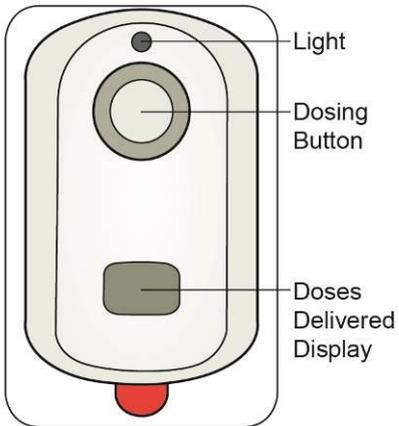
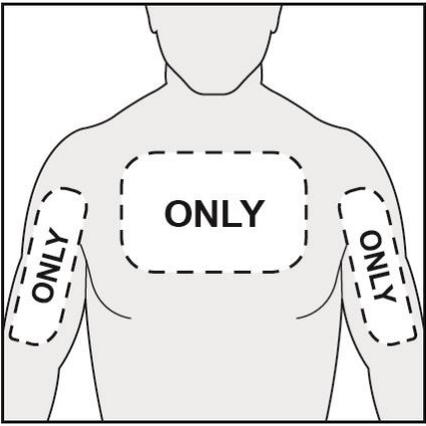
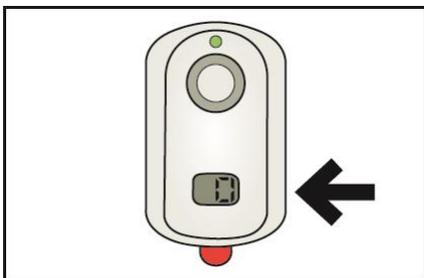
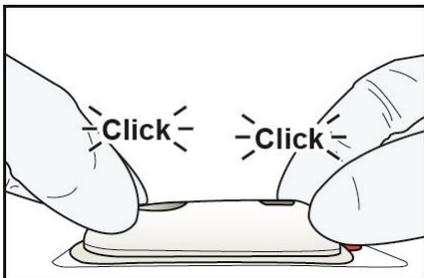
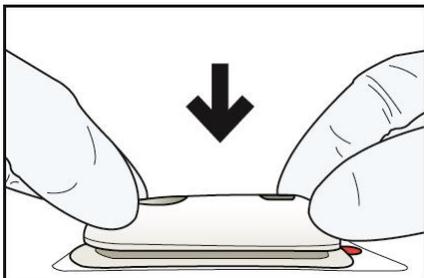
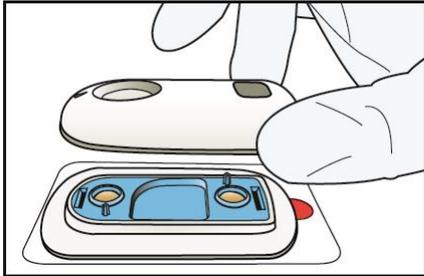
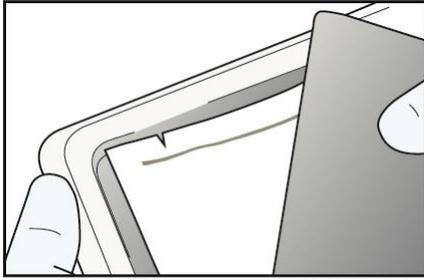


**Information for the Healthcare Professional:
Instructions for use and disposal**

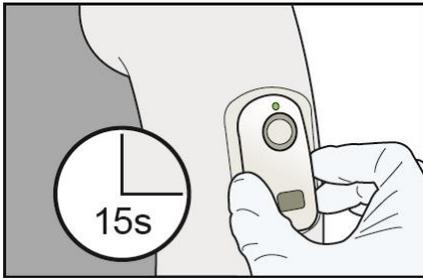
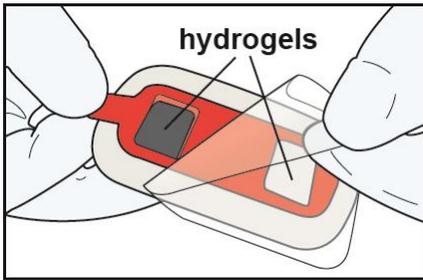
 <p>The diagram shows the front view of the IONSYS device. It is a rectangular, light-colored device with rounded corners. At the top center is a small circular light. Below the light is a larger circular area labeled 'Dosing Button'. At the bottom center is a rectangular area labeled 'Doses Delivered Display'. A red tab is visible at the very bottom edge.</p>	<p>IONSYS (fentanyl 40 micrograms per dose transdermal system, maximum of 80 doses (3.2 mg/24 hours)).</p> <p>For single use only.</p> <p>IONSYS should not be used if the seal on the tray or the sachet containing the drug unit is broken or damaged.</p> <p>IONSYS will operate for 24 hours after it is applied or for 80 doses, whichever comes first, and will then become inoperative.</p> <p>Refer to the Summary of Product of Characteristics (SmPC) for more information about IONSYS.</p>
 <p>The diagram shows a human torso and upper arms. A dashed rectangular box is drawn on the chest area, and the word 'ONLY' is written inside it. Similar dashed boxes are drawn on the upper outer arms, and the word 'ONLY' is written vertically inside each of them.</p>	<p>1. Preparation of the Application Site</p> <ul style="list-style-type: none">• Only 1 IONSYS system should be applied at any given time.• Choose healthy, unbroken skin (non-irritated and non-irradiated skin) site on the chest or upper outer arm ONLY. IONSYS should not be placed on abnormal skin sites, such as scars, burns, and tattoos, or on skin on which topical medicines have been applied.• Excessive hair at the application site should be clipped (not shaved as this can irritate the skin) before application. IONSYS should not be applied to a previously used skin site.• The application site should be wiped with a standard alcohol swab and the skin should be allowed to dry completely before IONSYS is applied. No soaps, oils, lotions, or any other agents that might irritate the skin or alter its absorption characteristics, should be used to clean the application site.• When replacing an IONSYS system, the new system must be applied to a different site on the chest or upper outer arm.



2. Assembly of IONSYS

Complete these steps before applying IONSYS to the patient:

- Gloves should be worn during the assembly/handling of IONSYS. Open the tray by peeling back the tray lid. Remove the sachet and the controller. Open the sachet containing the drug unit starting at the pre-cut notch and then carefully tearing along the top of the sachet.
- Remove the drug unit from the sachet and place on a hard, flat surface.
- Align the matching shapes of the controller and the drug unit and firmly press the two parts together at both ends.
- Once assembled, the digital display of the controller will complete a short self-test during which there will an audible beep, the red light will flash once, and the digital display will flash the number "88". At the end of the self-test, the display will show the number "0" and a green light will flash at a slow rate to indicate IONSYS is ready for application.



3. Application of IONSYS

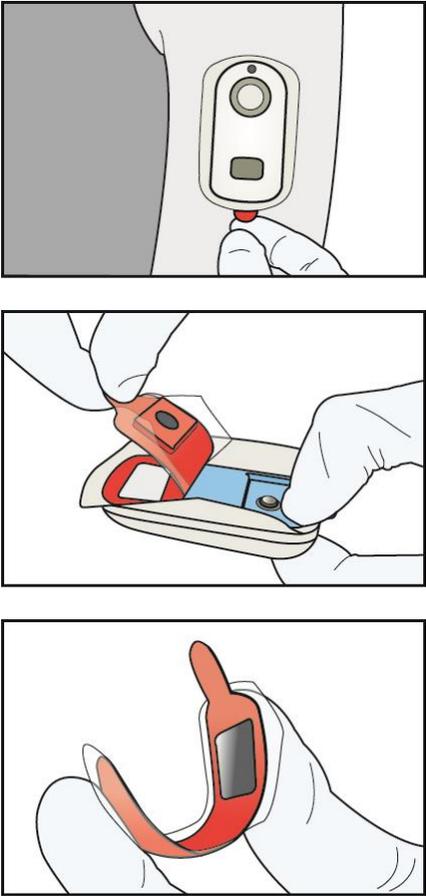
- Remove and discard the clear plastic liner covering the adhesive. Take care not to touch the hydrogels.
- Press IONSYS firmly in place for at least 15 seconds with the sticky side down on the skin of the chest or upper arm of the patient. Apply pressure with the fingers around the outer edges to ensure adhesion to the skin site. **Do not press the dosing button.**
- If at any point during use IONSYS loosens from the skin, a non-allergenic tape may be used to secure the edges to ensure complete contact with the skin. When applying tape, care should be taken not to tape over the light window, the digital display, or the dosing button.
- Each IONSYS may be used for 24 hours from the time of assembly or until 80 doses have been administered, whichever comes first. IONSYS will then shut down and will not deliver any further doses. If additional opioid analgesia is required, a new IONSYS should be applied to a different skin site, after removal and disposal of the previous IONSYS.
- Patients should not wear more than one IONSYS at the same time. A used IONSYS should not be reapplied to patients.



4. Instructing the patient how to use IONSYS

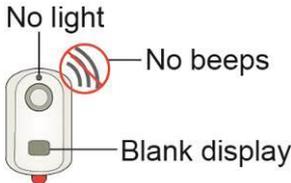
Remember that **only** the patient may touch the dosing button. Tell your patient the following:

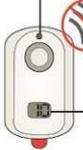
- The slow blinking green light means IONSYS is ready to dose.
- To start a dose, press and release the dosing button 2 times within 3 seconds. You will hear one single beep upon successful dose initiation.
- You will know the dose is being delivered when you see the fast blinking green light.
- IONSYS will ignore any button presses during the 10-minute dosing period.
- You will know the 10-minute dose is complete when the fast blinking green light returns to a slow blinking green light.

	<ul style="list-style-type: none"> • Call your doctor or nurse if you hear additional beeps.
	<p>5. Removal and disposal of IONSYS</p> <p>See also instructions in SmPC Section 6.6.</p> <ul style="list-style-type: none"> • Gloves must be worn while removing IONSYS from the skin and care should be taken to avoid touching the hydrogels. If the fentanyl hydrogel contacts the skin during removal, the contact area should be thoroughly rinsed with water without using any soap. • IONSYS may be removed at any time. However, once it has been removed, the same IONSYS should not be reapplied. • At the end of 24 hours of use, or after 80 doses have been delivered, remove IONSYS by gently lifting the red tab and loosening it from the skin application site. If the patient requires additional or continuation of pain relief, a new IONSYS may be applied to a new skin site on the upper outer arm or chest. • Hold the controller in one hand and pull the red tab with the other hand to separate the hydrogel housing from the system. • Fold the hydrogel housing in half with the sticky side facing in. • Dispose of the folded hydrogel housing in accordance with local requirements for opioid medicinal products • Dispose of remainder of the system, containing electronics, according to hospital procedures for battery waste.

IONSYS Troubleshooting

Each IONSYS is designed to deliver up to 80 10-minute doses of fentanyl over a period of 24 hours. The table below represents the different error messages that may occur, together with the probable cause and the action to be taken.

Error message/feedback	Probable cause	Action required
	<p>Low battery or defective system</p>	<ol style="list-style-type: none"> 1. Do not use the system. 2. Dispose of system per above Step 5 - Removal and Disposal of IONSYS. 3. Place a new system on a different skin site.
	<p>Poor skin contact</p>	<ol style="list-style-type: none"> 1. If IONSYS appears to be loose or lifting from the skin, secure it to patient's skin by pressing the edges firmly or by applying non-allergenic tape. 2. If using tape, apply it along the edges of IONSYS system, do not cover the

<p>Blinking red for 15 seconds</p>  <p>Beeping for 15 seconds</p> <p>Steady number</p> <p>IONSYS is not securely adhered</p>  <p>Tape along long edges</p>		<p>dosing button or display.</p> <ol style="list-style-type: none"> 3. If system beeps again, then remove and dispose of system, and place a new system on a different skin site.
<p>Blinking red</p>  <p>Beeping continuously</p> <p>Steady number</p>	<p>System error</p>	<ol style="list-style-type: none"> 1. Remove system from patient. 2. Hold down dosing button until beeping stops and display goes blank. 3. Dispose of system per above Step 5 - Removal and Disposal of IONSYS. 4. Place a new system on a different skin site.
<p>No light</p>  <p>No beeps</p> <p>Blinking number</p>	<p>End of use at 24 hours or 80 doses</p>	<ol style="list-style-type: none"> 1. Remove system from patient. 2. Hold down dosing button until display goes blank. 3. Dispose of system per above Step 5 - Removal and Disposal of IONSYS. 4. Place a new system on a different skin site.

If device failure or malfunction is suspected by a healthcare professional, IONSYS should be immediately removed from the patient and The Medicines Company contacted straightaway. The healthcare professional must ensure the patient understands that if they suspect a device failure or malfunction, they must inform a healthcare professional immediately.