Instructions for Use
Mode d’emploi
Gebrauchsanleitung
Instrucciones de Uso
How to use the In-Check DIAL 6T&S

1a

1b

2

3

Sterile

121°C

4

5

6

7

e.g.

Clinically Effective Flow Rate
30-90L/Min

8
Instructions for Use

Consult ‘Instructions for Use’.

This product complies with the essential requirements of the medical devices directive (93/42/EEC). Compliance has been verified by UK notified body per 0120 (SGS Yarsley).

Introduction
The In-Check DIAL is an inhalation airflow meter that can help educate and assess patients who use inhaler devices.

Inhaler devices are designed to deliver medication to the respiratory tract, and the speed of inhalation through them (the inspiratory flow) can have a significant effect on the quantity of drug delivered and the clinical efficacy of the product.

The In-Check DIAL is designed to simulate the “internal resistance” of several common inhaler devices, and measure inspiratory flow. These measurements enable the healthcare professional to encourage patients to modify their inspiratory technique (by inhaling with more, or less effort), in order to achieve a flow rate consistent with clinical efficacy. The green bars show the clinically effective flow ranges for each of these inhaler devices. These bars do not imply any comparison between devices.

Patients that cannot achieve the suggested inspiratory flow for their inhaler may not gain maximum benefit from their prescribed medication, and healthcare professionals may wish to take this factor into account when selecting with the patient, the device that is the most suitable.

Inspiratory Flow and Clinically Effective Flow Range
The inspiratory flow through an inhaler is one of the factors that will influence the clinical effect of the drug delivery from that device. The most effective delivery occurs when the patient achieves a flow within the clinically effective flow range. Flow rates outside this range, may result in a diminished deposition and clinical efficacy.

Inhaler devices
Drug delivery from the various types of inhaler devices is produced by different methods.

Inhaler devices are designed to deliver drug particles of a certain size to the small airways during inhalation. Particles of this size (generally agreed to be approximately between 1 and 5 microns) are known as the “respirable fraction”. The particles are either in aerosol (in a suspension or a solution) or dry powder form.

Pressurised Metered Dose Inhalers (pMDIs)
With most pMDIs, the aerosol is delivered under pressure at high speed (often over 90 kilometres per hour). The inhalation should be timed with actuation of the device and should be slow and steady. Inhaling too fast may cause a greater proportion of the aerosol to impact at the back of the throat and be subsequently swallowed, thus reducing the beneficial clinical effect and increasing the potential for local and systemic side effects.
With the majority of pMDIs, manual depression of the drug canister actuates the drug delivery. However, with breath-actuated metered dose inhalers (e.g. Autohaler™), the aerosol is released by mechanical actuation, triggered by the patient breathing in through the device at any flow rate above a minimum level. At inspiratory flows below this, the patient will not receive any of the medication, because a dose will not be released.

**pMDIs with Holding Chamber/Spacer**

It is recognised that the optimum inhalation technique for using a pMDI with a holding chamber/spacer is a slow inhalation (30 to 60 l/min). As the resistances of the values of most chamber/spacer devices are low, the *In-Check DIAL* can be set to “conventional pMDI” to provide an approximate resistance for inspiratory flow measurements to be made.

**Dry Powder Inhalers (DPIs)**

Drug delivery from DPIs is triggered by inhaling through the device. A metered quantity of powder is drawn into the airflow, and follows a specific pathway within the inhaler, through internal features that create a resistance that is designed to break up the medication into particles of a respirable size.

As the internal design of each DPI is different, and the formulation of medication is not identical, the resistance the patient encounters when inhaling is different from device to device.

The effort required for the patient to achieve a given inspiratory flow will increase as the internal resistance of the device increases. For the same patient effort, the higher the resistance the lower the resulting inspiratory flow.

As the great majority of asthma medication is delivered via inhalers, correct inhaler technique is an important factor in the management of this disease. Patients require their medication for both short-term relief and long-term prevention, and the delivery of these drugs to the lungs is affected by inspiratory flow. Assessing inspiratory flow is an important aspect of device education and review. Determining whether or not a patient can obtain the appropriate inspiratory flow rate for a device can be an important factor in improving inhaled treatment.

**In-Check DIAL**

The *In-Check DIAL* is a low-range inspiratory flow meter (15 to 120 l/min) that has a selectable resistance, calibrated to enable the measurement of airflow as if the patient was using the following inhalers:

- Multi-dose powder inhaler (Accuhaler®/Diskus®)
- Turbulent flow powder inhaler (old style) (Turbohaler®/Turbuhaler®)
- Turbulent flow powder inhaler (new style) (Turbohaler®/Turbuhaler®)
- Conventional pressurised metered dose aerosol (Conventional pMDI)
- Auto release pMDI inhaler (Autohaler®) (Easi-Breathe®)

The dial has one more position - one where the orifice is entirely closed.

The “Conventional pMDI” position can be used to approximate the resistance when a conventional pMDI is attached to a holding chamber or spacer device.

Should new types of inhaler become available, then *In-Check DIAL* can be adapted to measure the new inspiratory flow, by placing a resistance adaptor (as used in the *In-Check Inhaler Assessment Kit*) in the mouthpiece, and selecting “Conventional pMDI” on the dial.
!! IMPORTANT
As with any inhalation device, it is important to check for loose foreign objects before the device is used. The transparent material used in the construction of the In-Check DIAL enables the user to make a visual check before inhalation. Patients should be prevented from exhaling through the device prior to use.

To reset the In-Check DIAL
Hold the instrument vertically with the mouthpiece uppermost, so that the rounded end of the meter can be tapped against the other hand or a horizontal surface, such as a table.
A hard tap will dislodge the magnetic resetting weight, which will return the red cursor to a start position. When this has happened, the meter must turn through 180 degrees to return the magnetic weight to its resting position.

!!! Do Not try to reset the In-Check as if it were a mercury thermometer – this action causes serious damage to the piston and pointer

How to use the In-Check DIAL
1. Reset the In-Check DIAL
2. Align the scale with the desired inhaler device – an audible “click” should be heard.
3. Attach a clean mouthpiece (small mouthpieces can be used with the supplied adaptor).
   Disposable one-way inspiratory mouthpieces are preferred.
4. Ask the patient to exhale fully.
5. Seal lips around the mouthpiece.
   According to the inhaler chosen, instruct the patient to inhale in the manner recommended by the manufacturer. There is a reminder of inhalation technique beside each inhaler icon on the laminated card.
6. Record the inspiratory flow from the position of the red cursor against the scale. Reset, and repeat two more times, ensuring correct technique each time.
7. Compare values achieved with target flows for that device. To operate an inhaler device correctly, the patient should be able to achieve a flow rate within the clinically effective range.
8. If after repeated training the patient is not able to achieve these values, then the healthcare professional may wish to assess the patient’s ability to use an alternative type of inhaler.

Performance Accuracy
Accuracy +/- 10% or 10 l/min (whichever is the greater) and repeatability of +/- 5 l/min.

Cleaning your In-Check DIAL
Where local infection control guidelines exist, these should be respected.
Immerse In-Check DIAL in warm (but not hot) mild detergent solution for 2-3 minutes (maximum 5 minutes). Agitate the meter to ensure thorough cleaning.
Rinse in warm water and shake to remove any excess water. It is important to rinse thoroughly to prevent salt spots appearing on the inside of the body and the spindle.

To shake excess water from the In-Check, hold only at the end furthest away from the DIAL selector.
Allow to dry thoroughly before using again.

The expected life of the In-Check DIAL, in normal use, is two years.

!!! To maintain hygiene the In-Check DIAL should be used with disposable inspiratory one-way mouthpieces. If use of this product is governed by local infection control guidance, that guidance should be respected in the absence of local guidance.
Interpreting information from the In-Check DIAL

In-Check DIAL was modified in September 2010, in response to customer feedback, to provide information about inspiratory flow rates that are associated with clinical efficacy. The new scale is shown above.

The information provided is for guidance only. It does not imply that any particular product will be clinically effective. There are other aspects than inspiratory flow that contribute towards clinical efficacy. The information is based on published clinical studies. In some cases studies may have been performed on a particular formulation in a specific device and may be suggestive that other formulations will behave similarly.

The DPIs have been represented in a single block from 30-90 L/Min because the clinical studies support this (see details on laminated card). Laboratory studies also demonstrate that DPIs have a degree of flow-dependence, meaning that improved delivery is achieved at higher flow rates. This does not always equate to improved clinical efficacy. A pale arrow represents the intention that flow rates of a higher level may be beneficial for DPIs.

The pMDIs have been represented in a single block from 30-60 L/Min because the clinical studies support this (see details on laminated card). The pale arrow is pointed in the opposite direction for pMDIs, indicating that a slower rather than higher flow rate is beneficial in this type of inhaler.

The products are individually represented on the laminated card.
Bibliography for In-Check
(Please note that references for Clinical Efficacy of different inhaler systems are provided on the laminated card.)


