Guidelines on the Automation of Heart-Lung Machines

Recent advances in medical technology have been remarkable. Advances in IT (Information Technology) and AI (Artificial Intelligence) have led to the advancement of technologies such as autopilot systems in aviation[1] and autonomous car[2], which have become integral parts of society. In the field of Heart-Lung Machines, discussions on automation have increased alongside efforts to enhance device safety[3] and reform the workstyle of medical staff[4]. Research and development are progressing primarily in medical institutions, companies, and university laboratories, and automated blood reservoir level stabilization is already beginning to be clinically applied[5,6]. Therefore, referring to the example of automotive autonomous driving, we have created these guidelines on the automation of Heart-Lung Machines. This purpose is to provide recommendations to medical teams and companies regarding the extent to which automated operation for cardiopulmonary bypass (CPB) has been achieved. These guidelines are not intended to reduce perfusionists or restrict their activities but were developed from the perspective of enhancing safety and cost-effectiveness. Just as pilots remain on board even in aircraft capable of fully autonomous flight[7], this does not negate the need for Certified Clinical Perfusionists (CCPs) with advanced knowledge and skills to respond to unexpected situations, changes in surgical procedures, or system errors.

I. Industry Survey and Trend Analysis

The Japan Agency for Medical Research and Development (AMED)[8] promotes the utilization of AI, IoT, and robotics technologies in its medium-to-long-term goals (Phase 2). Priority research areas include "technologies for simplifying and improving the accuracy of diagnostic testing, enabling earlier implementation of continuous monitoring, and advancing the sophistication and integration of diagnosis and treatment through digitalization, data utilization, and the integration of multiple devices and systems."

Currently, AI-based image diagnosis support represents a leading advanced medical technology, already commercialized as a program medical device. A report issued by the Ministry of Economy, Trade and Industry (METI)[9] titled "Issues Surrounding the Medical Device Industry" forecasts expansion in the global market for medical software devices. It anticipates that these devices will "create innovative value not only in diagnosis, treatment, and prevention through unprecedented new mechanisms of action and diagnostic technologies, but also for reducing the burden on medical professionals and lowering costs for medical institutions."

At present, heart-lung machines are specialized medical devices (Class III, where the therapeutic device and operating technology are integrated), far from being medical software devices. However, they have a high potential to evolve into surgical-assist systems, exemplified by surgical assistance robots. This evolution is expected to enable the integration of multiple devices through the application of the aforementioned measurement technologies and reduce the burden on medical professionals. Medical safety must be guaranteed, and circulatory control (partial control) for safety is worth considering.

II. Classification Levels of Heart-Lung Machine Automation

Level 0: No Automatic Control, No Safety Automation

Level 1: Operation Support, Safety Control

Level 2: Partial Operation Automation

Level 3: Conditional Operation Automation

Level 4: Advanced Operation Automation

Level 5: Full Operation Automation

III. Level 0 (No Automatic Control, No Safety Automation)

1. Definition

   ● The perfusionist performs all dynamic operational tasks.

2. Responsible Entity for Monitoring and Responding to Automation

   ● Primary operation of the heart-lung machine: Perfusionist

3. Automation Description

   ● Safety devices are either incomplete or provide only alarms with no automatic control.

   ● No heart-lung operation support system exists

   ● Perfusionist operation is mandatory

   ● A dedicated CPB team capable of performing double checks, emergency response, laboratory tasks, etc., is mandatory

IV. Level 1 (Operation Support, Safety Control)

1. Definition

   ● The system performs a limited subset of operational control tasks for either blood delivery or drainage within a restricted domain.

2. Responsible Entity for Monitoring and Responding to Automation

   ● Primary operation of the heart-lung machine: Perfusionist

3. Automation Description

   ● Safety control follows the latest Standards for the Installation of Safety Devices during

Cardiopulmonary Bypass issued by the Japanese Society of Extra-Corporeal Technology in Medicine

● Partially equipped with auxiliary functions for CPB operation

● Perfusionist operation is mandatory

● A dedicated CPB team capable of performing double checks, emergency responses, and laboratory tasks, etc., is required

4. Specific Examples of Automation

● ON/OFF control of the pump triggered by low blood reservoir levels

● Stopping arterial flow when air bubbles are detected

● ON/OFF control of the arterial pump based on pressure

● ON/OFF control to maintain rotation without retrograde flow in the centrifugal pump

V. Level 2 (Partial Operation Automation)

1. Definition

● The system performs subtasks of operational control within a limited domain.

2. Responsible Entity for Monitoring and Response Related to Automation

● Primary operation of the heart-lung system: heart-lung system (or perfusionist if continued operation is difficult)

3. Automation Description

● Automatic control assists extracorporeal circulation operations such as stabilizing blood reservoir levels

● Automatic control is possible under certain conditions, but the perfusionist must remain ready to intervene at any time.

● A dedicated CPB team capable of performing double checks, emergency responses, and laboratory tasks, etc., is essential.

4. Specific Examples of Automation

● Automatic control of arterial flow based on venous return

● Automatic control of arterial pump or venous occluder based on blood reservoir level

● Automatic blood reservoir level control in closed circuit

● Automatic control to maintain rotation without retrograde flow in the centrifugal pump

● Automatic control of sweep gas to achieve target blood gas values

VI. Level 3 (Conditional Operation Automation)

1. Definition

● The system performs the main task of operational control within a limited domain.

2. Responsible Entity for Monitoring and Responding Related to Automation

● The heart-lung system performs dynamic operational tasks within a limited domain based on all dynamic operational instructions from the physician or perfusionist.

● If continued operation becomes difficult, the perfusionist appropriately responds to requests for intervention from the heart-lung system.

3. Automation Description

● Automatic control to achieve physiological target values.

● Automatic control allows full adjustment of arterial flow automatically from zero to the full flow.

● Automatic operation is possible under specified conditions, freeing the perfusionist from CPB operation during those conditions; however, the perfusionist must take over operation in emergencies.

● A CPB team capable of performing double checks, emergency responses, laboratory tasks, etc., as needed, is essential; however, staff reduction becomes possible through perfusionist dual roles.

4. Specific Examples of Automation

● Automatic control of blood flow and sweep gas to match the oxygen demand of the target organ or tissue

● Automatic control of blood flow and blood reservoir levels to maintain target arterial pressure and venous pressure

● Automatic control of suction and vent flow to achieve bloodless field

● Automatic control of vent flow in response to pulse pressure

VII. Level 4 (Advanced Operation Automation)

1. Definition

● The system will perform operations based on all operational instructions from the physician or perfusionist and only limited actions when it is difficult to continue tasks.

2. Responsible Entity for Monitoring and Responding to Automation

● Primary operation of the heart-lung system: the heart-lung system

3. Automation Description

● Semi-automation without using clamps

● Full operation possible without perfusionist intervention under certain conditions

● Perfusionist alone can complete extracorporeal circulation duties except in emergencies

4. Specific Examples of Automation

● Initiation of extracorporeal circulation (automatic flow increase, sweep gas, etc.) performed automatically with a single start button operation

● Administration of cardioplegia solution, fluid replacement, and medication performed via

button operation

● Weaning from extracorporeal circulation (automatic flow/volume adjustments) performed with a single weaning button operation

VIII. Level 5 (Full Operation Automation)

1. Definition

● The heart-lung system will perform operations based on all operational instructions from the physician or perfusionist and actions without limitation when it is difficult to continue tasks.

2. Responsible Entity for Monitoring and Responding to Automation

● Primary operation of the heart-lung system: Fully automated heart-lung system

3. Automation Description

● Perfusionist performs only target value setting and operation monitoring under automatic control

● Full automation under all conditions; perfusionist completes CPB duties via remote monitoring and alarm response only

● Fully autonomous operation possible under specified conditions without perfusionist intervention

● Perfusionists can simultaneously monitor multiple CPB operations, enabling staff reduction

4. Specific Examples of Automation

● Specific instructions from physicians or perfusionists are input via voice or button commands for automated control

● The control system reports current status to physicians or perfusionists via voice or screen display

IX. Definitions of Terms

● Heart-lung machine: The machine requires perfusionist operation (corresponding to Level 0 or 1).

● Heart-lung system: The machine equipped with various control and safety mechanisms (corresponding to Level 2, 3, or 4).

● Fully Automated Heart-lung system: The machine requires no perfusionist intervention (corresponding to Level 5)

● ON/OFF Control: Controls only the activation and deactivation of operations

● Automatic Control: Multi-step or continuous adjustment

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