HTA Austria
Austrian Institute for
Health Technology Assessment
GmbH

Implantation of a wireless pulmonary artery pressure sensor in patients with advanced heart failure

1. Update 2026
Systematic Review

AIHTA Decision Support Document: 119/1 Update 2026
ISSN-online: 1998-0469

HTA Austria
Austrian Institute for
Health Technology Assessment
GmbH

Implantation of a wireless pulmonary artery pressure sensor in patients with advanced heart failure

1. Update 2026
Systematic Review

Vienna, February 2026

Project Team

Project leader: Julia Kern-Kim, MSc

Authors: Romy Schönegger, BSc, MScPH
Julia Kern-Kim, MSc
Yui Hidaka, PhD, MSc

Project Support

Systematic literature search: Tarquin Mittermayr, MA

External Review: OA Dr. med. Clemens Seelmaier, MSc, University Clinic for Medicine II, Cardiology and Internal Intensive Care Unit, Salzburg University Hospital

Internal Review: Gregor Goetz, Dr.PH, MPH, MSSc

Correspondence: Romy Schönegger, BSc, MScPH; romy.schoenegger@aihta.at

This report should be referenced as follows:

Schönegger R., Kern-Kim J., Hidaka Y. Implantation of a wireless pulmonary artery pressure sensor in patients with advanced heart failure. AIHTA Decision Support Documents No. 119/1; Update 2026; 2026. Vienna: Austrian Institute for Health Technology Assessment GmbH.

Conflict of interest

All authors and the reviewers involved in the production of this report have declared they have no conflicts of interest in relation to the technology assessed according to the Uniform Requirements of Manuscripts Statement of Medical Journal Editors (www.icmje.org).

Disclaimer

The external reviewers did not co-author the scientific report and do not necessarily all agree with its content. Only the AIHTA is responsible for errors or omissions that could persist. The final version and the policy recommendations are under the full responsibility of the AIHTA.

The HTA Core Model®, developed within EUnetHTA (www.eunethta.eu), has been utilised when producing the contents and/or structure of this work. The following version of the Model was used: [HTA Core Model®, Version 4.2]. Use of the HTA Core Model does not guarantee the accuracy, completeness, quality or usefulness of any information or service produced or provided by using the Model.

Commissioned by the Austrian Ministry of Health, this report systematically assessed the intervention described herein as decision support for the inclusion in the catalogue of benefits.

IMPRINT

Publisher:
HTA Austria – Austrian Institute for Health Technology Assessment GmbH
Josefstädter Str. 39 | 1080 Vienna – Austria
https://www.aihta.at/

Responsible for content:
Dr. rer. soc. oec. Ingrid Zechmeister-Koss, managing director

AIHTA Decision Support Documents do not appear on a regular basis and serve to publicize the research results of the Austrian Institute for Health Technology Assessment.

AIHTA Decision Support Documents are only available to the public via the Internet at http://eprints.aihta.at/view/types/hta_report.html.

AIHTA Decision Support Documents No.: 119/1 Update 2026

ISSN online 1998-0469

Content

List of figures

List of tables

List of abbreviations

ACC.....American College of Cardiology Foundation

AHA .....American Heart Association

AI.....Artificial Intelligence

AiC .....Academic in Confidence

ARNI.....Angiotensin Receptor-Neprilysin Inhibitor

AWMF .....Working Group of the Scientific Medical Association *(German: Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften)*

BNP.....Brain Natriuretic Peptide

Bristol TAG .....Bristol Technology Assessment Group

CAD .....Coronary Artery Disease

CG .....Control Group

CI.....Confidence Interval

CV.....Cardiovascular

DHT(s) .....Digital Health Technologies

DSRC.....Device- or System-Related Complications

ESC .....European Society of Cardiology

f/u.....Follow-Up

FDA.....Food and Drug Administration

GDMT.....Guideline-Directed Medical Therapy

GRADE.....Grading of Recommendations, Assessment, Development and Evaluation

HF .....Heart Failure

HR.....Hazard Ratio

HRQoL .....Health-related Quality of Life

HFmEF.....Heart Failure with Mildly Reduced Ejection Fraction

HFpEF.....Heart Failure with Preserved Ejection Fraction

HFrEF.....Heart Failure with Reduced Ejection Fraction

HFSA .....Heart Failure Society of America

HTA .....Health Technology Assessment

HTW .....Health Technology Wales

ICER .....Incremental Cost-Effectiveness Ratio

IQWiG .....Institute for Quality and Efficiency in Health Care *(German: Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen)*

IG .....Intervention Group

KCCQ .....Kansas City Cardiomyopathy Questionnaire

LBI .....Ludwig Boltzmann Institute

LCA.....Lifecycle Approach

LKF.....Performance-based hospital financing *(German: Leistungsorientierte Krankenanstaltenfinanzierung)*

LVEF .....Left Ventricular Ejection Fraction

MA.....Meta Analysis

MAUDE.....Manufacturer and User Facility Device Experience

MDR .....Medical Device Regulation

MLHFQ.....Minnesota Living with Heart Failure Questionnaire

MRAs .....Mineralocorticoid Receptor Antagonists

NICE.....National Institute for Health and Care Excellence

NT-proBNP.....N-terminal pro-Brain Natriuretic Peptide

NYHA .....New York Heart Association

OSF .....Open Science Framework

PA.....Pulmonary Artery

PAP .....Pulmonary Artery Pressure

QALY.....Quality-Adjusted Life-Year

RCT.....Randomised Controlled Trial

RoB.....Risk of Bias

(S)AE.....(Serious) Adverse Event

SAT .....Single-Arm Trial

SGLT2 .....Sodium Glucose Cotransporter-2

SR.....Systematic Review

US.....United States

USA.....United States of America

VAS .....Visual Analogue Scale

Executive Summary

Introduction

Health Problem

In chronic heart failure (HF), pulmonary artery pressure (PAP) rises days to weeks before clinical decompensation. Since symptom-based monitoring often detects deterioration late, implantable PAP telemonitoring is intended to reduce HF-related hospitalisations by detecting early haemodynamic changes and enabling timely therapy adjustment in patients with New York Heart Association (NYHA) class III HF.

Description of Technology

The CardioMEMS HF System (Abbott) is a wireless, battery-free sensor implanted in the pulmonary artery for remote PAP telemonitoring. Patients perform daily home measurements, and the data are transmitted to clinicians for therapy adjustments. The system received CE marking in 2016 and is classified as a class III medical device.

Methods

A systematic search (Nov. 2025) in Medline, Embase, Cochrane Library, and INAHTA was performed. Two researchers independently performed study selection and quality assessment of the included studies; data extraction was performed by one researcher and verified by another. An identified high-quality Bristol TAG report (2025) was used as the basis for evaluating efficacy and safety; for the quantitative synthesis, pooled estimates were adopted from the meta-analysis. Internal validity was assessed using Cochrane RoB 2.0, and certainty of evidence was graded using GRADE. Outcome prioritisation (critical/important) was performed by an external clinical expert. For the effectiveness analysis, randomised controlled trials (RCTs) comparing CardioMEMS with standard care were included, while for safety, RCTs and prospective observational studies were included as single-arm cohorts.

Results

Available evidence

Three RCTs with 1,898 participants and 12 to 24 months of follow-up were included in the effectiveness and safety analyses. Additionally, four observational studies were included to provide further evidence on safety (1,637 implantations with 12 to 24 months of follow-up).

Clinical effectiveness

Across three RCTs, a statistically significant between-group reduction in HF hospitalisations was found in the intervention group (HR 0.66; 95% CI 0.57-0.76; $I^2=0\%$). All-cause hospitalisations were also reduced in one RCT (HR 0.84; 95% CI 0.75-0.95; $p=0.0032$). The certainty of evidence was high.

There was no statistically significant difference in all-cause mortality (HR 0.91; 95% CI 0.70-1.17; $I^2=0\%$) or cardiovascular mortality (HR 0.98; 95% CI 0.74-1.29; $I^2=0\%$). Similarly, urgent HF care (2 RCTs) did not differ between groups (HR 1.05; 95% CI 0.56-1.96). The certainty of evidence was moderate.

For health-related quality of life, findings were mixed and pooled analyses showed no significant effects with substantial heterogeneity ($I^2=71\text{-}87\%$), leaving the effect uncertain. Use of guideline-directed medical therapy (2 RCTs) did not differ significantly between groups, although medication adjustments were reported more frequently in the intervention group.

Safety

Device- or procedure-related complications were rare (pooled proportion 0.7%; 95% CI 0.3-1.3%), and sensor failures were very rare (pooled proportion 0.1%; 95% CI 0.0-0.6%); certainty of evidence was moderate. Serious adverse events beyond device/procedure-related complications and sensor failure were insufficiently reported to support synthesis.

Upcoming evidence

Currently, three CardioMEMS RCTs are ongoing (n=60, 150, 554), evaluating endpoints including change in quality of life, unplanned intravenous HF therapy, HF hospital admission, cardiovascular death, and a composite of unplanned HF-related rehospitalisations plus all-cause mortality; completion is expected between December 2025 and June 2026. In one sham-controlled Cordella RCT (planned enrolment: 1,750), the primary composite endpoint is time to first HF event or death, with primary completion planned for 2028.

Discussion

Risk of bias was low to moderate for clinical endpoints (mortality, hospitalisation) and guideline-directed medical therapy, whereas patient-reported outcomes (health-related quality of life) were at high risk of bias (lack of blinding/sham-control, incomplete follow-up, selective reporting). Observational safety studies are inherently more prone to bias. Mortality and urgent-care outcomes may be limited by a lack of statistical power and short follow-up.

External validity is constrained by variation in background care intensity and outcome definitions. Real-world effectiveness depends on adequate resources and whether the entire "service chain" can be implemented in everyday care (adherence to measurements, data transfer, qualified team, personalised thresholds, prompt response, therapy adjustment, etc.). In addition, safety follow-up was limited; an analysis of MAUDE records reported increasing adverse events post-market approval.

In the Bristol TAG assessment, the base-case result was not cost-effective and highly sensitive; however, Austria-specific health economic evaluations are needed.

Conclusion

Evidence suggests that PAP telemonitoring reduces HF hospitalisations in NYHA class III patients compared to standard care. No statistically significant differences were observed for mortality, urgent care, or guideline-directed medical therapy use. The effect on health-related quality of life remains unclear. The intervention shows a promising safety profile with very rare complications and sensor failures reported. Effectiveness depends on implementation of structured care pathways and adequate resources.

Zusammenfassung

Einleitung

Indikation und therapeutisches Ziel

Chronische Herzinsuffizienz (HI; ICD-10 I50) ist ein klinisches Syndrom, bei dem das Herz den Bedarf des Körpers an Blut und Sauerstoff nicht mehr ausreichend deckt. Die Prävalenz liegt bei Erwachsenen bei etwa 5 % und steigt bei 80- bis 95-Jährigen auf bis zu 47 %. Akute Dekompensationen führen häufig zu Krankenhausaufnahmen und Wiederaufnahmen. Tatsächlich ist HI eine der führenden Ursachen für Krankenhausaufnahmen und Wiederaufnahmen im höheren Alter. Die Schwere der Symptomatik wird klinisch nach der New York Heart Association-Klassifikation (NYHA I-IV) eingestuft. Patient:innen mit NYHA-Klasse III zeigen eine deutliche Einschränkung der körperlichen Belastbarkeit; die 2-Jahres-Mortalität beträgt etwa 31 %.

Zielpopulation dieser Bewertung sind Patient:innen mit HI in NYHA III (unabhängig von der linksventrikulären Ejektionsfraktion) mit rezenter Dekompensation, operationalisiert als ≥1 HI-Hospitalisation in den letzten 12 Monaten.

Beschreibung der Intervention

Der pulmonalarterielle Druck (engl. pulmonary artery pressure/PAP) steigt häufig bereits Tage bis Wochen vor einem Dekompensationsereignis an. Ein rein symptombasiertes Monitoring erkennt Dekompensationen daher oft verspätet. Ziel des implantierbaren PAP-Monitorings ist es, frühe hämodynamische Veränderungen zu erkennen und dadurch Therapieanpassungen rechtzeitig zu ermöglichen, um insbesondere HI-Hospitalisationen zu reduzieren.

Das CardioMEMS™ HF-System (Abbott) ist ein kabelloser, batterieloser, implantierbarer Sensor zum Telemonitoring des PAP. Der Sensor wird mittels minimalinvasiver Rechtsherzkatheterisierung dauerhaft in die Pulmonalarterie implantiert. Patient:innen führen täglich Druckmessungen zu Hause durch; die Messwerte werden elektronisch an eine sichere Website übertragen, auf die das Behandlungsteam zur Trendbeurteilung und Therapieanpassung zugreift. Das System erhielt 2016 die CE-Kennzeichnung und ist als Klasse-III-Medizinprodukt klassifiziert. In Österreich ist das PAP-Telemonitoring derzeit im LKF-Katalog keine vollständig erstattungsfähige Leistung.

Als alternative CE-gekennzeichnete Technologie existiert das Cordella-System, das aktuell jedoch nicht in Österreich kommerziell verfügbar ist und daher für diese Bewertung getrennt betrachtet wird.

Methoden

Das Ziel dieser Bewertung war es, zu analysieren, ob implantierbares PAP-Telemonitoring bei HI NYHA III im Vergleich zur Standardversorgung gleich sicher und wirksamer ist.

Die systematische Literatursuche wurde am 7. November 2025 in Medline, Embase, Cochrane Library und INAHTA durchgeführt. Außerdem wurde eine ergänzende Suche nach laufenden Studien in internationalen Registern (Stichtag 02.12.2025) durchgeführt. Die Studienauswahl und die Bewertung der methodischen Qualität der Studien wurden von zwei Autor:innen unabhängig voneinander durchgeführt; die Datenextraktion wurde von einer Autorin vorgenommen und von einer zweiten verifiziert. Zur Bewertung von Wirksamkeit und Sicherheit wurde ein identifizierter hochwertiger Bristol-TAG-Bericht (2025) als Grundlage herangezogen; für die quantitative Synthese wurden die gepoolten Effektschätzer der Metaanalyse übernommen und die zugrunde liegenden Inputs mit den Originalpublikationen abgeglichen. Die interne Validität wurde mittels Cochrane RoB 2.0 bewertet und die Vertrauenswürdigkeit der Evidenz nach GRADE eingestuft. Die Priorisierung der Endpunkte (kritisch/wichtig/nicht wichtig für die Entscheidungsfindung) erfolgte durch einen externen klinischen Experten.

Klinische Wirksamkeit

Für die Wirksamkeitsbewertung wurden ausschließlich randomisiert-kontrollierte Studien (RCTs) eingeschlossen, die das CardioMEMS-System mit der Standardversorgung verglichen.

Die folgenden Ergebnisse zur Wirksamkeit wurden als entscheidungsrelevant definiert:

- gesamt- und kardiovaskuläre Mortalität,
- gesamt- und HI-bedingte Hospitalisierungen,
- dringende Krankenhausversorgung,
- Anwendung leitliniengerechter Therapie,
- gesundheitsbezogene Lebensqualität.

Sicherheit

Für die Sicherheitsbewertung wurden neben RCTs auch prospektive Beobachtungsstudien eingeschlossen; alle Studien wurden als einarmige Studien behandelt, da das Risiko durch die Implantation und das Gerät bedingt ist.

Die folgenden Endpunkte wurden für die Bewertung der Sicherheit als entscheidend definiert:

- geräte-, system- oder verfahrensbedingte Komplikationen,
- Sensorausfälle,
- schwerwiegende unerwünschte Ereignisse (SUE) abseits von geräte-, system- oder verfahrensbedingten Komplikationen sowie Sensorausfällen.

Ergebnisse

Verfügbare Evidenz

Insgesamt erfüllten sieben Studien die Einschlusskriterien; davon wurden drei RCTs mit 1.898 Teilnehmer:innen und einem Follow-up von 12 bis 48 Monaten in die Wirksamkeitsanalyse eingeschlossen. Zusätzlich wurden vier prospektive Beobachtungsstudien (prä-/post-Designs) in die Sicherheitsanalyse eingeschlossen. Insgesamt wurden 1.637 Implantationen mit 12- bis 24-monatigem Follow-up berichtet; Implantationsfehlversuche lagen bei etwa 1-3 % (n=19) mit 30-Tage-Sicherheits-Follow-up.

Klinische Wirksamkeit

Für HI-bedingte Hospitalisierungen (3 RCTs, n=1.898) lag ein statistisch signifikanter Unterschied zugunsten der Interventionsgruppe vor (HR 0,66; 95 %-KI 0,57-0,76; I^2=0 %; hohe Vertrauenswürdigkeit der Evidenz), was einem im Mittel um 34 % niedrigeren Hospitalisierungsrisiko entspricht. Für Gesamt-Hospitalisierungen (1 RCT, n=550, hohe Vertrauenswürdigkeit der Evidenz) zeigte sich ebenfalls eine statistisch signifikante Reduktion zugunsten der Intervention (HR 0,84; 95 %-KI 0,75-0,95; p=0,0032), entsprechend einem um 16 % niedrigeren Hazard, wobei dieses Ergebnis nur auf einer Studie basiert.

Für Gesamtmortalität und kardiovaskuläre Mortalität (3 RCTs, n=1.898) lag kein statistisch signifikanter Unterschied zwischen den Gruppen vor (HR 0,91; 95%-KI 0,70-1,17; I^2=0 %; HR 0,98; 95 %-KI 0,74-1,29; I^2=0 %). Auch für dringende HI-Versorgung (2 RCTs, n=1.348) fand sich kein statistisch signifikanter Unterschied (HR 1,05; 95 %-KI 0,56-1,96; I^2=18 %). Die Vertrauenswürdigkeit der Evidenz für diese Outcomes war moderat.

Bei der Anwendung leitliniengerechter Therapie (2 RCTs, n=1.348) lagen nach 12 Monaten keine signifikanten Unterschiede zwischen den Gruppen vor, allerdings wurden in der Interventionsgruppe häufiger Medikationsanpassungen berichtet. Für gesundheitsbezogene Lebensqualität (EQ-5D-5L, KCCQ, MLHFQ; 3 RCTs, n=1.898) waren die Ergebnisse inkonsistent; gepoolte Analysen zeigten keine signifikanten Effekte bei hoher Heterogenität (I^2=71-87 %).

Sicherheit

Für geräte-, system- oder verfahrensbedingte Komplikationen (7 einarmige Studien, ~3.419 Implantationsversuche) lag die gepoolte Proportion bei 0,7 % (95%-KI 0,3-1,3 %; I^2=44%); berichtet wurden u. a. Arrhythmien, Blutungen und Infektionen. Sensorausfälle (6 einarmige Studien, n=2.355) traten ebenso selten auf (gepoolte Proportion 0,1 %; 95%-KI 0,0-0,6 %; I^2=44%); als Ursachen wurden anatomie-/ haltungsbezogene Faktoren und Sensordislokation genannt. Die Vertrauenswürdigkeit der Evidenz war moderat. Für SUE war die Datenlage insgesamt unzureichend: MONITOR-HF berichtete zwei SUE (Blutung, Sepsis), die als nicht geräte- bzw. verfahrensbezogen eingestuft wurden, und GUIDE-HF berichtete 57 % (Intervention) versus 53 % (Kontrolle) mit mindestens einem SUE, ohne kategoriale Aufschlüsselung. Eine Synthese war daher nicht möglich; der Endpunkt bleibt unbeantwortet.

Laufende Studien

Drei laufende RCTs zum CardioMEMS-System wurden identifiziert mit jeweils 60, 150 und 554 Teilnehmer:innen. Zu den primären Endpunkten zählen Veränderungen der gesundheitsbezogenen Lebensqualität; ungeplante intravenöse HI-Therapien, HI-bedingte Krankenhausaufenthalte und kardiovaskuläre Todesfälle; sowie eine Kombination aus ungeplanten HI-bedingten Rehospitalisierungen und Gesamtmortalität. Der Abschluss der Studien ist zwischen Dezember 2025 und Juni 2026 geplant. Eine Sham-kontrollierte Cordella-Studie mit 1.750 Teilnehmer:innen untersucht den zusammengesetzten primären Endpunkt Zeit bis zum ersten HI-Ereignis oder Tod; der primäre Abschluss ist für 2028 geplant.

Diskussion

Das Verzerrungsrisiko für klinische Endpunkte und leitliniengerechte Therapie war in CHAMPION und GUIDE-HF insgesamt niedrig; MONITOR-HF zeigte aufgrund des Open-Label-Designs ohne Sham-Kontrolle ein moderates bis hohes Verzerrungsrisiko. Für patient:innenberichtete Endpunkte war das Verzerrungsrisiko hoch, bedingt durch fehlende Verblindung, unvollständige Nachverfolgung und partiell selektives Berichten. Beobachtungsstudien sind methodisch inhärent stärker verzerrungsanfällig. Mortalitätsendpunkte und dringende HI-Versorgung sind zudem durch unzureichende statistische Power und in einigen Fällen durch kurzes Follow-up begrenzt.

Die externe Validität ist teils eingeschränkt: CHAMPION wurde in spezialisierten HI-Management-Programmen durchgeführt, die möglicherweise nicht die Routineversorgung widerspiegeln, und die Intensität der Hintergrundtherapie variierte zwischen den Studien. Der Zusatznutzen des PAP-Telemonitorings wird durch die Intensität der jeweiligen Standardversorgung beeinflusst. Gleichzeitig ist PAP-Telemonitoring eine komplexe digitale Intervention und der Effekt hängt davon ab, ob die gesamte „Service-Kette“ im Versorgungsalltag umgesetzt werden kann (Messadhärenz, Datenübertragung, qualifiziertes Team, personalisierte Schwellen, zeitnahe Reaktion, Therapieanpassung). Darüber hinaus können Unterschiede in der Definition und Erfassung von Outcomes die Interpretierbarkeit beeinflussen. Beispielsweise wurde Hospitalisation in MONITOR-HF nach sechs Stunden, in CHAMPION/GUIDE-HF nach 24 Stunden gezählt. Außerdem waren die Beobachtungszeiträume für Sicherheit begrenzt. Eine MAUDE-Analyse zeigte nach der Marktzulassung eine Zunahme unerwünschter Ereignisse.

Für die Entscheidungsfindung ist zudem die ökonomische Dimension bedeutsam: In der Bristol-TAG-Bewertung war das Basisfall-Ergebnis nicht kosteneffektiv und zeigte hohe Sensitivität; österreichspezifische gesundheitsökonomische Evaluierungen bleiben daher eine zentrale Evidenzlücke.

Für Cordella liegt bisher überwiegend einarmige Evidenz vor; die Effekte auf Hospitalisationen/Mortalität und gesundheitsbezogene Lebensqualität sind unsicher, bei insgesamt günstiger Sicherheitsbilanz. Für Österreich ist die unmittelbare Relevanz aktuell durch die fehlende Verfügbarkeit begrenzt.

Schlussfolgerung

Die Evidenz deutet darauf hin, dass PAP-Telemonitoring mit einem implantierbaren Sensor bei Patient:innen mit NYHA-Klasse III die Zahl der HI-bedingten Hospitalisierungen reduziert (hohe Vertrauenswürdigkeit der Evidenz). Für Mortalität und dringende Versorgung zeigen die Daten keine signifikanten Unterschiede zwischen den Gruppen (moderate Vertrauenswürdigkeit der Evidenz). Der Effekt auf gesundheitsbezogene Lebensqualität bleibt unklar. Geräte- und verfahrensbedingte Komplikationen sowie Sensorausfälle wurden insgesamt sehr selten berichtet. Aussagen zu SUE abseits von geräte-, system- oder verfahrensbedingten Komplikationen und Sensorausfällen sind auf Grundlage der verfügbaren Daten nicht verlässlich möglich.

Die Umsetzung sollte in Zentren mit etablierten Protokollen und Ressourcen für die Datenüberwachung, die klinische Interpretation sowie die schnelle Therapieanpassung erfolgen. Auch Schulungen für Patient:innen und Behandlungsteams sind notwendig. Zusätzlich sollte eine prospektive Registerführung zur Generierung österreichspezifischer Daten erfolgen (etwa, um fortlaufend Wirksamkeit, Sicherheit und Adhärenz zu überprüfen).

Eine Neubewertung wird für 2029 empfohlen. Bis dahin werden Ergebnisse aus laufenden Studien (inkl. Alternativen wie Cordella) erwartet.

Summary of previous assessment(s) 2020

Update des LBI-HTA-Berichts von 2020

The initial HTA-report "Implantation eines telemedizinischen Pulmonalarterien-Drucksensors bei PatientInnen mit fortgeschrittener Herzinsuffizienz" was published in 2020 [1]. This chapter summarises the results and the recommendations of the initial assessment. Additionally, it outlines the key updates since 2020. These include, for example, new epidemiological data and developments in implantable Pulmonary artery pressure (PAP) monitoring.

Health problem and characteristics of the technology

Overview of the disease, epidemiology and target population[1]

Herzinsuffizienz (HI): unzureichende Pumpleistung mit verminderter Sauerstoffversorgung

Heart failure (HF) (ICD-10 Code 150 [2]) is a condition where the heart cannot pump enough blood to meet the body's needs. This leads to insufficient oxygen delivery to the tissues [3]. In 2021, an international consensus document was published, which proposed the following definition of HF: 'A clinical syndrome with symptoms and/or signs caused by a structural and/or functional cardiac abnormality, and corroborated by elevated natriuretic peptide levels and/or objective evidence of pulmonary or systemic congestion' [4].

häufigsten Ursachen für HI: koronare Herzkrankheit, arterielle Hypertonie und deren Kombination

HI-Klassifikation nach betroffener Herzseite, Zeitrahmen, Ursache

Coronary artery disease (CAD), arterial hypertension and a combination of the two are the most common causes of HF, accounting for around 70 to 90% of cases [3]. HF can be classified by the side of the heart affected (left, right, or global), by time frame (acute or chronic) and by the cause [3]:

- Reduced left ventricular pump function: HF with reduced left ventricular ejection fraction (Heart Failure with reduced Ejection Fraction, HFrEF)
- Impaired filling of the heart with preserved pump function: HF with preserved left ventricular ejection fraction (Heart Failure with preserved Ejection Fraction, HFpEF)

HFrEF has a Left Ventricular Ejection Fraction (LVEF) of less than 40%; mildly reduced ejection fraction (HFmrEF) ranges from 40 to 49%; and HFpEF is 50% or higher [3].

New York Heart Association (NYHA) Skala von I bis IV misst Schwere der Symptome

The severity of symptoms is measured using the New York Heart Association (NYHA) I to IV scale [3]:

[1] This section addresses the following assessment elements:
A0001 – For which health conditions, and for what purposes is the technology used?
A0002 – What is the disease or health condition in the scope of this assessment?
A0003 – What are the known risk factors for the disease or health condition?
A0004 – What is the natural course of the disease or health condition?
A0005 – What is the burden of disease for the patients with the disease or health condition?
A0006 – What are the consequences of the disease or health condition for the society?
A0023 – How many people belong to the target population?

Table 1: NYHA Functional Classification for Heart Failure [3]

NYHA I	No physical limitation. Every day physical activity does not cause excessive fatigue, arrhythmia, shortness of breath, or angina pectoris.
NYHA II	Slight limitation of physical activity. No symptoms at rest or during light activity. Greater physical activity (e.g., walking uphill or climbing stairs) causes excessive fatigue, arrhythmia, shortness of breath, or angina pectoris.
NYHA III	Marked limitation of physical activity. No symptoms at rest. Minor physical activity (e.g., walking on level ground) causes excessive fatigue, arrhythmia, shortness of breath or angina pectoris.
NYHA IV	Unable to carry out any physical activity without symptoms, bedridden.

Abbreviations: NYHA … New York Heart Association

***Explanation:** Arrhythmia … irregular heartbeat; Angina Pectoris … pain and tightness in the chest*

Belastung Herzinsuffizienz: Prävalenz ~5 % (Erwachsene) mit starkem Altersanstieg bis 47 % bei 80- bis 95-Jährigen

HF places a significant burden on both epidemiology and health systems. Its prevalence is around 4.7% among adults aged 18 and older, further increasing with age. Among 65- to 69-year-olds, the annual prevalence was 6.9%, increasing to 24 to 47% among people aged 80 to 95 years (data from 2010) [5]. The more recent Framingham cohort study (2018) revealed that, over the last three decades, the prevalence of HFpEF has increased in relation to the overall prevalence of HF (from 41% to 56%), while the prevalence of HFmrEF and HFpEF has decreased (from 15% to 13% and from 44% to 31%, respectively) [6]. However, few studies provide recent estimates of the prevalence and incidence of HF in Austrian or European populations.

akute Dekompensation führt häufig zu Hospitalisation

HI als führende Ursache für Krankenhausaufnahmen und Wiederaufnahmen bei älteren Personen

A German retrospective study from 2017 provided some epidemiological data on NYHA class III HF in Germany (2009-2014) [7]. In 2011, the overall incidence of newly diagnosed HF in NYHA class III was 74 cases per 100,000 persons at risk. The disease often leads to episodes of acute decompensation, which require hospitalisation. HF is a leading cause of hospital admissions in older adults [8]. HF admissions are not only common but often happen repeatedly, as many patients are readmitted multiple times due to exacerbations [3]. For example, in Germany, the age-standardised hospitalisation rate for HF was about 464 per 100,000 population in 2023 [9]. Similarly, in Austria, there were approximately 46,800 hospital stays for HF in 2019, which accounted for roughly 12% of all cardiovascular (CV) admissions [10].

fast ein Drittel mit neu diagnostizierter NYHA-III-HI verstirbt innerhalb von zwei Jahren; 2015 verantwortlich für 5 % aller Todesfälle → zweithäufigste Todesursache

Furthermore, HF is associated with significant mortality. In Germany, for example, the 2-year mortality rate for NYHA class III was 30.8% [7]. This shows that almost one-third of patients with newly diagnosed NYHA III heart failure die within two years of diagnosis [7]. Additionally, in 2015, HF was responsible for 5.1% of all deaths, making it the second most common cause of death after chronic coronary heart disease [3]. A more recent review suggests an average one-year heart failure case fatality rate of 33% and a five-year survival rate of around 50%, whereby a reduced survival time was significantly associated with increasing age at diagnosis [11].

Managementstrategien haben großen Einfluss auf die Prognose

HF is an incurable disease, and management strategies aimed at preventing rehospitalisation have a major impact on prognosis. The NARA-HF study (2020) showed that patients readmitted within 90 days of discharge due to poor management have a significantly worse survival rate [12].

Current clinical practice[2]

Diagnose von HI basiert auf Symptomen, klinischer Untersuchung, Biomarker-Analyse, kardialer Bildgebung

Chronic HF is diagnosed based on typical symptoms, clinical examination, biomarker analysis, and cardiac imaging [3]. Typical symptoms include arrhythmia (irregular heartbeat), angina pectoris (pain and tightness in the chest), exertional dyspnoea (during activity), fatigue, or peripheral oedema (accumulation of fluid causing swelling). A clinical examination may show signs such as elevated jugular venous pressure (neck vein swelling), pulmonary crackles, or a third heart sound. The foundation of diagnosis is transthoracic echocardiography, which allows for the measurement of LVEF. Additionally, measurement of natriuretic peptides, such as Brain Natriuretic Peptide (BNP) or N-terminal pro-Brain Natriuretic Peptide (NT-proBNP), provides diagnostic support. Elevated levels boost diagnostic certainty, especially when echocardiographic findings are unclear or in the presence of comorbidities [3]. Additional tests, such as electrocardiography and chest radiography, provide more information.

typische Symptome: unregelmäßiger Herzschlag, Schmerzen und Engegefühl in der Brust, Atemnot bei körperlicher Aktivität, Müdigkeit, Schwellungen

Behandlung von HI: Kombination aus Medikamenten, Änderungen der Lebensweise, Gerätetherapien, regelmäßiges klinisches Monitoring

The treatment of HF involves a combination of medication, lifestyle changes, and device therapies (in certain cases) to alleviate symptoms, improve quality of life, and reduce mortality [3, 13]; alongside this, regular clinical monitoring helps detect and address deterioration early. According to the 2023 AWMF (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften) S3 German National Guideline on Chronic Heart Failure [3], regular clinical assessment should include monitoring of NYHA functional class, daily functioning, quality of life, psychosocial status, heart rate, blood pressure, body weight, hydration status, electrolyte balance, kidney function, and medication adherence (recommendation level A = strong positive recommendation).

[2] This section addresses the following assessment elements:
A0024 – How is the disease or health condition currently diagnosed according to published guidelines and in practice?
A0025 – How is the disease or health condition currently managed according to published guidelines and in practice?

Features of the intervention[3]

Pulmonalarteriendruck (PAP)-Anstieg vor Dekompensation; implantierbares PAP-Monitoring erkennt Frühzeichen und ermöglicht frühe Therapie

Although HF is often characterised by clinical symptoms leading to hospitalisation, haemodynamic congestion usually arises before clinical manifestations [14]. PAP begins to rise gradually about 20 days before a decompensation event [15]. This means that a traditional clinical symptom-based approach makes early detection of HF worsening difficult. Implantable PAP monitoring aims to capture this rise early and enable timely therapeutic intervention.

CardioMEMS™ HF-System: kabelloser, batterieloser, implantierbarer Sensor, der Telemonitoring des PAP ermöglicht

The CardioMEMS™ HF System (Abbott, Atlanta, GA, United States of America (USA) [16]) is a wireless, no-battery-based, implantable sensor that allows remote monitoring of PAP (Figure 1). This small device, about the size of a paperclip, is permanently implanted in a branch of the pulmonary artery (PA) through a minimally invasive right-heart catheterisation procedure [17] and is designed to remain stable over the long term [18]. When exposed to an external radiofrequency field, the sensor vibrates at a frequency that changes with the surrounding pressure [17].

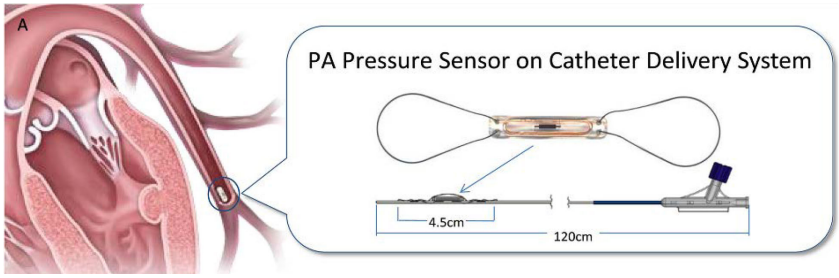

Figure 1: CardioMEMS TM HF System sensor. Reproduced from [19], published under CC BY-NC license

tägliche Heimmessung und elektronische Übertragung an Ärzt:innen →

After implantation, the patient takes daily pressure measurements at home using an external electronics unit and antenna built into a special pillow. Each measurement takes only a few minutes [17]. When the patient lies on this pillow and activates the system by pressing a button, it powers the im-

…

[3] This section addresses the following assessment elements:
A0007 – What is the target population in this assessment?
A0011 – How much are the technologies utilised?
A0020 – For which indications has the technology received marketing authorisation or CE marking?
A0021 – What is the reimbursement status of the technology?
B0001 – What is the technology and the comparator(s)?
B0002– What is the claimed benefit of the technology in relation to the comparators?
B0003 – What is the phase of development and implementation of the technology and the comparator(s)?
B0004 – Who administers the technology and the comparators and in what context and level of care are they provided?
B0008 – What kind of special premises are needed to use the technology and the comparator(s)?
B0009 – What supplies are needed to use the technology and the comparator(s)?
ASSESS-DHT (CUR): What is the intended use or purpose of the DHT?
ASSESS-DHT (TEC): The functions the DHT performs and the features of the DHT.
ASSESS-DHT (TEC): Whether any health content is interpreted by a human.

planted sensor and records the PAP reading. These readings are then transmitted electronically to a secure website, which the attending physician can access. Consequently, early rises in PAP that signal worsening HF can be detected [17, 18]. By tracking PA pressure trends, the system supports a proactive approach. Clinicians can adjust diuretics or other treatments at the first sign of haemodynamic issues [17, 18].

… trendbasiertes, proaktives Management mit frühen Therapieanpassungen

For effective use, education for both patients and providers is needed. After the procedure, patients learn to measure PAP at home with the device, while clinicians set personalised pressure goals and alert thresholds. These are fine-tuned over several weeks through regular medication adjustments. This "optimisation phase" usually lasts three to six months with the goal of normalising PAP. After achieving stability, care moves to a "maintenance" mode, with fewer medication changes and focused interventions for any deviations from the thresholds [19].

Schulungen und Festlegung personalisierter Zielwerte/Alarm-Schwellen

The target population for implantable PAP monitoring includes patients with chronic HF who are still at elevated risk for worsening despite standard care, primarily including patients with NYHA class III symptoms who have had a recent HF hospitalisation [18]. The goal of the intervention is to spot early signs of worsening congestion in this group and help break the cycle of frequent hospitalisations [8, 17, 18]. Clinical trials and regulatory approvals have included patients regardless of LVEF. Therefore, those with HFrEF, HFmrEF, or HFpEF can qualify if they meet the symptoms and hospitalisation requirements.

Zielpopulation: HI mit erhöhtem Risiko trotz Standardversorgung → NYHA III + rezente HF-Hospitalisation

The US Food and Drug Administration (FDA) first approved the CardioMEMS HF system in May 2014 [20] and expanded the indication in March 2022 to include NYHA class II or III heart failure who have either been hospitalised for heart failure in the last year or have elevated natriuretic peptides [21]. The system obtained CE Mark approval in Europe in 2016 (all EC-certifications were provided to us by the manufacturer) for NYHA class III heart failure patients with at least one hospitalisation in the last twelve months [22]. Additionally, the PA sensor is classified as a Class III medical device by the EU Medical Device Regulation (MDR).

FDA-Zulassung 2014, Indikationserweiterung 2022; CE-Kennzeichnung 2016; EU-Medizinprodukte-verordnung: Klasse-III-Medizinprodukt

The Cordella Pulmonary Artery Sensor System (Endotronix, now part of Edwards Lifesciences [23]) is the second CE-approved PAP-monitoring device [24]. It got FDA Premarket Approval in June 2024 for patients with NYHA class III HF [25]. In July, the first patient was enrolled in the CE mark trial, SIRONA II [26]. The Cordella system also measures vital signs, including blood pressure, heart rate, weight, and oxygen levels. It allows seated pressure measurements rather than lying down [24]. Several other devices have been studied, but none have gained market approval or clinical adoption.

Cordella PAP-Monitoring-System: Zweites CE-zugelassenes Gerät; Zusatzmessungen (Vitalzeichen) und sitzende Druckmessung

In the USA, more than 5,500 CardioMEMS implants were performed in the first three years after FDA approval from 2014 to 2017 [27]. In Europe, published post-market evidence includes the MEMS-HF registry, which enrolled 234 patients across 31 centres in Germany, the Netherlands, and Ireland [28]. Outside of clinical trials, data on regular commercial implants are scarce.

USA: >5.500 Implantationen nach FDA-Zulassung (2014-2017)

Currently, PAP telemonitoring with the CardioMEMS HF system is not fully reimbursable in the Austrian healthcare system, as it is not included in the LKF. A provisional code exists: XN140 ("Implantation of a system for telemedical monitoring of pulmonary arterial pressure") [2]. These provisional codes apply to services for which the evidence base is not yet considered sufficient for routine care and allow limited hospital billing, but they do not guarantee full reimbursement [2].

keine vollständig erstattungsfähige Leistung

Results

LBI-HTA 2020 (DSD 119): Evidenzbasis: 1 RCT (CHAMPION, n=550) + 2 kontrollierte Beobachtungsstudien (n=2.174; n=77)

The 2020 Ludwig Boltzmann Institute (LBI)-HTA report (DSD 119) [1] examined the effectiveness and safety of PAP-telemonitoring using the CardioMEMS™ HF System in patients with chronic HF, with NYHA class III and a recent hospital stay. At that time, only limited long-term data were available, and most of the supporting evidence came from a single randomised controlled trial (RCT; CHAMPION [29]). For qualitative synthesis, the report included three controlled studies:

- One randomised controlled trial (CHAMPION trial; single-blinded, multicentre) with 550 patients,
- and two observational studies with control groups (CGs) with 2,174 and 77 patients, respectively.

Wirksamkeit: weniger HI-Hospitalisationen; keine Mortalitätsreduktion; mögliche Verbesserung in Lebensqualität

The CHAMPION trial showed a decrease in HF-related hospitalisations and a possible improvement in quality of life compared with standard symptom-based care, but no benefit in mortality. The two controlled observational studies also showed statistically significant decreases in hospitalisations. Additionally, one of the observational studies found that after 90 days, 62% of patients in the intervention group (IG) showed improvement in NYHA class.

Sicherheitsprofil sehr gut

Overall, the intervention had a low rate of (serious) adverse events (SAEs), including sensor-related complications or sensor failure. However, the reported observation period was very short.

Recommendation

Schlussfolgerung 2020: CardioMEMS wirksamer als Standard-Monitoring bei kritischen Endpunkten

Empfehlung: Aufnahme in den LKF-Leistungskatalog nur mit Einschränkungen

The authors concluded that, at that time, the intervention appeared more effective than standard monitoring programs on critical outcomes. Given the limited, non-generalisable evidence (primarily the single CHAMPION trial), the inclusion of PAP telemonitoring in the national health service catalogue (*Leistungskatalog*) "LKF (Leistungsorientierte Krankenanstaltenfinanzierung)" of the Austrian health care system was recommended with restrictions. The report suggested re-evaluating the intervention after completion of the ongoing European trials to clarify its effectiveness and safety.

Assessment of Digital Health Technologies

Digitale Gesundheits-Technologien (DHT): Zusätzliche Technik-/ Implementierungsaspekte- ASSESS-DHT-Manual in Entwicklung → Interim-Version pilotiert

Digital Health Technologies (DHTs) pose a new challenge for traditional health technology assessment (HTA) methods, as they require consideration of DHT-specific technical and implementation issues beyond those relevant to conventional, non-digital health technologies. In response, the ASSESS-DHT project is developing a new assessment manual to support health technology developers and HTA agencies in generating evidence and conducting assessments. In the present assessment, we pilot the interim version of the ASSESS-DHT manual to capture DHT-specific assessment considerations [30].

ASSESS DHT Taxonomy

DHT-Taxonomie

The diversity of DHTs necessitates variation in assessment approaches depending on their specific characteristics. Taxonomies can support the HTA process by defining criteria that classify DHTs into distinct categories, each associated with different assessment requirements. According to the ASSESS-DHT taxonomy's definition and classification, the CardioMEMS HF system is categorised as having "**Prevention**" and "**Monitoring**" as its medical purposes. The significance of information provided (Directness) of this device is classified as "**Make**[4]", and the patient vulnerability (state of healthcare situation/condition) is considered "**Critical**[5]" (see Figure 2) [31].

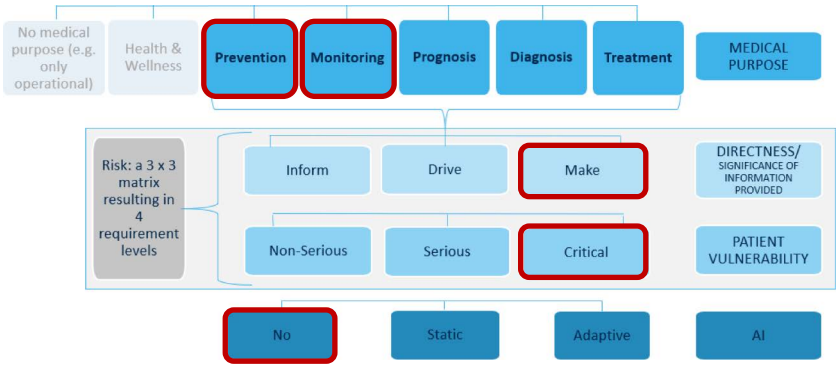

Figure 2: Categorisation of the Device [31]

Anforderungsniveau IV

Based on these classifications, the CardioMEMS HF system is assigned a requirement level of **IV** (Figure 3).

höheres Risiko
→ größerer Einfluss
→ robustere Evidenz nötig

This taxonomy remains provisional and is subject to further revision. Although the manual does not explicitly define the relationship between the risk levels (determined by Directness and Patient Vulnerability) and the necessary evidence for DHTs yet, there is a clear implication: as the potential impact on patients and clinicians increases with risk, it is implicit that higher risk levels entail a greater impact on patients and healthcare providers. Consequently, more robust evidence is required to assess the effectiveness and safety of such technologies.

[4] Make: DHT that provide information to treat or diagnose a disease or condition (information provided will be used to take an immediate or near-term action by health care provider/patient).

[5] Critical: Situations or conditions where accurate and/or timely diagnosis or treatment action is vital to avoid death, long-term disability or other serious deterioration of health of an individual patient or to mitigate the impact on public health.

Vulnerability of patients (state of healthcare situation/ condition)	'Directness' Intention of using DHT-collected or -produced information for health care decisions (by health care provider or patient)		
	Make (treat or diagnose)	Drive (clinical) management	Inform (clinical) management
Critical	IV Provides information to treat or diagnose a disease or conditions in a critical situation or condition → very high impact on patient or public health	III Provides information to drive clinical management of a disease or conditions in a critical situation or condition → high impact on patient or public health	II Provides information to inform clinical management of a disease or conditions in a critical situation or condition → medium impact on patient or public health
Serious	III Provides information to treat or diagnose a disease or conditions in a serious situation or condition → high impact on patient or public health	II Provides information to drive clinical management of a disease or conditions in a serious situation or condition → medium impact on patient or public health	I Provides information to inform clinical management for a disease or conditions in a serious situation or condition → low impact on patient or public health
Non-serious	II Provides information to treat or diagnose a disease or conditions in a non-serious situation or condition → medium impact on patient or public health t	I Provides information to drive clinical management of a disease or conditions in a non-serious situation or condition → low impact on patient or public health	I Provides information to inform clinical management for a disease or condition in a non-serious situation or condition → low impact on patient or public health

Figure 3: Requirement levels of Digital Health Technologies [31]

Lifecycle approach

Lebenszyklus-Ansatz für DHTs: Evaluation entlang Entwicklungs-/ Implementierungsphasen

DHTs evolve through a series of stages, from early concept development to widespread implementation. Accordingly, the ASSESS-DHT interim manual adopts a lifecycle approach (LCA) to evaluation. This approach ensures that relevant evaluation questions are addressed at appropriate stages using suitable methodologies.

Lebenszyklus Phase

The LC stage of a DHT can be identified using the flowchart provided in the manual (see Figure 4). Based on this framework, the CardioMEMS HF system is positioned at the "**Comparative stage**[6]" [30], indicating that RCTs are available to assess its effectiveness, safety and other outcomes.

[6] Comparative stage: the technology is benchmarked against existing standards of care. Often, randomised controlled trials are used for therapeutic interventions, though other sources of comparative evidence may be used if applicable. Diagnostic and prognostic tools are commonly compared with "gold standard" methods using blinded, parallel evaluations of the same patient. Cost-effectiveness analyses are often integrated into this stage.

Empfehlungen nach ASSESS-DHT-Anwendung

In line with the identified LC stage, as well as the device's functions (**Prevention** and **Monitoring**) and its system modifiers[7] (**Telemedicine**, **Risk**, and **Human Factor**), specific assessment recommendations are generated and applied in the present assessment.

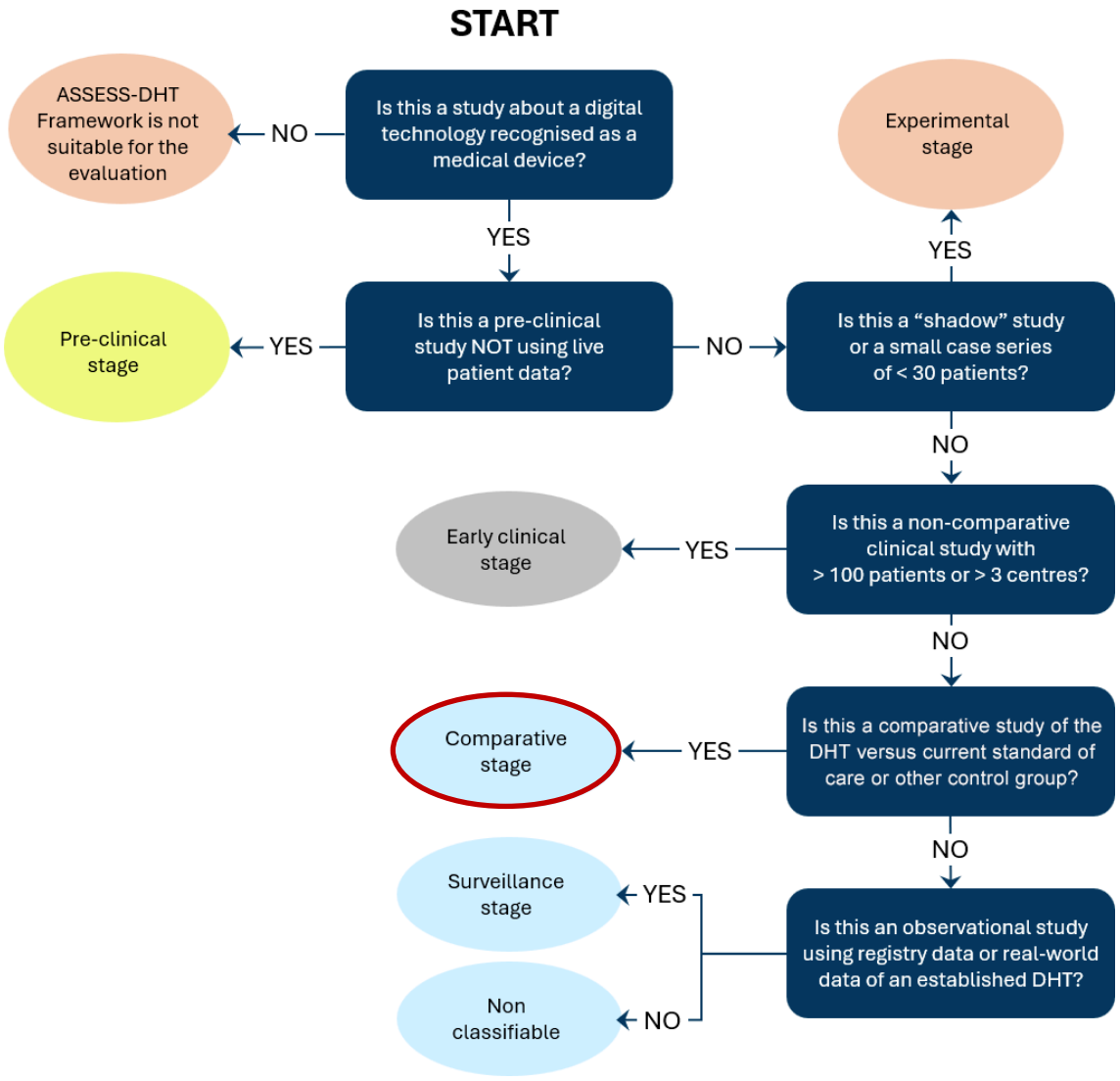

Figure 4: Lifecycle stage of a Digital Health Technology [30]

[7] The LCA proposes six cross-cutting "system modifiers" (level of risk, AI integration, autonomy, Human Factors, Interoperability and telemedicine) that give additional evaluation recommendations that affect safety and evidence requirements.

UPDATE 2026

1 Objectives and Scope

1.1 PICO question

PIKO-Frage

What is the evidence that using an implantable pulmonary artery pressure sensor (e.g. CardioMEMS™ HF System) for telemonitoring in patients with advanced heart failure (NYHA class III) can improve outcomes, such as hospitalisation rates, health-related quality of life (HRQoL) compared to standard monitoring programs, and what are the associated device- or system-related safety outcomes, such as device- or system-related complications (DSRC) or sensor failures (SF)?

1.2 Inclusion criteria

Einschlusskriterien für relevante Studien

Inclusion criteria for relevant studies are summarized in Table 1-1.

Table 1-1: PICO Inclusion Criteria

Population	Patients with chronic HF (HFrEF, HFmrEF, or HFpEF) in NYHA class III (ICD-10 Code I50.13), who have a recent history of HF decompensation, defined as ≥1 hospitalisation for HF within the past twelve months MeSH Term: Heart Failure (C14.280.434) Rationale: Informed and supported by information from relevant guidelines [32, 33], HTA reports [8, 34] and recent reviews [35, 36]
Intervention	Implantable wireless PAP-sensor telemonitoring systems to guide future medical therapy: ■ CardioMEMS HF System ■ Similar CE-marked implantable PAP sensors (e.g., Cordella System) MeSH Terms: Pulmonary Artery (A07.015.114.715), Haemodynamics (G09.330.380), Telemetry (E01.370.520.750, E05.925, L01.462.500.847.675), Wireless Technology (L01.462.500.847.950), Implants, Experimental (E07.695.340)
Control	Guideline-directed standard HF monitoring care (according to AWMF S3 national health care guideline for chronic HF [3]) MeSH Term: Monitoring, Physiologic (E01.370.520) Rationale: Informed and supported by information from relevant guidelines [32, 33], HTA reports [8, 34] and recent reviews [35, 36]
Outcomes	
Clinical Effectiveness	■ All-cause mortality ■ Cardiovascular mortality ■ HF-related hospitalisations ■ All-cause hospitalisations ■ Urgent hospital care with the necessity for intravenous diuretics ■ Guideline-Directed Medical Therapy ■ Health-related quality of life and/or perceived health status (EQ-5D-5L, KCCG, MLHFQ) Rationale: Informed and supported by information from relevant guidelines [32, 33], HTA reports [8, 34] and recent reviews [35, 36]

Safety	■ Device-related and procedural complications (e.g., arrhythmia, bleeding, cardiac complications, infection, hematoma, hospitalisation, (pulmonary) artery complications, renal failure, thrombus formation, etc.) ■ Pressure-sensor failures (e.g., complete loss of function), malfunctions (e.g., signal errors), or migrations (shifting or displacement of the device) ■ Any adverse events; any serious adverse events
Study design	
Clinical Effectiveness	Randomised controlled trials (with or without a sham device implantation)
Safety	Randomised controlled trials (with or without a sham device implantation) Non-randomised comparative trials Analytical observational studies (case-control, longitudinal and cohort studies)

Abbreviations: AWMF … Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaft (English: working group of the scientific medical association); HF … Heart Failure; HFrEF … Heart Failure with Reduced Ejection Fraction; HFmrEF … Heart Failure with Mildly Reduced Ejection Fraction; HFpEF … Heart Failure with Preserved Ejection Fraction; HTA … Health Technology Assessment; NYHA … New York Heart Association; PAP … Pulmonary Artery Pressure

2 Methods

2.1 Research questions

EUnetHTA Core Model® (Rapid REA v4.2) angepasst

Assessment elements from the European Network for HTA (EUnetHTA) Core Model® for the production of Rapid Relative Effectiveness Assessments (Version 4.2) were customised to the specific objectives of this assessment. Please refer to Appendix ("Research questions") for the detailed research questions.

ASSESS-DHT-Interim-Manual angepasst und pilotiert

In addition, to address considerations specific to DHTs, relevant assessment considerations and recommendations from the ASSESS-DHT interim manual were customised and piloted. The used assessment elements are shown in the appendix (Table A-12).

2.2 Clinical effectiveness and safety

2.2.1 Systematic literature search

systematische Literatursuche in 4 Datenbanken

The systematic literature search was conducted on the 7th of November 2025 in the following databases:

- Medline via Ovid
- Embase
- The Cochrane Library
- International Network of Agencies for Health Technology Assessment (INAHTA)

411 Treffer nach Deduplikation

After deduplication, 411 citations remained. The Medline search strategy is provided as an example in the Appendix ("Search strategy for Medline via Ovid"). The other searches are published on OSF (https://osf.io/3zatq).

Suche nach laufenden Studien

Furthermore, to identify ongoing and unpublished studies, a search of three clinical trial registries (ClinicalTrials.gov, WHO-ICTRP, and EU Clinical Trials) was conducted on 02.12.2025, yielding 37 (+ six for Cordella Pulmonary Artery Sensor System) potentially relevant hits.

insgesamt 597 Publikationen identifiziert

Manufacturers from the commercially available product (CardioMEMS™ HF System) submitted 37 publications of which 20 new citations were identified, resulting in 617 hits before deduplication.

2.2.2 Flow chart of study selection

Literaturauswahl

Overall, 431 hits were identified. The references were screened by three independent reviewers (JK, RS, YH). Every reference was assessed by at least two reviewers. Any disagreements between reviewers or uncertainty regarding inclusion were resolved through discussion and consensus. If consensus could not be reached, a fourth reviewer (GG) was involved in solving the differences. The selection process is displayed in Figure 2-1.

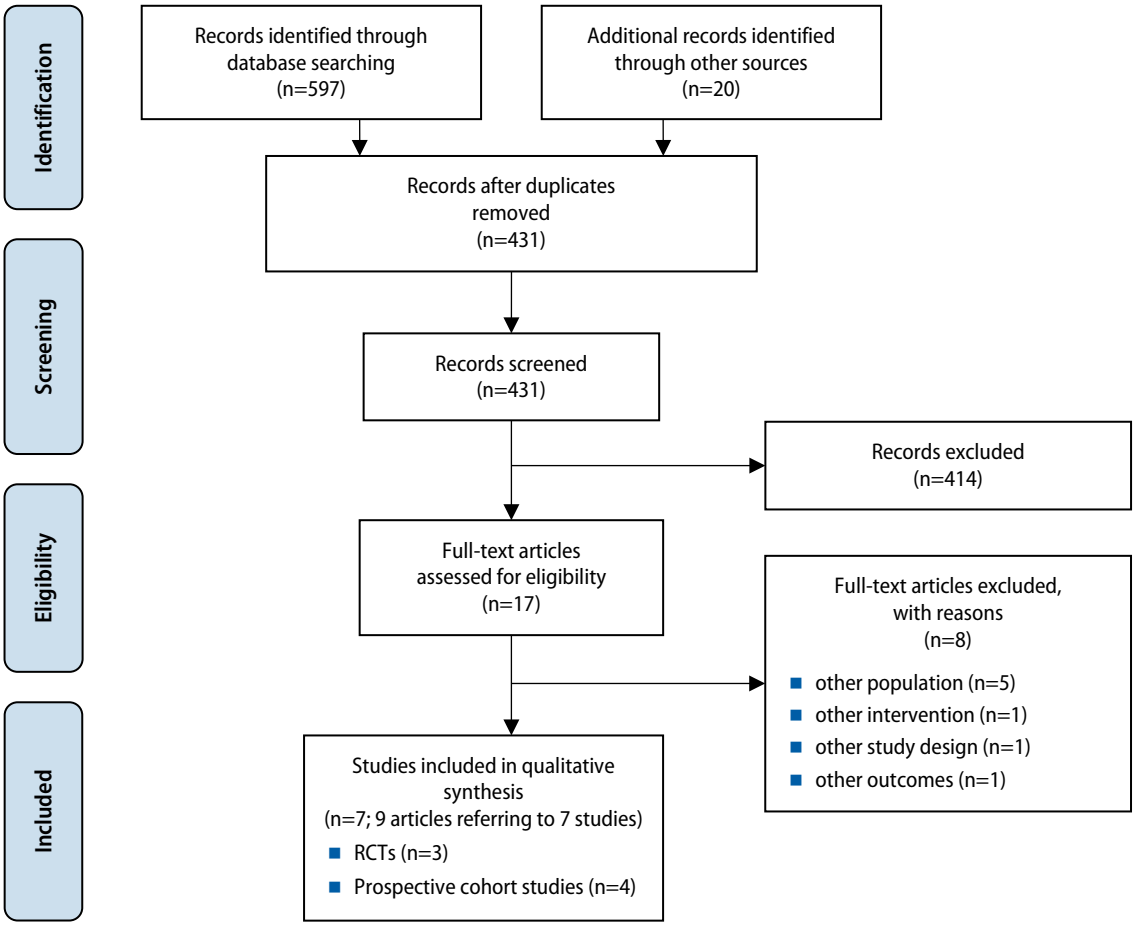

Figure 2-1: Flow chart of study selection (PRISMA Flow Diagram)

2.2.3 Analysis[8]

Bristol TAG Review 2025 als Basis für quantitative Synthese;
ROBIS: niedriges Verzerrungsrisiko (RoB)

eigene Datenextraktion, RoB, GRADE

After literature screening, we identified a recent (2025) evidence review by the Bristol Technology Assessment Group (Bristol TAG) addressing a highly similar research question. Because the review was published only on the National Institute for Health and Care Excellence (NICE) website, it was not captured by our systematic search. We assessed the methodological quality of the Bristol TAG review using ROBIS [37] (see Table A-5 in Appendix) and judged it to be at low risk of bias (RoB). We therefore used the pooled estimates of the report as the basis for our quantitative synthesis. To ensure transparency, accuracy, and independent judgment, we conducted data extraction, RoB assessment, and evidence grading independently.

[8] This section addresses the following assessment elements:
LCA Recommendation 32: Have systematic reviews of comparative studies been evaluated for validity and confidence in recommendations using ROB2 or similar tools, and GRADE?

We extracted relevant data from the original studies de novo into piloted data extraction tables (see Appendix, Table A-1 and Table A-2). A second author checked the data for accuracy. We cross-checked all study-level inputs used in the Bristol TAG evidence tables against the original publications (e.g., sample sizes, event counts, follow-up (f/u) times, effect estimates, etc.) for primary and secondary outcomes.

Datenextraktion de novo; Gegenprüfung Bristol-TAG-Studiendaten

Two reviewers (RS, YH) independently assessed the internal validity of included studies using the Cochrane RoB tool v.2 [38] for RCTs (see Appendix, Table A-3); any disagreements were settled through discussion. Single-arm trials (SAT) were classified as having a high RoB according to the methodological guidance by the HTA Coordination Group pursuant to the HTA Regulation, and, as a result, were not subject to further assessment [39]. We then assessed the certainty of the evidence using GRADE (Grading of Recommendations, Assessment, Development and Evaluation) [40].

interne Validität: Cochrane RoB2 für RCTs; einarmige Studien = hohes RoB

GRADE-Bewertung für Vertrauenswürdigkeit der Evidenz

2.2.4 Synthesis

We addressed each research question in a narrative format, supported by Summary of Findings and GRADE evidence tables (Table 4-1, Table A-4 in the appendix). Outcome importance (critical/important/not important for Austrian decision-making) was ranked independently by an external clinical expert based on the prespecified PICO; only outcomes rated critical or important were prioritised in the main results and summary of findings.

Ergebnisdarstellung: Narrativ + GRADE; Endpunkte-Priorisierung

Pooled effect estimates were retrieved from the Bristol TAG meta-analyses, which used fixed-effect inverse-variance models when heterogeneity was low and DerSimonian-Laird random-effects models when heterogeneity was substantial. Outcomes were pooled on the log scale for HRs/rate ratios, as mean differences for continuous outcomes, and as proportions using Freeman-Tukey transformation (including zero-event studies without continuity correction). For GUIDE-HF, Bristol TAG used manufacturer-supplied NYHA III subgroup results where available[9]; these subgroup data were not accessible to us for independent verification, which we acknowledge as a limitation. Evidence on the Cordella system was handled separately as an emerging technology (see Chapter 5)[10]. Outcomes not analysed by Bristol TAG, such as use of guideline-directed medical therapy (GDMT) and any (serious) adverse events (SAEs) excluding DSRC/SF were derived from our own data extraction and synthesised narratively.

quantitative Synthese: Bristol TAG gepoolte Schätzer;

weitere Endpunktees narrativ synthetisiert;

Cordella separat als aufkommende Technologie

[9] Where NYHA III subgroup data were unavailable, overall trial estimates were used; considered as indirectness (population mismatch).

[10] The Cordella system is treated as an emerging CE-marked PAP monitoring technology not currently available in Austria; therefore, it was not included in the main effectiveness assessment and is summarised separately based on the Bristol TAG assessment [41].

3 Results: Clinical effectiveness and safety

3.1 Outcomes

3.1.1 Outcomes effectiveness

kritische Endpunkte: gesamt- und kardiovaskuläre Mortalität; gesamt- und HI-Hospitalisation; akute Krankenhausversorgung (<24 h, i. v. Diuretika)

The following outcomes were defined as *critical* to derive a recommendation:

- All-cause mortality and CV mortality, defined as death due to cardiovascular causes
- All-cause hospitalisation and HF hospitalisation, defined as admission primarily due to worsening HF
- Urgent hospital care, defined as an urgent visit/observation stay or hospitalisation less than 24 hours, requiring intravenous diuretics

wichtige Endpunkte:

The following endpoints were defined to be *important*, but not critical, for decision-making:

- GDMT, defined as the between-group difference at f/u in use and/or dose intensity of recommended HF drug classes
- HRQoL (patient-reported outcome) assessed using established instruments (e.g., EQ-5D-5L [42], Kansas City Cardiomyopathy Questionnaire (KCCG) [43], or Minnesota Living with Heart Failure Questionnaire (MLHFQ) [44])

Anwendung von leitliniengerechter Therapie; gesundheitsbezogene Lebensqualität

Outcome-Set reflektieren Symptombelastung, Funktionsstatus und Behandlungsverbesserung

The selected effectiveness outcomes reflect the main patient-related endpoints recommended in HF guidelines and HTA practice. All-cause and HF hospitalisations, all-cause and CV death rates, and urgent hospital care are critical because they represent major clinical events and healthcare utilisation. HRQoL (EQ-5D-5L, KCCQ, MLHFQ) and GDMT use are important, non-critical outcomes. They reflect symptom burden, functional status, and treatment improvement, which help interpret clinical effects.

3.1.2 Outcomes safety

kritische Sicherheits-Outcomes:

Geräte-, System- oder Verfahrensbedingte Komplikationen, Sensorausfälle, schwerwiegende unerwünschte Ereignisse

The following outcomes were defined as *critical* to derive a recommendation:

- DSRC attributable to the implant procedure, device, or monitoring system
- SF to provide reliable measurements and/or need for device revision/replacement
- Any (S)AE; defined as the occurrence of any adverse event during f/u, irrespective of causality, excluding DSRC and/or SF or other procedure-related (S)AEs

Überblick über Sicherheitsprofil

Safety outcomes were selected to characterise specific device-related risks and overall harm. DSRC and procedural-related complications, as well as SF, were identified as critical outcomes because they directly reflect procedural and device-related complications, whereas overall adverse event rates provide a summary of the safety profile.

3.2 Included studies

In total, seven unique studies reported across nine publications met the inclusion criteria. Period extensions from the same study were treated as a single study to avoid double-counting.

eingeschlossene Evidenz: 7 Studien (9 Publikationen)

3.2.1 Included studies effectiveness[11]

Three multicentre RCTs comparing PAP telemonitoring using the CardioMEMS HF system with guideline-directed standard care were included in the effectiveness assessment: CHAMPION [29, 45] (2011), GUIDE-HF [46] (2021) and MONITOR-HF [46] (2023). CHAMPION and GUIDE-HF were conducted in North America (and Canada in GUIDE-HF). MONITOR-HF was conducted in the Netherlands. All RCTs were sponsored by Abbott, and MONITOR-HF received cofunding from the Dutch Ministry of Health and the National Health Care Institute. Conflicts of interest were disclosed in all three studies, with some investigators or authors employed by, or receiving research grants, consulting fees, or speaker fees from, Abbott or other medical device companies. Protocols were available for all three studies, although the protocol for CHAMPION was published after the study already started.

RCTs zur Wirksamkeit: CHAMPION (2011), GUIDE-HF (2021), MONITOR-HF (2023)

Two of the trials were single-blind, sham-controlled RCTs (CHAMPION, GUIDE-HF), while the third was an open-label trial without a sham control (MONITOR-HF). In both sham-controlled trials, both arms were implanted with the CardioMEMS sensor and received standard HF treatment. Sham control was achieved by the clinicians not having access to the PAP monitoring data in the CG. In MONITOR-HF, the CardioMEMS sensor was implanted only in the IG, whereas the CG received standard therapy. The primary endpoints in the different studies were HF hospitalisations at six months (CHAMPION) and mean change in quality of life (KCCQ) at twelve months (MONITOR-HF). The primary endpoint in GUIDE-HF was a composite outcome comprising all-cause mortality and heart failure hospitalisations at twelve months. Additionally, CHAMPION assessed DSRC and pressure SF as primary safety outcomes.

Studiendesign: CHAMPION/GUIDE-HF verblindet mit Sham-Kontrolle (Sensor in beiden Armen; Kontrollarm ohne PAP-telemonitoring); MONITOR-HF offen, ohne Sham-Kontrolle

While CHAMPION and MONITOR-HF enrolled only patients with chronic HF in NYHA class III, GUIDE-HF was the only study that enrolled patients in NYHA classes II, III, and IV who qualified through prior heart failure hospitalisations or elevated natriuretic peptide levels. Still, they included a majority of patients in NYHA III class (65%). For this assessment, subgroup results were used, where available. All three trials further specified at least one hospitalisation in the last twelve months as an inclusion criterion, while MONITOR-HF and GUIDE-HF extended this criterion to include patients without a hospitalisation but with an urgent hospital visit with intravenous diuretics in the last twelve months (MONITOR) or with elevated natriuretic peptides within 30 days before consent (GUIDE-HF), respectively.

Population: CHAMPION/MONITOR-HF nur NYHA III; GUIDE-HF NYHA II-IV (65% NYHA III) → Subgruppen Ergebnisse von Hersteller bereitgestellt

[11] This section addresses the following assessment elements: LCA Recommendation 33: Has the DHT's clinical effectiveness been compared with current standard of care using robust study designs (e.g., RCTs), with clear reporting of relevant outcomes and subgroup effects?

A total of 1,898 participants were included across the studies, with 943 participants in the IG and 955 in the CG. The number of participants in the individual studies ranged from 348 (MONITOR-HF) to 1,000 (GUIDE-HF). The average age was between 61 and 71 years in the IGs, and between 62 and 70 years in the CGs. The percentage of male participants ranged from 62% to 78% in the IG and from 63% to 73% in the CGs. Finally, the f/u length was 18 months in CHAMPION (mean 15±7), twelve months in GUIDE-HF, and 48 months in MONITOR-HF (mean 1.8±0.9 years). In CHAMPION, six participants in the IG and four in the CG were lost to f/u at 18 months. GUIDE-HF reported three lost-to f/u in the IG and nine lost to f/u in the CG at twelve months; MONITOR-HF reported no lost to f/u.

Studienumfang: n=1.898 (Interventionsarm: 943; Kontrollarm: 955)

Follow-up: CHAMPION 18 Monate, GUIDE-HF 12 Monate, MONITOR-HF 48 Monate

Study characteristics and results of included studies are displayed in Table A-1, and in the evidence profile in Table A-4.

3.2.2 Additional included studies safety[12]

In addition to the three RCTs, four prospective multicentre observational cohort studies with a pre-post comparison evaluating the CardioMEMS HF system in routine practice were included in the analysis of safety outcomes (CardioMEMS Post-Approval Study (PAS, 2020) [47], COAST UK (2022) [48], COAST France (2024) [48], MEMS-HF (2020) [28]). The studies included data from participants in the USA (PAS), the UK (COAST), France (COAST), and MEMS-HF involved centres in Germany, the Netherlands and Ireland. All four studies were sponsored by Abbott, and all participants were implanted with the CardioMEMS sensor. Furthermore, all four studies provided a protocol and reported their conflicts of interest, with multiple authors reporting employment, support, consultancy, or speaker fees from Abbott.

4 prospektive multizentrische Kohortenstudien (Pre-Post): PAS, COAST UK/France, MEMS-HF

The safety-related primary outcomes in the four studies were DSRC and freedom from pressure sensor failure at twelve (MEMS-HF) or 24 months (PAS, COAST UK, and COAST France), with performance goals of over 80% or 90%. The studies included patients with NYHA class III HF, who had been hospitalised for HF at least once in the last twelve months (COAST UK and COAST France, MEMS-HF, PAS). Across the included studies, eligibility criteria did not specify LVEF thresholds. However, several studies used anatomical and body-size limits for implantation. These included a minimum PA branch diameter of 7mm and upper BMI limits of 35kg/m^2; if exceeded, chest circumference had to be less than 65 inches (COAST UK and France, PAS).

Population: NYHA III + ≥1 HF-Hospitalisation/12 Monate

The number of successful implants in the observational studies ranged from 100 (Coast-UK) to 1,200 (PAS), for a total of 1,637 successful attempts. Three studies reported unsuccessful implantation attempts ranging from 1% to 3%, totalling 19 across studies (COAST UK, MEMS-HF, PAS). Unsuccessful attempts had a 30-day f/u period for safety. PAS reported 21 participants lost to f/u (24 months), while the remaining studies did not report any lost to f/u. The mean participant age across studies ranged from 67.2±11.5 years to 69± 12 years, while the percentage of male participants ranged from 63% to 78%.

insgesamt 1.637 Implantationen; Fehlversuche 1-3 % (n=19) mit 30-Tage-Sicherheits-Follow-up

Study characteristics and results of included studies are displayed in Table A-1 and Table A-2, and in the evidence profile in Table A-4.

[12] This section addresses the following assessment elements: LCA Recommendation 118: For devices in MDR Class 2b or 3, has a large prospective cohort study or a randomised trial been performed which reports on safety and risk outcomes?

3.3 Results

3.3.1 Clinical Effectiveness Outcomes

Mortality[13]

All-Cause Mortality

Gesamtmortalität (RCTs): 3 Studien (n=1.898)

All-cause mortality was reported by all three RCTs [29, 46, 49] included in the effectiveness analysis (n=1,898).

kein signifikanter Unterschied

Punktschätzer zugunsten der Intervention

sehr unpräzise (breites Konfidenzintervall)

The effects between the studies were inconsistent in direction, and none were statistically significant. In CHAMPION (18 months f/u), deaths occurred in 50 out of 270 (19%) participants in the IG compared to 64 out of 280 (23%) participants in the CG (HR (Hazard Ratio) 0.80; 95% CI 0.55-1.15; p=0.23). In GUIDE-HF (twelve months f/u; all NYHA II-IV) deaths occurred in 40 out of 497 (8%) participants in the IG compared to 37 out of 503 (7%) participants in the CG (HR 1.09; 95% CI 0.70-1.70; p=0.71), and in MONITOR-HF (48 months f/u) deaths occurred in 42 out of 176 (24%) participants in the IG compared to 45 out of 172 (26%) participants in the CG (HR 0.96; 95% CI 0.63-1.46; p=0.85).

Heterogenität sehr gering

In the Bristol TAG meta-analysis (Figure 3-1[14]), the pooled effect for all-cause mortality was HR 0.91, with a broad CI (95% CI 0.70-1.17). Between study heterogeneity was very low (I^2=0%) [41].

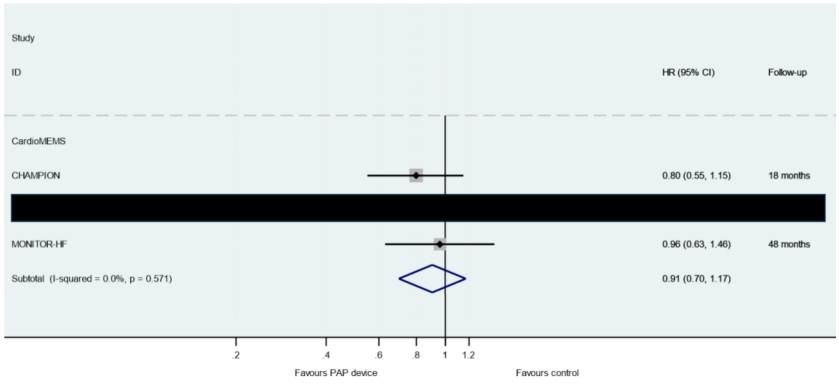

Figure 3-1: Forest Plot for all-cause mortality [41]

[13] This section addresses the following assessment elements:
D0001 – What is the expected beneficial effect of CardioMEMS on mortality?

[14] Some study-level inputs in the Bristol TAG forest plots are redacted because they originate from information submitted under academic-in-confidence (AiC) arrangements, including manufacturer-provided subgroup results that are not available publicly.

Cardiovascular Mortality

Similarly, CV mortality was reported by all three RCTs [29, 46, 49].

kardiovaskuläre Mortalität (RCTs): 3 Studien (n=1.898)

Reported event rates ranged from 0.081 to 0.10 events per patient-year in the IGs versus 0.086 to 0.11 events per patient-year in the CGs.

kein signifikanter Unterschied

None of the studies demonstrated statistical significance, and findings were mixed. In CHAMPION (18 months f/u), GUIDE-HF (twelve months f/u) and MONITOR-HF (48 months f/u), CV deaths were 40 out of 270 (15%) compared to 48 out of 280 (17%) participants (HR 0.87; 95% CI 0.51-1.49), 30 out of 497 (6.04%) compared to 24 out of 503 (5%) participants (HR 1.16; 95% CI 0.77-1.77), and 25 out of 176 (14%) compared to 31 out of 172 (18%) participants (HR 0.83; 95% CI 0.49-1.39; p=0.485) (intervention vs control), respectively.

Punktschätzer minimal zugunsten der Intervention

sehr unpräzise (breites Konfidenzintervall)

In the Bristol TAG meta-analysis (Figure 3-2), the pooled effect on CV mortality was HR 0.98, with a broad CI (95% CI 0.74-1.29)[15]. Heterogeneity between the studies was very low (I^2=0%)[41].

Heterogenität sehr gering

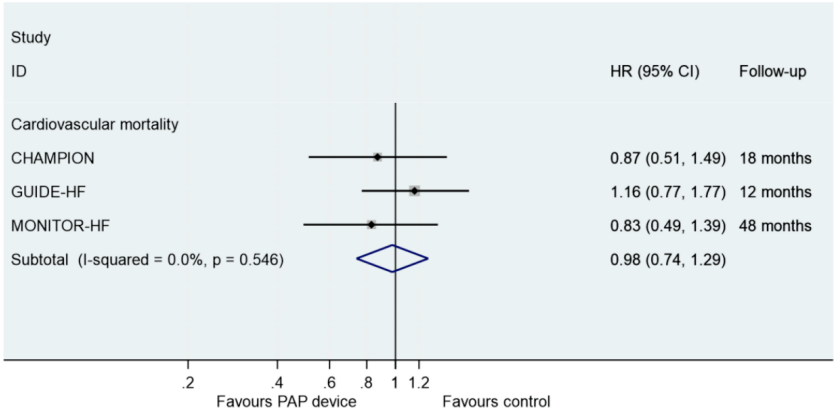

Figure 3-2: Forest Plot for cardiovascular mortality [41]

Only GUIDE-HF [49] reported HF-related mortality: 17 deaths in the IG group compared to 15 events in the CG at twelve months (0.034 vs 0.030 events per patient-year; HR 1.13; 95% CI 0.57-2.27).

HI-bezogene Mortalität: 1 Studie; 17 vs 15 Ereignisse/ Patientenjahr

[15] GUIDE-HF was analysed in the overall population because NYHA class III subgroup data were unavailable.

Morbidity[16]

Heart Failure-related Hospitalisation

HI-Hospitalisationen (RCTs): 3 Studien (n=1.898)

HF-related hospitalisations were reported by all three RCTs [29, 46, 49].

Across trials, event rates ranged from 0.34 to 0.46 events per patient-year in the IGs and from 0.50 to 0.68 events per patient-year in the CGs.

signifikanter Effekt zugunsten Interventionsgruppe

Hazard für HI-Hospitalisationen im Mittel um 34 % niedriger

HF hospitalisation events were lower in the IG in two trials, both of which showed a statistically significant effect. CHAMPION (6 months f/u) demonstrated a statistically significant result with 182 events in the IG compared to 279 events in the CG (HR 0.67; 95% CI 0.55-0.80; p<0.0001) and 158 compared to 254 during the full randomised access period at mean 15 months (HR 0.63; 95% CI 0.52-0.77; p<0.0001). Similarly, MONITOR-HF (48 months f/u) demonstrated a statistically significant effect with 106 compared to 195 events (HR 0.56; 95% CI 0.38-0.82; p=0.003). GUIDE-HF (twelve months f/u) also reported lower events in the IG, 185 compared to 225 (HR 0.83; 95% CI 0.68-1.01; p=0.06), but without statistical significance.

Heterogenität sehr niedrig

In the Bristol TAG meta-analysis (Figure 3-3[14]), the combined effect across studies was HR 0.66 (95% CI 0.57-0.76; I^2=0%) [41].

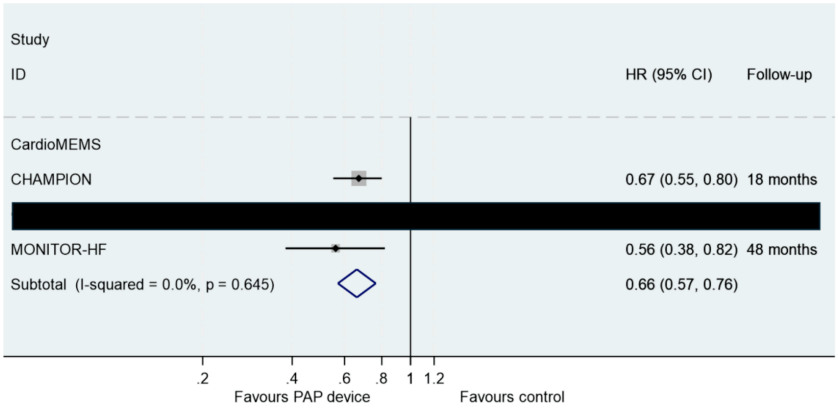

Figure 3-3: Forest Plot for heart failure hospitalisations [41]

All-Cause Hospitalisation

Gesamt-Hospitalisationen: 1 Studie

All-cause hospitalisation was reported in only one RCT (CHAMPION, n=550 [29]).

signifikanter Effekt zugunsten Interventionsgruppe, Hazard um 16 % niedriger

Total hospitalisation events were lower in the IG, with 554 compared to 672, corresponding to 1.38 events per patient-year compared to 1.65 (6 months f/u). The statistically significant effect estimate reported was HR 0.84 (95% CI 0.75-0.95; p=0.0032) [29].

[16] This section addresses the following assessment elements:
D005 – How does CardioMEMS affect symptoms and findings (severity, frequen-cy) of heart failure?
D0006 – How does CardioMEMS affect progression (or recurrence) of heart failure?
LCA Recommendation 111: Was the difference in outpatient visits and admission rate between patients using the telemedicine DHT and the comparator group reported?

Urgent Hospital Visits

dringende HI-Versorgung: 2 RCTs (n=1.348)

Urgent hospital visits for HF were reported in two RCTs (GUIDE-HF and MONITOR-HF [46, 49]; n=1,348).

Ereignisraten ähnlich

Urgent hospital visit event rates ranged from 0.036 to 0.065 events per patient-year in the IG and 0.054 to 0.063 events per patient-year in the CG. Effects were inconsistent, reported events were 28 compared to 27 in GUIDE-HF after twelve months (HR 1.04; 95% CI 0.61-1.77; p=0.89) and eleven compared to 17 in MONITOR-HF after 48 months (HR 0.65; 95% 0.23-1.88; p=0.44) (intervention vs control). None of the effect sizes were statistically significant.

keine signifikanten Effekte

Heterogenität relativ niedrig

In the pooled analysis (Figure 3-4[14]), there was no difference between groups (HR 1.05; 95% CI 0.56-1.96) [41]. Heterogeneity across studies was relatively low (I^2=18.1%).

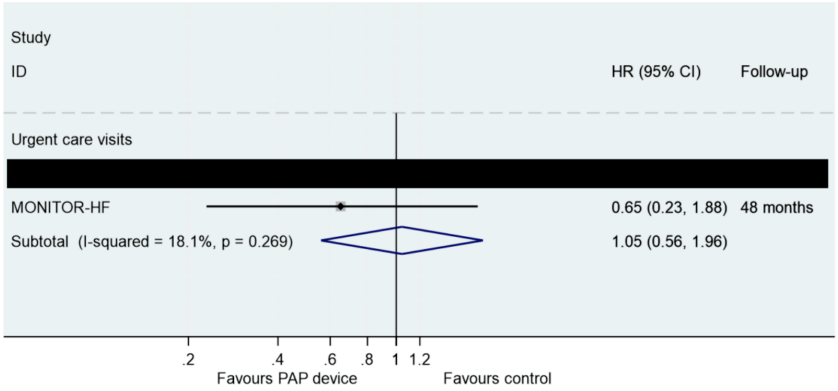

Figure 3-4: Forest Plot for urgent care visits [41]

Guideline-directed Medical Therapy

leitliniengerechte Therapie: 2 RCTs (n=1.348)

Similarly, GDMT use was reported only in GUIDE-HF and MONITOR-HF [46, 49].

insgesamt ähnlich zwischen Intervention und Kontrolle nach 12 Monaten

At twelve months, the use of GDMT was mostly similar between the intervention and control groups in the two trials, and all between-group comparisons were non-significant. The use of angiotensin receptor-neprilysin inhibitor (ARNI) was higher in the IG (60.6% vs 49.7%; p=0.059), while the use of ACE inhibitors was lower (10.6% vs 18.5%; p=0.054). Other medication classes, including beta-blockers, overall RAAS inhibitors, mineralocorticoid receptor antagonists (MRAs), SGLT2 (sodium glucose cotransporter-2) inhibitors, Ivabradine, Digoxin, and diuretics, were broadly similar between the groups. In GUIDE-HF, the proportions of GDMT were also similar (ACEi/ARB/ARNI 57% vs 56%; MRA 48% vs 43%; Hydralazine 16% vs 15%; Nitrate 21% vs 20%; diuretics 94% vs 93%). Beta-blocker use was lower in the CG (87% vs 80%), and SGLT2 inhibitor use increased similarly from baseline to twelve months in both groups (around 8% vs around 7%).

keine signifikanten Unterschiede

Medikationsanpassungen: Interventionsarm häufiger als Kontrollarm in allen RCTs; …

All three trials furthermore reported that the IG had more frequent HF medication changes than the CG. In CHAMPION, the IG had more HF drug changes per patient than the CG (mean 9.1 vs 3.8; p<0.0001). Similarly, in GUIDE-HF and MONITOR-HF, medication changes occurred more often in

the IG, with 1.031 compared to 0.608 and 0.93 compared to 0.55 changes per patient-month, respectively. This measure was not part of the prespecified GDMT outcome and is presented descriptively as additional information.

… nicht Teil des prespezifischen Endpunkt (deskriptiv)

Health-related quality of life[17]

HRQoL using the EQ-5D-5L Visual Analogue Scale (VAS) Questionnaire (generic HRQoL) was also reported in GUIDE-HF and MONITOR-HF [46, 49] (n=1,348). Similar to the KCCG score, in GUIDE-HF, the difference between groups from baseline to twelve months was not statistically significant (p=0.17),[18] but in MONITOR-HF, the average difference between groups from baseline to twelve months was statistically significant, with a difference of +6.0 points (95% CI 1.1-10.9; p=0.016) in favour of the IG.

gesundheitsbezogene Lebensqualität (EQ-5D-5L VAS) 2 RCTs (n=1.348); kein signifikanter Effekt in gepoolter mittlerer Differenz; im Mittel zugunsten der Intervention; sehr unpräzise; Heterogenität sehr hoch

The Bristol TAG meta-analysis (Figure 3-5) reported a combined average difference between groups of +1.75 (95% CI –6.03-9.53)[15] [41]. Between-study heterogeneity was substantial (I^2=87%).

HRQoL using the KCCG (disease-specific HRQoL) was reported in two RCTs (GUIDE-HF and MONITOR-HF [46, 49]; n=1,348), with higher scores indicating better health status. In GUIDE-HF, the difference between groups from baseline to twelve months was not statistically significant (p=0.48)[18]. In MONITOR-HF, the difference between groups from baseline to twelve months was statistically significant, with a difference of +7.13 points (95% CI 1.51-12.75; p=0.013) in favour of the IG.

KCCQ: 2 RCTs (n=1.348); kein signifikanter Effekt in gepoolter mittlerer Differenz; im Mittel zugunsten der Intervention

The Bristol TAG meta-analysis (Figure 3-5) reported a combined mean difference between groups of +3.62 points (95% CI –2.24-9.47)[15] [41] with high heterogeneity across the two studies (I^2=71%).

sehr unpräzise; Heterogenität sehr hoch

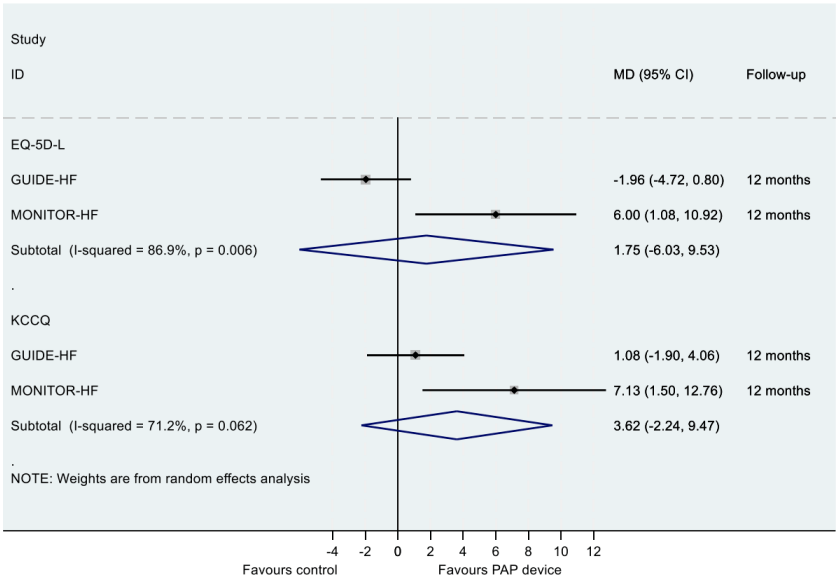

Figure 3-5: Forest Plot for health-related quality of life [41]

[17] This section addresses the following assessment elements:
D0012 – What is the effect of the technology on generic health-related quality of life?
D0013 – What is the effect of the technology on disease-specific quality of life?

[18] Data only available for overall trial population (NYHA class II–IV).

HRQoL using the MLHFQ (disease-specific HRQoL) was reported only in CHAMPION [29] (n=550). The range went from 0 to 105, with higher scores indicating worse HRQoL. At six months, the IG showed a statistically significant improvement compared to standard care (mean±SD 45±26 vs 51±25; p=0.02), as well as at twelve months (mean 47.0 vs 56.5; p=0.0267).

MLHFQ: 1 Studie; signifikante Verbesserung Interventionsarm vs Kontrollarm

3.3.2 Safety Outcomes[19]

For safety, seven SAT were included. Three studies were initially RCTs, but due to the risk being determined by exposure to implantation and the device, not by group assignment, the trials were considered SAT for the safety analysis.

Sicherheit: 7 einarmige Studien eingeschlossen – 3 ursprünglich RCTs

Device- or System or Procedural-related Complications/

DSRC or procedural-related complications were reported in all studies included in the safety analysis (evidence from 7 SAT: CHAMPION, GUIDE-HF, MONITOR-HF, COAST-UK, COAST-France, MEMS-HF, and CardioMEMS-PAS [28, 29, 46-50], ~3,419 attempted implants).

Geräte-/System/ Verfahbedingte Komplikationen: 7 einarmige Studien; 3.419 Implantationen

Reported DSRC counts were eight out of 1,022 (0.78%) in GUIDE-HF over twelve months (HR 0.008; 95% CI 0.0004-0.015), four out of 172 (2.33%), including two haemoptysis, two arrhythmias, in MONITOR-HF over 48 months (HR 0.024; 95% CI 0.001-0.060), 8 out of 575 (1.39%) in CHAMPION over six months (HR 0.014; 95% CI 0.001-0.027), four out of 236 (1.69%) in MEMS-HF, including lead dislodgement/migration, haemoptysis, infection, endocarditis, over twelve months (HR 0.017; 95% CI 0.001-0.043), and five out of 1,214 (0.41%) in CardioMEMS-PAS over 24 months (HR 0.004; 95% CI 0.000-0.010) (no further events in the extended f/u period of 24 months, n=710). No DSRC were reported in COAST-UK (0/103 at 12 months) or COAST-France (0/103 at 12 and 24 months; HR 0.000; 95% CI 0.000-0.036). Across the seven studies, DSRC or procedural complications were uncommon, ranging from 0.0% to 2.3%.

Raten: 0,0-2,3%

In CHAMPION, procedure-related SAEs included bleeding and anticoagulation management issues, arrhythmias, febrile illness, cardiogenic shock, pulmonary thrombus treated with anticoagulation, atypical chest pain, and a delivery-system failure requiring snare retrieval. MEMS-HF reported 21 procedure-related events (most of them peri-procedural), including arrhythmia, bleeding, cardiac decompensation, haemoptysis, infections, pulmonary artery perforation, renal failure, pseudoaneurysm, and sudden death.

Ereignisse: z. B. Arrhythmien, Blutungen, Fiebererkrankungen, Infektionen, kardiogener Schock u. a.

In the Bristol TAG meta-analysis (Figure 3-6), the overall proportion of DSRC was 0.7% (95% CI 0.3-1.3%) (HR 0.007; 95% CI 0.003-0.013) with a broad CI and moderate heterogeneity (I^2=44%) [41].

gepoolte Proportion ~ 7 pro 1.000; moderate Heterogenität

[19] This section addresses the following assessment elements:
C0007 – Are CardioMEMS and the standard of care associated with user-dependent harms?
C0008 – How safe is the technology in comparison to the comparator(s)?
ASSESS-DHT (SAF): Have any additional harm or adverse events on the user or the care/treatment they receive by using the DHT been adequately identified, assessed, addressed, and monitored?

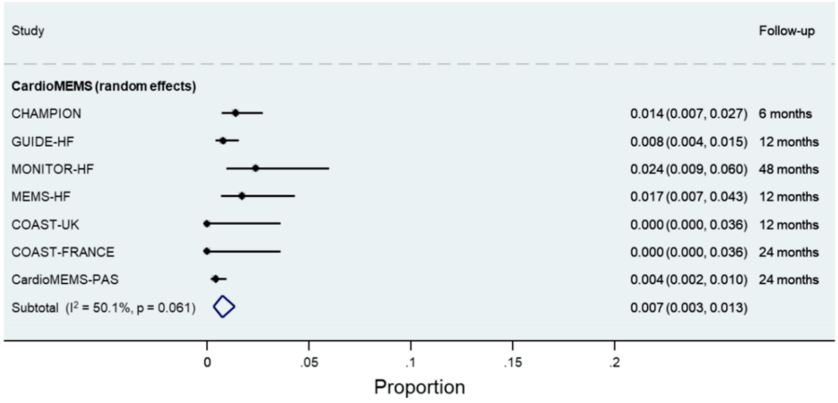

Figure 3-6: Forest Plot for device- or system-related complications [41]

Sensor Failure

SF was reported in all studies included in the safety analysis except for GUIDE-HF (CHAMPION, MONITOR-HF, COAST-UK, COAST-France, MEMS-HF, and CardioMEMS-PAS [28, 29, 46-48, 50]; 2,355 participants with implants).

Sensoren-Ausfälle: 6 einarmige Studien (2.355 Implantate)

In CHAMPION, there were no reported SFs at six months, nor at 31 months (n=246), while MONITOR-HF reported two out of 168 (1.19%) SFs (168 active sensors of 172 implanted), one anatomy/posture-related, and one sensor displacement (at 48 months). CardioMEMS-PAS reported one out of 1,200 (0.08%) SFs at 12 months (HR 0.001; 95% CI 0.000-0.005; no further events in the extended f/u period of 24 months, n=710), COAST UK reported one out of 100 (1.00%) at 12 months (HR 0.010; 95% CI 0.002-0.054), COAST France reported zero out of 103 at 24 months (HR 0.000; 95% CI 0.000-0.036) and, finally, MEMS-HF reported one out of 234 (0.43%) at 24 months (HR 0.004; 95% CI 0.001-0.024). Across the six studies, SF proportions ranged from 0.0% to 1.2%.

Ereignisse waren z. B. anatomie-/haltungsbezogen, Verschiebung des Sensors

Raten: 0,0-1,2 %

In the Bristol TAG meta-analysis (Figure 3-7), the HR was 0.001 (95% CI 0.000-0.006), corresponding to a summary SF proportion of 0.1% (95% CI 0.0-0.6%), with moderate heterogeneity (I^2=44%).

gepoolte Proportion 1 pro 1.000; moderate Heterogenität

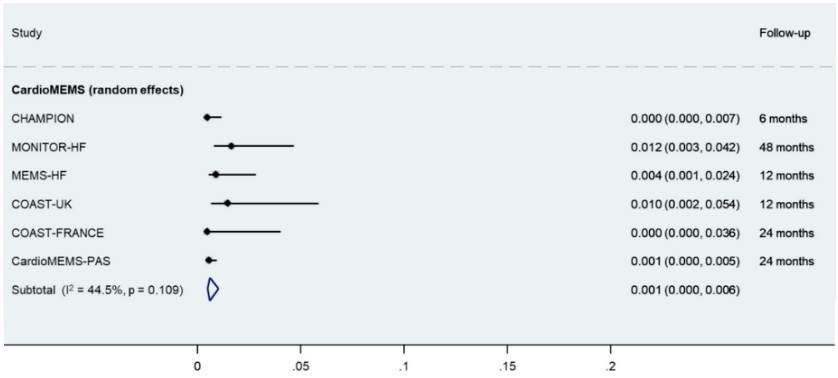

Figure 3-7: Forest Plot for sensor failure [41]

Any (Serious) Adverse Events

andere (schwerwiegende) unerwünschten Ereignisse: Daten begrenzt

Data on AE that are not related to DSRC or sensor failures, as well as other procedure-related SAEs, were limited and not aligned with the prespecified outcome definition.

MONITOR-HF: 2 schwerwiegende unerwünschte Ereignisse: Blutung, Sepsis

MONITOR-HF [46] (48 months f/u) was the only trial that documented two general SAEs: bleeding and sepsis. An independent safety committee reviewed both cases and determined they were not related to the device or procedure. However, the trial does not report the overall incidence of any (S)AEs.

GUIDE-HF: ≥1 SAE bei 57% (Interventionsgruppe) vs 53% (Kontrollgruppe); kein klarer Unterschied

GUIDE-HF [49] (12 months f/u) reported the percentage of participants who experienced at least one SAE, defined as an event leading to death or a decline in health. In the IG, 282 out of 497 participants (57%) experienced an SAE, while in the CG, 268 out of 503 participants (53%) did (absolute difference +4 percentage points, higher in the intervention arm), with similar patterns pre-COVID and overall. This indicates no clear between-group difference in the proportion experiencing at least one SAE. However, the available information did not allow separation of events consistent with our prespecified definition (i.e., excluding DSRC/sensor failure and other procedure-related events).

keine Synthese möglich

Therefore, this outcome could not be synthesised and is presented descriptively.

4 Certainty of evidence

RoB for individual studies was assessed with the Cochrane RoB tool v.2 and is presented in Table A-3 in the Appendix.

RoB

Overall, the RoB for clinical outcomes (mortality, hospitalisation, and urgent hospital care) was low in CHAMPION and GUIDE-HF. However, MONITOR-HF raised some concerns about clinical outcomes, mainly due to bias from its open-label design. In contrast, patient-reported outcomes had a higher risk of bias: in CHAMPION, primarily due to missing outcome data and some concerns about selective reporting; and in MONITOR-HF, mainly due to measurement issues in an unblinded setting and the lack of a sham procedure. GUIDE-HF raised concerns in patient-reported outcomes due to incomplete follow-up data (less than 95%) and the absence of sensitivity analyses. However, this is likely linked to challenges in data collection related to COVID-19. For GDMT use, the risk of bias was low in GUIDE-HF and raised some concerns in MONITOR-HF. This largely reflected the open-label trial context.

klinische Endpunkte: niedrig bis moderat;

patient:innen-berichtete Endpunkte: moderat bis hoch;

leitliniengerechte Therapie: niedrig bis moderat

The strength of evidence was rated according to GRADE Scheme [40] for each endpoint individually. Each study was rated by two independent researchers. In case of disagreement, a third researcher was involved to resolve the difference. A more detailed list of criteria applied can be found in the recommendations of the GRADE Working Group [40].

Vertrauenswürdigkeit der Evidenz nach GRADE

GRADE uses four categories to rank the strength of evidence:

- **High** = We are very confident that the true effect lies close to that of the estimate of the effect;
- **Moderate** = We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different;
- **Low** = Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect;
- **Very low** = Evidence either is unavailable or does not permit a conclusion.

GRADE-Kategorien (Vertrauen in Effektschätzer):

hoch, mittel, niedrig, sehr niedrig

The ranking according to the GRADE scheme for the research question is presented in the summary of findings table below and in the evidence profile in Appendix Table A-4.

The strength of evidence for the effectiveness and safety of PAP telemonitoring compared with standard of care was rated as high for hospitalisation (all-cause and HF-related) and moderate for mortality (all-cause and CV-related), as well as for urgent hospital care. The certainty of evidence for safety was also rated moderate (DSRC or procedural-related complications and SF). Only the outcomes judged critical by the external clinician were graded.

Vertrauenswürdigkeit der Evidenz (kritisch): Hospitalisation: hoch; Mortalität, dringende Versorgung und Sicherheit: moderat

Table 4-1: Summary of findings table of CardioMEMS

Outcome	Anticipated absolute effects (95% CI)	Number of participants (studies)	Quality	Comments
Mortality (all-cause)	Pooled HR across studies = 0.91 (95% CI 0.70 to 1.17)	1,898 (3 RCTs)	⨁⨁⨁◯ Moderate	
Mortality (CV)	Pooled HR across studies = 0.98 (95% CI 0.74-1.29) HF-related (1 RCT): 1.13 (95% CI 0.57-2.27)	1,898 (3 RCTs)	⨁⨁⨁◯ Moderate	Data not available for NYHA III subgroup in GUIDE-HF trial (indirectness); HF mortality was recorded by only one study
Hospitalisation (HF)	Stat. significant; pooled HR across studies = 0.66 (95% CI 0.57-0.76)	1,898 (3 RCTs)	⨁⨁⨁⨁ High	
Hospitalisation (all-cause)	Stat. significant; HR = 0.84 (95% CI 0.75-0.95; p=0.0032)	550 (1 RCTs)	⨁⨁⨁⨁ High	Only one study included in outcome assessment
Urgent Hospital Care	Pooled HR across studies = 1.05 (95% CI 0.56-1.96)	1,348 (2 RCTs)	⨁⨁⨁◯ Moderate	
GDMT	No consistent evidence of between-group differences in GDMT use	1,348 (2 RCTs)	-	No statistically significant difference in GDMT at 12 months between groups; only critical outcomes were graded
HRQoL (EQ-5D-5L))	Pooled HR across studies = 1.75 (95% CI -6.03-9.53)	1,348 (2 RCTs)	-	Higher scores indicate worse health status; data not available for NYHA III subgroup in GUIDE-HF trial (indirectness); only critical outcomes were graded
HRQoL (KCCG)	Pooled HR across studies = 6.62 (95% CI -2.24-9.47)	1,348 (2 RCTs)	-	Higher scores indicate better health status; data not available for NYHA III subgroup in GUIDE-HF trial (indirectness); only critical outcomes were graded
HRQoL (MLHFQ)	Stat. significant; IG: 47.0 vs. CG: 56.5 (p=0.0267)	550 (1 RCTs)	-	Only critical outcomes were graded
DSRC	Summary proportion of DSRC = 0.7% (95% CI 0.3-1.3%)	Attempted implant: 3,419 (7 Single-Arm)	⨁⨁⨁◯ Moderate	Analysed in the implanted/exposed population for GUIDE-HF, this corresponds to the overall implanted trial population; NYHA class is not expected to materially affect exposure-dependent event risk
Sensor Failure	Summary proportion of failed sensors that failed = 0.1% (95% CI 0.0-0.6%)	Implanted: 2,355 (6 Single Arm)	⨁⨁⨁◯ Moderate	Analysed in the implanted/exposed population; for GUIDE-HF, this corresponds to the overall implanted trial population; NYHA class is not expected to materially affect exposure-dependent event risk
Overall SAE(s)	NR	NR	NR	No study reported overall incidence of any AE/SAE in an extractable way consistent with the prespecified definition

Abbreviations: CI … Confidence Interval; CV … Cardiovascular; DSRC … Device- or System-Related Complication; GDMT … Guideline Directed Medical Therapy; HF … Heart Failure; HR … Hazard Ratio; HRQoL … Health Related Quality of Life; KCCQ … Kansas City Cardiomyopathy Questionnaire; M … Minnesota Living with Heart Failure Questionnaire; NR … Not Reported; NYHA … New York Health Association; RCT … Randomised Controlled Trial; (S)AEs … (Serious) Adverse Event

5 Emerging CE-marked technologies

Cordella (CE-zertifiziert, nicht verfügbar in Österreich): In Hauptanalyse ausgeschlossen

This section addresses Cordella Pulmonary Artery Sensor System, a CE-marked telemonitoring system that is not currently commercially available in Austria. While the Cordella system met the technical CE-marking criterion specified in the protocol, commercial availability in Austria was applied as an additional pragmatic criterion for the main effectiveness assessment, as non-available technologies cannot inform current implementation decisions.

Evidenz zu Cordella separat zusammengefasst (keine Primäranalyse); Synthese aus Bristol TAG Meta-Analyse

To maintain transparency regarding all CE-marked technologies and acknowledge Cordella's regulatory approval status and potential relevance for future assessment, we provide a summary of available evidence on the Cordella system. Given the current non-implementability, full primary data analysis was not performed; instead, findings are synthesised from the most recent high-quality systematic review and meta-analysis [41].

Evidenzbasis: 3 prospektive einarmige Studien; n=597

The Bristol TAG assessment identified three prospective SAT that provide quantitative outcome data for Cordella in NYHA III HF who had at least one HF hospitalisation or a similar HF event in the past twelve months and/or elevated natriuretic peptides (total n=597):

- **SIRONA**: small feasibility study (n=15; 3-month f/u).
- **SIRONA-2**: single-arm study (n=70; 12-month f/u; plus patient experience survey).
- **PROACTIVE-HF**: initially an open-label RCT (Cordella vs GDMT), then expanded into a large single-arm cohort (n=456 + 66 former control arm; 6-12-month follow-up; plus patient experience survey).

HF-Hospitalisationen: nicht signifikanter Effekt

Across these studies, HF hospitalisation rates declined after implantation. In the RCT phase of PROACTIVE-HF, the Cordella system showed a HR for HF hospitalisations of about 0.6 versus standard care at twelve months, but with a wide CI (95% CI 0.36-1.04; p=0.07). The certainty of evidence for this outcome was rated low.

Mortalität: nicht signifikanter Effekt

Effects on all-cause mortality are uncertain. In the RCT phase, the HR for all-cause mortality was 0.51 with a wide CI (95% CI 0.20-1.32; p=0.17). Therefore, the report did not conclude a clear all-cause mortality benefit (rated as low certainty).

Lebensqualität: gemischte KCCQ-Verläufe; Funktion: 6-Minuten-Gehtest verbessert; NYHA-Klasse verbessert (~70% ≥1 Klasse in SIRONA-2)

Reported QoL and functional outcomes generally improved over time. For the KCCQ score, SIRONA and SIRONA-2 showed no relevant change between baseline and twelve months, but PROACTIVE-HF reported an improvement from 52.8 to 58.5 at 12 months (p<0.0001). The certainty of evidence for HRQoL was rated as very low. Furthermore, both SIRONA-2 and PROACTIVE-HF reported moderate improvements in 6-minute walk distance (~20-35m increases) over 12 months. Lastly, all three studies reported shifts toward lower NYHA classes, e.g. in SIRONA-2, around 70% of patients improved by at least one NYHA class over twelve months.

Medikationsanpassungen: häufig, v. a. Frühphase (PROACTIVE-HF: signifikante Änderungen ~1,1/Patient/Monat)

The studies also showed frequent changes in HF medication, especially in the first months after the implant. For example, there were 2,956 HF medication changes over six months in PROACTIVE-HF, with a mean of 1.1 changes per patient each month; this difference between the early and later phases was significant (p<0.001). Study participants consistently adhered to daily measurement and data transmission, with rates typically at 88%-99%.

Device-related safety appears favourable. In the synthesis, implant failure occurred in a minority of attempted implants (4.9%; 95% CI 3.1-7.0%), SF after implantation was very rare (essentially 0%; 95% CI up to 0.1%), and DSRC were also uncommon (0.1%; 95% CI 0-0.9%). The certainty of evidence for device-related safety outcomes was rated as high.

Sicherheit: Implantations-Fehler 4,9%; Sensor-Ausfälle ~0%; Komplikationen 0,1%

The review concludes that the Cordella Pulmonary Artery Sensor System shows promising but uncertain evidence for reducing HF hospitalisations; the effects on mortality and QoL are very unclear, but the device has a reassuring safety profile. If stronger comparative evidence and clear plans for market entry in Austria are provided, the system may need re-evaluation.

Reevaluierung bei besserer Evidenz und Marktverfügbarkeit in Österreich

6 Discussion

6.1 Summary of findings

Ziel: PAP-Telemonitoring bei NYHA III vs Standardversorgung; 7 Studien (3 RCTs, 4 Beobachtungsstudien); Follow-up 6-48 Monate

The aim of the current assessment was to assess the effectiveness and safety of pulmonary artery pressure (PAP) telemonitoring in patients with advanced heart failure (HF) in NYHA (New York Heart Association) class III, compared to standard HF care without telemonitoring. We identified seven studies, of which three were randomised controlled trials (RCTs), and four were prospective observational studies. Follow-up ranged from six to 48 months.

- Regarding *mortality outcomes*, all-cause and cardiovascular mortality (three RCTs), pooled effects were close to the null with no statistical between-group differences (low heterogeneity).
- *HF hospitalisation* (three RCTs) was associated with a reduction in HF hospitalisations, supported by high-certainty evidence (no heterogeneity). Similarly, a significant reduction in the intervention group was shown for all-cause hospitalisations, but evidence comes from a single RCT.
- Additionally, for *urgent hospital visits* (two RCTs), the pooled effects were close to the null and demonstrated no significant differences between the intervention and control groups (low heterogeneity).
- *Guideline-directed medical therapy* use (2 RCTs) did not differ significantly between groups. Haemodynamic-guided telemonitoring care led to more frequent medication adjustments, but that does not necessarily translate into higher GDMT use or target dosing.
- For *Health-reported quality of life*, one study reported significant improvements, but across pooled analyses (two RCTs), there was no significant difference between groups, and substantial heterogeneity suggests inconsistent results. Therefore, the effect remains unclear.
- *Device- or system- or procedural-related complications* (seven single-arm trials) and *sensor* failure (six single-arm trials) rates remained consistently very low among participants who underwent implantation.
- Overall, safety data beyond device- or system-related complications, sensor failures, or procedure-specific harms were not reported consistently across studies. As a result, we still do not know the risk of non-device-related SAEs.

6.2 Interpretation

Internal validity, external validity and evidence gaps

Risk of bias was generally low for clinical outcomes in CHAMPION and GUIDE-HF, whereas MONITOR-HF raised some concerns due to its open-label design, lack of a sham control, and limited statistical power. Across studies, risk of bias was higher for patient-reported outcomes, particularly in MONITOR-HF, where lack of blinding may bias subjective measures such as health-related quality of life. Additional concerns included missing/selective outcome reporting in CHAMPION and incomplete follow-up in GUIDE-HF (likely COVID-19 related). For the use of guideline-directed medical therapy, risk of bias was low in GUIDE-HF but showed some concerns in MONITOR-HF. Observational studies were judged at inherently high risk of bias. Furthermore, several outcomes, particularly mortality and urgent visits, lacked statistical precision to detect between-group differences, and follow-up (often 12 months) may be too short to detect survival differences. Reporting of non-device/procedure (serious) adverse events was inconsistent, precluding firm conclusions about broader safety. Differences in follow-up duration and event recording likely contributed to the high heterogeneity in device- and system-related complication and sensor failure rates.

Risk of Bias:
klinische Endpunkte:
niedrig bis moderat;
Patient:innen-berichtete Endpunkte:
moderat bis hoch;

leitliniengerechte Therapie:
niedrig bis moderat;

Beobachtungsstudien:
inhärent hoch

Manufacturer sponsorship (all trials) and financial and non-financial relationships between investigators and device manufacturers, including employment, consultancies or advisory roles, as well as honoraria or research support, were common. Sponsor involvement, where reported, ranged from direct participation to no involvement in the research process. When interpreting the results, it should be considered that sponsor involvement and authors' financial ties may influence design, conduct, analysis, and reporting of a trial [51].

Herstellersponsoring in allen Studien, häufige finanzielle/nicht-finanzielle Beziehungen, potenzieller Einfluss auf Design, Durchführung, Analyse, Berichten

Considering external validity, study settings and patient characteristics broadly match the intended use, but some factors limit generalisability.

externe Validität

CHAMPION took place in specialised HF management programs, which may not reflect routine care [52]. Across trials, the intensity of background therapy (e.g., guideline-directed medical therapy) differed, and in GUIDE-HF, the control group received scheduled calls every two weeks for the first three months, which may not reflect typical care [53]. The added benefit of PAP-guided management will depend on intensity of routine care. CHAMPION took place from 2007 to 2011, when guideline-directed medical therapy differed [53]. Still, the RCTs were conducted across different periods, yet showed broadly consistent results, so this may be negligible in terms of applicability.

Effekt abhängig von Intensität der Routineversorgung/Hintergrundtherapie

Furthermore, outcome definitions and reporting across studies influence applicability. MONITOR-HF counted hospitalisation after 6 hours versus 24-hours in CHAMPION and GUIDE-HF [8]. Similarly, criteria for urgent visits differed. Such differences can affect event counts and interpretations.

Endpunktedefinitionen und Berichterstattung unterschiedlich über Studien

Safety generalisability is limited because trial reporting covered only some possible harms and often used short observation windows. A real-world analysis using the FDA MAUDE (Manufacturer and User Facility Device Experience) database [54] reported 1,109 cases of inaccurate measurements requiring replacement, 70 haemoptysis events, 24 major bleeds, and 167 events linked to death, with adverse events increasing post-approval. While passive surveillance data have uncertain completeness and denominators [54], these observations highlight the need for ongoing safety monitoring.

Berichten von Endpunkten und Beobachtungsfenster für Sicherheit limitiert; MAUDE-Analyse zeigt zunehmende unerwünschte Ereignisse → Bedarf an laufendem Sicherheitsmonitoring

Inclusion and exclusion criteria were broadly similar across the studies. However, GUIDE-HF enrolled a broader population (NYHA II-IV) than our target (NYHA III). Where possible, we used NYHA III subgroup results to align with the target population (in accordance with the Bristol TAG analysis), noting that subgroup estimates are less robust than overall trial effects (not used to infer effect modification). In cases where that was not possible, this limits how well the findings apply to the target population, and including NYHA class II patients in the pooled analysis could influence effect sizes and lessen health-related quality-of-life differences, as these patients typically have better underlying functional status. There is increasing interest in the potential use of PAP telemonitoring in other patient groups, particularly following the Food and Drug Administration approval expansion. In the overall GUIDE-HF population (NYHA II-IV), treatment effects were not clearly demonstrated; effects suggesting broader applicability were mainly observed in pre-COVID analyses [49]. Evidence for NYHA II and IV thus remains uncertain. The Bristol TAG analysis [41] found no clear effect modifiers for HF hospitalisations, but highlighted prognostic factors, such as frailty, older age, and multimorbidity, as likely relevant to baseline risk. Furthermore, women and patients with heart failure with perceived ejection fraction were underrepresented in key studies [35]. This limits the applicability of the evidence to these patients, where baseline risk and responses to monitoring may differ.

Zielpopulation NYHA III, GUIDE-HF breiter (NYHA II-IV); NYHA-III-Subgruppen genutzt, sonst „Indirektheit" – kann Effekte abschwächen

Evidenz für NYHA II/IV unklar; GUIDE-HF Gesamtpopulation ohne klaren Effekt

relevante Prognosefaktoren (Gebrechlichkeit, Alter, Multimorbidität) für Ausgangsrisiko

Furthermore, the level of complexity of telemonitoring is higher compared to standalone medical devices. Effectiveness relies on a multi-component delivery chain [55]: implantation, daily measurements by the patient, data transmission, clinical interpretation, treatment adjustments, communication back to the patient, and subsequent patient action. Weakness at any stage may reduce real-world applicability. Key requirements include reliable measurements, trained clinicians, personalised thresholds, timely therapy adjustments, and sufficient clinical capacity supported by clear protocols for data review and responding to alerts, including safeguards against overtitration. The effectiveness of these components is inherently linked to healthcare system and the operational capacity of the healthcare organisations.[20] Connectivity problems or device malfunctions can interrupt information flow and lessen effectiveness. Furthermore, while the device focuses on PAP, it does not capture broader physiological signals such as rhythm or oxygenation, which could be important if clinical deterioration is caused by mechanisms not primarily reflected in PAP [35]. Recent literature has therefore highlighted the potential value of decision-support tools for more targeted management [35].[21]

Komplexe Intervention: Wirksamkeit abhängig von Service-Kette (Implantation bis Patient:innenaktion); Implementierungsanforderungen: verlässliche Messung, geschulte Teams, personalisierte Schwellen, rasche Therapieanpassung, Kapazitäten/Protokolle, Alarm-Management

The model also depends on patient adherence and education. While adherence was high within the studies (80-90% [46, 49]), it remains uncertain whether this can be maintained at scale outside trial structures. These operational uncertainties could be addressed in pragmatic studies and local or national registries to capture real-world evidence [35].

Studien mit hoher Adhärenz (80-90%); Skalierung außerhalb Studien unsicher

[20] This section addresses the following assessment elements:
ASSESS-DHT (EFF): What is the organisational (added) value?
ASSESS-DHT (EFF): What are the benefits of the DHT when used in practice?

[21] This section addresses the following assessment elements: ASSESS-DHT (TEC): The steps and plans that have been made to ensure reliable performance of the DHT, that the DHT and its components work as expected in terms of technological and technical stability, that the DHT creates accurate measurements and data, and that the DHT can deal with significant increase or spike in demand.

These features demonstrate that evaluating complex interventions with DHTs requires a framework that extends beyond traditional medical device assessments. We piloted 12 items from the ASSESS-DHT manual in addition to the EUnetHTA Core Model. Our findings support the implicit logic of the taxonomy that higher risk and complexity require more robust evidence standards.

DHT – Bedarf an erweitertem HTA-Rahmenwerk (ASSESS-DHT)

Given high costs and potential equity implications, health economic evaluations tailored to the Austrian healthcare context are needed, considering whether value differs by region, particularly where telemedicine could mitigate access barriers in rural settings and/or among patient populations [35]. In the Bristol TAG economic model [41], CardioMEMS was not cost-effective in the base case (ICER ~£42,000/QALY; ~£10,000 incremental costs, 0.25 QALYs), with results highly sensitive to assumptions about utility, monitoring costs, staffing, adherence, and direct mortality effects.

Bristol TAG-Modell: Basisszenario nicht kosteneffektiv, hohe Sensitivität; Bedarf an österreichspezifischer Kosten-Nutzen-Analyse

Finally, current evidence primarily compares PAP telemonitoring using CardioMEMS with usual care. Future research should evaluate the CardioMEMS HF system against emerging structured remote non-invasive monitoring (e.g., [52, 53]) and, once evidence permits, conduct direct comparisons with other implantable haemodynamic monitoring systems, such as the Cordella system.

künftige Studien vs nicht-invasives Telemonitoring und direkter Vergleich mit implantierbaren Alternativen (z. B. Cordella)

Embedding our findings into existing knowledge

Building on the Bristol TAG review [41], this update extends the evidence base by including additional observational data on safety beyond the key RCTs. In addition, we applied validated risk-of-bias instruments [37, 38] and used GRADE [40] to assess certainty, with outcome prioritisation informed by external clinical expert input. We also assessed additional outcomes.

weitere Beobachtungsdaten und Endpunkte (plus Priorisierung), Risk of Bias-Instrumente und GRADE

In Austria, the 2020 Ludwig Boltzmann Institute for Health Technology Assessment report on PAP telemonitoring [1] concluded that the intervention appeared more effective than standard monitoring for HF-related and all-cause hospitalisations, and possibly improved quality of life, with rare safety events. However, these conclusions were limited by a small evidence base (one RCT and two observational studies). Since then, the evidence has grown. This update includes three RCTs along with additional observational evidence. Compared to the 2020 assessment, the overall pattern remains, with stronger support for reductions in HF hospitalisations and favourable safety than for mortality or health-related quality of life.

Evidenzzuwachs in Vergleich zu LBI-HTA 2020; Muster bestätigt

The broader HTA and review literature largely align with this interpretation. Across the evidence base, PAP-guided management is consistently associated with fewer HF hospitalisations [8, 34, 53, 56], with the Institute for Quality and Efficiency in Health Care (IQWiG's) 2024 rapid review/addendum [8, 57] also suggesting a hint of benefit for shorter hospital stays. Safety evidence demonstrates low rates of device-, system-, or procedure-related complications and sensor failure [8, 34, 53, 56]. In contrast, mortality [8, 34, 53, 56] and urgent visits [34] showed no clear difference between groups. This could be due to limited power and follow-up in the underlying trials, rather than a clear absence of effect [53]. Finally, for health-related quality of life trial-based syntheses show mixed [34] or only "hint" improvements [8], whereas a recent (2025) meta-analysis [56] of non-RCT studies reported significant health-related quality of life improvements in practice – consistent with the possibility of health-related quality of life being more detectable in routine care settings, whereas RCT estimates may be influenced by study design and context.

HTA-Assessments und Meta-Analysen/ systematische Reviews zeigen weitgehend übereinstimmende Ergebnisse

Finally, haemodynamic monitoring was acknowledged in guidelines but without strong endorsement. The 2021 European Society of Cardiology's (ESC) HF guideline [13] and the 2022 AHA (American Heart Association)/ACC (American College of Cardiology Foundation)/HFSA (Heart Failure Society of America) guideline [33] both assigned wireless PAP monitoring a Class IIb recommendation. This suggests selective rather than routine use.

Leitlinien: keine starke Empfehlung; ESC 2021 und AHA/ACC/HFSA 2022 = Klasse IIb → selektiver Einsatz statt Routine

Ongoing randomised controlled trials

Three ongoing RCTs investigating PAP telemonitoring using the CardioMEMS HF system compared to usual care were identified through a search of clinical trial registries: SAINTS B, SELFle-HF and PASSPORT-HF. SAINTS-B is planning to include 60 participants with change in QoL as the primary outcome. SELFle-HF includes 150 participants with acute decompensated HF; the primary endpoints in SELFle-HF are, among others, unplanned intravenous HF therapy, HF hospital admission, and CV death. Both trials were scheduled to conclude in December 2025. The third trial, PASSPORT-HF, plans to include 554 participants and has reported its primary outcome as a composite of unplanned heart failure-related re-hospitalisations and all-cause mortality. Additionally, the primary safety outcome is designated as DSRC. This study indicated a primary completion date of June 2026.

CardioMEMS: laufende RCTs: SAINTS-B (n=60; geplantes Studienende 12/2025), SELFle-HF (n=150; geplantes Studienende 12/2025); PASSPORT-HF (n=554; primäre Fertigstellung 06/2026)

Furthermore, one sham-RCT evaluating the Cordella system in 1,750 participants was identified. The trial includes patients in NYHA classes II and III. The composite primary endpoint is time to first HF event or death, and the primary safety outcomes are DSRC or pressure SF. This trial has scheduled its primary completion for 2028. Further information regarding ongoing studies is provided in Table A-7 in the Appendix.

Cordella: laufende Sham-kontrollierte RCT: n=1.750; NYHA II-III; Fertigstellung 2028

6.3 Limitations

Our report should be viewed in light of some limitations. We excluded post hoc publications and real-world data (except long-term follow-up of randomised populations), which may limit insight into routine-care effectiveness and adverse events. We did not perform de novo meta-analyses; instead, we used pooled estimates from the Bristol TAG analysis after verifying study-level inputs, noting that their modelling assumptions (e.g., constant hazard over time) may not always hold. For GUIDE-HF, Bristol TAG pooled NYHA III estimates relied on manufacturer-supplied subgroup data not reported in the trial publication. When NYHA III subgroup results were unavailable, we used the overall trial estimates and treated this as indirect evidence.

praxisnahe-Evidenz/ Post-hoc-Publikationen ausgeschlossen (außer Langzeit-Follow-up); keine de novo-Metaanalyse;

GUIDE-HF: NYHA-III-Schätzer von Hersteller bereitgestellt (nicht publikationsbasiert)

6.4 Conclusion

High-certainty evidence demonstrates that haemodynamic telemonitoring reduces HF hospitalisations in patients with chronic HF, particularly in NYHA class III. Evidence for all-cause hospitalisations is limited (single RCT) and therefore uncertain. Moderate-certainty evidence suggests device- or procedure-related complications and sensor failure are uncommon, but the evidence is insufficient to determine effects on serious adverse events beyond device- or procedure-related events. Moderate-certainty evidence indicates that mortality (all-cause and cardiovascular) and urgent hospital visits remain inconclusive, possibly due to limited follow-up and imprecision. Trials showed no clear between-group differences for guideline-directed medical therapy use. Health-related quality of life findings remain unclear and are likely sensitive to study design. Real-world effectiveness will depend on how well routine care replicates the full-service model, including data transmission, training, clinical review, rapid response, and patient adherence, and on what "usual care" means in a particular health system.

Kernergebnis: PAP-telemonitoring mit CardioMEMS ist sicher und reduziert HF-Hospitalisationen (hohe Vertrauenswürdigkeit der Evidenz); Real-World-Wirksamkeit abhängig vom Service-Modell und Definition von Standardversorgung

Future research should combine adequately powered studies with longer follow-up to clarify effects on mortality and other patient-relevant outcomes, alongside high-quality real-world data generation (prospective registries and active post-market surveillance) to characterise long-term safety, rare adverse events, and routine-care effectiveness, with improved reporting of baseline risk and prognostic factors to identify who benefits most. As data from ongoing studies of alternative systems (e.g., Cordella) develop, comparative effectiveness studies will be needed to assess relative benefits and harms, as well as practical considerations such as monitoring workflows, adherence, and real-world availability.

Forschungsbedarf: Studien mit längerem Follow-up (Mortalität) + Praxisnahe-Evidenz; Bedarf an Vergleichsstudien vs CardioMEMS und Praxisaspekten (z. B. Workflows, Adhärenz)

7 Evidence-based conclusions

Empfehlung

In Table 7-1 the scheme for evidence-based conclusion is displayed and the according choice is highlighted.

Table 7-1: Evidence based conclusions

	1	Strong evidence for added benefit in routine use.
X	2a	**Evidence indicates added benefit only in specific indications.**
	2b	Less robust evidence indicating an added benefit in routine use or in specific indications
	3	No evidence or inconclusive evidence available to demonstrate an added benefit of the intervention of interest.
	4	Strong evidence indicates that intervention is ineffective and or harmful.

Reasoning:

Begründung

The current evidence indicates that PAP-telemonitoring (particularly in NYHA class III patients and within structured monitoring and response pathways) is more effective and similarly safe than standard care without access to PAP data, mainly by reducing HF hospitalisations, while device- and procedure-related complications (device-/system- or procedural-related complications and sensor failure) appear uncommon. New study results will potentially influence the effect estimate, especially for mortality, health-related quality of life, urgent-care outcomes, and serious adverse events beyond device- or procedure-related events.

Reevaluation in 2029

The re-evaluation is recommended in 2029. Results from ongoing studies on alternative implantable PAP-telemonitoring systems, including the Cordella Pulmonary Artery Sensor System, should be available around 2028 or 2029. Additionally, several ongoing studies are evaluating PAP telemonitoring using the CardioMEMS HF system in NYHA classes beyond NYHA III, with results expected between 2026 and 2029.

8 References

[1] Winkler R. and Wild C. Implantation eines telemedizinischen Pulmonalarterien-Drucksensors bei PatientInnen mit fortgeschrittener Herzinsuffizienz. Vienna: Ludwig Boltzmann Institut für Health Technology Assessment, 2020 [cited 28.10.2025]. Available from: https://eprints.aihta.at/1254/1/DSD_119.pdf.

[2] Bundesministerium für Soziales Gesundheit Pflege und Konsumentenschutz (BMSGPK). ICD-10 BMSGPK 2022 – Systematisches Verzeichnis. Vienna: 2022 [cited 27.10.2025]. Available from: https://www.statistik.at/fileadmin/pages/388/ICD-10_BMSGPK_2022.pdf.

[3] Bundesärztekammer (BÄK), Kassenärztliche Bundesvereinigung (KBV) and Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften (AWMF). Nationale Versorgungs Leitlinie Chronische Herzinsuffizienz – Langfassung. 2023 [cited 28.10.2025]. Available from: https://register.awmf.org/assets/guidelines/nvl-006l_S3_Chronische_Herzinsuffizienz_2023-12.pdf.

[4] Bozkurt B., Coats A. J. S., Tsutsui H., Abdelhamid C. M., Adamopoulos S., Albert N., et al. Universal definition and classification of heart failure: a report of the Heart Failure Society of America, Heart Failure Association of the European Society of Cardiology, Japanese Heart Failure Society and Writing Committee of the Universal Definition of Heart Failure: Endorsed by the Canadian Heart Failure Society, Heart Failure Association of India, Cardiac Society of Australia and New Zealand, and Chinese Heart Failure Association. European Journal of Heart Failure. 2021;23(3):352-380. Epub 20210303. DOI: 10.1002/ejhf.2115.

[5] Kaduszkiewicz H., Gerste B., Eisele M., Schäfer I. and Schwerer M. Herzinsuffizienz: Epidemiologie und Versorgung. In: Klauber J., Gerste B., Robra B-P. and N. S., editors. Versorgungs-Report 2013/2014 Schwerpunkt „Depression". Stuttgart: Schattauer 2024. p. 209-229.

[6] Vasan R. S., Xanthakis V., Lyass A., Andersson C., Tsao C., Cheng S., et al. Epidemiology of Left Ventricular Systolic Dysfunction and Heart Failure in the Framingham Study: An Echocardiographic Study Over 3 Decades. JACC: Cardiovascular Imaging. 2018;11(1):1-11. Epub 20171005. DOI: 10.1016/j.jcmg.2017.08.007.

[7] Stork S., Handrock R., Jacob J., Walker J., Calado F., Lahoz R., et al. Epidemiology of heart failure in Germany: a retrospective database study. Clinical Research in Cardiology. 2017;106(11):913-922. Epub 20170726. DOI: 10.1007/s00392-017-1137-7.

[8] Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWIG). Messung und Monitoring des pulmonalarteriellen Druckes mittels implantierten Sensors zur Therapieoptimierung bei Herzinsuffizienz im Stadium NYHA III; Rapid Report [online]. 2024 [cited 28.10.2025]. Available from: https://dx.doi.org/10.60584/D23-02.

[9] Deutsche Herzstiftung. Deutscher Herzbericht – Update 2025. Frankfurt am Main: 2025 [cited 29.10.2025]. Available from: https://epaper.herzstiftung.de/epaper/36_DHzB_2025.pdf#:~:text=Die%20altersstandardisierte%20Hospitalisierungsrate%20von%20Patienten%2C,Pandemie%202020%20fiel%20diese.

[10] Griebler R., Winkler P., Delcour J. and Eisenmann A. Herz Kreislauf-Erkrankungen in Österreich. Update 2020. Vienna: Bundesministerium für Soziales, Gesundheit, Pflege und Konsumentenschutz (BMSGPK), 2021 [cited 29.10.2025]. Available from: https://www.sozialministerium.gv.at/dam/jcr:ef1ec0fd-01a7-4047-9828-42ce906a2239/Bericht__HKE_2020_2021_Mit_Titelbild.pdf.

[11] Jones N. R., Roalfe A. K., Adoki I., Hobbs F. D. R. and Taylor C. J. Survival of patients with chronic heart failure in the community: a systematic review and meta-analysis. European Journal of Heart Failure. 2019;21(11):1306-1325. Epub 20190916. DOI: 10.1002/ejhf.1594.

[12] Ishihara S., Kawakami R., Nogi M., Hirai K., Hashimoto Y., Nakada Y., et al. Incidence and Clinical Significance of 30-Day and 90-Day Rehospitalization for Heart Failure Among Patients With Acute Decompensated Heart Failure in Japan – From the NARA-HF Study. Circulation Journal. 2020;84(2):194-202. Epub 20191226. DOI: 10.1253/circj.CJ-19-0620.

[13] McDonagh T. A., Metra M., Adamo M., Gardner R. S., Baumbach A., Bohm M., et al. 2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. European Heart Journal. 2021;42(36):3599-3726. DOI: 10.1093/eurheartj/ehab368.

[14] Adamson P. B. Pathophysiology of the transition from chronic compensated and acute decompensated heart failure: new insights from continuous monitoring devices. Current Heart Failure Reports. 2009;6(4):287-292. DOI: 10.1007/s11897-009-0039-z.

[15] Zile M. R., Bennett T. D., St John Sutton M., Cho Y. K., Adamson P. B., Aaron M. F., et al. Transition from chronic compensated to acute decompensated heart failure: pathophysiological insights obtained from continuous monitoring of intracardiac pressures. Circulation. 2008;118(14):1433-1441. Epub 20080915. DOI: 10.1161/CIRCULATIONAHA.108.783910.

[16] Abbott. CardioMEMS HF-System. n.d. [cited 27.10.2025]. Available from: https://www.cardiovascular.abbott/de/de/hcp/products/heart-failure/pulmonary-pressure-monitors/cardiomems.html.

[17] Herrmann E., Ecke A., Fichtlscherer S., Zeiher A. M. and Assmus B. [Pulmonary artery pressure sensor for ambulatory assessment of ventricular filling pressure in advanced heart failure : What should be considered for the follow-up care?]. Herzschrittmacherther + Elektrophysiologie. 2018;29(4):393-400. Epub 20181010. Pulmonalarterieller Drucksensor zur ambulanten Beurteilung des ventrikularen Fullungsdrucks bei fortgeschrittener Herzinsuffizienz : Was ist bei der Nachsorge zu beachten? DOI: 10.1007/s00399-018-0597-4.

[18] Ayyadurai P., Alkhawam H., Saad M., Al-Sadawi M. A., Shah N. N., Kosmas C. E., et al. An update on the CardioMEMS pulmonary artery pressure sensor. Therapeutic Advances in Cardiovascular Disease. 2019;13:1753944719826826. DOI: 10.1177/1753944719826826.

[19] Cowie M. R., de Groote P., McKenzie S., Brett M. E., Adamson P. B. and Cardio M. P.-M. S. I. Rationale and design of the CardioMEMS Post-Market Multinational Clinical Study: COAST. ESC Heart Failure. 2020;7(3):865-872. Epub 20200207. DOI: 10.1002/ehf2.12646.

[20] U.S. Food and Drug Administration. Premarket Approval – CardioMEMS HF System. 2014 [cited 30.10.2025]. Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100045.

[21] U.S. Food and Drug Administration. Premarket Approval – CardioMEMS HF System. 2022 [cited 30.10.2025]. Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100045S056.

[22] Visco V., Esposito C., Rispoli A., Di Pietro P., Izzo C., Loria F., et al. The favourable alliance between CardioMEMS and levosimendan in patients with advanced heart failure. ESC Heart Failure. 2024;11(5):2835-2848. Epub 20240518. DOI: 10.1002/ehf2.14838.

[23] Edwards Lifesciences Corporation. Implantable Heart Failure Management. Cordella® Pulmonary Artery (PA) Sensor and HF System. n.d. [cited 27.10.2025]. Available from: https://www.edwards.com/healthcare-professionals/products-services/pap-guided-therapy.

[24] Guichard J. L., Cowger J. A., Chaparro S. V., Kiernan M. S., Mullens W., Mahr C., et al. Rationale and Design of the Proactive-HF Trial for Managing Patients With NYHA Class III Heart Failure by Using the Combined Cordella Pulmonary Artery Sensor and the Cordella Heart Failure System. Journal of Cardiac Failure. 2023;29(2):171-180. Epub 20220930. DOI: 10.1016/j.cardfail.2022.09.006.

[25] U.S. Food and Drug Administration. Premarket Approvel – Cordella Pulmonary Artery Sensor System (CorPASS). 2024 [cited 30.10.2025]. Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P230040.

[26] BIBA MedTech InsightsBIBA Medical E. First patient enrolled in CE mark trial of Cordella pulmonary artery sensor system. 2025 [cited 30.10.2025]. Available from: https://www.bibamedtech.com/biba-briefings-top-stories/first-patient-enrolled-in-ce-mark-trial-of-cordella-pulmonary-artery-sensor-system/.

[27] Ciotola F., Pyxaras S., Rittger H. and Buia V. MEMS Technology in Cardiology: Advancements and Applications in Heart Failure Management Focusing on the CardioMEMS Device. Sensors (Basel). 2024;24(9). Epub 20240503. DOI: 10.3390/s24092922.

[28] Angermann C. E., Assmus B., Anker S. D., Asselbergs F. W., Brachmann J., Brett M. E., et al. Pulmonary artery pressure-guided therapy in ambulatory patients with symptomatic heart failure: the CardioMEMS European Monitoring Study for Heart Failure (MEMS-HF). European Journal of Heart Failure. 2020;22(10):1891-1901. Epub 20200809. DOI: 10.1002/ejhf.1943.

[29] Abraham W. T., Adamson P. B., Bourge R. C., Aaron M. F., Costanzo M. R., Stevenson L. W., et al. Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial. Lancet. 2011;377(9766):658-666. DOI: 10.1016/S0140-6736(11)60101-3.

[30] Bowie D., Needham-Taylor A., Garrett Z. and Chalkidou A. D4.5 Manual for piloting assessment methods for digital health technologies (interim/piloting version of the full manual D4.6). 2025 [cited 07.01.2026]. Available from: https://zenodo.org/records/18175054.

[31] Henschke C., Rödiger H., Goetz G. and Busse R. D2.1 Taxonomy of DHT for assessment purposes. Zenodo, 2025 Report No. 07.01.2026 [cited 07.01.2025]. Available from: https://zenodo.org/records/17910908.

[32] NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE (NICE). Interventional procedure overview of percutaneous implantation of pulmonary artery pressure sensors for monitoring treatment of chronic heart failure. 2021 [cited 28.10.2025]. Available from: https://www.nice.org.uk/guidance/ipg711/evidence/overview-final-pdf-10888997149.

[33] Heidenreich P. A., Bozkurt B., Aguilar D., Allen L. A., Byun J. J., Colvin M. M., et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. 2022 May 3. Report No. 18 [cited 28.10.2025]. Available from: https://www.ncbi.nlm.nih.gov/pubmed/35363499.

[34] Health Technology Wales. Percutaneously implanted pulmonary artery pressure sensors to monitor treatment of people with chronic heart failure. 2023 [cited 28.10.2025]. Available from: https://healthtechnology.wales/wp-content/uploads/2023/02/EAR052-PAPS-WEB.pdf#:~:text=,to%20support%20its%20use.

[35] Tolu-Akinnawo O., Akhtar N., Zalavadia N. and Guglin M. CardioMEMS Heart Failure System: An Up-to-Date Review. Cureus. 2025;17(1):e77816. Epub 20250122. DOI: 10.7759/cureus.77816.

[36] NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE (NICE). Pulmonary artery pressure technologies for remote monitoring of chronic heart failure. Final scope. 2025 [cited 28.10.2025]. Available from: https://www.nice.org.uk/guidance/gid-dg10087/documents/final-scope#:~:text=non,Heart%20rate.

[37] Whiting P., Savovic J., Higgins J. P., Caldwell D. M., Reeves B. C., Shea B., et al. ROBIS: A new tool to assess risk of bias in systematic reviews was developed. Journal of Clinical Epidemiology. 2016;69:225-234. Epub 20150616. DOI: 10.1016/j.jclinepi.2015.06.005.

[38] Sterne J.A.C., Savović J., Page M.J., Elbers R.G., Blencowe N.S., Boutron I., et al. RoB 2: a revised tool for assessing risk of bias in randomised trials. BMJ. 2019;366(l4898).

[39] HTA CG. Guidance on Validity of Clinical Studies. 2024 [cited 27.11.2025]. Available from: https://health.ec.europa.eu/document/download/9f9dbfe4-078b-4959-9a07-df9167258772_en?filename=hta_clinical-studies-validity_guidance_en.pdf.

[40] Guyatt G., Oxman A. D., Akl E. A., Kunz R., Vist G., Brozek J., et al. GRADE guidelines: 1. Introduction-GRADE evidence profiles and summary of findings tables. Journal of Clinical Epidemiology. 2011;64(4):383-394. Epub 20101231. DOI: 10.1016/j.jclinepi.2010.04.026.

[41] James R., Carroll J., Thorn J., Cooper C., Tomlinson E., Nightingale A. K., et al. Pulmonary artery pressure technologies for remote monitoring of chronic heart failure [DG10087]. A systematic review and economic model. Bristol TAG, 2025 [cited 01.12.2025]. Available from: https://www.nice.org.uk/guidance/GID-DG10087/documents/supporting-documentation.

[42] Herdman M., Gudex C., Lloyd A., Janssen M., Kind P., Parkin D., et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Quality of Life Research. 2011;20(10):1727-1736. Epub 20110409. DOI: 10.1007/s11136-011-9903-x.

[43] Green C. P., Porter C. B., Bresnahan D. R. and Spertus J. A. Development and evaluation of the Kansas City Cardiomyopathy Questionnaire: a new health status measure for heart failure. Journal of the American College of Cardiology. 2000;35(5):1245-1255. DOI: 10.1016/s0735-1097(00)00531-3.

[44] Rector T. S., Kubo S. H. and Cohn J. N. Patient's self-assessment of their congestive heart failure: Content, reliability and validity of a new measure: The Minnesota living with heart failure questionnaire. Heart Failure. 1987;3:198-219.

[45] Abraham W. T., Stevenson L. W., Bourge R. C., Lindenfeld J. A., Bauman J. G., Adamson P. B., et al. Sustained efficacy of pulmonary artery pressure to guide adjustment of chronic heart failure therapy: complete follow-up results from the CHAMPION randomised trial. Lancet. 2016;387(10017):453-461. Epub 20151109. DOI: 10.1016/S0140-6736(15)00723-0.

[46] Brugts J. J., Radhoe S. P., Clephas P. R. D., Aydin D., van Gent M. W. F., Szymanski M. K., et al. Remote haemodynamic monitoring of pulmonary artery pressures in patients with chronic heart failure (MONITOR-HF): a randomised clinical trial. Lancet. 2023;401(10394):2113-2123. Epub 20230520. DOI: 10.1016/S0140-6736(23)00923-6.

[47] Shavelle D. M., Desai A. S., Abraham W. T., Bourge R. C., Raval N., Rathman L. D., et al. Lower Rates of Heart Failure and All-Cause Hospitalizations During Pulmonary Artery Pressure-Guided Therapy for Ambulatory Heart Failure: One-Year Outcomes From the CardioMEMS Post-Approval Study. Circulation: Heart Failure. 2020;13(8):e006863. Epub 20200806. DOI: 10.1161/CIRCHEARTFAILURE.119.006863.

[48] de Groote P., Thuny F., Blanchart K., Gueffet J. P., Habib G., Salvat M., et al. Remote haemodynamic-guided heart failure management in France: Results from the CardioMEMS HF System Post-Market Study (COAST) French cohort. Archives of Cardiovascular Diseases. 2024;117(11):624-632. Epub 20240912. DOI: 10.1016/j.acvd.2024.08.003.

[49] Lindenfeld J., Zile M. R., Desai A. S., Bhatt K., Ducharme A., Horstmanshof D., et al. Haemodynamic-guided management of heart failure (GUIDE-HF): a randomised controlled trial. Lancet. 2021;398(10304):991-1001. Epub 20210827. DOI: 10.1016/S0140-6736(21)01754-2.

[50] Cowie M. R., Flett A., Cowburn P., Foley P., Chandrasekaran B., Loke I., et al. Real-world evidence in a national health service: results of the UK CardioMEMS HF System Post-Market Study. ESC Heart Failure. 2022;9(1):48-56. Epub 20211209. DOI: 10.1002/ehf2.13748.

[51] Boutron I., Page M. J., Higgins J. P., Altman D. G., Lundh A. and Hróbjartsson A. Chapter 7: Considering bias and conflicts of interest among the included studies. Cochrane Handbook for Systematic Reviews of Interventions version 65 (updated August 2024): Cochrane; 2024.

[52] Angermann C. E. and Rosenkranz S. [Telemonitoring and pulmonary artery pressure-guided treatment of heart failure]. Der Internist. 2018;59(10):1041-1053. Telemonitoring und Pulmonalisdruck-geführte Therapie der Herzinsuffizienz. DOI: 10.1007/s00108-018-0495-1.

[53] Clephas P. R. D., Radhoe S. P., Boersma E., Gregson J., Jhund P. S., Abraham W. T., et al. Efficacy of pulmonary artery pressure monitoring in patients with chronic heart failure: a meta-analysis of three randomized controlled trials. European Heart Journal. 2023;44(37):3658-3668. DOI: 10.1093/eurheartj/ehad346.

[54] Lin A. L., Hu G., Dhruva S. S., Kinard M. and Redberg R. F. Quantification of Device-Related Event Reports Associated With the CardioMEMS Heart Failure System. Circulation: Cardiovascular Quality and Outcomes. 2022;15(10):e009116. Epub 20221011. DOI: 10.1161/CIRCOUTCOMES.122.009116.

[55] Iaconelli A., Pellicori P., Caiazzo E., Rezig A. O. M., Bruzzese D., Maffia P., et al. Implanted haemodynamic telemonitoring devices to guide management of heart failure: a review and meta-analysis of randomised trials. Clinical Research in Cardiology. 2023;112(8):1007-1019. Epub 20221014. DOI: 10.1007/s00392-022-02104-0.

[56] Kapelios C. J., Liori S., Bonios M., Abraham W. T. and Filippatos G. Effect of pulmonary artery pressure-guided management on outcomes of patients with heart failure outside clinical trials: A systematic review and meta-analysis of real-world evidence with the CardioMEMS Heart Failure System. European Journal of Heart Failure. 2025;27(10):1857-1865. Epub 20250513. DOI: 10.1002/ejhf.3687.

[57] Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWIG). Messung und Monitoring des pulmonalarteriellen Druckes mittels implantierten Sensors zur Therapieoptimierung bei Herzinsuffizienz im Stadium NYHA III; Addendum zum Projekt D23-02 (Rapid Report) [online]. 2024 [cited 21.01.2026]. Available from: https://dx.doi.org/10.60584/D24-01.

[58] Heywood J. T., Zalawadiya S., Bourge R. C., Costanzo M. R., Desai A. S., Rathman L. D., et al. Sustained Reduction in Pulmonary Artery Pressures and Hospitalizations During 2 Years of Ambulatory Monitoring. Journal of Cardiac Failure. 2023;29(1):56-66. Epub 20221102. DOI: 10.1016/j.cardfail.2022.10.422.

[59] EUnetHTA Joint Action 2 WP. Levels of evidence: Internal validity (of randomized controlled trials). 2013 [cited 27.11.2025]. Available from: https://web.archive.org/web/20220423155912/https://www.eunethta.eu/wp-content/uploads/2018/01/16_WP7-SG3-GL-int_val_RCTs_amend2015.pdf.

[60] EUnetHTA Joint Action 2. Internal validity of non-randomised studies (NRS) on interventions. 2015 [cited 27.11.2025]. Available from: https://web.archive.org/web/20221007180355/http://www.eunethta.eu/wp-content/uploads/2018/01/Internal-validity-of-non-randomised-studies-NRS-on-interventions_Guideline_Final-Jul-2015.pdf.

Appendix

Evidence tables of individual studies included for clinical effectiveness and safety

Table A-1: CardioMEMS: Results from randomised controlled trials

Author, year	Abraham, 2011, 2016 (CHAMPION) [29, 45]	Lindenfeld, 2021 (GUIDE-HF) [49]	Brugts, 2023 (MONITOR-HF) [46]
Country	USA (64 centres)	USA and Canada (118 centres; 1007 patients at 114 centres in USA, 15 patients in 4 sites in Canada)	Netherlands (25 centres)
Sponsor	Abbott (CardioMEMS device manufacturer)	Abbott (CardioMEMS device manufacturer)	Dutch Ministry of Health & National Health Care Institute (conditional coverage programme); Abbott Laboratories co-funded clinical study costs
Intervention/Product	CardioMEMS	CardioMEMS	CardioMEMS
Surgical Procedure	Right-heart catheterisation with transcatheter implantation of sensor into distal branch of the PA; Implant attempts: 575 implant attempts with 25 unsuccessful implants	Right-heart catheterisation with transcatheter implantation of sensor into a distal branch of the descending PA; Implant attempts: 1022 first attempts with 22 unsuccessful implants (followed for 30-day safety)	Right-heart catheterisation with transcatheter implantation of sensor into distal branch of the left PA; Implant attempts: 168 first attempts + 4 second attempts; all second attempts successful (8 did not receive the intervention because of withdrawal of informed consent)
Comparator	Standard HF care with CardioMEMS sensor implanted but PAP data not available to treating clinicians (included drug changes in response to patients' clinical signs and symptoms)	Standard HF care with CardioMEMS sensor implanted but PAP data not available to treating clinicians	Standard HF care: GDMT and diuretics guided by symptoms, signs, labs, and imaging according to ESC guidelines; no PA sensor implanted
Study design	Prospective, multicentre, single-blind RCT (with sham control)	Prospective, multicentre, single-blind RCT (with sham control)	Prospective, multicentre, open-label RCT (no sham control)
Blinding	Single-blinded	Single-blinded	Non-blinded
Duration (months)	18	12	48
Number of pts	550 (270 vs 280) (intention-to-treat analysis) Extended f/u: 246 (119 vs 127)	1,000 (497 vs 503) (intention-to-treat analysis)	348 (176 vs. 172) (intention-to-treat analysis)
Key inclusion criteria	■ ≥18 years ■ NYHA class III chronic HF for ≥3 months ■ Prior HF hospitalisation within last 12 months ■ Any LVEF ■ On optimal or maximally tolerated GDMT	■ ≥18 years ■ NYHA II-IV chronic HF ■ Either ≥1 HF hospitalisation in previous 12 months or elevated natriuretic peptides within 30 days before consent ■ Any LVEF	■ ≥18 years ■ NYHA III chronic HF ■ ≥1 HF hospitalisation or urgent visit with IV diuretics in past 12 months ■ Any LVEF ■ HF with reduced EF patients required optimal or maximally tolerated GDMT and evaluation for ICD/CRT where indicated

Author, year	Abraham, 2011, 2016 (CHAMPION) [29, 45]	Lindenfeld, 2021 (GUIDE-HF) [49]	Brugts, 2023 (MONITOR-HF) [46]
Key exclusion criteria	■ History of recurrent (>1) pulmonary embolism or deep vein thrombosis ■ Cardiac resynchronisation therapy device implanted within previous 3 months ■ Stage IV-V chronic kidney disease […]	■ Expected heart transplant or LVAD within 12 months ■ ACC/AHA stage D HF ■ inotrope use in past 6 months […]	■ Active infection ■ History of recurrent (>1) pulmonary embolism or deep vein thrombosis ■ Major CV event (e.g., myocardial infarction) within 2 months […]
Age of patients, mean ± SD (yrs)	61 ± 13 vs 62 ± 13	71 (64-76) vs 70 (64-77)[22]	69 (61-75) vs 70 (61-75)[22]
Sex, n (male/female) (%)	Treatment: 194 (72%) vs 76 (28%) Control: 205 (73%) vs 75 (27%)	Treatment: 310 (62%) vs 187 (38%) Control: 315 (63%) vs 188 (37%)	Treatment: 138 (78%) vs 38 (22%) Control: 125 (73%) vs 47 (27%)
Primary Endpoint(s)	Efficacy: Rate of HF-related hospitalisations during 6 months after implant (events per patient over 6 months) Safety: DSRC, pressure SF	Composite of all-cause mortality and total HF events (HF hospitalisations + urgent HF hospital visits requiring IV diuretics) at 12 months	Mean change in KCCQ overall summary score from baseline to 12 months between groups
Follow-up (months)	At least 6 Extended f/u: 18 (mean 15±7)	12	48 (mean 1.8±0.9 years)
Loss to follow-up, n	1 (6 months) Extended f/u: 6 (IG) + 4 (CG)	3 (IG) + 9 (CG)	0
Outcomes			
Clinical Effectiveness			
Mortality (all-cause) (events)	50 vs 64 HR 0.80 (95% CI 0.55-1.15), p=0.23	40 vs 37 0.094 vs 0.086 per pt-year HR 1.09 (95% CI 0.70-1.70), p=0.71	42 vs 45 0.137 vs 0.144 per pt-year HR 0.96 (95% CI 0.63-1.46), p=0.846
Mortality (CV) (events)	40 vs 48 0.099 vs 0.114 per pt-year HR: 0.87 (95% CI: 0.51-1.49)	30 vs 24 0.10 vs 0.086 HR: 1.16 (95% CI: 0.77-1.77) HF mortality: 17 vs 15 0.034 vs 0.030 HR: 1.13 (95% CI: 0.57-2.27)	25 vs 31 0.081 vs 0.099 per pt-year HR 0.83 (95% CI 0.49-1.39), p=0.485
Hospitalisation (all-cause) (events, recurrent)	554 vs 672 1.38 vs 1.65 per pt-year HR 0.84 (95% CI 0.75-0.95), p=0.0032	NR	NR
Hospitalisation (HF) (events, recurrent)	182 vs 279 0.46 vs 0.68 per pt-year HR 0.67 (95% CI 0.55-0.80), p<0.0001 Entire f/U period (mean: 15 months): 158 vs 254 HR 0.63 (0.52-0.77), p<0.0001	185 vs 225 0.410 vs 0.497 per pt-year HR 0.83 (95% CI 0.68-1.01), p=0.064	106 vs 195 0.345 vs 0.624 per pt-year HR=0.56 (95% CI 0.38-0.82), p=0.003

[22] Only median, lower and upper range reported.

Author, year	Abraham, 2011, 2016 (CHAMPION) [29, 45]	Lindenfeld, 2021 (GUIDE-HF) [49]	Brugts, 2023 (MONITOR-HF) [46]
Urgent hospital visits (events, recurrent)	NR	28 vs 27 0.065 vs 0.063 per pt-year HR 1.04 (95% CI 0.61-1.77), p=0.89	11 vs 17 0.036 vs 0.054 per pt-year HR 0.65 (95% 0.23-1.88), p=0.44
HRQoL (EQ-5D-5L)	NR	Mean within-group change: +0.94 (± 20.17), p=0.34 vs +2.90 (± 20.71), p=0.0048 Between-group difference in change in baseline to 12 months, p=0.17	Mean between-group difference in change in baseline to 12 months: +6.0 points (1.1-10.9), p=0.016 CardioMEMS (+3.0 vs -3.0)
HRQoL (KCCQ-12)	NR	Mean within-group change: +5.20 (± 21.35), p<0.0001 vs +4.12 (± 22.50), p=0.0002 Between-group difference in change in baseline to 12 months, p=0.48	Mean within-group change: +7.05 (95% CI 2.77-11.33; p=0.0014) vs –0.08 (95% CI –3.76 to 3.60; p=0.97) Between-group difference in change in baseline to 12 months: 7.13 (95% CI 1.51-12.75), p=0.013)
HRQoL (MLFHQ)	47.0 vs 56.5, p=0.0267	NR	NR
GDMT	NR	All between-group comparisons non-significant, p>0.05 Beta-blockers (87/80%), ACE-inhibitor/ARB/ARNi (57/56%), MRAs (48/43%), diuretics (94/93%), SGLT2-inhibitor (8/7%), Hydralazine (16/15%), Nitrate (21/20%)	All between-group comparisons non-significant, p>0.05 Beta-blockers (82/87%), RAAS inhibitors (91/88%), ARNI (61% vs 50%; p=0.059), ACE-inhibitor (11% vs 19%; p=0.054), MRAs (84/83%), loop diuretics (91/88%), SGLT2-inhibitor (31/33%), Ivabradine (9/7%), Digoxin (30/25%)
Safety			
Overall (S)AE, n	7 SAEs (procedural-related)	282/497 (57%) treatment vs 268/503 (53%) control	2 SAEs: bleeding, sepsis
Device- or system- or procedural-related complications, n	8 (6 months) 7 SAEs (procedural-related): bleeding, anticoagulation management issues, arrhythmias, febrile illnesses, one cardiogenic shock, one pulmonary thrombus treated with anticoagulation, one atypical chest pain, and one delivery-system failure that required a snare to remove the delivery system HR 0.014 (95% CI 0.0007-0.027)[23]	8 HR 0.008 (95% CI 0.0004-0.015)[23]	4: 2 haemoptysis, 2 arrhythmias HR 0.024 (95% CI 0.0009-0.060)[23]
Sensor failures, n	0 (6 months) HR 0.000 (95% CI 0.000-0.007)[23] Extended f/u period (mean: 31 months): no further events)	NR	2: 1 anatomy/posture related, 1 displacement HR 0.012 (95% CI 0.003-0.042)[23]

Abbreviations: CI … Confidence Interval; CV … Cardiovascular; DSRC … Device- or System-Related Complication; EF … Ejection Fraction; F/U … Follow Up; GDMT … Guideline Directed Medical Therapy; HF … Heart Failure; HR … Hazard Ratio; HRQoL … Health Related Quality of Life; KCCQ … Kansas City Cardiomyopathy Questionnaire; LVEF … Left Ventricular Ejection Fraction; M … Minnesota Living with Heart Failure Questionnaire; NR … Not Reported; NYHA … New York Health Association; PA … Pulmonary Artery; PTS … Patients; RCT … Randomised Controlled Trial; (S)AEs … (Serious) Adverse Event; SF … Sensor Failure; YRS … Years

[23] Calculated by Bristol TAG group [41].

Table A-2: CardioMEMS: Results from observational studies

Author, year	Shavelle, 2020; Heywood 2023 (CardioMEMS-PAS) [47, 58]	Angermann, 2020 (MEMS-HF) [28]	Cowie, 2022 (COAST – UK cohort) [50]	de Groote, 2024 (COAST – French cohort) [48]
Country	USA (104 centres)	Germany (26 centres), the Netherlands (1 centre), Ireland (4 centres)	United Kingdom (14 centres)	France (12 centres)
Sponsor	Abbott (CardioMEMS device manufacturer)	Abbott (CardioMEMS device manufacturer	Abbott (CardioMEMS device manufacturer	Abbott (CardioMEMS device manufacturer
Intervention/Product	CardioMEMS	CardioMEMS	CardioMEMS	CardioMEMS
Comparator	None (single-arm study)	None (single-arm study)	None (single-arm study)	None (single-arm study)
Surgical Procedure	Right-heart catheterisation with transcatheter implantation of sensor into distal branch of the PA; Implant attempts: 1214 implant attempts with 14 unsuccessful implants	Right-heart catheterisation with limited pulmonary angiography to identify suitable PA branch Implant attempts: 234 implant attempts with 2 unsuccessful implants	Right-heart catheterisation with transcatheter implantation of sensor into distal branch of the PA; Implant attempts: 100 implant attempts with 3 unsuccessful implants	Right-heart catheterisation with transcatheter implantation of sensor into distal branch of the PA;
Study design	Multicentre, open-label, single-arm observational post-approval study	Prospective, multicentre, non-randomised, single-arm observational study (registry) with pre-post-comparison	Prospective, multicentre, open-label, single-arm post-market study with historical (pre-implant) control period	Prospective, multicentre, open-label, single-arm post-market study with historical (pre-implant) control period
Duration (months)	24	12	12	24
Blinding	None-blinded	None-blinded	None-blinded	None-blinded
Number of pts	1200 Efficacy analyses: all 1200 implanted patients (1-year pre vs 1-year post implant); Safety analyses: 1214 patients (including 14 without successful implant) Extended f/u: 710	234 Efficacy analyses: 234 implanted patients; Safety analysis: 236 implant attempts (including 2 without successful implant)	100 Efficacy analyses: all 100 implanted patients; Safety analyses: 103 patients (including 3 without successful implant)	103 Efficacy analyses: all 103 implanted patients; Safety analyses: all 103 implanted patients
Key inclusion criteria	■ ≥18 years ■ Chronic HF with NYHA III symptoms ■ ≥1 HF hospitalisation within past 12 months ■ Any EF	■ ≥18 years ■ Chronic HF with NYHA III symptoms ■ ≥1 HF hospitalisation within past 12 months ■ Any LVEF	■ ≥18 years ■ Chronic HF with NYHA III symptoms ■ ≥1 HF hospitalisation within past 12 months ■ Any EF	■ ≥18 years ■ Chronic HF with NYHA III symptoms ■ ≥1 HF hospitalisation within past 12 months ■ Any EF
Key exclusion criteria	■ Active infection ■ >1 prior pulmonary embolism or DVT ■ inability to tolerate right-heart catheterisation ■ Major CV event in prior 2 months […]	■ Candidates for heart transplant, ventricular assist device or hospice care […]	■ Active infection ■ >1 prior pulmonary embolism or DVT ■ inability to tolerate right-heart catheterisation ■ Major CV event in prior 2 months […]	■ Active infection ■ >1 prior pulmonary embolism or DVT ■ inability to tolerate right-heart catheterisation ■ Major CV event in prior 2 months […]
Age of patients, mean ± SD (yrs)	69 ± 12	68 ± 11	69 ± 12	67 ± 12
Sex, n (male/female) (%)	748 (62%) vs 452 (38%)	83 (78%) vs 51 (22%)	70 (70%) vs 30 (30%)	80 (78%) vs 23 (22%)

Author, year	Shavelle, 2020; Heywood 2023 (CardioMEMS-PAS) [47, 58]	Angermann, 2020 (MEMS-HF) [28]	Cowie, 2022 (COAST – UK cohort) [50]	de Groote, 2024 (COAST – French cohort) [48]
Primary Endpoint(s)	Efficacy: Annualised rate of heart-failure hospitalisations (HFH) during the 1-year post-implant period compared with the 1-year pre-implant period Safety: freedom from DSRC at 2 years; freedom from pressure SF at 2 years	Co-primary safety endpoints: (1) freedom from DSRC at 12 months with performance goal >80% (2) freedom from pressure SF at 12 months	Efficacy: HF hospitalisation (HFH) rate during 12 months post-implant vs 12 months pre-implant. Safety: Freedom from DSRC and freedom from pressure SF at 24 months, compared with performance goals of 80% and 90%, respectively	Efficacy: HF hospitalisation (HFH) rate during 12 months post-implant vs 12 months pre-implant. Safety: DSRC and freedom from pressure SF at 24 months, compared with performance goals of 80% and 90%, respectively
Follow-up (months)	12 Extended follow-up: 24	12	12	24
Loss to follow-up, n	6 Extended follow-up: 21	0	0	0
Safety				
Overall (S)AE, n	NR	21 SAEs: 4 DSRC and 21 procedure-related	NR	NR
Device- or system- or procedural-related complications, n	5 HR 0.004 (95% CI 0.0002-0.010)[23] Extended follow-up (24 months). No further events	4 DSRC: Lead dislodgement or migration, Haemoptysis, infection, endocarditis (none were fatal or required sensor removal) 21 procedure-related: Most periprocedural; 2 abnormal heart rate or rhythm, 2 bleeding, 1 cardiac decompensation, 2 haemoptysis, 4 infection, 3 lead dislodgment or migration, 1 pulmonary artery perforation, 3 renal failure, 3 other, 1 endocarditis, 1 pseudoaneurysm formation, 1 sudden death HR 0.017 (95% CI 0.0007-0.043)[23]	0 HR 0.000 (95% CI 0.0000-0.036)[23]	0 HR 0.000 (95% CI 0.0000-0.036)[23]
Sensor failures, n	1 HR 0.001 (95% CI 0.000-0.005)[23] Extended follow-up (24 months). No further events	1 HR 0.004 (95% CI 0.001-0.024)[23]	1 HR 0.010 (95% CI 0.002-0.054)[23]	0 HR 0.000 (95% CI 0.000-0.036)[23]

Abbreviations: CI … Confidence Interval; CV … Cardiovascular; DSRC … Device- or System-Related Complication; EF … Ejection Fraction; F/U … Follow Up; GDMT … Guideline Directed Medical Therapy; HF … Heart Failure; HR … Hazard Ratio; LVEF … Left Ventricular Ejection Fraction; NR … Not Reported; NYHA … New York Health Association; PA … Pulmonary Artery; PTS … Patients; (S)AEs … (Serious) Adverse Event; SF … Sensor Failure; YRS … Years

Risk of bias tables and GRADE evidence profile

Internal validity of the included studies was judged by two independent researchers. In case of disagreement, a third researcher was involved to solve the differences. A more detailed description of the criteria used to assess the internal validity of the individual study designs can be found in the Guidelines of EUnetHTA [59, 60].

Table A-3: Risk of bias – study level (randomised studies), see [40]

Trial	Endpoints	Bias arising from the randomisation process	Bias due to deviations from intended interventions	Bias due to missing outcome data	Bias in measurement of the outcome	Bias in the selection of the reported result	Overall risk of bias
CHAMPION	Clinical Outcomes	Low	Low	Low	Low	Low	Low
	Patient-reported Outcomes	Low	Low	High[24]	Low	Some concerns[25]	High
MONITOR-HF	Clinical Outcomes	Low	Some concerns[26]	Low	Low	Low	Some concerns
	Patient-reported Outcomes	Low	Some concerns[26]	Low	High[27]	Low	High
	GDMT	Low	Some concerns[26]	Low	Low	Low	Some concerns
GUIDE-HF	Clinical Outcomes	Low	Low	Low	Low	Low	Low
	Patient-reported Outcomes	Low	Low	Some concerns[28]	Low	Low	Some concerns
	GDMT	Low	Low	Low	Low	Low	Low

[24] Data missing for 15.5% at 6 months (465/550 analysed).

[25] Data missingness potentially related to poorer health, with no adjustment or sensitivity analyses reported.

[26] Open Label Trial; no evidence of unplanned interventions.

[27] Expectations (intervention) and disappointment (control) could introduce bias; protocol explicitly notes potential bias from the lack of a sham procedure.

[28] <95% outcome data available; no sensitivity analyses for missingness; missing data likely related to COVID-19-related collection difficulties.

Table A-4: Evidence profile: clinical effectiveness and safety of CardioMEMS in HF NYHA III

Quality assessment							Summary of findings			
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Number of patients [intervention]	Number of patients [comparison]	Effect (HR)	Quality
Mortality (All-Cause)										
3	Randomised controlled trials	Not serious	Not serious	Not serious	Serious[29]	none	943	955	0.91 (95% CI 0.70-1.17) 6 months (CHAMPION): IG: 50/270 (18.5%) vs CG: 64/280 (22.9%) 12 months (GUIDE-HF): IG: 40/497 (8.0%) vs CG: 37/503 (7.4%) 24 months (MONITOR-HF): IG: 42/176 (23.9%) vs CG: 45/172 (26.2%)	⊕⊕⊕◯ Moderate
Mortality (Cardiovascular)										
3	Randomised controlled trials	Not serious	Not serious	Not serious[30]	Serious[29]	none	943	955	0.98 (95% CI 0.74-1.29) Range: IG: 0.081-0.10 events per pt-year vs CG: 0.086-0.11events per pt-year HF-related (1 RCT): 1.13 (95% CI 0.57-2.27) IG: 17 events vs CG: 15 events	⊕⊕⊕◯ Moderate
Hospitalisation (All-Cause) (Follow-Up: 18 Months)										
1	Randomised controlled trial	Not serious	NA	Not serious	Not serious	none	270	280	0.84 (95% CI 0.75-0.95), p=0.0032 IG: 554 (1.38 events per pt-year) vs CG: 672 (1.65 events per pt-year)	⊕⊕⊕⊕ High[31]
Hospitalisation (Heart Failure related)										
3	Randomised controlled trials	Not serious	Not serious	Not serious	Not serious	none	943	955	0.66 (95% CI 0.57-0.76) Range: IG: 0.34-0.46 events per pt-year vs CG: 0.50-0.68 events per pt-year	⊕⊕⊕⊕ High
Urgent Hospital Care										
2	Randomised controlled trials	Not serious	Not serious	Not serious	Serious[29]	none	673	675	1.05 (95% CI 0.56-1.96) Range: IG: 0.036-0.065 events per pt-year vs CG: 0.054-0.063 events per pt-year	⊕⊕⊕◯ Moderate

[29] Wide Confidence Interval, crossing 1.

[30] One contributing trial (GUIDE-HF) enrolled NYHA II-IV patients, although most participants were NYHA III; we found no evidence of important effect modification by NYHA class and therefore did not rate down for indirectness, but applicability to strictly NYHA III populations should be interpreted with this in mind.

[31] It should be considered that only one study was included in the assessment of this outcome.

Quality assessment							Summary of findings			
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Number of patients [intervention]	Number of patients [comparison]	Effect (HR)	Quality
Device/System or Procedure-Related Complications										
7	Single-arm trials[32]	Serious [33]	Serious[34]	Not serious	Not serious	none	Attempted implant: 3,419	-	0.007 (95% CI 0.003-0.013) Range: 0.0%-2.3%	⨁⨁⨁◯ Moderate
Sensor Failure										
6	Single-arm trials[32]	Serious [33]	Serious[35]	Not serious	Not serious	none	Implanted: 2,355	-	0.001 (95% CI 0.000-0.006) Range: 0.0%-1.2%	⨁⨁⨁◯ Moderate
Any (Serious) Adverse Events										
NA	NA	NA	NA	NA	NA	NA	NA	NA	Not estimable[36]	Not rated

Abbreviations: CI … Confidence Interval; HR … Hazard Ratio; NA … Not Applicable

Comments: [If serious or very serious, please give reasons for the classification (mandatory)

Nomenclature for GRADE table:

Limitations: 0: no limitations or no serious limitations; -1: serious limitations

Inconsistency: NA: Not applicable (only one trial); 0: no important inconsistency; -1: important inconsistency

Indirectness: 0: direct, no uncertainty, -1: some uncertainty, -2 major uncertainty

Other modifying factors: publication bias likely (-1), imprecise data (-1), strong or very strong association (+1 or +2), dose-response gradient (+1), Plausible confounding (+1)

[32] All RCTs were treated as single-arm; outcome is exposure-dependent. Starting point set at moderate rather than low: while single-arm extraction precludes comparative analysis, RCT-derived data retains methodological strengths.

[33] No randomisation (inherent high risk of bias); however, not downgraded as outcome is exposure-dependent and therefore based on implanted cohorts (single-arm data) and objective outcome, so very high RoB is unlikely; additionally, moderate starting point already accounts for limitations inherent to single-arm analysis.

[34] Heterogeneity at 50% (I2=50.1); not downgraded as absolute event rates were uniformly very low, I2 might therefore be driven by design/follow-up (range: 6-48 months) differences rather than conflicting findings.

[35] Heterogeneity at 45% (I2=44.5); not downgraded as absolute event rates were uniformly very low, I2 might therefore be driven by design/follow-up (range: 6-48 months) differences rather than conflicting findings.

[36] No study reported overall incidence of any AE/SAE in an extractable way; see results for details.

ROBIS: Risk of bias assessment of the Bristol TAG systematic review

Table A-5: ROBIS risk of bias table of the Bristol TAG systematic review

	Bristol TAG, 2025 [41]	Notes/Rationale
Domain 1	**LOW**	Clear, appropriate, pre-specified PICO with documented post-hoc changes (e.g., outcome change from HF-related mortality to CV-related mortality).
Domain 2	**LOW**	Comprehensive search; additional hand search and reference list review; independent screening; no language/date restrictions.
Domain 3	**LOW**	Pre-defined outcomes; piloted extraction, risk of bias not done independently but checked by second reviewer; RoB2 for RCTs; JBI checklist for single-arm studies not ideal but acknowledged; guidance for reviewers.
Domain 4	**LOW**	Appropriate, explicit handling of heterogeneity; no sensitivity analyses because of small number of studies of each outcome, checked for unpublished studies.
RoB in the review	**LOW**	Overall processes judged robust across domains; main limitations reported.

Applicability table

Table A-6: Summary table characterising the applicability of a body of studies

Domain	Description of applicability of evidence
Population	The target population was defined by guidelines and the CE-marked indication for CardioMEMS. No applicability concerns were identified. Across trials, mean age was ~61-71 years in the IG and ~62-70 years in CG, with a predominance of men (about 62-78% (IGs) vs 63-73% (CGs)). Most included studies matched the CE-marked population (NYHA III chronic HF, irrespective of EF, and ≥1 HF hospitalisation in the previous 12 months) (CHAMPION, CardioMEMS-PAS, COAST-UK/France, MEMS-HF). MONITOR-HF used slightly broader eligibility (NYHA III with prior HF admission or urgent visit requiring IV diuretics in the prior 12 months). GUIDE-HF enrolled NYHA II-IV patients (based on prior HF hospitalisation or elevated natriuretic peptides) but still included a majority with NYHA III (65%); where available, effectiveness analyses were based on NYHA III subgroup data. Important prognostic features for routine care (e.g., frailty, older age, multimorbidity) were not consistently reported, which limits assessment of applicability for the sickest and multimorbid patients.
Intervention	Intervention characteristics are consistent across studies. These include an implanted PAP sensor, daily pressure measurements, and clinicians adjusting HF therapy in response to changes in PAP trends. The studies describe structured reviews of PAP data at least weekly, with more frequent reviews during significant changes. Applicability relies on trained clinicians, sufficient resources, reliable measurements, defined thresholds, algorithms for data review and quick response, and patient adherence and education. Other physiological signals except PAP are not captured by the device, which may matter when deterioration is driven by mechanisms not primarily reflected in PAP.
Comparators	Comparators in the RCTs were standard care without access to PAP data; in two studies, the comparator also involved a sham procedure. The control setting may not reflect "usual care" uniformly across settings. CHAMPION was conducted in specialised HF centres, likely increasing the baseline standard of care and potentially reducing the incremental benefit compared with less organised HF management. In GUIDE-HF, the control group received scheduled calls every two weeks during the first three months, which may exceed typical routine monitoring. Background therapy also varied across studies and time periods (e.g., CHAMPION 2007-2011), so the incremental effect in routine practice may be smaller where usual care is already highly structured and intensive, and larger where routine monitoring is less consistent (including settings with access barriers).
Outcomes	The critical endpoints of highest relevance are arguably mortality (all-cause and CV) and reductions in HF-related hospitalisations. HF hospitalisation was measured in all RCTs (primary in one trial; secondary in others) with follow-up ranging from ~6 to 48 months. Mortality was assessed but remains difficult to interpret because trials may be underpowered and follow-up may be too short to detect realistic differences. Key device-related safety outcomes (DSRC or procedural-related complications and SF) were frequently reported, often up to 12 months (primary safety endpoints in several studies), while any (S)AEs not including DSRC or SF were not reported by any study. Other critical endpoints, like urgent HF care (<24h with IV diuretics), all-cause hospitalisation, and GDMT changes, were reported less consistently and partly with varying definitions across studies. HRQoL was assessed in three RCTs (KCCQ, EQ-5D-5L, MLHFQ at 6 or 12 months; primary in MONITOR-HF), but applicability is limited because HRQoL can be influenced by contact intensity and expectations, especially in open-label and/or non-sham-controlled designs (1/3 RCTs). Considering that the main purpose of the intervention is to monitor PAP, reduce the risk of deterioration, and improve quality of life, these outcomes are appropriate. The safety outcomes also reflect key device-related harms, with 12 months being an appropriate timeframe, but longer follow-up is needed to inform long-term safety.
Setting	Evidence comes from North America (USA/Canada: CHAMPION, GUIDE-HF, CardioMEMS-PAS) and Europe (Netherlands: MONITOR-HF; France: COAST, UK: COAST, Germany/Ireland/Netherlands: MEMS-HF). It is not expected that the applicability of the results is limited by geographic settings.

Abbreviations: CG … Control Group; *CV … Cardiovascular; DSRC EF … Ejection Fraction; F/U … Follow-Up; HF … Heart Failure; HRQoL … Health-Related Quality of Life;* IG … Intervention Group; IV … Intravenous; *NYHA … New York Health Association; PAP … Pulmonary Artery Pressure; RCT … Randomised Controlled Trial; DSRC … Device- or System-Related Complication; GDMT … Guideline Directed Medical Therapy; HRQoL … Health Related Quality of Life; SF … Sensor Failure; QoL … Quality of Life*

List of ongoing randomised controlled trials

Table A-7: List of ongoing randomised controlled trials of a wireless pulmonary artery pressure sensor

Identifier/ Trial name	Patient Population/Inclusion Criteria	Intervention	Comparison	Primary Outcome	N of pts (planned)	Primary completion date	Sponsor
CardioMEMS							
NCT05284955/ SAINTS B	Included in SAINTS A and fulfilling criteria for advanced HF (i.e., meeting primary endpoint for SAINTS A), although with a lower NT-proBNP cut-off level at ≥1000 pg/ml, but not referred for heart transplantation or LVAD due to contraindications or patient preference NYHA III	Pharmacological HF treatment guided by an implanted wireless pulmonary artery haemodynamic monitor (CardioMEMS HF system)	Standard HF medical treatment	Change in Quality of Life from baseline measured using KCCQ score (6 months)	60	12/2025	Finn Gustafsson
NCT04441203/ SELFIe-HF	NYHA III with recent HF admission in the previous year (12 months) OR Patient with at least one ER visit or unplanned HF clinic requiring IV diuretics within 12 months will be eligible if they have in addition a N-terminal pro-BNP (NT-proBNP) level > 800pg/ml at screening AND NYHA II on diuretics (furosemide ≥ 40mg qd), III or ambulatory IV. HF with reduced or preserved EF of at least 3 months duration	Treatment group will be implanted with a CardioMEMS HF sensor and managed using remote access to haemodynamics	Usual care	Acute decompensated HF requiring emergency department consultation (12 months); Unplanned intravenous HF therapy in an outpatient clinic (12 months); hospital admission for HF (12 months); CV death (12 months)	150	12/2025	Montreal Heart Institute
NCT04398654/ PASSPORT-HF	≥18 years of age; NYHA III at least 30 days prior to consent; objectified HF diagnosis for more than 3 months; hospitalisation in the last 12 months; able to tolerate dual antiplatelet therapy or anticoagulation therapy for one month after sensor implantation; Chest circumference of <165 cm if BMI >35 kg/m^2. Accessible by telephone (via fixed or mobile network). For the IG: pulmonary artery branch intended for implantation diameter ≥7 mm	Implantation of CardioMEMSTM HF sensor; evaluation of the pressure curves by telemetric transmission and coordination of necessary adjustments of the therapy	Monitoring and therapy adjustment within the scope of the basic care described in the clinical trial plan	**Efficacy:** Composite of unplanned HF-related rehospitalisations and all-cause death (12 months); **Safety:** Rate of device/system related complications, rate of sensor failures (12 months)	554	06/2026	IHF GmbH – Institut für Herzinfarkt-forschung
Cordella							
NCT05934487/ PROACTIVE-HF-2	Diagnosis and treatment of HF (regardless of LVEF) for ≥3 months and NYHA Class II HF (NYHA II Cohort) or NYHA III (NYHA III Cohort) at time of screening	Cordella™ Pulmonary Artery Sensor System Clinicians will manage the subjects to target PAP per protocols specific treatment guidelines and according to GDMT	**Active control:** Subjects and clinicians will be blinded to PAP for 6 months	**Efficacy:** Composite of first HF event or death (6, 24 months) **Safety:** Device/system related complications, pressure sensor failure (12, 24 months) test of non-inferiority at 12 months of the percentage of patients at or below trend seated mPAP of 25 mmHg	1,750	09/2028	Endotronix, Inc.

Abbreviations: CV … Cardiovascular; EF … Ejection Fraction; f/u … Follow-Up; GDMT … Guideline-Directed Medical Therapy; HF … Heart Failure; IG … Intervention Group; KCCQ … Kansas City Cardiomyopathy Questionnaire; LVAD … Left Ventricular Assist Device; LVEF … Left ventricular ejection fraction; NT-proBNP … N-Terminal pro B-Type Natriuretic Peptide; NYHA … New York Heart Association; PAP … Pulmonary Artery Pressure.

Comments: PASSPORT-HF was also submitted by the manufacturers of the CardioMEMS™ HF System

Research questions

Table A-8: Health problem and Current Use

Element ID	Research question
A0001	For which health conditions, and for what purposes is the technology used?
A0002	What is the disease or health condition in the scope of this assessment?
A0003	What are the known risk factors for the disease or health condition?
A0004	What is the natural course of the disease or health condition?
A0005	What is the burden of disease for the patients with the disease or health condition?
A0006	What are the consequences of the disease or health condition for the society?
A0024	How is the disease or health condition currently diagnosed according to published guidelines and in practice?
A0025	How is the disease or health condition currently managed according to published guidelines and in practice?
A0007	What is the target population in this assessment?
A0023	How many people belong to the target population?
A0011	How much are the technologies utilised?

Table A-9: Description of the technology

Element ID	Research question
B0001	What is the technology and the comparator(s)?
A0020	For which indications has the technology received marketing authorisation or CE marking?
B0002	What is the claimed benefit of the technology in relation to the comparators?
B0003	What is the phase of development and implementation of the technology and the comparator(s)?
B0004	Who administers the technology and the comparators and in what context and level of care are they provided?
B0008	What kind of special premises are needed to use the technology and the comparator(s)?
B0009	What supplies are needed to use the technology and the comparator(s)?
A0021	What is the reimbursement status of the technology?

Table A-10: Clinical Effectiveness

Element ID	Research question
D0001	What is the expected beneficial effect of the technology on mortality?
D0005	How does the technology affect symptoms and findings (severity, frequency) of the disease or health condition?
D0006	How does the technology affect progression (or recurrence) of the disease or health condition?
D0012	What is the effect of the technology on generic health-related quality of life?
D0013	What is the effect of the technology on disease-specific quality of life?

Table A-11: Safety

Element ID	Research question
C0008	How safe is the technology in comparison to the comparator(s)?
C0007	Are the technology and comparator(s) associated with user-dependent harms?

Table A-12: ASSESS-DHT manual assessment considerations

Element ID	Consideration
ASSESS-DHT (CUR)	What is the intended use or purpose of the DHT?
ASSESS-DHT (TEC)	The functions the DHT performs and the features of the DHT.
ASSESS-DHT (TEC)	Whether any health content is interpreted by a human.
ASSESS-DHT (TEC)	The steps and plans that have been made to ensure: ■ the reliable performance of the DHT, ■ that the DHT and its components work as expected in terms of technological and technical stability, ■ that the DHT creates accurate measurements and data, ■ that the DHT can deal with significant increase or spike in demand.
ASSESS-DHT (SAF)	What is the risk class for the DHT?
ASSESS-DHT (SAF)	Have any additional harm or adverse events on the user or the care/treatment they receive by using the DHT been adequately identified, assessed, addressed, and monitored?
ASSESS-DHT (EFF)	What is the organisational (added) value?
ASSESS-DHT (EFF)	What are the benefits of the DHT when used in practice?
LCA Recommendation 32	Have systematic reviews of comparative studies been evaluated for validity and confidence in recommendations using ROB2 or similar tools, and GRADE?
LCA Recommendation 33	Has the DHT's clinical effectiveness been compared with current standard of care using robust study designs (e.g., RCTs), with clear reporting of relevant outcomes and subgroup effects?
LCA Recommendation 111	Was the difference in outpatient visits and admission rate between patients using the telemedicine DHT and the comparator group reported?
LCA Recommendation 118	For devices in MDR Class 2b or 3, has a large prospective cohort study or a randomised trial been performed which reports on safety and risk outcomes?

Abbreviations: CUR … Health problem and current use of the DHT; TEC … Technical characteristics; SAF … Safety; EFF … Effectiveness; LCA … Lifecycle approach.

Literature search strategies

Search strategy for Medline via Ovid

Search Name: Ovid MEDLINE(R) ALL <1946 to November 06, 2025>	
Search date: 07.11.2025	
ID	Search
#1	exp Heart Failure/ (162462)
#2	heart failure*.mp. (294157)
#3	1 or 2 (295452)
#4	(New York Heart Association or NYHA*).mp. (28246)
#5	3 and 4 (15875)
#6	((arter* or atrial) adj5 pressure).mp. (140104)
#7	exp Pulmonary Artery/ (51968)
#8	pulmonary arter*.mp. (113759)
#9	lung arter*.mp. (229)
#10	7 or 8 or 9 (113867)
#11	6 and 10 (28303)
#12	exp Blood Pressure Monitoring, Ambulatory/ (12709)
#13	exp Hemodynamics/ (761645)
#14	(sensor* or monitor* or tele?monitor* or tele-monitor* or tool* or device* or system* or manag*).mp. (10333238)
#15	13 and 14 (276630)
#16	((pressure or h?emodynamic* or h?emo-dynamic*) adj5 (sensor* or monitor* or tele?monitor* or tele-monitor* or tool* or device* or system* or manag*)).mp. (119010)
#17	12 or 15 or 16 (344420)
#18	11 and 17 (8866)
#19	((pulmonary arter* or lung arter*) adj5 (sensor* or monitor* or tele?monitor* or tele-monitor* or tool* or device* or system* or manag*)).mp. (6774)
#20	18 or 19 (13541)
#21	exp Wireless Technology/ (5423)
#22	exp Monitoring, Physiologic/ (208838)
#23	wire?less*.mp. (28545)
#24	wire-less*.mp. (10)
#25	lead?less*.mp. (1594)
#26	lead-less*.mp. (46)
#27	exp Telemedicine/is [Instrumentation] (3535)
#28	tele?monitor*.mp. (3154)
#29	tele-monitor*.mp. (255)
#30	exp Telemetry/ (16628)
#31	(ambula* adj5 (monitor* or sensor* or supervis*)).mp. (31054)
#32	20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 (259521)
#33	20 and 32 (13541)
#34	5 and 33 (305)
#35	cardio?mems*.mp. (237)
#36	34 or 35 (481)
#37	limit 36 to dt=20191216-20251107 (201)
#38	limit 36 to ed=20191216-20251107 (158)
#39	37 or 38 (212)
#40	remove duplicates from 39 (211)
Total hits: 211	

HTA Austria
Austrian Institute for
Health Technology Assessment
GmbH