

URGENT: MEDICAL DEVICE CORRECTION

Arial[®] Server Software Versions 11.1.4 through 11.1.6 as part of the Arial Emergency and Nurse Call System

October 31, 2024

Dear Valued Client:

Problem	
Description	Securitas Healthcare LLC ("Securitas Healthcare") has become aware of an issue whereby the Arial Server Software versions 11.1.4 through 11.1.6 (the "Arial Server Software") will not notify end users of calls initiated by call points with the Arial Emergency and Nurse Call System. When an end user utilizing the Arial Server Software "completes" a call initiated by a call point, either through the Arial Mobile Application or Arial Care Giver Mobile Application (each an "Arial App") and later "declines" that same call within the Arial App, the Arial Server Software will not notify end users of further calls from that call point.
	This communication applies only to those users of the Arial Server Software versions 11.1.4.9, 11.1.5.5, and 11.1.6.2 in conjunction with the Arial Mobile Application or Arial Care Giver Application.
	Instructions for determining which version of Arial Server Software you are using are attached hereto as <u>Exhibit C</u> .
Affected Product	Arial Server Software version 11.1.4.9, 11.1.5.5, and 11.1.6.2 UDI Numbers: (01) 00840948102769 (10) 11149; (01) 00840948102769 (10) 11155; (01) 00840948102769 (10) 11162
Potential Hazard Involved	The following potential hazard has been identified for clients using the affected versions of the Arial Server Software:
	The Arial Server Software will not notify end users of calls initiated by call points with the Arial Emergency and Nurse Call System when an end user utilizing the Arial Server Software "completes" a call initiated by a call point, either through the Arial Mobile Application or Arial Care Giver Mobile Application (each an "Arial App") and later "declines" that same call within the Arial App, the Arial Server Software will not notify end users of further calls from that call point. If this occurs, End Users may not receive calls from residents which may lead to injury.
	To date Securitas Healthcare has received 5 complaints regarding affected versions of the Arial Server Software. No injuries or deaths have been reported.
Necessary Actions to be Taken by Clients	Instructions for determining which versions of the Arial Server Software you are using are attached hereto as <u>Exhibit C</u> . Clients using Arial Server Software versions 11.1.4.9, 11.1.5.5, or 11.1.6.2 should:

1. Not "decline" previously cleared calls through the Arial App;



- Restart the Arial Server Software if an end user has "declined" a previously "completed" call using the Arial App. After restarting the Arial Server Software, calls from the affected call point(s) will begin to be received by the Arial Server Software and the Arial Server Software will notify end users as intended. Instructions for restarting the Arial Server Software are included on <u>Exhibit B</u>.
- 3. Contact Securitas Healthcare Technical Support at 1 (800) 380-8883 to upgrade the Arial Server Software to version 11.1.7 or later.

FurtherFor general questions concerning this communication please contact Securitas HealthcareInformationTechnical Support at 1 (800) 380-8883.Support

We ask that you please complete and return a copy of the acknowledgement form attached hereto as Exhibit A.

This notification is being performed with the knowledge of the US Food and Drug Administration (FDA).

If you wish to contact the FDA regarding any adverse events or quality problems associated with this notice, use the following contact information.

- <u>www.fda.gov/medwatch</u>
- 1 (888) 463-6332

Securitas Healthcare is committed to providing quality products and services to our clients. We apologize for any inconvenience this situation may cause.

Sincerely,

Garth Jack Senior Director of Quality & Regulatory Compliance



Exhibit A MEDICAL DEVICE FIELD SAFETY NOTICE RETURN RESPONSE Acknowledgement and Receipt Form Response Required

Please execute this acknowledgment regarding Securitas Healthcare's Medical Device Correction Notice for the Arial[®] Server Software Versions 11.1.4 through 11.1.6 as part of the Arial Emergency and Nurse Call System and return it to the address noted below:

By signing below, you Acknowledge and Certify, that your facility has read and understands this communication.
Facility Name:
Address:
Print Name:
Signature:
Title:
This facility does not have any affected software and/or is not using Arial Caregiver or Arial Mobile Application.
Initials:
This facility has affected software and is using Arial Caregiver or Arial Mobile Application. Units were found and corrected.
Initials:

Please return a copy of this acknowledgment to:

Mr. Garth L. Jack Senior Director of Quality & Regulatory Compliance Securitas Technology Corporation 4600 Vine Street, Lincoln, NE 68503 Phone: 402-742-9335

Exhibit B Instructions for Restarting Arial Server Software

Arial Server Software can be restarted by following the steps below. Please note that Arial Server Software will not receive calls from Arial call points while shutting down and restarting, calls will not be received from Arial call points.

1. Right-click on the Windows Taskbar on the machine that is running your Arial Server Software.

2. Select Task Manager.

Securitas He	althcare		Arial						
Home Sy	ne System								
?	Alerts (5) -	Notifications (4) -							
нер	Туре	Apartment	Description		Location	Time/Date			
Device Wizard				Toolbars		>			
				Search					
Message				News and inter	ests	>			
				Show Cortana I	outton				
				Show Task View	/ button				
Reports				Show People o	n the taskbar				
				Show Windows	Ink Workspace button				
				Show touch ke	yboard button	_			
				Cascade windo	ws				
				Show windows	stacked				
				Show windows	side by side				
				Show the deskt	op				
				Task Manager					
				Lock the taskba					
Connected (localhost)			Taskbar setting:					
🗄 Р Ту	ype here to search	🦄 💽 📰				🦲 🎒 62°F Sunny			

Opening Task Manager

3. Once the Task Manager window opens, select "Services", then scroll down (or type "ps") to find "psServices" in the list of services.

4. Right-click on "psServices" and select "Restart".

👰 Task Manager					– 🗆 ×	<	
File Options View							
Processes Performance	App history	Startup Us	ers Details Services				
Name	PID	Descriptio	on	Status	Group	1	
p2pimsvc		Peer Netv	vorking Identity Manager	Stopped	LocalServiceP		
ap2psvc		Peer Netv	vorking Grouping	Stopped	LocalServiceP		
ReaSvc	9652	Program	Compatibility Assistant Ser	Running	LocalSystemN		
ReerDistSvc		BranchCa	iche	Stopped	PeerDist		
k perceptionsimulation		Windows	Perception Simulation Ser	Stopped			
🔍 PerfHost		Performa	nce Counter DLL Host	Stopped			
PhoneSvc Ph			rvice	Stopped	LocalService		
ReinindexMaintenanceSvc		Contact [Contact Data		UnistackSvcGr		
Q PimIndexMaintenanceSvc Cont		Contact [Contact Data_d0fb3b		UnistackSvcGr		
🔍 pla	Performance		nce Logs & Alerts	Stopped	LocalServiceN		
🔍 PlugPlay	944 Plug and Pla		Play	Running	DcomLaunch		
🔍 PNRPAutoReg		PNRP Ma	chine Name Publication Se	Stopped	LocalServiceP		
RNRPsvc	Start		Resolution Protocol	Stopped	LocalServiceP		
RolicyAgent	Stop		Agent	Running	NetworkServic		
🔍 Power	Restart			Running	DcomLaunch		
🔍 PrintNotify			hsions and Notifications	Stopped	print		
🔍 PrintWorkflowUserSv	Open Services		pw	Stopped	PrintWorkflow		
RintWorkflowUserSv	Search online		pw_d0fb3b	Running	PrintWorkflow		
🔍 ProfSvc	Go to deta	ails	Service	Running	netsvcs		
Service	4504	psService	-	Running			
🔍 PushToInstall		Windows	PushToInstall Service	Stopped	netsvcs		

Restarting psService

Securitas Healthcare

5. The "Status" column values for "psService" will go through a sequence of "Stopping", "Stopped", "Restarting", and finally return to "Running" indicating the restart was successful.

👰 Task Manager								-		×
File Options View										
Processes Performance	App history	Startup	Users D	etails	Services					
Name	PID	Descrip	tion				Status	Gro	up	
p2pimsvc		Peer Ne	tworking	g Identi	ty Manag	er	Stopped	Loc	alService	P
🔍 p2psvc		Peer Ne	tworking	g Grou	oing		Stopped	Loc	alService	P
ReaSvc	9652	Program	n Compa	atibility	Assistant	Ser	Running	Loc	alSystem	N
PeerDistSvc		Branch	Cache				Stopped	Pee	rDist	
aperceptionsimulation		Window	ws Percep	otion S	mulation	Ser	Stopped			
RefHost		Perform	nance Co	ounter l	OLL Host		Stopped			
PhoneSvc		Phone	Service				Stopped	Loc	alService	
ReimIndexMaintenance	Svc	Contact Data		Stopped	Uni	stackSvc(Gr			
ReimIndexMaintenances	Svc	Contact Data_d0fb3b		Stopped	Uni	stackSvc(Gr			
🔍 pla		Perform	nance Lo	gs & A	lerts		Stopped	Loc	alService	N
🔍 PlugPlay	944	Plug an	id Play				Running	Dee	mLaunch	h
PNRPAutoReg		PNRP N	/lachine l	Name I	ublicatio	n Se	Stopped	Loc	alService	P
RNRPsvc		Peer Na	ame Reso	lution	Protocol		Stopped	Loc	alService	P
PolicyAgent	4144	IPsec P	olicy Age	ent			Running	Net	workServ	ic
Rower 2	944	Power					Running	Dco	mLaunch	h
PrintNotify		Printer	Extensio	ns and	Notificati	ons	Stopped	prin	nt	
RintWorkflowUserSvc		PrintW	orkflow				Stopped	Prir	ntWorkflo	w
RintWorkflowUserSvc_	d0f 15272	PrintW	orkflow_o	d0fb3b			Running	Prir	ntWorkflo	w
ProfSvc	2364	User Pr	ofile Serv	ice			Running	net	svcs	
Service	4504	psServi	ce				Stopping			
🔍 PushToInstall		Window	vs PushT	olnstal	Service		Stopped	net	svcs	
QWAVE		Quality	Window	s Audi	video E	cperi	Stopped	Loc	alService	A

Services screen showing psService "Stopping" status during restart sequence

6. Your Arial Client Screens may show a "Lost Communication" message during this process. Once "psService" has returned to "Running" status, this message should clear within a minute or so on your Arial Server Software.

	Securitas Hea	althcare			Arial				
	Home (1)	System							
?		Notifications (4) -							
	Негр	Туре	Apartment	Description	Lo				
Device Wizard	System		Lost Comm	unic					

Example of Lost Communication message

7. Check other Arial Client stations in your community to verify the Arial screen is displayed and the "Lost Communication" message has resolved



1

Exhibit C

Instructions for determining which version of Arial Server Software you are using

- 1. In the "Type here to search" box on the taskbar of the Windows screen, type "This PC" and then click Enter.
- 2. On the window that appears, double-click on the icon for the "Window (C:) Drive", then navigate to "Program Files (x86)" and then the "Healthcare Platform Server" directory.
- 3. Scroll down through the list of files in the "Arial" directory and find one called "hpServ". Hover over this with your mouse. After a couple seconds details will appear.
- 4. If the "File Version" is 11.1.4.9, 11.1.5.5, or 11.1.6.2, then you will need to have a software update. Contact Tech Support at 800-380-8883 to coordinate this update.

🕂 🔎 Tł	nis PC	Ħ	t 📀		0
l 🗟 📙 🤿 📔 Manage	C:\Program Files (x86)\Healthcare Pla	atform Server			
File Home Share View Application 1	Tools Copy to Delete Rename Organize New Tools New To	s Properties Mistory	Select all		
← → ∽ ↑ <mark> </mark> → This PC → Local Disk (C:)	> Program Files (x86) > Healthcare Platform	Server 2			
* Quick access	Name	Date modified	Туре	Size	
	🖉 Google.Api.Gax.xml	9/24/2020 9:17 AM	XML File	165 KB	
	Google.Apis.Auth.dll	8/17/2020 1:09 PM	Application exte	138 KB	
Ranorex Code Backup - Arial Tests Trunk 🖈	Google.Apis.Auth.PlatformServices.dll	8/17/2020 1:09 PM	Application exte	5 KB	
Reports 📌	Google.Apis.Auth.xml	8/17/2020 1:09 PM	XML File	167 KB	
💻 rndfs 🛛 🖈	Google.Apis.Core.dll	8/17/2020 1:08 PM	Application exte	72 KB	
🚽 @PE QA 🛛 🖈	Google.Apis.Core.xml	8/17/2020 1:08 PM	XML File	97 KB	
PE 🖈	Google.Apis.dll	8/17/2020 1:08 PM	Application exte	78 KB	
Arial 11 1 SCREENSHOTS	Google.Apis.PlatformServices.dll	8/17/2020 1:09 PM	Application exte	5 KB	
	Google.Apis.xml	8/17/2020 1:08 PM	XML File	98 KB	
N START_SIMS_BATCH *	🖻 hlvdd.dll	3/28/2016 3:35 PM	Application exte	259 KB	
O QA 📌	hpControls.dll	7/9/2024 6:24 PM	Application exte	1,698 KB	
👩 Simulators 🛛 🖈	📑 hpEC.exe	7/9/2024 6:25 PM	Application	418 KB	
🏪 Local Disk (C:) 🛛 🖈	/ hpEC.exe.config	12/8/2023 12:17 PM	CONFIG File	1 KB	
🛕 1- ТЕМР 🛷	Impoutput.exe	7/9/2024 6:25 PM	Application	166 KB	
Don (10.65.171.30)	/ hpOutput.exe.config	4/18/2024 4:46 PM	CONFIG File	3 KB	
Software Arial 1120	💷 hpR3.exe	1/9/2020 1:47 PM	Application	4,872 KB	
Software_Anal_11.2.0	hpRA_IF.ocx	3/28/2016 3:35 PM	ActiveX control	47 KB	
	🐺 HPSCARoot.cer	12/8/2023 12:16 PM	Security Certifica	2 KB	
📙 Healthcare	🦻 HPSCASERVER.pfx	12/8/2023 12:16 PM	Personal Inform	5 KB	
🚽 builds 🛛 🕄 🕄	📑 hpSenvexe	7/9/2024 6:25 PM	Application	588 KB	
	hpServ File description: hpServ	12/8/2023 12:17 PM	CONFIG File	3 KB	
	ap Company: Securitas Healthcare	3/28/2016 3:35 PM	Application exte	1,910 KB	
💻 This PC	File version: 11.1.5.5	3/28/2016 3:35 PM	Application exte	344 KB	
3D Objects	All. Date created: 10/31/2024 1:41	PM12/8/2023 12:16 PM	Rich Text Format	2 KB	
Desktop	mstallf Size: 588 KB	12/8/2023 12:16 PM	Rich Text Format	3 KB	
	📴 installsp.rtf	12/8/2023 12:16 PM	Rich Text Format	3 KB	