

23 October 2023

URGENT MEDICAL DEVICE CORRECTION

Infusomat® Space® Pump Administration Sets

Air-in-Line Alarms

Dear Valued Customer:

B. Braun Medical Inc. (BBMI) is informing you of an Urgent Field Safety Correction for Infusomat® Space® Pump Administration Sets. The administration sets may cause the Infusomat® Space® Large Volume Infusion Pump to generate false air-in-line alarms. The Infusomat® Space® Large Volume Infusion Pump continues to function as intended in the detection of true air bubbles within the administration set and is not subject to this Urgent Field Safety Correction.

Affected Product and Distribution Information:

This notice applies to all Infusomat® Space® Pump Administration Sets manufactured between 01 January 2022 – 17 August 2023. For a specific list of the impacted lot numbers which have been distributed since February 10, 2022, please refer to Attachment 01. Note that only pump administration sets identified in this notice are impacted. Other articles are not affected.

The products are distributed in the United States and Canada. The depth of this voluntary correction is to the user/consumer level. This voluntary correction is being conducted with the knowledge of the United States Food & Drug Administration and Health Canada.

Reason for the Field Correction:

In the identified lot number range of administration sets, the tubing outer diameter may vary in size. Additionally, the length of the tubing which contacts the air sensor may be too short resulting in the need to stretch the tubing to properly fit within the Infusomat Space Pump. If the tubing is stretched or the tubing outer diameter is too small, this may result in suboptimal coupling between the administration set and the air-in-line sensor dampening the signal of the air-in-line sensor. If the signal is dampened, the Infusomat Space Pump may generate false air-in-line alarms. To date, there have been 491 reported complaints of air-in-line alarms received (with and without confirmed false alarms) and 32 reports of patient injury with 8 reports considered serious.

Risk to Health:

If the pump alarms for air-in-line alarm, the running infusion is stopped resulting in an interruption to therapy. If the alarms repeat and are unable to be resolved this can lead to further delays in administration. Interruptions or delays in medication administration may result in serious injury to patients which may be life-threatening (e.g. interruption of a vasopressor to a hemodynamically unstable patient) or may lead to death.

Actions Taken by BBMI:

As of 18 August 2023, BBMI began production of Infusomat® Space® Pump Administration Sets with revised specifications which limit unit-to-unit variation in tubing outer diameters and increased the length of the tubing that contacts the air sensor. The reduced variation in tubing outer diameter and length revision improves the coupling between the administration set and the air-in-line sensor reducing the potential for false air-in-line alarms. Administration sets with lot number 0061902124 or higher have been manufactured with these revised specifications. Lots with these revised specifications are being released as they are available and after 30 November 2023 all lots distributed by BBMI will have been manufactured with these revised specifications.

Interim Measures for Users:

The following Interim Measures for Users are being recommended to address any false air-in-line alarms (if the device alarms for air-in-line with no visible air in the infusion line):

1. **Caution:** Do not use tubing with a noticeably smaller outer diameter or which needs to be stretched to fit within the Infusomat® Space Pump.
2. Review your current inventory frequently.
 - a. If possible, upon receipt, divert product with lot number 0061902124 or higher (unaffected lots), to areas that infuse high risk medications (e.g. vasopressors) or other infusions with acute clinical effects (e.g. electrolytes) due to initial limited supply of the new administration sets.
 - b. If possible, divert lot numbers lower than 0061902124 (affected lots) to care areas that do not infuse high risk medications (e.g. vasopressors) or other infusions with acute clinical effects (e.g. electrolytes).
3. When infusing high risk medications (e.g. vasopressors) or infusions with acute clinical effects (e.g. electrolytes):
 - a. Have a second pump with an administration set available for exchange in the event of a false alarm.
 - b. If a second pump with an administration set is not available, have a second administration set available for exchange in the event of a false alarm.
 - c. Additional patient monitoring is required
4. If there is a false alarm and changing the administration set is not an option, wipe the administration set with 70% isopropyl alcohol as directed in Attachment 02. This may improve coupling between the administration set and air sensor allowing the infusion to continue. Refer to Attachment 02 for further details.

In addition to the measures above, Attachment 03 contains information from the product Instructions For Use (IFU) and additional data sources which may reduce the presence of air in the administration set. Small amounts of air in the infusion line (e.g. microbubbles) may also trigger false air-in-line alarms due to suboptimal coupling between the administration set and the sensor even if their volume does not exceed the thresholds normally required for air-in-line alarms. Reducing the presence of these microbubbles may further decrease the potential for these false alarms.

Actions Required by B. Braun Medical Inc. (BBMI) Customer/User:

1. **Review this notice in its entirety.** Ensure that all users in your organization of the above-mentioned product, and other concerned personnel are informed about this voluntary correction and ensure that suitable interim measures are applied as described above. Post this notification where the affected products are stored. If you are a distributor and have further distributed the product, please forward this notice to your consignees. The correction is to be extended to the consumer level.
2. **Determine your current inventory.** If your facility has received lot number 0061902124 or higher, we recommend directing those lots to areas that administer high risk medications prior to stocking other areas due to initial limited supply of the new administration sets. Review your inventory frequently to check these lot numbers.
3. **Return the completed "Product Correction Acknowledgement Form"** to B. Braun Medical Inc. Quality Assurance department by faxing the form to (610) 849-1197 or e-mail to PA_QualityAssurance@bbraunusa.com within two (2) weeks of receipt, even if the total inventory in your possession is zero (0).

Adverse Reactions or Quality Problems:

Adverse reactions or quality problems experienced with this product, or questions about this correction may be reported to BBMI's Postmarket Surveillance Department by calling 1-833-425-1464.

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In the United States:

Adverse Reactions or quality problems in the United States may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report [Online](#)²
- Regular Mail or Fax: [Download form](#)³ or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

In Canada:

Adverse Reactions or quality problems in Canada may also be reported to Health Canada Online, via URL:

<https://health.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/problem-reporting/medical-device-consumer.html>.

We apologize for the inconvenience that this issue may have caused you and your facility, but we appreciate your understanding of our commitment to assuring our products are safe and effective for both health care professionals and patients.

Sincerely,



Electronically signed by:
Jonathan Severino
Reason: For the reason(s)
specified in the document.
Date: Oct 24, 2023 00:49
EDT

Jonathan Severino
Director, Postmarket Surveillance
B. Braun Medical Inc.

Enclosures:

Product Correction Acknowledgement Form

Notes:

1. Source: AAMI Quick Guide: Managing Smart Pump Alarms Reducing Alarm Fatigue | AAMI Foundation | 2018
2. URL for reporting online: <https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda>
3. URL for Downloadable Form: <https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting>

Attachment 01 List of Impacted Lots

Article Number	Article Description	GTIN	Impacted Lots
362031	Infusomat® Space Administration set with Caresite® Injection Site	04046964837807	0061809812; 0061822006; 0061826547; 0061842006; 0061844316; 0061850548; 0061863075; 00VL881443; 00VL881444; 00VL881445
362032	15 drops/mL, priming volume: 22mL, length: 119in, SafeLine®	04046964182556	0061825440; 0061826518; 0061841107; 0061859898; 0061891206; 00VL881446; 00VL881447; 00VL881448
362033	UNIV. 15 DR ADMINISTRATION SET, 1.2 FIL, 2 CRSITE	04046964837821	0061825491; 0061832933; 0061841016; 0061844319; 0061852088; 0061859899; 0061861528; 0061880107; 0061888294; 0061891613; 0061900150
362034	Priming volume: 19mL, length: 120in, SafeLine®	04046964182570	0061809813; 0061875347; 0061880110; 0061895436; 00VL845496
362035	INFUSOMAT SPACE PUMP IV SET	04046964699047	0061815242; 0061820766; 0061821992; 0061821993; 0061826531; 0061829597; 0061831769; 0061832958; 0061844310; 0061847255; 0061853102; 0061855700; 0061863625; 0061888327; 0061894407
362043	Priming volume: 39mL, length: 120in, SafeLine®	04046964182631	0061863076
362050	15 drops/mL, priming volume: 26mL, length: 124in, SafeLine®	04046964182655	0061822091; 0061840508; 0061852666; 0061861244; 00VL881402; 00VL881403; 00VL881404
362420	SPACE ADMINISTRATION SET 15 DROP W/2 SAFEDAY	04046955592715	0061822004; 0061823035; 0061823071; 0061826688; 0061831761; 0061837001; 0061837884; 0061837891; 0061842996; 0061843033; 0061847222; 0061849999; 0061855839; 0061855840; 0061859988; 0061859990; 0061859991; 0061874588; 0061876229; 0061880059; 0061883209; 0061885064; 0061888323; 0061891571; 0061892316; 0061895535; 0061895682; 0061898768; 0061898950; 00VL880878; 00VL882007; 00VL882008
362432	15 drops/mL, priming volume: 21mL, length: 118in, ULTRASITE®	04046964182679	0061806560; 0061864982
362911	Priming volume: 14mL, length: 84in, CARESITE®, Spin-Lock®	04046964837845	0061829592; 0061847275; 0061852087; 0061855702; 0061859902; 0061868581; 0061876580; 0061878508; 0061880060; 00VL866594; 00VL866595; 00VL866596
363010	Priming volume: 21mL, length: 121in, SafeLine®	04046964294174	0061815475; 0061822081; 0061841080; 0061852668; 0061863624; 0061875604
363019	Priming volume: 40mL, length: 123in, SafeLine®	04046964294198	0061818130; 0061832938; 0061865704
363030	15 drops/mL, priming volume: 22mL, length: 119in, SafeLine®	04046964294259	0061815476; 0061838037; 0061851854; 0061864873; 0061892484; 0061895683; 00VL817533; 00VL817534
363032	20 drops/mL, priming volume: 20mL, length: 119in, SafeLine®	04046964294297	0061815254; 0061817792; 0061836642; 0061841018; 0061847266; 0061859903; 0061882707; 0061895431; 0061900141; 00VL865134; 00VL865135; 00VL865136
363230	15 drops/mL, priming volume: 22mL, length: 123in, ULTRASITE®	04046964294495	0061823073; 0061826527; 0061829582; 0061837002; 0061844306; 0061855699; 0061862022; 0061875596; 0061876683; 0061882709; 0061885068; 0061894394; 0061901576; 00VL867493; 00VL867494; 00VL867495
363410	15 drops/mL, priming volume: 23mL, length: 119in, CARESITE®	04046964294556	0061816472; 0061821960; 0061829599; 0061841019; 0061846809; 0061853103; 0061859904; 0061872871; 0061879899; 0061895432; 0061901579

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Article Number	Article Description	GTIN	Impacted Lots
363419	Priming volume: 41mL, length: 120in, CARESITE®	04046964294570	0061815247; 0061819597; 0061822034; 0061823076; 0061826505; 0061837003; 0061852675; 0061854000; 0061854058; 0061859905; 0061862023; 0061863609; 0061865591; 0061869283; 0061875291; 0061877613; 0061877614; 0061891634; 00VL831041; 00VL831042; 00VL831043; 00VL890369; 00VL890370; 00VL890371
363420	15 drops/mL, priming volume: 24mL, length: 120in, CARESITE®	04046964294594	0061818061; 0061823079; 0061829586; 0061837004; 0061844308; 0061855701; 0061861240; 0061868575; 0061874532; 0061885035
363421	15 drops/mL, priming volume: 22mL, length: 120in, CARESITE®	04046964294617	0061811559; 0061814341; 0061815238; 0061817977; 0061817988; 0061819668; 0061821991; 0061823068; 0061825476; 0061825478; 0061826194; 0061826501; 0061826502; 0061826683; 0061827330; 0061828023; 0061829580; 0061830091; 0061831739; 0061832096; 0061833564; 0061837005; 0061837006; 0061837007; 0061837892; 0061841117; 0061842994; 0061843029; 0061844303; 0061845291; 0061847169; 0061847170; 0061850000; 0061850532; 0061850540; 0061851939; 0061853106; 0061855697; 0061855830; 0061855831; 0061855832; 0061855833; 0061858279; 0061858284; 0061859442; 0061859663; 0061859950; 0061859952; 0061860125; 0061861840; 0061862010; 0061864612; 0061870697; 0061870720; 0061870721; 0061870750; 0061870848; 0061870849; 0061875466; 0061876678; 0061879942; 0061879963; 0061880063; 0061880088; 0061880101; 0061883210; 0061887529; 0061888288; 0061888326; 0061891632; 0061891645; 0061892039; 0061894272; 0061894273; 0061894274; 0061895684; 0061896879; 0061901583; 0061901584
363422	Priming volume: 21mL, length: 130in, CARESITE®	04046964294631	0061815266; 0061859730; 0061882161; 0061891576; 00VL817535; 00VL866368
363423	60 drops/mL, priming volume: 21mL, length: 118in, CARESITE®	04046964294655	0061815478; 0061832935; 0061837009; 0061844317; 0061863077; 0061873206; 0061885065; 0061891577
363424	UNIV. 15 DR ADMINISTRATION SET, 1.2FIL, 2CRSTE ASV	04046964837906	0061815480; 0061822066; 0061826553; 0061833595; 0061841020; 0061846766; 0061852672; 0061861524; 0061870722; 0061876834; 0061890407; 0061901588

Article Number	Article Description	GTIN	Impacted Lots
363430	15 drops/mL, priming volume: 23mL, length: 123in, CARESITE®	04046964294679	0061811558; 0061815235; 0061815482; 0061816435; 0061816796; 0061817978; 0061817993; 0061817994; 0061818676; 0061821595; 0061821987; 0061821988; 0061823069; 0061826499; 0061826686; 0061827329; 0061829577; 0061831759; 0061832974; 0061833566; 0061837010; 0061837011; 0061837012; 0061837303; 0061837893; 0061838870; 0061841083; 0061841110; 0061842992; 0061843027; 0061844304; 0061845289; 0061847042; 0061847171; 0061847172; 0061847173; 0061848289; 0061848662; 0061849508; 0061850001; 0061850330; 0061850533; 0061850547; 0061850626; 0061853107; 0061853143; 0061855835; 0061855836; 0061855837; 0061855838; 0061856842; 0061856843; 0061858164; 0061858283; 0061859228; 0061859444; 0061859912; 0061859944; 0061859946; 0061859947; 0061860121; 0061860122; 0061860863; 0061861839; 0061862002; 0061862498; 0061865302; 0061866000; 0061869278; 0061869381; 0061869386; 0061870725; 0061870726; 0061870850; 0061870852; 0061871267; 0061876676; 0061876679; 0061877002; 0061877512; 0061879881; 0061879882; 0061879964; 0061880064; 0061880090; 0061880241; 0061880243; 0061883211; 0061883582; 0061885062; 0061887080; 0061888453; 0061891617; 0061894396; 0061894402; 0061895663; 0061895831; 0061895832; 0061897187; 0061899940; 0061901589; 0061901590; 0061902095; 00VL885536; 00VL885537; 00VL885538
363433	UNIV. 15 DROP ADMINISTRATION SET, 3 CARESITE, ASV	04046964837920	0061815484; 0061822042; 0061826551; 0061841021; 0061852667; 0061862536; 0061891578; 0061895410; 0061898734; 00VL851146; 00VL851147; 00VL851148
363901	60 drops/mL, priming volume: 11mL, length: 129in	04046964294716	0061818804; 0061861261; 0061863628; 0061891579; 0061898773
363902	Priming volume: 25mL, length: 130in	04046964294730	0061814358; 0061820767; 0061822011; 0061829591; 0061843401; 0061855824; 0061866016; 0061879922; 0061888263; 00VL862530; 00VL862531; 00VL862532
363904	UNIV. 15 DROP ADMINISTRATION SET, ASV	04046964699061	0061819595; 0061824861; 0061835511; 0061837015; 0061843000; 0061847230; 0061855825; 0061862025; 0061866010; 0061873207; 0061876025; 0061876420; 0061891570; 0061891637; 0061895443; 0061898775; 00VL865910; 00VL865911; 00VL865912
470119	15 drops/mL, priming volume: 23mL, length: 119in, CARESITE®	04046964298714	0061823046; 0061833291; 0061833546; 0061844318; 0061883002; 0061888319; 00VL855548; 00VL855549; 00VL855550
480254	SPACE PUMP IV SET 15D, 110 IN.	04046955324798	0061812951; 0061812953; 0061820106; 0061820768; 0061823072; 0061825485; 0061827900; 0061830164; 0061838275; 0061855847; 0061863078; 0061863645; 0061867150; 0061876581; 0061879097; 0061879921; 0061881414; 0061885059; 0061889916; 0061900325; 0061901361; 00VL844669; 00VL852455; 00VL852456; 00VL852457
480255	SPACE PUMP IV SET, 127 IN	04046955324804	0061897302

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Article Number	Article Description	GTIN	Impacted Lots
480257	60 DROP NITRO SPACE SET, 88 IN.	04046955324828	0061820769; 0061826079; 0061826528; 0061843406; 0061865427; 0061873209; 0061887372; 0061888287; 00VL836623; 00VL836624; 00VL836625; 00VL857207; 00VL857208; 00VL857209
480258	15 DROP ADMINISTRATION SET 1 SAFEDAY 0.2 FILTER	04046955324835	0061815489; 0061824599; 0061829587; 0061850550; 0061861239; 00VL847051; 00VL847052; 00VL847053
480263	SPACE PUMP IV SET 15D, 90 IN.	04046955693931	0061874472; 0061888448; 0061894265; 0061900139
480264	SPACE PUMP IV SET, 15 DRPS/ML, 95 IN.	04046955778744	0061871461; 0061872801; 0061894264; 0061898761
490037	Priming volume: 25mL, length: 136in	04046964185922	0061825492; 0061832970; 0061837017; 0061843413; 0061847236; 0061852663; 0061858285; 0061862021; 0061870727; 0061874590; 0061877625; 0061885070; 0061898771; 00VL835478; 00VL835479; 00VL835480
490038	60 drops/mL, priming volume: 11mL, length: 129in	04046964185946	0061826523; 0061836898; 0061843414; 0061850530; 0061895022; 0061895023; 0061895024; 0061900137; 00VL891503

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490100	15 drops/mL, priming volume: 22mL, length: 120in, CARESITE®	04046964186080	0061814343; 0061814994; 0061815236; 0061815493; 0061816436; 0061816798; 0061816862; 0061817574; 0061817575; 0061817979; 0061817980; 0061817996; 0061817997; 0061817998; 0061818438; 0061818439; 0061818455; 0061819064; 0061819551; 0061819699; 0061819700; 0061820703; 0061821596; 0061821597; 0061821598; 0061821599; 0061821983; 0061821984; 0061821985; 0061822585; 0061822586; 0061822891; 0061822892; 0061822894; 0061823030; 0061823067; 0061824460; 0061824461; 0061824462; 0061824463; 0061824594; 0061825229; 0061825230; 0061825379; 0061825482; 0061825757; 0061826026; 0061826191; 0061826192; 0061826193; 0061826496; 0061826497; 0061826682; 0061827324; 0061827326; 0061827353; 0061828019; 0061828020; 0061829576; 0061830088; 0061830089; 0061830090; 0061830883; 0061831121; 0061831122; 0061831677; 0061831678; 0061831679; 0061831732; 0061831733; 0061831850; 0061832098; 0061832099; 0061832100; 0061832101; 0061832978; 0061833561; 0061833562; 0061833969; 0061834646; 0061834647; 0061834648; 0061835418; 0061835419; 0061835420; 0061835421; 0061836361; 0061836362; 0061836363; 0061836364; 0061836627; 0061837019; 0061837020; 0061837021; 0061837022; 0061837023; 0061837024; 0061837025; 0061837026; 0061837027; 0061837298; 0061837299; 0061837300; 0061837301; 0061837894; 0061838869; 0061841116; 0061842866; 0061842867; 0061842991; 0061843026; 0061844301; 0061845035; 0061845290; 0061847040; 0061847041; 0061847174; 0061847175; 0061847176; 0061848287; 0061848661; 0061849512; 0061850002; 0061850323; 0061850324; 0061850534; 0061850538; 0061850622; 0061850667; 0061851933; 0061852394; 0061852500; 0061853139; 0061853140; 0061853490; 0061853491; 0061853900; 0061854180; 0061854483; 0061854484; 0061854485; 0061854486; 0061855757; 0061855826; 0061855827; 0061855828; 0061855829; 0061856050; 0061856051; 0061856714; 0061856715; 0061856845; 0061856846; 0061857204; 0061857684; 0061858277; 0061858282; 0061858742; 0061858743; 0061858744; 0061859432; 0061859433; 0061859434; 0061859664; 0061859939; 0061860117; 0061860119; 0061860864; 0061860865; 0061861498; 0061861499; 0061861772; 0061861835; 0061861901; 0061861997; 0061861998; 0061861999; 0061862000; 0061862491; 0061862492; 0061862493; 0061862494; 0061862627; 0061863081; 0061863082; 0061863083; 0061863084; 0061863780; 0061863781; 0061866020; 0061866487; 0061867583; 0061867659; 0061868583; 0061869277; 0061869546; 0061869547; 0061869548; 0061870695; 0061870732; 0061870733; 0061870739; 0061870740; 0061870741; 0061870742; 0061870836; 0061870837; 0061870838; 0061870839; 0061870840; 0061871264; 0061871265; 0061871266; 0061871684; 0061872019; 0061872020; 0061872021; 0061872617; 0061873211; 0061873212; 0061873213; 0061873269; 0061875343; 0061875463; 0061875464; 0061875465; 0061875889; 0061876297;
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Article Number	Article Description	GTIN	Impacted Lots
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490101	Priming volume: 19mL, length: 120in, CARESITE®	04046964186103	0061836643; 0061852089; 0061859908; 0061865711; 0061879873; 0061879966; 0061883202; 0061888317; 0061898681; 00VL841919; 00VL843987; 00VL844536

490102	15 drops/mL, priming volume: 22mL, length: 120in, CARESITE®	04046964186127	<p>0061814344; 0061815234; 0061815495; 0061816433; 0061816434; 0061816799; 0061817576; 0061817981; 0061817982; 0061817999; 0061818000; 0061818001; 0061818002; 0061818003; 0061818440; 0061818441; 0061818710; 0061819705; 0061819706; 0061820091; 0061821592; 0061821593; 0061821980; 0061821981; 0061821982; 0061822587; 0061822588; 0061822924; 0061823031; 0061823066; 0061824458; 0061824886; 0061825227; 0061825228; 0061825484; 0061826189; 0061826190; 0061826492; 0061826493; 0061826681; 0061827327; 0061828017; 0061828018; 0061830095; 0061830096; 0061830105; 0061831681; 0061831734; 0061831735; 0061831736; 0061831851; 0061831852; 0061833558; 0061833559; 0061834650; 0061834651; 0061835422; 0061835423; 0061836366; 0061836367; 0061837030; 0061837031; 0061837032; 0061837033; 0061837034; 0061837035; 0061837036; 0061837037; 0061837038; 0061837039; 0061837204; 0061837296; 0061837297; 0061837895; 0061840200; 0061841548; 0061842989; 0061843025; 0061843266; 0061843596; 0061844300; 0061845181; 0061845292; 0061847043; 0061847177; 0061847178; 0061847179; 0061847390; 0061848009; 0061848370; 0061848659; 0061848660; 0061848898; 0061849509; 0061849510; 0061850326; 0061850535; 0061850537; 0061850624; 0061850668; 0061851936; 0061853135; 0061853136; 0061853137; 0061853138; 0061853893; 0061853894; 0061854480; 0061854481; 0061854482; 0061855696; 0061855842; 0061855843; 0061855844; 0061856054; 0061856055; 0061856056; 0061856057; 0061856058; 0061856716; 0061856717; 0061856718; 0061856719; 0061856720; 0061857399; 0061857687; 0061857688; 0061857725; 0061857863; 0061858260; 0061858276; 0061858281; 0061858463; 0061858693; 0061858694; 0061858746; 0061858747; 0061858748; 0061858749; 0061859368; 0061859437; 0061859438; 0061859439; 0061859440; 0061859941; 0061859942; 0061860112; 0061860113; 0061860115; 0061860726; 0061861502; 0061861505; 0061861836; 0061861867; 0061861989; 0061861990; 0061862488; 0061862489; 0061862490; 0061863086; 0061863087; 0061863088; 0061863089; 0061863784; 0061863785; 0061863786; 0061865296; 0061865297; 0061865775; 0061865848; 0061865973; 0061865974; 0061866001; 0061866504; 0061867655; 0061867656; 0061868573; 0061868594; 0061868742; 0061869275; 0061869549; 0061869550; 0061869551; 0061869569; 0061869670; 0061870693; 0061870694; 0061870696; 0061870729; 0061870730; 0061870745; 0061870746; 0061870842; 0061870844; 0061870845; 0061870846; 0061870847; 0061871236; 0061871237; 0061871238; 0061871310; 0061872022; 0061872023; 0061872618; 0061873215; 0061873216; 0061873217; 0061873271; 0061873455; 0061874836; 0061875082; 0061876131; 0061876298; 0061876673; 0061877509; 0061878605; 0061878724; 0061878948; 0061879039; 0061879874; 0061879967; 0061880066; 0061880091; 0061880092; 0061880095; 0061881431; 0061881432; 0061881433;</p>
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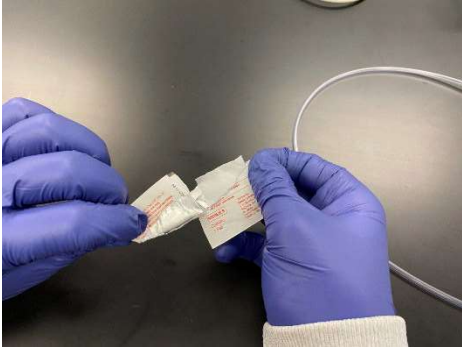
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			0061881777; 0061881778; 0061882927; 0061883213; 0061883579; 0061883580; 0061883581; 0061885069; 0061885136; 0061885137; 0061886216; 0061886530; 0061886531; 0061886532; 0061887073; 0061887075; 0061887530; 0061888296; 0061888452; 0061888458; 0061888459; 0061888646; 0061888647; 0061888648; 0061888652; 0061889345; 0061889346; 0061889347; 0061890597; 0061891573; 0061891615; 0061891635; 0061891636; 0061891646; 0061892036; 0061892037; 0061893520; 0061893521; 0061893522; 0061894137; 0061894138; 0061894140; 0061895353; 0061895656; 0061895657; 0061895658; 0061895659; 0061895687; 0061896693; 0061896694; 0061896695; 0061896875; 0061896877; 0061896878; 0061897235; 0061897294; 0061897295; 0061899651; 0061899652; 0061901299; 0061901300; 0061901301; 0061901363; 00VL853455; 00VL853456; 00VL853457
490103	15 drops/mL, priming volume: 24mL, length: 120in, CARESITE®	04046964302107	0061814346; 0061818627; 0061819708; 0061822003; 0061823034; 0061823070; 0061826541; 0061826687; 0061838000; 0061840199; 0061841084; 0061842995; 0061843030; 0061844305; 0061847221; 0061853904; 0061859985; 0061859987; 0061864613; 0061867900; 0061868102; 0061873218; 0061874587; 0061875823; 0061877674; 0061879968; 0061883203; 0061885072; 0061887373; 0061889045; 0061891574; 0061891616; 0061895139; 0061895549; 00VL860460; 00VL860461; 00VL860462; 00VL861165; 00VL861166; 00VL861167; 00VL861217; 00VL861353
490104	60 drops/mL, priming volume: 21mL, length: 115in, CARESITE®	04046964186141	0061822008; 0061823080; 0061829562; 0061837041; 0061842985; 0061850544; 0061862594; 0061869523; 0061879923; 0061891639; 0061898725
490105	Priming volume: 39mL, length: 120in, CARESITE®	04046964186165	0061814347; 0061816474; 0061818012; 0061818013; 0061818014; 0061821978; 0061823074; 0061824110; 0061824715; 0061826543; 0061826689; 0061829581; 0061833570; 0061837042; 0061837896; 0061843032; 0061844307; 0061847181; 0061852676; 0061853895; 0061853896; 0061854072; 0061854075; 0061855235; 0061855848; 0061857698; 0061858692; 0061862082; 0061866266; 0061867714; 0061869299; 0061870723; 0061870724; 0061870747; 0061872024; 0061872445; 0061875081; 0061875083; 0061875280; 0061875281; 0061876490; 0061876503; 0061880102; 0061883157; 0061885063; 0061888286; 0061891572; 0061891593; 0061894400; 0061894404; 0061898690; 0061898694; 0061898954; 0061900291; 00VL827899; 00VL827913; 00VL827914; 00VL863825; 00VL863826; 00VL863827; 00VL871688; 00VL871689; 00VL871690; 00VL872182; 00VL872183; 00VL872184

Attachment 02

Isopropyl Alcohol Application to Administration Set

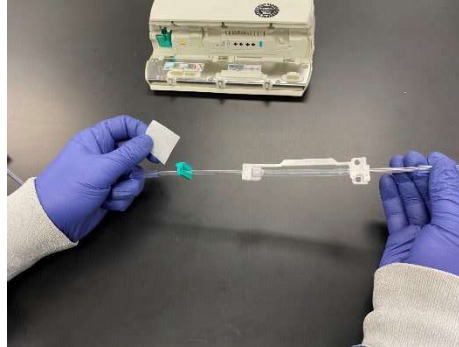
Instructions on wiping Infusomat® Space Administration sets with 70% Isopropyl Alcohol (IPA) to improve coupling with the air sensor in the event of a false alarm (if air-in-line alarm is encountered with no visible air in the infusion line).

Step 1



Using aseptic technique, open IPA wipe

Step 2



Close the roller clamp and remove the administration set from the infusion pump following the product instructions for use.

Step 3



Using the IPA pad, wipe the segment of the pump tubing between the silicone pump segment and the green, set-based anti-freeflow protection clamp

Step 4



Reinstall administration set into pump from right-to-left following product instructions for use.

Step 5

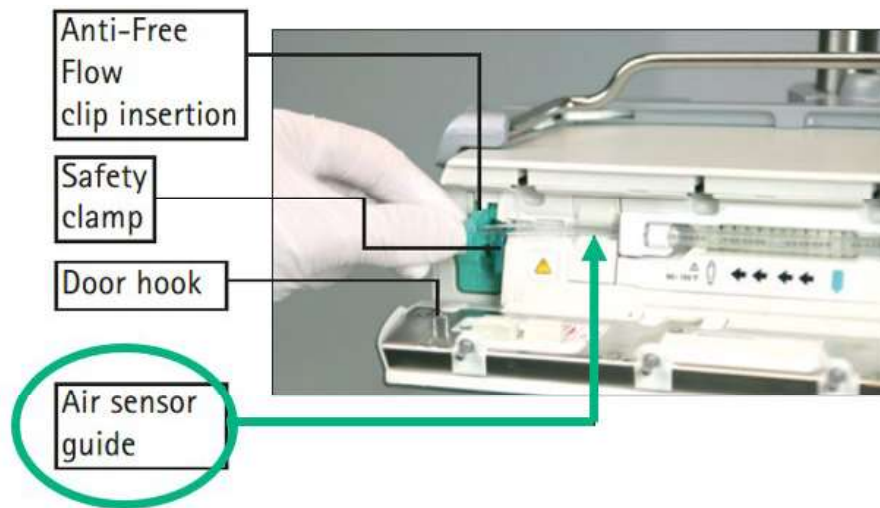


Close pump door and resume infusion following the product IFU and on-screen prompts.

Attachment 3

Actions which May Reduce the Presence of Air in the Administration Set

1. Ensure that personnel follow all applicable product Instructions for Use for proper priming of infusion lines to prevent and address actual occurrences of air in the infusion line. These include, but are not limited to:
 - a. Close roller clamp. Fully spike container. Hang fluid container. Gently squeeze and release drip chamber until 2/3 full. Note: Vent cap should remain in the closed position unless infusing from a glass bottle.
 - b. Caution: Do not connect to patient while priming. Prime set by slowly opening roller clamp and allow fluid to fill tubing. Invert and tap components while fluid is flowing. Close roller clamp. Ensure air is expelled.
 - c. Firmly press tubing into the air sensor guide to make sure the line is properly inserted into the sensors. Thread the tubing through the notches on the right and left side of the pump.



2. In addition to the instructions for use, the following measures may aid in reducing the presence of actual air in the infusion line¹:
 - a. Utilize the pump priming feature to avoid turbulence during priming. Use of the pump for priming ensures a consistent rate of priming when compared with gravity priming where rates may vary depending on user technique. Note: Disconnect IV line from patient before priming.
 - b. Where feasible, consider allowing refrigerated medications to warm to room temperature prior to infusion. Allowing solutions to warm prior to infusion may reduce the formation of microbubbles in the infusion line.
 - c. Where clinically feasible, consider the use of antisiphon valves (ASV). Use of ASV at the end of the infusion line may help reduce the formation of microbubbles.
 - d. When changing IV containers, pause the infusion to prevent air from entering the tubing. If not clinically advisable during critical life support situations, take care not to invert the drip chamber and spike the new container in the hanging position. Inverting the IV spike assembly allows air to be pulled into the IV tubing.

¹ Source: AAMI Quick Guide: Managing Smart Pump Alarms Reducing Alarm Fatigue | AAMI Foundation | 2018