

Bluetooth[™] CompactFlash Adapter

Users' Guide

The easy way to add Bluetooth functionality to: $_{\odot}~$ Microsoft[®] Windows 2000®

- Microsoft[®] Windows 98 SE®
 Microsoft[®] PocketPC[®]
- Microsoft[®] PocketPC 2002[®]
- Microsoft[®] CE.NET[®] (future support)





GigaWaveTech (Pte) Ltd (a member of schmidt electronics asia)

DISCLAIMER:

This manual is published by Gigawavetech Pte Ltd, without any warranty. Improvements and changes to this manual necessitated by typographical errors, inaccuracies of current information or improvements to equipment may be made by Gigawavetech Pte Ltd at any time and without notice. Such changes will however be incorporated into new editions of this manual. Hardware, software and firmware mentioned in this document are subject to continuous development and improvement. Consequently, there may be discrepancies between the information in this document and the performance and design of the product.

Table of Contents

Chapter 1:	Introduction	4
Installation	Overview – PocketPC/PocketPC 2002	4
Installation	o Overview – Windows 2000, Windows 98 SE	4
Minimum S	System Requirements	5
Chapter 2	Windows 2000 Driver installation & removal	6
Step 1:	Copy the files to a hard disk directory	6
Step 2:	Inserting the Card	6
Step 3:	Driver installation	7
Step 4:	Completing the Installation	8
Step 5:	Configuring the driver	8
Step 7:	Reboot the system	10
Step 8:	Driver Removal – only if you wish to remove the driver	10
Chapter 3	Pocket PC 2002 Driver installation & removal	11
Step 1 (c	optional) Card validation and mobile computer functionality che 11	ck
Step 2	Preparing for Driver installation	11
Step 3	Driver installation	12
Step 4	Driver removal - only if you wish to remove the drivers	12
Chapter 4:	Basic Troubleshooting Guide	14
Chapter 5:	Specifications	15
Chapter 6:	Useage & Safety Considerations	17
Appendix A:	Limited Product Warranty	19
Copyright No	otice	21
Regulatory C	Compliance Notice	22
Life Support	Policy	23

CHAPTER 1: INTRODUCTION

Congratulations on the purchase of your GigaWaveTech Type 1 Bluetooth CompactFlash adapter. This adapter will allow you to easily add Bluetooth functionality to your handheld PC, running Microsoft® PocketPC[®], PocketPC 2002[®] or and Windows CE.NET[®].

This adapter will also allow you to easily add Bluetooth functionality to a desktop/laptop PC running Microsoft Windows98 SE and Windows 2000.



A CF-PCMCIA adapter quickly and easily allows the use of this card in a standard PCMCIA/PC-Card slot

The CF card package includes:

- o Drivers on a driver disk
- Installation guide (this document)

This **Users' Guide** shows you how to quickly install the drivers. The following graphics show the GUI for PocketPC 2002 and Windows 2000; however, the operation is the same for PocketPC and Windows 98 SE respectively.

Installation Overview – PocketPC/PocketPC 2002

- 1. **Important**: Read chapter on "Useage and Safety Considerations" before first using the card
- 2. Turn on the mobile computer
- 3. Copy the drivers into the mobile computer via ActiveSync and install the drivers.
- 4. Insert card into available CompactFlash (CF) slot
- 5. Drivers will be loaded.

Installation Overview – Windows 2000, Windows 98 SE

1. **Important**: Read chapter on "Useage and Safety Considerations" before first using the card

- 2. Turn on the computer
- 3. Copy driver files into a directory of your choice.
- 4. Insert card into a CF-to-PC-Card adapter, then insert both into an available PCMCIA or PC-Card slot.
- 5. When prompted, request Windows to do a search for drivers. Then, point driver source to directory where files were earlier copied to. Follow the on-screen instructions.

Minimum System Requirements

- Operating System:
 - Pocket PC (PPC) or Pocket PC 2002(PPC 2002) using *Intel StrongArm SA1110* processor.
 - Microsoft Windows 2000 Professional or Server Edition.
 - Microsoft Windows 98 SE
- o Hardware:
 - PPC or PPC2002:
 - PPC or PPC2002 with available CompactFlash slot
 - Windows 2000 or Windows 98 SE:
 - Computer with available CF card slot
 - CF to PCMCIA card adapter

WINDOWS 2000 DRIVER INSTALLATION & REMOVAL

This chapter covers the steps you need to take to install the card and its drivers. It also covers the procedure on how to remove the drivers, if desired.

Step 1: Copy the files to a hard disk directory

 Create a directory in your local hard disk (e.g. C:\GWTBTCF) and copy all the files located under \GWTBTCF of the GWTBTCF Driver Disk into this newly created directory.

Step 2: Inserting the Card

CHAPTER 2

• Fit the GigaWaveTech Bluetooth CF Card into a CF-PCMCIA Card adapter, as shown on the right.

Push it in firmly and ensure it is seated properly

- Insert the GigaWaveTech Bluetooth CF Card (fitted into the CF-PCMCIA adapter) into an available PCMCIA slot of your notebook computer, as shown on the right.
- GRAWAUETECH
 Charles
 Charles



 Push it in firmly and ensure it is seated properly. Only the thicker portion will protrude from the slot.



• A screen will pop-up indicating that the card was successfully detected by the operating system.

sand New Hardware Wa	urd
	Welcome to the Found New Hardware Wizard
55.	This visand helps you install a device driver for a headwave device.
	Te continue, dick/Maxt
	(Best) Best) Devod

Step 3: Driver installation

- Windows will then ask you where to search for a suitable driver.
 - Select "Search for a suitable driver for my device (recommended)"
 - o Click on "Next"
- Check "Specify a location"
- Click on "Next"

- Now, enter the full path of the driver's directory, this should be the same as the directory created earlier (e.g. C:\GWTBTCF).
- Click on "OK"



- The Operating System will detect the necessary driver installation file.
- Click on "*Next*" to continue.

Found New Hardware Woard
Driver Files Search Results The viced has finished reaching for driver flas for your hardware device.
The wicted loanst a driver for the following device:
👰 - Gigerineve Tech Education CP-, Cand
Windows found a driver for this device. T is install the driver Windows found, di phiNext,
igerbeitgebeiter
4 Ends. Head > Central

Step 4: Completing the Installation

• Click on "Finish" to continue.



Step 5: Configuring the driver

- Open *Device Manager* and expand the "*Ports (COM & LPT)*".
- The driver is displayed as
 "GigaWaveTech Bluetooth CF+ Card-A8A4 (COMx)" where x is the actual COM port number assigned by the operating system. This number varies from system to system. In this example, it is assigned to COM6.
- You may need to this COM6 value for setting up of certain applications. If the application requires a lower COM port value, refer to the end of this section on changing the COM port number.



- Open the driver properties page by double-clicking on it.
- Click on the "*General*' tab on the Properties Page to view the status of the driver.

igowave	Tech Billetooth C	2++ Card-ABA4 (COMp) Properties	T A
General	Setings FFOx	Data rate Driver Resources	
Ì	GigeWeiveTech Bisecoth CF+ Cerd-ABA4 (COWE)		
	Device type:	Parts (COM & LPT)	
	Manufacturer:	GigóVaseTect	
	Location:	CardBas Slot0	
Devic	e status		- 1
if you thank	a one hovingprobler vableshooler.	reparty. na věh třís device, click Troubleshooter to stort <u>z</u> nasbloshooter.	
Device	ange:		- 1
Useth	is allevi de je kola le)	ox l ow	

- Click on the "*Data Rate*" tab on the Properties Page.
- Click on "Detect Crystal Frequency".

After a few seconds, the *Crystal Frequency* setting should show: 14.7456.

- Check "Use default baud rate".
- Click on the "*FIFOs*" tab on the Properties Page.

Check "Use FIFO buffers".

aWaveTech Bluetooth CF+ Card-AB	A4 (COMG) Properties
eneral Sense (PPCs: Dokree Dr.	er Handburden 160950 (0)
Input Clack Detect Crystal Frequency	Crystal Fraquency (MHz) 147456
Baud rate configuration options	₽ Use default boud role
E Baud reformality for	1 -
E Bood rese divider (pressence)	1.000
	Bestore Detaults
	OK Cancel

Gig#WaveTech Bluetooth CE+ Card-ABA4 (COM5) Properties	? ×
General Settings PPOs Data rate Driver Resources	
	182950 (G)
IF Use RF0 buffers	
-RFO InterruptTrigger levels	
Trensmitter - J	4
Receiver	100
Receiver FIFO Flow Control Thresholds	
Play On	16
RovOt	112
Berto	e Detaults
OK	Cancel

• Click on the "*Settings*" tab on the Properties Page to set the default communication parameters.

(If you would like to change the assigned COM port number, click on the "*Advanced*" button and go to next optional step)

•	This is an optional step to
	change the COM port number

 Choose a COM port number that is not currently in use by other COM devices, then click on "OK"

Step 7: Reboot the system

- Save any open application data.
- Reboot the system for the driver to take effect

Step 8: Driver Removal – only if you wish to remove the driver.

- Open Device Manager and expand the "Ports (COM & LPT)". Select "GigaWaveTech Bluetooth CF+ Card-A8A4 (COMx)". Right click the mouse and choose "Uninstall".
- Follow the on-screen instructions.



SigdWaveTech Bluetooth CE+ Card-A8A4 (COM5) Properties	? ×
General Settings FIFOx Data rate Driver Resources	
	19C950 (Q)
Hastware config	
P RS212 RS/85bofeterseb1c Normel	×
- Detault Communications parameters	
Bits per second: 9600	•
Data bits: 8	•
Eastly None	•
Stop bits: 1	*
Elow control: None	*
Advanced Be sto	e Detaulto
OK	Cancel

Advanced Settings for COM6		
COM Port Number:	COM6 💌	OK
	Bestore Defaults	Cancel

CHAPTER 3

POCKET PC 2002 DRIVER INSTALLATION & REMOVAL

This chapter covers the steps you need to take to install the card and its drivers. It also covers the procedure on how to remove the drivers, if desired.

Step 1 (optional) Card validation and mobile computer functionality check

- This step checks whether the GigaWaveTech Bluetooth CF card can be detected by PPC/PPC2002.
- Turn on the mobile computer and wait until all the startup procedures are completed.
- Plug in the CF card into an empty slot. Ensure that it is inserted face up and in the direction of the arrow.
- A dialog box should pop-up indicating an unrecognized card as shown on the right.
- Click on "*Cancel"*, and then unplug the CF card.
- You have just validated the card and socket functionality.



Step 2 Preparing for Driver installation

• You will need to setup a prior communication channel to the mobile computer, e.g. a USB connection.

 Copy the file GWTBTCF.PPC2000_2002_ARM.CAB into the PPC/PPC2002 via ActiveSync software. The file could be placed in any folder of your choice. Double click on this file. It will automatically install GWT BT CF driver on your system.

Step 3 Driver installation

- If step 1 was performed, re-insert the card.
- If step 1 was skipped, insert the card, taking care to insert it right side up, and in the direction of the arrow.
- If the driver has been loaded and initialized, there will not be any error message/pop-up dialog an error message will only appear if there was an error loading and initializing the driver.

Congratulations, you have successfully installed the drivers.

Step 4 Driver removal – only if you wish to remove the drivers

- First, remove the card.
- Go to Settings / System Properties Page and click on "Remove Programs"



- Select "*GigaWaveTech Bluetooth CF Driver*" and click on "*Remove*"
- At the completion of this stage, the driver will have been successfully uninstalled.
- To re-use the card, you will have to re-install the driver.

🎊 Settings	┥€ 11:16	•	
Remove Programs			
Programs in storage memory:			
GigaWaveTech Bluetooth	CF Driver		
Remove			
Total storage memory available	e: 303	48k	
Adjust memory allocation.			
	E	≝ ^	

Properties

CHAPTER 4: BASIC TRO UBLESHOOTING GUIDE

Card does not insert all the way

• Card may have been inserted the wrong way. Check orientation and direction and re-try

"Unrecognized card" pop-up dialog box

• Drivers have not been installed. Remove the card and re-install the drivers.

Cannot find other Bluetooth devices

- Other devices are out of range. Either move closer, or move them closer so that the maximum distance is less than 10m
 Note that the maximum range occurs when there is clear line-of-sight in free space. Obstructions such as concrete walls will reduce the range.
- The other Bluetooth devices are not turned on. Ensure they are turned on.
- The other Bluetooth devices are not in discoverable mode. Ensure they are in discoverable mode when you try to find them. Read their user documentation if necessary.
- The other Bluetooth devices may support a different type of device (or mode of operation), and the application software may not show the device e.g. an OBEX push client may not discover a headset – the discovery process first looks for all devices, then it queries whether the discovered device's applications will support the requested operation. If not, the discovered device(s) will not be listed, and hence may appear as "not discovered"). For more details, please refer to the application software documentation.

My mobile computer keeps powering down

• Your mobile computer battery power is low. Recharge it.

CHAPTER 5:

SPECIFICATIONS

Bluetooth:

- Bluetooth Protocol Bluetooth 2.45 GHz ISM band frequency hopping
- Bluetooth Antenna Integrated
- Bluetooth Radio range Up to 30 ft (10 m)
- Bluetooth Connection Point-to-point and Point-to-Multipoint
- Bluetooth Security Supports Encrypted Link Authentication
- Data Rate up to 720kbps. Actual data rate is dependent on factor such as maximum data rate supported by remote device, obstacles preventing clear line of sight etc.

RF/Radio:

- RF Output Power Greater than 0 dBm, Power Class 2, 20dBm E.I.R.P max, Power Class 1
- Receiver Sensitivity -81dBm at 0.1% BER (typical)
- Modulation and Transmission Rate Frequency Hopping, Spread Spectrum (FHSS), Gaussian Frequency Shift, Keying (GFSK), 1 Mbps

Electrical:

- Power Supply: 3.3V from CompactFlash Connector
- Active: 110 mA (maximum) for Class 2; 175mA (maximum) for Class 1
- Idle: 18 mA
- Power Management: Active Power Saving Mode
- LED state:
 - Power On: Steady
 - o Bluetooth connection/data transmission: Blinking

Interface compatibility:

- CompactFlash Interface:
- CompactFlash I/O, Type 1
- PCMCIA/PC Card Interface:

PCMCIA I/O, Type II (with CompactFlash to PCMCIA adapter)

Hardware compatibility:

PocketPC[®], PocketPC 2002[®], CE.NET (future support), Windows98 SE[®], Windows 2000[®]

Operating System support:

- Microsoft Windows CE 3.0
- PocketPC 2000[®]
- PocketPC 2002[®]
- CE.NET (future support)
- Microsoft Windows 2000 (requires third party stack, applications)
- Microsoft Windows 98 SE (requires third party stack, applications)

Software access method:

• Windows COM port

Mechanical:

- CompactFlash Card Size: 2.05 x 1.69 x 0.19 in (52 x 43 x 4.8mm)
- Weight: 10g
- Interface: CompactFlash I/O; PC Card (with CF Type I-to-PC Card adapter, available separately)

Environmental:

- Operating Temperature: 0°C to +35°C •
- Storage Temperature: 20°C to +70°C •
- Humidity: 5-95% non-condensing •

Certification & regulatory compliance:

- Bluetooth v1.1 Bluetooth: •
- FCC part 15, IEC 60950 USA: •
- ETS 300 328, ETS 300 826, IEC 60950 • Europe:

Hardware warranty:

- One (1) year •
- For warranty information, you can contact us at: •
 - WWW: <u>http://www.gigawavetech.com</u>
 Telephone: +65 6377 4801
 Fax: +65 6377 65

CHAPTER 6: USEAGE & SAFETY CONSIDERATIONS

Please read this section before using your card

Care for your CF card

- Keep product within operating and storage temperature ranges
- Keep product away from liquids, moisture or extremes in humidity.
- Keep product away from lit candles, cigarettes, open flames and volatile solvents.
- The CF Card is a precision product, do not drop, bend or subject to rough treatment. Keep it in a clean and dust-free environment.
- Do no apply stickers and/or paint the card. These can prevent proper insertion and operation.
- This card contains an antenna. Do not place a metallic shield over it, as this will reduce the radio's transmission efficiency.
- There are no user-serviceable parts within the card. Do not attempt to dissemble the card. Please contact us at <u>info@gigawavetech.com</u> if the card fails to work properly.
- Use of this card is subject to national and local regulations. Please check for any exceptions, due to national requirements or limitations, with respect to Bluetooth equipment, before using this card.
- Modifications without the written permission of GigaWaveTech (Pte) Ltd may void your authority to operate this card.

Use in a car

- Always give full attention to driving and pull off the road and park before using any equipment, if driving conditions require.
- This card emits Radio Frequency energy, which may affect operation of some car electronic systems. Check with your vehicle's manufacturer's representative to be sure that the systems are compatible with Bluetooth equipment.

Use in aircraft

- Turn off all your Bluetooth equipment before boarding any aircraft. For this card, ensure that the LED is off.
- To prevent interference with the aircraft communications and navigation systems, do not operate your Bluetooth equipment while you are onboard the aircraft, even when the aircraft is on the ground and stationary.
- If in doubt, please seek permission from the crew.

Other electronic equipment

 Most modern electronic equipment is shielded from RF energy, however, certain electronic equipment may not be, therefore do not use your Bluetooth equipment near medical equipment without requesting prior permission

Use in areas where transmitting devices are prohibited e.g. Blasting areas or potentially explosive atmospheres

• Certain places may restrict the use of transmitting devices, for safety purposes. Please observe such restrictions by turning off your Bluetooth equipment. For this card, ensure that the LED is off.

Radio Frequency (RF) exposure

• Your Bluetooth card is a radio transmitter and receiver. When in use, it communicates with a Bluetooth-equipped device by transmitting and receiving radio frequency

electromagnetic fields (microwaves) in the frequency range of 2.4 to 2.5 GHz. The output power is low at 0.001 watt.

 Your Bluetooth card is designed to operate in compliance with the RF exposure guidelines and limits set by national authorities and international health agencies when used with a properly certified Bluetooth device.

APPENDIX A: LIMITED PRODUCT WARRANTY

GigaWaveTech (Pte) Ltd ("GigaWaveTech") warrants this product to be free from defects in material and workmanship at the time of original purchase by a consumer, under normal use and service, for a subsequent period of one (1) year.

Incompatibility is not a defect covered under GigaWaveTech's warranty.

If during the warranty period, the product fails to operate under normal use and service, due to improper materials and workmanship, GigaWaveTech (including their subsidiaries, authorised distributors, or Service Partners) will at their option, either repair or replace the product in accordance with the following terms and conditions.

Conditions:

- 1. The warranty applies only to the original retail purchaser, and is not transferable.
- 2. The warranty is valid only if the original receipt issued to the original retail purchaser by the dealer, specifying the date of purchase and the serial number, is presented with the product to be repaired. GigaWaveTech reserves the right to refuse warranty service if this information has been removed or changed after the original purchase of the product from the dealer.
- 3. The product may be returned directly to GigaWaveTech, GigaWaveTech's dealers, or to GigaWaveTech's authorised Service Centre. If you ship the product, you must use the original container or a container with equivalent protection, and pay for shipping and insurance (if desired) back to GigaWaveTech. GigaWaveTech will pay shipping charges back to any location in Asia-Pacific.
- 4. If GigaWaveTech repairs/replaces the product, the repair/replaced product shall be warranted for the remaining time of the original warranty period, or ninety (90) days from the date of the repair/replacement, whichever is longer. Repair/replacement may involve the use of functionally equivalent reconditioned parts/units. Replaced faulty parts or components will become the property of GigaWaveTech.
- 5. This warranty does not cover any failure of the product due to normal wear and tear, or due to misuse, including but not limited to use in other than the normal and customary manner, in accordance with GigaWaveTech's instruction for use and maintenance of the product. Nor does this warranty cover any failure of the product due to accident, modification or adjustment, acts of God, improper ventilation or damages resulting from liquid or exposure to environmental conditions outside the specifications.
- 6. This warranty does not cover product failures due to improper repair installations, modifications or service performed by a non-GigaWaveTech

Service Partner, or opening of the product by non-GigaWaveTech certified persons.

- 7. Tampering with any of the seals, or attempting to open/dissemble the product will void the warranty.
- 8. THERE ARE NO EXPRESS WARRANTIES, WHETHER WRITTEN OR ORAL, OTHER THAN THIS PRINTED LIMITED WARRANTY. ALL IMPLIED WARRANTIES, INCLUDING WITHOUT LIMITATION THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, ARE LIMITED TO THE DURATION OF THIS LIMITED WARRANTY. IN NO EVENT SHALL GIGAWAVETECH BE LIABLE FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY NATURE WHATSOEVER, INCLUDING BUT NOT LIMITED TO LOST PROFITS OR COMMERCIAL LOSS, DAMAGE TO PROPERTY, OR DAMAGES FOR PERSONAL INJURY, TO THE FULLEST EXTENT THOSE DAMAGES CAN BE DISCLAIMED BY LAW.
- Some countries/states do not allow the exclusion or limitation of incidental and consequential damage, or limitation of the duration of implied warranties, so the preceding limitations or exclusions may not apply to you.
- 10. The warranty provided does not affect the consumer's statutory rights under national legislation in force, nor does it affect the consumer's rights against the dealer arising from their sales/purchase contract.
- 11. This product may contain fully tested, recycled parts, warranted as if new.

COPYRIGHT NOTICE

Copyright © 2001, 2002 GigaWaveTech (Pte) Ltd. All rights reserved.

GigaWaveTech, GWT, and the GigaWaveTech logo are trademarks of GigaWaveTech (Pte) Ltd. Bluetooth and the Bluetooth logos are trademarks owned by the Bluetooth SIG, Inc., USA, and licensed to GigaWaveTech (Pte) Ltd. All other brand and product names are trademarks of their respective holders.

No part of this document may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopying and recording, for any purpose without the express written permission of GigaWaveTech (Pte) Ltd.

Accompanying software and/or drivers may be copied only for backup purposes. All other forms of reproduction and/or transmittal in any form or by any means, electronic or mechanical, for any other purpose, is expressly prohibited without the express written permission of GigaWaveTech (Pte) Ltd.

REGULATORY COMPLIANCE NOTICE

The GWT Bluetooth CF Card is designed to be compliant with the rules and regulations in locations where they are sold, and will be labeled as required. The card is type approved, which means that users are not required to obtain license or authorization before use.

Radio Frequency Interference Requirements

This device complies with Part 15 of the FCC rules. Operation is subject to the following requirements: (1) This device may not cause harmful interference, and (2) this device may accept any interference received, including interference that may cause undesired operation.

This equipment is also compliant to ETS 300 328, ETS 300 826. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment.

This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. This device and its antenna must not be co-located nor operated with any other antenna or transmitter.

This equipment generates and radiates radio frequency energy. To comply with FCC RF exposure compliance requirements, the following antenna installation and device operating configurations must be satisfied: (1) Users are not permitted to make changes or modify the system in any way, and (2) connecting external antennae to the card is prohibited. Operation of this equipment in a residential area is likely to cause harmful interference, in which case the user will be required to correct the interference at his or her own expense.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user may try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna of the radio or television
- Increase distance separating the equipment and the receiver
- Connect the equipment to an outlet on a different branch circuit than that of the receiver
- Consult the dealer or an experience radio/TV technician for help

The user may find the following booklet helpful: *How to Identify and Resolve Radio-TV Interference Problems*. This booklet is available from the U.S. Government Printing Office, Washington, D.C. 20402.

Caution : Changes or modifications to this Bluetooth CF card not expressly approved by the manufacturer could void the user's authority to operate the equipment.

LIFE SUPPORT POLICY

GIGAWAVETECH'S PRODUCTS ARE NOT AUTHORIZED FOR USE AS CRITICAL COMPONENTS IN LIFE SUPPORT DEVICES OR SYSTEMS WITHOUT THE EXPRESS WRITTEN APPROVAL OF THE MANAGEMENT OF GIGAWAVETECH PTE LTD

As used herein:

1. Life support devices or systems are devices or systems which, (a) are intended for surgical implant into the body, or (b) support or sustain life, and whose failure

to perform, when properly used in accordance with instructions for use provided in the labeling, can be reasonably expected to result in a significant injury to the

user.

2. A critical component of a life support device or system whose failure to perform can be reasonably expected to cause the failure of the life support device or system, or to affect its safety or effectiveness.