



On approval of the Rules for the implementation of service maintenance of medical devices in the Republic of Kazakhstan

Unofficial translation

Order of the Minister of Healthcare of the Republic of Kazakhstan dated December 15, 2020 No. ҚР ДСМ-273/2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on December 20, 2020 No. 21805

Unofficial translation

In accordance with subclause 52) of article 7 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On Public Health and Healthcare System", **I HEREBY ORDER:**

1. To approve the rules for the implementation of service maintenance of medical devices in the Republic of Kazakhstan according to Appendix 1 to this order.

2. To recognize as invalid certain orders of the Ministry of Healthcare of the Republic of Kazakhstan under the list according to Appendix 2 to this order.

3. The Department of Medicines Policy of the Ministry of Healthcare of the Republic of Kazakhstan, in accordance with the procedure, established by the legislation of the Republic of Kazakhstan, shall ensure:

1) state registration of this order with the Ministry of Justice of the Republic of Kazakhstan;

2) placing this order on the Internet resource of the Ministry of Healthcare of the Republic of Kazakhstan;

3) within ten working days after the state registration of this order, submission to the Legal Department of the Ministry of Healthcare of the Republic of Kazakhstan of information about implementation of measures, stipulated by subclauses 1), 2) of this clause.

4. Control over implementation of this order shall be entrusted to the supervising Vice Minister of Healthcare of the Republic of Kazakhstan.

5. This order shall come into force upon expiry of ten calendar days after the date of its first official publication.

*Minister of Healthcare
of the Republic of Kazakhstan*

A. Tsoy

Appendix to the order
of the Minister of Healthcare
of the Republic of Kazakhstan
dated December 15, 2020
No. ҚР ДСМ-273/2020

Rules for the implementation of service maintenance of medical devices in the Republic of Kazakhstan

Chapter 1. General Provisions

1. These Rules for the implementation of service maintenance of medical devices in the Republic of Kazakhstan (hereinafter referred to as the Rules) have been developed in accordance with subclause 52) article 7 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On Public Health and Healthcare System" and shall determine the procedure for service maintenance of medical equipment in the Republic of Kazakhstan.

2. The service maintenance of medical equipment within the warranty and post-warranty period shall be its compulsory condition of its safe operation.

Operation of medical equipment, which is not provided with service maintenance, removed from service maintenance, or operation of medical equipment by the unqualified personnel, not passed training on the use of medical equipment.

3. Basic concepts, used in these Rules, are as follows:

1) warranty service maintenance – a complex of services for maintaining the delivered medical equipment in good condition, including any types of maintenance, technical diagnostics and equipment flaw detection, repair and restoration work, technical consultations provided by the supplier (manufacturer, contractor), including remotely (online, with use of specialized programs and equipment, a data transmission channel identified by a barcode or other method), subject to its proper use and storage, free of charge for the period specified by purchase agreements, long-term supply agreements, trilateral purchase and financial leasing agreements, with the exception of the restoration of consumables and wear units installed by the manufacturer;

2) medical devices – medical products and medical equipment;

3) medical equipment (hereinafter referred to as the medical equipment) – apparatuses, devices, equipment, complexes, systems used separately or in combination with each other for the provision of medical care in accordance with the functional purpose and operational characteristics established by the manufacturer;

4) service maintenance of medical equipment – a set of measures and operations regulated by regulatory and operational documentation, including remotely (online, using specialized programs and equipment, a data transmission channel identified by a barcode or other method), to maintain and restore the health and functionality of a medical device when using it according to appointment;

5) technical condition of the medical equipment – a state at a certain point in time, which is characterized by the actual values of technical, functional and design parameters and characteristics, and is assessed by their compliance with the parameters and characteristics given in the technical documentation of the manufacturer of medical equipment;

6) medical equipment maintenance guide – a document developed by a manufacturer of medical equipment for engineering and technical personnel, containing information about the design, principles of operation, parameters, technical characteristics (properties) of a medical

device, its components, instructions on actions necessary for the correct, timely and safe maintenance of medical equipment, information about the manufacturer, and their warranty obligations;

7) current repair of medical equipment – repair for the purposes of restoring serviceability (operability), as well as maintaining the operational characteristics of medical equipment, including the replacement of defective parts;

8) major repair of medical equipment – repair of medical equipment, in which disassembly and revision of the structure is carried out in order to identify hidden faults and assess the resource of parts;

9) safety class of medical equipment – a set of medical equipment included in a certain class depending on the degree of potential risk of harm to the health of patients, personnel operating the medical device and other persons;

10) operating manual – a document developed by a manufacturer of medical equipment for medical personnel, containing information about the principle of action, parameters, characteristics (properties) of medical equipment, instructions necessary for the correct and safe operation of medical equipment (use as intended, storage, transportation and recommendations for the care of the product), information about the manufacturer and their warranty obligations;

11) operational documentation – operating manual and maintenance guide;

12) maintenance department – an organization or a separate subdivision of an organization that has a staff of a specialist (specialists) in the repair and maintenance of medical equipment who has undergone (passed) training at manufacturing enterprises of the corresponding types (names) of medical equipment or in organizations that have the right to carry out training in the maintenance of the corresponding types of medical equipment technicians, or an organization or a separate subdivision of an organization that have documentary confirmation from the manufacturer of medical equipment for the right to provide technical support.

Chapter 2. Procedure for service maintenance of medical equipment

4. Service maintenance of medical equipment in the Republic of Kazakhstan shall be carried out by:

healthcare entities which have a full-time specialist (specialists) in the repair and maintenance of medical equipment, trained at manufacturing enterprises of the corresponding types (names) of medical equipment or in organizations entitled to carry out professional training in the maintenance of the relevant types of medical equipment (hereinafter referred to as the entities);

maintenance departments.

When carrying out service maintenance works, the entities and maintenance departments shall provide the following list of documents:

certificate of the existence of a valid quality management system in accordance with GOST ISO 9001 or GOST ISO 13485;

valid technical and operational documentation of the manufacturer (producer).

The service maintenance of medical devices of 2a, 2b and 3 safety classes shall be carried out by:

maintenance departments of the manufacturer of medical equipment;

maintenance departments, which have documentary confirmation from the manufacturer of medical equipment for the right to carry out service.

5. The types, volumes and frequency of work on the maintenance of medical equipment shall be carried out taking into account the hours worked, the conditions and terms of operation of medical equipment, and are also determined in accordance with the requirements :

1) manufacturing plant (information contained in the user manual, maintenance guide);

2) safety class of medical equipment.

6. service maintenance of medical devices includes the warranty service maintenance and post-warranty service maintenance.

7. Warranty service maintenance includes periodic control of technical condition of medical equipment (at least once a year), current and major repair.

8. Post-warranty service maintenance includes:

1) current monitoring of technical condition of medical equipment;

2) periodic monitoring of the technical condition of medical equipment (at least once a year);

3) current and major repair.

9. In order to prevent downtime, the period for repairing medical equipment does not exceed fifteen working days from the date the service department identifies the cause of the breakdown of medical equipment (if it is necessary to replace spare parts, the repair period is extended by the time of delivery of spare parts).

In case of the major repair of medical equipment, the repair time is determined by the terms of the service agreement.

In the event of downtime necessary to ensure operability during a planned repair (modernization and (or) software update), service maintenance and verification, as well as in the event of reorganization or liquidation of a healthcare entity, this type of downtime shall be planned.

10. Current repair of medical equipment shall be carried out by maintenance departments, as well as by healthcare entities that have a specialist (specialists) in the repair and maintenance of medical equipment.

11. Current repair shall be carried out at the place of operation of medical equipment, or at the production facilities of the service department, depending on the complexity, scope of work and the possibility of transporting medical equipment.

12. The maintenance department, which carried out the current or overhaul repairs, provides warranties for repaired units, parts, medical equipment with a warranty period provided by the manufacturer of the replaced unit (part), provided that the user observes the requirements of the operating manual.

13. By the end of the warranty service period, medical equipment is transferred to an individual or legal entity, a health care subject in good working order.

At the same time, the service department provides the healthcare organization with information about the work performed, replaced spare parts and consumables.

14. Monitoring of the technical condition of medical equipment is subdivided into current and periodic.

The current monitoring of the technical condition of medical equipment shall be carried out by the health care subject directly operating the medical equipment, or by a person authorized to carry out these works.

Before the start of the current monitoring of medical equipment, the compliance of the values of parameters and characteristics of medical equipment with those declared in the documentation, visual identification of worn out and damaged parts, check of protective devices, shall be carried out in accordance with the operating manual.

15. Current monitoring of technical condition of medical equipment includes:

- 1) visual inspection of the working place and the medical equipment itself;
- 2) verification of compliance with safety measures when preparing medical equipment for work (the integrity of power cords and device plugs, connecting wires of devices, the presence of protective screens, fences, protective devices);
- 3) checking the readiness of medical equipment for use (checking the initial positions of controls, consumables);
- 4) switching on and checking the operability of medical equipment, its components and devices, in the presence of alarms and interlocks, self-testing of medical equipment in the presence of this function.

In case of revealing inconsistencies or breakdowns during the current monitoring of the technical condition of medical equipment, an entry is made in the technical condition log about the identified inconsistencies or breakdowns, a conclusion is formed and the service services are immediately notified.

The technical log shall be maintained, according to Appendix 1 to these Rules.

16. Periodical monitoring of technical condition includes:

monitoring of indication and signaling for integrity, clarity of fixation, absence of backlash, actuation of protective devices and interlocks;

monitoring the condition of parts, assemblies, mechanisms subject to increased wear;

checking the functioning of the main and auxiliary units, measuring, recording and protective devices;

checking medical equipment for compliance with electrical safety requirements;

instrumental control of the main technical characteristics, other operations specified in the operational documentation, specific for a particular type of medical equipment;
replacement of spare parts, tools, accessories and consumable tools, if necessary.

Periodic monitoring of the technical condition of medical equipment is documented by an act of work performed in the form, according to Appendix 2 to these Rules.

17. Types, terms, volumes, technological sequence of work on service maintenance of medical equipment are determined in accordance with the requirements of the operation manual and maintenance guide, requirements for the safety of medical equipment, as well as the results of monitoring the technical condition of medical equipment.

18. Documents, confirming the scope of works performed under the periodic monitoring of technical condition of the medical equipment shall be the certificate of completion of works and a record in the Technical Log.

19. The decision on the need for current repairs is made by healthcare entities and maintenance departments based on the results of monitoring the technical condition of medical equipment.

20. Major repair is carried out by maintenance departments at the place of operation of medical equipment, or at the production areas of the service department, depending on the complexity, scope of work and the possibility of transporting medical equipment. The need for repairs at the production areas of the service department is determined by the maintenance department.

21. Decision of conducting major repair, shall be made by the healthcare entity taking into account economic feasibility.

22. The decision on termination of maintenance service or the impossibility of repairing medical equipment is taken by the healthcare entity, taking into account the depreciation of medical equipment and due to the expiration of the technical support period by the manufacturer of medical equipment. Medical equipment based on this decision is subject to disposal.

Maintenance department, providing services on maintenance servicing of this medical equipment, provides recommendations on decommissioning of medical equipment.

23. When carrying out service, spare parts are used, including consumables provided for by the current technical and operational documentation of the manufacturer (producer).

In the absence of access to spare parts, similar spare parts are used with confirmation of the preservation of the required technical and functional characteristics of medical equipment and guarantees of its safety.

24. The period of warranty service for medical equipment is at least thirty-seven months from the date of commissioning and the frequency recommended by the manufacturer.

implementation of service
maintenance of medical devices in
the Republic of Kazakhstan
Form

Technical log

Date	Condition of medical equipment	Types of works performed	Surname, name, patronymic (if any) of the engineer	Signature	Note
1	2	3	4	5	6

Appendix 2
to the Rules for the
implementation of service
maintenance of medical devices in
the Republic of Kazakhstan
Form

Certificate of completion of works

Contract No. _____ **dated** _____ " ____ " _____ **20** __.

Code of the engineer	Number and date of submission of application	Time of arrival	Time of departure	Time spent	
Healthcare organization:		Locality:			
Department:		Address:			
Medical equipment		Serial number:	Date of installation of medical equipment:		
warranty <input type="checkbox"/>					
p o s t - w a r r a n t y other <input type="checkbox"/>					
Works completed					
Diagnostics	Repair	Modernization	Maintenance point*	Installation	Training
Materials spent during the repair of the medical equipment					
Name of material			Measuring unit	Quantity	Total amount (tenge)
Fault modes					
Program errors		Technical fault <input type="checkbox"/>	Mechanical fault <input type="checkbox"/>		
Types of repair					
Warranty repair		Non-warranty repair			

Comments and technical opinion:

Acceptance-Transfer of Medical Equipment

Services in the territory of the customer

Services in a service center

Medical equipment is delivered by: _____ _____ (surname, name, patronymic (if any)) _____ _____ of the representative of healthcare organization Date "___" "___" 20___. Signature _____	Medical equipment is accepted by: _____ _____ (surname, name, patronymic (if any)) _____ _____ of the representative of the service provider Date "___" "___" 20___. Signature _____
Medical equipment is delivered by: _____ _____ (surname, name, patronymic (if any)) _____ _____ of the representative of the service provider Date "___" "___" 20___. Signature _____	Medical equipment is accepted by: _____ _____ (surname, name, patronymic (if any)) _____ _____ of the representative of healthcare organization Date "___" "___" 20___. Signature _____
Representative of the healthcare organization: _____ _____ _____ Position (surname, name, patronymic (if any)) _____ "___" "___" 20___. Seal _____ (if any)	Representative of the service provider: _____ _____ _____ Position (surname, name, patronymic (if any)) _____ "___" "___" 20___. Seal _____ (if any)

Appendix 2
to the order

List of certain invalid orders of the Ministry of Healthcare of the Republic of Kazakhstan

1. Order of the Minister of Healthcare and Social Development of the Republic of Kazakhstan dated May 29, 2015 No. 427 "On approval of the Rules for the implementation of service maintenance of medical equipment in the Republic of Kazakhstan" (Registered in the Register of State Registration of Regulatory Legal Acts under No. 11481, published on July 23, 2015 in "Adilet" Legal information system).

2. Order of the Minister of Healthcare and Social Development of the Republic of Kazakhstan dated February 29, 2016 No. 166 "On amendments to the order of the Minister of Healthcare and Social Development of the Republic of Kazakhstan dated May 29, 2015 No. 427 " On approval of the Rules for the implementation of service maintenance of medical equipment in the Republic of Kazakhstan " (Registered in the Register of State Registration of Regulatory Legal Acts under No. 13563, published on April 14, 2016 in "Adilet" Legal information system).

3. Order of the Minister of Healthcare of the Republic of Kazakhstan dated December 24, 2018 No. ҚР ДСМ-44 " On amendments to the order of the Minister of Healthcare and Social Development of the Republic of Kazakhstan dated May 29, 2015 No. 427 " On approval of the Rules for the implementation of service maintenance of medical equipment in the Republic of Kazakhstan " (Registered in the Register of State Registration of Regulatory Legal Acts under No. 18054, published on January 10, 2019 in the Reference Control Bank of the Regulatory Legal Acts in an electronic form).

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