SMARTBYTE

SMARTBYTE® DEVICE

USER GUIDE

Rx Only

Caution:
Federal law restricts this Device to sale
by or on the order of a physician.

Read this information completely before
using your SmartByte® device.

1. Indications for Use

The SmartByte Device is intended to aid in weight management in overweight to obese individuals. The Device is indicated for individuals with a body mass index (BMI) in the range 27-35 kg/m² in conjunction with behavioral modification instruction.

2. Description of the SmartByte Device

The SmartByte Device is intended to be used by overweight to obese individuals. Overweight means a body mass index (BMI) in the range of 27-29.9 kg/m². Obese means a BMI in the range of 30-35 kg/m².

The SmartByte Device will be made specifically for you to take up space in the upper palate (the roof) of your mouth. The Device will be made from a mold of your palate taken by a trained healthcare provider using the Palatal Mold Kit component of the Device in your healthcare practitioner's office. The SmartByte Device should be worn during meals. The Device is designed to limit bite size and reduce the amount of food or caloric liquid consumed. The Device is available with wire clasps or wrap-around wires to position the Device in the mouth (Figure 1). The **parts** that occupy the space in your mouth (pink and clear parts in the pictures below) are the same.

Figure 1: SmartByte Device and Temperature Sensor
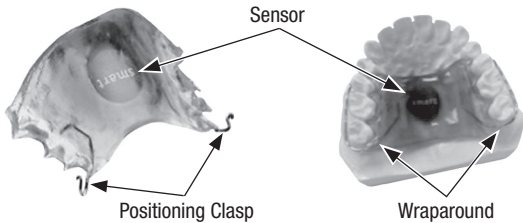
SmartByte Devices using the positioning clasp method (left) and wraparound method (right)

The SmartByte Device is made of acrylic. The soft edges are made of Silident polymers. The clasps and wraparound wires are made of Elgiloy (a type of flexible metal material).

The SmartByte Device contains a small sensor that measures and records environmental conditions (such as temperature) at 5 minute intervals and stores the data for up to 56 days. The sensor detects when the Device has been inserted in your mouth. If you wish to use the optional SmartByte Reader component, you will be able to track your actual Device usage.

If you desire, your healthcare provider and/or support group can also see your progress. The SmartByte Reader is described below.

The sensor is operated by a small 3-volt coin battery. The battery and the SmartByte Device have a life span of 1.2 years. The battery and sensor are both sealed in the Device and cannot be replaced. The only purpose of the sensor is to monitor Device usage. As noted above and discussed below, optional components (SmartByte case / reader, iPhone or Android phone app that can be downloaded) are available with the Device to upload and view the sensor data. The data provide feedback and graphs on how often you use the Device.

3. Contraindications, Warnings and Precautions
Contraindications

Eating Disorder: Do not use the Device if you have eating disorders (such as anorexia nervosa (abnormally low body weight, intense fear of gaining weight, and distorted perception of body weight), bulimia nervosa (eat large amounts of food and then purge (e.g., vomit) to not gain weight). The Device is a weight management aid and is contraindicated (means do not use) in individuals with eating disorders. There may be safety risks if you have an eating disorder and use this Device.

Pregnancy: Do not use the Device if you are pregnant. The Device is a weight management aid and weight loss is contraindicated (means do not use) in pregnancy. There may be safety risks if you are pregnant and use this Device.

Warnings

Hot Liquid/Food Hazard: Test the temperature of any hot liquids or foods before drinking or eating while using the SmartByte Device. As you normally would when you are eating (without using the SmartByte Device), make sure the liquid or food is at a comfortable temperature for you to drink or eat. This may be different temperatures for different people. Do not swallow the liquid or food without sensing the temperature first. The SmartByte Device covers the roof of your mouth. Once the Device is in your mouth, you may not be able to sense the temperature of liquid or food before swallowing.

Removal at Night: Do not sleep with this Device in your mouth as it may cause breathing difficulties. The Device is intended to be used only during eating or drinking (caloric beverages).

Precautions

Gag Reflex: Ask your physician for help to see if you have a sensitive gag reflex. If you do, you may not be a good candidate to use this Device.

Get Used to Your Device: Take some time to get used to the feel of the Device in your mouth. You may need time to adapt to using the Device (having the Device in your mouth when eating or drinking).

Wear Only When Eating or Drinking Caloric Beverages: Remove the Device when finished eating or drinking. The SmartByte Device is intended to be placed in the mouth only during eating, including meals, snacks, and drinking calorie-containing beverages.

Taking Small Bites: Take small bites of food. Since you will have less space in your mouth when the SmartByte Device is in place, you will want to take small bites of food. If you take large bites, you might need to take some food out of your mouth, or you might choke or gag on the food when trying to chew or swallow.

Loose Fit: Make sure the Device feels like it fits properly and is in place in your mouth before you eat or drink. You should not feel the Device moving or wobbling in your mouth. Do not attempt to eat if the Device is loose when inserted, and contact your healthcare professional who prescribed the Device for you. The healthcare professional will arrange for the manufacturer or its representative to examine and, if necessary, replace or repair your Device.

Biting Down with Device in Place: You do not need to take any action if you feel contact with the Device when biting down. However, if a piece of the Device becomes loose (such as wobbling or falls out of place) or breaks off, stop using the Device. Your healthcare professional will arrange for the manufacturer to examine, and if necessary, replace or repair your SmartByte Device.

Individuals with a BMI <27 and BMI >35: Do not use if your BMI is <27 or > 35 kg/ m². The SmartByte Device has not been studied in these individuals.

Oral Health: Do not use the SmartByte Device if you have not had a dental examination within the last 12 months. Do not use the Device if you are not in good oral health. You should follow up with your dentist regularly to maintain oral health.

Conditions in the Oral Cavity: Do not use the SmartByte Device and tell your prescribing healthcare professional if you have any of the following conditions (or develop any of these conditions):

- Deformed oral shape (e.g., bony protrusion on palate or prior surgery such that Device cannot sit flush against the palate)

- Removable partial dentures (false teeth) in your upper arch (roof of mouth)

- Inadequate oral anatomy (e.g., 3 or more loose or missing teeth on the upper arch, molars or pre-molars either missing or worn down to within 4 mm above gum line, teeth with too much curvature that make placing and removing the Device difficult, an ore-nasal fistula (hole connecting the mouth and the nasal cavity) secondary to cleft palate, or a large torus palatinus (bony growth or protruding part on the palate)

- Veneers (a thin covering for the front surface of a tooth)

- Temporary crowns (tooth-shaped cap that is placed over a tooth)

- Placement of dental implants within 12 months of Device use

- In the process of having teeth moved or have completed a tooth moving procedure in the past 6 months and use any removable retainer Device (e.g., retainers, or aligner trays)

- Removable or fixed bridges (replacements of missing teeth attached to the neighboring teeth or implant)

The SmartByte Device has not been studied in patients with these conditions. Patients with these conditions may not be able to properly use the SmartByte Device.

Other conditions: Tell your prescribing healthcare professional before using the SmartByte Device if you have or had the following conditions, or if you develop any of these conditions after you start using the Device:

- Neurological disease or condition(s) (e.g., history of stroke, or other diseases that cause problems swallowing);

- Diabetes;

- Current smoker or user of smokeless tobacco or nicotine gum; or

- Sjogren's syndrome (immune system disorder that causes dry mouth) or chronic dry mouth.

The SmartByte Device has not been studied in patients with these conditions. There might be more risks for these patients if they use the SmartByte Device.

Risks and Benefits

The discussion provided below describes results from clinical studies conducted by Scientific Intake (SI). The pivotal study was the larger study of the Device. The confirmatory study included fewer subjects and was intended to confirm the findings from the larger pivotal study.

3.1. Pivotal Study

The SmartByte Device was tested in a clinical study in the United States. The study evaluated if the SmartByte Device is safe and helps weight management in 173 overweight to obese individuals. The study looked at people with body mass index [BMI] between 26 to 36 kg/m². The study compared the weight loss between SmartByte Device users and control subjects (who did not use the SmartByte Device) after four months. Few SmartByte Device users had adverse events (negative side effects) related to the Device.

Study subjects were randomly assigned (like 'drawing straws') to either the SmartByte Device group or a control group. Device group users received a SmartByte Device plus nutrition, diet and exercise counseling on a DVD. The control group did not receive a SmartByte Device and received only the same nutrition, diet and exercise counseling on a DVD. The information contained on this DVD included guidelines for healthy eating and exercise. The DVD also includes information about realistic weight loss goals and the importance of personal and professional support systems for subjects. Subjects were evaluated in the 16-week study (or 4 months) every two weeks. During visits to the clinical site, subjects were weighed, had vital signs taken, and watched the counseling video. Any adverse events were recorded. For SmartByte Device subjects, the amount that the Device was used was also recorded.

SmartByte Device and control subjects were similar, including in age, gender, ethnic background, height, weight, and BMI.

The safety results are shown below for the full study population: 102 subjects in the Device group and 71 in the control group. The full study population includes subjects who followed the protocol as well as those who did not use the Device as often as instructed or did not attend at least 4 of the 7 study visits. The weight loss results are shown for the full study population, as well as for the subgroup of subjects who followed the study protocol during the 4-month study. Subjects who followed the protocol (41 in the Device group and 67 in the control group) included subjects who used the Device during at least one-third (33%) of meals, and went to at least 4 of the 7 follow-up visits. The control subjects had to attend at least 4 of 7 visits to be considered to have followed the protocol.

Of the 173 subjects enrolled in the study, 65 subjects (61 Device subjects and 4 control subjects) did not use the Device as instructed, did not follow the protocol, or did not finish the study/attend enough visits. Subjects who used the SmartByte Device were supposed to wear the Device when eating any food and drinking any caloric liquid. Subjects in the control group did not use any Device, and only had to go to the clinic visits every 2 weeks and watch the DVD.

3.1.1 Safety

Few Device-related adverse events happened during the study. There were a total of 6 minor adverse events in 5 of the 102 subjects who used the SmartByte Device.

The minor adverse events reported included gum irritation in 2 subjects. There was soreness in mouth in 1 subject. One subject reported "gag reflex" (gagging when placing the Device in the mouth). Two subjects reported temporary choking on food. These events were not serious, and went away quickly without medical treatment.

3.1.2. Effectiveness

The benefits of the SmartByte Device were tested in a clinical study in the United States. The data demonstrated significantly more weight loss with the SmartByte Device compared to the control groups at the end of four months. Results measured the subjects' total body weight loss compared to their body weight at baseline.

In the full study population, including those who did not use the Device as often as instructed or attended less than 4 of the 7 study visits, the average weight loss in the SmartByte Device group (102 subjects) was 1.65% compared to 0.36% in the control group (71 subjects). For the subjects who followed the protocol, the average total body weight loss in the SmartByte Device group (41 subjects) was 4.39% compared to 0.29% in the control group (67 subjects). Therefore, 4.39% total body weight loss in a subject who weighs 200 lbs. at baseline would translate to a weight loss of 8.8 lbs. with the SmartByte Device.

3.2. Confirmatory Study

Another clinical study was conducted in the United States to study the SmartByte Device in overweight to obese individuals whose body mass index [BMI] measured 27 to 35 kg/m². All of the study subjects received the SmartByte Device plus weight loss counseling using a DVD. The DVD used in this study was the same used for the pivotal study. Subjects were

evaluated in the 16-week study once every 2 weeks. During study visits, subjects were weighed and checked for adverse events, viewed the counseling DVD, and had a physical examination. All subjects received the SmartByte Device. The data for how often they used the Device was also uploaded from the Device to the health care provider's computer during the visit. The study encouraged subjects to follow the protocol. The study emphasized that the subject needs to use the Device often to help weight loss. There was a screening period before subjects were qualified to join the study to make sure that he or she was motivated to lose weight. Subjects were not paid based on their amount of weight loss.

Study subjects were 20 to 49 years old and had an average BMI of 31.70 kg/m² before starting to use the SmartByte Device. The subject received the wraparound or side clasps version of the SmartByte Device based on evaluation of the subject's oral anatomy. These two versions are very similar, and the safety and weight loss results were also similar.

Data about how effective the SmartByte Device is to help weight loss were collected. The full study population consisted of 76 subjects all in the Device group. The full study population includes subjects who followed the protocol as well as those who did not use the Device as often as instructed or did not complete the last study visit. The weight loss results are shown for the full study population, as well as for the subgroup of subjects who followed the study protocol during the study. Subjects who followed the protocol (40 of the 76 subjects) included subjects who used the Device at least 7 times per week for at least 14 of the 16 weeks of the study, during at least one-third (33%) of eating episodes, and completed the last study visit at week 16. This use rate is lower than recommended for clinical testing purposes. You should use the Device during all meals and when drinking caloric beverages to maximize potential benefit from using the Device. The safety results are from all 76 subjects who received the SmartByte Device. Nine (9) of these 76 subjects did not complete the study due to withdrawal of consent (n=7), lost to follow up (n=1), and adverse event (pregnancy) (n=1). None of their reasons for leaving the study were due to safety events related to the SmartByte Device.

3.2.1. Effectiveness

As described below, the results of this study were similar to those reported in the other study (described above). Subjects who used the Device as instructed showed a consistent rate of weight loss over the 16-week period, and more weight loss on average compared to the full study population.

On average, the full study population lost 2.05% of their total body weight by the end of the study. Subjects in this group lost an average of 3.75 lbs. (range 9.9 lbs. weight gain to 19.4 lbs. weight loss) from their baseline weight. The subjects who followed the protocol lost 2.93% of their total body weight at the end of the study. Subjects in this group lost an average of 5.2 lbs. (range 9.9 lbs. weight gain to 18.7 lbs. weight loss) from their baseline weight.

How much weight subjects lost depended on how often they used the Device. For example, the 17 subjects who used the Device for 15 or more times per week lost an average of 6.5 pounds. The 47 subjects who used the Device for 7-14 times per week lost an average of 3.1 pounds (including the 16 subjects who showed no weight change or gained weight). The 12 subjects who used the Device for 0-6 times per week lost an average of 2.5 pounds (including the 7 subjects who showed no weight change or gained weight).

Weight loss increased over time for those who used the Device as instructed. Subjects who used the Device as instructed for 1 month lost 1.9 lbs., for 2 months lost 2.1 lbs., for 3 months lost 3.2 lbs., and for 4 months lost 5.2 lbs. on average compared to their weight at baseline (before using the Device).

3.2.2. Safety

Few adverse events occurred during the study that were considered to be related to the Device. These events, one hard palate abrasion event (Device scratching the roof of the mouth) and two tongue laceration events (Device scratching the tongue), were not considered to be serious, and resolved during the study without any medical treatment. A few additional adverse events happened in the study that were not considered to be related to use of the SmartByte Device.

3.3. Risks of Device Use

The risks of using the Device, based on the events seen in the studies described above, are presented in Table 1. No unexpected risks were reported in the studies. Some of the risks below may be prevented by following the instructions in this manual and from your healthcare provider. However, there may be some risks with correct Device use too. Although some of these hazards were reported only for the older version of the Device, they may be potential risks of using the SmartByte Device.

Table 1: Risks of Device Use

Hazard	Subjects with Hazard	Harm/Potential Harm	Affected Subjects
Loose fit of Device	16 of 178 subjects	Needed new Device	16
Device worn down or bending*	11 of 178 subjects	Needed new Device	11
Soft edge separation**	15 of 178 subjects	Needed new Device	15
Wire felt upon biting	8 of 178 subjects	Needed new Device	8
Acrylic, ball clasp, or other breakage*	7 of 178 subjects	Needed new Device	7
Device lost	7 of 178 subjects	Needed new Device	7
Reaction to Device†	6 of 178 subjects	Gag reflex upon insertion of the Device	1
		Choked on food while using Device	2
		Gum irritation	2
		Soreness in mouth	1
Food caught in Device	5 of 178 subjects	Needed new Device	2
		Hard palate abrasion; temporarily suspended use of the Device	1
		Tongue laceration (scratched)	2
Uncomfortable fit of Device	3 of 178 subjects	Needed new Device	3
Device retained food flavor of previous meal	2 of 178 subjects	Needed new Device	2
Device damaged by study subject or third party	2 of 178 subjects	Needed new Device	2
Difficult removal	1 of 178 subjects	Needed new Device	1

* Reported in pivotal study
** Reported in confirmatory study
†These reactions resolved without medication, and the subjects were able to continue the study.

The information in the table above is based on the first 4 months of the study. It is unknown what adverse events may develop after 4 months and how many subjects may develop them. In these studies, we did not observe some adverse events we thought were possible. It is not known the possible harm from these types of events or how often they might happen (for example, with longer use or more widespread use). In addition, there may be other risks that are not known yet.

Most of the Devices lasted throughout the clinical studies. The few Devices that showed breakage or separation were of the older Device design. For example, soft edge separation was reported for 15 subjects in the

confirmatory study. However, after this material was changed to use a better material, no subjects reported soft edge separation. Similarly, after the material of the positioner wires was changed to Elgiloy (a type of flexible metal material), there was no clasp breakage (which was reported with the earlier version of the Device).

Other risks include uses of the Device by patients having certain oral conditions who are not suitable to use the SmartByte Device. Those conditions are listed in the Precautions above (such as deformed oral shape, removable false teeth in your upper arch, crowns, etc.). The SmartByte Device has not been studied in patients with these conditions. Patients with these conditions may not be able to properly use the SmartByte Device.

In addition, persons with reduced physical, sensory, or mental capabilities should not use the Device, unless they have approval from a person responsible for their safety, or from their doctor. Diabetic patients may not use the Device because they have a higher than normal risk of gum disease, including infections of the gum and bone that hold the teeth in place. In advanced stages, these conditions could lead to painful chewing problems and even tooth loss. Smokers and users of tobacco or nicotine gum may also be at greater risk for gum disease. Use of the SmartByte Device in these individuals has not been studied. Individuals with Sjogren's syndrome may have dry mouth symptoms, and use of the SmartByte Device has not been studied in these individuals. Further, if you do not read or follow this User Guide, there is a risk that you will not use this Device correctly.

4.4 Benefits of Device Use

The SmartByte Device is intended to aid weight management in overweight to obese individuals. Therefore, the benefit of using this Device is to potentially help you manage or lose weight. Changes in weight were associated with use of the SmartByte Device in both studies described above.

In the pivotal study, the average total body weight loss for the full study population (102 subjects) who used the SmartByte Device was 1.65%. For subjects who did not use the SmartByte Device, there was only 0.36% total body weight loss. As an example, in a subject who weighs 200 lbs. at baseline, a 1.65% total body weight loss would mean that he lost 3.3 lbs.

In addition, for the subjects who followed the protocol and used the SmartByte Device (41 subjects) as they were instructed, the average total body weight loss was 4.39%, compared to 0.29% for the 67 control subjects (who did not use the SmartByte Device). As an example, in a subject who weighs 200 lbs. at baseline, a 4.39% total body weight loss would mean that he lost 8.8 lbs.

Similar rates were observed in the confirmatory study for all 76 subjects who used the SmartByte Device. The mean total body weight loss was 2.05% for all of the study subjects. The mean weight loss in this group was 3.75 lbs. (range 9.9 lbs. weight gain to 19.4 lbs. weight loss) compared to the subjects' baseline weight.

Of these subjects, the subjects who followed the protocol (used the Device at least 7 times per week for at least 14 of the 16 weeks of the study, during at least one-third (33%) of eating episodes, and completed the last study visit at week 16) lost an average of 2.93% in weight. The mean weight loss in this group was 5.2 lbs. (range 9.9 lbs. weight gain to 18.7 lbs. weight loss) compared to the subjects' baseline weight.

The data from these studies showed that there is more weight loss when the SmartByte Device is used more often.

Good things about the SmartByte Device

• Convenient use (only needs to be worn during meals)

• Does not require surgery (no anesthesia, no implant)

• No medication required

• Device can be taken out and you can stop using it at any time

• Continue to eat the foods you like

• Support to help you change your eating habits and manage your weight

4.5 Conclusion

Overall, there was gradual and steady weight loss in the SmartByte Device subjects over the 16-week study period in both studies. Subjects showed total body weight loss of 2.93% to 4.39% when the SmartByte Device was used as instructed in the two studies described above. This would mean weight loss of about 5.86 lbs. to 8.78 lbs. for someone who weighed 200 lbs. at baseline. The amount of weight loss was related to the frequency of use of the Device and you should use the Device for every eating episode to obtain the best results. Results also demonstrated that few adverse events happened. None of the events were serious.

5. How to Use the SmartByte Device
When to Use the SmartByte Device

Review the Warnings and Precautions above before using the SmartByte Device. For example, you should make sure the liquids or foods are not too hot. Tell your health care provider if you have any conditions described in the Warnings and Precautions, such as pregnancy, dental work, or tobacco use. Follow the instructions from your health care professional and in this manual.

If you develop conditions after you start using the Device (see Precautions), stop using the Device and talk to your health care professional. For example, if a sore spot develops on your gum or the roof of your mouth after using the Device, stop using the Device until the soreness goes away. Contact your health care professional who prescribed use of the SmartByte Device.

If you feel or see that there is a change in how your Device fits your mouth, or if the Device is damaged, broken, or distorted, you should contact your health care professional. The health care professional will examine and, if necessary, replace or repair the Device.

Place your SmartByte Device in your mouth before eating all snacks and meals, and before consuming beverages that have calories. The clinical studies described in the above section showed an increasing trend of weight loss when the Device is used more often. To increase your chances of weight loss, you should use the Device during meals, snacks, and caloric beverages.

Remove the Device to clean it and store it after meals.
Your Device is made to fit your mouth, and should always be comfortable. If you insert the Device in your mouth and it is loose or is not seated properly, remove it. Then reinsert the Device.
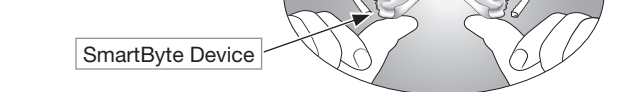
Inserting the SmartByte Device
To insert, gently hold the Device by the sides and align the Device between your teeth. Push upward until the Device is seated in the roof of the mouth or the Device is in contact with the roof of the mouth, as illustrated in the drawing. The same method for inserting the SmartByte Device can be used for both positioning methods. After the Device has been inserted, the Device should feel seated and should contact the roof of the mouth. Eat and drink as you would normally (when not wearing the SmartByte Device). You might be able to take only smaller bites of food or smaller gulps of liquids.

Inserting the SmartByte Device

To Insert:
Align the Device between appropriate teeth and push upward until it clicks into place.
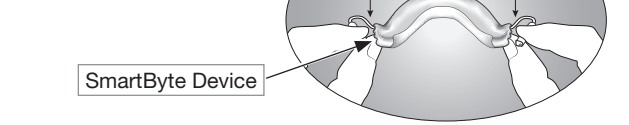
SmartByte Device

Removing the SmartByte Device
To remove, gently pull the SmartByte Device straight down and off of your teeth using the positioning clasps or wraparound part on the sides of the Device. Do not pull the Device sideways or forward when removing. Then take the SmartByte Device out of your mouth. Always remove the Device after you have finished eating and drinking. You should not nap or sleep with the Device in your mouth. After removing the Device, follow the instructions for "Care of the SmartByte Device" below and place the Device in the case.

Removing the SmartByte Device

To Remove:
Pull ball clasps straight down and off your teeth.

SmartByte Device

The SmartByte Device should not be used in the mouth for more than an hour at a time. The Device should not be used for more than 2.5 hours a day. The SmartByte Device has not been studied for use exceeding 1 hour at a time or 2.5 hours a day.

6. Care of the SmartByte Device

a) Your SmartByte Device should always be removed after eating and cleaned.

  • Clean or rinse the Device after you finish eating or drinking caloric liquids. You should clean it soon after use so that it will be easier to clean and to prevent build-ups of food debris on the Device.

  • Do not use extremely hot water. Your SmartByte Device might distort if extremely hot water is used.

b) Use a toothbrush and toothpaste to gently clean the Device. Always rinse with water and dry your SmartByte Device after cleaning and store it in the case that is provided when not in use. All food debris should be removed. Hold the Device in one hand and clean with the other.

c) Address your personal oral hygiene as you normally would when the Device is removed. Regular brushing, flossing and the use of mouth rinses all contribute to good oral health.

d) When your SmartByte Device is not in use, store the Device in its case. This will prevent it from getting lost, damaged, or misplaced.

e) Avoid soaking the Device in any liquid. Never use effervescent (fizzy) denture cleaners or boil the Device in water.

f) If you have pets at home, such as dogs, keep the Device out of their reach.

7. Information Regarding Optional Components of SmartByte Device
Along with the SmartByte Device, you were provided with optional components:

• SmartByte Case/Reader (including a USB cable for charging), which is a reader for reading the usage data stored in your SmartByte Device using infrared and Bluetooth data transfer.

• An app that will need to be downloaded from the Apple App Store or Google Play and loaded on your smartphone in order to upload and access the data stored in your SmartByte Device.
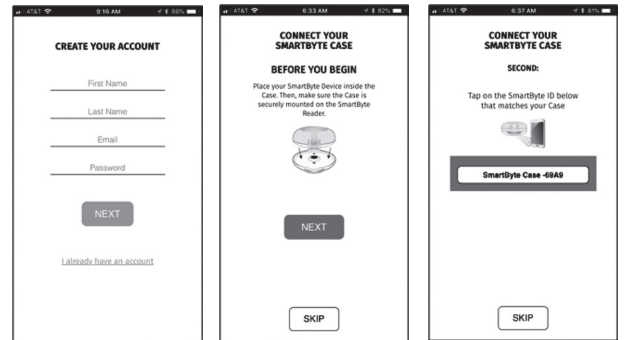
SmartByte® Bluetooth Reader - User Manual
Your SmartByte Device case has been designed so that you can use the case's built-in Bluetooth reader to periodically upload the stored sensor data from your SmartByte to your smartphone to keep track of your usage of the Device, compliance history, and progress to weight goal.

To use the SmartByte case as a reader, please follow these step-by step instructions:

Getting Ready
1. Make sure the Bluetooth feature is enabled on your smartphone by making the appropriate selection in your phone's "Settings" menu.

2. If you haven't already, download and install the SmartByte App from your app store.

3. Follow the instructions in the app to create an account and connect your SmartByte case to your phone. Sample screenshots are provided below.

CREATE YOUR ACCOUNT

First Name

Last Name

Email

Password

NEXT

I already have an account

CONNECT YOUR
SMARTBYTE CASE

BEFORE YOU BEGIN

Place your SmartByte Device inside the Case. Then, make sure the Case is securely mounted on the SmartByte Reader.

NEXT

SKIP

CONNECT YOUR
SMARTBYTE CASE

SECOND:

Tap on the SmartByte ID below that matches your Case

SmartByte Case -49A9

SKIP

If you ever need to connect a new SmartByte case to your phone, click the Settings icon in the upper right corner of the screen and select "Manage SmartByte Case." Tap the button that says "Change your SmartByte Case" and follow the instructions in the app.

Initial Set Up & Activation
Complete all the steps below to activate your SmartByte Device and turn on the sensor BEFORE you wear it for the first time. If you need assistance, call Customer Care at 1-833-843-7324

Step 1. Download the SmartByte App & Create an Account

1a. Go to the app store, search for and download the SmartByte App to your smartphone.

1b. Once downloaded, create an account in the app.

1c. Be sure your phone's Bluetooth is on and you have a wifi or cellular signal.

Step 2. Place the SmartByte Device in the Case

2a. Open the blue cover on the Case and place your SmartByte Device inside with the wire arms of the SmartByte Device resting on the bottom of the Case.

2b. Close the blue cover.

2c. Make sure the Case is securely mounted on the SmartByte Reader.
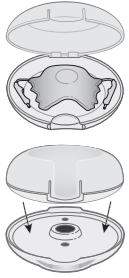
Step 3. Pair SmartByte Reader with SmartByte App

3a. To turn the reader on, press and hold the curved button on front of the SmartByte Reader until the button lights up green and the Case is illuminated with blinking blue lights.

3b. Follow the prompts on the SmartByte App to complete the pairing of the SmartByte Reader to the SmartByte App.

3c. Once your SmartByte Reader is paired with your SmartByte App, the SmartByte Reader will automatically shut off.
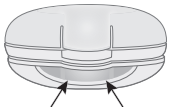
IMPORTANT: You must complete the pairing to activate the sensor in your SmartByte Device before using it, allowing your data to be recorded.

Charging Your SmartByte Case/Reader
The case does not need to be attached to the reader while charging.

1. Locate the USB charging port on the hinge side of the SmartByte reader.

2. Connect the reader/case to a powered USB port (on a laptop or charger), using the mini-USB charging cable supplied.

3. The charge status LED will be RED while the battery is charging and will turn GREEN when charging is complete (approximately 1 hour).

4. Disconnect and store the mini-USB cable.

5. Your SmartByte reader/case can now be used for uploading your data.

Sample Combined FCC/IC Label

FCC ID: **2AJ3RBA10248**
IC ID: **22044-BA10248**

Regulatory Statements
This Device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This Device may not cause harmful interference, and (2) this Device must accept any interference received, including interference that may cause undesired operation.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Information to User
The user's manual or instruction manual for an intentional or unintentional radiator shall caution the user that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. In cases where the manual is provided only in a form other than paper, such as on a computer disk or over the Internet, the information required by this section may be included in the manual in that alternative form, provided the user can reasonably be expected to have the capability to access information in that form. The user's manual or instruction manual for an intentional or unintentional radiator shall caution the user that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. In cases where the manual is provided only in a form other than paper, such as on a computer disk or over the Internet, the information required by this section may be included in the manual in that alternative form, provided the user can reasonably be expected to have the capability to access information in that form.

8. Warranty
Scientific Intake warrants that the SmartByte Device is free from defects in materials and workmanship when used properly in the application for which it was intended. Any such defects should be noted and returned to Scientific Intake within ninety (90) days following receipt of the SmartByte Device or this warranty is null and void. The warranty is void when used with non-Scientific Intake products.

Defective SmartByte Devices must be returned following Scientific Intake's then most current instructions. In the event the SmartByte Device does not conform to the warranty above; your sole and exclusive remedy and Scientific Intake's sole and exclusive liability shall be to replace the SmartByte Device. No assurance is made regarding the outcome of any treatment using the SmartByte Device. Results will vary depending on a person's individual biology and other factors. Scientific Intake excludes from its liability all other expressed or implied expenses directly or indirectly arising from the use of the SmartByte Device. Except for the limited warranty provided above, neither Scientific Intake nor its agents assume any other liability or responsibility in connection with the SmartByte Device.

9. Contact Information
Please contact your health care provider or Scientific Intake at the number provided below if you feel or have any irritations or other medical problems in your mouth. Please also contact the health care provider or Scientific Intake if you have questions about the fit or use of your SmartByte Device, if the Device does not fit or shows damage, breakage, or distortion, or if there are functional problems with the Device (such as if the sensor, reader, data transfer, etc. does not work properly).

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