

Minnesota LIVING WITH HEART FAILURE® Questionnaire (MLHFQ)

The Minnesota LIVING WITH HEART FAILURE® Questionnaire (MLHFQ) is a validated patient-oriented measure of the adverse effects of heart failure on a patient's life.

The United States Food and Drug Administration (FDA) has [qualified](#) the Minnesota LIVING WITH HEART FAILURE® Questionnaire as Medical Device Development Tool (MDDT) for use in controlled clinical trials designed to test superiority or non-inferiority of medical devices in support of regulatory submissions. This patient-reported outcomes questionnaire can be used to determine whether a treatment for heart failure is effective for improving patients' quality of life by reducing the adverse impact of heart failure.

License Required to use MLHFQ

A license from the University of Minnesota is required to use MLHFQ for any purpose. Purchase the license that best matches your intended use. The Questionnaire (version 3) and supporting materials will be available for download after online completion of license agreement and payment of fee.

Commercial Licenses (For-profit entity to evaluate a product or service)

- **Unlimited Commercial License** - For-profit entity using the Questionnaire to evaluate a product or service that is in development or on the market. For use in an unlimited number of protocols. Term is 5 years. Price is \$15,000 USD.
- **Commercial License** - For-profit entity using the Questionnaire to evaluate a product or service that is in development or on the market. For use in a single protocol. Term is 10 years or the length of the protocol, whichever is shorter. Price is \$3,000 USD.

Research Licenses (Not-for-profit research projects)

- **Unlimited Non-profit Research License** - Any researcher using the Questionnaire in not-for-profit research projects. For use in an unlimited number of projects. Term is 5 years. Price is \$5,000 USD.
- **Non-profit Research License** - Any researcher using the Questionnaire in not-for-profit research projects. For use in a single project. Term is 10 years or the length of the project, whichever is shorter. Price is \$1,000 USD.

Patient Care Licenses (Health care professional or organization in care of patients)

- **Unlimited Patient Care License** - Health care professional or health care organization using the Questionnaire in the care of patients or to evaluate in-house services. For use in all of the healthcare organization's facilities. Term is 10 years. Price is \$2,500 USD.
- **Patient Care License** - Health care professional or health care organization

Technology ID

94019

Category

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using the Questionnaire in the care of patients or to evaluate in-house services. The fee is per location or facility where the Questionnaire is used. Term is 10 years. Price is \$1,000 USD.

Instructional or Student Use License (Students or teachers)

• **Instructional or Student Use License** – Student or a teacher who will use the Questionnaire exclusively for student projects or for instructional purposes. This is a free license.

MLHFQ Translations

The Questionnaire is available from the University of Minnesota in the English language version only.

Once you obtain a license for the English version, we recommend you work with the [MAPI Research Trust \(MRT\)](#) to obtain validated translations of the Questionnaire. The list of languages the Questionnaire has been translated into is at the bottom of [this webpage](#). A nominal fee may apply.

Quality of Life Questionnaire - Scoring Criteria

The questionnaire is comprised of 21 questions around several physical, emotional and socioeconomic ways heart failure can adversely affect a patient's life. After receiving brief standardized instructions, the patient marks a 0 (zero) to 5 (five) scale to indicate the extent to which each itemized adversity of heart failure has prevented the patient from living as they wanted to live during the past 4 weeks. The questionnaire is simply scored by summation of all 21 responses.

This questionnaire can be used as a key outcome measure in studies and evaluations of outpatients with symptomatic (NYHA class II to IV) heart failure with a reduced or preserved ejection fraction. This patient-reported outcome measurement tool can be used to determine whether a treatment for heart failure is effective for improving patients' quality of life by reducing the adverse impact of heart failure.

MLHFQ Detailed Information

More detailed information about the Minnesota Living with Heart Failure Questionnaire is available in the [FDA MDDT Qualification Package](#). A license from the University of Minnesota is required before using the Questionnaire.

Researchers

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Please send your inquiries to mlhfq@umn.edu