# Concardio Medical Instruments Inc.

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October 18, 2004

Dr. Andrew Rawicz
School of Engineering Science
Simon Fraser University
Burnaby, BC V5A 1S6

**Re: ENSC 340 Functional Specifications: The CMI Cardiac Action Potential Imaging System (CAPIS)**

Dear Dr. Rawicz:

Attached with this letter is the *Functional Specifications: The CMI Cardiac Action Potential Imaging System*, which was previously described in our project proposal. We are developing an optical mapping tool that will record electrical signals from a small heart for analysis of irregular heart pulses associated with JET arrhythmia.

This functional specification outlines the requirements and goals of our product for our proof-of-concept phase. The specification and test plans for individual modules are presented. Each specification is prioritized, within each module, during development of the product.

Concardio Medical Instruments Inc. consists of eight experienced, dedicated, and hard working engineering students who want to make a difference: Ronnie Chan, Yindar Chuo, Allen Lai, Deanna Lee, Seddrak Luu, Jimmy Tsui, Edwin Wong, and Stephen Wong. Please contact us if there are any questions or concerns via email, *ensc-bcri@sfu.ca* or by phone through Ronnie Chan at 778-891-3837. Thank you.

Sincerely,

*Ronnie Chan*

Ronnie Chan
Chief Executive Officer
Concardio Medical Instruments Inc.

Enclosure: Functional Specifications for the CMI Cardiac Action Potential Imaging System

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# *Functional Specifications for the* Cardiac Action Potential Imaging System

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# EXECUTIVE SUMMARY

Junctional ectopic tachycardia (JET) is a severe form of arrhythmia frequently seen in babies who have undergone open heart surgery. The pathophysiology of JET is not well understood, and as a result, a cure has not yet been found. Current treatments for the disease are crude and expensive, and finding the cause will become critical in improving the quality and affordability of patient care. Unfortunately, the JET research community today lacks a research tool capable of mapping electrical signals in a small heart over a certain time frame. Concardio Medical Instruments Inc. (CMI) aims to fill this need, by constructing a multipurpose imaging system that can help researchers visually track the movement of electrical and chemical signals in a small heart. As a first step toward achieving this vision, CMI would like to introduce the Cardiac Action Potential Imaging System (CAPIS). The purpose of CAPIS is to help cardiologists map the electrical patterns in the heart associated with JET.

Developed with support from our primary client, Dr. Glen Tibbits of the BC Research Institute for Children's and Women's Health, CMI's CAPIS will acquire optically mapped potentiometric images and display them in a comprehensive manner suitable for analysis. Currently, CMI is entering the proof-of-concept (POC) phase in the CAPIS development cycle, spanning from September to December of 2004. In the POC stage, a mock-up model for each critical module in CAPIS will be built so that the CMI design team may evaluate the feasibility of constructing an integrated functional prototype. Due to the large size of the project, and lengthy development period, only the mock-up models constructed in the POC stage will constitute the project submitted for ENSC 340.

CAPIS is divided into three critical modules: Image Generation, Image Acquisition, and Image Analysis. The mock-up model for each module has its own set of functionalities to satisfy for evaluation purposes. The basic functions of each module are outlined below:

- **Image Generation Module:**
  Obtain optical signal from the heart tissues and display them without loss of data

- **Image Acquisition Module:**
  Capture and display live test images of various formats

- **Image Analysis Module:**
  Correct for motion artifacts related to capturing images of a beating heart

Upon completion of the proof-of-concept mock-up, the CMI design team will be more equipped to further assess and consolidate, together with Dr. Glen Tibbits, the feasibility and expected functionalities of the CAPIS functional prototype.

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# ABBREVIATIONS

| | |
|---|---|
| **BCRI** or **BCRICWH** | BC Research Institute for Children's and Women's Health |
| **CAPIS** | Cardiac Action Potential Imaging System |
| **CCD camera** | charge-coupled device camera |
| **CMI** | Concardio Medical Instruments Inc. |
| **IAqM** | image acquisition module |
| **IAnM** | image analysis module |
| **IEEE** | Institute of Electrical and Electronic Engineers |
| **IGM** | image generation module |
| **JET** | junctional ectopic tachycardia |
| **POC** | proof-of-concept |
| **RN** | requirement number |
| **TTL** | transistor-transistor logic |

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# 1 INTRODUCTION

## *1.1 Purpose Statement*

The Cardiac Action Potential Imaging System (CAPIS) is an optical mapping tool designed to show the propagation of action potential in a small heart. The input to the system is an in-vitro baby rabbit heart, treated with a potentiometric dye and chemically simulated to mimic the conditions of JET arrhythmia. When development is complete, CAPIS will be able to generate images showing the intensity of the action potential in various locations of the heart across the time frame in which the experiment is conducted.

## *1.2 Development Cycle*

The development of CAPIS is projected to be a one year process, and the entire development cycle can be broken down into three four-month phases: a) Research, b) Proof-of-concept (POC), and c) Prototyping.

The Research phase took place during May to August of 2004 and was responsible for laying the ground work for the project. The outcomes in this stage were: a) determined overall system requirements, b) conducted background scientific and technology research, c) assembled the advisory board, and d) coordinated various resources needed for the later stages of the project.

The second stage in the cycle, the Proof-of-Concept phase, will span from September to December 2004. The goal of this stage is to construct models of the critical modules of the system and demonstrate their functionalities in a testable and repeatable manner. Integration is not critical in the Proof-of-Concept phase; hence, no prototype of the system is created in this stage.

Lastly, the Prototyping phase is projected to commence in January through April of 2005. This final stage of the development cycle will be dedicated to implementing the models from the POC phase to work in an actual laboratory setting and to performing system integration to produce a working prototype.

The above describes the macro-picture of CAPIS development. However, it should be noted that only the current Proof-of-Concept phase is concerned with ENSC 340, and that the requirements in this functional specification are written for the models to be constructed in the POC phase. In the subsequent sections, we will define in further detail the specific development objectives we expect to achieve in this POC stage.

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## 1.3 Intended Audience

This document is intended to be a design guideline for engineers within Concardio Medical Instruments (CMI) Inc., with a purpose of ensuring that the product developed by CMI meets the specified requirements. Marketing will use this document to arrange sales strategies. Any descriptions mentioned in this document will be protected as CMI's intellectual property.

## 1.4 Convention

Each requirement is denoted by a Requirement Number (RN), and the RN format proceeds as follows:

R-[XY-Z]

Below is a description of the RN.

**R** Denotes the word "Requirement."
**X** Denotes module, and can take on one of three values: **A** for Image Generation, **B** for Image Acquisition, and **C** for Image Analysis.
**Y** Denotes the requirement number.
**Z** Denotes the priority, and can take on one of two values: **H** for high priority, and **L** for low priority.

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# 2 SYSTEM OVERVIEW

The Cardiac Action Potential Imaging System (CAPIS) consists of three modules: Image Generation, Image Acquisition, and Image Analysis. The final prototype of CAPIS will be an imaging system that uses the Image Acquisition module to capture light emitted from a testing rabbit heart through a series of filters and lenses in the Image Generation module. The captured image from the Image Acquisition module will be used for research and study by the BC Research Institute (BCRI) after the Image Analysis module modifies the captured raw image into useful data.

Concardio Medical Instruments Inc. is currently in the proof-of-concept (POC) stage in the CAPIS development cycle. Since the 4 month stage (from September to December 2004) coincides with ENSC 340, the scope of the ENSC 340 project will be limited to the mock-up models built in the POC stage only. Thus, each individual module will not be integrated and will have its own separate functional specifications.

General module descriptions are given as followed. The Image Generation module will use light emitted from a heart tissue specimen as input and perform appropriate filtering to extract and separate specified wavelengths from the input light. The Image Acquisition module will capture test images and output and save the images as a streaming video (as a series of still images) or still image onto a computer. The Image Acquisition module will perform other operations to manipulate the output images for simple analytical display as well. Finally, the Image Analysis module will take a series of test images (simulated with the artifact from imaging a beating heart) and perform the necessary correction to restore them to a comprehensible state for analysis.

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# 3 SYSTEM REQUIREMENTS

## *3.1 Image Generation Module Requirements*

The purpose for the Image Generation Module (IGM) proof-of-concept model is to excite a fluorescence-reactive cell with a light source so that it releases photons in two different wavelengths for analysis. The following diagram, Figure 3-1 shows the components of the module's proof-of-concept model.

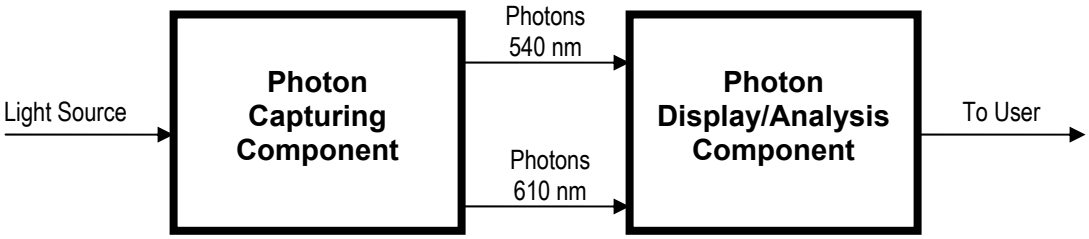


**Figure 3-1: The Image Generation Module Proof-of-concept model**

### 3.1.1 Input Requirements

R-[A1-H] Power input to IGM must be derived from a power adapter.
R-[A2-H] Light source to the IGM must emit wavelengths that can cause a potentiometric agent to fluoresce.

### 3.1.2 Physical Requirements

R-[A3-H] The entire IGM system must operate under a light-tight environment in order to produce accurate results.
R-[A4-H] The IGM system must be compatible with the computer that contains the software for analysis.
R-[A5-L] The IGM system must be compatible to the Institute of Electrical and Electronics Engineers (IEEE) standard.

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### 3.1.3 Photon Capturing Performance Requirements

R-[A6-H] A potentiometric agent that can fluoresce and release photons greater than 510 nm must be used in this component.

R-[A7-H] IGM must be able to capture released photons and separate them at 540 nm and 610 nm (Knisley et al., 2000).

R-[A8-H] Capturing of photons at each of the two wavelengths must have an error margin of no more than ±20 nm.

R-[A9-H] IGM must be able to capture sufficient photons such that optical signals of any degree can be sensed by the photon analysis component.

### 3.1.4 Photon Display/Analysis Performance Requirements

R-[A10-H] IGM must be able to display clearly the transistor-transistor logic (TTL) curve with the absence of noise generated by equipment.

R-[A11-H] IGM must provide a feature for the user to save the TTL curve into a data file that is readable through programs in the Windows environment.

R-[A12-H] IGM must include features that enable the user to zoom in and zoom out of the curve.

R-[A13-L] IGM must display, at minimum, the intensity of specific wavelengths according to the number of photons counted from the TTL curves.

### 3.1.5 General Requirements

R-[A14-H] IGM must contain a graphical user interface (GUI) that provides image saving, opening, displaying and digital scaling functionalities as described above in the photon capturing and displaying performance requirements.

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## *3.2 Image Acquisition Module Requirements*

The Image Acquisition Module (IAqM) proof-of-concept model will capture images and display them in real-time. The IAqM will also save the images to file as still images or as a video stream (a series of still images). The following block diagram illustrates the functionality of the IAqM mock-up model.

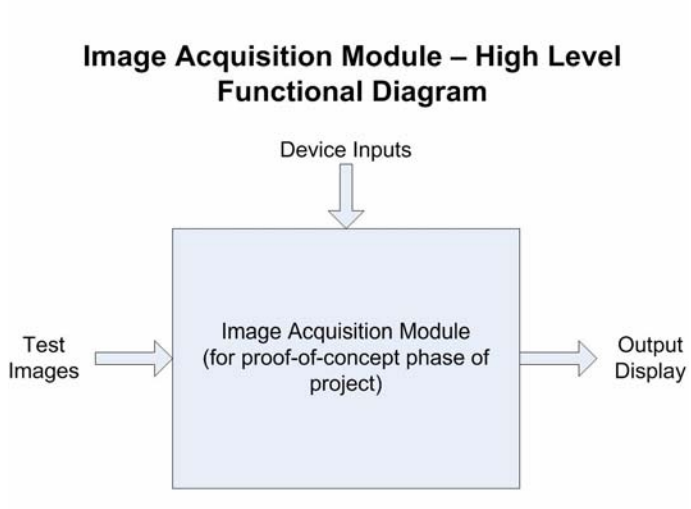


**Figure 3-2: High level function diagram of the Image Acquisition Module**

### 3.2.1 Input Requirements

R-[B1-H] Power input to IAqM must be derivable from standard British Columbian power outlets.

### 3.2.2 Physical Requirements

R-[B2-H] Mass of IAqM must be less than 22.6 kg (50 lb.) so that it may be easily transported between various testing facilities.

R-[B3-H] Total size of IAqM must be smaller than one cubic metre so that it may be easily transported between various testing facilities.

### 3.2.3 Image Capturing Performance Requirements

R-[B4-H] IAqM must be able to capture a time-position and time-intensity variant streaming video from a 300 to 800 nm wavelength light source.

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R-[B5-H] IAqM must be able to capture a streaming video for at least 20 seconds.

R-[B6-H] [1] IAqM must be able to capture a streaming video at a rate anywhere between 0.91 to 4194 frames per second.

R-[B7-H] [1] IAqM must be able to capture both image and video at a resolution anywhere between a pixel size of 6.35 μm by 7.4 μm and 16 μm by 16 μm, and array size of 128 by 128 pixels and 1920 by 1080 pixels.

R-[B8-H] [1] IAqM must be able to capture both image and video of a low intensity source, have quantum efficiency (sensitivity of the camera) anywhere between 21% and 90% from 300 to 800 nm wavelength.

R-[B9-H] IAqM must be able to save both an image and a streaming video, after it has been captured, in a format such that no data will be lost (eg. PNG, BMP file formats).

R-[B10-H] IAqM must have enough storage space to at least hold a 20 second video of streaming images.

### 3.2.4 Image Display Performance Requirements

R-[B11-H] IAqM must be able to display captured still images and streaming videos where the streaming video is close to real-time within a delay of no more than 2 seconds.

R-[B12-H] IAqM must provide a digital scale in and out feature for the images and videos displayed offline (i.e. processing of the images at a later time, after the images have been captured).

R-[B13-H] IAqM must provide a feature to display pseudo-coloring versions of images and videos offline.

R-[B14-H] IAqM must provide a feature to open and display saved images and videos of compatible formats as described in R-[B9-H].

### 3.2.5 General Requirements

R-[B15-H] IAqM must provide a graphical user interface (GUI) that can perform image saving, opening, displaying, digital zooming, and pseudo-coloring functionalities as described above in the image capturing and displaying performance requirements.

R-[B16-H] IAqM must have noise reduction mechanism if the image capture is believed to be subjected to significant noise introduced by the capturing and transmission hardware, where significant noise is defined by more than 25% noise-to-signal ratio.

R-[B17-L] The IAqM must be compatible with existing GUI module previously developed by British Columbia Research Institute (BCRI).

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[1] *The frame rate, resolution, and quantum efficiency have been determined from various sources of CCD camera vendors. These quantities represent the performance of a typical image capturing device. See references at the end of the document for more information.*

## *3.3 Image Analysis Module Requirements*

The Image Analysis Module (IAnM) proof-of-concept model will be capable of taking a series of test images, correct for the motion artifacts, and save or display the corrected images. Test images will be gradient polygons; these images will simulate image complexities and/or motion artifacts that might be present in a real setup. Users will specify landmarks that mark a certain boundary of a figure, and the software will match these landmarks on different images to correct for the shape alteration caused by motion artifacts. Figure 3-3 below outlines the operation of the IAnM module:

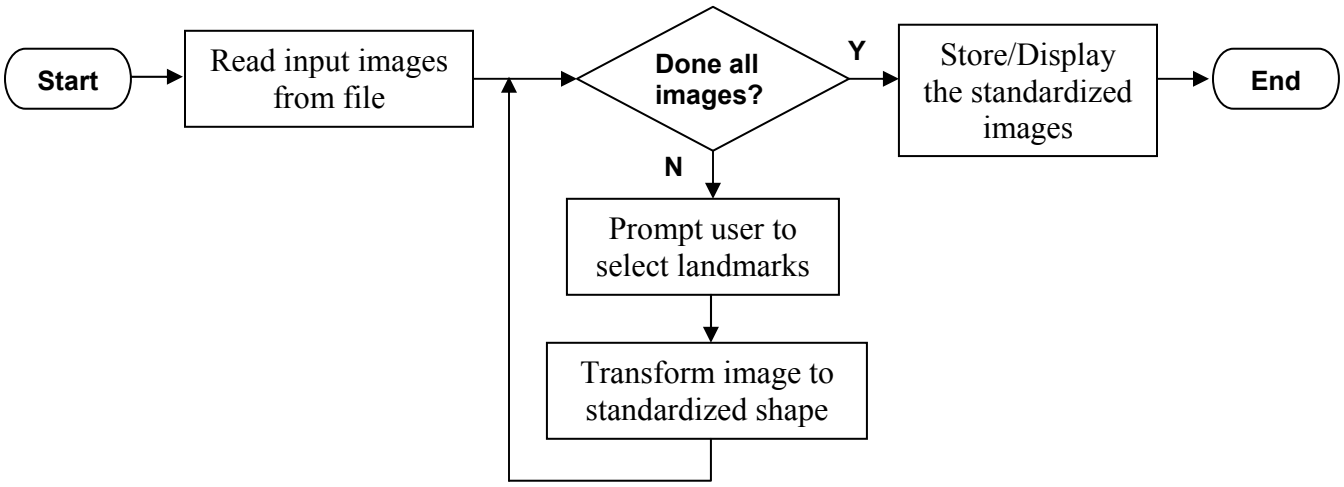


**Figure 3-3: Operation of the Image Analysis software**

### 3.3.1 General Requirements

R-[C1-H] The IAnM software must be able to restore a given series of images, containing an object with various degrees of deformations, into a standardized shape.

R-[C2-H] The algorithm for motion artifact correction will be landmark-based.

R-[C3-L] The IAnM software will be a console based program, encapsulated in a simple user interface (UI).

R-[C4-H] The IAnM software will be performing solely offline processing.

R-[C5-H] Documentation must be provided with all software components to ensure future users can run this software properly.

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### 3.3.2 Hardware Requirements

R-[C6-H] The IAnM software must run on a computer with either Windows or Linux operating systems.

R-[C7-H] The IAnM software must run on a computer that can support processing of at least one image.

### 3.3.3 Input Requirements

R-[C8-H] Input images must be 8-bit grayscale images.

R-[C9-H] All input images must be of the same dimensions.

R-[C10-H] Input images must contain grayscale gradient polygons.

R-[C11-H] User must specify an image (the “standard” image) to which subsequent images will be transformed.

R-[C12-H] User must specify image landmarks on each image.

### 3.3.4 Performance Requirements

R-[C13-H] The IAnM software must be able to retrieve images files from disk.

R-[C14-H] The IAnM software must be able to save processed images to disk.

R-[C15-H] The IAnM software must give the user the option of displaying saved images.

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# 4 TEST PLAN

The proof-of-concept models for CAPIS will each have specific test plans to verify their respective functionalities. These test plans are detailed in the subsections below.

## *4.1 Image Generation Module*

**Photon Emission**

- Determine whether or not the photons from the potentiometric agent are emitted greater than a wavelength of 510 nm.

**Photon Separation**

- Determine whether or not IGM will isolate photons of wavelengths 540 nm and 610 nm within error margin as described in the system requirements of this module.

**Data Collection**

- Ensure the collected photons generate transistor-transistor logic (TTL) pulses on the photometer properly.

**Quality of Signal**

- Visually inspect whether the clarity of the TTL curves is acceptable for submission to the photon analysis component.

**Photon Counting and Display**

- Count the number of TTL pulses for each of the two wavelengths, and display the results, in the form of light intensity emitted from these two wavelengths.

**Preparation for Integration**

- The photometer and the photon display/analysis component is part of the proof-of-concept model, and thus they will only be used to test and demonstrate the working ability of the IGM.
- Once the model has been tested and the IGM is ready for integration with the other modules, the photometer and the display/analysis component are no longer needed.
- To prepare for integration, ensure the two different wavelengths of light from the photon capturing component can be properly projected into the Image Acquisition Module, where further analysis will occur.

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## *4.2 Image Acquisition Module*

**Basic Features**

- Capture a test image in normal room lighting, display the image, save the image, open the image, and perform pseudo-coloring and digital zooming on the image.
- Capture a 20 second streaming video in normal room lighting, display the image, save the image, open the image, and perform pseudo-coloring and digital zooming on the image.

**Noise Reduction**

- Captured images will be corrupted by system noise. After initial visual inspection of the captured images on the GUI, we will implement noise removal algorithms to clean up the images.

After we have confirmed that our IAqM's basic display features are functioning properly, we will proceed with verifying that the image capturing functionalities are met.

**Frame Rate**

- Have a LED blink at the rate that emulates a typical cardiac action signal to test if the IAQM can capture the information without loosing any data.

**Intensity**

- Capture a still image and 20 second streaming video of a low intensity light image source.

**Wavelength**

- Capture a still image and 20 second streaming video of a light source composed of wavelengths between 300 to 800nm.

**Resolution**

- Capture a still image and 20 second streaming video of a calibration grid to verify the resolution requirements.

The above test plan addresses most of the performance and general functionalities proposed. The physical and input requirements are obvious in its verification, and are thus not discussed in this document.

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## *4.3 Image Analysis Module*

To accomplish the requirements set out, the Image Analysis module plan to construct two algorithms. These two algorithms are:

- Geometric transformation using MATLAB, and
- Customized non-rigid landmark transformation program from Dr. Faisel Beg.

In testing these two algorithms, we compare which of the two performs better in our motion artifact reduction goal, and choose that algorithm. Quantifying these results will be done in the following manner.

- Provide a standard set of images and landmarks to test both algorithms.
- Apply both algorithms to the set of images.
- Take the image difference from the "standard" image and each transformed image, and take the average.
- Perform this test analysis on different sets of input images.

The concept of "image difference" should be described with a bit more detail. As mentioned, we will determine which algorithm is better by numerically determining how well the transformed images, processed by each algorithm, match the "standard" image. In quantifying the algorithm's results, we will use a simple image difference – that is, we will take the difference of values of each pixel of the "standard" image by each pixel of the transformed image. Comparing the cumulative difference with total image intensity will result in a percentage error – this error will be used as the benchmark in determining which algorithm performs better.

Testing will not occur with one set of images and landmarks only. To increase the variety of data, we will verify that the better algorithm indeed performs better with different sets of test images.

To test usability, we will have beta users operate the software without prior knowledge. These users will have the resource of our documentation provided. The results of this test will allow us to determine whether unforeseen aspects of the design were not considered, and whether documentation is clear and concise.

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# 5 CONCLUSION

The requirements set in this document will provide a hard limit on the features of the CAPIS imaging system. At the end of the Proof-of-Concept phase, ending in December 2004, our system should be able to demonstrate each of the stated requirements. We are hopeful that the outcomes of this POC phase will lead to the construction of an integrated prototype, with the potential to develop into a useful research aid for Dr. Tibbits and the rest of the JET research community.

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