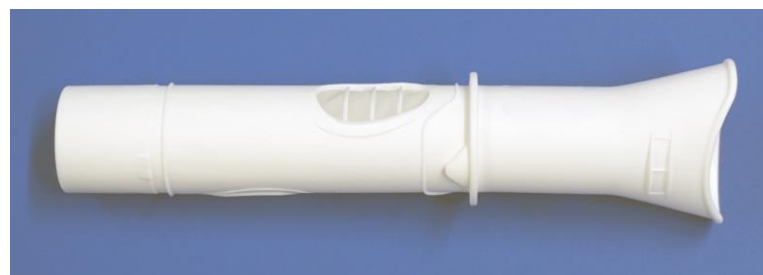


Figure 8: Photo of a Spirette (Example)

## 2.2.2 Spirette - Technical Specifications

Operating conditions:	Temperature:	5 to 40 °C
	Relative humidity:	15 % to 90 % (non condensing)
	Ambient pressure:	700 to 1060 hPa
Transport and storage:	Temperature:	-25 to 70 °C
	Relative humidity:	5 % to 90 % (non condensing)
	Ambient pressure:	400 to 1060 hPa
REACH:	The Spirette complies with the REACH regulations	
Classification:	Class I: U.S	
	Class IIa: EU	

## 2.2.3 Spirette - Labelling



Figure 9: Spirette bag label (Example)

### 2.3 Certificate of Stability

A Certificate of Stability is delivered with each Spiro-SP TrueFlow Sensor as a quality statement certifying that the unit has passed all the performance requirements at ndd. This also provides insights on the proven long term stability of ndd TrueFlow technology.



Figure 10: Certificate of Stability (Example)

## 2.4 Quick guide

Each Spiro-SP TrueFlow Sensor is supplied with a quick start guide which directs the user to the website where the IFU can be downloaded in the desired language.

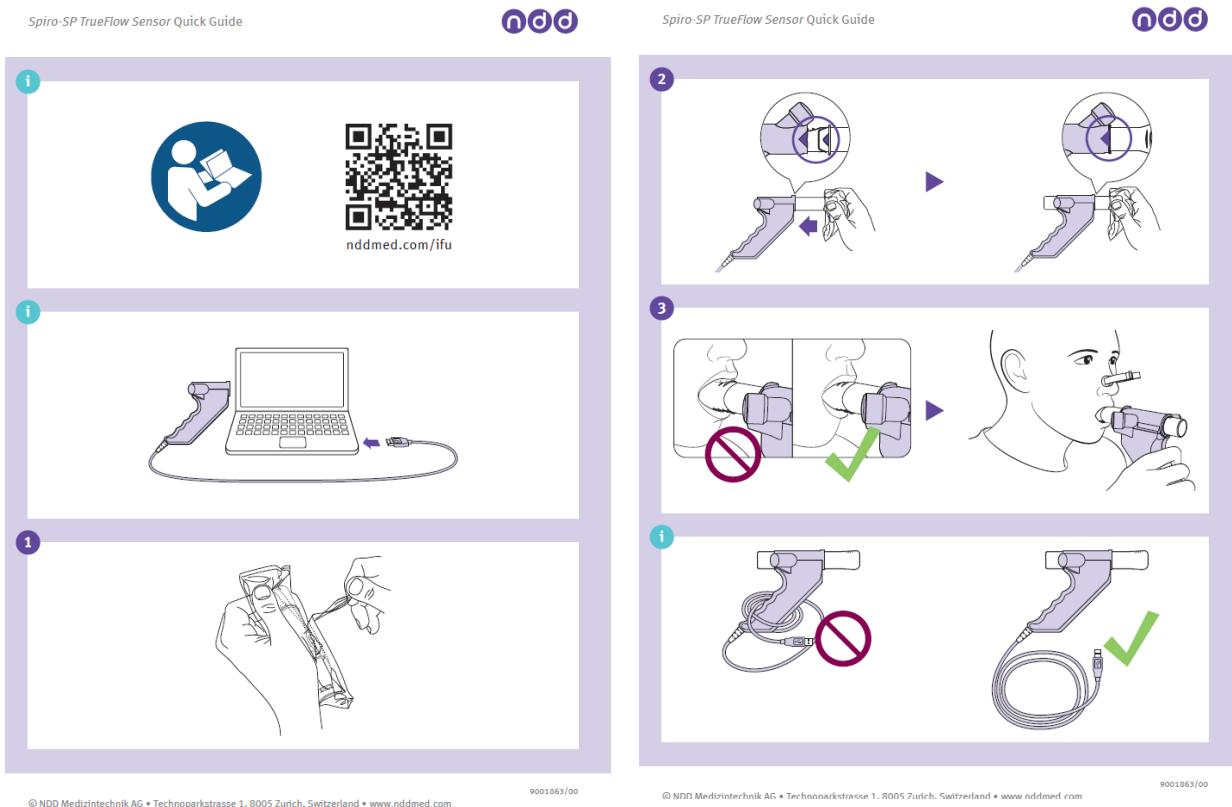


Figure 11: Quick Guide (Example)

## 2.5 Packaging box

### 2.5.1 Packaging box - Design



Figure 12 - Visualization of printing on product box (Example)

### 2.5.2 Packaging box – Main label

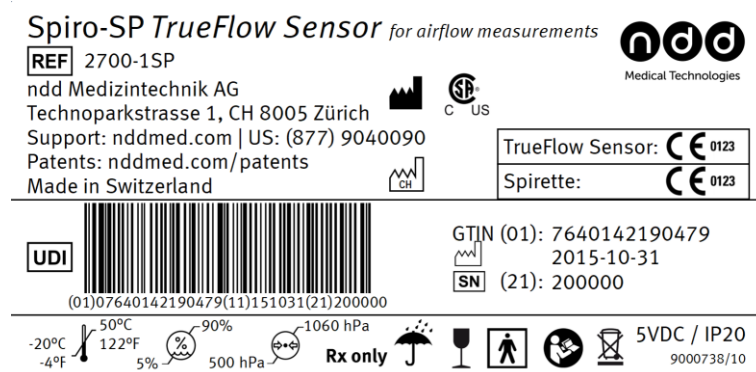


Figure 13: Spiro-SP TrueFlow Sensor main label (Example)

### 2.5.3 Packaging box – Additional label

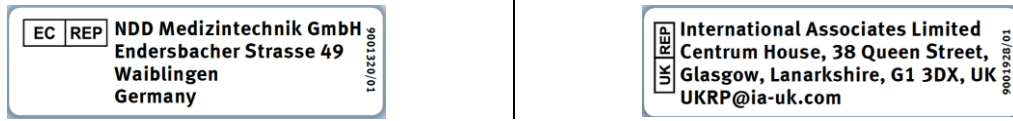


Figure 14: Spiro-SP TrueFlow Sensor additional label (Examples)

### 3 Packaging box details

Overall Packaging Dimensions: 25 x 19 x 6 cm

Weight: 0.64 kg

#### 4 Instructions for Use

The Instructions for Use of the Spiro-SP TrueFlow Sensor can be found on ndd webpage ([nddmed.com/ifu](http://nddmed.com/ifu)) and is directly accessible via the QR code placed on the Quick Guide (see Chapter 2.4)

Instruction of Use is available in the following languages:

English	Estonian	Hungarian	Norwegian	Slovakian
Croatian	Finnish	Italian	Polish	Slovenian
Czech	French	Japanese	Romanian	Spanish
Danish	German	Korean	Portuguese	Swedish
Dutch	Greek	Lithuanian	Russian	Turkish

5 List of symbols used for the Spiro-SP TrueFlow Sensor with explanations:

	Follow the Instructions for Use		Fragile—handle with care
	Manufacturer		Date of manufacture
	Country of manufacture: Switzerland		Compliance with requirements of the European Medical Devices Regulation (EU) 2017/745 since 2021
	Compliance with additional USA and Canada safety requirements for medical electrical equipment		Medical Device
	Serial number		Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner
	Batch code (applicable to the <i>Spirette</i> breathing mouthpiece)		Humidity limitation
	Temperature limit		Keep dry
	Atmospheric pressure limitation		Catalog number
	Authorized representative in the European Community		Universal Serial Bus (USB)—standard for data transfer, connecting devices, and battery charging; applies to cables and connectors
	Do not reuse, i.e., single-patient use (applicable to the <i>Spirette</i> breathing mouthpiece)		Instrument classification: Type BF applied part
IP 20	Ingress Protection class		Do not use if package is damaged
	Unique device identifier		United Kingdom Conformity Assessed
	Authorized representative in the United Kingdom		The product you have purchased should not be disposed of as unsorted municipal waste. Please make use of your local Waste of Electrical and Electronic Equipment (WEEE) collection facilities to dispose of this product and otherwise observe all applicable requirements.
GTIN (01)	Global trade item number		Expiration date

Table 3 List of directly printed symbols (from the Spiro-SP TrueFlow Sensor IFU)