SAFETY INFORMATION
SICHERHEITSHINWEIS

Technical Bulletin
Technisches Bulletin

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Restricted access Nr.	Target audience Zielgruppe	Date Datum	Nr of pages Anzahl der Seiten
004	all users / alle Anwender	2008-01-15	14
Concerned products Betroffene Produkte	Serial numbers / Lot identification Seriennummern / Chargenbezeichnung	Software / Firmware	
corpuls³	up to / bis 0870000	**Firmware Patient Box 1.N** **Software 1.3.0**	

Issue: [1. Mandatory Update of Firmware 1 O (Patient box)]
[2. Mandatory modification of presetting]

Thema: [1. Vorgeschriebenes Firmwareupdate 1 O (Patientenbox)]
[2. Vorgeschriebene Änderung der Voreinstellungen]

Dear corpuls³ operator,

This letter will inform you about 2 malfunctions of the device **corpuls³**.

Error #1: The device may display an “electrical neutral line” which could be misinterpreted as an asystoly of the patient. Please see detailed information under chapter “1. Mandatory Update of Firmware 1 O (Patient box)” in this letter.

Error #2: Reboot of the Monitoring Unit if the view number 4 is selected and the realtime printout is being started. Please see detailed information under chapter “2. Mandatory modification of presetting” in this letter.

Please read this customer information carefully and return the filled in and signed confirmation letter (Annex B1) to GS until **2008-01-31** at the latest.

All Patient boxes up to serial number 0870000 are affected by these malfunctions.

The error description as mentioned under item 1 and the warning as per item 2 is only limited to those **corpuls³** devices that have been delivered until 2008-01-14. All other devices of the manufacturer GS Elektromedizinische Geräte G. Stemple GmbH are not affected by this error / warning.

The serial numbers of the devices used in your company – according to our company documentation – are listed in Annex C.

German Version see below

SECURITY ADVICE
SICHERHEITSHINWEIS

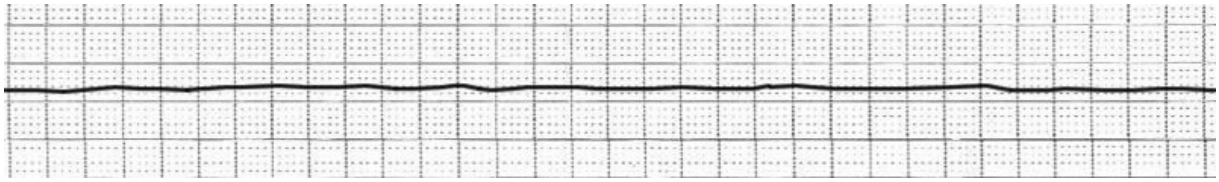
corpuls®

1. Mandatory Update of Firmware 1 O (Patient box)

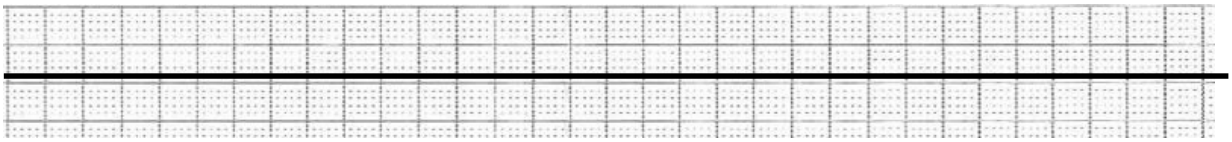
1.1. Error description

If you use the 4pole-cable (ECG-M) under some special external conditions you can see an electrical neutral line displayed. This could be misinterpreted as an asystoly of the patient.
The malfunction does not affect ECG derivation via the therapy electrodes.

Asystoly
Undulated base line



Electrical neutral line (failure)
„dead straight“ line, - will not occur under regular conditions !



Trouble shooting
In case the above ECG is shown the user should proceed through as described below:

a) Check if all ECG Electrodes are applied to the patient firmly; all cable and connectors are on-line.
b) Switch to the DE-lead. The DE-lead is not affected by this malfunction.
c) User should not touch patient and device at the same time.
d) Separate device from the charging connector of the vehicle.
e) Patient must not have direct contact to the device.
f) Separate the Monitoring Unit from Patient box and Defibrillator Unit
g) Remove or power-down possible electrical disturbance sources

1.2. Immediate measure

Please inform immediately all users in your organization about the device's possible malfunction as described above. If your users are in doubt, they have to do the workaround described in chapter 'Trouble shooting' immediately.

1.3. Corrective measure of manufacturer

The mentioned error is eliminated in a new firmware, available as of week **04/2008**.
The new firmware has the Revision 1 O (character "O", not "zero") or higher.
The implementation of the firmware updates are carried out by the manufacturer (GS Elektromedizinische Geräte G. Stemple GmbH) and its authorised service agents and distributors.
In case the maintenance of your **corpuls®** devices is done by another company except the **corpuls®** service partners or distributors , we urgently request you to contact an authorised **corpuls®** service agent in order to make an appointment for this measure.

1.4. Deadline

The implementation of this measure has to take place until **2008-07-01** at the latest. For all **corpuls³** devices without the updated ECG - firmware (Rev. 1 N or lower) the manufacturers guarantee will be cancelled by this date and an operation will no longer be allowed. (You may check the actual revision in the menu 'System – Info')

2. Mandatory modification of presetting

2.1. Error description

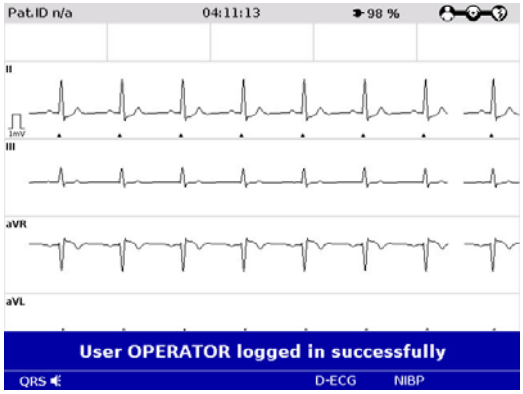
The **corpuls³** may reboot if „view 4“ is selected (quod vide user manual **corpuls³**, Vers. 1.3.0, chapter 7.1.3) and the realtime printout is being started.

2.2. Immediate measure

Please inform immediately all users in your organization. The view no. 4 must not be used until the adjustment is done by the operator / device responsible person.

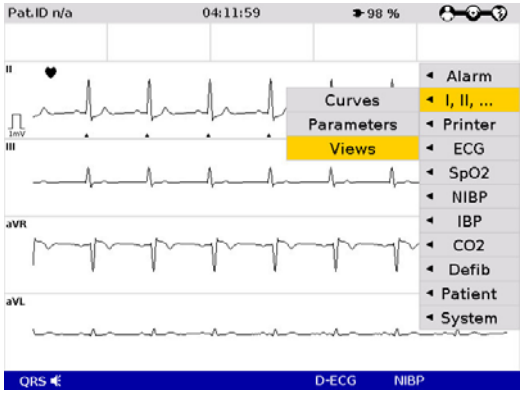
2.3. Adjustment by operator

a)



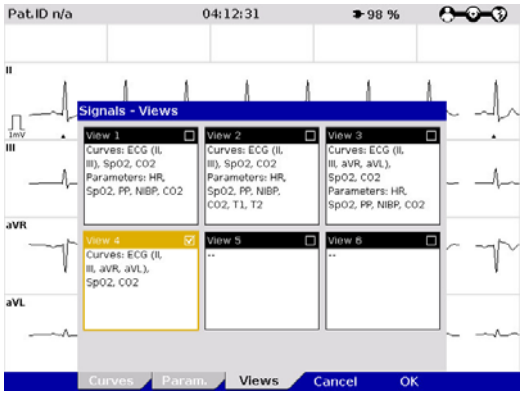
Login as OPERATOR.
(quod vide user manual **corpuls³**, chapter 7.5.1)

b)



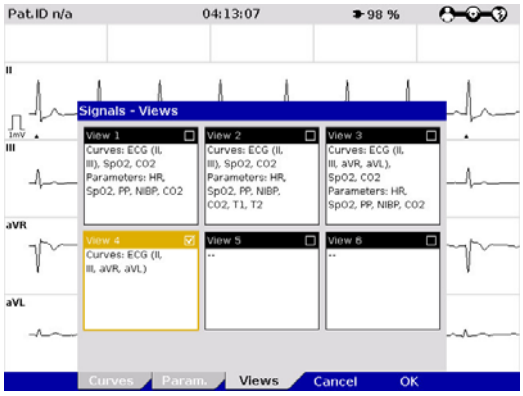
In function menu select
„I,II,...“ > „Displays“.

c)



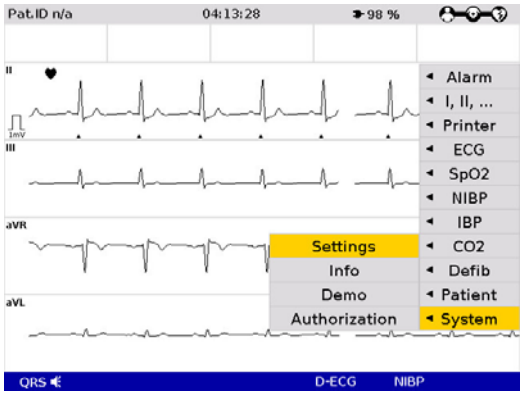
Choose „View 4“.
Press „Back“ key.

d)



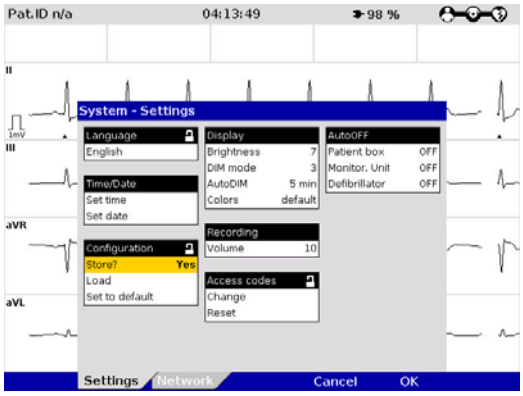
The line „SpO2, CO2“ disappears.
Press the softkey „OK“.

e)



In function menu choose
„System“ > „Settings“.

f)



Choose „Store“, „Yes“
and confirm by pressing the jog dial.

g)

The message „configuration stored“ appears.
Quit the system setting with softkey OK.

h) Restart the device. Select “View 4” as mentioned above and test the printer function. Press button “printer”.

Caution:

This adjustment must be repeated also after resetting the settings to the default configuration!

2.4. Corrective measure of manufacturer

The bug will be fixed with the next software version. This update will be performed by GS Elektromedizinische Geräte G. Stemple GmbH or its authorised service agents and distributors.

In case the maintenance of your **corpuls®** devices is done by another company except the **corpuls®** service partners or distributors , we urgently request you to contact an authorised **corpuls®** service agent in order to make an appointment for this measure.

2.5. Deadline

The adjustment of „View 4“ must be performed by the operator until **2008-01-31** at the latest.

We count on your understanding for the realisation of this quality assuring procedure.
Further queries can be addressed to your **corpuls®** service agent in charge or the local distributor (see http://www.corpuls.com).

Annex B 1
- replay form GB -

Please cross all fields which apply your company.

O Hereby we confirm to be read and understood the safety information of GS Elektromedizinische Geräte G. Stemple GmbH of **2008-01-15**.

O We have following **corpuls³** devices: (please note serial numbers)

No	Monitoring unit	Patient box	Defibrillation / Pacer unit
1			
2			
3			
4			
5			

O We have briefed the users in our company / organisation about the failure mangement and the Safety information.

O We've discontinued operation of **corpuls³**, whose serial number is listed in Annex C of this document. (Please describe what was done with this device e.g: sorted out, scraped, sold to ... . If possible, give us please a copy of the cross-reference.)

_____

_____

_____

_____

To be filled in by customer (please in block letters):

Company /
Organisation:

Address:

City: Country:

Name: First name:

Title: Fax:

Phone: Company stamp:

e-mail-address:

Date / Signature:

Please fill in this reply form and send or fax it to us by **2008-01-31** latest.

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Anhang B 2
- Antwortformular DE-

Bitte kreuzen Sie ALLE für Ihr Unternehmen zutreffenden Felder an.

O Wir haben die Sicherheitsinformation der Firma GS Elektromedizinische Geräte G. Stemple GmbH vom 15.01.2008 gelesen und verstanden.

O Wir besitzen die folgenden Geräte **corpuls³**: (bitte die Seriennummern unten eintragen)

Nr.	Monitoreinheit	Patientenbox	Defibrillator / Schrittmacher
1			
2			
3			
4			
5			

O Wir haben unsere Anwender in geeigneter Weise über die Fehlerbehebung und den Sicherheitshinweis informiert.

O Wir besitzen den/die **corpuls³**, dessen/deren Seriennummer/n im Anhang D dieses Schreibens aufgeführt ist/sind, nicht mehr. (Bitte beschreiben Sie, was mit dem Gerät/Modul geschehen ist, d. h. ob dieses ausgemustert/aussortiert oder weitergegeben wurde. Nach Möglichkeit bitte Verwendungsnachweis beilegen.)

Vom Kunden auszufüllen (bitte in Druckbuchstaben):

Firma / Organisation:

Adresse:

Ort: Land:

Name: Vorname:

Anrede / Titel: Fax:

Telefon: Firmenstempel:

E-Mail-Adresse:

Datum/Unterschrift:

Bitte senden Sie dieses Antwortformular ausgefüllt bis **31.01.2008** an:
GS Elektromedizinische Geräte G. Stemple GmbH
Hauswiesenstrasse 26
D-86916 Kaufering
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Annex C / Anhang C
– Serial numbers / Seriennummern –

Dear Sir or Madam
Sehr geehrte Damen und Herren,

According to our notes you have following **corpuls³** units with serial numbers:
nach unseren Aufzeichnungen sind Sie im Besitz von **corpuls³** mit folgenden Seriennummern:
(as described in annex A / zu finden wie in Anhang A beschrieben):

04200 Patientbox: Number of
04200 Patientenbox: Anzahl
Serial numbers / Seriennummern:

Annex D /Anhang D

- authorised service agents and distributors -
- autorisierte Servicestellen und Gebietsvertretungen -

Deutschland

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