

Clinical Commentary

Using Electronic Monitoring Devices to Measure Inhaler Adherence: A Practical Guide for Clinicians

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ABSTRACT: Use of electronic monitoring devices (EMDs) for inhalers is growing rapidly because of their ability to provide objective and detailed adherence data to support clinical decision making. There is increasing potential for the use of EMDs in clinical settings, especially as cost-effectiveness is realized and device costs reduce. However, it is important for clinicians to know about the attributes of different EMDs so that they can select the right device for their patients and understand the factors that affect the reliability and accuracy of the data EMDs record. This article gives information on where to obtain EMDs, describes device specifications, and highlights useful features for the clinician and the patient, including user feedback data. We discuss the benefits and potential drawbacks of data collected by EMDs and provide device users with a set of tools to optimize the use of EMDs in clinical settings, such as advice on how to carry out brief EMD checks to ensure data quality and device reliability. New EMDs on the market require pretesting before use by patients. We provide information on how to carry out EMD pretesting in the clinic and patients' homes, which can be carried out by health professionals or in collaboration with researchers or manufacturers. Strategies for interpreting and managing common device malfunctions are also discussed. © 2015 American Academy of Allergy, Asthma & Immunology (J Allergy Clin Immunol Pract 2015;■:■-■)

Key words: Adherence; Electronics; Equipment and supplies; Electronic devices; Materials testing; Quality control; Medication adherence; Remote sensing technology

Despite effective medications for asthma and chronic obstructive pulmonary disease, adherence with inhalers is often suboptimal.¹⁻³ In asthma, poor adherence with preventive treatment is associated with reduced quality of life and increased asthma symptoms, oral steroid use, hospitalization, and mortality.⁴⁻⁹ Overuse of rescue medication is also an important issue, associated with poorer health status and mortality.⁹⁻¹²

It is difficult to accurately measure inhaler use in clinical settings because the most commonly used measurement methods suffer from subjectivity, poor reliability, and lack of precision.^{13,14} Physician judgment of patient adherence is inaccurate,¹⁵⁻¹⁷ patient self-report is unreliable and overestimated,^{13,17} and proxy measures such as prescription refill data¹⁸ may not indicate ingestion and are vulnerable to recording bias owing to the use of multiple pharmacies or stockpiling.^{13,19} Access to reliable adherence data could benefit clinicians and patients by better informing health care decisions, for example, by distinguishing poor treatment response from suboptimal adherence—thus avoiding unnecessary dose escalations or add-on therapies²⁰—or by enabling the clinician to evaluate the effect of a regimen change or an adherence-enhancing intervention.

An ideal measure of adherence should be objective, accurate, and unobtrusive to minimize impact on patient behavior²¹ and allow reliable data collection in real-world settings. Electronic monitoring devices (or EMDs) address more of these requirements than do other methods.²² EMDs have been expensive in the past, but prices are falling as the technology becomes more commonplace,²³ with EMDs already within the \$100 to \$500 unit price estimated to facilitate wider uptake of monitoring devices in health care settings.^{24,25} Digital remote monitoring is becoming established in health care and is likely to increase rapidly in the future, with research increasingly supporting the cost-effectiveness of such interventions.^{24,26,27} In 2006, structured billing codes were approved by the Centers for Medicare & Medicaid Services for analysis of remote data from implantable cardiac devices,²⁸ and monitoring and assessment of continuous positive airway pressure adherence in obstructive sleep apnea is a requirement for Medicare and other payers to provide ongoing reimbursement.²⁹

Although EMDs are considered to be the “criterion standard” adherence measurement method for inhaled treatments,^{19,30} available EMDs for inhalers vary in function, capability, robustness, accuracy, and reliability.³¹⁻³⁸ To optimize the use of these devices, clinicians need to be well informed about the range of different devices, their potential adherence support functions,

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*Abbreviations used**EMD- Electronic monitoring device**FDA- Food and Drug Administration*

and their potential pitfalls and benefits to ensure that clinical decision making is enhanced by their use. Devices may become damaged during shipping or storage or in patients' homes. Brief, simple, and standardized device checks before dispensing and after return of devices from patients can ensure data accuracy and minimize data loss. When a brand new EMD comes onto the market it may have limited reliability data available, so clinicians should consider running lengthier and more thorough device checks^{39,40} before using it in patients. However, there is currently little guidance available in the literature on how to carry out brief or extended checks of EMDs or how to interpret collected data.³⁸

This article describes the range of available EMDs for inhalers, user feedback and useful device features, and specifications for the clinical setting. It provides practical guidance on how to carry out simple, standardized device checks based on the existing literature, and offers practical strategies for identifying, minimizing, and managing EMD malfunctions if and when they occur.

AVAILABLE EMDs

Food and Drug Administration—approved EMDs

Table I provides detailed information on the useful clinical attributes (eg, features, functions, battery life, and storage capacity) of available EMDs, and Table II summarizes factors to consider when clinicians and patients use devices in terms of device acceptability (eg, user feedback) and regulatory considerations. At the time of writing, a number of EMDs for pressurized metered-dose inhalers have been approved by the US Food and Drug Administration (FDA). The oldest of the FDA-approved devices is the Doser, which is the least expensive and the most basic (Tables I and II; Figure 1). It records the number of daily actuations but does not record the time of each puff, and it is not possible to download adherence data, which is read from the device screen. The Doser's memory capacity (maximum 30 days) is significantly less than that of other EMDs for pressurized metered-dose inhalers, but it may be a suitable choice where budget is low, where short monitoring periods between face-to-face visits are planned, and where the number of actuations per day is a sufficient measure of adherence. The SmartTouch (recently rebranded, formerly SmartTrack) and the Propeller sensor are more sophisticated devices that record the date and time of each actuation, provide real-time adherence data, by uploading remotely to a Web page or application, and feature onboard reminders for missed doses customizable to the patient's regimen or daily routine, to prompt optimal adherence. The SmartTouch also has an onboard color screen, and the Propeller sensor has a Global Positioning System that tracks the location of inhaler use. Patients and clinicians can access detailed adherence data from these devices and use it to discuss current adherence, barriers, and strategies for improving future adherence.⁴⁷

Non-FDA-approved EMDs

EMDs for other inhalers, such as for the Accuhaler and Turbuhaler, are relatively new products (manufacturer: Nexus6

Ltd, Auckland, New Zealand) that do not yet have FDA or other country-specific regulatory approval and no published data on their accuracy and reliability (Table II). We recommend contacting the manufacturer for an update on EMD performance and approval for your location because the situation may have changed since this article was written.

REGULATION AND INSURANCE FOR EMDs

EMDs currently fall under the FDA's "low-risk" category of medical devices and are therefore subject to less regulatory control than are other medical devices such as powered wheelchairs and pacemakers⁴⁸; however, regulatory control differs between countries and approval bodies and can change with time.⁴⁹ At present, there is an increasing call for medical devices and their associated applications, such as smartphone applications, to be regulated⁵⁰ and patients and clinicians are likely to feel more confident using a regulatory body—approved device. Before purchasing devices, manufacturers should be asked to provide the status and evidence of appropriate regulatory approval(s) for use in the target patient population and location. Manufacturers should also provide buyers with information about the compliance of their product with local privacy laws, such as the Health Insurance Portability and Accountability Act 1996 in the United States⁵¹ (Table II).

As government agencies such as the Department of Veterans Affairs begin to adopt e-health solutions and medical devices,²⁴ consumer demand increases,^{25,52} and cost-effectiveness is demonstrated,^{26,27} insurers are likely to increase coverage for a wider range of monitoring devices and services. Regulatory approval may become increasingly relevant in the context of insurance cover, and the need to demonstrate the cost-effectiveness of adherence monitoring is important for securing reimbursement for EMDs. Data are beginning to emerge. For example, the cost of a program that improves controller adherence by 50% could be as low as US \$130 per person annually to be cost-effective.⁵³ EMDs are already around this price range, and the reducing cost of technology and increasing competition will reduce their price further. To achieve cost-neutrality at present, monitors may need to be reserved for patients with more severe asthma and/or high use of health care resources.

USING EMDs IN CLINICAL SETTINGS

Electronic monitoring has been used in clinical settings as part of adherence-promoting interventions^{54,55} to provide accurate, objective, and detailed information on adherence patterns, without significant disruption to patients' natural medication-taking behavior.^{56,57} When used appropriately, EMD data can be a powerful tool to engage patients in active discussions about their unique medication-taking behaviors, beliefs about their disease, and attitudes to their prescribed treatment.^{4,42,54,57-59} The patient's general views on monitoring as well as the perceived usability of the chosen device should be discussed to encourage participation in the decision to use this technology and ascertain potential barriers to sustained use.⁶⁰ Independent published data on patient and clinician satisfaction with EMDs are available for some devices (see Table II). Other data may be obtainable directly from manufacturers.

To facilitate patient engagement, the information provided by the EMD must be accurate and reliable. To maximize data reliability, it is also important to train the patient on how to use

TABLE I. Useful features of currently available EMDs for clinical practice*

Useful features for clinical practice							
Device name	Battery life	Storage capacity	Remote upload	Manufacturer software	Medication reminder option	Patient feedback option	Online EMD information
Propeller sensor	Not rechargeable—battery lasts 18 mo after which device needs to be replaced	Up to 3900 events	✓ Connects with a smartphone application (app) via Bluetooth syncing; downloads wirelessly and uploads data to remote servers	✓ Propeller Health Platform: Smartphone app shows details of time, date, and location of use along with weather and air quality data and asthma control status at a glance—accounts can created for the patient or the patient and his or her family group	✓ Reminders given through customizable alerts and notifications for missed doses, or changes in level of asthma control or medication usage sent via e-mail, text, or other push notification options. App also displays patient-friendly health advice, eg “second-hand smoke: never allow any kind of smoking in your home or car,” or how to reduce triggers, eg, “mould: use a hygrometer to monitor humidity levels...”	✓ Medication usage reports can be provided to patients via weekly e-mail reports and smartphone app	✓ Online FAQs, video tutorials, and online/phone support center. Online step-by-step troubleshooting guide available
Doser	13 mo	Stores 30 d of data in memory ³²	✗ No uploading function available	✗ Nil software	✗ Nil reminders available	✓ Medication usage can be read from the screen—shows daily use and number of doses remaining. Beeps when only 20 doses are left. ³² Display and audio alerts may be disabled ³⁴	✗ Minimal—online FAQs, setup instructions, and contact details listed on the manufacturer’s Web site

(continued)

TABLE I. (Continued)

Useful features for clinical practice							
Device name	Battery life	Storage capacity	Remote upload	Manufacturer software	Medication reminder option	Patient feedback option	Online EMD information
Smartinhaler Tracker	Minimum 24 wk ³⁶	~3000 events	X	✓	✓	✓	X
			Uploads to PC via USB cable—no remote upload	Web program supplied by manufacturer to set up and monitor device. Can track specific devices and calculate adherence shown as a report or bar graph ³⁵	Audiovisual reminder available—beeps once every 30 s for up to 60 min if the EMD is not used, or stops when the EMD is used. ⁴¹ Reminders are not customizable. LED light changes from green to red once the dose is taken	LED light changes from green to red once the dose is taken. Nil additional feedback given	Minimal—contact details listed on the manufacturer's Web site for enquiries
SmartTrack†	Rechargeable via the USB port; lasts 1-3 mo from full charge depending on usage. Battery level displayed on screen and Web site ³¹	Up to 1400 logs	✓	✓	✓	✓	X
			Syncs medication usage information from device to manufacturer's Smartinhalerlive.com platform via the Smartinhaler Connection Centre through Bluetooth, SIM card, and external aerial or USB upload to PC, smartphone, or tablet. Manual upload also possible ³¹	Smartinhaler platform: EMDs link into the central SmartinhalerLive cloud platform via Smartphone app or SmartKey device	Optional, customizable twice-daily audio reminders that ring for up to 15 min, or another set duration, until the MDI is actuated—personalized to routine, frequency, and time of day; different reminder tunes available. Reminders can be switched off or cancelled individually. "Flight" option available for reminders when traveling ⁴²	Customizable feedback options with onboard user interface to view medication usage and change EMD settings; graphical or numerical adherence data available via secure Web site ⁴²	Minimal—contact details listed on the manufacturer's Web site for enquiries

SmartTouch†	Two versions available depending on EMD type: Rechargeable type via the USB port; lasts 1-3 mo from full charge depending on usage; nonrechargeable type has a minimum 1-y battery life	Holds between 4000 and 6000 logs depending on device	✓	✓	✓	✓	✗
			Syncs medication usage information from device to manufacturer's Smartinhalerlive.com platform via the Smartinhaler Connection Centre through Bluetooth or USB upload to PC, smartphone, or tablet	Smartinhaler platform: EMDs link into the central SmartinhalerLive cloud platform via Smartphone app or SmartKey device	Optional customizable twice-daily audiovisual reminders available via Smartinhaler App or embedded into the EMD on request—weekday and weekend reminders. LED indicator to indicate usage and battery level	Customizable feedback options with onboard user interface to view medication usage and change EMD settings; graphical or numerical adherence data available via secure Web site	Minimal—contact details listed on the manufacturer's Web site for enquiries
SmartDisk†	Rechargeable via the USB port; lasts 2-3 mo from full charge depending on usage	Up to 1400 logs	✓	✓	✓	✓	✗
			Syncs via Bluetooth to SmartinhalerLive via Smartinhaler App or USB upload to PC, smartphone, or tablet to SmartinhalerLive via the Smartinhaler Connection Centre	Smartinhaler platform: EMDs link into the central SmartinhalerLive cloud platform via Smartphone app or SmartKey device	Twice-daily audio reminders customizable for weekdays and weekends; LED indicator shows usage and battery level	Customizable feedback options; graphical or numerical adherence data available via the manufacturer's Smartinhaler Live platform	Minimal—contact details listed on the manufacturer's Web site for enquiries
SmartTurbo†	Lasts minimum of 1 y. Not rechargeable	Up to 6000 logs	✓	✓	✓	✓	✗
			Syncs via Bluetooth to SmartinhalerLive via Smartinhaler App or USB upload to PC, smartphone, or tablet to SmartinhalerLive via the Smartinhaler Connection Centre	Smartinhaler platform: EMDs link into the central SmartinhalerLive cloud platform via smartphone app or SmartKey device	Reminder option available via Smartinhaler App or embedded in the device (on request). LED indicates usage and battery level	Customizable feedback options; graphical or numerical adherence data available via the manufacturer's Smartinhaler Live platform	Minimal—contact details listed on the manufacturer's Web site for enquiries
SmartFlow†	Rechargeable via the USB port; lasts 2 mo from full charge depending on usage	Up to 125 actuations	✗	✓	✗	✓	✗
			Syncs via USB upload to PC. No wireless or Bluetooth capability	Smartinhaler platform: EMD links into SmartinhalerLive cloud platform via Smartinhaler Connection Centre via USB	LED indicates usage and battery level but no formal medication reminders	Customizable feedback options; graphical or numerical adherence data available via the manufacturer's Smartinhaler Live platform	Minimal—contact details listed on the manufacturer's Web site for enquiries

(continued)

TABLE I. (Continued)

Useful features for clinical practice							
Device name	Battery life	Storage capacity	Remote upload	Manufacturer software	Medication reminder option	Patient feedback option	Online EMD information
SmartMat†	Rechargeable via the USB port; lasts 2-3 mo from full charge depending on usage	Up to 4000 logs	✓ Syncs via Bluetooth to SmartinhalerLive via Smartinhaler App or USB upload to PC, smartphone, or tablet to SmartinhalerLive via the Smartinhaler Connection Centre	Smartinhaler platform: EMD links into SmartinhalerLive cloud platform via Smartinhaler Connection Centre	✗ LED indicates usage and battery level but no formal medication reminders	✓ Customizable feedback options; graphical or numerical adherence data available via the manufacturer's Smartinhaler Live platform	✗ Minimal—contact details listed on the manufacturer's Web site for enquiries
SmartSpray†	Rechargeable via the USB port; lasts minimum of 1 y from full charge depending on usage	Up to 4000 logs	✗ Syncs via USB upload to PC. No wireless or Bluetooth capability	Smartinhaler platform: EMD links into SmartinhalerLive cloud platform via Smartinhaler Connection Centre via USB	✗ LED indicates usage and battery level but no formal medication reminders	✓ Customizable feedback options; graphical or numerical adherence data available via the manufacturer's Smartinhaler Live platform	✗ Minimal—contact details listed on the manufacturer's Web site for enquiries

FAQ, Frequently asked question; LED, light-emitting diode; MDI, metered-dose inhaler; PC, personal computer; SIM, subscriber identity module; USB, universal serial bus.

*Information sourced from references as cited; where no reference is given, the information has been provided to authors by the respective manufacturer as of October 2014. To the authors' knowledge, information included in the table is correct at the time of writing. Please contact your local manufacturer for updated information.

†The Smartinhaler range (excluding the Smartinhaler Tracker) produced by Nexus 6 Ltd has the following core features/specifications: (1) usage data showing date and time of last use can be uploaded for review by the clinician; (2) communicates with SmartinhalerLive, which shows medication usage reports, charts, graphs, and device reports—option to generate automatic e-mail reports; (3) different account types for patient vs clinician; (4) can integrate with other health information systems and track lung function; (5) available in English, German, French, and Spanish; (6) device clock drifts by up to 20 min after 1 y with no uploads; and (7) operates between 0°C and 40°C at 15% to 95% humidity.

TABLE II. Considerations for the use of EMDs by clinicians and patients and regulatory considerations *

Device name	EMD use considerations for clinicians (clinician feedback; simplicity of use by clinicians)	EMD use considerations for patients (patient experience and feedback)	Regulatory considerations and privacy law compatibility
Propeller sensor	1. Real-time objective data with time/location of use remotely available via a secure provider dashboard; 2. Health provider can customize alerts and patient notifications to intervene with patients whose condition is worsening; 3. More than 84% of health providers report benefits to patients and clinical care (M. Barrett, 2013, personal communication)	1. Actuation detection mechanism tuned and bench tested to match the forces required to actuate a range of MDIs ⁴³ ; 2. Patient satisfaction with device 99%, with 94% satisfied with information provided by the platform and 92% finding the device easy to use (personal communication)	FDA-approved device and mobile applications. Compatible with the HIPAA privacy laws—patients can choose to share as much or as little information with their clinician, friends, and family regarding their usage
Doser	1. Relatively cheaper than other EMDs—more affordable but fewer functions available; 2. Currently available model less prone to EMD faults/data losses than older models as reported in the literature ^{34,44,45} ; 3. Short memory of events (only last 30 d) and inability to download information makes data more cumbersome; 4. Shows date, but not time of actuation, so cannot provide information about adherence patterns ³² ; 5. Maximal daily dose displayable is “99” owing to 2-digit window ³⁴	1. Young children with small fingers may have difficulty pressing the device with enough force to register a puff ³⁴ ; 2. Difficulty with registering “double puffing” or puffs that are done in quick succession because the device records only 1 actuation per second; however, this does prevent spurious recording arising from an unsteady hand ^{22,32} ; 3. Plastic ring structure at the bottom of the device can prevent delivery of full dose of medication; 4. Patient device training identified as necessary to reduce errors ^{22,34} ; 5. Actuators that occur when the Dosier is depressed on the side rather than the center may not be recorded ³⁴ ; 6. Device is small and compact so easily portable ³² ; 7. Dosier device can fall off—the need to reattach can lead to spurious actuators; 7. Spurious actuators can arise during setup and transportation ³⁴	FDA approved; no information on privacy law compatibility
Smartinhale Tracker	1. Adherence data accessible via a Web-based program displaying adherence as a report/graph that may be downloaded into a standard spreadsheet; 2. Each device gives a timestamp to each event to a resolution of seconds ³⁵ ; 3. Computer software has a TEST function to check device functionalities ⁴⁴	1. Shape similar to that of a standard pMDI ³⁵ ; 2. Spurious actuators can occur on canister insertion into the device, though canisters fit firmly and do not fall out; 3. For doses actuated in quick succession, all are given the same timestamp to the second, correlating to the time of the first actuation; 4. The device will not detect actuators achieved by gentle depression of the canister that do not activate the detection switch, leading to underrecording ³⁵ ; 5. Incorrect date/time logs and data uploading issues have occurred ^{36,46} ; 6. Potential issues of nozzle blockage affecting medication delivery may require frequent device replacement; 7. Broken switches and hardware faults have been reported ⁴⁴ ; 8. Qualitative patient feedback available from 1 study—feedback included that “recording dosing time made (me) more conscious of taking (my) medicine” and “knowing someone is going to check the (dosing) times makes you comply” ⁴⁶	No information on regulatory approval or privacy law compatibility available

(continued)

TABLE II. (Continued)

Device name	EMD use considerations for clinicians (clinician feedback; simplicity of use by clinicians)	EMD use considerations for patients (patient experience and feedback)	Regulatory considerations and privacy law compatibility
SmartTrack†	1. Data uploads can be automatized with e-mail reporting option to minimize the risk of data loss ^{31,42} ; 2. One study reported on clinicians' perceptions of the usefulness of the EMD. The average rating was high: mean score 80/100, with higher scores indicating increasing usefulness ⁴²	1. Onboard LED screen shows date, time of last use, and number of doses taken in the last 24 h; 2. Some functions impaired when battery is low; 3. Some patients report that reminders ring too regularly and are annoying at times and that the device is bulky to handle; 4. Older patients may need additional training on the use of the LED screen when first using the EMD; 5. One study reported on patient acceptability. The average rating of "how easy it is to use the EMD to take medication" was high: mean score 6/100, with lower scores indicating greater ease of use ³¹	FDA approved; no information on privacy law compatibility
SmartTouch†	Onboard color screen available, which can be customized to show medication usage charts, adherence metrics, and patient questionnaires	Onboard color touch screen shows date, time of last use, and total doses taken in the last 24 h	FDA approved—cleared as a prescribable MDI with a handful of intended uses: in clinical trials, in clinical practice, and for patient self-management; no information on privacy law compatibility
SmartDisk†	Nil additional features to basic "Smart" features	Onboard color touch screen shows date, time of last use, and the total doses taken in the last 24 h	No information on regulatory approval or privacy law compatibility available
SmartTurbo†	Nil additional features to basic "Smart" features†	Nil additional features to basic "Smart" features	No information on regulatory approval or privacy law compatibility available
SmartFlow†	Records and stores information about the flow rate the patient uses when inhaling the medication	Nil additional features to basic "Smart" features	No information on regulatory approval or privacy law compatibility available
SmartMat†	Nil additional features to basic "Smart" features†	Nil additional features to basic "Smart" features	No information on regulatory approval or privacy law compatibility available
SmartSpray†	Nil additional features to basic "Smart" features†	Nil additional features to basic "Smart" features	No information on regulatory approval or privacy law compatibility available

HIPAA, The Health Insurance Portability and Accountability Act of 1996; LED, light-emitting diode; MDI, metered-dose inhaler; pMDI, pressurized metered-dose inhaler.

*Information sourced from references as cited; where no reference is given, the information has been provided to authors by the respective manufacturer as of October 2014. To the authors' knowledge, information included in the table is correct at the time of writing. Please contact your local manufacturer for updated information.

†The Smartinhaler range (excluding the Smartinhaler Tracker) produced by Nexus 6 Ltd has the following core features/specifications: (1) usage data showing date and time of last use can be uploaded for review by the clinician; (2) communicates with SmartinhalerLive, which shows medication usage reports, charts, graphs, and device reports—option to generate automatic e-mail reports; (3) different account types for patient vs clinician; (4) can integrate with other health information systems and track lung function; (5) available in English, German, French, and Spanish; (6) device clock drifts by up to 20 min after 1 y with no uploads; and (7) operates between 0°C and 40°C at 15% to 95% humidity.

Device name	Manufacturer name and website address	EMD development status (New / Established) [†]	Mechanism for detecting inhaler use	Inhaler compatibility	Device image
Propeller sensor	Propeller Health, Madison, WI http://propellerhealth.com/ (Previously branded as Asthmapolis until September 2013)	New	Exact mechanism information not available; transmission of collected data to smartphone is via a secure, low-power, wireless radio protocol (Bluetooth Low Energy).	Standard pMDIs: the canister needs to sit outside of the housing to allow sensor attachment to top of canister. A silicon sleeve allows for easy fitting to almost all MDIs. Compatible with spacers.	
Doser	Meditrack Products, Easton, MA http://www.doser.com/	Established	Electromechanical switch - completes circuit when depressed	Standard pMDIs: the canister needs to sit outside of the housing to allow sensor attachment to top of canister. Not compatible with some MDIs e.g. ipratropium, cromolyn, nedocromil - canister may not actuate effectively if attached to these ^{32,35} . Compatible with spacers and doesn't interfere with drug delivery ³² .	
Smartinhaler Tracker	Nexus6, Auckland, NZ http://www.smartinhaler.com/	Established; Currently rebranded to Smart Touch (New EMD - see below)	Physical switch [†]	Standard pMDI: the canister fits into the EMD casing which is moulded for the canister	
SmartTrack	Nexus6, Auckland, NZ http://www.smartinhaler.com/	Established; Currently rebranded to Smart Touch (New EMD - see below)	Optical sensing [†]	Standard pMDIs: EMD wraps around existing plastic housing so compatibility not dependent on position of canister in relation to plastic housing. Product datasheet only specifies compatibility with GlaxoSmithKline MDIs. Able to be used with Volumatic spacers ³¹	
SmartTouch	Nexus6, Auckland, NZ http://www.smartinhaler.com/	New	Information not provided by manufacturer	Standard pMDIs: EMD wraps around existing plastic housing so compatibility not dependent on position of canister in relation to plastic housing. Product datasheet lists different EMDs available for different MDIs. Different colours and types available for specific MDI types.	
SmartDisk	Nexus6, Auckland, NZ http://www.smartinhaler.com/	New	Information not provided by manufacturer	Accuhalers - product datasheet only lists compatibility with GSK preventer Accuhalers (i.e. not for use with GSK Ventolin® Accuhaler)	
SmartTurbo	Nexus6, Auckland, NZ http://www.smartinhaler.com/	New	Information not provided by manufacturer	Dry Powder Inhalers. Product datasheet lists compatibility with AstraZeneca DPIs (Symbicort®, Pulmicort® and Bricanyl®)	

FIGURE 1. Images of currently available EMDs and details on where to obtain supply, development status, mechanism of actuation detection, and inhaler compatibility. *DPI*, Dry powder inhaler; *MDI*, metered-dose inhaler. *Information sourced from references as cited; where no reference is given, the information has been provided to authors by the respective manufacturers as of October 2014. To the authors' knowledge, information included in the table is correct at the time of writing. Please contact your local manufacturer for updated information. †New development status refer to EMDs entering the market with limited independent published data on their performance and use. ~ indicates the authors' personal experience with the product.

SmartFlow	Nexus6, Auckland, NZ http://www.smartinhaler.com/	New	Information not provided by manufacturer	Boehringer Ingelheim Berodual pMDI	
SmartMat	Nexus6, Auckland, NZ http://www.smartinhaler.com/	New	Information not provided by manufacturer	Boehringer Ingelheim Respimat® SMI	
SmartSpray	Nexus6, Auckland, NZ http://www.smartinhaler.com/	New	Information not provided by manufacturer	Boehringer Ingelheim Berodual LS	

*Information sourced from references as cited; where no reference is given, the information has been provided to authors the respective manufacturers as at October 2014. To the authors' knowledge, information included in the table is correct at the time of writing - please contact your local manufacturer for updated information.

^New development status refer to EMDs entering the market with limited independent published data on its performance and use

pMDI – pressurised metered dose inhaler

FIGURE 1. (Continued).

the EMD before issue. Training should include how to insert/remove the inhaler from the EMD; inhalers compatible/not compatible with the EMD; use of any EMD menu system, application, or Web site; and appropriate EMD storage, such as keeping the EMD away from direct sunlight and water and removing the EMD from pockets before putting clothes in the laundry.

Clinical staff using the EMD should be trained on how to use the EMD, how to undertake routine device checks, and what to do if a device fails any of the checks (see Table III). The checking process should be simple enough to be followed by any staff member who has had basic training on how to use the EMD and need not be limited to clinical personnel. The following, separate, storage containers should be set up for new EMDs received from the manufacturer: “checked and passed,” “checked and failed,” and “not checked.” A similar system can be established for used devices requiring reuse by the same patient, with precautions to prevent cross-contamination and to manage device-patient allocation. A basic electronic database can be set up, for example, in an electronic spreadsheet to track the location of the EMD and its patient allocation. Some manufacturers provide software or applications to assist with EMD checking and management (see Table I).

IMPLEMENTING EMD CHECKS

EMD faults can lead to poor data quality, data retrieval problems, or data loss.^{30,34,61,62} To check for any damage acquired in the storage or shipping process or during patient use, a brief EMD check is recommended before the EMD is issued to the patient and immediately after return from the patient to ensure that the EMD is recording accurately and that collected data are correct.

The following section provides practical guidance on how to implement such EMD checks in a standardized way. Such

standardization simplifies the process and, if needed, allows comparison of results within and between devices.

How to carry out brief EMD checks?

The existing literature on EMD testing has focused on the types of tests needed for new EMDs entering the market, rather than brief EMD checks for more established devices (Figure 1). However, the underlying principles are much the same. The key recommended tests are for accuracy of single and multiple actuation recording.^{30,32,33,63} Checks for the accuracy of single actuation recording require actuation of the inhaler once, while simultaneously recording the time and date in a paper diary. This is usually done 3 to 4 times in succession. EMD records are subsequently checked against the paper diary. Checks for multiple actuation recording differ from checks for single actuation recording in that multiple, closely spaced, sequential actuations are carried out (10-300 actuations can be used for testing³⁷) to ensure that the device can reliably record a behavior known as “dose dumping.”⁶⁴ *Dose dumping* is a series of deliberate multiple actuations usually occurring before clinic visits in an attempt to disguise poor adherence. Dose-dumping data points can be easily seen in a printout or graph of a patient's adherence record, and on the Doser may be indicated by an unusually large daily count of puffs made close to an appointment. These data points need to be removed from the adherence record to correctly gauge the patient's adherence.

Checks of other clinically important device functions may also be important. For instance, if an EMD has failed to deliver adherence reminders as expected, a patient's adherence may not improve, so it is advisable to check the performance of reminder functions in a random sample or all devices.³¹

Checks for physical damage and power source performance are recommended. A quick inspection of the physical state of the EMD is a simple, important check that can identify any damage or loose parts that may cause a safety issue or impede device

TABLE III. Common EMD malfunctions and their management

Problem	Possible causes	Suggested action
The number of puffs recorded by the EMD is greater than the number of puffs actuated (“overrecording”)	The EMD has responded to an external stimulus that has activated the recording function of the EMD	Report the fault and return the device to the manufacturer for test and repair or replacement
The number of puffs recorded by the EMD is less than the number of puffs actuated (“underrecording”)	The energy source powering the EMD is faulty, leading to a failure to record events	Check battery connection—intermittent connection/disconnection events may lead to intermittent data recording. Report the fault and if not resolved return the device to the manufacturer for test and repair
	Insufficient force used to lead to detection of the actuation (eg, for switch-activated EMD for pMDIs)	Check actuation technique to identify patients who are unable to use enough force to depress pMDIs (eg, young children or the elderly). Check EMD compatibility with other devices that the patient may be using, eg, spacer and Haleraid. Report the fault to the manufacturer
	The standard threshold for detection of puffs has been set too high, leading to loss of sensitivity of actuation detection	Report the fault and return the device to the manufacturer for test and repair or replacement
The EMD has failed to record any data	An incompatible inhaler type has been used with the EMD	Check device compatibility specifications and ensure that the patient has received adequate EMD training, eg, on compatible inhalers and fitting the inhaler correctly to the device
	The energy source (eg, internal battery) powering the EMD has been depleted or is absent	Charge battery before dispensing and provide battery chargers or battery charging docking stations to patients Check expected battery life with the manufacturer before purchasing the device for your clinic. Consider more frequent EMD replacement/charging. Replacement devices can be mailed to patients familiar with the EMD
	The circuitry responsible for powering the EMD is malfunctioning	Check battery levels and charge the device. Check for loose connections or parts or physical damage (eg, water damage). Report the fault and if the problem persists, return the device to the manufacturer for test and repair or replacement
	The internal memory capacity for data storage is full	Check the maximum storage capacity (number of events/days stored) with the manufacturer and ensure that it meets intended needs before purchasing the device for your clinic. If the device allows data upload, upload data onto an external server to free up device memory
The EMD has recorded the correct number of puffs but the time/date is incorrect	The clock for the EMD is incorrect	If the device has a screen, check whether the screen time matches an external time source (eg, your computer) Check the disparity in the log. If the disparity is consistently 1 h, then the EMD may have incorrectly adjusted for daylight saving Check the battery connection. If the battery is loose, or has been removed by the user, the clock may stop or be incorrect Reset time or send the device to the manufacturer for reset. If issues persist, report the fault and return the device to the manufacturer for test and repair or replacement

(continued)

TABLE III. (Continued)

Problem	Possible causes	Suggested action
The EMD will not switch on	Battery empty	Charge the battery if possible, or send the device to the manufacturer for battery replacement and reset
	The energy source powering the EMD is faulty	Check the battery and charger connection. If possible, replace with a new energy source/battery. Report the fault and return the device to the manufacturer for test and repair or replacement
	The power button on the EMD is faulty	Check whether the other buttons/functions work on the device. Report the fault and return the device to the manufacturer for test and repair or replacement

pMDI, Pressurized metered-dose inhaler.

functionality.⁴⁰ A check of the EMD power source will ensure that the device is powering correctly and that the power level is sufficient to last for the duration of use. It can also help troubleshoot EMD data inaccuracies because recording errors or data loss can occur when EMD power is unstable, low, or absent.^{33,44,61}

On the basis of this literature and our own experience with implementing EMD checks, we have developed a simple checklist of recommended factors to include when performing brief device checks (see Table E1 and Appendix E1 in this article's Online Repository at www.jaci-inpractice.org). Recommended checks, before issue and after return from the patient, fall into 3 categories: (1) physical check of the device, (2) accuracy of actuation recordings and other functions, and (3) power source check. A laboratory is not needed to carry out EMD checks; any space with a small storage area for devices and a computer, desk, and chair is sufficient.

Interpreting EMD check results

It is helpful to set a threshold for "pass" or "failure" for each checking step to determine the degree of acceptable variation between the EMD and the paper record of the checks done. This will mostly be determined by the manufacturer's EMD specifications, but also by the clinician's and/or patient's reason for adherence measurement and how important a particular function is for the intended purpose. For some functions, such as actuation recording, only near 100% reliability will be acceptable, whereas recording of other functions, such as time of battery removal, may be less stringent if they provide nonessential data.

Troubleshooting common EMD malfunctions

Table III describes common EMD malfunctions and provides recommendations on how to manage them. The most commonly reported EMD failures are inaccurate time recordings of performed actuations^{33,40,45,61} or incorrect numbers of actuation recordings (ie, missing or extra recordings).⁴⁰ "Time drift" can occur if the EMD has not made contact for a period of time with an external time source (eg, a server or computer) that automatically synchronizes with coordinated universal time. A moderate degree of time drift may not necessarily be a reason to mistrust the adherence data from an EMD, particularly if the degree of time drift is known from the manufacturer's specifications. For example, a time drift of plus 1 hour may not affect the interpretation of adherence data, although actuations taken

just after 2300 hours would theoretically be recorded as occurring the next day. Some older EMDs have had an impact on medication delivery owing to clogging of the EMD nozzle.^{36,61} Although EMD actuation recording is not affected, this can lead to inaccurate patient dosing records because the EMD will have recorded actuations that the patient may not have been able to take because of poor medication delivery.

Battery depletion or failure can lead to data loss, inaccurate actuation recordings, failure in data upload, or EMD failure,^{33,44,61} though newer EMDs appear to have improved battery life.³⁶ Battery failure may occur because of deliberate or inadvertent removal of the power source by the patient-user or excessive power consumption owing to simultaneous use of multiple functions on the EMD (eg, continuously sounding reminders during a data upload). Some devices, such as the SmartTouch and Propeller sensor, can register low power or battery removal, which may be recorded on data printouts. Other possible explanations for EMD malfunctions or recording inaccuracies are outlined in Table III.

Explaining and managing EMD malfunctions

Overrecording and underrecording of actuations may occur in different ways. For example, an EMD that detects actuations using an optical system may falsely record actuations in the presence of external beams of light if the wavelength triggers the actuation detection mechanism. In EMDs relying on a physical method for actuation detection, failure to record an actuation may indicate that insufficient force was used during actuation (Table III). Elderly, frail, or pediatric patients may perform weaker actuations so it may be important to ask manufacturers whether the EMD has been tested in a broad population of people representing various actuation techniques. Although one can assume to some extent that actuation detection malfunctions have been identified and addressed by manufacturers during the development process, it is helpful to note and report any potentially unrecognized sources of error.

A blank event record, or the recording of a high number of multiple actuations in rapid succession, may be a sign of battery failure or malfunction of the EMD memory. Multiple actuations caused by battery failure can usually be differentiated from dose dumping because battery failure usually results in a high number of actuation recordings far in excess of the "maximum number of actuations recordable in one second" described in the manufacturer's specification. Data uploading issues can occur with low

MondayPlease fill in below, all the prescribed puffs you take today

Time of day	Time 1 st puff taken	Time 2 nd puff taken
AM	____ / puff not taken	____ / puff not taken
PM	____ / puff not taken	____ / puff not taken

Please fill in below, any extra puffs you take today

Time of day	Time puff taken
AM / PM	____
AM / PM	____
AM / PM	____
AM / PM	____

TuesdayPlease fill in below, all the prescribed puffs you take today

Time of day	Time 1 st puff taken	Time 2 nd puff taken
AM	____ / puff not taken	____ / puff not taken
PM	____ / puff not taken	____ / puff not taken

Please fill in below, any extra puffs you take today

Time of day	Time puff taken
AM / PM	____
AM / PM	____
AM / PM	____
AM / PM	____

FIGURE 2. Example of a patient actuation diary.

battery power, but this may also be caused by connection port malfunction or water damage to electronics used for connectivity, for example, Bluetooth and universal serial bus (USB).⁴⁴ A common cause of water damage is leaving the EMD in clothing and washing in a washing machine.

WORKING WITH NEWLY DEVELOPED EMDs

Potential buyers cannot assume that EMDs newly available on the market have undergone the prototype and preproduction testing needed to ensure adequate reliability, though as the market grows, it is likely that new EMDs will increasingly be delivered patient-ready to the clinician or researcher. However, at present, before using any new EMD, we recommend running a series of detailed checks in your clinic, in collaboration with researchers or the manufacturer, to ensure that adequate checks, similar to those discussed in the next paragraphs, have been carried out. Clinicians can increasingly contribute to the design and production of EMDs by providing feedback to manufacturers and researchers about their needs when using EMDs in practice.⁶⁵

Two phases of checks are recommended for new EMDs before using them for the first time in patients: (1) “clinic-based checks,” which can be done in a clinic, and “patient-based checks,” which need to be performed in the homes of a small number of patients.⁶³

Clinic-based checks of a new EMD

During clinic-based checks, any errors in EMD function are checked under controlled conditions. These checks are similar to brief EMD checks but are more detailed and include checks for storage capacity, EMD-inhaler fit and compatibility (Figure 1), and device robustness, as well as checks for physical damage or faults⁴⁰ and accuracy of inhaler actuation recording and other relevant functions. Further information on clinic-based checks, including a checklist of recommended tests and guidance on interpreting test results, can be found in Appendix E1 and Tables E2 and E3 in this article’s Online Repository at www.jaci-inpractice.org.

Patient-based checks of a new EMD

Before patient use, any new EMD should undergo patient-based checks with patients to ensure not only suitability and

reliability but also acceptability of the EMD in the target population. Ease of EMD handling, likelihood of tampering, and EMD robustness should be checked. A small number of patients should be asked to record the date and time of every actuation taken over a few days in a paper diary (Figure 2), for comparison with the EMD record upon device return. On return of the EMD, patient feedback should be sought about the acceptability of the EMD and ease of use, for example, via structured questionnaires or interviews. Specific details on how to carry out patient-based checks can be found in Appendix E1 and Table E4 in this article’s Online Repository at www.jaci-inpractice.org.

SUMMARY

There is increasing potential for EMD use in clinical settings, especially as costs reduce and user interfaces become simpler for clinicians and patients.⁵⁷ EMDs appear feasible and effective for improving patients’ inhaler adherence in primary and secondary care settings,^{42,59} although more data on the cost-effectiveness of monitoring are needed to secure EMD reimbursement. Clinic staff need to be prepared to carry out brief standardized checks of EMDs to ensure data quality and reliability. This article has provided a starting guide for health professionals on the attributes and user acceptability of different EMDs, and how to carry out brief device checks in established EMDs or more detailed evaluation of new devices, based on published methodology. Device checking processes can be carried out in clinic settings and should be simple enough for clinic personnel to do after receiving basic device training. Clear procedures should be in place for the storage of devices and for responding to device failures. Informed clinicians can select appropriate EMDs for their patients and implement reliable EMD checking processes to allow confident interpretation of their patients’ adherence data to inform clinical decisions.

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APPENDIX E1. DETAILED TESTING OF NEW EMD DEVICES

Newly available EMDs require rigorous checks to ascertain acceptable EMD function and accuracy.^{E1,E2} Two types of checks, that is, “clinic-based checks” (checks that can be done in the clinic) and “patient-based checks” (checks that need to be done with patients), are recommended for new EMDs before using them for the first time.^{E3}

EVALUATING NEW EMDs IN THE CLINIC OFFICE SETTING

A laboratory is not needed to carry out checks for new EMDs; any space with a small storage area for devices and a computer, desk, and chair is sufficient to provide controlled conditions. During clinic-based checks, systematic errors in EMD functionality can be checked under controlled conditions. A checklist of parameters to assess in a new EMD, as described below, can also be found in [Tables E2 and E4](#).

Physical checks

An initial physical check for loose parts or cracks should be carried out,^{E2} with a focus on device joints, compartment/ports for the power source, and overall finish. A once-over of the physical state of the EMD is a simple, important, check that can identify any damage or loose parts that may cause a safety issue or impede device functionality.^{E2}

EMD-inhaler compatibility

Poor or incorrect EMD-inhaler fit can lead to data inaccuracies. Before using a particular EMD, it is important to obtain information about EMD-inhaler compatibility from the manufacturer. Most EMDs are for pressurized metered-dose inhalers and although these may appear to fit a range of inhalers, some will provide reliable data only for a specific pressurized metered-dose inhaler. Breath-actuated or dry powder devices generally require specifically designed EMDs. Other issues to consider include compatibility with inhaler aids such as the Haleraid or spacers, and the presence of dose counters, which may alter the shape of the pressurized metered-dose inhaler. EMD setup can be simple or complex, with some EMDs fitted by the user and others requiring specialized setup by the manufacturer.^{E3,E4} The ease of setup can affect patient acceptability of use and should be considered by the clinician when choosing an EMD for the patient.

Actuation recording accuracy

Given the EMD's essential purpose, its actuation recording accuracy is one of the most important tests to carry out. EMDs will record, at minimum, the number of doses taken over a set period. More sophisticated EMDs will provide a time and date log for each dose taken.^{E7} Before checking the actuation recording accuracy of an EMD, it is important to understand the method of detection used by the EMD because this can influence other factors, such as inhaler compatibility, power consumption, and type of faults encountered. Devices generally use 1 of 3 methods. *Physical* detectors use a pressure sensor or switch to record an actuation.^{E7} *Optical* devices detect actuations via interruption of energy beams or specific wavelengths of light, whereas others use an *electromagnetic* system in which actuations are monitored via the position of a lever as sensed by magnets.^{E8} [Table I](#) and [Figure 1](#) in the main article list currently available

EMDs and their specifications, including their method of detection.

Actuation recording should be checked by actuating the inhaler and keeping a paper diary of the date and time of each actuation. A detailed description of recommended actuation accuracy checks is given in [Table E3](#) as a guide; clinicians may wish to adopt an abbreviated version for more established EMDs ([Table E1](#)). An independent time source, not the EMD clock, should be used to ascertain the time of each check carried out. A different, validated EMD^{E9,E10} or canister weight at baseline and after each actuation^{E5,E11} can be used as a second independent check. Different actuation patterns should be tested to mimic real patient use, such as overuse and underuse and periods of no use as well as usual regimes, for example, 2 puffs twice daily.^{E12}

Recording of multiple actuations or “dose dumping” should be tested. Dose dumping usually occurs before clinic visits in an attempt to disguise poor adherence. Dose dumping can be defined by setting an arbitrary threshold of a number of puffs in succession (a minimum of 10 and a maximum of 300 have been used in the literature^{E8}) and comparing the EMD record with the paper record. It is important to check actuation recording logs carefully. A faulty EMD may record spurious “extra” actuations or fail to record executed maneuvers (see [Table III](#) in the main article).

Accuracy of other functions

Contemporary EMDs can provide medication reminders. Reminder systems are more complex than simple digital alarm clocks because they are usually designed to ring only when an actuation/dose has been missed within a certain window. Reminders can be checked by setting the reminder for a specific time and then, after failing to actuate the device, checking the accuracy of the reminder ring time relative to the reminder time set on the EMD using an external time source. Other useful tests include checking that reminders stop in response to actuation if the EMD is programmed to do so. We recommend checking the reminder function on at least 2 different occasions, for example, morning and evening.

Other contemporary EMD functions may include adherence feedback (eg, via an onboard screen), recording of reminder on/off, inhaler or power source removal/insertion, and inhaler shaking and inhalation. These functions should be checked by performing the appropriate action and recording feedback and/or the date and time of each action in a paper diary. The EMD log should then be compared with the paper diary for any discrepancies.

Storage/memory capacity

EMDs have a prespecified limit on data storage capacity, defined either by a maximum number of days of data or by a maximum number of events.^{E9} If the maximum storage threshold is reached, the EMD will be unable to record any further events. It is important to obtain information about EMD storage capacity because this will dictate the frequency of EMD replacement and/or data uploading by the clinician or patient.

Robustness

Robustness requirements may depend on the target population; for example, EMDs used by children may be more likely to be dropped or handled roughly. It is important that the EMD records inhaler removal and insertion and, if not, that tamper-

proofing strategies are used to prevent inhaler removal between clinic visits.

Environmental conditions may influence the reliability of the EMD. EMD specifications such as temperature and humidity range within which the EMD can function, water- or splash-proofing, tolerance to sunlight exposure (for optical EMDs), and the maximum external force that the device can tolerate, for example, when dropped from a height or placed under an object, should be checked with the manufacturer.

Energy/power source

EMDs are usually powered by a single use or rechargeable battery and rely on regular battery replacement or recharging to function. EMD power consumption rates should be checked with the manufacturer to ensure adequate power for the duration of intended use. Generally, the greater the number of functions active on an EMD, the greater the energy use, so power usage will be increased under conditions of high activity (eg, reminders ringing constantly) than under conditions of low activity (eg, audiovisual functions disabled). Some EMDs have internal auxiliary (backup) batteries and the extent to which these protect data integrity if the main battery becomes empty or faulty should be ascertained from the manufacturer. For longer duration monitoring, it may be necessary to adjust the frequency of clinic visits to facilitate charging. [Table E3](#) describes battery testing in more detail.

Reusability

Some EMDs are disposable or specified for single use only, whereas others may be used within the same patient over several months.^{E4} Reusability may introduce difficulties such as keeping track of device damage or patient tampering over long periods of use. Remote data uploading, which is a common feature of contemporary EMDs ([Table 1](#)), may be useful in these circumstances.

PATIENT-BASED CHECKS OF THE NEW EMD

It is useful to record battery life before and after patient-based checks to check power consumption.^{E13} It may be useful to obtain patient feedback on the device during the patient-based checks as well; the degree of patient satisfaction with the EMD will affect patient uptake and duration of use. Usability testing provides information about the participants'

subjective assessment of the EMD. This can be done via interview, rating scales, and/or questionnaires to collect quantitative and qualitative data.^{E13}

Providing participants with a thorough demonstration of the EMD, clear instructions, and reinforcing that the aim of the field test is to study EMD performance rather than the participants' medication use may optimize reporting of device faults. Explain clearly to participants that the EMD should be used in a normal manner, simulating "real life." A checklist of steps for patient-based checks of new EMDs is available in [Table E4](#).

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TABLE E1. Brief EMD performance checklist

- ☐ Physical check (eg, check for loose parts and cracks)
- ☐ Accuracy of functions
 - Actuation recording accuracy.
 - Single actuation recording
Perform 4 actuations. Make a simultaneous, written record of the date and time (to the second)* of each actuation in a paper diary and subsequently compare the diary and EMD record.
 - Multiple actuation recording
Perform a set of actuations in quick succession, to mimic “dose dumping” (eg, 10 puffs). Make a simultaneous, written record of the date and time (to the second)* of the first and last actuations in the set of actuations in a paper diary and subsequently compare the diary and EMD record.
 - Accuracy of other essential functions.
 - Check core functions for the intended use (eg, reminder function should be checked if the EMD is used by the patient primarily for its reminder function) by performing the chosen maneuvers(s) once. Make a simultaneous, written record of the date and time (to the second)* of each maneuver in a paper diary and subsequently compare the diary to the EMD record.
- ☐ Energy source (check battery level and recharge or replace battery)
 - The energy source powering the EMD should be fully charged, and its charge status checked and recorded before issue and on return from the patient.

*Use a single external time source (even if the EMD has an onboard clock).

TABLE E2. Clinic-based checks—A checklist of parameters to check in a new inhaler EMD*

- ☐ Physical check of EMD—loose parts, cracks
- ☐ EMD compatibility—choice of inhaler type/brand
- ☐ Accuracy of functions
 - Actuation recording accuracy†
 - Actuation detection method—Clinician should become acquainted with the specific mechanism used by the new EMD to identify reliability risks and perform checks that are appropriate for the EMD detection method.
 - Physical detection method?
 - Optical detection method?
 - Electromagnetic detection method?
 - Other detection method?
 - Usual dosing
 - Underdosing/overdosing
 - No usage
 - Dose dumping
 - Accuracy of other functions
 - Reminder (time, type, duration, response to actuations)
 - Onboard screen/buttons
 - Inhaler insertion and removal
 - Power source connection and removal
 - Inhaler shaking
 - Inhalation
 - Other key functions (see device specifications)
- ☐ Energy/power source
 - Life of power source†
- ☐ Storage/memory capacity
- ☐ Robustness
 - Child safety
 - Tampering
 - Durability under different conditions (temperature, humidity, wet/dry, light/dark, drop test)
- ☐ Reusability
- ☐ Regulation and approval

*The creation of a standard device checking record that lists each checking procedure to be carried out on each EMD is recommended. The form should include fields for recording the device number, the overall result of the series of checking procedures (eg, pass/fail), and a comments section for explaining the overall result of the checks.

†See Table E3 for a more detailed description of actuation recording accuracy and power source/battery life tests.

TABLE E3. Recommended actuation recording accuracy and battery life checks^{E3-E6}

1. Set up the EMD as per manufacturer's instructions and record baseline battery life.
2. It is important to emulate normal inhaler use as closely as possible when performing EMD checks, eg, shaking pMDIs (while attached to the EMD) before actuation.
3. Phase 1 Actuation Recording Accuracy Checks.
 - Perform a series of actuations at different times of the day for a period of several days. Make a simultaneous, written record of the date and time (to the second)* of each actuation in a paper diary.† If the inhaler has a dose counter, record the counter number or weigh the canister before and after each actuation to provide an additional record of the number of actuations made.
 - Perform at least 1 series of fast sequential actuations (eg, 10 puffs) to check how the device records dose dumping. Make a simultaneous, written record of the date and time (to the second)* of the first and last actuations in the set of actuations in a paper diary, and record the counter number or weigh the canister before and after the set of actuations.
 - Compare the diary, dose counter, canister weight, and EMD records to determine whether the device has passed or failed phase 1 tests.
4. Phase 2 Actuation Recording Accuracy Checks.
 - A patient use simulation checking procedure‡ of normal prescribed regimens (eg, 2 puffs AM and PM) as well as underuse, overuse, and no use (eg, 0-20 puffs/d) should be conducted over a number of sequential days (eg, 7 d). Make a simultaneous, written record of the date and time (to the second)* of each actuation in a paper diary, record the counter number, or weigh the canister before and after each actuation.
 - Compare the diary, dose counter, canister weight, and EMD records to determine whether the device has passed or failed phase 2 tests.
5. Battery Life Checks.
 - Check the battery life in a subset of devices over several days, and check no data are lost because of low or empty batteries.
 - If possible, carry out a longer battery life check for 30-90 d in 3 devices (one each with high, low, and zero daily use, eg, actuations, screen use, and/or data uploads) to test longer-term battery life and/or internal backup battery problems.

pMDI, Pressurized metered-dose inhaler.

*Use a single external time source (even if the EMD has an onboard clock). The EMD clock should be synchronized with the external time source at baseline to provide a criterion standard comparison with device logs.

†The creation of a standard device checking record that lists each checking procedure to be carried out on each EMD is recommended. The form should include fields for recording the device number, the overall result of the series of checking procedures (eg, pass/fail), and a comments section for explaining the overall result of the checks.

‡Where relevant, apply a pharmacy dispensing label to a proportion of inhalers to check for any effects on EMD data recording.

TABLE E4. Patient-based checks—A checklist of parameters to check in a new inhaler EMD

Patient-based checks should ideally be a minimum of 7-d duration, to provide sufficient data, and should include the following^{E9,E13}:

1. Set up the device as per the manufacturer's instructions.
2. Carry out a brief performance check (Table E1) of the EMD as close as possible before the patient visit, or if the EMD is new, a full clinic-based check may be required (see Appendix E1 and Tables E2 and E3).
3. At the baseline visit, attach the EMD to the inhaler. Record the dose counter number on the inhaler, if available, or the weight of the canister.
4. At the baseline visit, train the patient on EMD use (eg, inhaler compatibility and appropriate storage to avoid water damage). Provide a clear instruction manual and a physical demonstration of the EMD functions. Ask the patient to demonstrate the functions and correct any errors. Remind the patient to use the device and the inhaler normally to check its capacity to withstand normal wear and tear.
5. At the baseline visit (and also at follow-up), record patient-reported ease of use. Where appropriate, check EMD compatibility with any other inhaler aids the patient usually uses, eg, a spacer or Haleraid.
6. At the baseline visit, provide the patient with a simple actuation diary (Figure 2) and demonstrate how to use it. Show example time and date record produced by the EMD to reinforce the need for accuracy (eg, time recordings to the second). Encourage accuracy by stating "Your diary entries gives us accurate data which we use to check how well the device records each puff" and "It is much better to leave a diary entry blank than to fill in an estimate or guess later." Record the date and end time of the baseline visit so that any maneuvers made during the visit can be identified.
7. At the follow-up visit, record the dose counter number (if available), or weigh the canister (for pMDIs) and carry out a return EMD performance check. Record the date and start time of the follow-up visit so that any maneuvers made during the visit can be identified and excluded.
At the follow-up visit, upload EMD data and compare it with the patient diary and any dose-counter/weight records. Ask the patient to clarify any discrepancies. Avoid leading the patient by concealing the full details of any disparity initially. Normalize discrepancies to encourage the patient to report events as openly as possible.

pMDI, pressurized metered-dose inhaler.