

- *Ne pas immerger ou rincer le SHC ou ses périphériques. Si vous renversez accidentellement du liquide sur l'appareil, déconnectez l'appareil de la source d'alimentation. Contactez votre service Biomed en ce qui concerne la sécurité continue de l'unité avant de la remettre en service.*
- *Ne pulvérisez pas de produit de nettoyage sur le châssis.*
- *N'utilisez pas de désinfectants contenant du phénol. Ne pas autoclaver ou nettoyer le SHC ou ses périphériques avec des solvants forts aromatiques, chlorés, cétoniques, éthers ou Esther, des outils tranchants ou des abrasifs. Ne plongez jamais les connecteurs électriques dans l'eau ou d'autres liquides.*
- *Ne rayez pas la surface de l'écran avec des objets durs.*
- *Ne vaporisez pas de liquide directement sur l'écran ou laissez l'excès de liquide s'égoutter dans l'appareil.*
- *Ne placez aucun objet, tel que de la nourriture et des boissons, sur l'écran à tout moment pour éviter d'endommager l'écran.*
- *Nettoyez l'écran LCD uniquement avec un chiffon doux imbibé de 70% d'alcool isopropylique ou de 70% d'alcool éthylique.*

1.6 INTENDED USER PROFILE

Age: 25 - 60

Weight: Not relevant

Health: Not relevant

Nationality: Not relevant

Patient state: The patient will be the operator

Part of the body or type of tissue applied to or interacted with: Hands and fingers, expected contact time shall be less than 1 min.

Education level: At least 8 years of intensive reading experience (school)

Knowledge:

Minimum – Can read and understand “westernized Arabic” numerals when written in Arial font

– Can distinguish every part of the body as described in the user manual

– Understands the potential risks and hazards regarding misjudgment of diagnostic images.

Language understanding: English or Chinese

Experience: Mentally and physically competent, specific medical training to read medical images and to have a basic understanding of symbols.

Permissible impairments:

– Mild reading vision impairment or vision corrected to log MAR 0,2 (6/10 or 20/32)

– One arm/hand capable of guiding and holding the device

– An average degree of aging-related short-term memory impairment

– Hearing impairment of 40 % resulting in 60 % of normal hearing levels at 500 Hz to 2 kHz

Operating Principle:

A computer processing system panel with the following main components: the arithmetic logic unit (ALU), the control unit, the memory, and the input and output devices (collectively termed I/O).

These parts are interconnected by buses, the control unit, ALU, and registers are collectively known as a central processing unit (CPU), the unit processes and delivers patients electronic information to an internal touchscreen.

Environment:

– General Requirements:

- Hospital or clinics, professional healthcare personnel use only.
- Indoor use only
- Not for use in the shower, bathtub, or sink
- The display is to be placed on a desk.

– Expected to function normally

– Conditions of visibility:

- Ambient luminance range: 100 lux to 1,500 lux
- Viewing distance: 20 cm to 40 cm
- Viewing angle: Normal to the display $\pm 45^\circ$

– Physical:

- Temperature range: 0 °C to 40 °C
- Relative humidity range: 10 % to 90 %, non-condensing
- Relative altitude range: 0 to 3000m

The frequency of use: 1 to 10 times a day.

Mobility:

- Fixed MEDICAL DEVICE to be used beside a resting PATIENT.
- Fixed MEDICAL DEVICE to be used on a nursing cart.

Quality related risks are considered in FMEA (doc no. EFH00-PM-004), quality-related risks are not considered as a result of harm; therefore risk evaluation only lists those which may cause harm to the user.

Chapter 2 Hardware Description

2.1 SPECIFICATIONS

Hardware	CPU	Intel® Core™ i5 7200U, 2.5GHz Processor, KBL Intel® Core™ i5 7300U, 2.6GHz Processor, KBL
	Memory	4G DDR4 SODIMM 2133/2666MHz (up to 32G)
	Storage	500G HDD (Optional: SSD)
	Camera	8 Megapixel
	Graphic Chip	Intel® HD Graphics
	Chip Set	Support Intel® Trusted Platform Module (TPM2.0) & Wake-on-LAN/WiFi
	Bus Expansion	M.2
Display	Size	21.5" (54.6cm), 16:9
	Max Resolution	Full HD 1920x1080
	Brightness	LED backlight, 250 nits
	Contrast	1000:1
	Cleaned by Disinfectant	Isopropyl alcohol 70%, Ethyl alcohol 70%
Touchscreen	Type	Capacitive Touch (Multi-touch:10)
	Light Transmission	95%
	Durability	30 million touches
	Surgical Glove Friendly	Need
I/O	USB Port	Rear: USB3.0*1+USB2.0*3, Side:USB2.0*1
	Microphone in	1(included in USB ports, support Skype for Business)
	NFC/RFID	1 (support 14443A、14443B、SR1X4K)
	HDMI out	1
	Earphone/Microphone	1 (Combo audio jack)
	COM Port	1 (RS-232)
	Smart Card Reader Card Reader(3合1)	1 1
Audio	Speaker	3 W x 2
	Microphone	1 (Integrated)
Network	LAN	10/100/1000/Gigabits Mbps RJ-45
	WLAN	802.11 a/b/g/n/ac
	WiFi antenna	integrated or external
	Bluetooth	BT 4.1
Bus Expansion	Mini-PCIe	1
Platform	Operating System	Win10

Mechanical	Mounting	VESA 100*100 & 75*75 mm
	Dimensions (W x H x D)	535.2 x 375.7 x 50.4 mm
	Weight	6.3 kg (with stand: 8.5 kg)
Options	SSD	256G
	accessory port	ODD/ COM2+ USB2.0*3
	Hand Set Holder	Optional (support Skype for Business)
Power Supply	Input Voltage	100 - 250 Vac, 1.5 - 0.75 A, @ 50 - 60 Hz
	Output	19 VDC, 3.15A
Environment	Cooling System	Fanless
	Operating Temperature	0 - 40° C
	Storage/transportation Temperature	-20 - 60° C
	Operating Humidity	10% - 90% (No Condensation)
	Storage/transportation Humidity	10% - 90% (No Condensation)
	Operating Altitude	700 - 1060 hPa
	Storage/transportation Altitude	500 - 1060 hPa
	LED indicator	White = turn on
	Vibration	1 G
	Shock	10 G
	Certifications	BSMI, CE,FCC Class B approval, IEC/ANSI60601-1 approved, UL 60950, UL 62368, RoHS, CCC, CEL

2.2 EXTERNAL VIEW

2.2.1 Front View

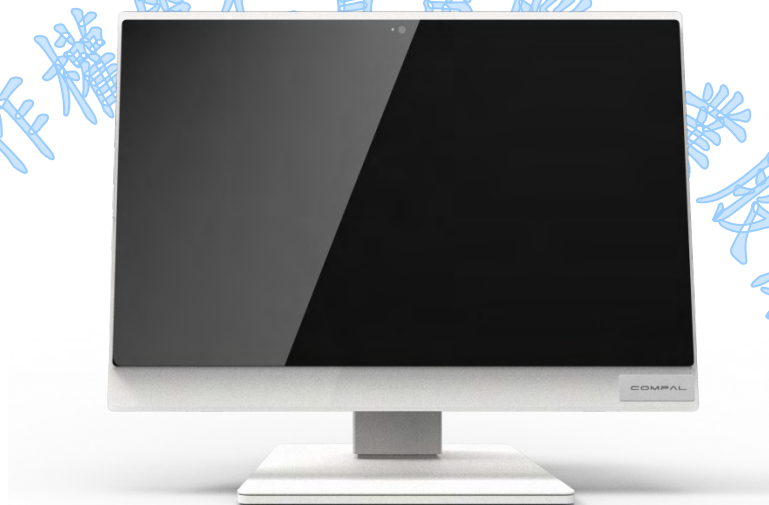


Figure 2.2.1-1 Front View

2.2.2 Side View

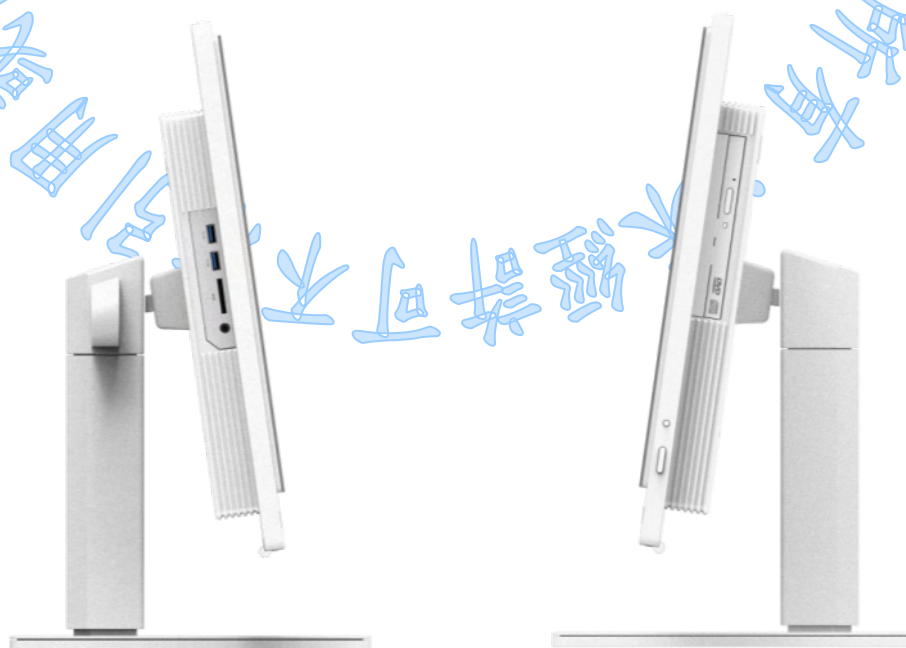


Figure 2.2.2-1 Side View

2.2.3 Rear View



Figure 2.2.3-1 Rear View

Chapter 3 Installation

3.1 INSTALLATION PROCEDURES

3.1.1 Connecting the Power Cord

The SHC-100 should only be powered by a DC power adapter (DELTA MDS-060AAS19 B). Be sure to always handle the power cords by holding the plug ends only.

Follow these procedures sequentially:

1. Connect the female end of the power adapter to the DC-in power port of the PC. (See Figure 3.1.1-1)
2. Connect the female end of the power cord to the DC power adapter.
3. Connect the 3-pin male plug of the power cord to an electrical outlet.

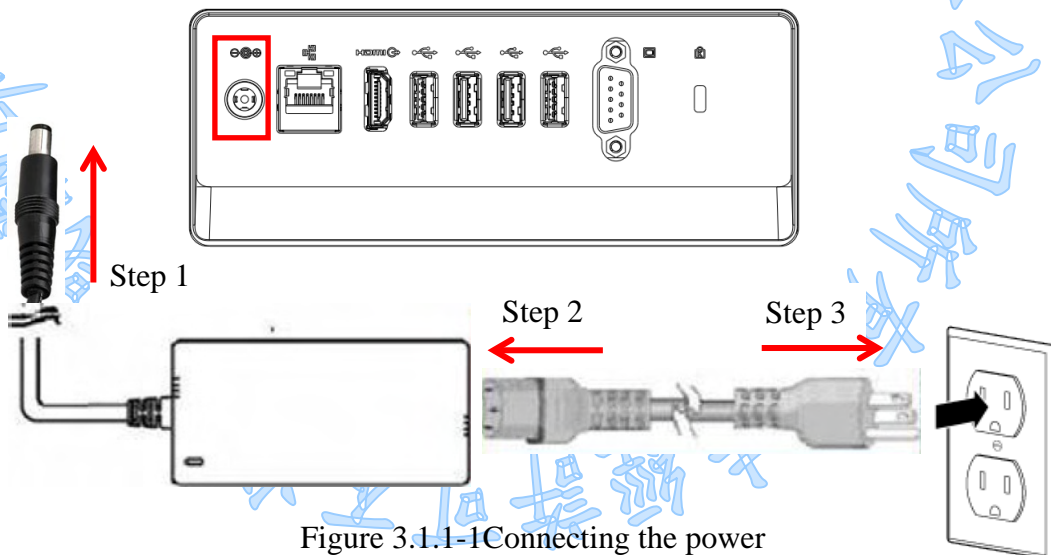


Figure 3.1.1-1 Connecting the power

Warning! The SHC-100 is supplied by a 60 Watt power supply and a special adapter as depicted
Avertissement! for the mode above.



If a medical adaptor is connected to the SHC-100, the customer must ensure legal and regulatory compliance and that the device meets the law and standards compliance requirements of this hardware.

Le SHC-100 est alimenté par une alimentation de 60 watts et un adaptateur spécial tel que représenté pour le modèle ci-dessus.

Si un adaptateur médical est connecté au SHC-100, le client doit s'assurer de la conformité légale et réglementaire et que l'appareil répond aux exigences légales et aux exigences de conformité de ce matériel.

3.1.2 Switching on the power

Push down the power button on the front panel of the SHC-100. (The color of the indicator will turn white)

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3.2 RUNNING THE BIOS SETUP PROGRAM

Your SHC-100 is likely to have been properly set up and configured by your dealer prior to delivery. You may still find it necessary to use the BIOS (Basic Input-Output System) setup program to change system configuration information, such as the current date and time or your type of hard drive. The setup program is stored in read-only memory. It can be accessed either when you turn on or reset the panel PC, by pressing the " F1 " key on your keyboard immediately after powering on the computer.

The settings you specify with the setup program are recorded in a special area of memory called CMOS RAM. This memory is backed up by a battery so that it will not be erased when you turn off or reset the system. Whenever you turn on the power, the system reads the settings stored in CMOS RAM and compares them to the equipment check conducted during the power on self-test (POST). If an error occurs, an error message will be displayed on the screen, and you will be prompted to run the setup program.

3.3 INSTALLING SYSTEM SOFTWARE

Recent releases of operating systems from major vendors include a setup program which loads automatically and guides you through hard disk preparation and operating system installation. The guidelines below will help you determine the steps necessary to install your operating system on the PC's hard drive.

Note! *Some distributors and system integrators may have already preinstalled system software prior to shipment of your PC.*



If required, insert your operating system's installation or setup diskette into the external diskette drive until the release button pops out.

The BIOS supports system boot-up directly from the CD-ROM drive. You may also insert your system installation CD-ROM disk into your external CD-ROM drive. Power on or reset the system and then enter the BIOS menu by pressing the "F1" key. And adjust the boot device sequence.

Or you can press "F12" key when booting, a bootable device popup menu will appear, you can then select the bootable device that you want. The SHC terminal will automatically load the operating system from the USB disk or CD-ROM. If you are presented with the opening screen of a setup or installation program, follow the instructions on the screen. The setup program will guide you through the preparation of your hard drive, and installation of the operating system.

3.4 INSTALL VESA MOUNTING

The SHC-100 also allows standard VESA mounting to help system integrators conveniently integrate the PC into their system.

Only use mounting brackets provided by Compal to prevent unreliable mounting of the SHC-100. VESA mount installation should be carried out by a professional technician; please contact a service technician or your retailer if you need mounting service.

Installation instructions:

1. First attach the wall-mount to the heat-sink of the SHC-100, securing it in place with the four Phillips-head screws provided (M4 x L10).
2. Mount on the wall, stand or another flat surface.

Warning! Be sure to secure the screws of the mounting bracket tightly. A loose joint between the SHC-100 and mounting bracket may create a risk of injury.

Avertissement! Assurez-vous de bien serrer les vis du support de montage. Un joint lâche entre le SHC-100 et le support de montage peut créer un risque de blessure.

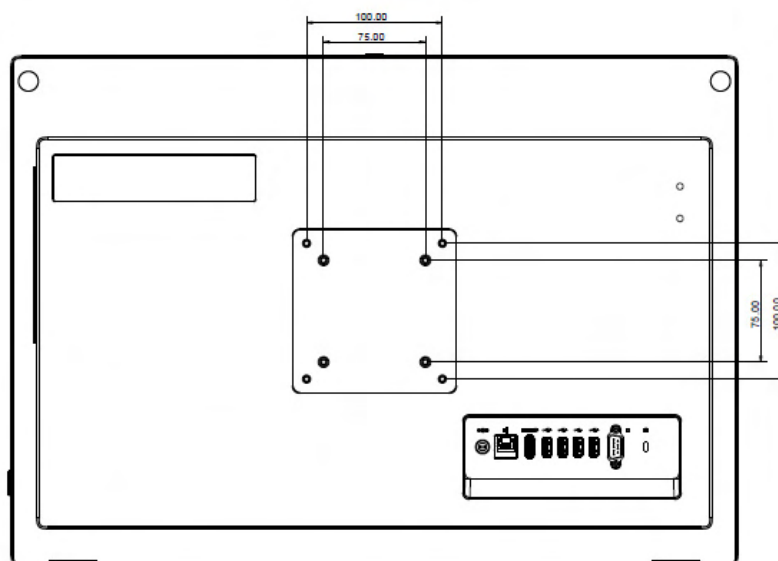


Figure 3.4-1 VESA mount

3.5 TROUBLESHOOTING

See the technical support instructions below when the system behaves abnormally, such as in the following conditions:

- Failure to power on
- Failure to power off
- Power LED ON but no DC power output
- AC power in and all switches ON, but the system doesn't power on

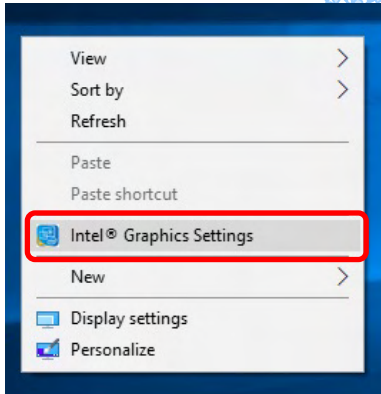
Contact your distributor, sales representative, or Compal's customer service center for technical support if you need additional assistance. Please have the following information ready before you call:

- Product name and serial number
- Description of your peripheral attachments
- Description of your software (operating system, version, application software, etc.)
- A complete description of the problem
- The exact wording of any error messages
- Symptoms, photo or video if available.

Chapter 4 Software

4.1 DISPLAY CONTROL SETTINGS

Step 1: Right-click on the desktop and select “Intel® Graphics Settings”

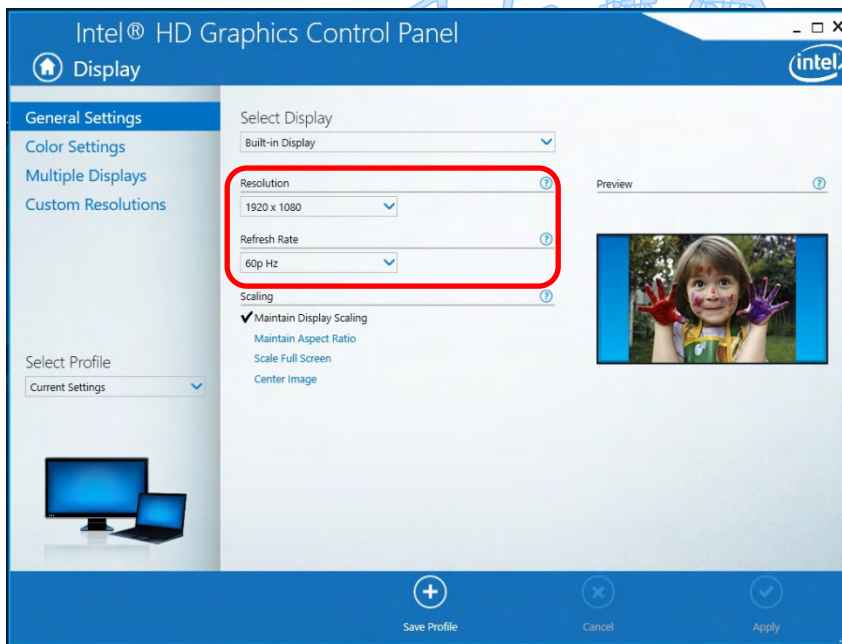


Step 2: Select “Display”



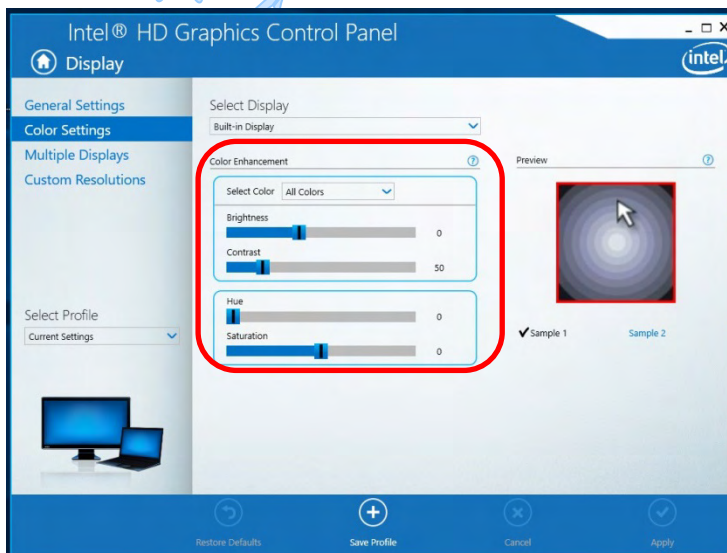
Step 3: Select “General Settings”

Set the **Resolution** and **Refresh Rate**.



Step 4: Select “Color Settings”

Set the **Brightness**, **Contrast**, **Hue** and **Saturation**.



Step 5: After all the settings have been completed, click “Apply”.

4.2 WINDOWS DRIVERS LIST

Please install the proper driver based on the SHC-100's OS version (Win 10).

The following drivers are located on the driver CD in the path\Driver\ Folder.

Please install the drivers based on the sequence below:

Install sequence	Folder Name	Note
1	Chipset_Intel	
2	Graphics_Intel	
3	Audio	
4	LAN_Realtek	
5	Card reader	
6	WLANBT_QCA	
7	MEI	
8	NFC	
9	PL2303_Prolific_DriverInstaller_v1190	

Chapter 5 Appendix

5.1 ANNEX

5.1.1 Guidance and manufacturer's declaration – electromagnetic emissions

The model SHC-100 is intended for use in the electromagnetic environment specified below. The customer or the user of the model SHC-100 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment –guidance
RF emissions CISPR 11	Group 1	The model SHC-100 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The model SHC-100 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Pass	

Table 5.1

5.1.2 Recommended separation distances between portable and mobile RF communications equipment and the model SHC-100

The model SHC-100 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the model SHC-100 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model SHC-100 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to the frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			


Table 5.2

5.1.3 Guidance and manufacturer's declaration – electromagnetic immunity

The model SHC-100 is intended for use in the electromagnetic environment specified below. The customer or the user of the model SHC-100 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge(ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV 100 kHz repetition frequency	±2 kV 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	line to line ±0.5 kV, ±1 kV line to earth ±0.5 kV, ±1 kV, ±2 kV	line to line ±0.5 kV, ±1 kV line to earth ±0.5 kV, ±1 kV, ±2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips IEC 61000-4-11	0% U_T ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0% U_T ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the model SHC-100 requires continued operation during power mains interruptions, it is recommended that the model SHC-100 be powered from an uninterrupted power supply or a battery.
	0% U_T ; 1 cycle and 70% U_T ; 25/30 cycles Single phase: at 0°	0% U_T ; 1 cycle and 70% U_T ; 25/30 cycles Single phase: at 0°	
Voltage interruptions IEC 61000-4-11	0% U_T ; 250/300 cycles	0% U_T ; 250/300 cycles	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level			

Table 5.3

5.1.4 Guidance and manufacturer's declaration – electromagnetic immunity

The model SHC-100 is intended for use in the electromagnetic environment specified below. The customer or the user of the model SHC-100 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance result	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms	Pass	Portable and mobile RF communications equipment should be used no closer to any part of the model SHC-100, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^α , should be less than the compliance level in each frequency range ^β . Interference may occur in the vicinity of equipment marked with the following symbol: 
	50 kHz to 80 MHz 6Vrms in ISM bands between 150 kHz and 80 MHz		
	180% AM at 1 kHz		
Radiated RF EM IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	Pass	
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
<p><i>α</i> : Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM, and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the model SHC-100 is used exceeds the applicable RF compliance level above, the model SHC-100 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model SHC-100.</p> <p><i>β</i> : Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

5.1.5 Names and contents of harmful substances in products (TW)

單元 Unit	限用物質及其化學符號					
	鉛 (Pb)	汞 (Hg)	鎘 (Cd)	六價鉻 (Cr ⁺⁶)	多溴聯苯 (PBB)	多溴二苯醚 (PBDE)
印刷電路板組件 (含處理器)	—	○	○	○	○	○
硬碟	—	○	○	○	○	○
光碟機(選配)	—	○	○	○	○	○
記憶體	—	○	○	○	○	○
電腦I/O配件	—	○	○	○	○	○
電源供應器	—	○	○	○	○	○
機殼	—	○	○	○	○	○
螢幕	—	○	○	○	○	○
配件 (含電源線)	—	○	○	○	○	○
散熱模組	—	○	○	○	○	○
喇叭(選配)	—	○	○	○	○	○
相機(選配)	—	○	○	○	○	○
麥克風(選配)	—	○	○	○	○	○
無線裝置(選配)	—	○	○	○	○	○
腳架(選配)	—	○	○	○	○	○

備考1. “超出0.1 wt %”及“超出0.01 wt %”係指限用物質之百分比含量超出百分比含量基準值。
 備考2. “○”係指該項限用物質之百分比含量未超出百分比含量基準值。
 備考3. “—”係指該項限用物質為排除項目。

Tabel 5.5 Taiwan RoHS

5.1.6 产品中有害物质的名称及含量 (China)

部件名称	有害物质					
	铅(Pb)	汞(Hg)	镉(Cd)	六价铬 (Cr(VI))	多溴联苯 (PBB)	多溴二苯醚 (PBDE)
印刷电路板组件	X	○	○	○	○	○
硬盘	X	○	○	○	○	○
光驱	X	○	○	○	○	○
内存	X	○	○	○	○	○
计算机I/O附件	X	○	○	○	○	○
电源	X	○	○	○	○	○
机箱/附件	X	○	○	○	○	○
电池	X	○	○	○	○	○

本表格依据SJ/T 11364的规定编制
 ○：表示该有害物质在该部件所有均质材料中的含量均在GB/T 26572规定的限值要求以下。
 X：表示该有害物质至少在该部件的某一均质材料中的含量超出GB/T 26572规定的限值要求。
 注：表中标记“X”的部件均符合欧盟 RoHS 立法。

Tabel 5.6 China RoHS