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URGENT MEDICAL DEVICE RECALL (CORRECTION)
(MMS-25-5311-FA)
Revised performance data for BD Alaris™ Pump Module Model 8100 with Guardrails™ Suite MX software when used with a subset of BD Alaris™ Compatible Pump Infusion Sets (Attachment A)

Type of Action: Medical Device Correction

Date: July 08, 2025

Affected Products:
BD Alaris™ Pump Module Model 8100 associated with all BD Alaris™ with Guardrails™ Suite MX software versions up to v12.5
Subset of BD Alaris™ Compatible Pump Infusion Sets

Please see Attachment A for complete list of affected products

For the Attention of:
Director of Nursing
Director of Risk Management
Director of Pharmacy

BD is initiating this voluntary recall notice to inform customers of worse performance, under certain use cases, for the BD Alaris™ Pump Module model 8100 (pump module) when used with a subset of compatible pump infusion sets. Pump infusion set design features such as in-line filters, back check valves, and Y-sites were discovered to adversely impact infusion performance, particularly at programmable rates under 1 mL/h and at or under 1 mL of volume. Compared to the performance described in the User Manual, the flow rate and bolus dose accuracy for a subset of compatible Pump Infusion sets have decreased, and the time to alarm for upstream and downstream occlusions and associated post-occlusion bolus have increased.

In this letter, BD is sharing the latest performance data, reiterating existing warnings and mitigations from User Manuals, and requesting customers to acknowledge and disseminate this notice within their institutions.

To date, BD has not received any complaints associated with this issue.

Description of the problem:
Through internal testing, BD has identified a subset of compatible pump infusion sets listed in **Attachment A** that may perform outside the performance ranges published in the User Manuals for

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flow rate and bolus accuracy, downstream and upstream occlusion time to alarm, and post-occlusion bolus volume (POBV). The deviations in performance from the previously published ranges are attributable to these pump infusion sets' design features, such as filters and other in-line components. Filters with very fine pores (i.e., 0.2 micron) and other in-line components (i.e., back check valves and Y-sites) may impact performance such as flow rate accuracy and time to alarm, particularly at very low flow rates.

The most notable performance variations have been observed with the 0.2-micron in-line filter infusion set at flow rates below 1 mL/h, resulting in upstream time to alarm extending from ≤ 2h 22 min to ≤ 3h 44 min; downstream time to alarm extending from < 59 min to < 1h 57 min; and rate accuracy extending from -8% to 5.5% to -12.5% to 5.5% at very low flow rates. These results are shown in **Attachment B.**

Clinical Impact:

Variations in pump performance, **most commonly at programmable rates under 1 mL/h and at or under 1 mL of volume and when infused through the affected subset of compatible infusion sets,** can impact infusion delivery in the following ways:

1. **Flow rate inaccuracy - over infusion:**
   Description: The pump delivers fluid or medication at a rate higher than prescribed.
   Potential Clinical Outcomes: Drug toxicity, drug overdose, fluid overload, electrolyte disturbances.
2. **Flow rate inaccuracy - under infusion:**
   Description: The pump delivers fluid or medication at a rate lower than prescribed.
   Potential Clinical Outcomes: Subtherapeutic drug levels leading to ineffective treatment. Delayed therapeutic effects in time sensitive situations.
3. **Loading bolus dose accuracy - over infusion:**
   Description: The delivered bolus volume exceeds the intended dose
   Potential Clinical Outcomes: Acute overdose with immediate toxic effects. Increased risk of adverse reactions to drugs particularly ones with narrow therapeutic windows.
4. **Loading bolus dose accuracy under-infusion:**
   Description: The delivered bolus volume is less than intended.
   Potential Clinical Outcomes: Inadequate response in acute settings. Delay in achieving therapeutic drug levels.
5. **Upstream and downstream occlusion alarm delay:**
   Description: Delay in alarm notification due to upstream or downstream occlusion.
   Potential Clinical Outcomes: Patients are at risk for missed or delayed treatment.
6. **Post occlusion bolus volume over infusion:**
   Description: Upon release of an occlusion, accumulated pressure causes an unintended bolus delivery.
   Potential Clinical Outcomes: Sudden administration of a large volume of drug or drug dose, potentially resulting in acute toxicity, overdose, or fluid overload.

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The severity and nature of these outcomes depend on the type of medication, fluid, or infusate being administered, as well as the individual patient's condition. See **Attachment B** for the detailed performance data as compared to what is stated in the User Manual.

Mitigations:

The User Manuals provide applicable warnings and actions for clinical users to take to mitigate the risks associated with conditions that shift flow rate accuracy, time to alarm, and bolus accuracy performance. See **Attachment C** for examples of warnings and recommended clinical actions.

The following actions should be considered for the 0.2-micron in-line filter infusion set:

1) Ensure all clamps are open; there are no kinks or collapses in the tubing outside of the pump; drops are flowing in the drip chamber
2) Avoid infusion flow rates below 1 mL/h
3) Avoid using Selectable pressure mode with a setting above 50 mmHg for rates less than 10 mL/h.

Please Take the Following Actions:

1. Devices can continue to be used as intended. Please refer to 'Mitigations' referenced above.
2. Refer to **Attachment B** for the new set performance data as compared to the existing set performance data found in your User Manuals.
3. Post this Customer Notification on or near the affected products. If you experience any issues, contact BD at productcomplaints@bd.com
4. Please review your clinical procedures to confirm if the affected compatible Pump Infusion Sets are used as part of your clinical practice.
5. Circulate this notice within your facility network to ensure that all concerned personnel are made aware of this issue.
6. Complete the attached Customer Response Form and return to the BD contact noted on the form whether or not you have any of the impacted material so that BD may acknowledge your receipt of this notification.
7. Report any adverse health consequences experienced with the use of this product to BD at 1-844-8BD-LIFE or email productcomplaints@bd.com. Events may also be reported to the FDA's MedWatch Adverse Event Reporting program via:
   - Web: MedWatch website at www.fda.gov/medwatch
   - Phone: 1-800-FDA-1088 (1-800-332-1088)
   - Mail: MedWatch, HF-2, FDA, 5600 Fisher's Lane, Rockville, MD 20852-9787

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Actions Taken by BD:

1. BD is contacting all impacted customers to notify them of this Medical Device Correction.

Product Distribution Time Frame:
Pumps: 2004 June to present
Sets: All sets within expiration to present, as this is defined in use with the pump

Appendix or Attachment:
Attachment A- Affected Product List
Attachment B- Associated Sets and Performance
Attachment C- BD Alaris™ Recommendations and Warnings

Contact Information:
If you require further assistance, please contact:

BD Contact	Contact Information	Areas of Support
Post Market Quality Operations	Email: BDRC49@bd.com	Customer Response Forms
BD Alaris Medical	Email: Alarismedicalaffairs@bd.com	Clinical Questions
BD Technical Support	Phone: 888-812-3229 Phone hours: 6:00am to 5:00pm PT Monday – Friday Email: DL-US-INF-TechSupport@bd.com	Technical Service / Customer Service

BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with quality products. We apologize for any inconvenience this issue may have caused you and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

Sincerely,

Chad Modra
Vice President, Quality Management
Medication Management Solutions

Idal Beer
SVP, Medical Affairs
Medication Management Solutions

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Attachment A: Affected Product

Product Name	Catalog/Model (Ref) No.	Software Version	UDI-DI
BD Alaris™ Pump Module Model 8100	8100	All software versions	10885403222054 10885403517723 10885403810015 10885403810039 10885403810046
BD Alaris™ System with Guardrails Suite MX (PCU)	8015	All software versions up to v12.5	10885403801549 10885403801532 10885403801518 10885403519284 10885403519215 10885403517921 10885403516023 10885403515231 10885403519291
BD Alaris™ Pump Infusion Set, Back Check Valve, 3 SmartSite™ Y-sites	10013186	NA	07613203021173
BD Alaris™ Pump Infusion Set, 2 Back Check Valves, 3 SmartSite™ Y-sites	2452-0007	NA	10885403219870
BD Alaris™ Pump Infusion Set	2204-0007	NA	10885403199363
BD Alaris™ Pump Infusion Set, Back Check Valve, SmartSite™ Y-site	24001-0007	NA	10885403238666

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Product Name	Catalog/Model (Ref) No.	Software Version	UDI-DI
BD Alaris™ Pump Infusion Burette Set, 0.2 Micron Filter, Smallbore Tubing, SmartSite™ Port (Burette), SmartSite™ Y-site	10015012	NA	10885403233951
BD Alaris™ Pump Infusion Set, 0.2 Micron Filter, Back Check Valve, 3 SmartSite™ Y-sites	2432-0007	NA	10885403232329
BD Alaris™ Pump Infusion Set, 0.2 Micron Filter, Back Check Valve, SmartSite™ Y-site	2434-0007	NA	07613203019682
BD Alaris™ Pump Infusion Set, 1.2 Micron Filter	2202-0007	NA	10885403274039
BD Alaris™ Pump Infusion Set, Back Check Valve, 5 SmartSite™ Y-sites	11426965	NA	10885403232558
BD Alaris™ Pump Infusion Set, 15 Micron Filter, Back Check Valve, 3 SmartSite™ Y-sites	10561554	NA	10885403232565
BD Alaris™ Pump Infusion Set, 15 Micron Filter	10863358	NA	10885403232466
BD Alaris™ Pump Infusion Set, 2 Back Check Valves, 3 SmartSite™ Y-sites	11171447	NA	07613203021234
BD Alaris™ Pump Infusion Set, 0.2 Micron Filter, Back Check Valve, PE Lined Tubing, 2 SmartSite™ Y-sites	11532269	NA	10885403232343
BD Alaris™ Pump Infusion Set, 0.2 Micron Filter, PE Lined Tubing, SmartSite™ Y-site	10010454	NA	07613203015806

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Product Name	Catalog/Model (Ref) No.	Software Version	UDI-DI
BD Alaris™ Pump Infusion Set, SmartSite™ Bag Access Non-Vented, 0.2 Micron Filter, PE Lined Tubing, SmartSite™ Y-site	2465-0007	NA	10885403221941
BD Alaris™ Pump Infusion Set, 1.2 Micron Filter, PE Lined Tubing, SmartSite™ Y-site	10010453	NA	07613203021135

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Attachment B: Associated Sets and Performance

Essential performance of the affected products as published in the v12.3[1] – 12.5 BD Alaris™ with Guardrails™ Suite MX User Manuals are described in column A of Table 1 below. A subset of compatible sets (Table 2) may experience performance up to the values listed in columns B and C of Table 1 below. Data represents performance at environmental standard operating conditions.

Table 1. Essential Performance Data Described in BD Alaris™ with Guardrails™ Suite MX User Manuals v12.3[1] - 12.5 compared to New Performance Data

	A	B	C
	Performance Described in BD Alaris™ User Manuals v12.3[1] - 12.5	New Performance Data for pump sets with an in-line filter	New Performance Data for pump sets with backcheck valve and SmartSite™ Y-sites
Flow Rate Accuracy [Flow Rates]	±5% [1 – 999mL/h] -8% to +5.5% [Less than 1mL/h]	-6% to +5% [1 – 999mL/h] -12.5% to +5% [Less than 1 mL/h]	-6% to +5% [1 – 999mL/h] -8% to +5.5% [Less than 1 mL/h]
Bolus Accuracy – Loading Dose[2] [Bolus Volumes]	-3.5% to +3.0% [greater than or equal to 5 mL] -11.7% to +6.1% [1 – less than 5 mL] 0% to +49.8% [Less than 1mL]	±4% [greater than or equal to 5 mL] -5% to +11.5% [1 – less than 5 mL] -15.1% to +102.4% [Less than 1mL]	-5% to +7% [greater than or equal to 5 mL] -3% to +10% [1 – less than 5 mL] -12.2% to +96.4% [Less than 1mL]
Bolus Accuracy – Subsequent Doses[3] [Bolus Volumes]	±5% [greater than or equal to 5 mL] ±10% [0.6 – less than 5 mL] 0% to +55% [Less than 0.6 mL]	±5% [greater than or equal to 5 mL] ±10% [1 – less than 5 mL] 0% to +55% [Less than 1mL]	-6% to +5% [greater than or equal to 5 mL] ±10% [1 – less than 5 mL] 0% to +55% [Less than 1mL]
Downstream Occlusion Time to Alarm[4] [Flow Rates]	5 min or less [1 – 999 mL/h] 59 min or less [Less than 1mL/h]	8 min 25 sec or less [1 – 999 mL/h] 1 hour 57 min or less [Less than 1mL/h]	5 min 34 sec or less [1 – 999 mL/h] 1 hours 50 min or less [Less than 1mL/h]
Upstream Occlusion Time to Alarm [Flow Rates]	2 min or less [5 – 999 mL/h] 13 min or less [1 – less than 5 mL/h]	5 min or less [5 – 999 mL/h] 23 min or less [1 – less than 5 mL/h]	5 min or less [5 – 999 mL/h] 23 min or less [1 – less than 5 mL/h]

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	A	B	C
	2 h 22 min or less [Less than 1 mL/h]	3 h 44 min or less [Less than 1 mL/h]	3 h 44 min or less [Less than 1 mL/h]
Post Occlusion Bolus Volume [Flow Rates]	0.3 mL or less [0.1 – 999 mL/h]	0.9 mL or less [0.1 – 999 mL/h]	0.3 mL or less [0.1 – 999 mL/h]

1. User Manuals for BD Alaris™ Systems prior to v12.3 disclose performance differently than as presented in column A of Table 1, based on different standards and testing methodology applied prior to v12.3.
2. A bolus delivered by the Pump Module at the beginning of an infusion is also known as a loading dose.
3. Subsequent bolus dose worst case data is collected without a running continuous infusion.
4. Downstream occlusion time to alarm tested with "Pump Mode" pressure setting.

Table 2. BD Alaris™ Compatible Pump Infusion Sets characterized by New Performance Data

Product Name	Catalog (Ref) No.	Representative New Performance Data
BD Alaris™ Pump Infusion Burette Set, 0.2 Micron Filter, Smallbore Tubing, SmartSite™ Port (Burette), SmartSite™ Y-site	10015012	Table 1, Column B
BD Alaris™ Pump Infusion Set, 0.2 Micron Filter, Back Check Valve, 3 SmartSite™ Y-sites	2432-0007	Table 1, Column B
BD Alaris™ Pump Infusion Set, 0.2 Micron Filter, Back Check Valve, SmartSite™ Y-site	2434-0007	Table 1, Column B
BD Alaris™ Pump Infusion Set, 1.2 Micron Filter	2202-0007	Table 1, Column B
BD Alaris™ Pump Infusion Set, 0.2 Micron Filter, Back Check Valve, PE Lined Tubing, 2 SmartSite™ Y-sites	11532269	Table 1, Column B
BD Alaris™ Pump Infusion Set, 0.2 Micron Filter, PE Lined Tubing, SmartSite™ Y-site	10010454	Table 1, Column B
BD Alaris™ Pump Infusion Set, SmartSite™ Bag Access Non-Vented, 0.2 Micron Filter, PE Lined Tubing, SmartSite™ Y-site	2465-0007	Table 1, Column B
BD Alaris™ Pump Infusion Set, 1.2 Micron Filter, PE Lined Tubing, SmartSite™ Y-site	10010453	Table 1, Column B
BD Alaris™ Pump Infusion Set, SmartSite™ Bag Access Non-Vented, 0.2 Micron Filter, PE Lined Tubing, Bonded Texium™ Closed Male Luer with Priming Cap, SmartSite™ Y-site	24301-0007T	Table 1, Column B
BD Alaris™ Pump Infusion Set, Back Check Valve, 3 SmartSite™ Y-sites	10013186	Table 1, Column C

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Product Name	Catalog (Ref) No.	Representative New Performance Data
BD Alaris™ Pump Infusion Set, 2 Back Check Valves, 3 SmartSite™ Y-sites	2452-0007	Table 1, Column C
BD Alaris™ Pump Infusion Set	2204-0007	Table 1, Column C
BD Alaris™ Pump Infusion Set, Back Check Valve, SmartSite™ Y-site	24001-0007	Table 1, Column C
BD Alaris™ Pump Infusion Set, Back Check Valve, 5 SmartSite™ Y-sites	11426965	Table 1, Column C
BD Alaris™ Pump Infusion Set, 15 Micron Filter, Back Check Valve, 3 SmartSite™ Y-sites	10561554	Table 1, Column C
BD Alaris™ Pump Infusion Set, 15 Micron Filter	10863358	Table 1, Column C
BD Alaris™ Pump Infusion Set, 2 Back Check Valves, 3 SmartSite™ Y-sites	11171447	Table 1, Column C
BD Alaris™ Pump Infusion Set, Back Check Valve, Manifold, 3-Way Stopcock, 5 SmartSite™ Y-sites	11419365	Table 1, Column C
BD Alaris™ Pump Infusion Set, Back Check Valve, 3 Ganged 4-Way Stopcocks, 4 SmartSite™ Y-sites	10813621	Table 1, Column C
BD Alaris™ Pump Infusion Set, Back Check Valve, 2 Ganged 4-Way Stopcocks, 4 SmartSite™ Y-sites	2423-0007	Table 1, Column C
BD Alaris™ Pump Infusion Set, Back Check Valve, 2 Ganged 4-Way Stopcocks, 3 SmartSite™ Y-sites	10015896	Table 1, Column C
BD Alaris™ Pump Infusion Set, Bonded Texium™, Closed Male Luer with Priming Cap, Back Check Valve, 3 SmartSite™ Y-sites	24010-0007	Table 1, Column C
BD Alaris™ Pump Infusion Set, Vented Syringe Adapter, Smallbore Tubing	10010483	Table 1, Column C
BD Alaris™ Pump Infusion Set, Half Set, SmartSite™ Y-site	2403-0007	Table 1, Column C

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Attachment C: Recommendations and Warnings from the BD Alaris™ User Manual

For Rate and Bolus accuracy:

a) Avoid delivering extremely small volumes (less than 0.2 mL) via the Pump Module bolus feature. Over infusion and/or under infusion by 15% beyond the standard bolus volume accuracy can occur, which can be particularly concerning for the low, very low, and extremely low birth weight neonates. Consider giving extremely small volume boluses IV push rather than through the Pump Module bolus feature.

b) Avoid delivering loading bolus volumes less than 5 mL as significant bolus volume inaccuracies can occur, resulting in under or over infusions (potentially up to 50% over infusion at 0.1 mL).

c) When using the Pump Module bolus feature, avoid delivering bolus volumes that are less than 0.6 mL with durations of less than 1 minute. Over infusions from significant bolus volume inaccuracies can occur (potentially up to 45% over infusion beyond the standard bolus volume accuracy for bolus volumes less than 0.6 mL). To avoid over infusions when delivering extremely small volume boluses, which are of particular importance to the low, very low, and extremely low birth weight neonate, consider giving boluses IV push rather than through the Pump Module bolus feature, or giving boluses over the longest recommended duration.

For Time to Alarm (TTA):

a) When an occlusion occurs below the Pump Module (downstream occlusion), a longer time-to alarm (greater than 5 minutes) leading to an interruption of therapy, can occur. To minimize the time-to-alarm:
   - Avoid infusion flow rates below 1 mL/h.
   - Avoid using Selectable pressure mode with a setting above 50 mmHg for rates less than 10 mL/h.
   - Avoid infusate temperatures from 22 °C up to 40 °C (71.6 °F up to 104 °F). Standard temperature range is 20 °C ±2 °C (68 °F ±3.6 °F).

b) When infusing at flow rates below 5 mL/h, the LVP may take an extended period of time to detect an upstream occlusion and sound an alarm. To minimize the time-to-alarm:
   - Ensure all clamps are open; there are no kinks or collapses in the tubing outside of the pump; drops are flowing in the drip chamber.
   - Use compatible sets with a small priming volume to minimize the time it takes for medication to reach the patient. This is particularly important when infusing at low rates (for example, less than 5 mL/h) or very low flow rates (less than 0.5 mL/h). It also helps to maintain delivery accuracy and reduces the time to alarm for an occlusion.
   - Consider use of the Syringe Module instead of the Pump Module using the smallest syringe size necessary, along with a pressure sensing disc set at the lowest occlusion setting when delivering low volumes of high-risk medication for a faster time-to-alarm for occlusion.
   - Within the BD Alaris™ Guardrails™ Editor User Manual: A new PCU is preloaded with three Profiles (Adult, Neonate, Pediatric) with applicable configuration settings (drug library not included). The preloaded profile configuration data set is named BD Sample Configurations. This data set provides BD recommended settings applicable for specific patient populations. For example, the Default Pressure (mmHg) recommendation is 200 for the Neonatal profile to facilitate a faster time to alarm. Users cannot increase the pressure limit above 200 mmHg; it can only be lowered.

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c) When an occlusion occurs above the pump (upstream occlusion), a longer time to alarm (more than 5 minutes) can occur leading to an interruption of therapy. Detecting an upstream occlusion can take up to 13 minutes at 1 mL/h and up to 2 hours and 22 minutes at 0.1 mL/h, which is of particular importance for neonatal populations, including low, very low, and extremely low birthweight neonates.

For POBV:

a) Minimizing the post-occlusion bolus volume is particularly important when infusing high-risk or life-sustaining medications. To minimize the post-occlusion bolus volume when a downstream occlusion is cleared, which can lead to unintended bolus (over infusion), do the following:
   - When addressing or clearing an occlusion, ensure that the fluid flow to the patient is OFF. An occlusion may pressurize the infusion tubing, which can result in an unintended bolus when the occlusion is cleared, which is of particular importance for the low, very low, and extremely low birth weight neonate. To prevent an additional bolus, disconnect the tubing or relieve the excess pressure through a stopcock, if present. The clinician should weigh the relative risks of disconnection with the risks of an unintended bolus.
   - Pump Module characterization studies demonstrate that post-occlusion bolus volume increases as conditions change from standard operating conditions and/or certain infusion set components are used as listed. Increase in infusate temperature from 22 °C up to 40 °C (71.6 °F up to 104 °F). Pump Module above patient heart level. Use of a downstream filter (dead space). A combination of the above conditions may result in a post-occlusion bolus volume that exceeds 0.3 mL as listed. With an infusate temperature 40 °C (104 °F), an occlusion pressure limit of 525 mmHg, and a Pump Module 12 inches above patient heart level, the post-occlusion bolus volume is approximately 0.6 mL. With an occlusion pressure limit of 525 mmHg, and an infusion set with a downstream filter (model number 2202-0007) at a flow rate of 30 mL/h, the average post-occlusion bolus volume is 0.272 mL [0.392 mL].

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CUSTOMER RESPONSE FORM
(MMS-25-5311)

BD Alaris™ Pump Module Model 8100 associated with all BD Alaris™ Guardrails Suite MX software versions up to v12.5

BD Alaris™ Compatible Pump Infusion Sets

Please assist BD by acknowledging this field action using one of the following methods:

Email: BDRC49@bd.com
Fax No.: (312) 949-0068

Facility: _____

Please print full, current facility name. Do not use initials.

Street Address: _____

City:_____ **State**: _____ **Zip**: _____

Response Form Completed By:	
Name:	
Title:	
Telephone No.:	
Fax No.:	
Email Address:	

Please check all that apply:

☐ I have read and understood the attached notice and taken appropriate actions.

☐ We do not have any of the affected product(s) on hand.

Please assist BD with assuring these communications are delivered to the appropriate person/function within your facility if that is not you.

Name:	
Title:	
Telephone No.:	
Fax No.:	
Email Address:	

This response includes responses for the following locations as well:

Facility	**Street Address**	**City**	**State**	**Zip**