

SAVJETODAVNA OBAVIJEST O SIGURNOSTI KORISNIKA

Za korisnike ultrazvučnih sustava ACUSON NX2, ACUSON NX2 Elite, ACUSON NX3 i ACUSON NX3 Elite sa sljedećim verzijama softvera:

Ultrazvučni sustav	ACUSON NX3 ACUSON NX3 Elite		ACUSON NX2 ACUSON NX2 Elite	
	Verzija softvera	VA10A VA10B VA10C VA10D VA10E VA10F	VB20A VB20B	VA10A VA10B
Verzija softvera koja otklanja sljedeći problem	VA10G	VB20C	VA10C	VA11C

Cijenjeni korisniče,

ovim dopisom želimo Vas obavijestiti o problemu na Vašem ACUSON NX2, ACUSON NX2 Elite, ACUSON NX3 i ACUSON NX3 Elite ultrazvučnom sustavu.

Kada se pojavljuje taj problem i koji su mogući rizici po zdravlje?

Kao dio naših inicijativa provjere kvaliteta, interno testiranje otkrilo je problem u kojem pod određenim uvjetima snimanja tijekom pulsirajućeg Doppler-a postoji mogućnost da sonde premaše vrijednosti izlazne akustičke snage (AOP) definirane u Zapisu 3 dokumenta *FDA Guidance for Industry and Staff: Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers* (FDA vodič za industriju i osoblje: Informacije za proizvođače koji traže odobrenje za stavljanje u promet dijagnostičkih ultrazvučnih sustava i sondi) i u Standardu za izlazni prikaz (ODS) IEC 60601-2-37.

Vjerojatnost javljanja ovog problema je neznatna. Za vrijeme redovite kliničke uporabe, ulazne vrijednosti za izračun izlazne akustičke snage se ažuriraju svaki put kad korisnik pritisne tipku **UPDATE** radi pribavljanja u realnom vremenu (uživo). Ako bi se javio ovaj problem, postoji iznimno mala vjerojatnost da bi okolnosti snimanja mogli rezultirati opeklinom ili oštećenjem tkiva zbog kavitacije.

Nemamo izvješća o ozljedama ili neželjenim događajima zbog ovog problema.

Koje korake korisnik može poduzeti da bi izbjegli mogući rizici vezani za ovaj problem?

Kako bi se izbjegla situacija u kojoj se koriste netočne vrijednosti izlazne akustičke snage korištene tijekom pulsirajućeg Doppler-a, uvijek pritisnite tipku **UPDATE** prije pribavljanja spektra pulsirajućeg Doppler-a u realnom vremenu (uživo). Ultrazvučni sustav ažurira vrijednosti izlazne akustičke snage na ispravne vrijednosti nakon svakog pritiska na tipku.

Također, nemojte koristiti simultani format za kontinuirano pribavljanje. Morate pritisnuti tipku **UPDATE** prije pribavljanja spektra pulsirajućeg Doppler-a u realnom vremenu (uživo). Za dodatne informacije o simultanom formatu, pogledajte Poglavlje A4 u priručniku Features and Applications Reference.

Pridržavajte se sljedećih uputa za izlaznu akustičku snagu u Poglavlju 2 Uputa za uporabu.

Akustični izlaz — mehanički i toplinski indeksi

UPOZORENJE: Ultrazvučne postupke je potrebno provoditi iz opravdanih razloga, trebaju trajati što je kraće moguće, te uz najmanje moguće mehaničke i toplinske indeksne postavke potrebne za izradu klinički prihvatljivih snimki.

Ultrazvučni sustav prikazuje izlazne vrijednosti mehaničkih i toplinskih indeksa koje vam omogućuju nadgledanje i ograničavanje količine ultrazvučne energije koja se prenosi na bolesnika.

Napomena: Za sustave koji se distribuiraju u Sjedinjenim Američkim Državama, pogledajte informativnu brošuru *Medical Ultrasound Safety* (Sigurnost medicinskog ultrazvuka) programa edukacije za uporabu ultrazvuka koju je osmislio AIUM i koja se dostavlja zajedno s ultrazvučnim sustavom.

Kako će se taj problem riješiti?

Trenutno se razvija ažuriranje softvera koje će riješiti ovaj problem. Kad taj softver postane dostupan, predstavnik korisničke službe Siemens Healthineers će vas kontaktirati kako bi zakazao ažuriranje vašeg sustava. Ako imate dodatnih pitanja, obratite se našem centru za korisnike.

Podijelite ove informacije sa svim osobljem u tvrtki ili ustanovi koje bi trebalo biti upoznato s ovim problemom.

Iskreno žalimo zbog neugodnosti koje bi vam ovaj problem mogao izazvati u svakodnevnom radu.

Srdačan pozdrav,

Mazi Kiani

Potpredsjednik, Odjel za kvalitetu i regulatorne poslove

Siemens Medical Solutions USA, Inc.

Ultrasound Business Area

Hrvatski/Croatian

ACUSON NX2, NX3

Update Instructions

Safety Update - US038/18/S

ACUSON NX Series CSAN Update

Update within deadline 1 month

Mandatory Yes No

Affected Warranty Contract Others

Update by Customer Informatics RSC Apps CSE

Remote update Yes No

Intranet download available Yes No

Update material required Yes No

Material free of charge Yes No No, credit if returned

Return of parts Yes No

Application training needed Yes No Recommended

Application training time 0 h

Estimated completion time 1/4 h Number of CSEs: 1

Remarks: N/A

Scope

Material number	11254336, 11284381, 11284500
Software version	NX2: Below VA10C, VA11C NX3: Below VA10G, VB20C
Component material number	N/A
Related to Update Instructions	N/A

Change reference no.: 690283
 Name: Yang, Jaehyuk
 Department: SHS CS US SLM

Document Version

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1.1 General Information

1.1.1 Systems/Products Affected

ACUSON NX2 and NX2 Elite systems with system software versions VA10A, VA10B, VA11A and VA11B.

ACUSON NX3 and NX3 Elite systems with system software versions VA10A, VA10B, VA10C, VA10D, VA10E, VA10F, VB20A and VB20B.

1.1.2 Reason for the Update

When does this issue arise and what is the potential risk to health?

As part of our ongoing quality initiatives, internal testing revealed a situation where under specific imaging conditions during pulsed wave Doppler, there is a possibility for transducers to exceed the acoustic output power (AOP) values defined in Track 3 of the FDA Guidance for Industry and Staff: Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers and the Output Display Standard in IEC 60601-2-37.

The probability of occurrence of this issue is remote. During routine clinical use, input values to the calculations for acoustic output power are updated each time the user presses the UPDATE key for real-time acquisition. If the issue were to occur, there is an extremely remote likelihood these imaging conditions could result in a burn or tissue damage from cavitation. We have no reports of injuries or adverse events due to this issue.

What steps can the user take to avoid potential risks associated with this issue?

To avoid a situation where incorrect acoustic output power values are used during pulsed wave Doppler, always press the **UPDATE** key prior to acquiring a real-time (live), pulsed wave Doppler spectrum. The ultrasound system updates the acoustic output power values to the correct values after each press of the key.

Also, do not use a simultaneous format for continuous acquisition. You must press the **UPDATE** key prior to acquiring a real-time (live), pulsed wave Doppler spectrum. For additional information on simultaneous format, refer to Chapter A4 in your Features and Applications Reference manual.

Observe the following instructions provided for acoustic output power in Chapter 2 of your Instructions for Use.

- Acoustic Output - Mechanical and Thermal Indices

Warning: Ultrasound procedures should be used for valid reasons, for the shortest period of time, and at the lowest mechanical/thermal index setting necessary to produce clinically acceptable images.

The ultrasound system incorporates an output display of Mechanical and Thermal Indices to allow you to monitor, and to limit, the amount of ultrasound energy that is transferred to the patient.

Note: For systems distributed in the United States of America, refer to the Medical Ultrasound Safety ultrasound education program brochure produced by the AIUM that is shipped with the ultrasound system.

How will this issue be resolved?

A software update which will address this issue is currently being developed. When this software becomes available, a Siemens Healthineers customer service representative will contact you to schedule your system update. If you have any further questions, please contact your Customer Care Center.

Please share this information with all personnel within your organization who need to be aware of this issue.

1.1.3 Prerequisites

The latest version of this document can be downloaded from the (→ Services Knowledge Base (SKB), <https://skb.healthcare.siemens.com>).

1. Use **PKI card** or **Windows Login** to login.
2. Check the document type "**UI**".
3. Type in the update number **US038/18/S** in the search field.
4. Click **Search**.

1.1.4 Special Tools

N/A

1.2 Material Information

1.2.1 Ordering Information

There is no material kit for this Update program.

The document below is included with this UI in the SKB.

Quantity.	Update material number	Description
1	11507581	NX2/NX3 Customer Safety Advisory

1.2.2 Content of the Update Material

N/A

1.2.3 Return of Parts

N/A

2.1 Work Steps

To the Regional Director Customer Service

- Review the complete Update Instruction.
- Identify affected systems within your region, inform BA US if any affected systems are not already included in this update.
- Distribute the attached user's country specific language Advisory Notification PN 11507581 in form of a certified mail. The reception needs to be acknowledged. Keep a record within the country to prove the letter was sent & received.

2.1.1 Final Check

N/A

2.1.2 Final Work Steps

1. If necessary, fill out and make a copy of the attached "Completion Protocol" and file it in the corresponding binder.
2. The update shall be reported by authorized personnel, either via an intranet application or by automated data transfer (only for countries connected via update handling interface).



The update is not considered to have been performed until the IVK structure in the Installed Base is updated.

2.1.3 Customer Information

N/A

2.1.4 Changes to Previous Version

N/A

3.1 ACUSON NX Series CSAN Update

3.1.1 Reason for the Update

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3.1.2 Protocol

This update has been completed successfully. The customer was informed of the solution to the "Customer (Safety) Advisory Notice": **US038/18/S**.

Customer:

Customer No.: Func. Location

Material No. Serial number
of the system: of the system:

Notification:

Remark:

Remark:

Country: Site:

Performed by: Telephone:

Date: Signature:



File the protocol in the corresponding binder.

There are no Hazard IDs in this document.

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Print No.: US34-105.896.01.01.02 | Replaces: n.a.
Doc. Gen. Date: 01.19 | Language: English
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