SORIN | ORCHESTRA PLUS LINK

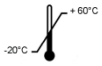
USER MANUAL

KA 351

CARDIAC RHYTHM MANAGEMENT SOLUTIONS

TABLE OF CONTENTS

1. LIST OF SYMBOLS

	This symbol is used to encourage you to consult the documentation and manual enclosed in the packaging.
FCC icon	This symbol confers the approval of the US Federal Communications Commission.
	Name and address of the manufacturer
	Serial number
	Keep the device dry. Keep it away from liquids and do not spill or drip water on it.
	The monitor shall be powered only with direct current.
	Non-ionizing magnetic radiation
	This electronic product is subject to disposal and recycling regulations that vary by country and region. Many countries prohibit the disposal of waste electronic equipment in standard waste receptacles. For more details, please refer to the European Directive 2002/96/CEE.
	Temperature limits for storage and transportation
	Humidity limits for storage and transportation
	Pressure limits for storage and transportation
	Sorin Reference of the ORCHESTRA PLUS LINK
	USB Type A Power supply connector to Orchestra Plus

FCC ID : **YSGKA351**
IC ID: **10270A-KA351**

2. SYMBOLS USED IN THIS MANUAL

This icon is used to call your attention to a particularly important point.

This icon alerts you to a hazard that may result in equipment damage or personal injury. Carefully read the instructions provided with this icon.

ABOUT THIS MANUAL

If you have technical or usage questions that are not covered in this manual or you want more in-depth information, please contact your sales representative.

3. INTRODUCTION

The ORCHESTRA PLUS LINK is part of the RF Programmer System. This system has been specially designed to program and interrogate Sorin Radio Frequency implantable medical devices.

Sorin cardiac devices are equipped with a transceiver which receives clinical commands and sends clinical information and device parameters through the ORCHESTRA PLUS LINK Radio Frequency wireless technology.

This manual does not explain how to use the SmartView programming software; please refer to the online help.

4. USER PROFILE

Any person who followed the required training based on the local regulation. Training completion and effectiveness are under his/her medical supervisor’s responsibility.

5. INDICATION

The ORCHESTRA PLUS LINK is designed for use with:

- Sorin Radio Frequency implantable medical devices,
- Sorin Orchestra Plus programmer equipped with a Sorin inductive programming head.

6. WARNINGS AND PRECAUTIONS

6.1 SAFETY PRECAUTIONS

Alteration – Your ORCHESTRA PLUS LINK and supplied accessories shall not be modified, altered, or changed in any way without signed written permission from Sorin. Unauthorized modification may void the equipment authorization from the certified body (compliance to standards) and compromise system performance. Use only Sorin supplied accessories.

Environmental factors - To reduce the risk of system failure, fire, personal injury, do not expose this appliance to humidity, moisture, extreme temperatures or electrical storms. If the ORCHESTRA PLUS LINK is damaged due to a mechanical shock or liquid, do not plug it in again and call your sales representative.

Keep the device dry – Do not spill or drip liquids on it.

6.2 PRECAUTIONS FOR SAFE OPERATION

Location – Preferably the ORCHESTRA PLUS LINK should be placed in a stable position as close as possible to the patient.

Power supply – The ORCHESTRA PLUS LINK shall be connected exclusively to one of Sorin Orchestra Plus USB ports. Refer to Orchestra Plus user manual for location of ports E & C (dual ports).

Power supply protection –ORCHESTRA PLUS LINK USB cable shall be routed so it is not likely to be walked on or pinched by items placed on or against it. In addition, USB cable extensions shall not be used to connect ORCHESTRA PLUS LINK to Orchestra Plus.

Power supply connection – ORCHESTRA PLUS LINK USB cable shall be plugged into Orchestra PLUS before interrogating the implantable medical device. It will not be possible to establish an RF communication with the implantable medical device if the interrogation starts before the ORCHESTRA PLUS LINK has been connected.

Power supply disconnection – You can only remove power from ORCHESTRA PLUS LINK by disconnecting its USB cable from Orchestra Plus. Always carefully disconnect ORCHESTRA PLUS LINK by pulling on the USB plug and not on the cable.

Do not remove the USB cable during the Orchestra Plus programming session of the implantable medical device.

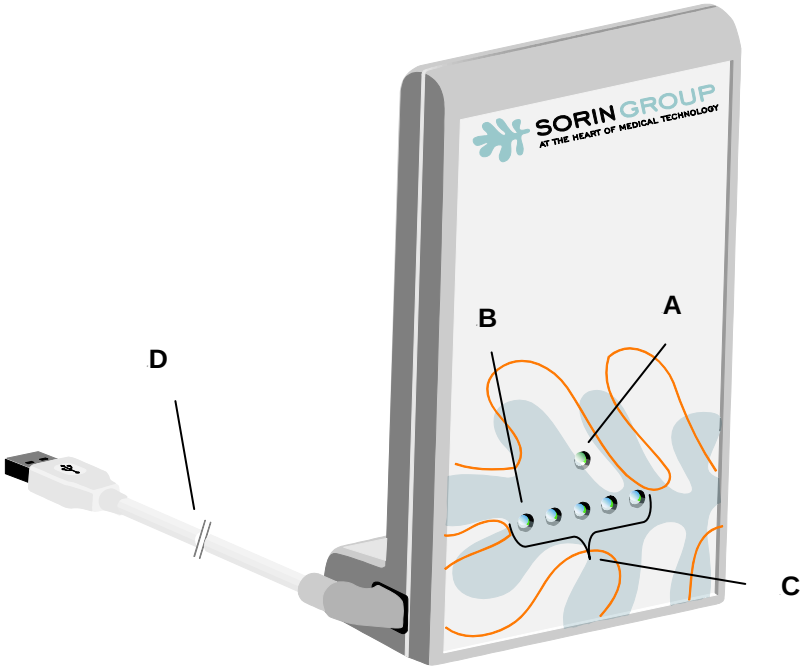
Interferences – ORCHESTRA PLUS LINK can be subject to disturbances from other products in the vicinity which emit electromagnetic interference (see Troubleshooting section 10). Keep the space clear between the ORCHESTRA PLUS LINK and the implantable medical device.

7. PACKAGE CONTENTS

Inside the box you will find ORCHESTRA PLUS LINK and its user manual (CD-Rom).

Do not use any other parts than those supplied with the ORCHESTRA PLUS LINK.

8. DESCRIPTION



A/ Functioning status LED

B/ RF link indicator LED

C/ RF signal strength 5 LEDs

D/ USB cable

9. USING ORCHESTRA PLUS LINK

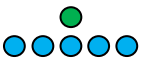
9.1 SETTING-UP ORCHESTRA PLUS LINK

In order to setup ORCHESTRA PLUS LINK, follow the instructions below.

Step	Operation
1	Install & switch on Orchestra Plus programmer (refer to Orchestra Plus user manual)
2	Take ORCHESTRA PLUS LINK out of the box.
3	Place your ORCHESTRA PLUS LINK on a stable and flat surface, (on a trolley, table or the patient's bed) as close as possible to the patient.
4	Plug ORCHESTRA PLUS LINK USB cable into an Orchestra Plus USB port.
	Once connected to Orchestra Plus, ORCHESTRA PLUS LINK will automatically run SW initialization and self-tests for a few seconds (status LED will light-up orange). 
	Once self-tests have passed, ORCHESTRA PLUS LINK is ready for use. The status LED becomes green. 

9.2 USING THE ORCHESTRA PLUS LINK

To interrogate an implantable medical device compatible with ORCHESTRA PLUS LINK, follow the instructions below:

Step	Operation
1	Place the inductive programming head on the implantable medical device and select the Interrogate button in the Programmer User Interface.
	After a few seconds the RF communication will start automatically (if previously selected in the programmer User Interface) The RF link indicator will light-up and RF signal strength LEDs will indicate the RF communication quality. 5 LEDs lit up indicate the optimal communication 
2	Move the inductive programming head away from the implantable medical device once the RF communication has started
	Full interrogation and programming of the implantable medical device can now be performed via ORCHESTRA PLUS LINK.
3	Quit the programming session before the patient leaves the operating room or follow-up. RF programming communication will be in any case automatically disabled after a time of inactivity (RF still active for Remote Monitoring).

Quitting the programming session reduces battery consumption and optimizes device longevity.

9.3 ENSURING STABLE RF COMMUNICATION

For stable RF communication between ORCHESTRA PLUS LINK and the implantable medical device, it is recommended to position ORCHESTRA PLUS LINK in order to light at least 4 LEDs.

It is highly recommended to obtain stable communication before performing device tests such as pacing and defibrillation threshold tests.

Keep the space clear between the ORCHESTRA PLUS LINK and the implantable medical device, and do not cover the implanted device when performing defibrillation threshold tests.

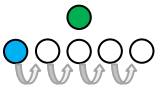
In some cases the RF communication can be disturbed and disrupted (see Troubleshooting section 10).

When RF communication is disrupted Orchestra Plus will automatically try to restore it. During RF communication restoration, the RF link LED will blink.

9.4 ORCHESTRA PLUS LINK SOFTWARE UPDATE

ORCHESTRA PLUS LINK software update, if any, will start automatically after connection to Orchestra Plus. (Orchestra Plus shall be on.)

During the update the functioning status LED is green and the RF signal strength LEDs indicate the action in-progress by blinking sequentially.



10. ORCHESTRA PLUS LINK BASIC CARE

Protect the ORCHESTRA PLUS LINK from splashes. To clean it, please only use a soft dry cloth. Any other cleaning method could damage the ORCHESTRA PLUS LINK. Do not use any kind of detergents even dry ones. Do not sterilize.

11. MAINTENANCE AND RECYCLING

11.1. COMPATIBILITY

For more information about implant Radio Frequency wireless programming compatibility with ORCHESTRA PLUS LINK, please refer to the implant user manual.

The ORCHESTRA PLUS LINK requires neither maintenance, nor calibration (periodical electrical test).

As with all electronic devices, recycling the ORCHESTRA PLUS LINK is mandatory, therefore please return it to Sorin if no longer used.

Please contact your sales representative for more information on the collection procedure. Sorin will be in charge of collecting and recycling it in compliance with European Directive 2002/96/CEE.

12. TROUBLESHOOTING

Start-up problems

If the ORCHESTRA PLUS LINK functioning status LED is not green, verify USB connection with Orchestra Plus. If the problem persists, call your sales representative.

Unstable or no RF communication with implantable medical device

To recover stable communication:

- Verify USB connection with Orchestra Plus
- Move the inductive programming head away from the implantable medical device during the implantation or follow-up session, when the RF session is initiated.
- Remove any objects between ORCHESTRA PLUS LINK and implantable medical device
- Re-position (5 - 10 cm) or rotate the ORCHESTRA PLUS LINK
- Move the ORCHESTRA PLUS LINK closer to the implantable medical device
- If none of the above works, switch to inductive telemetry

13. TECHNICAL SPECIFICATIONS

Part number	KA351
Dimensions	Height: 176 mm Width: 106mm Depth: 54,4 mm
Weight	450 g
Power supply	USB input : 5 V / 500mA
Operating conditions	from 0°C to +35°C Atmospheric pressure: from 700 to 1060 hPa
Transport and storage conditions	from -20°C to +60°C from 5% to 95% RH (non condensing) Atmospheric pressure: from 500 to 1060 hPa
Transmitter frequency	2400-2483 MHz (ISM) 402-405 MHz (MedRadio)
Characteristics of the transmitters	ISM: uses frequency hopping EIRP = 10 mW max, OOK modulation. MedRadio: uses Listen Before Talk algorithm, EIRP = 25 µW max, FSK modulation.
Receiver frequency	402-405 MHz (MedRadio)

The ORCHESTRA PLUS LINK may be disturbed by other equipment, even if said equipment complies with CISPR emission requirements.

14. DECLARATION OF CONFORMITY

Sorin declares that this device conforms to the following Product Specifications:

Safety - IEC 60601-1: 2005 (Ed. 3) - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

EMC - IEC 60601-1-2: 2012 (Ed. 3) - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and Tests.

EN 50371: 2002 - Generic standard to demonstrate the compliance of low power electronic and electrical apparatus with the basic restrictions related to human exposure to electromagnetic fields (10 MHz – 300 GHz).

EN 50385: 2002 - Product standard to demonstrate the compliance of radio base stations and fixed terminal stations for wireless telecommunication systems with the basic restrictions or the reference levels related.

EN 60950-1:2006/A12:2011 - Information technology equipment - Safety -- Part 1: General requirements.

EN 62311: 2008 - Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz to 300 GHz)

EN 301 489-1 v1.8.1 - Electromagnetic compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services - Part 1: Common technical requirements.

EN 301 489-1 V1.9.2 - Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements

EN 301 489-7 V1.3.1 - Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment; Part 17: Specific conditions for Broadband Data Transmission Systems

EN 301 489-17 v2.1.1 - Specific conditions for Broadband Data Transmission Systems.

EN 301 489-27 v1.1.1 - Specific conditions for Ultra Low Power Active Medical Implants (ULP-AMI) and related peripheral devices (ULP-AMI-P).

EN 300 328 v1.7.1 - Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonized EN covering essential requirements under article 3.2 of the R&TTE Directive.

ETSI EN 301 839-1 v1.3.1 - Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz - Part 1: Technical characteristics and test methods.

ETSI EN 301 839-2 v1.3.1 - Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz - Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive.

Federal Communication Commission Interference Statement 47 CFR Section 15 and 105(b)

The FCC product ID is **YSGKA351.**

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. 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 is encouraged to try to correct interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.

- Increase the separation between the equipment and receiver.

- Connect the equipment into an outlet on circuit different from that to which the receiver is connected.

- Consult the dealer or an experienced radio/TV technician for help.

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

This device complies with FCC RF radiation exposure limits set forth for general population. This device must be installed to provide a separation distance of at least 20cm from all persons and must not be co-located or operating in conjunction with any other antenna or transmitter.

FCC Interference Statement 47 CFR Section 15.21 - No Unauthorized Modifications

CAUTION: This equipment may not be modified, altered, or changed in any way without signed written permission from SORIN. Unauthorized modification may void the equipment authorization from the FCC and will void the SORIN warranty.

Identification of the equipment according Section 95.1217(a)

This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150-406.00 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Device Radiocommunication Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

IC Requirements for Canada

The IC product ID is **10270A-KA351**.

This class B digital apparatus meets all requirements of the Canadian Interference- causing equipment regulations.

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

This device complies with Industry Canada RF radiation exposure limits set forth for general population (uncontrolled exposure). This device must be installed to provide a separation distance of at least 20cm from all persons and must not be collocated or operating in conjunction with any other antenna or transmitter.

This device may not interfere with stations operating in the 400.150–406.000 MHz band in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation.

Cet appareil numérique de la classe B respecte toutes les exigences du règlement sur le matériel brouilleur du Canada.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes: (1) il ne doit pas produire de brouillage, et (2) l'utilisateur du dispositif doit être prêt a accepter tout brouillage radioélectrique reçu, même si ce brouillage est susceptible de compromettre le fonctionnement du dispositif.

Conformément à la réglementation d'Industrie Canada, le présent émetteur radio peut fonctionner avec une antenne d'un type et d'un gain maximal (ou inférieur) approuvé pour l'émetteur par Industrie Canada. Dans le but de réduire les risques de brouillage radioélectrique à l' intention d'autres utilisateurs, il faut choisir le type d'antenne et son gain de sorte que la puissance isotrope rayonnée équivalente (p.i.r.e.) ne dépasse pas l'intensité nécessaire à l'établissement d'une communication satisfaisante.

Le présent appareil est conforme aux niveaux limites d'exigences d'exposition RF aux personnes définies par Industrie Canada. Cet appareil doit être installé afin d'offrir une distance de séparation d'au moins 20cm avec l'utilisateur, et ne doit pas être installé à proximité ou être utilisé en conjonction avec une autre antenne ou un autre émetteur.

Le présent dispositif ne doit pas causer de brouillage aux stations du service des auxiliaires de la météorologie, des satellites météorologiques, du service d'exploration de la terre par satellite, exploitées dans la bande 400,150-406,000 MHz, et il doit accepter tout brouillage reçu, y compris le brouillage pouvant entraîner un mauvais fonctionnement du dispositif.

15. GUIDANCE AND MANUFACTURER'S DECLARATION

15.1 ELECTROMAGNETIC EMISSIONS

The ORCHESTRA PLUS LINK is intended for use in the electromagnetic environment specified below. The user of the ORCHESTRA PLUS LINK should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The ORCHESTRA PLUS LINK uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference to nearby electronic equipment.
RF emissions CISPR 11	Class B	The ORCHESTRA PLUS LINK is suitable for use in all clinical establishments, as an accessory of Orchestra Plus programmer
Harmonic emissions IEC 61000-3-2	Class A	

15.2 ELECTROMAGNETIC IMMUNITY

The ORCHESTRA PLUS LINK is intended for use in the electromagnetic environment specified below. The user of the ORCHESTRA PLUS LINK should ensure 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	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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 %.

The ORCHESTRA PLUS LINK is intended for use in the electromagnetic environment specified below. The user of the ORCHESTRA PLUS LINK should ensure that it is used in such an environment.

Portable and mobile RF communications equipment should be used no closer to the ORCHESTRA PLUS LINK, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance:

Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 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 metres (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]

Interference may occur in the vicinity of equipment marked with the following symbol:

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.

[a] 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 ORCHESTRA PLUS LINK is used exceeds the applicable RF compliance level above, the ORCHESTRA PLUS LINK should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting, relocating the ORCHESTRA PLUS LINK, or use inductive telemetry.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

15.3 RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE ORCHESTRA PLUS LINK

The ORCHESTRA PLUS LINK is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the ORCHESTRA PLUS LINK can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ORCHESTRA PLUS LINK as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to 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.

16. TECHNICAL ASSISTANCE

For any assistance you may need or question you may have about your ORCHESTRA PLUS LINK, please call your sales representative.

Last revision date of this manual: 2014-10

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

2014-10
U386A

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AT THE HEART OF MEDICAL TECHNOLOGY

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