

ADHERENCE AND CONTROL

The Reliability and Patient Acceptability of the SmartTrack Device: A New Electronic Monitor and Reminder Device for Metered Dose Inhalers

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Objective: The SmartTrack (ST) is a new adherence monitoring device for pressurized metered-dose inhalers (pMDI), with remote upload and ringtone reminder capabilities. Our aim was to assess its reliability and patient acceptability. **Methods:** Baseline Quality Control (QC): Actuation log accuracy and device functionality tests were undertaken. Simulated Patient Use: Salmeterol/fluticasone inhalers with STs were actuated two times twice daily for 48 h. Accuracy of reminders, data logging, and uploads was tested. Patient Field Testing: Devices were quality tested before dispensing. Asthma patients each field-tested one ST for 7 days and recorded actuations in a diary. Uploaded data were compared to pMDI dose counter and patient diaries. Patient-reported ease of use for the ST was recorded. **Results:** Baseline QC: 9/10 devices had 100% accuracy; one had an electrical circuit failure. Simulated Patient Use: Accuracy was 99% (2/342 actuations duplicated). Patient Field Testing: One device failed pre-dispensing testing (electrical circuit failure). Eight devices were field-tested by asthma patients (mean age 45, 5 females). Mean actuation log accuracy was 97%. Reminders were 100% accurate. All devices successfully uploaded data. Average patient-rated difficulty of use was 6/100 (1 = extremely easy, 100 = extremely difficult). **Conclusions:** The ST has acceptable reliability and utility comparable to other electronic monitoring devices. Its remote data upload capability, reminder functions for missed doses, and graphical display of medication use for patient- and physician-feedback are useful additional features.

Keywords adherence, electronic medication monitoring, materials testing, metered-dose inhaler, patient compliance

INTRODUCTION

Although controller medications are usually highly effective asthma treatments, patient adherence continues to be poor, and under-use is associated with greater health resource use, morbidity, and mortality (1, 2). In clinical research, it is important to obtain accurate data on patients' adherence, and in clinical practice there is increasing interest in differentiating between poor adherence and treatment failure, for example, before adding expensive and/or toxic therapies in severe asthma. Despite some limitations, electronic monitoring provides more accurate data about medication use than self-report, canister weighing, or pharmacy dispensing data (3). In addition, electronic monitoring provides precise data about the timing/pattern of inhaler actuation, including dose dumping (4).

The role of electronic adherence monitoring in self-management is likely to increase with some new generation devices providing reminders for missed doses, remote data uploads, and adherence feedback to patients and/or

clinicians. Audiovisual reminders in adults and adherence feedback in children may also promote adherence with controller medications (5, 6). These advances are exciting as they potentially offer different avenues to patient engagement with asthma management. However, past devices have had problems with inaccuracy and device failure (7, 8). Thus it is important to verify the reliability and utility of new monitoring devices to ensure accuracy, feasibility, and patient acceptability prior to their use in trials or clinical settings (9).

The aim of the study was to assess the reliability and utility of the SmartTrack (ST) (Nexus6, Auckland, New Zealand), an electronic adherence monitor and reminder device for pressurized metered-dose inhalers (pMDI). We investigated the ability of the device to accurately and reliably record actuations of fluticasone/salmeterol pMDIs, provide reminders, and upload data, as well as patient-perceived ease of use and satisfaction.

METHODS

SmartTrack

The ST adherence monitor clips around a standard pMDI (Figure 1) without obstructing its dose counter, drug

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delivery path, or actuation mechanism. The user interface includes a 27×13 mm LCD screen and four buttons.

Device Functions

The device records date and time (nearest second) of pMDI insertion/removal, actuations, and configuration changes (e.g., switching reminders on/off). The supplied devices were factory preset to upload data twice weekly via a SIM card and an external aerial, with up to three upload attempts each time; manual upload was also possible. Uploaded adherence data were accessed on a secure website and displayed in bar graph or time/date format.

Devices had the following basic functions in non-reminder mode: time, date, and battery life displayed on start screen, and Upload menu with Flight mode, Automatic upload or Manual upload options.

Devices configured to reminder mode displayed “Last taken” on the start screen, with time (seconds/minutes/hours/days) since the last actuation (see Figure 1). The message “Inhaler in” or “Inhaler out” appeared during pMDI insertion/removal and was logged. Reminder-mode devices also had a menu for customizing audiovisual reminders for weekday/weekend mornings and evenings, a ringtone selection menu (14 ringtones) and a menu for enabling/disabling reminders. The devices withheld scheduled reminders if pMDI actuation had occurred within the previous 6 h, and actuation cancelled ringing reminders.



FIGURE 1.—Seretide™ pMDI inside a ST in reminder mode with adherence feedback: “Last taken” is displayed on the start screen, stating time since last actuation.

The ST was powered by a rechargeable battery, with battery level displayed on the screen and the website. Some functions were impaired at ≤ 2 bars of battery life, for example, no data uploads, and short beeps replaced reminder ringtones.

Phase 1: Bench Quality Control Testing

Basic quality control (QC) tests are advisable for monitoring devices prior to issue (3). Ten ST devices (two configured in non-reminder and eight in reminder mode) were, therefore, fitted with Seretide™ pMDIs (GlaxoSmithKline, Boronia, Australia). Table 1 shows the functions tested. All steps and times were recorded in a paper log by one researcher using a single external time source. Uploaded data were compared with actions/times/dates in the log. Devices were considered to have failed QC testing if major errors were detected such as complete malfunction (e.g., failure to switch on) or repeated over/under recording of actuations.

Phase 2: Simulated Patient Use

Devices that passed Phase I testing were fitted with Seretide™ pMDIs. Each pMDI was actuated two puffs twice daily for 2 days, then 30 times in fast succession to mimic dose dumping (total 38 actuations) (4). Time/date of all testing steps was recorded in a log. The number of doses on the pMDI dose counter was recorded before/after each pair of actuations and before/after the dose-dumping test.

After simulated patient use testing, ST data were manually uploaded and compared with actions/times/dates recorded by the researcher.

Phase 3: Patient Field Testing

Devices which passed Phase I–II testing underwent 7 days of field testing and patient acceptability testing. The study protocol was approved by the Ethics Committee of University of Sydney, and all patients provided written consent.

Participants. Inclusion criteria were doctor-diagnosed asthma and current use of Seretide™ pMDI as maintenance asthma treatment. Participants were recruited from

TABLE 1.—Key functions tested in bench QC testing.

Non-reminder ST functions tested (all devices)

Button, screen, and menu system functionality

Accuracy of device, date, and time

Accuracy of actuation (three actuations) and pMDI insertion/removal logs (time/date)

Functionality of pre-set uploading by internal SIM-card (i.e., correct timing/success of upload attempt)

Reminder ST functions (reminder configuration only)

Accuracy of reminder ringtones/times

Reminder ringtone silencing on actuation (one actuation)

Accuracy of reminder enable/disable logs (time/date)

Accuracy of “last [puff] taken” (after each actuation) and “Inhaler in”/

“Inhaler out” screen display (during each pMDI insertion and removal)

Abbreviations: pMDI, pressurized metered-dose inhaler; QC, quality control; ST, SmartTrack.

the inner Sydney area and selected to provide a range of age and gender.

SmartTrack Function Tests—All Devices. Patients received brief ST training in how to switch on the device, use the menu system, and how to insert/remove a pMDI in the ST. They were asked to take Seretide™ for 7 days at their usual dose/frequency, treat the device normally (e.g., carry it around/keep in bathroom as per their usual practice), and to record in a paper diary the date/time of every actuation for 7 days. The need for accurate and consistent diary completion was reinforced. After device return, data were uploaded manually and again QC tested. STs were fully charged prior to dispensing and battery levels were recorded on return.

Percentage accuracy was calculated for each device as: $[\text{total number of doses used from pMDI dose counter} - \text{total number of doses missed or extra on ST}] \times 100 / [\text{total number of doses used from pMDI dose counter}]$, and averaged. The time/date of each actuation recorded in the diary was compared to the time/date recorded by the ST.

SmartTrack Function Tests—Reminder Mode. Patients configured twice-daily reminder times for weekdays and weekends and were asked to wait for the reminder before taking their dose(s). They recorded in the diary whether reminders rang on time and were appropriately silenced after actuation.

Data Uploads. STs were set up to auto-upload data to the secure website between 4 and 5 a.m. on 2 days. Dates, times, and numbers of upload attempts per session were examined to assess feasibility of remote uploads.

Utility and Patient Acceptability. On returning the device, patients were asked to report how easy it was to use the ST to take their medication on a visual analog scale from 1 = extremely easy to 100 = extremely difficult and to write comments about the ST.

RESULTS

Phase 1: Bench QC Testing

All functions were performed correctly by 9/10 devices, and function logs were 100% accurate compared with the paper diary. One device (ST14), configured in reminder mode, did not pass QC testing due to failure to log any actuation or pMDI insertion/removal.

Phase 2: Simulated Patient Use

Average accuracy of actuation recording was 98.8%. All functions were performed correctly by 6/9 devices, with function logs 100% accurate compared with the paper diary and pMDI counter. For ST13, 2/38 actuation times differed from diary times by up to 35 s, probably due to human error. The remaining devices passed simulated patient use testing with the following acceptable minor errors: ST10 duplicated 1/38 actuations; ST12 erroneously recorded one actuation during pMDI insertion.

Phase 3: Patient Field Testing

Eight of nine devices passed pre-dispensing QC testing and were available for field testing. One device (ST18) failed pre-dispensing QC testing, switching off during SIM card upload and failing to switch back on due to electrical circuit failure.

Eight patients participated in the 7-day field test (see Table 2). Six had devices configured in reminder mode and two in non-reminder mode.

SmartTrack Logging Accuracy and Functionality. Average accuracy of actuation recording compared with pMDI dose counter was 97% (Figure 2), with 6/8 STs 100% accurate, and two STs (both non-reminder) recording a small number of extra actuations (ST12 = 1/15 extra actuation; ST13 = 6/30 extra actuations). The paper diary showed that these extra actuations were recorded during installation of the pMDI. For one other patient, both ST and pMDI dose counter recorded four more actuations than the diary, suggesting patient rather than ST error. There was no evidence of ST missing actuations. Overall, 95.6% of actuations had the same time/date on the ST record as the paper diary.

The six reminder STs consistently rang ringtones on time and were appropriately silenced after actuations.

Data Uploads. Field testing was performed in areas known for variable cellphone connectivity. All devices were auto-uploaded at least once during the 7-day test. Two of the eight devices (ST15 and ST19; both reminder mode) failed to auto-upload in one of the two sessions, but all data were subsequently uploaded in either the second

TABLE 2.—Patient characteristics.

Age	44.6	(26–72)
Female gender (%)	63	
Highest education level secondary school (%)	38	
Daily inhaled corticosteroid dose ^a	1525	(200–2000)
FEV1 % Pred. [mean (SD)]	84.1	(23)
Years since first controller prescribed ^b	15.8	(10–30)

Note: All results are mean (range) unless otherwise stated.

^aBDP equivalent: 500 mcg FP = 1000 mcg BDP.

^bMissing data for one patient.

Abbreviation: FEV1, forced expiratory volume in one second.

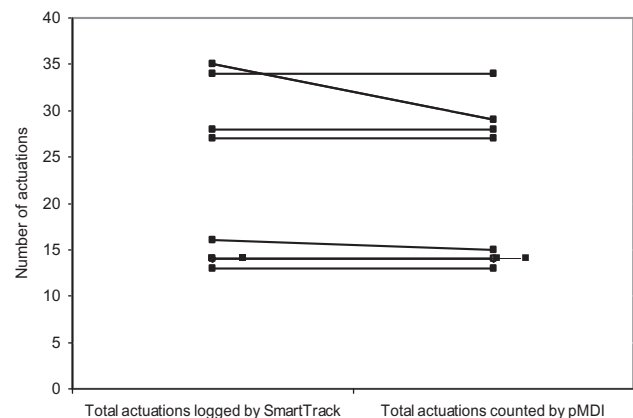


FIGURE 2.—Agreement between ST and pMDI actuation records.

TABLE 3.—Patients' free text comments about the ST.

Topic	Comments
Button functionality	Buttons are small and sometimes hard to register (M26)
Reminder schedule	Would not have the reminders play every 1 minute. Suggest every 5 minutes (M26) [Reminders] rang too regularly perhaps once every 5–10 minutes; short ringtones were good (F22)
Ringtones ^a	Some ringtones were annoying (M26; F35) Some ringtones made me feel under pressure (M26) Great [ringtone] choices, something for everyone (F22)
Attitude to the reminder concept	My partner found [the ringtones] irritating (F35) Since I take my puffs on time usually . . . if the reminder went off when it wasn't convenient . . . I found myself resenting it sometimes; I showed [the SmartTrack reminders] to my colleagues with asthma. (F22)
Reminder volume	I quite liked having a reminder (F35) Someone hard of hearing may not hear [the ringtones] (F32) [The ringtones] were too loud. (F35)
Size	I have 87% hearing loss and I could still hear [the ringtones] without difficulty (M69)
Spacer fit	Was a bit bulky to take away for a weekend (F32)
Ease of use	Does not fit in an Ablespacer (F35) To begin with it was hard to use [the SmartTrack menu system] but after 2 days it was easy (F72)

Note: Data in parentheses represent gender and age, for example, M26 = male, 26 years.

^aRingtones included alarm sounds, jazz, rock, or classical music.

auto-upload or manually when the device was returned to the researcher. Successful uploads were achieved with a mean of 1.8 (median = 1.75) upload attempts.

Battery Life. At 7 days, median battery level was 3 bars, with 1/6 (17%) reminder devices (ST17) and 1/2 (50%) non-reminder devices (ST12) having a full battery (4 bars), and one reminder device (ST11) and one non-reminder device (ST13) having ≤ 2 bars. There was no relationship between battery life and number of data upload attempts.

Utility and Patient Acceptability. All patients reported that it was easy to use the ST to take their medication (mean score 5.6 (range 1–14); 1 = extremely easy, 100 = extremely difficult). Comments on patient acceptability were made by 7/8 patients (Table 3).

DISCUSSION

This is the first study on the reliability and utility of the ST electronic monitoring and reminder device for pMDIs. We conducted a three-phase study comprising bench QC testing, simulated patient use, and patient field testing which included more than 550 actuations across multiple days and devices. Two of ten devices failed bench testing, but the remaining eight devices performed well, accurately recording the number of actuations and the date and time of actuation, providing patients with reminders to use their inhaler, and uploading data to a secure website. The patients reported that the ST was very easy to use.

Although for any electronic monitoring device failure rates should ideally be as low as possible, the failure rate of the ST is similar to other available adherence monitoring devices such as the Chronolog/MDILog (Westmed Inc, Colorado, USA) (10–53%) (4, 9–11), Doser (Meditrack Products, Hudson, USA) (0–21%) (4, 8, 12), and Smartinhaler (Nexus6, Auckland, New Zealand) (0–20%) (13–15). Routine QC testing prior to dispensing and after return remains essential for any electronic monitoring

device, in both research and clinical practice (3). These tests will help to reduce data errors and data loss due to device malfunction which may occur in up to 20% of devices. In addition, allowance should be made for 10–20% extra devices to cover replacements required as a result of this routine testing.

In our testing, accuracy of ST actuation recordings compared with the inbuilt pMDI dose counter averaged 97%. Patient diaries allowed us to identify the timing and cause of extra actuations. Two devices recorded spurious extra actuations when the pMDI was inserted. Patients should only need to replace the pMDI when it is empty, and any such errors would be easy to handle by removing from analysis any actuation(s) with the same time/date stamp as pMDI insertion record(s). The ST achieved a high level of accuracy in the field. Few studies have conducted field testing but by comparison, the Doser—a more basic device which counts only number of actuations/day—achieved 84.5% accuracy in a field study of 5 patients over 4 weeks (4).

The ST allows automatic data uploads to a secure website, reducing the risk of data loss between visits. In an area known for variable cellphone connectivity, a mean of 1.8 upload attempts/session were required, so three attempts per session appear appropriate. Poor connectivity in more remote or insufficiently serviced areas may require more frequent uploads or manual uploads by patients.

Patients reported that the STs were easy to use but one of eight patients commented that the buttons were small, the device was bulky, and it was not compatible with a particular spacer. The oldest participant (72 years, female) reported that she initially found the ST menu system difficult to use. Older patients may require some additional support when first using electronic devices such as the ST.

The ST has a number of advanced features. It provides real-time feedback on the last dose taken, plays twice daily customizable reminders for missed doses, and remotely uploads data automatically by SIM card to web-based

software allowing a graphical display of medication use for feedback to the patient and physician (Figure 3). The ST has good memory capacity (maximum storage of 1536 logs, equivalent to 15 actuations and two reminder logs daily over 90 days) and security. A screen icon, rechargeable battery, and external charger allow patients to monitor and control battery life. The ST logs the time and date of removal/insertion of the pMDI providing useful information about data loss due to pMDI removal from the ST. The device attaches firmly to a pMDI and is compatible with Volumatic spacers (Allen & Hanburys, Boronia, Australia).

The main disadvantage of this form of adherence monitoring, apart from device failure rates, is likely to be cost, although STs are potentially reusable with appropriate cleaning. Currently advertised prices for individual devices are ST (USD220), Doser (USD28), SmartInhaler (USD120), and MDILog (USD225). Other costs include SIM cards, activation, and wireless data transfer (for SIM card uploads), software, and any necessary software customization. Patients are increasingly willing to pay for remote health monitoring services (16). In the context of severe asthma, the high cost or risk associated with new biological add-on therapies may justify expenditure on electronic monitoring as disentangling poor treatment response from poor adherence can be extremely difficult in clinical practice (17). Challenges are the large number of different pMDIs and the vulnerability of clip-on devices to changes in pMDI design/dimensions.

In reminder mode for adherence promotion, devices may require more frequent charging than non-reminder

mode, particularly for less adherent patients because audiovisual reminders only ring if doses are missed. In battery tests carried out with three STs set for twice-daily reminders, and with actuations twice daily (100% adherence), once daily (50% adherence) or never (0% adherence), the ST battery became flat after 67, 58, and 49 days, respectively. Battery life may, therefore, be a limitation, but regular battery charging can be monitored/supervised by clinicians or researchers via a secure website which displays device-specific battery level at each upload.

The main limitation of this study is that in order to document the accuracy of the devices, field-testing required recruitment of adult patients with likely high compliance to device use and record keeping. Diaries are not a foolproof method for validation but, in this study, we emphasized accurate and consistent diary keeping at patient enrolment, and agreement between the pMDI counter and the patient diary on total actuations averaged 98.5%. In more typical populations, there may be problems with device logs or failure due to dropping, transportation in bags or pockets or difficulty actuating the device by children or the elderly (8). Concurrent comparison between the ST and other devices would have added useful information in this study, and further research could address this.

CONCLUSIONS/KEY FINDINGS

In conclusion, the ST is a feasible device which has acceptable accuracy and reliability, and several advanced features although it has some limitations with respect to

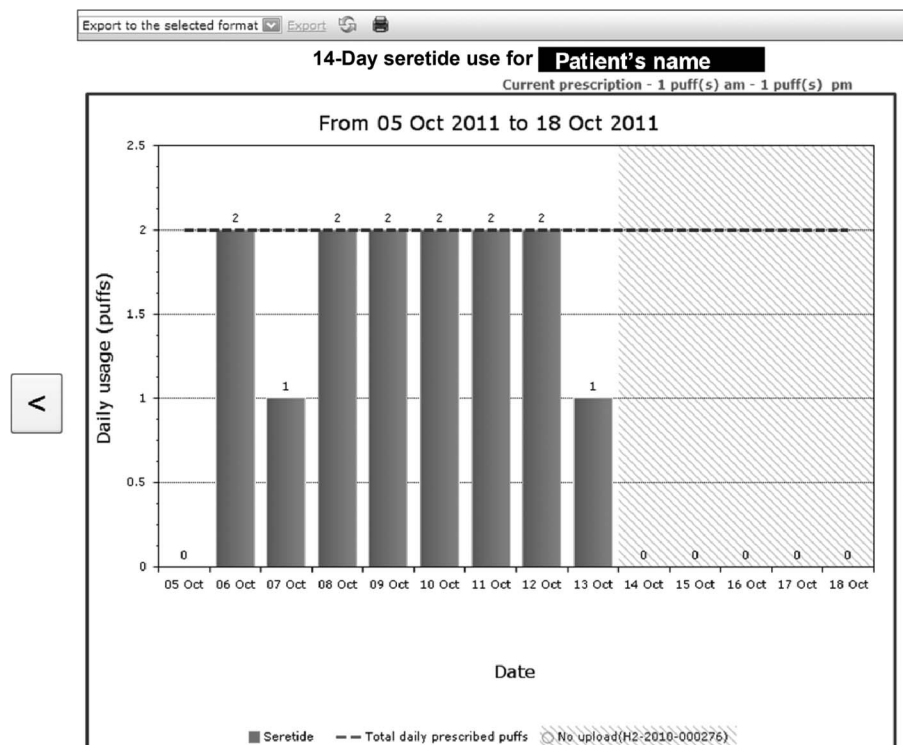


FIGURE 3.—Graphical display of medication use feedback. Bars show the number of puffs taken daily. The prescription (2 puffs daily) is represented as a horizontal dashed line (reproduced with the permission of Nexus6 Ltd).

device failure rate and battery life. It allows the clinician or researcher to ascertain precisely when each dose was taken, allowing observation of longitudinal patterns of patients' medication use, including under-use prior to exacerbations and over-use prior to clinic visits. These detailed data can help distinguish poor treatment response from poor adherence. In clinical trials, these devices can be used to monitor adherence, dose response, and the timing of side effects. As with other electronic monitoring devices, further work is needed to improve reliability. Future studies are needed to ascertain the efficacy of reminders and medication use feedback in adults with asthma.

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AUTHOR CONTRIBUTIONS

JF conceived the study, contributed to the study design, collected the data, carried out the analysis, drafted the manuscript and took overall responsibility for the integrity of the data and the accuracy of the analysis. LS, TU, SS and

CR contributed to the study design, interpretation, and editing of the manuscript. HR conceived the study and contributed to the study design, interpretation, and drafting of the manuscript.

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