

Assessment of health-related quality of life: A systematic review of the psychometric properties of HeartQoL

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Abstract. To analyze the evidence of the validity of HeartQoL in studies evaluating patients with heart disease who underwent clinical or surgical treatments. Systematic review of the literature for the analysis of psychometric properties reported from PRISMA. The analyses of the findings were carried out following the recommendations of the Joanna Briggs Institute. The synthesis of the findings revealed the psychometric properties of the HeartQoL in different countries. The two-dimensional model of the questionnaire, initially proposed by the authors, was confirmed in some studies through the verification of structural validity, content validity and convergent construct validity, through correlations, and discriminant validity, through the method of known groups using sociodemographic and clinical data. However, it was possible to highlight that in several adaptation studies, they were restricted to translation and back-translation. Although dimensionality has been fragile in some studies because of the loading of items in two domains, we observed the validity and reliability of the HeartQoL. However, we suggest that HeartQoL be adapted prior to its use in cultures other than its original version so that the analysis of psychometric properties is not impaired.

Keywords: Validation studies, Quality of life, Systematic review.

Introduction

In recent years, the recognition of the importance of patient reports about their health before, during, and after the treatment of certain diseases has become important for clinical practice.

For the quantitative assessment of the subjective constructs highlighted in patient-reported outcomes (PROs) (Cameron *et al.*, 2022; Mayo, 2017), tools for measuring such constructs, so-called patient-reported measures (PROMs), are suggested. PROMs can be classified as general and specific; the former assess the individual's health aspects, whereas the latter assess more specific aspects related to the symptoms of a particular disease and its impact on the individual's health (Lodge *et al.*, 2022).

Between 2002 and 2011, the European Society of Cardiology, with the collaboration of 22 countries of different languages and cultures, conducted the Heart project, with the objective of developing a specific instrument for the assessment of the health-related quality of life (HRQoL) of

people with heart disease in clinical condition. The Health-Related Quality of Life Questionnaire, also known as HeartQoL, was created on the basis of three existing instruments: the Seattle Angina Questionnaire (SAQ), the MacNew Heart Disease Health-Related Quality of Life Questionnaire (MacNew) and the Minnesota Living with Heart Failure Questionnaire (MLHFQ) (Huber *et al.*, 2020).

The HeartQoL consists of 14 items distributed in two domains: physical with ten items (numbers 1, 2, 3, 4, 5, 6, 7, 8, 13 and 14) and emotional with four (items 9, 10, 11 and 12). The items are answered on a four-point ordinal scale ranging from zero to three points. The overall score is calculated from the sum of the answers to the 14 items divided by the total number of items to obtain the average number of answers, with higher values indicating better HRQoL. The same procedure can be used for the calculations of domain scores (Oldridge *et al.*, 2014).

Originally, the HeartQoL was developed and validated in patients with heart disease in the clinical

context. Its use was subsequently expanded as a measure of HRQoL to patients undergoing surgical treatment. Two European studies used HeartQoL to assess HRQoL in patients after prosthetic valve implantation but lacked a prior presentation of the evaluation of psychometric properties for this specific population (Sibilitz *et al.*, 2025; Zacek *et al.*, 2025).

In view of the use of HeartQoL to assess the HRQoL of patients with heart disease in different contexts, we envisaged the elaboration of this systematic review to analyze the evidence of HeartQoL validity in studies that evaluated patients with heart diseases in clinical or surgical treatments.

Contextualization and analysis

This is a systematic review of measurement properties, recently reclassified by the Joanna Briggs Institute (JBI) as a methodology for the synthesis of external evidence⁸, developed to evaluate the measurement properties of HeartQoL, carried out in January 2025. This type of review has a consensus-based analysis standard for the selection of health measurement instruments, which is based on the initiative of an international multidisciplinary team of researchers with experience in the field of psychometrics, with expertise in the development and evaluation of measurement instruments, with the objective of providing evidence on the applicability of the instrument for measuring the construct of interest and identifying the contexts in which it was used (Elsman *et al.*, 2024).

The guiding question was elaborated on the basis of the PICO strategy recommended by the JBI for this type of systematic review, corresponding to the following question: "What is the evidence in the literature on the validity of HeartQoL for the assessment of health-related quality and life of patients with heart disease? "

To verify the eligibility of the articles, the following criteria were adopted: methodological studies, with no restriction on the date of publication or language. Studies that did not present an analysis of HeartQoL measurement properties were excluded. The Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) were used to report the present review (Page, *et al.*, 2021). Data selection and extraction were performed using the free software Rayyan Qatar Computing Research Institute (Rayyan QCRI) (Ouzzani *et al.*, 2016).

The searches were divided into stages. The first stage was carried out through independent searches by two researchers in the following databases: Medline/PubMed, Embase, Scopus and Web of Science, using controlled and uncontrolled descriptors (keywords), which composed the following equations: Medline, via Pubmed = ((HeartQoL) AND (Validation [All Fields]) AND ("Quality of life"[All Fields])); Scopus = (ALL(HeartQoL) AND ALL("Validation study") AND ALL("Quality of life")); Embase = (HeartQoL AND

"Validation study" AND 'quality of life'); and Web of Science = ALL=(HeartQoL AND "Validation study" AND "quality of life"), and a partial sample of eligible studies was established. Afterward, the second stage of the search phase began, manually and in the references of the eligible articles of the first stage. Once the final sample was established, the eligible studies were selected in the two stages.

On the basis of the evidence of HeartQoL validity, a descriptive analysis was performed according to the criteria established by the JBI (Elsman *et al.*, 2024). The protocol of this systematic journal is available on the online platform Figshare (Maier *et al.*, 2022).

Results and discussion

At the end of the search stage, seven articles were found from the electronic search, and five articles were found from the manual search, totaling

Thus, twelve articles were eligible for the composition of the corpus of the review, as reported in Figure 1.

To present the articles, it was first decided to prepare a characterization table of eligible studies according to the recommendations of the JBI (Elsman *et al.*, 2024), as shown in Figure 2.

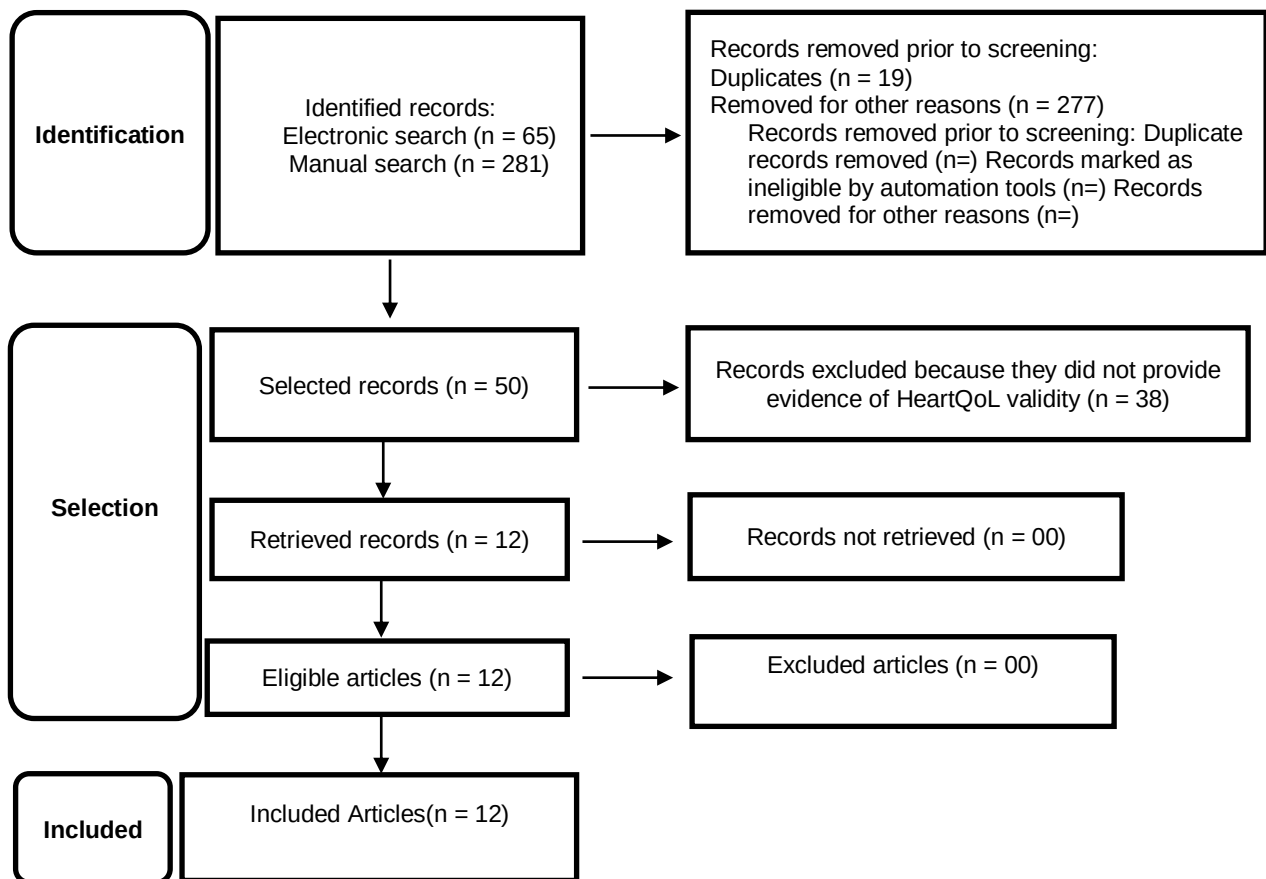
All the articles included were published in English between 2014 and 2021, mostly in European and Asian countries, and had very varied sample sizes, depending on the psychometric properties analyzed.

An analysis of the scientific literature revealed evidence of the validity of the HeartQoL for the assessment of HRQoL in patients with heart disease; however, the differences between the studies included in the final sample of this review need to be highlighted, given that the psychometric properties may vary according to the characteristics of the participants, the sample size and the guiding principles of cross-cultural adaptation.

Although the instrument was originally European and was developed and validated with participants from 22 countries, the studies included in this review provided evidence of its validity in other countries, such as the United States (USA) (Oldridge *et al.*, 2018), Iran (Lee *et al.*, 2016), Malaysia (Saba *et al.*, 2020) and China (Luan *et al.*, 2018), which expands the use of the instrument to other cultures.

In terms of the sample size, differences were observed, mainly because of the multicenter testing of the instrument (Smedt *et al.*, 2016; Oldridge *et al.*, 2018) and clinical characteristics (Huber *et al.*, 2020; Oldridge *et al.*, 2014; Lee *et al.*, 2016; Kristensen *et al.*, 2016; Smedt *et al.*, 2016; Ranjandish *et al.*, 2019; Saba *et al.*, 2020; Fattirolli *et al.*, 2022; Luan *et al.*, 2022.) or therapeutic procedures (Zangger *et al.*, 2018; Gronset *et al.*, 2019), which allowed us to identify the potential of the instrument for assessing HRQoL in different contexts.

Figure 1 - Flowchart adapted from Page *et al.* (2020), Ribeirão Preto, São Paulo, Brazil, 2025.



Source: Authors (2025).

Figure 2 - Characterization of the studies included in the systematic review, Ribeirão Preto, SP, Brazil, 2025

Authors	Country	Audience	Sample
Oldridge <i>et al.</i> , 2014.	22 countries	Participants in clinical condition (angina, myocardial infarction, and heart failure).	6.384
Lee <i>et al.</i> , 2016.	Malaysia	Participants in clinical condition (ischemic heart disease).	76
Kristensen <i>et al.</i> , 2016.	Denmark	Clinically conditioned, atrial fibrillation participants treated with radiofrequency ablation.	462
Smedt <i>et al.</i> , 2016.	24 countries	Participants in clinical condition, with coronary heart disease.	7.449
Zangger <i>et al.</i> , 2018.	Denmark	Participants in surgical condition, after implantable cardioverter defibrillator implantation.	358
Oldridge <i>et al.</i> , 2018.	United States	Participants in clinical condition (angina and myocardial infarction).	410
Ranjandish <i>et al.</i> , 2019.	Iran	Participants in clinical condition (myocardial infarction).	557
Gronset <i>et al.</i> , 2019.	Denmark	Participants in surgical condition, after surgical correction of valvular heart diseases.	742
Saba <i>et al.</i> , 2020.	Iran	Participants in surgical condition, after coronary artery bypass surgery.	150
Huber <i>et al.</i> , 2020.	Germany	Participants in clinical condition (angina, myocardial infarction, and heart failure).	305
Fattirolli <i>et al.</i> , 2022.	Italy	Participants in clinical condition (angina, myocardial infarction, and heart failure).	472
Luan <i>et al.</i> , 2022.	China	Participants in clinical condition (angina, myocardial infarction, and heart failure).	412

Source: Authors (2025).

The findings highlight that there is a consensus among scholars about the need to translate the original version into the target language and back-translation, with a view to the conceptual maintenance of the investigated construct; however, the process of cross-cultural adaptation is not restricted to these two stages (Machado et al., 2018).

Only five studies presented an adaptation process aligned with the verification of evidence of content validity; however, only two described how such validity was verified (Lee et al., 2016; Ranjandish et al., 2019). Verification of the existence of content validity is important to ensure the maintenance of the theoretical and operational bases of the construct (Almanasreh et al., 2019). Evaluating the psychometric properties of adapted instruments is of paramount importance to analyze whether the instrument maintains the theoretical and operational bases according to the original version.

Thus, nine studies confirmed the existence of convergent construct validity through the presentation of strong correlations between the construct assessed by *HeartQoL* and other instruments (SF-12 (Machado et al., 2018), SF-36 (Huber et al., 2020.; Oldridge et al., 2014; Kristensen et al., 2016; Oldridge et al., 2018), MacNew (Fattiroli et al., 2022), EQ-5D (Smedt et al., 2016), SF-36, and MacNew (Saba et al., 2020)), considering the strong correlations between global scales and their similar domains. This proves the link between the theoretical model of the items and the hypothetical model (Mayo, 2017; Souza et al., 2017).

Evidence of the reliability and validity of the *HeartQoL* was highlighted on the basis of the methodological evaluation proposed by the JBI.8 The psychometric properties of the *HeartQoL* in the included studies are presented and summarized in the figure (Lodge et al., 2022).

Figure 3 - Synthesis of the evidence of validity, reliability, and responsiveness found in the studies that made up the systematic review, Ribeirão Preto, São Paulo, Brazil, 2025.

Authors	Validity, Reliability and Responsiveness
Oldridge et al., 2014.	The convergent construct validity is proven by the existence of strong correlations between the similar domains of the SF-36 and the <i>HeartQoL</i> . Discriminative construct validity, on the other hand, was tested by known groups, and was confirmed in patients with compromised health status and symptoms of anxiety and depression. Reliability was assessed by internal consistency and confirmed by Cronbach's Alpha Coefficient on the global scale and domains.
Lee et al., 2016.	Only the translation and back-translation of the instrument were performed. They also referred to the verification of apparent validity, through specialists and testing with 5 patients. The responsiveness of the <i>HeartQoL</i> was verified by test-retest, presenting an acceptable Intraclass Correlation Coefficient (ICC).
Kristensen et al., 2016.	The convergent construct validity is proven by the existence of strong correlations between the similar domains of the SF-36 and the <i>HeartQoL</i> . On the other hand, the discriminative construct validity tested by known groups, being confirmed in patients who showed signs of anxiety or depression; with deterioration of health; gender; and severe comorbidity burden. Structural validity was verified by confirmatory analysis, presenting a two-factor structure, with the exception of item 9, with a high factor load for the physical domain. Reliability was evaluated and confirmed through internal consistency by Cronbach's alpha, on the global scale and in the domains. In the evaluation of responsiveness by test-retest, the ICC values were acceptable.
Smedt et al., 2016.	Convergent construct validity is proven by the existence of strong correlations between the similar domains of the EQ-5D and the <i>HeartQoL</i> . Discriminative construct validity, on the other hand, was verified using the known groups method, and was confirmed for: gender, education and age. Structural validity was verified by exploratory factor analysis, which showed a two-factor structure, except in item 8 carried in both factors. Reliability was assessed by internal consistency and confirmed by Cronbach's Alpha Coefficient on the global scale and domains.
Zangger et al., 2018.	Convergent construct validity is proven by the existence of strong correlations between the similar domains of <i>HeartQoL</i> and SF-36. Discriminative construct validity, on the other hand, was verified by the method of known groups, and was confirmed in patients with deterioration; with a lower burden of comorbidity index; presence of symptoms of anxiety and depression. Structural validity was verified by confirmatory factor analysis, and the two-dimensional structure of the <i>HeartQoL</i> was confirmed, except for item 9 that carried the physical domain and not the emotional domain as in the original version. Reliability was verified by the analysis of internal consistency and considered satisfactory using Cronbach's alpha. On the other hand, test-retest responsiveness (two-week interval) showed acceptable CHF.
Oldridge et al., 2018.	The convergent construct value is proven by the existence of strong correlations between the similar SF-36 and <i>HeartQoL</i> domains. On the other hand, the validity of the discriminative construct by known groups was confirmed for discrimination between diseases. Structural validity was verified by confirmatory factorial analysis, presenting the two-dimensional model of the original version. Reliability was assessed by internal consistency and was confirmed by Cronbach's alpha coefficient on the global scale and domains.
Ranjandish et al., 2019.	The cross-cultural adaptation process was carried out. Content validity was verified by the content validity ratio and with acceptable intervals. Structural validity was verified by confirmatory factor analysis, and the original structure was confirmed with two factors. Reliability was assessed by internal consistency and confirmed by Cronbach's Alpha Coefficient on the global scale and domains.

Gronset <i>et al.</i> , 2019.	Only the translation and back-translation of the instrument were performed. There was no verification of the validity of the content, however, the adequacy was mentioned in item 9. Convergent construct validity is proven by the existence of strong correlations between the similar domains of <i>HeartQoL</i> and SF-36. On the other hand, the validity of the discriminant construct was verified by the method of known groups, being confirmed for gender, deteriorated health status, symptoms of anxiety and depression, and for disease. The reliability of internal consistency was confirmed by Cronbach's alpha at the global scale and domains.
Saba <i>et al.</i> , 2020.	The cross-cultural adaptation process was carried out. The convergent construct validity was verified, considering the hypothesis of the existence of strong correlations between the similar domains of the <i>HeartQoL</i> , <i>MacNew</i> and SF-36. The validity of the discriminant construct was verified by the known groups method, and was confirmed by discriminating the groups by cardiac function by means of ejection fraction. Reliability was assessed by internal consistency using Cronbach's alpha on the global scale and domains. Test-retest responsiveness occurred through the ICC acceptable on the global scale and in the domains.
Huber <i>et al.</i> , 2020.	The convergent construct validity is proven by the existence of strong correlations between the similar SF-36 and <i>HeartQoL</i> domains. Discriminative construct validity, on the other hand, was tested by known groups, and was partially confirmed for age, sex, and disease severity; and confirmed discriminating compromised health status and symptoms of anxiety and depression. Structural validity was verified by confirmatory factorial analysis, confirming two-dimensional structure. Reliability was evaluated by internal consistency by Cronbach's Alpha Coefficient on the global scale.
Fattirolli <i>et al.</i> , 2022.	The convergent construct validity is proven by the existence of strong correlations between the physical and emotional domains of <i>MacNew</i> and <i>HeartQoL</i> . Discriminative construct validity, on the other hand, was tested by known groups and confirmed for: sex; disease; presence of symptoms of anxiety or depression. Structural validity was verified by confirmatory factorial analysis, confirming two-dimensional structure. Reliability was evaluated and confirmed through internal consistency using Cronbach's Alpha Coefficient on the global scale and in the domains.
Luan <i>et al.</i> , 2022.	Structural validity was verified by confirmatory factor analysis, and the two-dimensional structure was confirmed. Convergent construct validity is supported by the existence of strong correlations between the similar domains of <i>HeartQoL</i> and SF-12. Discriminative construct validity, on the other hand, was tested by known groups, and was confirmed for age, sex, HRQoL assessment, presence of anxiety or depression symptoms, and disease. Reliability was evaluated and confirmed through internal consistency using Cronbach's Alpha Coefficient on the global scale and in the domains.

Source: Authors (2025).

The review in question brought together the hypothetical models tested on the basis of convergent and discriminant construct validity. The analyses confirmed the convergent construct validity through the correlation of similar items between the scales used for this purpose and the discriminant construct validity for female patients in clinical condition (Huber *et al.*, 2020.; Kristensen *et al.*, 2016; Smedt *et al.*, 2016; Fattirolli *et al.*, 2022; Luan *et al.*, 2022); for the most severe cases of angina, infarction, and heart failure through the severity index (Huber *et al.*, 2020); for patients with ICD (Zangger *et al.*, 2016) and tachyarrhythmia (Zangger *et al.*, 2018); for patients with anxiety and depression symptoms in clinical and surgical conditions (Huber *et al.*, 2020; Oldridge *et al.*, 2014; Kristensen *et al.*, 2016; Zangger *et al.*, 2018; Gronset *et al.*, 2019; Fattirolli *et al.*, 2022; Luan *et al.*, 2022); and for infarcted participants (Oldridge *et al.*, 2014; Oldridge *et al.*, 2018; Fattirolli *et al.*, 2022; Luan, *et al.*, 2022). The *HeartQoL* of all those who had these characteristics was compromised, reinforcing the discriminative capacity of the instrument.

With respect to structural validity, eight studies performed exploratory and confirmatory factor analysis, or both, confirming the two-dimensional structure, physical domain, and emotional domain (Huber *et al.*, 2020; Kristensen *et al.*, 2016; Smedt *et al.*, 2016; Zangger *et al.*, 2018; Oldridge *et al.*, 2018; Ranjandish *et al.*, 2019; Fattirolli *et al.*, 2022; Luan *et al.*, 2022). However,

four of them (Kristensen *et al.*, 2016; Smedt *et al.*, 2016; Zangger *et al.*, 2018; Oldridge *et al.*, 2018) highlighted the problems found, such as lower explained total variance in infarcted patients (Oldridge *et al.*, 2018), items with low factorial loading for emotional domain loading (Saba *et al.*, 2020), and items with two-factor loading (Smedt *et al.*, 2016), an item with a loading factor different from that suggested in the original version (Zangger *et al.*, 2018). Although there is no consensus in the literature, in factor analysis, the sample value can be established according to the number of items in the instrument (Orçan *et al.*, 2018). Another measure evaluated was reliability, which consists of the ability to reproduce a result (Flora *et al.*, 2022; Ferreti-Rebustini, 2023). The Cronbach's alpha coefficient (Ferreti-Rebustini, 2023) of the included studies was greater than 0.70 (Huber *et al.*, 2020; Oldridge *et al.*, 2014; Kristensen *et al.*, 2016; Smedt *et al.*, 2016; Zangger *et al.*, 2018; Oldridge *et al.*, 2018; Ranjandish *et al.*, 2019; Gronset *et al.*, 2019; Saba *et al.*, 2020; Fattirolli *et al.*, 2022; Luan *et al.*, 2022). However, it is important to highlight that in four studies, the reliability evaluation revealed a lower Cronbach's alpha in the emotional domain than in the physical domain or on the global scale (Kristensen *et al.*, 2016; Zangger *et al.*, 2018; Ranjandish *et al.*, 2019; Gronset *et al.*, 2019; Saba *et al.*, 2020). It is believed that the lower values of Cronbach's alpha in more than one study may be related to the small number of items in the emotional domain.

With respect to the reliability evaluated by test-retest reliability, the results of these studies presented intraclass correlation coefficients between 0.80 and 0.90 (Lee *et al.*, 2016; Kristensen *et al.*, 2016; Zangger *et al.*, 2018; Ranjandish *et al.*, 2019; Gronset *et al.*, 2019; Saba *et al.*, 2020), which confirmed the stability and responsiveness of HeartQoL applied at different times and in different contexts.

In summary, the psychometric properties presented in the studies included in the review in question provided evidence of the validity and reliability of the HeartQoL in different scenarios around the world, with the use of combined techniques for data analysis, in line with contemporary psychometrics (Ferreti-Rebustini, 2023), which can help in clinical practice.

The exclusion of an article published in Russia was considered a limitation of the systematic review in question because of the difficulty in understanding the findings and characterizing selection bias. However, it should be noted that an extensive search of the literature was carried out; in addition, the use of specific guidelines for systematic reviews focused on measurement properties favored the synthesis of knowledge related to this measurement instrument.

Conclusion

The synthesis of the findings confirmed the evidence of HeartQoL validity through the verification of structural validity, construct validity, and reliability with different forms of analysis, revealing the presence of convergent and discriminant construct validity. Valid and reliable measurement instruments are important for the implementation of care processes.

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