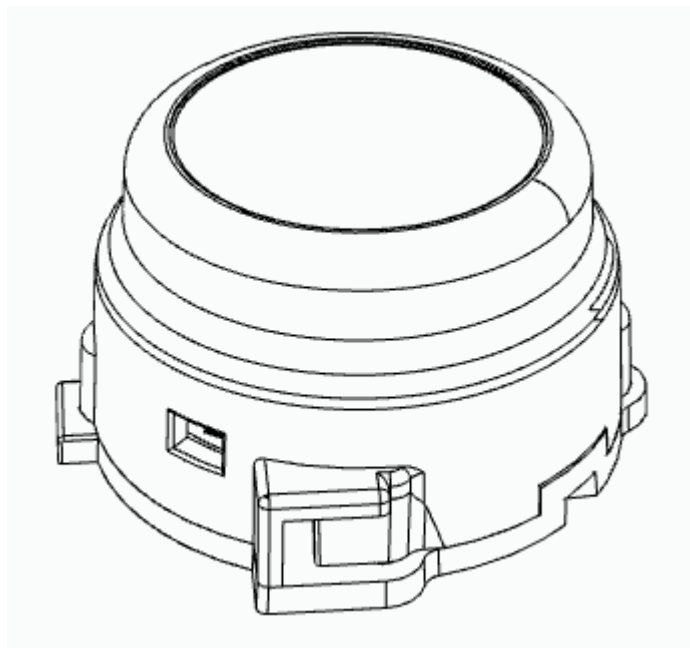




Inhaler Adherence

MODEL 4530

Instructions for Use



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1 Main Components of the Vitalograph Inhaler Adherence

The main components are shown below:

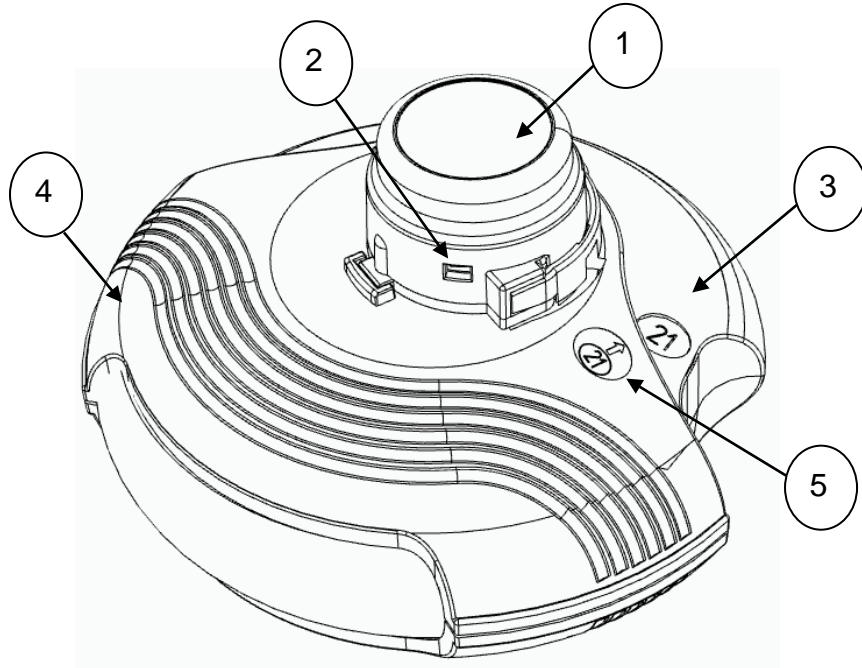


Figure 1: Parts Identification

1	Inhaler Adherence Device
2	LED
3	Diskus Inhaler (Not supplied with Inhaler Adherence Device)
4	Sleeve
5	Sleeve Orientation Indicator Label

1.1 Features of the Vitalograph Inhaler Adherence

The Inhaler Adherence features include:

- Sleeve to fit over the Inhaler. This is a single use component.
- Inhaler Adherence device is snapped into the Sleeve. Device can be used up to six times.
- A reed switch that starts the recording when inhaler is opened.
- LED to check operation of the device.
- Will store all recordings from the inhaler.
- Can download data to PC for subsequent analysis via the Docking Cradle.
- Real-time clock to date and time stamp all recordings.
- Small and light.
- Battery operated.

2 Setting up the Vitalograph Inhaler Adherence

Check that the contents of the packaging match what is outlined on the contents label on the inside of the carton.

The following equipment is required for the initial setup of the Inhaler Adherence by the medical professional before the device is given to the subject:

- 1 x Inhaler Adherence Device
- 1 x Magnet (*Supplied with device*)
- 1 x Sleeve (*Supplied with device*)
- 1 x LED cover label (*Supplied with device*)
- 1 x Device Usage Log (*Supplied with device*)
- 1 x Diskus Inhaler Outer Cover Removal Tool (*Supplied as an accessory*)
- 1 x Diskus Inhaler (*Not supplied with device*)

The following equipment is required to setup for downloading data by the medical professional:

- 1 x Inhaler Adherence device with Diskus Inhaler and Sleeve as returned by the subject after use
- 1 x Diskus Inhaler Outer Cover Removal Tool (*Supplied as an accessory*)

- 1 x Snipping Tool (*Supplied with Docking Cradle*)
- 1 x Docking Cradle (*Supplied as an accessory*)
- 1 x PC with Vitalograph Web Portal installed.

3 Operating Instructions

3.1 Operating the Vitalograph Inhaler Adherence

Note: These steps refer to figure 2 below.

1. Remove outer cover of Diskus Inhaler so magnet can be fitted. Vitalograph provide a tool for this.
2. Fit magnet to the inhaler
3. Re-fit outer cover of inhaler after magnet is fitted.
4. Slide Sleeve over Diskus Inhaler making sure the Sleeve orientation indicator label is pointing to the dose counter on the Diskus Inhaler.
5. Slide Inhaler Adherence onto Sleeve. Ensure clips on side of Sleeve are pushed fully into the corresponding holes on Inhaler Adherence device.
6. Check operation of Inhaler Adherence device by opening Diskus Inhaler as normal. The green LED on Inhaler Adherence device should be on constantly. Close the cover, and LED should go off. **Note:** If LED repeats the following flash sequence: - ½ Second On → ½ Second Off: this indicates data is already present on device. Please connect to the Web Portal application to download any data and clear recordings from device.
7. Fit adhesive cover label provided over opening for the LED.
8. The inhaler is now ready for use as per user instructions provided with the inhaler. The inhaler can administer doses to a subject over a period of 1 month and is generally used twice a day. The Inhaler Adherence device will record and store all doses. Recordings are date and time stamped. At the end of the month the inhaler with the Inhaler Adherence device attached is returned to the medical professional.

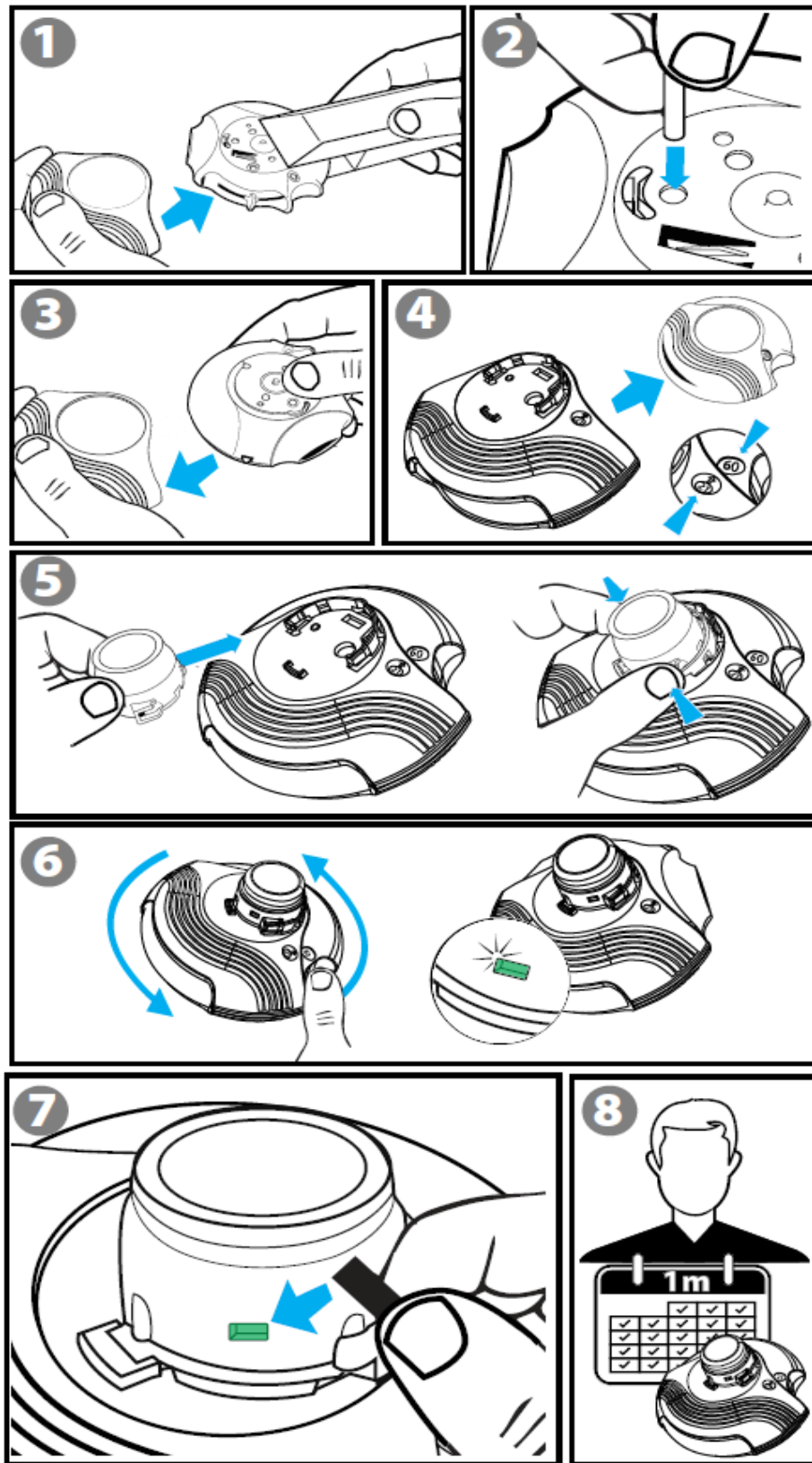


Figure 2: Setup of Inhaler Adherence Device for initial and subsequent use

3.2 Downloading data from Inhaler Adherence Device

In order to prepare the Inhaler Adherence device for download purposes please refer to figure 3 below:

1. Break and bend back tabs on the side of Sleeve and remove Inhaler Adherence device. Small snips supplied with Vitalograph Docking Cradle can be used to break the tabs if needed. **Note:** Be careful when tabs are removed, Inhaler Adherence device will be loose and may fall if not handled correctly.
2. Fit the Inhaler Adherence device to the Docking Cradle. If the device is connected correctly the green LED on the Inhaler Adherence device will be on constantly. Close the rotating cover on the Docking Cradle.
3. Remove Sleeve from the Inhaler and dispose of broken Sleeve in an appropriate recycling location.

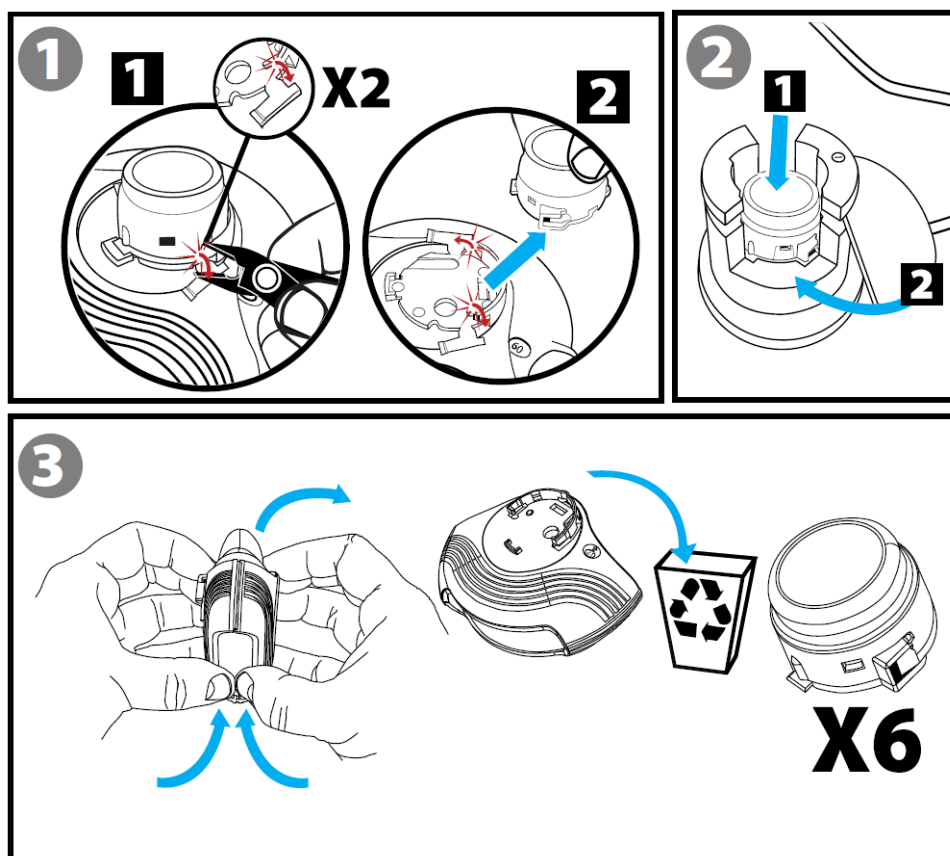


Figure 3: Getting Inhaler Adherence device ready for downloading.

4. Plug the USB connector on the Docking Cradle into USB port on the PC. Note: The cable must be plugged in before the PC app is opened.
5. Open the Vitalograph Web Portal to download data from the Inhaler Adherence device. (see section 7.2 Web Portal below)

3.3 Web Portal

Vitalograph can provide a link to the Web Portal application for download purposes. The Web Portal is used to enable the download of data from the Inhaler Adherence device using a PC. The Web Portal is designed for the collection of medical data from a variety of remote devices and to provide subjects and medical professional's access to this data. Please refer to the Web Portal Instructions for further information.

3.4 Setting up the Inhaler Adherence for subsequent use

When the Inhaler Adherence is required for subsequent use, the medical professional should ensure previous data has been downloaded and then set up the device for use by the next subject as per the steps outlined above at section 7. Operating the Vitalograph Inhaler Adherence.

Note: A new Sleeve must be used for each new inhaler. Six Sleeves are provided with each Inhaler Adherence device. The Inhaler Adherence device should be used a maximum of six times. The Inhaler Adherence device contains an internal battery and will become depleted if used in excess of six times.

4 Power Management in the Vitalograph Inhaler Adherence

The Inhaler Adherence device contains an internal battery for power and will become depleted if used in excess of six times. A new Sleeve must be used for each new inhaler. Six Sleeves are provided with each Inhaler Adherence device.

A use by date is provided on the Inhaler Adherence device which is based on the expected battery life. A device usage log is also provided with the Inhaler Adherence device so the medical professional can record the number of uses. The medical professional should check the use by date to ensure it is within the specified date and also check the usage log to ensure it has not been used more than six times.

If the battery level is too low to record then the LED will repeat the following flash sequence: - Long Flash On → Short Flash On.

5 Cleaning and Hygiene

5.1 Cleaning and Maintenance of the Vitalograph Inhaler Adherence

The surface of Inhaler Adherence device requires low level disinfection between device allocations. Figure 4 below shows an exploded view of the parts so the Inhaler Adherence device can be easily identified for cleaning purposes. Before re-using the device, wipe the surface with an alcohol wipe (70% isopropyl alcohol impregnated cloth). Rub surfaces to remove any visible soiling. Examine all surfaces to ensure they are visibly clean. If not visibly clean, repeat the cleaning process.

Note: The Inhaler Adherence device is not designed as a 'sterile' device.

Always follow the safety guidelines given by the manufacturer of cleaning and disinfection chemicals.

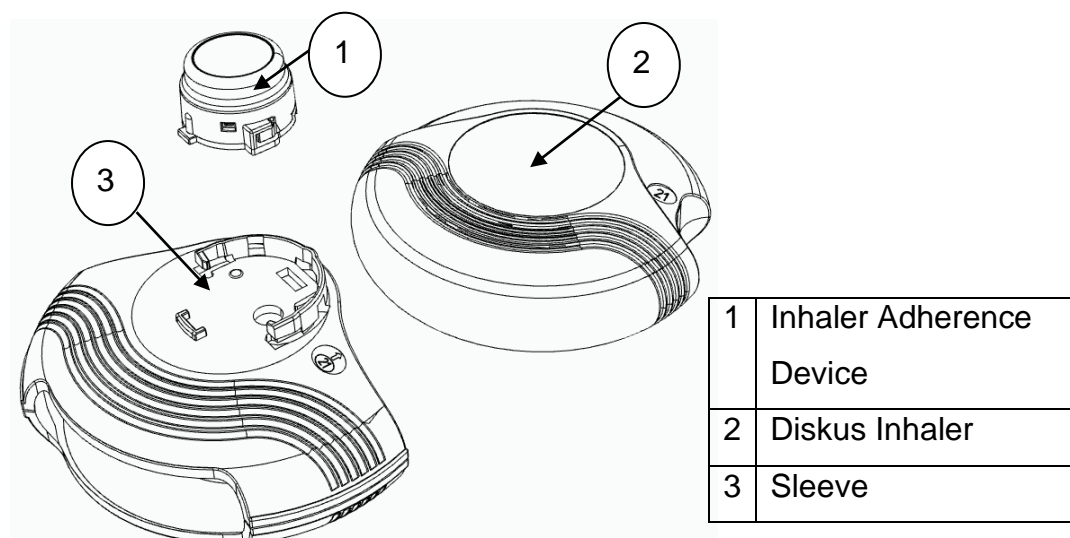


Figure 4: Exploded View of Parts

6 Fault Finding Guide

Below is a list of possible faults that may occur with the Inhaler Adherence device during normal standard operation.

Problem Fault Symptoms:	<ul style="list-style-type: none"> • Inhaler Adherence Device comes loose from the inhaler while it is being used by the subject.
Possible Causes: (In probable order)	<ul style="list-style-type: none"> • Inhaler Adherence device not correctly fitted to the Sleeve or Sleeve not correctly fitted to Inhaler. • Do not attempt to re-attach the Inhaler Adherence device. Leave it to one side. Return it to the medical professional when at the end of the prescription period.
Problem Fault Symptoms:	<ul style="list-style-type: none"> • Could not download data from the device.
Possible Causes: (In probable order)	<ul style="list-style-type: none"> • Ensure cable is connected to PC before the PC application is started. • Ensure rotating cover is fully closed.
Problem Fault Symptoms:	<ul style="list-style-type: none"> • Could not connect Inhaler Adherence device to the Sleeve.
Possible Causes: (In probable order)	<ul style="list-style-type: none"> • Follow visual instructions as provided at Section 7 above.

Problem Fault Symptoms:	• Could not fit Sleeve to the Diskus Inhaler.
Possible Causes: (In probable order)	• Follow visual instructions as provided at Section 7 above.
Problem Fault Symptoms:	• LED on Inhaler Adherence device does not come on when fitted to docking cradle.
Possible Causes: (In probable order)	<ul style="list-style-type: none"> • Check label over LED has been removed. • Ensure the cable is connected to the PC. • Ensure device is pushed fully down into docking cradle, and rotating cover is fully closed on docking cradle. • Remove Inhaler Adherence device from docking cradle and try again.
Problem Fault Symptoms:	LED repeats the following flash sequence: - ½ Second On → ½ Second Off.
Possible Causes: (In probable order)	• This indicates that data is already present on the device. Please connect to Web Portal application to download data and clear recordings.
Problem Fault Symptoms:	LED repeats the following flash sequence: - Long Flash On → Short Flash On.
Possible Causes: (In probable order)	• Battery level too low to record. Use new Inhaler Adherence device.

7 Customer Service

For further assistance, setting up, using or maintaining the device or to report unexpected operations or changes in performance, contact Vitalograph, using the contact information at the start of this manual. Also contact the healthcare provider on any changes to the performance of the device, as a precaution.

Service and repairs should be carried out only by the manufacturer, the approved importer or by Service Agents specifically approved by Vitalograph.

Any serious incident that has occurred in relation to the device should be reported to Vitalograph or its Authorized Representative and the Regulatory Authorities of the country. Refer to the Vitalograph contact information at the start of this manual.

8 Consumables and Accessories

















Cat. no	Description
45304	Inhaler Adherence Docking Cradle
49556	Inhaler Adherence Cover Removal Jig

9 Disposal

The device must be taken to separate collection at the product end-of-life. Do not dispose of these products as unsorted municipal waste.

The Sleeves are made from recyclable material (polycarbonate) and should be disposed of in line with local requirements.

10 Explanation of Symbols

Symbol	Description
VA	Power rating
	Direct current
	Instructions for Use; operating instructions
	Class II
	Manufacturer
	Year of Manufacture (Date format yyyy)
	Use by Date (Date format yyyy-mm-dd)
	The device must be taken to separate collection at the product end-of-life. Do not dispose of these products as unsorted municipal waste
	Fragile, handle with care
	Keep Dry
	Non sterile
	For single use only
	Recycle
	QR code - matrix bar code. All information in the bar code is included in the text under it
	Class III Device
	Serial Number
	Catalogue Number

11 Description of the Vitalograph Inhaler Adherence

The Inhaler Adherence device provides a means to record a subject as they use their Diskus Dry Power Inhaler (DPI) and the techniques they use. Data is stored to an internal memory on the device. The data is uncompressed, so no data is lost due to compression methods.

A magnet is fitted to the Diskus inhaler which is used to activate a reed switch and turn on the Inhaler Adherence device. The inhaler can administer doses to a subject over a period of 1 month and is generally used twice a day. The Inhaler Adherence device will record and store all doses. Recordings are date and time stamped. The Inhaler Adherence device is supplied with six single use adaptor Sleeves so that the Inhaler Adherence can be used up to six times.

Recordings are downloaded to a PC via a docking cradle. The cradle is not supplied with the device and may be ordered separately.

The results can be viewed and analysed on the Vitalograph Web Portal to determine if correct inhaler technique was used and if the inhaler was used at the right time. If adherence or technique is not correct it can result in a decreased drug delivery and potentially reduced efficacy.

This Instructions for Use is intended for use by a medical professional to set up and download data from the Inhaler Adherence device. These instructions are not intended for the subject.

11.1 Indications for Use

The Model 4530 is an accessory device intended to assist physicians and subjects in recording and monitoring the actuations of prescribed DPI usage for the Diskus Inhaler.

The Model 4530 is intended to be used in populations from Child (>2 years) to Adult.

The Model 4530 records and stores usage events to internal media. With the Vitalograph Web Portal the user can review information collected from the device with their medical professional.

12 Technical Specification

Inhaler Adherence Device	
Product	Vitalograph Inhaler Adherence
Model	4530
Safety standards	EN 60601-1, EN60601-1-11
EMC standards	EN 60601-1-2
Electrical Insulation Class	Class III
QA/GMP standards	EN ISO 13485, CMDR SOR/98-282 & FDA 21 CFR 820
Number of recordings	60 recordings of 90 seconds duration between data download. Device can be reused up to 6 times (of 60 recordings), before battery will deplete. This is typically 6 months of recordings in total.
Use by Date	Up to 2 Years. See device use-by-date (YYYY-MM-DD)
Power Supply	3.6V Lithium Thionyl Chloride wafer cell battery
Size	31.0mm x 30.0mm x 17.2mm
Weight	13 g
Operating Temperature	0–40°C
Communications	Serial Interface via 8-pin header. Communicates to a PC using a Docking Cradle over USB. Refer to Web Portal Instructions for Use for minimum PC System Requirements.
Sampling Rate	8,000 Hz
Docking Cradle	
Product	Inhaler Adherence Docking Cradle
EMC Standards	EN55032, EN55024
Electrical Insulation Class	Class II
Power Supply	5V USB Power
Size	120.0mm x 65.0mm x 70.8mm
Weight	345g

Communications	USB 2.0 Interface to connect to supporting PC
<i>Notes:</i>	
<ul style="list-style-type: none"> The operating conditions specified apply to the device plus accessories. 	

13 Contraindications, Warnings, Precautions and Adverse Reactions

- The output of the model 4530 is not intended to diagnose or replace a diagnosis provided by a licensed physician.
- The Model 4530 is not intended for use as an Inhaler dose counter, nor is it intended to indicate the quantity of medication remaining on an Inhaler.
- No modification of this equipment is allowed. Any unauthorised changes to the Inhaler Adherence device may compromise product safety and/or data and as such Vitalograph cannot be held responsible and the device will no longer be supported.
- The Vitalograph Inhaler Adherence is not designed as a sterile device. Always follow the safety guidelines given by the manufacturer of cleaning and disinfectant chemicals.
- For the device to be used as intended, there is no requirement to clean the supporting computer. If cleaning is required to remove any visible soiling, this should be done as per the computer manufacturer's instructions.
- Take note of the type of inhaler before attaching the Inhaler Adherence device to the Sleeve and fitting it over the Diskus Inhaler. The Sleeve and Adherence device will obscure this information on the inhaler when fitted, but it can be viewed again by removing the Sleeve.
- A new Sleeve must be used for each new inhaler. Six Sleeves are provided with each Inhaler Adherence device.
- The medical professional should check the use by date to ensure it is within the specified date and also check the usage log to ensure it has not been used more than six times.
- If the Inhaler Adherence device becomes detached during use, then continue to use the inhaler as normal.
- Do not expose the Inhaler Adherence device to liquids.
- The Inhaler Adherence should not be in the presence of flammable liquids or gases, dust, sand or any other chemical substances.
- Service and repairs should be carried out only by the manufacturer or by service agents specifically approved by Vitalograph.
- Use of accessories and cables other than those specified or provided by Vitalograph for this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of the Inhaler Adherence and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Inhaler Adherence, including cables specified by Vitalograph. Otherwise, degradation of the performance of this equipment could result.

15. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
16. Dry Powder inhalers are meant to be kept dry and as such the Inhaler Adherence device is intended to be used in a dry environment.
17. The contents of the packaging contains a number of small magnets, which are needed to be installed into the inhalers for the Inhaler Adherence device to work. These magnet are a choking hazard until they are installed into the inhaler. The magnet installation is intended to be done in the medical clinic environment, where children should be supervised at all times. Keep children away from the pack contents.

14 CE Notice

Marking by the symbol  indicates compliance of the Vitalograph Model 4530 Inhaler Adherence to the Medical Devices Directive of the European Community.

The Vitalograph Model 4530 Inhaler Adherence is intended for use in a variety of professional healthcare environments, e.g. primary care, hospital wards and occupational health centres, except for near active high frequency surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of electromagnetic disturbance is high. The customer or the user of the Inhaler Adherence should assure that it is not used in such an environment.

The Model 4530 Inhaler Adherence has been tested in accordance with:

EN60601-1:2006 + A1:2013 - Medical electrical equipment. General requirements for basic safety and essential performance

EN 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

EN 60601-1-2 - Emissions tests		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments.

EN 60601-1-2 Immunity tests		
Immunity test	Test level	Compliance level Reached
Electrostatic discharge (ESD) EN 61000-4-2	Contact: ± 6 kV Air: ± 2 kV, ± 4 kV, ± 8 kV	Contact: ± 6 kV Air: ± 2 kV, ± 4 kV, ± 8 kV
Radiated RF EN 61000-4-3	3 V/m 80MHz to 2500MHz	3 V/m 80MHz to 2500 MHz
Magnetic Field EN 61000-4-8	3 A/m, 50 & 60Hz	3 A/m, 50 & 60Hz

Medical Devices may be affected by mobile RF communications equipment including cellular telephones and other personal or household devices not intended for medical facilities. It is recommended that all equipment used near the Vitalograph product comply with the medical electromagnetic compatibility standard and to check before use that no interference is evident or possible. If interference is suspected or possible, switching off the offending device is the normal solution, as is required in aircraft and medical facilities.

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provide.

15 FDA Notice

Caution: Federal Law restricts this device to sale by, or on the order of a physician.

16 EU Declaration of Conformity

Product: Model 4530, Vitalograph Inhaler Adherence

Vitalograph hereby ensures and declares that the above product associated with this user manual, is designed and manufactured in accordance with the following QMS regulations and standards:

- European Medical Devices Directive {MDD} 93/42/EEC, as amended.

This device is classified as 2a per Annex IX of the MDD also meets the provisions of the Essential Requirements, Annex I, via compliance with Annex II of the Medical Devices Directive as per Article 11, section 3a, excluding point 4 of Annex II.



- EN ISO 13485 Medical devices. Quality management systems. Requirements for regulatory purposes.

Certifying Body: British Standards Institute {BSI}.

BSI Notified Body #: 0086

Certificate Nos. CE 00772, CE 85553, MD 82182

Signed on behalf of Vitalograph (Ireland) Ltd.

A handwritten signature in black ink that reads 'Frank Keane'.

*Frank Keane.
CEO, Vitalograph Ltd.*

17 Guarantee

Subject to the conditions listed below, Vitalograph Ltd. and its associated companies, (herein after called the Company) guarantee to repair or at its option replace any component thereof, which, in the opinion of the Company is faulty or below standard as a result of inferior workmanship or materials.

The conditions of this Guarantee are:

1. This Guarantee shall only apply to hardware defects which are notified to the Company or to its accredited distributor within 1 year of the date of purchase of the equipment, unless otherwise agreed in writing by the Company.
2. Software (meaning computer software, or user installable modules) is guaranteed for 90 days from the date of purchase.
3. The Company warrants that the software when correctly used in conjunction with the hardware will perform in the manner described in the Company's literature and user manuals. The Company undertakes to rectify at no expense to the customer any software failure notified within the period stated above, provided that the failure can be re-created, and the software has been installed and used in accordance with the user manual. Notwithstanding this clause, the software is not warranted to be free of errors.
4. This Guarantee does not cover any faults caused by accident, misuse, neglect, tampering with the equipment, use of consumable items or parts not approved by the Company, or any attempt at adjustment or repair other than by personnel accredited by the Company, nor does it cover reinstatement of any configuration changes caused by the installation of any software.
5. If a defect occurs, please contact the supplier from it was purchased for advice. The Company does not authorize any person to create for it any other obligation or liability in connection with Vitalograph® equipment.
6. This Guarantee is not transferable, and no person, firm or company has any authority to vary the terms or conditions of this guarantee.
7. To the maximum extent permitted by law, the Company does not accept liability for any consequential damages arising out of the use of, or inability to use any Vitalograph® equipment.
8. This Guarantee is offered as an additional benefit to the Consumer's statutory rights and does not affect these rights in any way.